THE DIVISION OF SURGERY
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EVALUATION OF VIDEO-MOTION ANALYSIS IN THE ASSESSMENT OF ENDOVASCULAR SKILL

PhD Thesis

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ABSTRACT

Endovascular intervention has undergone rapid expansion, largely driven by technological advancement, and has permitted the successful management of complex arterial disease in patients otherwise precluded from operative intervention. Despite refinement and expansion of available endovascular technologies, such techniques can be technically demanding and require considerable expertise. Furthermore, a growing body of evidence suggests that experience and competence have a direct bearing on outcome following such procedures. A number of professional bodies have sought to define competence in terms of number of procedures required to receive specialist certification, however raw procedural figures are regarded by some experts as crude surrogate markers of skill. Endovascular skills are presently assessed using a variety of methods including rating scales, procedure-specific check-lists, computer-generated scoring matrices and metrics derived from fluoroscopic imaging such as contrast volume and procedure time. Although the latter are used in live endovascular intervention to assess novel technologies and techniques, they provide little in the way of qualitative information. Qualitative rating scales have been extensively validated, but are time-consuming and are still largely restricted to experimental work. Video-motion analysis (VMA) is a relatively new concept and prior to this work was unexplored in the field of endovascular surgery. The principle behind this assessment method is the extraction of motion-descriptive data from video recordings. This body of work introduces a novel catheter tracking software capable of extracting this data from fluoroscopic sequences and providing information on the

efficiency of endovascular tool movement. Following in-depth examination of the components of endovascular skill on the basis of expert opinion, a comprehensive series of live and simulation-based experiments are presented which demonstrate feasibility and validate this novel software as an assessment method of endovascular technique. Finally, the VMA software is used to evaluate a novel robotic catheter technology, and further ideas for further development of this software are discussed.

RESEARCH AIMS

Following a description of recent advances in endovascular techniques and surgery, and identification of the role of endovascular technique and skill as a determinant of technical success and clinical outcome, this research will aim to *evaluate* the role of video-motion analysis (VMA) as a robust and objective tool for the assessment of endovascular efficiency and skill. A comprehensive discussion of existing training methods and surgical skills assessment tools is initially presented, in order describe present training strategies and delineate the advantages and limitations of existing skills assessment tools. Subsequently, expert opinion on the components of endovascular skill is sought with the objective of identifying markers of skill suitable for objective quantification using fluoroscopic digital footage as a medium. Novel VMA software is described, and its reliability is established using bench-top models initially. A series simulated pre-clinical and clinical studies are then performed in order to investigate the hypothesis that endovascular skill can be objectively assessed using software that semi-automatically tracks catheters and assesses efficiency of movement. Specifically, construct validity of VMA is examined in terms of its ability to differentiate between groups of experience and expertise, and to correlate the VMA-derivable metrics with existing markers of skill. This research concludes with a study describing the use of VMA in the assessment of novel robotic catheter technology, with the aim evaluating its ability to differentiate between conventional and robotic catheterisation techniques in terms of efficiency.

DECLARATION OF ORIGINALITY

I hereby declare that the work presented in this thesis is my own, except where work was carried out in collaboration with other individuals who are appropriately credited. I was responsible for designing all studies with guidance from my supervisors, except where previously acquired video-footage was used for evaluation of the software, in which case this has been appropriately indicated. I created the relevant databases and performed the data extraction and quantitative analyses. Sybghat Rahim contributed to the data collection and analysis for the bench-top validation chapter.

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DEDICATION

This work is dedicated to Nada, Nigel, Marissa and Rebeka.

You all know how important you are to me and I do not need a famous philospher's citation to emphasise this.

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LIST OF ABBREVIATIONS

AAA	Abdominal Aortic Aneurysm
ACAS	Asymptomatic Carotid Atherosclerosis Study
ACST	Asymptomatic Carotid Surgery Trial
CA	Coronary Angiography
CAS	Carotid Artery Stenting
CCA	Common Carotid Artery
CEA	Carotid Endarterectomy
CREST	Carotid Revascularisation Endarterectomy Versus Stenting Trial
CT	Cannulation Time
CV	Contrast Volume
DAP	Dose-Area Product
ECA	External Carotid Artery
ECST	European Carotid Surgery Trial
EVAR	Endovascular Aortic Repair
FEVAR	Fenestrated Endovascular Aortic Repair
FT	Fluoroscopy Time
GRS	Generic Rating Scale
IC3ST	Imperial College Complex Cannulation Scoring Tool
ICA	Internal Carotid Artery

IQR	Interquartile range
NASCET	North American Symptomatic Carotid Endarterectomy Trial
OSATS	Objective Structured Assessment of Technical Skills
PSRS	Procedure-Specific Rating Scale
PT	Procedure Time
TCD	Transcranial Doppler
VMA	Video-motion Analysis

CHAPTER 1.

ENDOVASCULAR THERAPY

1.1. THE DEVELOPMENT OF ENDOVASCULAR TECHNIQUE

Vascular surgery is a rapidly evolving specialty with a growing interest in the development and refinement of minimally invasive techniques. Particularly in vascular surgery a continuous technological drive lies behind this evolution. Endovascular intervention is concerned with the endo-luminal treatment of disease and permits the management of complex arterial problems in patients who would have otherwise been precluded from open surgery as a result of cardio-pulmonary co-morbidities. It reduces surgical trauma and a large body of evidence suggests a reduction in morbidity and mortality. European Vascular and Endovascular Monitor (EVEM) data from 2010 indicates that the number of endovascular procedures is steadily increasing in Europe, with a particular emphasis on thoracic pathology, aorto-iliac, and femoro-popliteal interventions (EVEM data, 2010). The number of infra-renal Endovascular Aneurysm Repairs (EVAR) is steadily growing, however there is a much greater penetration of this technique in the United States in the setting of ruptured aneurysm repair (Karthikesalingam et al., 2014). The past three decades have witnessed a dramatic technological evolution in terms of endovascular devices, imaging modalities, and endovascular simulation training.

1.1.1 EARLY DEVELOPMENTS

Possibly the first demonstration of an endovascular procedure, although via a venous route, was performed by *Werner Forssman* in 1929, when he inserted a plastic tube into his own right cubital vein and guided it successfully into the right atrium, taking an X-ray to prove his findings (Delfino and Cornet, 2006). Shortly prior to this in 1927, Portuguese physician *Egas Moniz* had developed the technique of angiography, initially imaging the cerebral vasculature. In 1953, *Ivan Seldinger* described the key principle that underpins modern endovascular access; the insertion of a guide-wire to establish arterial access, over which catheters could be advanced. Ten years later, *Thomas Fogarty* made the transition from diagnostic to therapeutic endovascular techniques by developing the first balloon-tip catheter for the removal of occlusive embolic debris (Fogarty and Cranley, 1965). At the time, uptake of this technique was slow given the widely held concept that contact with the intima of a vessel could precipitate occlusion. *Charles Dotter* and *Melvin Judkins* combined the techniques described by Seldinger and Fogarty in 1964 by accessing a left sided infra-inguinal arterial lesion via an ipsilateral puncture with a guide-wire and advancing a dilating Teflon balloon to the stenotic lesion, which was subsequently inflated repeatedly, resulting in successful intraluminal angioplasty (Dotter and Judkins, 1964). Further development in the venous field led to the development in 1973 of the vena cava filter, dramatically changing the treatment of pulmonary thromboembolism (Greenfield et al., 1973). The refinement of low-profile and fixed-volume balloon systems by *Andreas Grüntzig* led him to perform the first coronary balloon angioplasty on an awake patient in 1977 in Zurich

(Grüntzig, 1979). A further landmark development occurred with the design of a collapsed balloon-expandable bare-metal stent which was used to support a porto-caval fistula in a canine model (Palmaz et al., 1985).

1.1.2. BENEFIT OF ENDOVASCULAR THERAPY

Since these early developments, a number of studies have demonstrated the benefit of the endovascular approach in both aneurysmal (EVAR I, EVAR II) and peripheral occlusive arterial disease (Bypass Versus Angioplasty in Sever Ischaemia of the Leg-BASIL) in terms of morbidity and mortality (EVAR trial participants, 2005; Adam et al., 2005). Early outcomes following endovascular management of thoracic aneurysms have been extensively documented by the European Collaborators on Stent Graft Techniques for Thoracic Aortic Aneurysm and Dissection Repair (EUROSTAR) registry (Leurs et al., 2004). The use of endovascular stenting has been further expanded to the treatment of aortic dissection, with a proven benefit as demonstrated by the Investigation of Stent Grafts in Aortic Dissection (INSTEAD) trial (Nienaber et al., 2013). Since the early pioneering work of *Andreas Grüntzig*, the endovascular treatment of coronary disease has dramatically changed the nature of cardiological practice, with large randomised trials such as the Stent Restenosis Study (STRESS), and the Belgium Netherlands Stent Trial (BENESTENT) firmly establishing the position of coronary stents in the management of coronary disease (Fischman et al., 1994; Serruys et al., 1994). This has led to in increased use of endovascular techniques in routine vascular practice, and inclusion of a broader patient cohort who would have been otherwise considered unsuitable for open

surgery. A unique skill-set is required to practice these techniques safely, with experienced vascular surgeons having to re-train in many instances to acquire proficiency in endovascular techniques. In recognition of this, vascular training is shifting towards integrated vascular post-graduate programs, and multiple inter-disciplinary interventional societies have come to prominence in the last three decades.

1.2. CAROTID INTERVENTION

Carotid occlusive disease is the predominant pathology affecting the carotid arteries. Stroke, which is responsible for approximately 17000 deaths annually in the UK (Office for National Statistics, 2010 data), is defined as a focal or global loss of cerebral function, which lasts for >24 hours. Transient ischaemic attack can present with similar neurological deficit, although symptoms resolve prior to elapse of 24 hours from onset. The incidence of first-ever stroke is 2.4/1000, however increases with age. Eighty percent of all strokes are ischaemic, the remainder are haemorrhagic, and approximately 80% affect the carotid territory. The main causes of ischaemic stroke in this territory are thromboembolism (50%), and small vessel occlusion of end-arteries (25%). Other causes include cardiac embolism, and haematological disorders (eg polycythaemia). Whilst the carotid bifurcation is prone to atherosclerosis, the most frequent single cause for ischaemic stroke in the carotid territory is thromboembolism from the internal carotid artery (ICA).

1.2.1. THE OPEN PROCEDURE- CAROTID ENDARTERECTOMY

Felix Eastcott performed the first carotid revascularisation at St.Mary's Hospital in 1954 (Eastcott et al., 1954), and *Mike DeBakey* is credited with further developing this procedure and establishing it world-wide (DeBakey, 1975). Evidence from prospective randomised control trials suggest that surgical intervention is beneficial in symptomatic carotid artery disease with a stenosis of greater than 70%, with the risk of stroke in such cases as high as 26% if treated by medical means alone (ECST trial participants, 1991; NASCET trial participants, 1991). Combining the data from NASCET, ECST and Veterans Administration trials, the Carotid Endarterectomy Trialists Collaboration (CETC) (Rothwell et al., 2003) were able to demonstrate that one of the most striking predictors of success is the speed to treatment; if performed less than two weeks from the onset of symptoms dramatically reduces the number of strokes in symptomatic patients (302 strokes prevented per 1000 CEAs at 5 years). CETC also found that percentage of stenosis was a predictor of stroke, and that patients with a smaller degree of stenosis obtained a smaller degree of benefit from CEA; symptomatic patients with a stenosis ranging from 50%-69% have a smaller benefit (NNT=22), whilst in those with less than 50% stenosis, surgical treatment was found to be inferior to medical therapy. A 17% reduction in risk of stroke by two years was demonstrated by NASCET, the equivalent of 1 major stroke prevented for every six patients treated (NNT=6).

Controversy still surrounds the management of patients who are asymptomatic: the Asymptomatic Carotid Artery Stenosis (ACAS) and Asymptomatic Carotid Surgery

Trial (ACST) compared CEA with best medical practice for patients with stenoses of 60-99%, broadly concluding that CEA conferred a reduction in the risk of stroke as compared to medical therapy alone; 1% annual risk of stroke for CEA versus 2% for medical therapy alone (ACAS trial participants, 1995; Halliday et al., 2004). Furthermore, ACST demonstrated that CEA reduced the risk of fatal/disabling stroke, but that it was not beneficial in patients aged >75. However, it is still not possible to identify who benefits from treatment the most. Neither trial demonstrated that women gained benefit from CEA. It has been suggested that with recent advances in medical therapy, that the annual risk of ipsilateral stroke can be reduced to 0.34% (Marquardt et al., 2010). A systematic review identified that annual ipsilateral and any-territory stroke risk in asymptomatic patients with a severe proximal ICA stenosis receiving medical therapy alone has fallen since the mid-1980's (Abbott, 2009). It is apparent that successful identification of patients at risk of stroke is required to maximise benefit of CEA. A number of reports suggest that the use of degree of stenosis and symptomatology may be too crude in terms of indicators, and that more subtle predictors such as lesion progression, plasma biomarkers and plaque morphology or stability may represent fertile opportunities for further investigation (Carotid Stenting Guidelines Committee, 2010; Naylor, 2011).

1.2.2 THE ENDOVASCULAR APPROACH

The superiority of either Carotid Artery Stenting (CAS) or CEA is an ongoing subject which is extensively debated at multi-disciplinary vascular societies world-wide. Following an initial report in 1977 describing carotid angioplasty on a canine model by *Klaus Matthias*, an interventional radiologist, the first description of this technique on a human was described by Kerber and colleagues in 1980 (Kerber et al., 1980). This subsequently fuelled the development of carotid stent technology and the refinement of cerebral protection devices which filter embolic debris arising from this procedure. A number of high-powered prospective randomised controlled trials sought to clarify the efficacy of CAS over CEA, although the relatively low penetration of CAS in routine practice (approximately 25% of all carotid revascularisations), suggests that this technique has not been adopted perhaps as readily as other endovascular interventions (EVEM data, 2010).

CAS versus CEA

The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial sought to evaluate the benefits of CAS over CEA in patients with co-existing conditions which increase the risks associated with open surgery, and enrolled symptomatic patients with >50% stenosis and asymptomatic patients with >80% stenosis (Yadav et al., 2004). In this trial, CAS demonstrated significant benefit over CEA in terms of the primary end-point; a composite of death, stroke, or myocardial infarction within 30 days or death or ipsilateral stroke from 31 days up to 1 year. 20 CAS patients and 32 patients assigned to CEA reached this end-

point. In symptomatic patients the incidences of the primary end-point were equivalent at 1 year for both groups (CAS-16.8%, CEA-16.5, p = 0.95), however significantly greater for asymptomatic patients in the CEA group. The Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) was a multicenter study in which 251 patients were randomised to CAS and 253 to CEA. Re-stenosis >70% was found more often in the endovascular arm. In the 30-day perioperative period, there were 8 non-disabling strokes (resolution of neurological deficit by 7 days) in the angioplasty group versus one in the CEA group. This levelled out after this period, and there were no significant differences between the two groups at maximum follow-up (McCabe et al., 2005). The Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE) trial differed from previous studies in that only symptomatic patients were enrolled (within 180 days of a TIA or stroke). The primary end-point was ipsilateral stroke or death from the time of randomisation to 30 days after the procedure (SPACE Collaborative Group et al., 2006). The investigators did not find any significant differences between CAS or CEA in terms of this end-point, and were not able to demonstrate non-inferiority of CAS. The Endarterectomy Versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) study weakened the argument for the use of CAS, given that it was abandoned prematurely as a result of unanticipated mortality and morbidity in the CAS trial arm. The relative risk of death or any stroke within thirty days following CAS was 2.5 as compared to CEA. At 6 months, the incidence of any stroke or death was 6.1% after CEA and 11.7%, and the trial was stopped after 527 of the intended 872 patients were enrolled. At 4-year follow-up, the combined rate of peri-procedural stroke or death and non-procedural ipsilateral stroke was higher in CAS patients

(Mas et al., 2008). The Carotid Revascularization Endareterectomy versus Stenting (CREST) trial represents the largest attempt to compare CAS against CEA in symptomatic and asymptomatic patients with >70% stenosis. Stringent exclusion criteria applied to the patient cohort in terms of co-morbidities. The same stent and embolic protection devices were used across all centres. The primary end-point was a composite of stroke, MI, or death of any cause during the peri-procedural period, or any ipsilateral stroke during the 4-year follow-up (Brott et al., 2010). In terms of the primary end-point, there was no difference between the CAS or CEA groups. Both groups had similar procedural mortality rates, but CAS had significantly higher rates of stroke, whilst the CEA group had higher rates of myocardial infarction. The largest study to date documenting long-term outcomes in symptomatic patients with carotid artery stenoses greater than 50% is the International Carotid Stenting (ICSS) Study, which randomised 1713 patients to stenting or endarterectomy on a 1:1 basis (Bonati et al., 2014). At a median follow-up period of 4.2 years, there were no differences in the rate of fatal or disabling strokes, although the rate of any stroke was significantly higher in the stenting group. During the peri-procedural period there was no significant difference in terms of the primary end-point (composite of any stroke, myocardial infarction or death) between CEA (4.5%) and CAS (5.2%- p= 0.38).

1.2.3 SUMMARISING THE EVIDENCE

Carotid endarterectomy remains the gold standard, and considerable debate remains as to the efficacy and safety of the endovascular alternative. Randomised trials of CAS versus CEA are conflicting in terms of outcome, and do not provide an overall message in terms of efficacy of CAS over CEA. Possible reasons for this include heterogeneous patient populations, differing end-points, varying levels of endovascular expertise, varying endovascular techniques (including the use of embolic protection devices), and the use of varying stents. However, the outcome data points towards an increased rate of stroke associated with the CAS procedure, which is associated with a significant cerebral embolic burden (Bonati et al., 2010). The cause of this appears to be multi-factorial, including poor patient selection, anatomical variation (both arch configuration and carotid artery tortuosity), and plaque morphology. The use of an embolic protection device, as seen in EVA-3S, plays a role in the reduction of embolic events. Perhaps most importantly, the role of experience and expertise has been shown to have a direct bearing on the rate of neurological complications; Verzini and colleagues analysed all CAS procedures performed by a vascular team including a surgeon and an interventional radiologist, over two distinct intervals (2001-2003 and 2004-2006), and found that the 30-day stroke and death rate decreased from 3.1% for the first interval to 0.9% for the second (p = 0.047) (Verzini et al., 2006). This is extended to include the use of embolic protection devices; when a new protection device is introduced, there is still a demonstrable learning curve in terms of operator experience and 30-day risk of ipsilateral stroke; Lin and colleagues evaluated the first 200 CAS cases performed at

a single institution following introduction of a new embolic protection device, dividing this cohort into four sequential groups of 50 cases (P. H. Lin et al., 2005). They found the 30-day stroke and death rate to be 8% and 2% for the first two groups and 0% for the last two groups (p = <0.05). This suggests that a significant amount of emboli occur in the operative phases prior to the deployment of the device; ie. manipulation within the aortic arch and cannulation of the common carotid. The technical success of this phase therefore appears to be operator-dependent. The CAS procedure is extensively investigated in the subsequent data chapters, so a brief overview is given below.

Carotid Artery Stenting- Technique

The procedure can be performed under local anaesthesia (Roubin et al., 2001). Although practice varies amongst clinicians, pre- operative aspirin and clopidogrel are usually given. 5000 units of unfractionated systemic heparin are administered. Access is achieved percutaneously via the common femoral arteries, although brachial and cervical access routes are alternatives. An initial angiogram is performed to obtain views of the intra-cranial and extra-cranial circulation by placing a pig-tail catheter at the ascending aorta and obtaining an aortic flush view. There are a variety of ways of performing this procedure, and a comprehensive description of each would be inappropriate here, however an overview of the key principles is provided. After obtaining angiograms with the pig-tail, and acquisition of desired road-maps, the common carotid artery (CCA) is selectively cannulated with a pre-shaped angled catheter over a 0.035-inch guide-wire. The guide-wire is then exchanged for a 0.035-inch stiff wire, which secures access in the CCA and allows for

stable exchange of catheters and sheaths. Subsequently, a large access sheath or guiding catheter is introduced over the stiff wire into the CCA and positioned at a stable position 2-3 cm from the origin of vessel. Some operators prefer to advance the 0.035-inch wire into the ipsilateral external carotid artery (ECA) when advancing catheters into the CCA to act as an “anchor”, in order to afford further stability and avoid slipping out of the CCA when the sheath is being advanced. The latter results in a “flick” in the vicinity of the ostium of a target vessel with a stiff wire which is particularly risky in terms of releasing emboli. With the sheath in position, the stenotic lesion is crossed with a 0.014-inch guide-wire, and is selected specifically because its soft, low-calibre tip is less likely to cause embolisation. Subsequently, a balloon or filter type of protection device is inserted over the 0.014-inch guide-wire to catch particulate embolic material whilst the stent is being deployed. More recent systems, such as the FilterWire EZ^{TM} (Boston Scientific, Natick, MA, USA) consist of a 0.014-inch guide-wire with a pre-loaded filter system. Subsequently, the lesion is pre-dilated with a carotid artery balloon inflated to the appropriate pressure. After slow deflation of the balloon and withdrawal, the lesion is stented. Stents can be self-expanding or balloon-expandable mechanisms, however most operators tend to use self-expanding mechanisms. The stent may be post-dilated depending on the final disposition of the stent and lesion on check angiogram. After check angiography, filter is retrieved carefully and the long-sheath gently withdrawn and replaced with a shorter one of the same diameter. After clotting times have reverted to normal, the sheath is withdrawn and a femoral closure device applied to prevent haematoma formation.

Flow reversal systems make use of an artificially created arterio-venous shunt in combination with occlusion of the external and common carotid arteries and collateral perfusion via the Circle of Willis in order to direct the flow of blood away from the brain whilst the lesion is being manipulated. These are a comparatively new development and are not used in subsequent chapters so will not be discussed further detail.

1.3. CORONARY INTERVENTION

Coronary Heart Disease causes over 117,000 deaths a year in the UK, accounting for almost 1/5 deaths in men and 1/6 deaths in women (BHF Heart Statistics, 2013). Whilst mortality associated with CHD have fallen rapidly since the late 1970's, they are still among the highest in Western Europe.

Diagnostic coronary angiography (CA) is the most frequently performed arterial procedure, with 215,575 diagnostic coronary angiographies having been performed in 91 interventional centres in a year according to the most recent UK National Coronary Angioplasty Audit (Ludman, 2006). Percutaneous Coronary Intervention (PCI) is generally one of the most frequently performed procedures in contemporary medical practice with 1400/million performed annually in the UK.

1.3.1. EARLY DEVELOPMENTS

Surgical revascularisation of the myocardium was introduced in 1968, when Argentine cardiac surgeon *Rene Favoloro* performed the first bypass of native coronary arteries using saphenous vein grafts (Favaloro, 1968). Following Gruentzig's early experience, the first series of percutaneous transluminal coronary angioplasty (PTCA) appeared slightly less favourable in terms of durability, with a primary success rate of only 64% and a requirement for emergency CABG in 14%. The incidence of peri-procedural myocardial infarction was 6% (Grüntzig, 1979, 1982). During this first decade of percutaneous coronary revascularisation, the devices

available were unwieldy; there were no guidewires, catheters were large, and dilation balloons had low burst-pressures.

1.3.2 SUBSEQUENT DEVELOPMENTS

Between 1975 and 1985, guide-wire, catheter and balloon technology improved with the development of devices with slimmer profiles and high burst pressures. Despite subsequent acquisition of experience and a reduction in acute complications, the incidence of re-stenosis and re-intervention following the standard non-stenting technique, or POBA (plain old balloon angioplasty), remained as high as 40% (Holmes et al., 1984). Subsequent research into the causes for these high failure rates yielded information on three distinct pathophysiological entities; *elastic recoil*, *acute vessel closure*, and delayed *re-stenosis* or *neo-intimal hyperplasia*. In the first instance, elastic recoil typically occurred in 5-10% of patients following POBA (Bauters et al., 1996). Acute vessel closure is the consequence of altered lesion geometry which is caused by fracturing and fissuring of the atheroma, which in turn exposes the sub-endothelial matrix to circulating blood, resulting in platelet aggregation and thrombosis (Chandrasekar and Tanguay, 2000). Re-stenosis is a complex pathological process which is initiated by the initial traumatic insult caused by the balloon inflation; following the medial smooth muscle injury and necrosis, a phase of co-ordinated smooth muscle proliferation and migration occurs, known as *neo-intimal hyperplasia*. It is defined as a greater than 50% reduction in luminal diameter (Clowes et al; 1983).

1.3.3 CORONARY STENTING

Bare metal stents were designed to overcome this restenosis and reduce the deleterious effect of neo-intimal hyperplasia, since the increase in diameter gained by the stent exceeds the degree of narrowing caused by proliferation of smooth muscle cells through the struts of the stent (Ellis and Topol, 1989).

The first deployment of bare-metal stents into humans occurred in 1984 (Sigwart et al., 1987). Subsequent prospective RCTs sought to evaluate the efficacy of bare-metal stenting over POBA in terms of re-stenosis. The Stent Restenosis Study (STRESS) compared stenting with angioplasty only in patients with stable or unstable angina. Re-stenosis was reduced from 42% to 32% (p = 0.04) using stent procedures (Fischman et al., 1994). The Belgium Netherlands Stent (BENESTENT) Trial enrolled 520 patients and similarly demonstrated a significant reduction in terms of re-stenosis in the stented group (22%) versus balloon angioplasty (32%, p = 0.02). There was also a significant reduction in terms of the composite end-point of death, myocardial infarction, stroke, and need for repeat PTCA or CABG in the stenting group (Serruys et al., 1994).

Despite superiority of stenting over POBA, acute stent thrombosis was recognised as a serious complication and associated with a significant incidence of myocardial infarction. The presence of metal struts within the vasculature acts as a nidus for platelet aggregation and the early use of bare metal stents was associated with a high frequency of acute thrombosis (Nath et al., 1993). In BENESTENT and STRESS,

thrombosis occurred 3.5% of patients within a period of two weeks, despite anticoagulation and dual anti-platelet therapy. Earlier data suggests that this occurred in up to 24% of patients, and was associated with acute trans-mural infarction in 90% of these cases (Serruys et al., 1991). A number of subsequent trials such as the Intracoronary Stenting and Antithrombotic Regimen Study (ISARS) and the Stent Antithrombotic Regimen Study (STARS) resulted in optimisation of anticoagulation regimens and a reduction in adverse cardiac events (Schömig et al., 1996; Leon et al., 1998). In-stent re-stenosis refers to proliferation and migration of vascular smooth muscle cells within the stents, and occurred in 20-30% of cases (Hoffmann et al., 1996).

1.3.4. DRUG ELUTING STENTS

Drug Eluting Stents (DES) were developed to countenance restenosis; bare metal stents were coated with anti-proliferative agents. Early designs were coated with sirolimus, an immunosuppressive compound and paclitaxel, an anti-cancer drug. Both of these led to substantial reductions in the rate of in-stent re-stenosis (Moses et al., 2003; Morice et al., 2002; Stone et al., 2004). Subsequent prospective RCTs included the Randomized Comparison of a Sirolimus-Eluting Stent With a Standard Stent for Coronary Revascularization (RAVEL) trial, which demonstrated a significant improvement in terms of 5-year freedom from target lesion revascularisation in the DES group (89.7%) versus the bare-metal stent group (74%, p = <0.001) (Morice et al., 2007). The Sirolimus-Eluting Stent in De-Novo Native Coronary Lesions (SIRIUS) trial enrolled 1058 patients with de novo coronary artery lesions likewise demonstrated a reduction in terms of target vessel revascularisation rates (9.4% vs 24.2%, p=<0.001) (Weisz et al., 2009). None of these trials demonstrated an increase in rates of stent thrombosis, a concern with drug-eluting stents (Lagerqvist et al., 2009). Nonetheless, next-generation DES have been designed to reduce the risk of stent thrombosis including the use of biodegradable scaffolds, polymer-free DES, and DES with novel anti-proliferative agents such as zotarolimus and novolimus (Serruys et al., 2010).

1.3.5. ENDOVASCULAR MANAGEMENT OF MYOCARDIAL INFARCTION

In terms of the management of acute myocardial infarction, initial reports suggested that patients benefited from angioplasty without stenting (Grines et al., 1993). Given the potential risk of stent thrombosis associated with DES and bare metal stents, investigators have sought to evaluate carefully the use of these stents in myocardial infarction, which culminates in acute thrombosis and occlusion of a coronary vessel. The proposed mechanism is that the anti-proliferative effects of these agents also impairs epithelialisation of an already fractured plaque, continuing to expose the sub-endothelial matrix to circulating blood and exacerbating platelet aggregation (Lagerqvist et al., 2009). In The Stent versus Thrombolysis for Occluded Coronary Artery in Patients with Acute Myocardial Infarction (STOP-AMI) trial, the use of stenting plus abciximab was demonstrated to be superior to thrombolysis alone in terms of myocardial salvage and reduction in the incidence of death, re-infarction and stroke at six months (Schömig et al., 2000). The Stent Primary Angioplasty in Myocardial Infarction trial (Stent PAMI) enrolled 900 patients to either receive heparin coated stents or balloon angioplasty. Stent placement resulted in lower rates of angina, and reduced rates of the composite end-point (death, re-infarction, stroke and target vessel re-intervention) at six months (Stone et al., 1999). The Abciximab before Direct Angioplasty and Stenting in Myocardial Infarction Regarding Long-Term Follow-up (ADMIRAL) trial compared stenting plus abciximab with stenting alone, and demonstrated improved coronary flow and a lower incidence of major adverse cardiac events at six months in the stenting plus abciximab group (Montalescot et al., 2001). The Controlled Abciximab and Device Investigation to

Lower Late Angioplasty Complications (CADILLAC) trial did not suggest that any advantages were conferred from the addition of abciximab (Stone et al., 2002).

It is clear that perhaps in comparison to other endovascular interventions, percutaneous coronary intervention is the most widely adopted world-wide and has dramatically changed the nature of the management of occlusive coronary disease, allowing a broader cohort of patients who would have otherwise been precluded from open coronary revascularisation to undergo treatment. Furthermore, the use of coronary stenting has extended treatment options for patients suffering from acute MI who would have otherwise been precluded from systemic thrombolysis. The technique of coronary angiography is outlined below since this procedure is evaluated in a later data chapter.

Coronary Angiography- Technique

The procedure is started with administration of local anaesthesia and access to the common femoral artery is obtained percutaneously by puncturing the vessel with a hollow needle and advancing a guide-wire through it and into the aorto-iliac segment. A sheath is advanced over the wire and secured in the access vessel. A 0.035-inch J-shaped guide-wire is inserted into the sheath and advanced proximally under fluoroscopic guidance. A shaped diagnostic catheter is passed over the guide-wire and advanced over the aortic arch, further directing the wire tip over the arch, taking care not to inadvertently cannulate the supra-aortic vessels. The catheters typically used are angled Judkins catheters, pre-shaped and designated according to the side which is to be cannulated. Once the catheter is positioned at the ascending

aorta, the wire is withdrawn allowing the catheter to shape. The coronary vessel is cannulated and an angiogram performed to confirm successful and stable position. Views using multiple standardized C-arm angles are obtained to accurately evaluate the coronary anatomy and assess lesion morphology. After this assessment, a decision is made to proceed with intervention or withdraw the catheter. Femoral closure is usually performed with a femoral closure device.

1.4. AORTIC ANEURYSMS

Aortic aneurysms were first described by Roman physicians around AD 100. *Rudolf Matas* successfully ligated the aorta of a patient with an abdominal aortic aneurysm (AAA) in 1923. A further example of an early attempt to treat an aortic aneurysm occurred in 1948 when *Rudolph Nissen* was able to successfully prolong *Albert Einstein's* life by wrapping his aneurysm in cellophane, encouraging fibrosis of the arterial wall. The subsequent years have seen many advances and improvements in the diagnosis and treatment, however around 6000 deaths per year in England and Wales are caused by rupture (Office for National Statistics, 2010 data). Incidence increases with age; 85% of all cases occurring in patients 65 and over (National Center for Health Statistics, 2007 data). An aneurysm is defined as an abnormal, focal dilation of a vessel of greater than 50% increase in diameter. All three layers of the vessel, intima, media and adventitia are involved. Morphologically they can be fusiform, which is dilatation of the whole vessel, or saccular; a focal bulge arising from the side of the vessel. 90% are infra renal, the rest involve the renal and mesenteric vessels (thoraco-abdominal), or thoracic only. The majority of aneurysms are atherosclerotic or degenerative in nature (80%), 15% are due to dissection and the remainder are due to arteritis, connective tissue disorders and trauma (Griepp et al., 1999). Reports of annual growth rates vary, although it is accepted that annual growth rate is related to initial diameter: Two recent meta-analyses suggest that the mean rate of growth of small aneurysms is 2.3 mm/yr and that for each 0.5 cm increase in aneurysm sac diameter, the rate of growth increases by 0.5 mm/year (Powell et al., 2011; Thompson et al., 2013). Factors influencing rate of growth are

multifactorial and include smoking and blood pressure (Moxon et al., 2010; Thompson et al., 2013), and a further report suggests that inflammation further increases the rate of expansion (Richards et al., 2011). Annual rate of growth in diameter, and the annual risk of rupture is related to, and increases with the aneurysm size. Below 5 cm the risk is <2%, between 5 and 5.9 cm the annual risk of rupture is 5%, and increases to 6.6% for aneurysms between 6-7 cm, and 19% for aneurysms over 7 cm (Szilagyi et al., 1972).

1.4.1. EARLY MANAGEMENT OF AORTIC ANEURYSMS- OPEN REPAIR

In 1951, *Charles Dubost* dramatically changed the management aortic aneurysms by performing the first successful repair of an aortic aneurysm. The diseased aorta was resected and replaced by a 15 cm homograft taken from the thoracic aorta of a 20 year old who had died three weeks earlier. The graft was anastomosed to the aorta and the right common iliac artery. Following endarterectomy of the left common iliac, this was then anastomosed to the graft (Dubost et al., 1952). Although the technique has considerably changed, this approach became the mainstay of management for AAA over the next thirty years. Typically, open infra-renal aneurysm (IRAAA) repair is performed via an anterior midline approach and requires clamping below the renal arteries ideally, to maintain perfusion to the kidneys. Supra-renal clamping increases the risk of renal and visceral mal-perfusion and is less preferable although sometimes required depending on the length of the infra-renal neck. After proximal and distal control has been secured, the diseased aorta is repaired either

with a Dacron or polytetrafluoroethane (PTFE graft). Given the relative invasiveness of this procedure, it is surprising that the majority of procedures are still carried out with an open technique in Europe (69%), although this number has steadily decreased since 2003 (EVEM data, 2010). The repair of thoraco-abdominal aortic aneurysms (TAAA) is an even more demanding task, both for the surgeon and on the patient. Access is usually via a mid-line laparotomy which is extended to a lateral thoracotomy, with division of the diaphragm. These aneurysms are defined by involvement of the renal, mesenteric and coeliac arteries, and require clamping above these vessels. Revascularisation of major branches arising from the aorta frequently requires cardio-pulmonary bypass with hypothermic circulatory arrest, single-lung ventilation and CSF drainage, resulting in prolonged operative times and significant blood loss. Open thoracic aortic aneurysm (TAA) repair can be broadly classified into ascending repairs, which are usually performed by cardiothoracic surgeons and will therefore not be discussed here, and descending repairs. Similar to TAAA repair, CSF drainage, single-lung ventilation, permissive hypothermia, and sequential clamping are routinely used. Additionally, the kidneys can be intermittently perfused with cold crystalloid to minimise ischaemic injury. Balloon perfusion catheters can be used to perfuse individual visceral vessels, following connection to a left-heart bypass circuit. This allows the viscera to be perfused whilst intercostal and visceral branches are re-attached to the graft. A modified thoraco-abdominal incision is used, and following deflation of the lung, the 6^{th} rib is usually excised. The diaphragm is partially incised, the left atrium is cannulated after incision of the pericardium, and left-heart bypass is commenced. The latter is performed to maintain distal aortic and visceral perfusion. After placement of a proximal clamp,

usually between the left common carotid and subclavian arteries, the aorta is incised and the repair commenced. As vessels are re-attached to the graft, the clamp is sequentially placed to more distally to allow perfusion of the newly anastomosed vessels. After the distal anastomosis has completed the repair, the patient is gradually re-warmed with saline.

The traditional open approach is associated with significant morbidity and mortality rates: 1.4-6.5% for elective open IRAAA repair which increases to 23-69% for ruptured cases (Ernst, 1993; McPhee et al., 2009). TAAA has significantly worse mortality rates (8-30% for elective cases and 50-80% for ruptured cases) and is associated with a paraplegia incidence of up to 16% (Svensson et al., 1993; Safi et al., 1998; Schepens et al., 2007; Coselli et al., 2007)

1.4.2. ENDOVASCULAR AORTIC REPAIR (EVAR)

The first successful deployment of an endovascular prosthetic device for repair of the aorta was undertaken by Ukranian surgeon *Nicholas Volodos* in 1987, successfully treating a pseudoaneurysm of the thoracic aorta that had occurred as a result of a road traffic accident (Volodos et al., 1988). In 1991, *Juan Carlos Parodi* described the endovascular repair of IRAAA using a knitted Dacron graft which was sutured at the proximal and distal ends to balloon expandable ring stents, which provided friction seals at the ends of the graft. Successful exclusion of the aneurysm from blood flow was demonstrated in a small series of five patients, although longer-term follow-up was not provided in this paper (Parodi et al., 1991). This paper is also

the first to describe the principles of endograft planning; sonographic and CT measurements were obtained to successfully define required stent and balloon diameters. In 1994 Michael Dake described his unit's experience with custom-designed endoprostheses composed of woven Dacron and self-expandable stainless steel ring-stents in a series of 13 patients with descending thoracic aneurysms. At a follow-up period of 11 months there was no mortality, and no instances of stroke, paraplegia or distal embolism (Dake et al., 1994).

The grafts are placed via small groin incisions or through a percutaneous approach, and can in some instances be performed under local anaesthesia. The devices are deployed under fluoroscopic guidance. In contrast to the conventional open procedure which replaces the diseased aorta, the aneurysm sac is excluded and retained. This results in less blood loss, shorter procedure-times and faster recovery, however regular follow-up is required with CT-scanning or ultrasonography and debate exists as to which imaging modality should be used how frequently this should occur (Karthikesalingam et al., 2010). The evidence and techniques for intervention in other arterial territories subsequently described in experimental chapters are detailed in the next section.

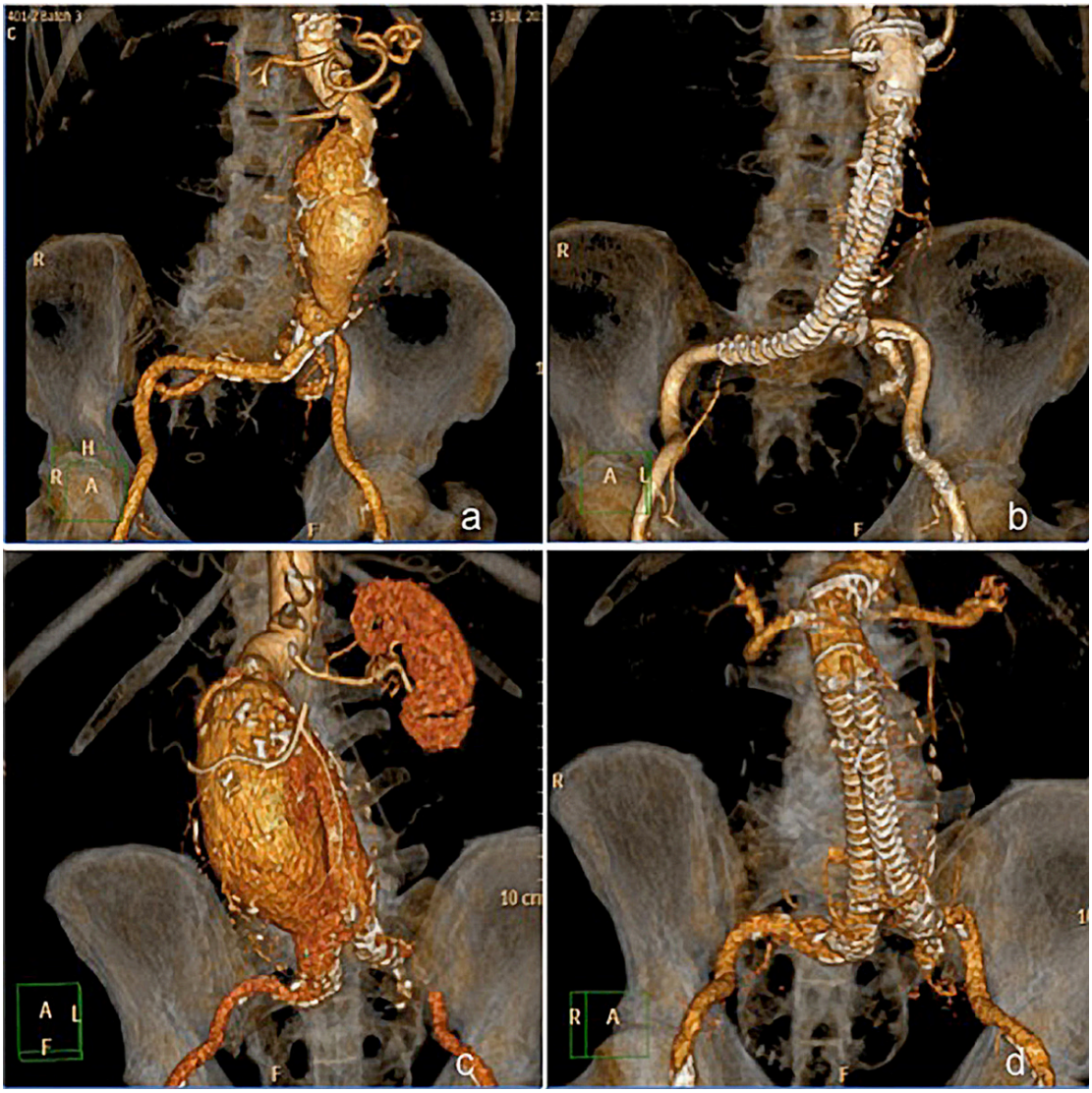


Figure 1. 3D reconstructions showing fenestrated endovascular aortic repair.

1.4.3. EVOLUTION OF EVAR TECHNIQUE

As described above, early grafts consisted of fabric tubes which relied on ring-stents exerting radial forces to affix them to the aortic wall. These were ultimately shown to be vulnerable to migration. Since then, most grafts have evolved to be bifurcated modular devices with additional mechanisms to actively reinforce proximal fixation. The normal fixation design is usually composed of a bare metal stent that extends into the supra-renal aorta or barbs and hooks. The benefit of EVAR versus open repair has been extensively investigated in prospective randomised trials, retrospective reviews and registries (Zarins et al., 1999; Harris et al., 2000; Moore et al., 2003; Matsumura et al., 2008), which have demonstrated reduced hospital stay, reduced morbidity and reduced blood loss. The EVAR I and Dutch Randomised Endovascular Aneurysm Management (DREAM) trials have confirmed fewer aneurysm-related deaths in the endovascular versus the open repair groups (EVAR trial participants, 2005; Blankensteijn et al., 2005). Four years after randomisation, all-cause mortality between the two groups was similar. The EVAR group had a significantly higher re-intervention rate, although most re-interventions were classified as benign. Between 30 days and 4 years, the majority of deaths were due to ischaemic heart disease or cancer. EVAR II compared EVAR with conservative management for patients unfit for open repair. It failed to demonstrate a significant difference in all-cause mortality between the two groups, and by 4 years 64% of the patients had died. EVAR was, however, associated with a significantly lower-rate of aneurysm related death as compared to no repair (United Kingdom EVAR Trial Investigators et al., 2010).

EVAR I and EVAR II have been subject to criticism; the latter trial has been criticised especially for several reasons. The definition of “unfit for repair” was inconsistent and varied between centres, whilst the crossover rate from conservative management to endovascular was high, and these patients generally did well but were treated statistically under intention to treat rules, thereby improving the results for the conservative management group. Furthermore, a lot of the outcome measures utilised in these trials are not applicable to current practice, since they were reported prior to the introduction of reporting standards by the Society for Vascular Surgery (Chaikof et al., 2002). Endoleak is a common phenomenon in endovascular aortic grafting, and occurs as a result of inadequate sealing between the graft and the aortic wall (Type I), leaking between modular components of the graft (Type III), and back bleeding from covered vessels, such as the inferior mesenteric or lumbar arteries (Type II). Type IV refers to leaking through the graft due to porosity, whilst type V -also known as “endotension”- is characterised by persistent pressurisation of the sac despite absence of a demonstrable leak on imaging. As a result, complete exclusion of the aneurysm has not occurred and continued pressurisation can result in aneurysm sac expansion and at worst rupture. Late rupture is associated with delayed aneurysm sac expansion, suggesting a late loss of seal and consequent endoleak, and carries a high mortality (Candell et al., 2014). The EVAR trials treated all three endoleak types as equal, however subsequent reporting standards state that type II endoleaks are frequently benign and resolve spontaneously. Although open repair is still considered the gold standard in younger patients with few co-morbidities because of the increased rate

of secondary interventions and requirement for prolonged follow-up with EVAR, it is still associated with considerable complications which require re-intervention; population-based studies have demonstrated that patients undergoing open repair are twelve times more likely to undergo laparotomy and adhesiolysis in the future (Schermerhorn et al., 2008).

1.4.4. COMPLEX ANEURYSMS

The applicability of conventional EVAR is considerably limited by aneurysm morphology, in particular two anatomical configurations. Juxta-renal aneurysms are classified surgically by the inability to apply a clamp below the renal vessels during open repair, whilst thoracoabdominal aortic aneurysms involve coeliac, superior-mesenteric and renal vessels (fig. 2). As described previously, EVAR requires a sufficient length of aorta which is relatively free of thrombus and not excessively angulated ($<60^0$) in order to obtain a sufficient proximal seal. This segment of aorta is frequently referred to as the Proximal Landing Zone (PLZ). If these anatomical requirements are not met, or aneurysmal change has involved the renal or visceral vessels, proximal sealing is required above these vessels, resulting in mal-perfusion of organs supplied by these vessels. Data from the EUROSTAR registry has shown that a neck length <15 mm or severe angulation result in increased frequency of type I endoleak post-operatively (Hobo et al., 2007; Leurs et al., 2006). Fenestrated and branched stent-grafts represent a more recent development in graft technology with the objective of overcoming these anatomical limitations without compromising visceral or renal branch perfusion.

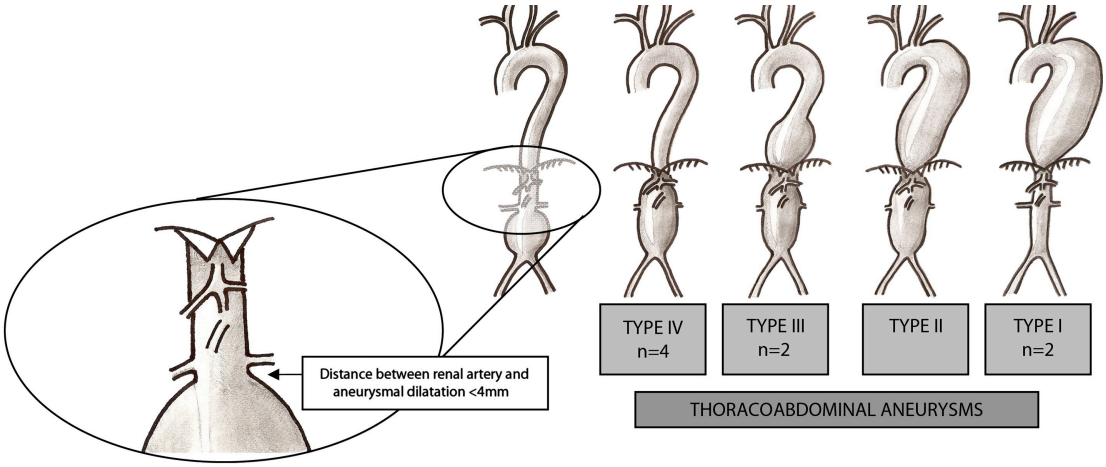


Figure 2. Classification of thoracoabdominal aortic aneurysms.

These devices have been designed to extend the proximal sealing zone from the infra-renal to the supra-renal and thoraco-abdominal segments. In comparison to standard infra-renal stent-grafts, these devices are modified to include *fenestrations* (windows) or directional branches which are incorporated into the main body of the graft. Both of these modifications are custom-made to match the patient's anatomy and require a considerable period of time for manufacture.

The concept of fenestrations was first introduced in 1999; Dacron grafts were modified manually and deployed in canine models (Browne et al., 1999). Early experiences in man with short-necked infra-renal aneurysms were positive; no acute vessel loss or deaths were reported (Anderson et al., 2001; Stanley et al., 2001). Subsequent reports followed and reviews of fenestrated stent-grafting suggest a 97% target vessel patency with a peri-operative mortality of 1.1% (O'Neill et al., 2006; Sun et al., 2006). A recent systematic review suggests there is no difference in peri-operative mortality between open repair and fenestrated EVAR (FEVAR) for juxta-renal aneurysms in the elective setting (Rao et al., 2014). The largest two series of fenestrated stent-grafting to date stem from the Cleveland Clinic in Ohio and France (Mastracci et al., 2013; Haulon et al., 2010), with 8 and 4.4 years follow-up respectively. The Cleveland Clinic series describe an 84% freedom from branch re-intervention over five years, and only three instances branch-stent related deaths in 650 patients. The French series describes 12 re-interventions and four instances of renal artery occlusion over the duration of follow-up, none of which resulted in aneurysm-, or branch-stent related deaths. Management of more extensive TAAA requires a different approach in that branched devices are required for their

management, if the aneurysm sac is to be excluded without the risk of type III endoleaks at the junction of the main body of the graft and the visceral/renal fenestrations, which would in theory occur in such lesions if the main body migrates as a result of aortic pulsatile flow. An initial report describes the use of a branched homemade device (Anderson et al., 2001), following which a number of studies documented the repair of complex aneurysms with a 5-9% mortality and a technical success rate of 90-98% (Greenberg et al., 2006; Roselli et al., 2007; Bicknell et al., 2009; Haulon et al., 2010).

Fenestrated and branched stent-grafting appear to be an effective and safe alternative to open repair, however the endovascular approach can be limited by anatomical constraints such as neck, iliac and target vessel angulation. More recent designs to overcome these limitations by removing the supporting metal struts in the main body, thus increasing options for positioning of fenestrations and flexibility in terms of deployment in very angulated aneurysms (Bungay et al., 2011). A brief description of the technique for fenestrated stenting is given below, since this procedure is studied in later chapters.

Fenestrated Stenting- Technique

Under general anaesthesia, the common femoral arteries are exposed surgically. Access is either via these vessels or an iliac conduit. The patient then receives systemic heparinisation with a 5000-unit bolus, and the main body of the device is introduced via one of the common femoral arteries over a standard stiff wire, and deployed under fluoroscopic control to verify the correct positions of the

fenestrations. The renal or visceral arteries are cannulated using a combination of shaped catheters which are advanced over soft angled hydrophilic guide-wires. Once the catheters have been advanced a sufficient distance into the target vessel to afford stability for wire exchanges (usually 3-4 cm), the guide-wire is withdrawn and a stiff wire is advanced the full length of the target vessel to secure access. Subsequently bridging stents are inserted into the target vessels through a supporting sheath, balloon expanded, and flared proximally to mould them to the main body of the device. Finally the contralateral iliac limb of the graft is deployed using a retrograde cannulation technique, and limb extensions are deployed. Following balloon moulding of all junctions, a check angiography is performed to check the patency of all branch stents and iliac limbs and to exclude endoleak. More recent devices such as the Anaconda^{TM} fenestrated stent-graft system (Vascutek, Inchinnan, Scotland) are re-deployable, allowing finer control when cannulating fenestrations, and do not have a top cap allowing cannulation of caudally oriented target vessels via brachial access (Rolls et al., 2014).

1.4.5. LIMITATIONS OF ENDOVASCULAR INTERVENTION

Data presented in the preceding sections have clearly demonstrated advantages of endovascular intervention in terms of management of complex vascular problems with outcomes comparable to open techniques, if not improved in terms of peri-operative morbidity, mortality, and enhanced recovery. Furthermore patients who would have previously been precluded from surgical intervention now have definitive treatment options available to them. Extensive evidence suggests that outcomes following complex endovascular procedures such as CAS, are significantly affected by levels of expertise. Initially reported by the CREST investigators, interventionists invited to participate in the "lead-in" phase of the trial were required to have a minimum baseline level of experience in terms CAS experience. Data from this phase of the trial suggests that there were no significant differences between various specialties performing the procedure, and that there was no clustering of adverse events around particular institutions (Hobson et al., 2004). Shortly after this, Lin and colleagues were able to demonstrate a clear reduction in the stroke rate coupled with increasing technical success rates at an institutional level with increasing cumulative experience (Lin et al., 2005). Cao and colleagues demonstrated a significant increase in the rate of stroke/death at 30 days following CAS as compared to CEA (Cao et al., 2006). Moreover, there was a progressive reduction in 30-day neurological complication rates with increasing experience. Importantly, 50% of disabling strokes occurred during cannulation of supra-aortic aortic target vessels, prior to deployment of protection devices, possibly suggesting that operator technique during the cannulation phase influences neurological

outcome. These findings were further corroborated by Verzini and colleagues who demonstrated a reduction in 30-day stroke and death rates with progressive cumulative experience at a single institution (Verzini et al., 2006). This may also reflect improvements in available devices and technology. The relationship between volume of experience and outcomes is mirrored in standard infra-renal EVAR: Klompenhouwer and colleagues have demonstrated in their series that treatment related mortality for EVAR dropped from 4.4% in an early cohort to 0% in the most recent cohort, whilst the re-intervention rate similarly dropped from 19.1% to 7.5% in the same cohorts (p = 0.039) (Klompenhouwer et al., 2013). Again, this may in part also reflect improved technology and patient selection. Another group evaluated the effect of endovascular specialty teams versus general vascular theatre teams in terms of operative outcomes (Mullenix et al., 2005). After the introduction of specialist endovascular teams, the same vascular unit was able to significantly reduce blood loss, intravenous contrast usage and procedure times. Similarly Forbes and colleagues were able to demonstrate that overall institutional experience significantly affects the learning curve of a less experienced surgeon undergoing accreditation in EVAR; time to reach plateau in terms of technical success and complication rate is significantly reduced in the novice attending surgeon, if established surgeons at the same institution have accrued significant prior expertise (Forbes et al., 2007).

Success of endovascular intervention is heavily influenced by anatomic constraints. In contrast to open surgery which provides open-field access to the desired area of intervention, endovascular procedures require navigation from a remote access site,

usually the femoral or brachial arteries to the target lesion. Access vessels can be heavily calcified, making the vessel difficult to puncture. Tortuosity can impede the delivery of larger devices such as aortic stent-grafts or longer access sheaths. Furthermore, tortuous access vessels can adversely influence finer manipulation of smaller tools such as guide-wires and catheters at the target site (Riga et al., 2012). Even if the access vessels are not challenging from an anatomical perspective, angulation of the target vessels in relation to the aorta or tortuous terminal branches can severely impair access to the desired lesion and significantly impair the efficiency of the performance (Riga et al., 2011; Willaert et al., 2012). Furthermore, atherosclerotic lesion composition and morphology can be prohibitive to successful balloon angioplasty and stent deployment, for instance in heavily calcified plaques. The nature of a plaque has been correlated with embolic burden; early reports suggest that ulcerated plaques are more likely to shed emboli (Gaunt et al., 1996), whilst the role of calcium content in carotid plaques remains conflicting (Timaran et al., 2010; DeRubertis et al., 2007). Two reports suggest a positive correlation between lipid-rich plaque composition and emboli (Bicknell, 2003, Brightwell et al., 2011; Timaran et al., 2010). Moreover, in aortic intervention existing devices are restricted by morphological aneurysmal configuration, with shorter and severely angulated aneurysm necks resulting in higher incidences of technical failure and endoleak (Hobo et al., 2007; Leurs et al., 2006).

Anatomical complexity and operator experience, given the heavy use of fluoroscopic guidance in endovascular procedures, can significantly impact the degree of radiation exposure to the operator and patient; screening times have been positively

correlated with increasing anatomical complexity (Willaert et al., 2012), and are inversely correlated with increasing experience (Van Herzeele et al., 2007). Moreover, cumulative patient radiation dosages have been shown to have a significant association with operator experience and grade in live coronary intervention (Clark et al., 2000; Vano et al., 2001). Follow-up after EVAR is a highly debated topic which is beyond the scope of this section although standard practice is to undertake annual surveillance scanning. Annual CT scanning is associated with a significant radiation burden to the patient (Kalef-Ezra et al., 2011). Increasing evidence suggests that Duplex scanning is a viable alternative to CT scanning (Karthikesalingam et al., 2012), and despite increasing uptake of this imaging modality, it still places a considerable burden on radiology services (Karthikesalingam et al., 2013).

Although endovascular intervention confers significant benefits which have been extensively discussed, it is evident that considerable draw-backs are associated with this practice. In particular, expertise and skill and anatomical complexity have a significant bearing on clinical outcome following these procedures. The purpose of the next chapter is to evaluate existing training and skill assessment methods and identify potential areas for future development.

CHAPTER 2.

TRAINING AND ACCREDITATION

2.1. TRAINING IN THE CURRENT ERA

The introduction of the European Working Time Directive has dramatically influenced the nature and delivery of surgical training, and in particular elective procedures, since its inception in 2003 (Blencowe et al., 2011; Hallam et al., 2013; Breen et al., 2013). Surgical trainees are now undertaking shorter, but more frequent on-call duties which detract from elective day-time training opportunities and a reduction in senior-house officer and registrar-led procedures (Blencowe et al., 2011) . Similarly, at night, cross-covering of a variety of divergent surgical sub-specialties have reduced the time available to more junior trainees to attend emergency procedures in their primary sub-specialty of interest. Introduction of the 80-hour resident working week in the United States has not significantly either improved surgical education (Sneider et al., 2009) or reduced objective measures of burn-out (Gelfand et al., 2004).

Furthermore, greater public scrutiny of the skill acquisition process in highly technical specialties such as surgery and interventional disciplines have led to a shift in the structure and design of surgical curricula away from the traditional apprenticeship model advocated by William Halsted (Osborne, 2007). It is no longer deemed acceptable for a novice trainee to undertake initial training experiences on patients, and the concept of the “pre-trained novice” has been widely popularised by a number of surgeons and educationalists (Van Sickle et al., 2006; Neequaye et

al., 2007), and refers to the concept of a trainee with automated basic psychomotor skills and spatial judgements (Di Giulio et al., 2004; Willaert et al., 2012). The advantage of this model is that the trainee would enter the operating room already equipped with basic automated skills which would allow a shift of focus to effective decision making processes without incurring additional risk to the patient. It also in theory presents a more cost-effective solution to surgical training; allowing the trainee to focus on the specifics of a case and acquire procedure-related experience rather focus on the basic technical skills which could have been perfected in a training lab.

Increased patient expectations do not only apply to acquisition of skills in the novice trainee. Incidences such as the Bristol Case (Walshe and Offen, 2001) have led to a shift towards increased transparency and accountability of already qualified consultant surgeons. This is evidenced by the recent introduction in December 2012 of re-validation by the General Medical Council as well as national publication of consultant-level morbidity and mortality data, with the sub-specialties of cardiac and vascular surgery being the first to do so in 2005 and 2013, respectively (National Vascular Registry, 2013).

The last four decades have witnessed the rapid evolution of minimally invasive endovascular therapies. A range of clinical specialists are claiming an interest in minimally invasive arterial procedures, including vascular surgeons, cardiologists, nephrologists, neurologists and neurosurgeons (Rosenfield et al., 2005). The traditional approach to training which is largely carried out on patients is based on

the principle of graded responsibility whereby the trainee is gradually progressed on to more complex tasks following subjective assessment usually by a single trainer. This is considered largely unacceptable particularly given evidence pertaining to operator experience and complications; several studies have demonstrated a direct relationship between operator experience and the incidence of complications, particularly in arterial territories supplying target organs sensitive to embolisation (Mas et al., 2008; Lin et al., 2005; Cai et al., 2014). Furthermore, this approach is expensive and time-consuming (Bridges and Diamond, 1999; Crofts et al., 1997). Trainees require 30-70% more time to complete open procedures than consultants, at an additional annual cost of 1.3 billion pounds (Crofts et al., 1997). The rapid development of new endovascular techniques and devices means that even experienced interventionists, who already possess generic endovascular skills need to acquire additional skills when a new device is introduced. In a retrospective analysis of 200 CAS cases with a new neuro-protective device, surgeons experienced in CAS still exhibited a demonstrable learning in terms of their complication rates, with reduced incidence in the last fifty patients in the cohort treated with the new device (Lin et al., 2005).

2.2. VIRTUAL REALITY SIMULATION

Virtual reality simulation in the generality of surgery was proposed by Satava in 1993 in laparoscopic surgery (Satava, 1993). The use of high-fidelity simulators in endovascular surgery was described in 2004 in the setting of carotid artery stenting (Dayal et al., 2004; Hsu et al., 2004). Since then, initial reports describing the use of

simulation in various vascular beds have been described including coronary angiography (Gallagher et al., 2006), renal intervention (Aggarwal et al., 2006; Berry et al., 2006), lower-limb angioplasty (Chaer et al., 2006) and intra-cranial angiography (Fargen et al., 2012). Subsequently, technological developments and refinements of simulator software have allowed the incorporation of patient-level CT-angiograms (Willaert et al., 2010, 2012) and MR-angiograms (Cates and Gallagher, 2012) into computer-based simulation devices resulting in extensive investigation of mission rehearsal or patient-specific rehearsal (PSR): This has largely been applied to CAS (Willaert et al., 2012, 2010) and more recently EVAR (Desender et al., 2013). These studies have demonstrated that although the real cases ultimately took longer to complete, PSR allowed operators to optimise fluoroscopy angles and in some instances tool usage. To truly validate a simulation device, it is necessary to demonstrate that skills obtained in virtual reality simulation can be *transferred* to live cases and that a benefit is conferred to those trainees who undertake VR simulation in terms of their technical skills. This can be achieved by randomising two groups of trainees to either ongoing apprenticeship training or on-going apprenticeship training with additional VR training and comparing performance between the two groups in terms of objective performance metrics and clinical outcomes. This line of study has provided convincing results in laparoscopic simulation (Gallagher et al., 2013; Grantcharov et al., 2004), although evidence is limited in endovascular surgery: Berry et al demonstrated that skills acquired in VR simulation are transferable to porcine models, but not vice versa (Berry et al., 2007). There are presently no simulator studies which demonstrate this transferability to live human endovascular cases.

In addition to validating simulators across a range of vascular beds, multi-societal guide-lines exist, which stipulate minimal cognitive and hands-on volume requirements to acquire baseline competence in complex procedures such as CAS, firmly stating that metric-based simulation should be incorporated into training programs (Rosenfield et al., 2005).

Recent work suggests that nontechnical skills, including team interaction and stress management have an impact on surgical technical skills, or at least on objective assessments thereof (Hull et al., 2012). Further study of VR simulation may need to incorporate non-technical skills components.

2.3. SKILL ACQUISITION

There is no clear evidence describing the components of endovascular skill, but a number of issues must be taken into account in order to develop sound training and assessment strategies. Previously, methods for acquiring base-line levels of skill in new procedures in certain centres relied on cadavers, mechanical models, animals, and supervised experience on patients. Problems with this approach include the ethical and anatomical constraints of performing procedures on animals, the costs of obtaining and storing cadavers, the lack of authentic haptic feedback on mechanical models and the cost of consuming real endovascular materials. In addition to the increased risk of clinical adverse events of training novices on human subjects, there

is a risk of inappropriate and excessive radiation exposure both to patient and trainee, as the latter familiarises him or herself with optimal fluoroscopic angles.

More than most interventional procedures, the consequences of embolisation in carotid stenting are catastrophic and can lead to stroke and death. CAS has been shown to have definite learning curve (Roubin et al., 2001). In the United States the Food and Drug Administration (FDA) have approved virtual reality simulation as an important part of a training package for CAS. As described above, when a new procedure is introduced a diverse group of specialists seek to acquire competence in it, however different specialties have unique psycho-motor skills requisite to their practice. For example, a vascular surgeon has considerable knowledge of three-dimensional vascular anatomy and knowledge of vascular disease processes, having seen them at first hand during open procedures, but may lack some of the psychomotor technical skills of wire and catheter manipulation, and may be unfamiliar with the optimal use of fluoroscopic equipment. Conversely, non-surgical intervenionists may not have the in-depth anatomical knowledge and understanding of clinical management issues of a vascular surgeon. Similar to laparoscopic surgery, the endovascular approach requires the operator to mentally perceive three-dimensional structures on the basis of two-dimensional visual input. The operator is also required to rapidly adapt to reduced tactile sensation or haptic feedback when learning endovascular technique initially. The acquisition of endovascular skill is further compounded the difficulty when rectifying complications which require urgent attention, such as vessel dissection, through the endovascular route.

Given the present educational climate, reductions in working hours and consequent reductions in training opportunities, increasing patient expectations, and rapidly evolving technology, simulation seems likely to play an increasingly important role in vascular education in the future.

2.4. TRAINING DEVICES

Training devices can be broadly classified into high-fidelity systems, which deliver physiological characteristics such pulsatile flow and fluoroscopy (Chong et al., 1998; Willaert et al., 2010), and low-fidelity models which are typically solid plastic replicas of vascular structures. The purpose of this section is to give an overview of the most commonly used training devices used presently.

2.4.1. Synthetic Models

Early descriptions of vascular models involved design of solid models typically made of transparent plastic materials. Chong et al describe a technique whereby a computed model of a symmetrical AAA including iliac and renal vessels was used to design a solid and transparent acrylic simulation model for the purposes training simple tasks. The same authors describe the design of silicone models using a rapid prototyping technique; real patient CTA data was used to create a solid model, after which an investment casting process was to create transparent silicone models (Chong et al., 1998). In order to mimic a C-arm, a monochrome camera was mounted onto an adjustable metal strut which can be manipulated to adjust “fluoroscopic

angles". Willems et al describe an innovative design that employs a camera mounted above a box containing a dry glass model of an aneurysmal aorta. The video feed is merged using a computer generated abdominal X-ray in order to create bony land-marks (Willems et al., 2009). Whilst such models are useful for training basic skills, potential criticisms include un-realistic physical properties of the rigid glass aortic wall, which doesn't expand with pulsatile flow. In particular, this model does not provide pulsatile flow, however most silicone devices can be attached to a pump which can generate such flow properties.

A number of companies such as Elastrat Sarl (Geneva, Switzerland) specialise in providing a diverse range of silicone models replicating a variety of generic arterial models, as well as patient specific replicas on the basis of CT-DICOM data. Custom-designed models have a fairly rapid turn-over from submission of DICOM data to delivery (roughly 4 weeks), although even the non-custom designs can be costly, with a standard infra-renal aneurysm model costing up to € 3000. These models have been widely used at our institution (Riga et al., 2011; Rafii-Taril et al., 2012) and in the United States (Narra et al., 2009). Advantages include the ease with which pulsatile flow can be generated, the durability and minimal maintenance requirements of the models. Furthermore, various models can be connected to each other, for instance an abdominal model and a thoracic model, re-creating the aorta in its entire length.

Further potential drawbacks of silicone models include image acquisition and the replication of fluoroscopic views: In our experience, a light source projected onto the

model in a coronal plane (ie. in an AP direction) can cause significant glare and problems visualising the endovascular tools. Ways around this involve placing the light source laterally or posteriorly and placing a black background behind the model. Successfully mimicking fluoroscopy can be challenging but can be achieved by using a monochrome camera. The silicone models are readily screened using fluoroscopy, although one could argue that this exposes trainees to inappropriate levels of radiation given the simulated nature of the procedures. Other disadvantages of non-VR training models in general are that they generally permit single use of more advanced endovascular tools only, for instance non-re-deployable aortic endo-grafts.

2.4.2. Animal Models

Animal models provide a high degree of realism in terms of the properties of the vasculature and interaction with endovascular instruments; it is possible to artificially create endothelial injury (Lin et al., 2000). Animal models have been used in a joint collaboration with our institution to test the safety profile of robotic catheter technology (Bismuth et al., 2011), and to assess the transferability of VR-acquired endovascular skills onto porcine models (Berry et al., 2007). The investigators of the latter study found that VR-acquired skills could be transferred onto the porcine model, but not vice versa. Disadvantages include the need to acquire and maintain animal licensing, ethical considerations, and the price of establishing and maintaining animal laboratories. In addition, differences between human and animal anatomy can limit the realism of the procedure. The size of most

animal vessels are too small to accurately represent those of a human, and in many cases preclude the use of certain endovascular devices such as introducer sheaths and aortic endo-grafts. The use of bovine and simian models would potentially facilitate this, although these animals are expensive and not permitted for use in certain countries such as the UK.

2.4.3. Human Cadavers

The use of human cadavers in training affords a degree of realism not provided by other simulation methods, provided they are prepared properly. Cadavers used for this purpose are donated by the individual and have usually been turned down by anatomical laboratories on the grounds of previous surgery or congenital abnormality. In principle they provide an ideal platform for training, given the appropriate calibre of vessels with multiple branches, and obviously a full complement of arterial systems. Challenges involve preservation of cadavers without significantly altering the elastic properties of vessel walls, and restoring antegrade and pulsatile flow. One approach describes the use of frozen cadavers which have not been embalmed (Garrett, 2001), which are then slowly thawed over a period of three days prior to preparation for use. In-flow and out-flow access is established via the common carotid and superficial femoral arteries, respectively, and two litres of solvent are flushed through the arterial tree to remove thrombus. In order to provide pulsatile antegrade flow a circuit incorporating a pulsatile flow pump is used: A large catheter is inserted into the descending thoracic aorta and large-bore cannula into the superficial femoral arteries. The profunda arteries are clamped

bilaterally. Human cadavers are limited in terms of availability and costs relating to appropriate storage. In keeping with training on animal and synthetic models, advanced endovascular tools can only be used once in this setting, adding to costs associated with this simulation technique.

It is apparent, as discussed in the previous section, that training requirements have accelerated with evolving endovascular technologies and increasing patient expectations. VR simulation appears to provide a means to achieve this, at least in the early stages of training, and further work is required to identify the potential of these devices at the "high-end" of expertise and to provide evidence of skills transfer to live cases. The next section describes the evolution and design of various assessment modalities.

2.4.4. Procedicus VIST™

The Procedicus VIST simulator (Mentice, Gothenburg, Sweden) is one of the two most commonly used Virtual Reality devices available for commercial use and has been extensively studied in terms of its validity both as a means for training and assessment. It is comprised of a mechanical unit which is covered by a plastic cover. The latter can be fashioned in the form of a mannequin or kept as a simple rectangular box for the purposes of transfer to training centres and conferences. The other key components include a high-performance desk-top computer and two flat-panel display screens which function as the fluoroscopy screen and physiological monitor. A variety of devices can be inserted through an access port. Most guide-

wires and catheters can be admitted through the port, although hydrophilic wires can sometimes cause damage to the haptics device. Generally speaking, “universal” wires and straight catheters are usually provided by Mentice during formal training sessions. The system allows the course convenor or participant to register the generic tool on the system which is then displayed on the fluoroscopy screen as a specific tool. The haptics interface device produces tactile feedback for the operator and is created by a series of motorised carts which lock on to the inserted tool and allow the operator to manipulate the instrument in real time with force-feedback; ie pushing a tool against a vessel wall results in increased resistance which is felt by the operator.

One of the key advantages of the VIST is that it can give real-time feedback on performance on a second-by-second basis. Full-physics characteristics of the catheter-vessel wall interaction allow for rapid collision detection between devices and the simulated vessel wall. The VIST uses programmed properties of the devices to calculate the forces of movement and then the shapes of the tools the operator sees on the screen. The anatomical detail is usually rendered from real patient CTA or MRA data. Qualitative feedback on performance is provided in response to interactions between the virtual devices and virtual anatomy, allowing the operators to identify in real time the nature of an error, and allowing them to correct it. Metrics are provided by an automated panel that provides quantitative metrics including procedure time, fluoroscopy time, contrast volume and number of cine-loops. Qualitative metrics include stent placement accuracy, percentage of lesion coverage and percentage of residual stenosis.

2.4.5. AngioMentor™

The AngioMentor platform (Simbionix, Airport City, Israel) offers a broad range of simulated procedures across most arterial systems, including trans-catheter aortic valve implantation (TAVI), CAS, TEVAR, Intracranial Aneurysm Coil Embolisation, and below-the-knee procedures. In comparison to the VIST, more emphasis is placed on physiological monitoring and drug administration, facilitating a more thorough immersion into a specific scenario. For instance, atropine or beta-blockers can be administered to regulate heart rate during a procedure. Along with the VIST, the AngioMentor is one of the most widely used simulators and has been extensively validated across a range of procedures (see systematic review). The simulation device is housed in a more compact and elongated casing and can be readily transferred to conferences and training facilities. It comes as a single device which includes a high-end haptics device, a high-performance desk-top computer, 2 LCD screens, controls for fluoroscopic image manipulation, contrast injection, table manipulation, cine-loop recording, road-mapping, balloon inflation and stent-deployment. The AngioMentor Ultimate is mounted onto a work-space, with physiological monitoring and fluoroscopy images provided by two integrated flat-panel monitors, and is used for more permanent training arrangements at designated institutions. By contrast, the AngioMentor Mini is a small, portable version which is designed for teaching of basic angiographic skills.

In comparison to the VIST, AngioMentor does provide an automated panel of quantitative and qualitative metrics at the end of the procedure, however lacks the

second-by-second provision of qualitative feedback on catheter and wire movements which are a key property of VIST. The ability to provide immediate and proximate feedback is a key component of training and accelerates procedural knowledge acquisition in trainees significantly (Cates and Gallagher, 2012). Whilst the simulator can provide summative feedback at the end of each procedure including total number of errors performed, it cannot tell the operator in real-time when these errors are being committed, for instance “advancing catheter ahead of guide-wire”, which can result in the procedure being performed in a risky fashion or the omission of key steps.

Drawbacks of VR simulation devices are the considerable time and financial requirements required in maintaining the devices. The haptics mechanism in the VIST system grasps the inserted tools in a series of motorised carts which provide the mechanism for “resistance”. The inserted tools are detected by optical sensors, which detect the size and diameter of the inserted device. Both of these mechanisms are sensitive and require on-going calibration, particularly after episodes of repeated use such as training courses. Standard annual maintenance contracts are approximately 10% of the purchase value.



Figure 3. Team training in a fully integrated and simulated interventional suite.

2.5. ASSESSMENT OF SURGICAL SKILLS

Traditionally, skills assessment throughout the generality of surgery and in endovascular procedures has relied upon direct observation in the operating room of a trainee by a dedicated trainer. In the United States this is usually performed by a single mentor or a small group of attending surgeons since most residencies are completed in the same institution. In the United Kingdom, higher surgical training is facilitated across a geographic region and a trainee rotates to different hospitals on a six-monthly or annual basis.

Advantages of this rotational approach include exposure to a diverse group of consultant trainers who can provide differing feedback, allowing the trainee to assimilate the a series of key learning points perceived as most favourable from a variety of sources. Rotations are centrally regulated by a Post-Graduate Deanery, and formal assessments are performed by the trainer in discussion with the trainee using work-based assessments derived from the Intercollegiate Surgical Curriculum Program (ISCP). This system of assessment was introduced by the Joint Committee on Surgical Training (JCST) in order to standardise assessments and to move away informal verbal feedback. Prior to this, surgical experience and expertise was assessed on the basis of log-book reviews. Whilst useful at documenting cumulative progress, they are considered by some to be a crude surrogate marker of skill, since experience is not necessarily thought to equate to skill (Beard, 2008). This was coupled with informal longitudinal assessments of patient outcomes in cases performed by trainees.

Drawbacks of the ISCP system include the potential for subjectivity; over a 6-month period it is common for the trainer and trainee to form a close professional relationship which may affect the authenticity and accuracy of feedback statements. Assessment of operative performance specifically is performed using retrospective procedural check-lists which score each procedural step on a Likert scale which is anchored according to the trainee's present stage of training. A potential criticism of this assessment method, even if it is performed correctly, is that it does not encourage excellence amongst trainees who are encouraged to perform to a level "appropriate" to their stage in training. Furthermore, no clear definition exists regarding precisely what this level of attainment is. The assessments are time-consuming and retrospective, and given the volume required to pass a given training year (40 work-based assessments in most Deaneries), critics of this method claim that it becomes little more than a tick-box exercise (Vesey et al., 2013). If completed properly, the trainee is given an impression as to whether each stage of the procedure has been completed to a level appropriate to his/her level of training, but there is little generic qualitative feedback in terms of the overall performance.

In summary, at the present time, guidelines regarding competence to perform endovascular procedures are based on the number of procedures performed (Gaines and Nicholson, 2006). Surgical logbooks rely on crude data which are considered unreliable and surrogate markers of skill (Moorthy et al., 2003). The purpose of the next section is to describe in detail existing assessment tools which have been investigated extensively in the assessment of both live and simulator performance.

2.5.1. THE REZNICK SCALE AND ITS DERIVATIVES

Richard Reznick, of the University of Toronto is largely credited with the conceptual design, introduction and validation of a Global Rating Scale sometimes referred to as the Reznick Scale. Often referred to as the OSATS (Objective Structured Assessment of Technical Skill), this is in fact is a misnomer; the latter refers to a formal examination methodology which was subsequently pioneered by the same department. In a hallmark paper (Reznick, 1993), he describes the department's initial efforts to develop a rating scale, known as the Structured Technical Skills Assessment Form. Underpinning this is the rationale to move away from subjective and informal assessments, which are largely unstructured and can be misleading for the trainee. Referred to as "direct observation without criteria", a key criticism of the latter technique is that it exhibits a low level of agreement between assessors. The same trainee might receive very different assessments from two different experts assessors which can be influenced by other factors within a department, for example bias as a result of previous conflict which occurs all too frequently in the intense environment of an acute surgical unit.

The key requirements for an effective test of skill are outlined and consist of feasibility, reliability and validity. Feasibility in this context refers to whether a department has the means, financial, and time-wise, and the necessary expertise to perform an assessment. Reliability refers to the consistency of a test. In other words, if the same test were administered to the same trainee on two separate days by the same assessor, and there was no technical or cognitive training within that interval, how similar would the results be? Inter-observer reliability refers to the same

principle, except describes the similarity of the scores on the same trainee between two different assessors. Validity refers to whether a test actually measures what we think it measures, and there are several domains of validity which need to be fulfilled if a test is to be used in high-stakes assessments such as board certification, selection to fellowships and training programs, and promotions. These are described in table 1 and have been summarised by multiple authors previously (Neequaye et al., 2007; Gould et al., 2006).

Type of Validity	Definition
Predictive	The extent to which the test will predict future performance
Content	The extent to which the trait intended to be measured is actually measured, eg technical skill rather than knowledge of anatomy.
Concurrent	The extent to which the test accurately assesses the desired domain in comparison to other existing validated tests known to assess the same domain.
Construct	The extent to which the test measures the trait it purports to measure, eg can procedure time differentiate across groups of experience
Face	The extent to which the examination resembles the situation in the real world, ie realism.

Table 1. Components of test validity

The Objective Structured Assessment of Technical Skills was first formally described in 1997 (Martin et al., 1997), and was inspired by the previously introduced Objective Structured Clinical Examination (OSCE) (Harden and Gleeson, 1979). This model of assessment involves direct observation of trainees performing standardised tasks, and although initially validated on bench-top models can be applied to VR tasks.

The scoring system introduced for this examination assesses global performance and is anchored around a 5-point Likert scale assigned to 7 qualitative statements. It is an example of “assessment with structured criteria”. The earliest mention of such an assessment model was by Liu and colleagues who describe a structured method of performance in spinal anaesthesia (Liu et al., 1980). The minimum score described in the Reznick Scale is 7 and the maximal achievable score is 35. The statements are generic in nature and describe key aspects of performance (fig. 4) across the entire procedure, rather than performance in specific phases of the operation as seen in procedure-specific check-lists. In the original study, surgical residents across a range of experience were asked to perform varying procedures on two circuits; a live circuit consisting procedures performed on pigs, and a bench-top circuit with specific tasks such as excision of skin lesions, T-tube insertion, hand-sewn and stapled bowel anastomosis, abdominal wall closure and control of inferior vena cava bleeding.

GLOBAL RATING SCALE OF OPERATIVE PERFORMANCE

Please circle the number corresponding to the candidate's performance in each category, irrespective of training level

Respect for Tissue :				
1 Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments	2	3 Careful handling of tissue but occasionally caused inadvertent damage	4	5 Consistently handled tissue appropriately with minimal damage
Time and Motion :				
1 Many unnecessary moves	2	3 Efficient time/motion but some unneccessary moves	4	5 Clear economy of movement and maximum efficiency
Instrument Handling :				
1 Repeatedly makes tentative or awkward moves with instruments by inappropriate use of instruments	2	3 Competent use of instruments but occasionally appeard stiff or awkward	4	5 Fluid moves with instruments and no awkwardness
Knowledge of Instruments :				
1 Frequently asked for wrong instrument or used inappropriate instrument	2	3 Knew names of most instruments and used appropriate instrument	4	5 Obviously familiar with the instruments and their names
Flow of Operation :				
1 Frequently stopped operating and seemed unsure of next move	2	3 Demonstrated some forward planning with reasonable progression of procedure	4	5 Obviously planned course of operation with effortless flow from one move to the next
Use of Assistants :				
1 Consistently placed assistants poorly or failed to use assistants	2	3 Appropriate use of assistants most of time	4	5 Strategically used assistants to the best advantage at all time
Knowledge of Specific Procedure :				
1 Deficient knowledge. Needed specific instruction at most steps	2	3 Knew all important steps of operation	4	5 Demonstrated familiarity with all aspects of operation

Figure 4. Original OSATS generic rating scale as described by Martin et al in 1999

Each candidate was assessed by two examiners. The authors found a strong relationship between year of training and the Global Rating Scale (GRS). There was no significant divergence between the examination formats as measured by the GRS, and inter-rater reliability between examiners using this rating scale was moderate to strong. Advantages of such an assessment method include transferability across different training and assessment settings; the Reznick Scale and modified derivative scoring tools can be applied to live cases (Niitsu et al., 2013), virtual reality simulations (Van Herzeele et al., 2008), animal models (Berry et al., 2007) and post-hoc video-based analysis of performance (Van Herzeele et al., 2009). Disadvantages are predominantly that two or more expert assessors are required, and the assessment of a full procedure, depending on its nature, can be time-consuming.

This system has been widely adapted in a number of surgical specialties, including ophthalmology (Fisher et al., 2006), orthopaedic surgery (Alvand et al., 2013), obstetrics and gynaecology (Hiemstra et al., 2011), urology (Matsumoto et al., 2001) and ear, nose and throat surgery (Diaz Voss Varela et al., 2012). A number of groups have attempted to use this tool in live cases, and have demonstrated construct validity between groups of residents in various years of training, but as expected for non-standardised live procedural assessments, the distributions of performance across the each group of experience were broad (Malik et al., 2013; Niitsu et al., 2013). In summary, the Reznick scale provides a valid method for skills assessment across a spectrum of procedures, specialties, and examination settings. It is an example of a holistic ***qualitative*** assessment method which provides information on

the generic aspects of a procedure rather than being oriented towards particular procedural phases.

2.5.2. ADAPTIONS IN VASCULAR SURGERY- QUALITATIVE RATING SCALES

The first description of the use of a rating scale in endovascular was described in 2004 (Dayal et al., 2004). Scores from 0-5 were assigned to key yet generic facets of endovascular tool manipulation in carotid artery stenting (CAS); guide-wire manipulation, catheter manipulation, catheter exchanges and use of the monorail. The authors do not describe the development of this rating scale or whether it was adapted from another source, however noted a significant improvement in this score in novice participants after a short period of intense CAS training as compared to base-line scores. Subsequent to this Chaer and colleagues describe a modification of the Reznick Scale specifically adapted for use in endovascular surgery.

In contrast to the assessment tool developed by Dayal and colleagues, the Modified Reznick Scale used in the latter paper scores more specific domains of endovascular tool manipulation such as awareness of wire position, in addition to generic aspects of the performance initially proposed by Reznick, such as flow of the procedure and knowledge of the procedure. A maximum score of 4 for each domain seemingly reflects the perfect procedure as performed by an expert who is able to forward-plan, never uses excessive movements, is perfectly confident in all aspects of wire and catheter manipulation such that the performance flows perfectly, and is obviously able to perform the procedure completely independently. Whilst this

system provides valuable information on multiple domains of endovascular performance, the process of assigning a numerical score to a qualitative statement predisposes the assessment to a degree of subjectivity. One could argue that the broad range of inter-observer reliability coefficients (Cronbach α 0.65-0.84) documented in a previous review (Bech et al., 2010) reflect subjective differences between examiners.

Other variants of global rating scales include hybrid scoring tools combining a procedural check-list with a Likert scale (Tedesco et al., 2008). In this paper, the key procedural elements were grouped as “angiography”, “wire access” and “intervention”. Each of these groups were sub-divided into a number of steps, such as “select proper wire/catheter for renal canalisation”, and assigned a numerical score from 1-5. This scoring system was labelled as a renal artery angioplasty global rating scale, which in itself is a misnomer; rating scales are broadly categorised as procedure-specific rating scales which provide a qualitative assessment of the procedural steps in a particular procedure, and global rating scales which provide a very generalised view of the quality of the endovascular technique itself, without specific reference to procedural components (Van Herzeele et al., 2009). The rating scale proposed by Tedesco et al does not provide a global assessment of endovascular technique, although the approach to its development involved incorporating procedural steps from previously validated examiner check-lists (Chaer et al., 2006; Hislop et al., 2006). Another potential weakness is the absence of inter-observer reliability, due to the lack of a second examiner. The authors however acknowledge this as a weakness and recommend that two examiners be used in

future assessments. Other examples of hybrid rating scales include a combined rating scale producing an overall Total Score (Willems et al., 2009). This was the product of a combination of OSATS to provide a generic component and a specific technical skill score, derived from a previously validated ICEPS rating scale for open vascular procedures (Pandey et al., 2006) and a procedure-specific check-list for renal artery stenting. In this study, each study participant was assessed by two examiners and inter-observer reliability for the combined score was high [Cronbach α 0.94]. A possible reason for this is the large total numerical score (max 100 points). Construct validity of this scoring system was clearly demonstrated, with a step-wise increase noted in Total Score across groups with progressing experience.

PROCEDURE-SPECIFIC RATING SCALES

Perhaps the most meticulous evaluation of qualitative rating scales using post-hoc analysis of video-footage is described by Van Herzeele et al in 2009 (Van Herzeele et al., 2009). In this paper the composition of a Generic Rating Scale (GRS), which is analogous to the Modified Reznick Scale (Hislop et al., 2006), is described and compared to a Procedure-Specific Rating Scale (PSRS) for CAS in terms of construct validity and inter-observer reliability. Importantly, the paper describes a systematic approach to the development of the PSRS by establishing consensus amongst five CAS experts in terms of the key steps required to complete the procedure. The PSRS splits the procedure into 5 operative phases and a Likert scale is applied to clearly defined qualitative statements for each phase. The last two domains describe the entirety of the procedure in terms of overall performance and quality of the final product, giving a maximum score of 35. Furthermore, in contrast to previous studies

employing coarse comparisons between inexperienced, moderately-experienced and highly-experienced groups, this study evaluated the performance of practitioners who had all performed at least 100 endovascular procedures but had varying levels of CAS experience, in an attempt to determine the ability of the PSRS to differentiate levels of CAS expertise amongst a group of generally experienced CAS interventionists. Interestingly, the Generic Rating Scale was able to differentiate between the groups of expertise, whilst the PSRS failed to demonstrate construct validity in that particular setting.

The IC3ST (Imperial College Complex Endovascular Cannulation Scoring Tool) is a further adaption of the Reznick Scale and was developed to specifically assess efficiency and technique in cannulation of target vessels during complex endovascular procedures such as FEVAR and CAS. This assessment tool specifically focuses on the operator's ability to reduce the likelihood of complications such as dissection and embolism by reducing contact with the arterial wall and paying attention to high-risk anatomical areas likely to cause embolism. The tool is able to differentiate between groups of experience and has also been used to compare novel catheter technologies against conventional techniques (Riga et al., 2010, 2011).

LIMITATIONS OF RATING SCALES

Criticism of these assessment forms is that they do not assess the entire spectrum of skills required to complete an endovascular procedure and focus specifically on the technical skills. In keeping with other surgical specialties, an ideal endovascular

performance is not specifically restricted to technical excellence, but requires additional attributes, such as cognitive and decision-making proficiency (Herzeele et al., 2008) and sound inter-personal interaction and communication (Ahmed et al., 2010). Given the complex environment of the hybrid operating suite, efficient interaction between two teams is often required; the interventional radiology team and the vascular surgical team, to the extent where both specialist interventional radiology nurses and surgical scrub nurses are often required to support the case. This environment is further complicated by the heavy requirement for fluoroscopic imaging, and meticulous communication between both teams and the radiographer is required to achieve optimal imaging, without unduly interrupting the work-flow of the case or compromising sterility of the surgical field. Albayati and colleagues identified in a prospective observational study of 66 open and endovascular procedure a total of 1145 failures or errors, which were then sub-categorised. The most frequent failures related to equipment, such as unavailability, and communication, whilst technical and psychomotor failures were less frequent. In general, endovascular and hybrid procedures were associated with an increased frequency of failures (Albayati et al., 2011). It is apparent that effective communication and sound cognitive strategies when considering alternative equipment, can in theory mitigate the effect of such errors.

In recognition of this, Bech and colleagues sought to develop a comprehensive Generic Rating Scale by synthesising existing rating scales, competence statements and task analyses/check-lists with expert opinion (Bech et al., 2010). The latter was achieved by video-recording trainees perform endovascular procedures. Each video

was watched by a trainee and an expert whilst being questioned in a semi-structured fashion, following which additional aspects of technique and performance were identified by asking a panel of experts to analyse the videos and interview transcripts using a list of items based on the literature search. The resulting points were synthesised to provide a scoring tool called SAVE (Structured Assessment of endoVascular Expertise). Based on a five-point Likert scale, it holistically assesses endovascular performance and includes additional domains of pre-planning, preparation of tools, management of imaging modalities, adaption of strategy and decision making, use of an assistant and inter-personal skills. Technical skills are further sub-divided into external skills, including appropriate tool selection, and internal skills, such as appropriate application of force during wire manipulation. Whilst this tool does not necessarily focus on the finer points of catheter and wire handling technique, it may prove useful for assessing the global performance in team-based simulations.

2.5.3. PROCEDURAL CHECK-LISTS

One of the earliest examples of a check-list being employed to assess candidates was used in parallel with a newly developed Generic Rating Scale (Martin et al., 1997). This initial report of a check-list was approved by a group of ten surgeons familiar with the University of Toronto surgical residency curriculum. An example of a typical check-list is given in figure 5. Check-lists generally function using a binaric scoring system; if a task is performed adequately, one point is awarded. If it is performed inadequately or not completed, no points are awarded. Additionally, if a trainee asks

for guidance, no points are awarded, even if the task is then completed successfully. It is evident that some procedural steps are key to successful completion of a procedure and can be particularly hazardous if completed incorrectly, and that there is therefore a need to weight the check-list appropriately. The study by Dayal et al in 2004 is one of the first to use a scoring check-list in endovascular surgery during simulated CAS procedures (Dayal et al., 2004). In recognition of the fact that some steps are more critical than others, certain manoeuvres were weighted to reflect the gravity of potential complications, such as vessel dissection or perforation, and awarded two points rather than one.

They found that this check-list was able to demonstrate an improvement in novices following focused simulator-based training, but that the expert group demonstrated no significant improvement. One of the criticisms of such a scoring system is that it has a ceiling effect in terms of assessment of endovascular skill (Bech et al., 2010). It does not necessarily assess the quality of a procedure, but rather provides information only on knowledge of procedural steps which can be acquired fairly easily by a novice. In the paper described above, this was reflected by a dramatic difference between pre- and post- simulator training task-specific check-list scores in novices, but limited improvement in the expert group, suggesting that it does not necessarily assess expertise (Dayal et al., 2004).

	Omitted or incorrect	Done correctly	Instruction required
1. Guidewire and diagnostic catheter positioned correctly?	0	1	
2. Distal aorta DSA conducted correctly?	0	1	
3. Proper guidewire technique used to gain contralateral access?	0	1	
4. Guiding catheter properly placed in the contralateral common iliac artery?	0	1	
5. “Stenosis” traversed with correct technique?	0	1	
6. External iliac artery DSA/roadmap conducted properly?	0	1	
7. Measurements and evaluations performed accurately?	0	1	
8. Proper stent catheter selection?	0	1	
9. Stent deployed accurately?	0	1	
10. Guidewire position maintained across lesion?	0	1	
11. PTA conducted correctly?	0	1	
12. Guidewire position maintained across lesion?	0	1	
13. Control DSA conducted correctly?	0	1	
14. Extraction of guidewire and guiding catheter performed correctly?	0	1	

Figure 5. Task-specific check-list: Iliac artery stenting procedure (Berry et al., 2007)

Whilst one could argue that it is actually simplicity of the simulation module which imposes restrictions on experts in terms of their ability to demonstrate true expertise, another study on a more advanced simulator demonstrated that a Generic Rating Scale, rather than an error-based check-list was able to differentiate between groups of experienced interventionists of varying CAS experience (Van Herzeele et al., 2009). One might argue that such check-lists are therefore useful for assessment and training of junior trainees, particularly if feedback is given immediately after the procedure, but less useful for expert practitioners already in possession key endovascular skills and extensive procedural knowledge.

2.5.5. SCORING MATRICES/ALGORITHMS

A different approach to skills assessment are scoring or assessment matrices, which involve a trainee performing a simulated case, for which he or she are assigned scores generated based on a complex scoring algorithm at key points of the procedure (Lipner et al., 2010). Another format involves the systematic extraction of performance data during each "check-point" of a procedure (Duncan et al., 2007). Lipner and colleagues adopted the former approach and used a rigorous testing protocol in a multi-centre study, testing a broad range of experience (novice, skilled and expert). Each participant was required to complete six simulated coronary interventions of varying difficulty. Cases were designed by the American Board of Internal Medicine (ABIM) Interventional Cardiology Testing Committee, who also decided upon key procedural phases and decision "nodes". Likewise, the scoring rubric was also determined by this select committee. The nature of this simulation

differentiates it from previous endovascular simulations in that structured yet unexpected complications were incorporated into the simulation, resulting in the addition of key decision nodes. Assessment of the participants' response to these crisis scenarios were structured and incorporated into the final score. For instance, if a candidate elected to treat a no re-flow scenario by pharmacologic means, administration of the correct drug and dose via the correct route was awarded a score for that node of +1. If the wrong route was selected, a point was deducted from the final score. Decision nodes were weighted according to the gravity of the situation, with no re-flow and onset of ventricular fibrillation being the most high-stakes decision nodes. The development of this algorithm and incorporation of unforeseen events facilitated the assessment of technical and cognitive skills in pressured scenarios, and successfully demonstrated construct validity across groups of experience.

Duncan and colleagues similarly adopted a methodical approach when designing their assessment protocol (Duncan et al., 2007). Three different simulated renal stent scenarios were used to identify and divide each operation into segments common to each procedure; preparation for angiography, acquisition and interpretation of an angiogram, selective catheterisation, assessment of stenosis, selection and appropriate positioning of a stent, deployment of the stent and finally, assessment of results. On review of the video-footage by multiple experts, it was apparent that operative phases were separated by check-points which required either an element of decision making or a particular procedural skill, such as crossing the lesion with a guide-wire. Five experienced interventionists subsequently

performed each simulation and efficiency data in the form of procedure time, contrast volume and tool use were extracted and aggregated to calculate an overall efficiency score. The investigators identified a broad range of efficiency particularly for the phases of selective catheterisation and assessment of final results, suggesting that these may be the discriminating phases during renal stenting.

Advantages of these more elaborate scoring systems include the incorporation of assessment of cognitive factors such as decision-making. Furthermore, they methodically break down each operation into its constituent phases, allowing the trainee to identify potential areas of weakness which require further development. Potential draw-backs include the complexity of the assessment protocols which appear more elaborate than the GRS and PSRS assessments both in terms of the expertise required to perform them effectively as well as the financial and logistical implications of such rigorous testing protocols, which may limit them to select testing centres in a given country.

2.6. ENDOVASCULAR EFFICIENCY- QUANTITATIVE METRICS

The nature of endovascular intervention and the heavy use of fluoroscopic imaging have facilitated the use of efficiency assessments in endovascular surgery as a result of a number of metrics which are automatically generated by the fluoroscopic equipment. Most fluoroscopic imaging systems such as Toshiba Infinix^{TM} (Toshiba Corporation, Tokyo, Japan) used in interventional cardiology, and the Philips Allura^{TM} (Philips Healthcare, Andover, MA, USA) used in vascular surgery automatically

generate data on dose-area product (DAP) as a measure of radiation exposure, number of cine-loops used and fluoroscopy or screening time. Additionally, standard practice involves the radiographers recording amount of radio-opaque contrast used during a case. The radiology nurses record numbers and types of catheters and guide-wires in order to facilitate appropriate re-imbursement from the healthcare provider. Early reports stem largely from interventional cardiology (Clark et al., 2000; Louvard et al., 2001; Salgado Fernández et al., 2003), using fluoroscopy times, procedure times, and numbers of catheters and DAP in live coronary intervention cases. Initial comparisons were typically of consultant versus non-consultant grades, coronary angiography with or without right or left heart catheterisation, and trans-radial versus trans-femoral approaches.

A number of high-fidelity endovascular simulators automatically provide this data in the form of a metric panel at the end of a procedure, including the VIST (Mentice AB, Gothenburg, Sweden) and the AngioMentor (Simbionix Ltd, Airport City, Israel). The earliest published report to document the use of simulator metrics as a measure of proficiency (Dayal et al., 2004), was able to demonstrate that procedure-time, fluoroscopy-time and contrast volume were all construct valid measures of proficiency in simulated CAS, and were able to differentiate experienced versus novice interventionists, but also that novices were able to reduce all these parameters significantly following an intensive simulator-based course, whilst the experienced group's metrics remained stable. Subsequently, a large number of simulator-based studies have used metrics as means to validate simulator modules (Van Herzeele et al., 2007), establish the benefit of training programs (Aggarwal et

al., 2006), differentiate between groups of experience (Passman et al., 2007), and to correlate with innate psychomotor aptitude (Hislop et al., 2006). These can similarly be used in phantom-based simulations used for assessment of novel catheter and stent technologies (Riga et al., 2011, 2012). Clearly visible aortic walls in this kind of a model allow for wall-hits to be counted; a metric which is used as a surrogate marker for embolic potential. Unfortunately, this usually requires 2 or more assessors since accurate visual counting of wall-hits is prone to a degree of subjectivity. More recently, a variety of groups have sought to quantify forces in endovascular intervention (Rafii-Taril et al., 2012) and unnecessary motion (Tercero et al., 2013). These studies were largely borne out of a necessity to assess the safety of novel catheter technologies in terms of potential damage to the arterial wall. Frequently used metrics and their definitions are given in table 2.

Both the VIST and the AngioMentor provide more advanced metrics in an automated fashion in the form of qualitative parameters, such as percentage of lesion coverage and residual stenosis and lesion coverage and error-based metrics, including wire and catheter-handling errors, such as advancing the catheter ahead of the guide-wire. Both of these metric types have demonstrated construct validity either in the form of a demonstrable learning curve or the ability to differentiate between groups of experience (Patel et al., 2006; Boyle et al., 2011). Advantages of such metric systems is that they provide instantaneous data in terms of endovascular efficiency, and are entirely objective, since they do not involve human interpretation of ability and are automatically produced by computer technology.

Metric	Definition
PT	Procedure time. Usually defined as the period of time (mins) between endovascular access and final angiogram
CT	Cannulation time. Period of time taken (mins) to successfully cannulate a target vessel. Usually measured from the resting position of a guiding catheter to stable position of that catheter 2-4 cm within the target vessel, although this is an arbitrary definition and varies between institutions.
FT	Fluoroscopy time. Period of time (mins) during which the fluoroscopic system is screening.
CV	Contrast volume. Total volume of contrast (mls) used for a case. Includes hand injection and aortic pump injection.
DAP	Dose-area product. Quantity used in assessing radiation risk. Defined as absorbed dose multiplied by the area irradiated (Gy cm^2)
Wall-hits	Number of times a catheter contacts the arterial wall. Can be counted visually or with the aid of a force sensor.
No of catheters	Total number of catheters used during a case.
No of cine-loops	Number of times a contrast run is re-played to the interventionist.

Table 2. Common performance metrics and their definitions

Although early enthusiasm for automated metrics prompted their wide-spread use in simulator-studies as well as studies involving live cases (Gould et al., 2006), a number of authors have queried the validity of automated metrics (Neequaye et al., 2007; Bech et al., 2010), citing poor correlations between metrics and levels of experience, and the need to provide more refined markers of endovascular skills. The latter criticism is borne out of the inability of metrics to provide information on the quality of the intra-operative performance and a lack of information on quality of final product, despite the fact that numerous simulators provide such qualitative metrics which have shown to be construct valid (Van Herzeele et al., 2007; Boyle et al., 2011). The reviews by Bech and Neequaye were largely focused on rating scales specifically in vascular surgery. Standard fluoroscopic metrics do not provide information in terms of quality of the product. It is perfectly feasible that expert operators do on occasions, for instance, take longer to perform a complex procedure, and this may simply reflect increased awareness of risks of certain manoeuvres and increased and more in-depth cognition when considering manipulation strategies. The following section therefore provides a review of studies describing objective metrics and qualitative rating scales to date across all specialties participating in endovascular intervention, with the objective of comprehensively appraising the available evidence surrounding these assessment methods in terms of their validity.

CHAPTER 3.

LITERATURE REVIEW ON THE VALIDITY OF EXISTING ENDOVASCULAR SKILLS ASSESSMENT METHODS

3.1. INTRODUCTION

The spectrum of simulation devices and assessment tools have been discussed in the preceding section, together with the evidence behind the rationale for their use and developments over time. A number of authors have reviewed endovascular skills assessment (Neequaye et al., 2007; Bech et al., 2010; Cates and Gallagher, 2012). Although useful in terms of providing a comprehensive understanding and overview of existing assessment and simulation modalities, a large number of studies across a diverse range of specialties have used both rating scales and endovascular metrics, which have not been documented in reviews thus far. Bech and colleagues focused their evaluation on generic rating scales and present potentially valid criticisms of simulator-derived metrics. This review seeks to provide a comprehensive appraisal of the evidence surrounding endovascular skill metrics, qualitative rating scales, and scoring matrices or protocols which.

AIMS

The primary aim of this review is to describe as comprehensively as possible, the evidence with regard to endovascular assessment methodologies of arterial procedures. Included are studies of live cases, VR simulations, and bench-top models including silicone phantoms and glass or plastic models. Further objectives include

the evaluation of evidence regarding the validity assessment methods, specifically their ability to either demonstrate construct validity or a significant learning curve. Finally, the review seeks to identify potential gaps in existing assessment methods and provide potential avenues for further metric development.

3.2. METHOD

Definitions

For the purposes of this review the assessment tools in these papers were classified into two groups: those that included “metrics”, in other words quantitative measures of endovascular performance such as fluoroscopy and procedure time, and those that described “non-metric” assessment tools, including qualitative rating scales, check-lists and scoring algorithms/matrices. A “significant” finding in terms of an assessment tool implies that it was either able to demonstrate significant construct validity and distinguish between groups of experience or expertise, or that it was able to demonstrate a learning curve over time with respect to a particular experimental task or procedure.

Overall search strategy and title screening

The following categories formed the basis of the literature search strategy throughout the review process, and abstracts were sought that described the following: 1) Studies using objective efficiency metrics to assess endovascular performance- studies had to either describe comparisons between groups of participants with varying experience, skill level or interventional technique and/or a significant learning curve across a cohort with progressive experience over time. 2) Studies describing a method of assessment which are not exclusively metric based, such as a qualitative rating scale. Included in this category are all rating scales and scoring matrices or protocols with or without a comparison between groups or demonstration of a learning curve.

An overview of the overall search strategy is given in the consort diagram (fig. 6). A literature search was conducted on Pubmed by one reviewer to identify all publications in the English language describing the categories described above on assessment of endovascular competence assessment (initial search on 21/06/2013). The following combination of MeSH-terms was used to formulate the search strategy: “endovascular procedures OR endovascular surgery OR endovascular OR stenting OR angioplasty AND (skill assessment OR task assessment OR metrics OR metric OR assessment tool OR validated assessment tool OR quantitative assessment OR qualitative assessment OR rehearsal OR simulator OR learning curves OR learning curve)”

Additionally, a cross-referenced manual search was performed based on reference lists in the reviews identified using the search strategy described above. Following initial screening of all abstracts and applying preliminary exclusion criteria (fig. 6), the same reviewer read the abstracts and selected each abstract for reading of the full paper on the basis of following pre-defined formal inclusion and exclusion criteria (table 3):

INCLUSION	EXCLUSION
• Arterial endovascular procedures. • Original Studies • Objective skill metrics. • Qualitative Rating Scales • Procedural Check-lists. • Scoring Matrices. • Live-cases • Bench-top models. • VR-simulations • Technical Skills assessments	• Venous Procedures. • Open Procedures. • Review papers. • Clinical outcome measures as measure of skill alone. • Studies describing only error capture. • Face validity only • Case descriptions • Non-technical skills assessments

Table 3. Inclusion/exclusion criteria for abstract screening.

Following extraction of abstracts meeting the inclusion criteria, two reviewers independently assessed each full paper and either included or excluded papers on the basis of the following statements:

Paper inclusion/exclusion criteria

-Each paper must describe a method of assessing endovascular skill between groups of experience, skill level or operative technique, and/or provide a metric or metrics of efficiency or skill applied for comparison between the groups described above. Papers describing metrics alone must describe an attempt at statistical comparison between groups or an attempt at demonstration of a learning curve.

-Descriptions of rating scales alone do not require statistical comparison for inclusion, although preferable, a description alone is sufficient.

-Papers must not be a technical description or case history of a VR simulator or bench-top model alone, and descriptions of a single run on a simulator, even with a single set of metrics, are insufficient.

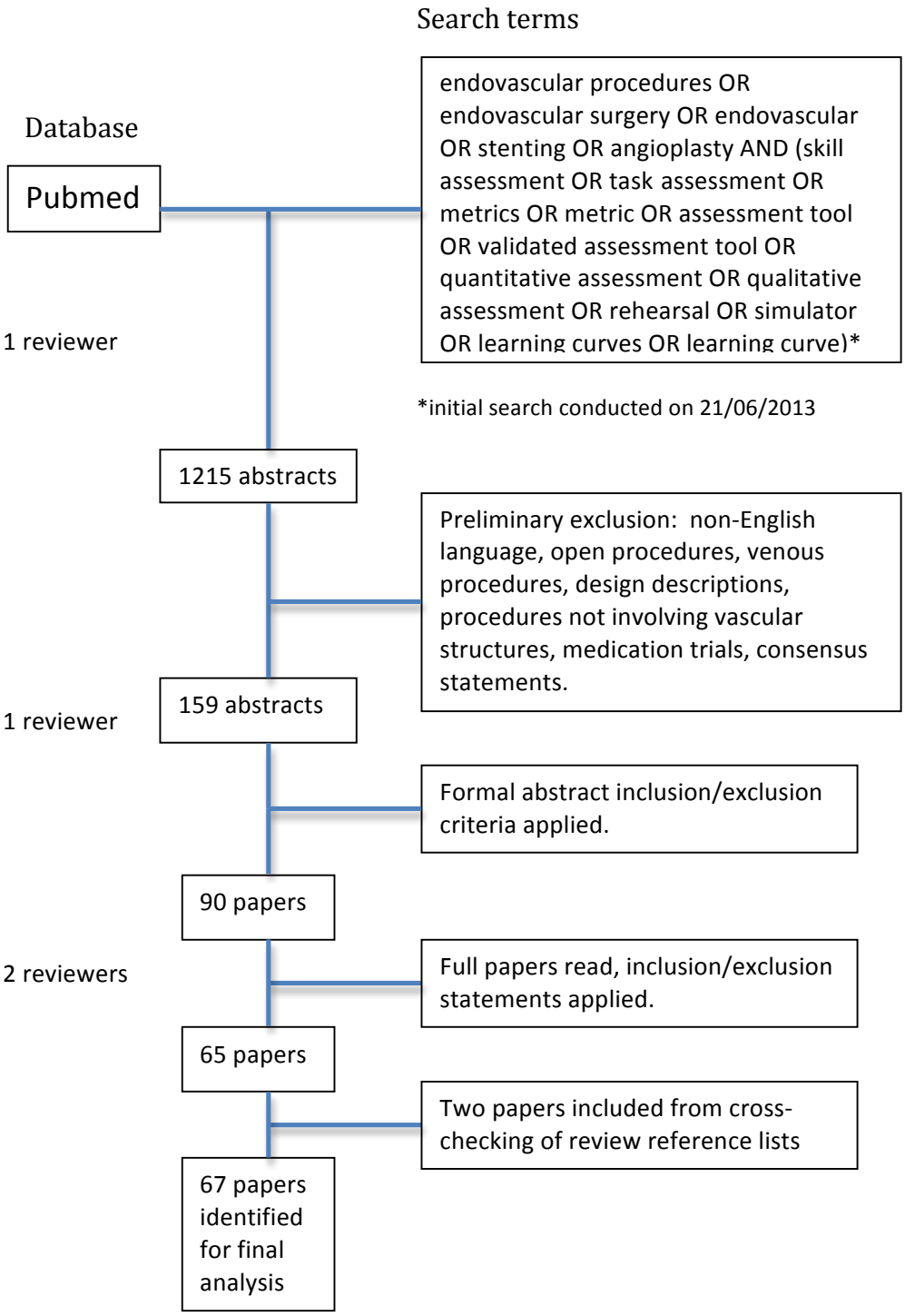


Figure 6. Consort diagram outlining search strategy

3.3. RESULTS

The search (refer to consort diagram) using the terms described yielded 1215 abstracts. Following initial screening, 159 abstracts were retrieved for further scrutiny. After applying pre-defined inclusion and exclusion criteria, 90 papers remained of which the full papers were read, and a further 25 papers were excluded on the basis of the discriminating statements. Two additional papers were added following cross-checking of review papers, resulting in 67 papers which were included in the final analysis, and described the use of metrics, rating scales, procedural check-lists, and scoring algorithms, or a combination of these. Of these 67 papers, 37 described “metrics” only, whereas 8 described “non-metric” tools only. 22 described “metrics” in combination with “non-metric” tools. Therefore, 59 papers in total described “metrics” (table 4), whilst 30 in total described “non-metric” tools (table 5). Of those papers describing both “metrics” and “non-metric” tools (n=22), a rating scale or scoring matrix/checklist was used on 33 occasions. For example, one paper might have applied a generic rating scale and a procedure specific rating scale for the assessment of its participants, together with a metric panel. Out of those papers describing metric and non-metric assessment tools only 7 attempts at correlation of ratings scales with metrics were provided and ultimately proven to be significant. Of all studies, the 46 (68%) were from vascular/interventional radiology units, 18 (28%) were from interventional cardiology units, 2 (2.9%) were from neurosurgical units, and 1 (1.4%) was from a

renal unit. Of all studies, the use of metrics in live cases was described in 17 studies only, 16 of which stemmed from interventional cardiology. The sole description of metrics in renal intervention was in a live case. Figure 7 gives the most commonly used metrics across the identified studies. They are grouped into common efficiency metrics (PT,FT,CV), imaging and radiation metrics (DAP,KAP,RPAK, No. cineloops), and errors (major, composite, No. wall-hits, No. times wrong target vessel accidentally cannulated). Qualitative metrics were frequently reported as composite or broken down into metrics like placement accuracy.

3.3.1. METRICS

By far the most frequently employed metrics were PT, FT and CV, allowing a reasonable assessment in terms of percentage of studies demonstrating significant construct validity or a learning curve for that particular metric. PT was found to be valid or demonstrated a significant learning curve in 85% (41 of 48 studies), FT in 72% (34/47), and CV in 43% (18/41). Other values for less frequently utilized metrics were: No. Cineloops (63%-7/11), radiation (88%-8/9), major errors (50%-1/2), composite errors (50%-5/10), wall-hits (100%-2/2), accidental cannulation of non-target vessel (50%-1/2), composite qualitative metrics (33%-1/3), lesion coverage (12.5%-1/8), stent placement accuracy (50%-3/6), and residual stenosis (28%-2/7).

Paper	Year	Intervention	Comparison	No. Procedures	Rating Scale	Modality
Clark et al	2000	CA	consultant v non-consultant	1337	Not used	Live
Louvard et al	2001	CA	femoral v left trans-radial v right trans-radial	442	Not used	Live
Salgado Fernandez et al	2002	CA, PTA	trans-femoral v trans-radial	526	Not used	Live
Dayal et al	2004	CAS	novice v exp. novice pre-and post-training, exp. pre-and post-training	42	GRS	VIST
Hsu et al	2004	CAS	untrained v advanced, both groups pre-test and final test, randomisation in each group to practice/ non-practice	58	Not used	VIST
Lin et al	2005	CAS with neuroprotection	LC	200	Not used	Live
Aggarwal R	2006	RAS	limited exp. v exp. limited exp. group LC	88	Not used	VIST
Hillock et al	2006	CA	Trainee v exp. LC	897	Not used	Live
Hislop et al	2006	CAS	Correlation of experience with video-gaming experience	61	GRS^*	VIST
Patel et al	2006	carotid angiography	LC over 5 sessions	100	Not used	VIST
Dawson et al	2007	IAS	Inexp. residents pre- and post course	85		SimSuite
Duncan et al	2007	renal angiography	between 5 exp. angiographers individually	16	Efficiency Data Extraction	Angiomentor
Neequaye et al	2007	RAS, IAS	LC novices performing RAS and iliac angioplasty, cross-over study	200	Not used	VIST
Passman et al	2007	IAS	Exp. V inexp. residents	33	Not used	SimSuite
Van Herzeele et al	2007	CAS	comparison of groups of exp.	45	Not used	VIST
Berry et al	2008	CAS	novice v exp.	31	Not used	VIST
Klass et al	2008	RAS	novice LC	52	Not used	VIST
Tedesco et al	2008	RAS	low-exp. v medium-exp.	17	Combined GRS/RAS checklist	VIST
Van Herzeele et al	2008	CAS	pre-v post-CAS course (exp. interventionsists)	22	PSRS^*, Error Scoring^*	Angiomentor
Van Herzeele et al	2008	IAS	novice (with/without cognitive training) v intermediate v highly exp.	47	Not used	VIST
Brueck et al	2009	CA, PCI	trans-femoral v trans-radial	1024	Not used	Live
Hislop et al	2009	CAS	PSR v live case	10	Not used	Angiomentor
Srimathveeravalli et al	2010	carotid angiography	robotic v.manual	16	Not used	VIST
Thompson et al	2009	PCI	high CTO volume, retrograde operators v low CTO volume, non-retrograde techniques	636	Not used	Live
Van Herzeele et al	2009	CAS	Inexp. v minor exp. v moderately exp. v highly exp.	21	GRS^*, PSRS^*, Weighted Error Score^*	VIST
Willems et al	2009	renal cannulation	novice v intermediate v expert	36	Total Score	Glass model
Willoteaux et al	2009	RAS	trainee v expert, occasional v regular	46	Not used	VIST
Coates et al	2010	aortography, renal angiography, IAS	(1) novice v experienced (2) novice pre- and post training	8(1) 28(2)	Not used	VIST
Lipner et al	2010	PCI	novice v skilled v expert	690	Technical/Cognitive Scoring Matrix	SimSuite
Riga et al	2010	FEVAR	robotic v conventional	30	IC3ST	Silicone

			techniques, low-exp, medium-exp, high-exp.			Phantom
Van Herzeele et al	2010	RAS	medical student LC, correlation metrics with psychomotor and visuo-spatial aptitude tests	200	GRS, PSRS	VIST
Ball et all	2011	PCI (trans-radial)	comparison of groups of exp. LC	12312	Not used	Live
Boyle et al	2011	RAS	sequential novice performance- no feedback, non-expert feedback, expert feedback	108	Error-based Procedure Specific Check-List	VIST
Fargen et al	2012	cerebral angiograms	pre-and post-course	14	Global Rating Scale	VIST-C
Fetterly et al	2011	PCI	single cohort	1827	Not used	Live
Jensen et al	2011	CA	novice LC v. expert IQR (FT)	24000	Not used	Live
Looi et al	2011	CA	trans-femoral v trans-radial, radial experienced v non-radial experienced	1001	Not used	Live
Naughton et al	2011	RAS	LC night v day shift patterns	140	GRS, PSRS	VIST
Rader et al	2011	CA	Novice LC v society ref. range v exp.	4200	Not used	Live
Riga et al	2011	arch vessel cannulation	robotic v conventional techniques	68	IC3ST^*	Silicone Phantom
Riga et al	2011	arch vessel cannulation	conventional v manually steerable v robotic catheters, LC	150	IC3ST	Silicone Phantom
Sciabahsi et al	2011	CA	left trans-radial v right trans-radial LC in trainees	1540	Not used	Live
Willaert et al	2011	CAS	part-task rehearsal v full task rehearsal in novices, IC	240	GRS, PSRS, IC3ST	Angiomentor
Chiocchi et al	2012	CAS	CAS+IVUS v CAS-IVUS	60	Not used	Live
Dominici et al	2012	CA	left trans-radial v right trans-radial groups	1032	Not used	Live
Hseino et al	2012	SFA	Exp. with or without assistance	16	GRS, PSRS	VIST
Rafii-Tari et al	2012	arch vessel cannulation	Exp. v inexp.	24	Not used	Silicone Phantom
Riga et al	2012	cannulation renal fenestrations	robotic v conventional techniques, grades of iliac tortuosity	120	IC3ST	Silicone Phantom
Tercero et al	2012	aneurysm navigation	novice v exp. Motion descriptive metrics	11	Not used	Silicone Phantom
Willaert et al	2012	CAS	PSR v live case	15	GRS, PSRS	Angiomentor
Willaert et al	2012	CAS	easy v medium v difficult real-life cases	60	GRS, PSRS	Angiomentor
Willaert et al	2012	CAS	Pre-trial training 10 CAS cases, crossover trial no warm-up, generic warm-up, PsR	260	GRS, PSRS	Angiomentor
Beathard et al	2013	AVF-PTA, AVG-PTA, AVF-Throm, AVG-Throm, Cath-In, Cath-Ex, Map	Between combinations of each procedure for each metric	17252	Not used	Live
Desender et al	2013	EVAR	PSR v live case	18	Not used	Angiomentor
Narra et al	2013	Visceral and carotid cannulation	students and IR residents randomised to videoscopic practice or control group	40	Not used	Silicone Phantom
Shah et al	2013	CA, PCI	trans-femoral v trans-radial	1696	Not used	Live
Weisz et al	2013	CAS	novices, intermediates, exp.	82	Scoring Algorithm (technical performance, medical management, angiographic results)	Angiomentor

Berry et al	2006	RAS	Exp. v novices	96	Not used	VIST
Gallagher et al	2006	PCI	novices v intermediate v exp.	89	Not used	VIST

Table 4. Studies which used objective metrics

CA- Coronary Angiography, CAS- Carotid Artery Stenting, IAS- Iliac angioplasty, EVAR- Endovascular Aortic Repair, FEVAR- Fenestrated EVAR, SFA- Superficial Femoral Artery Angioplasty, RAS- Renal Artery Stenting, PCI- Percutaneous Coronary Intervention, AVF-PTA-Fistula Angioplasty, AVG-PTA- Graft Angioplasty, AVF-Throm- Fistula Thrombectomy, AVG-Throm- Graft Thrombectomy, Cath-Ex- Tunneled Graft Exchange, Cath-In- Tunneled Catheter Placement. Exp.- Experience/Experienced/Expert. LC- Learning Curve. ^Correlation with metrics attempted, *Correlation with metrics significant.

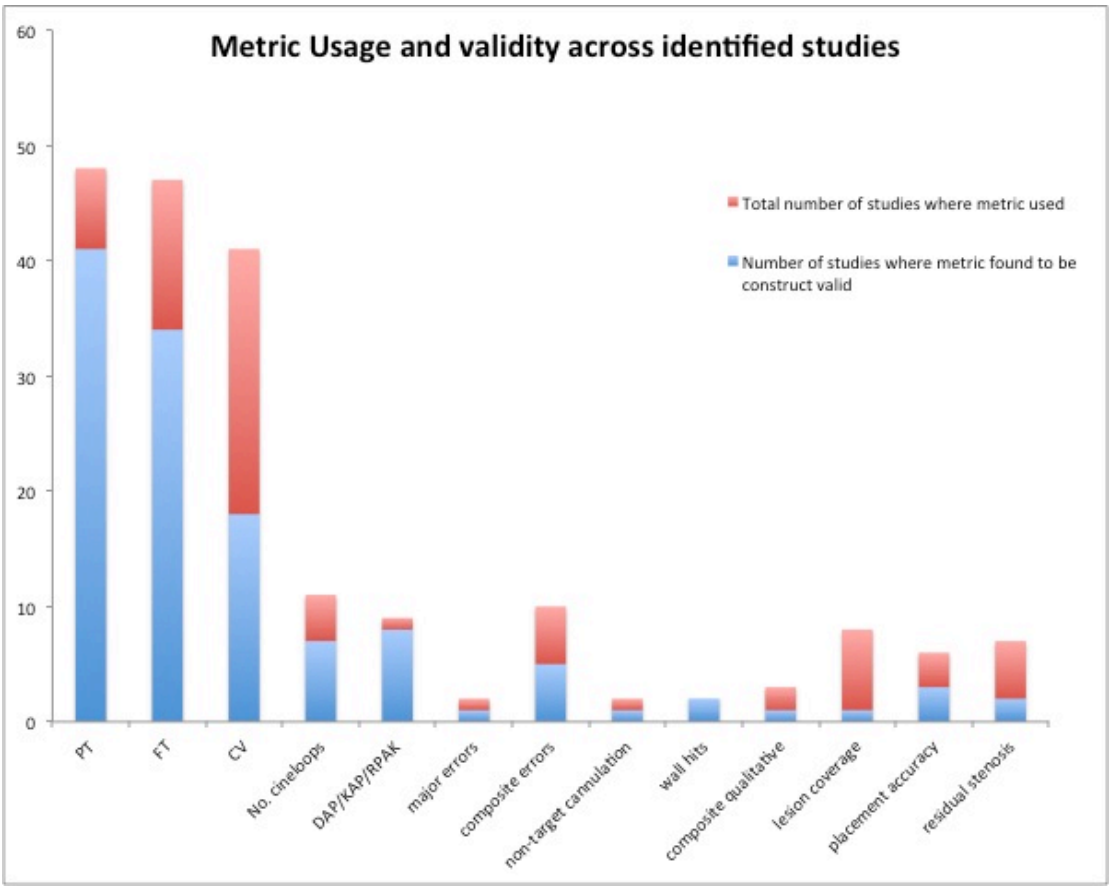


Figure 7. Metric utilisation and validity across studies

The X-axis gives the different metrics. The top of the red bar indicates the number studies a metric was utilised. The top of the blue bar is the number of studies in which a metric demonstrated construct validity or a significant learning curve.

Paper	Year	Scale/matrix	Derivation	Check-list	Task
Dayal et al	2004	GRS*	unspecified	54-item CAS check-list*	CAS
Chaer et al	2006	GRS*	Reznick Scale	18-item lower-limb angioplasty check-list*	IAS
Hislop et al	2006	GRS*	Reznick Scale	Not used	CAS
Berry et al	2007	Total Score (GRS-PSRS/Check-list hybrid)*	Reznick Scale	14-item procedure-specific IAS check-list*	IAS
Duncan et al	2007	Efficiency data extraction by phase^	Expert panel	Not used	RAS
Tedesco et al	2008	Combined GRS/RAS check-list*	Reznick Scale/procedure-specific check-list	Not used	RAS
Van Hezeele et al	2008	CAS PSRS*	Reznick Scale/Expert panel	Not used	CAS
Narra et al	2009	GRS (catheter handling)*	unspecified	Not used	Visceral and carotid cannulation
Van Herzeele et al	2009	GRS*, CAS PSRS	Reznick Scale	Weighted error score	CAS
Willems et al	2009	Total Score (GRS+ICEPS derivative (procedure-specific))*	Reznick Scale/ICEPS	Not used	renal cannulation
Bech et al	2010	SAVE^	Reznick Scale/task analysis/clinical competence statements/expert panel	Not used	NA
Berger et al	2010	Total Score (GRS+ICEPS derivative (procedure-specific))*	Reznick Scale/ICEPS	Not used	renal cannulation
Lipner et al	2010	Technical/Cognitive Scoring Matrix*	Expert panel	Not used	PCI
Riga et al	2010	IC3ST*	Reznick Scale	Not used	FEVAR
Van Herzeele et al	2010	GRS*, RAS PSRS*	Reznick Scale	Not used	RAS
Boyle et al	2011		NA	14-item error based procedure-specific check-list (not weighted)*	RAS
Fargen et al	2011	GRS*	Expert opinion	Not used	cerebral angiograms
Naughton et al	2011	GRS*, RAS PSRS*	Reznick Scale	Not used	RAS
Riga et al	2011	IC3ST*	Reznick Scale	Not used	arch vessel cannulation
Riga et al	2011	IC3ST*	Reznick Scale	Not used	arch vessel cannulation
Willaert et al	2011	GRS*, CAS PSRS,	Reznick Scale	Not used	CAS
Willaert et al	2011	GRS, CAS PSRS, IC3ST	Reznick Scale	Not used	CAS
Bagai et al	2012	GRS*	Reznick Scale/Chaer et al	11-item coronary angiography check-list (Technical Performance Score)*	CA
Hseino et al	2012	GRS*, SFA PSRS*	Reznick Scale	Not used	SFA
Hseino et al	2012	GRS*, SFA PSRS*	Reznick Scale	Not used	SFA
Riga et al	2012	IC3ST*	Reznick Scale	Not used	cannulation renal fenestrations
Willaert et al	2012	GRS*, CAS PSRS	Reznick Scale	Not used	CAS
Willaert et al	2012	GRS, CAS PSRS	Reznick Scale	Not used	CAS
Willaert et al	2012	GRS*, CAS PSRS	Reznick Scale	Not used	CAS
Weisz et al	2013	31- item Scoring Algorithm based on technical performance, medical management, angiographic results*	NA		CAS

Table 5. Studies which used rating scales, scoring matrices, and error and procedural check-lists

CA- Coronary Angiography, CAS- Carotid Artery Stenting, IAS- Iliac angioplasty, EVAR- Endovascular Aortic Repair, FEVAR- Fenestrated EVAR, SFA- Superficial Femoral Artery Angioplasty, RAS- Renal Artery Stenting, PCI- Percutaneous Coronary Intervention. *Construct validity demonstrated or significant learning curve. ^No attempt at statistical comparison made. GRS- Global Rating Scale, PSRS- Procedure Specific Rating Scale.

3.3.2. QUALITATIVE RATING SCALES, CHECK-LISTS AND SCORING MATRICES

The most frequently employed rating scales were Global or Generic Rating Scales and Procedure-specific Rating Scales. As can be seen in table 5, these, for the most part, stem from the Global Rating Scale developed by Reznick and colleagues for use in their initial OSATS examination (Martin et al., 1997). Four studies adopted the approach of combining the GRS with either a procedure-specific check-list or a PRS. Six studies describe the use of a procedure-specific check-list, and two studies describe the use of a complex scoring matrix or algorithm. The latter were derived in both instances from an expert panel who reviewed a number of videos and mutually agreed on a scoring protocol. Two studies (Duncan et al., 2007; Bech et al., 2010) either did not describe an application of the scoring tool for comparison between groups, or did not actually apply a statistical comparison despite having numerous test subjects. These were therefore excluded from the final analysis (fig. 8) but were included in the summary table describing studies using non-metric assessment methods (table 5). In total, 28 studies were from vascular/IR departments, one from interventional cardiology, and one from neurosurgery. The assessment tools described in 17 studies had been subject to formal statistical evaluations of inter-observer reliability, which was found to range from fair to strong. 13 studies made no formal attempt at assessment of inter-observer reliability. The number of studies demonstrating construct validity of the GRS was 14 (87.5% of those studies using it). Other values for less frequently utilised non-metric assessment tools were: PSRS (50%), TS/Combined Rating Scale+Check-list (100%), Procedure-specific check-lists/Error score (83%) and Scoring Matrix/Algorithm (100%).

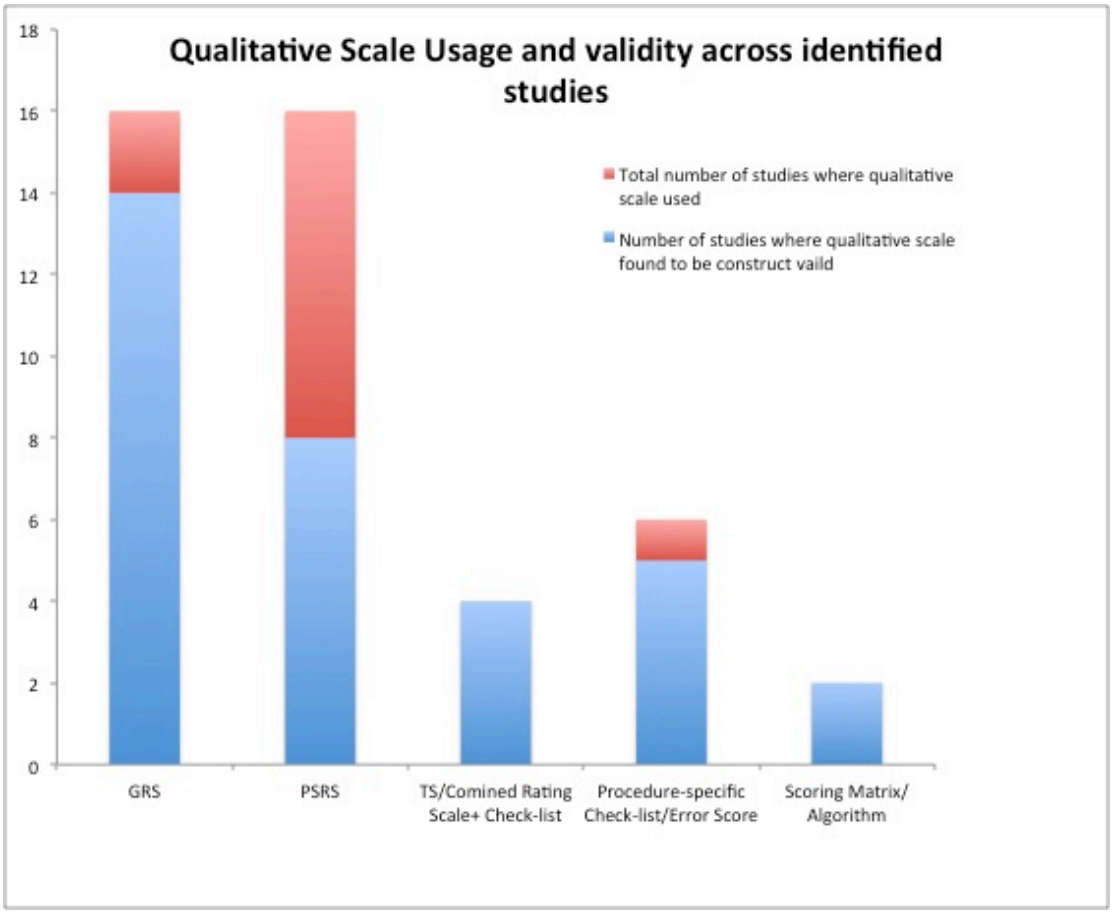


Figure 8. Non-metric assessment tools and validity across studies

The X-axis gives the different assessment tools. The top of the red bar indicates the number studies a tool was utilised. The top of the blue bar is the number of studies in which a tool demonstrated construct validity or a significant learning curve.

3.4. DISCUSSION

This review attempted to assess available evidence regarding validity of a comprehensive range of endovascular assessment tools across the entirety of specialties utilising endovascular arterial techniques, with a particular emphasis on objective metrics. The majority of data describing metric and non-metric assessment of endovascular technique stems from the fields of vascular surgery, interventional radiology, interventional cardiology, neurosurgical and renal specialties. Of interest, the use of endovascular metrics in live cases stems exclusively from the domain of interventional cardiology, which was also the first specialty to describe their use. Possible reasons for this include the high through-put of coronary cases as compared to other endovascular procedures, and the readily available efficiency data which is provided in an automated fashion by fluoroscopic imaging systems, such as radiation exposure, procedure- and fluoroscopy-time. Furthermore, such metrics provide an easy means by which to assess efficiency of access routes (trans-femoral v trans-radial), which were drivers of those initial studies. Additionally, the wide-spread use of endovascular simulations and hence metrics only became possible following the commercialisation of devices such as the VIST and the angioMentor after the year 2000. No descriptions were found describing the use of non-metric scoring tools such as qualitative rating scales in live cases, although other specialties have been able to achieve this (Liu et al., 1980; Niitsu et al., 2013).

Given the heterogeneity of the data, which included comparisons between groups of experience, interventional techniques, pre- and post-course assessments, and a

broad range of participant and procedures numbers, simple descriptive mathematical analysis was used to create an easily comprehensible evaluation of the evidence. An amalgamation of individual reliability stats was not possible.

In terms of metric evaluations, the most frequently utilised measures were procedure-time, fluoroscopy-time and contrast volume, although this may not accurately reflect the totality of the data obtainable in each study, since a simulation device such as the VIST can offer in the region of 170 different metrics. Included in the data-set above were all reported metrics, and every effort was made to avoid any omissions. The most frequently utilised metric (PT) was also proportionally one of the most reliable in terms of demonstrating construct validity or a significant learning curve. Although assessment of the number of wall hits yielded a very high percentage of validity (100%), the very low number of studies using this metric (n=2), make it difficult to compare this metric with other metrics in the context of this review. Wall hits were used by institutions developing robotic systems. Numerous reports (Gallagher et al., 2006; Bech et al., 2010; Cates and Gallagher, 2012) describe it as a crude “surrogate” marker of endovascular skill, stating that rapid completion of an endovascular procedure does not necessarily equate to expertise or quality. This notion seems acceptable given the lack of data correlating this metric, and other metrics such as PT and CV, with qualitative assessments and live outcome data. We identified only seven comparisons which significantly correlated qualitative assessment with metric data (Hislop et al., 2006; Van Herzeele et al., 2008; Van Herzeele et al., 2009; Riga et al., 2011). Furthermore, several studies reported a non-linear relationship between procedure-time and experience or expertise, with

experienced interventionists often taking longer to complete the cases than less-experienced operators (Van Herzeele et al., 2007; Gallagher et al., 2006). Potential reasons for this might include an increased awareness of risks; a number of studies demonstrate increased procedure times following intensive didactic and simulator-based training courses (Van Herzeele et al., 2008; Coates et al., 2010). Nonetheless, procedure time, for instance during technically demanding procedural phases such as CCA cannulation in CAS has been associated with increased risk of micro-embolism (Parlani et al., 2006; Verzini et al., 2006). Initial enthusiasm for automated error-based and qualitative metrics was soon curbed by the realisation that these were not weighted to reflect differing levels of importance (Van Herzeele et al., 2009; Cates and Gallagher, 2012). For instance, advancing a catheter in a large vessel without the guide-wire may be less threatening than failure to administer critical drugs such as heparin or failure to prevent air-emboli.

The most commonly utilised non-metric assessment tool were the GRS and PSRS, which in most cases were derived from the Reznick Scale. Although the numbers of studies reporting the use of such scales were relatively small as compared to those reporting the use of metrics, the data in figure 8 suggests that the GRS was more sensitive in terms of differentiating between groups of experience. This may have been favourably affected by fairly coarse comparisons between novices and experts prior to the development of the PSRS (Dayal et al., 2004; Hislop et al., 2006). The procedure-specific rating scale (PSRS) unable to differentiate between groups of experience was the CAS rating scale, and the relative simplicity of the lesion and anatomical configuration of the CAS module in those studies was implicated as a

possible cause for this (Van Herzeele et al., 2009; Willaert et al., 2011, 2012). Given that the CAS PSRS moves away from the generic domains to focus on procedural phases such as catheterisation and lesion crossing phases, it is easy to understand how it loses its discriminatory potential in non-challenging cases. This is further corroborated by previous studies in laparoscopic surgery which demonstrate limited benefit of the use procedure-specific scales in standard procedures (Aggarwal et al., 2008). In this study, combined Generic Rating Scales with a PSRS or procedural check-list were the most sensitive in terms of differentiation between groups of experience, although we fully acknowledge that small numbers in this category may not result in an accurate assessment of this group of tools. These hybrid assessment tools are either the result of two independent assessments (GRS and PSRS) combined to give a total score (TS), or a single integrated assessment form. The enhanced discriminatory potential may be due to the fact that both generic and procedure-specific components are included in their entirety, without any omissions from either assessment type. However, such assessment forms are long-winded and in many instances contain forty or more domains which need evaluating.

Potential draw-backs of this review include the heterogeneity of the data-set. Therefore, studies comparing comparatively simple procedures such as iliac artery stenting were included with studies describing complex procedures such as CAS. These studies would have been considered equal for the purposes of the descriptive statistical assessment, however achieving construct validity of a metric such as procedure-time in a complex procedure like CAS may be easier as compared to studies involving a procedure such as iliac artery stenting. If a metric was found not

to be construct valid therefore, this may have been a reflection on the relative ease of the procedure involved, or smaller procedure numbers in the study. An attempt at defining a threshold in terms of procedure numbers above which validity is triggered in a given metric was attempted, however deemed not feasible given the diversity of the procedures which were included. A further issue becomes apparent when one considers the small numbers presented for qualitative and error based metrics, as well as the less frequently used non-metric assessment tools such as scoring matrices and check-lists. This may have resulted in an inappropriate interpretation of the validity (ie scoring matrices), given the small sample size which may not be a true representation of this group of assessment tools. However, given the paucity of published data, this is unfortunately unavoidable.

3.5. CONCLUSION

A large number of studies describe a wide variety assessment tools. These can be divided into quantitative metrics and non-metric assessment tools including qualitative rating scales and scoring matrices. The most commonly validated metrics and rating scales are procedure-time, fluoroscopy-time, contrast volume, Generic Rating Scales and Procedure-specific Rating Scales. Given the available evidence, a highly discriminatory metric such as procedure-time would be of most value to assess efficiency combined with a GRS to provide a qualitative component to the assessment. There are very few studies that describe the mechanics of catheter motion such as number of movements, overall movement and force of interaction

with the arterial wall. These require further investigation and may add a valuable qualitative component to metric-based assessment.

CHAPTER 4.

IDENTIFICATION OF THE COMPONENTS OF ENDOVASCULAR SKILL- THE EXPERTS' OPINION

4.1. INTRODUCTION

With the rapid development of endovascular techniques and diversification of procedures to incorporate most vascular beds, a number of inter-disciplinary committees have sought to clarify credentialing requirements specific to particular procedures (Creager et al., 2004; Hirshfeld et al., 2004; Rosenfield et al., 2005; Hodgson et al., 2006; King et al., 2007). Most of these documents provide valuable information on credentialing requirements in terms of experience for multiple specialties. For instance, the American College of Cardiology/American Heart Association/American College of Physicians Task Force on Clinical Competence (ACC/ACP/SCAI/SVBM/SVS) consensus statement on competency in peripheral catheter-based intervention states that minimal requirements for vascular surgeons are 100 diagnostic peripheral angiograms (50 as primary operator), 50 peripheral interventional cases (25 as primary operator) and 10 aortic aneurysm endografts (5 as primary operator), over a formal 12 month period of training (Creager et al., 2004). Credentialing requirements for interventional cardiologists are similar except the requirement for aortic endo-grafting is replaced by 300 diagnostic coronary angiograms in the same time-period. These documents sub-divide endovascular competence into domains; "technical", "clinical" and "cognitive skills", further segmenting each into components. "Ability to manipulate guide-wires and catheters" and "ability to place and deploy angioplasty equipment" provide an

indication as to the range of skills required to perform endovascular procedures competently, however do not define exactly the nature of endovascular skill.

A number of investigators, as described in the introductory chapter have sought to identify the components of endovascular skill in order to develop and adequately weight components of generic- and procedure-specific rating scales, by utilising expert opinion to either modify existing rating scales (Chaer et al., 2006; Berry et al., 2006; Tedesco et al., 2008), or by generating rating scales or check-lists *de novo* (Fargen et al., 2012). The review in the previous chapter identified only three studies which describe a rigorous and systematic approach to define and categorise components of endovascular skill in an attempt to design and validate rating scales: Van Herzeele et al developed an error-based scoring system, by asking a panel of experts to weight the errors automatically generated by the VIST simulator on a questionnaire (Van Herzeele et al., 2009). Bech and colleagues developed a comprehensive endovascular assessment tool by first performing a systematic review on available rating scales, consensus statements, and procedural check-lists and creating a preliminary list of endovascular skill components. Subsequently, trainees performed a simulated iliac artery stenting procedure which was recorded on digital camera. Both the trainee and two experts underwent semi-structured interviewing whilst watching the videos, and the interview transcripts were marked by a second panel of experts using the list of points generated from the systematic review. The resulting rating scale describes a combination of technical as well as non-technical skills (such as communication), and is meant to capture the entirety of endovascular skill (Bech et al., 2010). Duncan et al performed a systematic task

analysis of renal artery stenting: Five interventionists were each asked to perform 3 different scenarios and a panel of experts analysed video and audio recordings to extract seven definitive procedural phases common to each scenario.

Drawbacks associated with reliance upon consensus statements are that they do not provide information on, or characterise generic endovascular skill. With the development of a new procedure, limited guidelines are often issued in a hurry on the basis of a limited evidence base. It is necessary therefore for educationalists and proctors, as well as physicians acquiring skills in a new technique, to have a sound understanding of the generic components of endovascular technique that can be applied to a diverse set of procedures. Furthermore, guidelines and consensus documents repeatedly state that it is necessary to be "skilled" in numerous facets of a procedure, including guide-wire and catheter manipulation, without actually defining what constitutes skill or expertise. Although the studies cited above have holistically appraised endovascular skill in terms of technical and non-technical skills, they do not address the key components of safe guide-wire and catheter manipulation.

A number of prospective registries and randomised control trials have shown that excessive catheter and wire manipulation has a bearing on clinical outcome (Verzini et al., 2006; Cao et al., 2006; King et al., 2007). The previous chapter identified a paucity of studies which utilise metrics that describe the mechanics of catheter and guide-wire movement, including movement and force measurements. The purpose of this chapter is to deconstruct endovascular skill into its constituent components

by examining expert opinion, and subsequently identifying components that might serve as potential targets for objective measurement. We therefore sought to characterise “skill” in terms of the finer points of endovascular tool manipulation and movement, applicable across a spectrum of procedures and interventions.

4.2. METHOD

Individuals were invited to participate if they were fully certified specialists from any specialty who performed endovascular arterial interventions on a regular basis. Eleven international experts were interviewed at multidisciplinary vascular and endovascular conferences. All interviews were conducted in a semi-structured manner using a standardised pro-forma. The interviews were conducted in open spaces within the conference halls during official break periods, although on a one-to-one basis and away from large groups of delegates. Interviews were initiated with an open question, as seen in the sub-heading below. Based on a need identified in the previous chapter, and our interest in catheter dynamics and fluoroscopy-based assessment, questions focused on the assessment of observable catheter movements, the relationship between catheter movements and anatomical and pathological variation, and potentially measurable parameters. The questions were developed in consultation with a surgeon, an interventional radiologist and a psychologist. Semi-structured interviews were selected, because of the flexibility associated with this method of data collection, resulting in rich and diverse narratives. Participants were invited to mentally picture realistic scenarios such as the assessment of a trainee, or observation of another colleague in order to identify preferable or undesirable manoeuvres. All participants were encouraged to provide free-flowing answers, and to elaborate on particular answers if it was felt that information was being withheld in the interests of brevity. There was no time-limit for each interview, although participants were advised that each interview would

last 10-15 minutes. The questions asked are given below. Verbal consent was obtained from each participant prior to starting the interviews.

4.2.2. Questions

General Questions

- Broadly speaking, what, in your opinion, are the key components of safe endovascular intervention?

- Over time, how do you think your practice has changed? Specifically, how do you think volume of experience has changed your guide-wire/catheter handling skills?

- If you were watching your junior resident perform a CAS procedure and your were looking exclusively at the angiography screen, what features would-

  - Encourage you to let him/her continue?

  - Prompt you to take control of the case?

Questions on catheter movement

- If you were looking specifically at the angiography screen of any endovascular case, what features of the catheter movements would be most important either in terms of judging skill or avoiding complications such as embolisation and vessel dissection?

For example, how important is-

Catheter/ Guidewire distance travelled

Catheter/ Guidewire velocity

Catheter/ Guidewire acceleration

Force during wall contacts

Number of wall contacts

Number of repeated/excessive movements

Stability of cather/guide-wire in target vessels

Reduction of overall “path-length”

Deviation from the centre-line

- If you were assessing the performance of an experienced colleague performing any endovascular case, which guide-wire/catheter movements would tell you that he/she is performing well?

Questions on the relationship between anatomy / pathology and catheter movements

- Are the movements you’ve mentioned above particularly dangerous in any particular areas of the aortic arch?

- Which areas would you specifically want to avoid, for example; the roof of the aorta, the ostia of the target vessels or the bifurcation of the carotid artery?

- Do the movements described above have more importance in areas with certain pathology?

- What about “contact with the vessel wall” should this be avoided in the same areas?

Questions on the opinions of suitable parameters to measure

- Do you think endovascular skill can be objectively assessed in terms of catheter movement? If so, which parameters would you want to assess?

- Please list those catheter/guide-wire movements you feel would be most important to measure.

Analysis

All interviews were recorded digitally and manually transcribed onto MS Word. NVIVO 10 (QSR International, Cambridge, MA, USA) qualitative data analysis software was used which facilitates coding and grouping of responses. Each interview manuscript was read by a single assessor who coded the detail of all responses, working up to more general categorisations. The emerging themes were assessed for connections, and grouped into related themes. The resulting data-set was organised into a hierarchical tree of "sub-themes", corresponding to different statements such as "awareness of complications", and overarching "themes". Each theme was a composite of statements related to each other conceptually. Tables with the number of times a particular theme was mentioned or "referenced" by the participant were produced. The data should not be interpreted as frequency or prevalence data because the interviews were semi-structured and content of each interview will have varied substantially. Furthermore, the interviews were weighted towards fluoroscopy-based assessment. However, the data provides an indication as to the themes discussed most frequently in the context of a semi-structured interview.

4.3. RESULTS

Six interventional radiologists and five surgical interventionists participated (four vascular surgeons, one cardiothoracic surgeon). Two females and nine males participated. Five were from the UK, two from the USA, two from Belgium, one from Sweden and one from Germany. No further interviews were arranged since no new themes emerged after the first 11 interviews.

A total of 13 overarching themes were identified comprising a total of 133 sub-themes, each representing a differing statement in terms content or concept (figure 9). The most prominent theme was *Observable Catheter Movements* [181 references in total- top three: ergonomic catheter movements (50), controlled movements (23), general observable ability (14)]. An example of typical comments are: "…I think the less movement you make, the less you have to do, the quicker you go away, especially in carotids, the quicker you are…" (cardiothoracic surgeon). "… if somebody can do it with very little movement, first of all it means they have chosen the appropriate catheter, they can do it in a very stable way, that means they immediately get into the vessel, keep it stable exchange and go to the next step..." (vascular surgeon). When comparing his present performance to what it would have been like ten years ago, one surgeon noted: "… I think there's an improved efficiency of movements now, and a more decisive and purposeful approach to movement …"

The next most frequently mentioned theme was *Catheter Manipulation* [121 references in total: generally careful (22), appropriate pressure on catheter and wire

(13), accuracy of target vessel cannulation (12)]. Specifically relating to arch procedures; "… the key thing is manipulation in the arch and to do it deliberately, carefully, slowly, to do the manoeuvres that get the catheter in a very targeted location …" (vascular surgeon), and "… Its also its understanding the pressure forces on the wire and on the catheter because one of the most common things that can happen is that as a catheter makes a last turn if you will from the aortic arch up into the carotid, as the catheter begins to straighten and the wire becomes more of a rail, the entire apparatus can shoot forward …" (vascular surgeon).

The third-most frequently mentioned overarching theme was harder to specifically define and was therefore very broad in terms of its sub-themes: *General Procedural Ability* [99 references in total: general catheter handling skills (19), general wire handling skills (16), appropriate and timely progression of procedure (11)]. The statements attributed to this groups were less precise: "… You just get a feel for whether they've got any hope of doing what they set out to achieve, if they've been doing it for about fifteen minutes without success, then its time for me to go in …" (radiologist), or "… intuitive feeling about your own evaluation of whether their movements are purposeful or whether they have the potential to achieve what they are trying to do …" (vascular surgeon). Although not part of the interview questioning, several further themes emerged following open, un-prompted discussion: *Skills Acquisition*, *Awareness of Technological Advancement* and *Tool Knowledge*. Figure 9 gives all overarching themes together with all the sub-themes. Given the volume of data it has been extended over three pages out of necessity.

The overarching themes together ranked in order of reference frequency are given in figure 10.

Figure 9 a). Overarching themes (blue heading), with total number of references in red



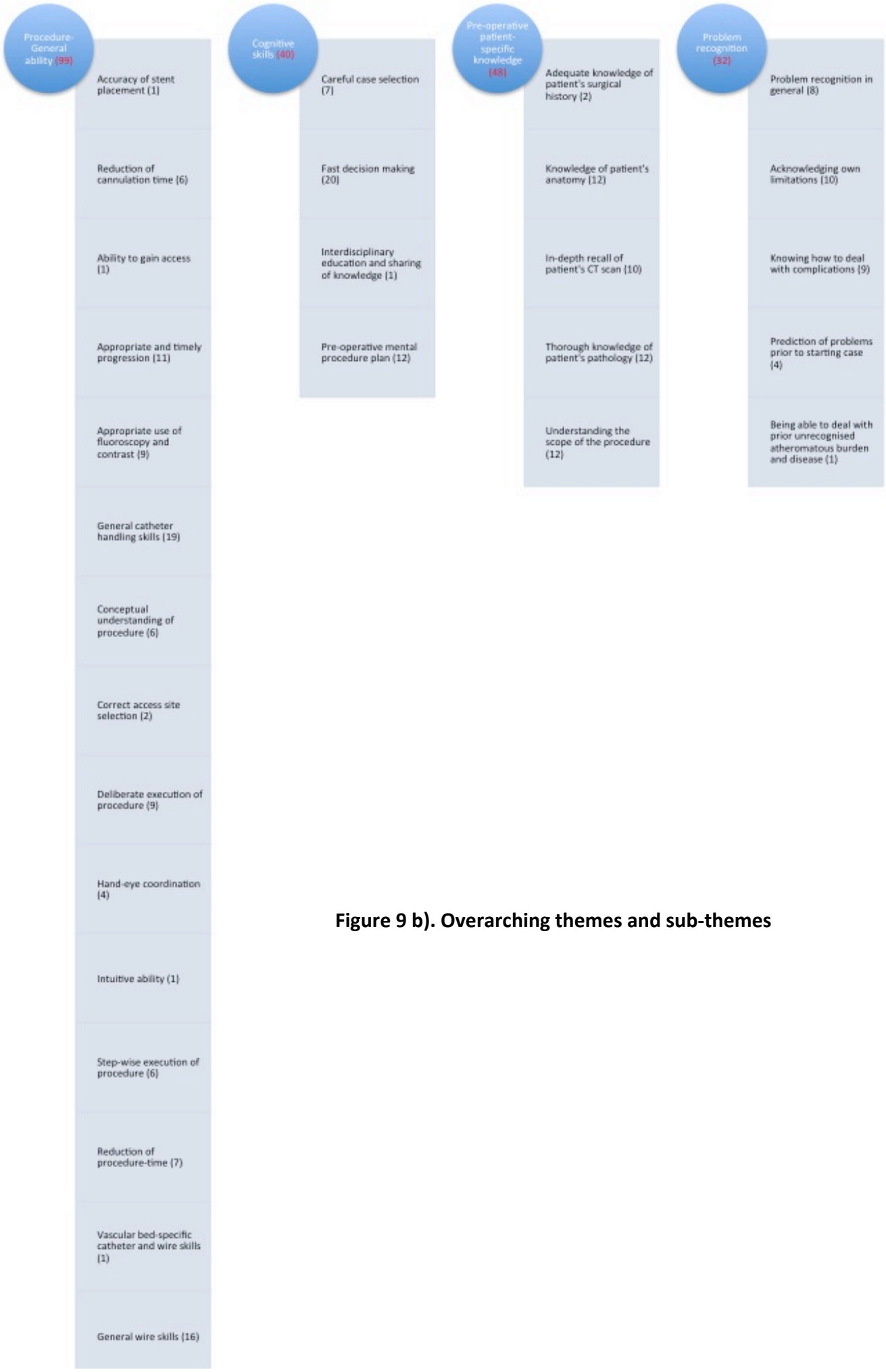


Figure 9 b). Overarching themes and sub-themes

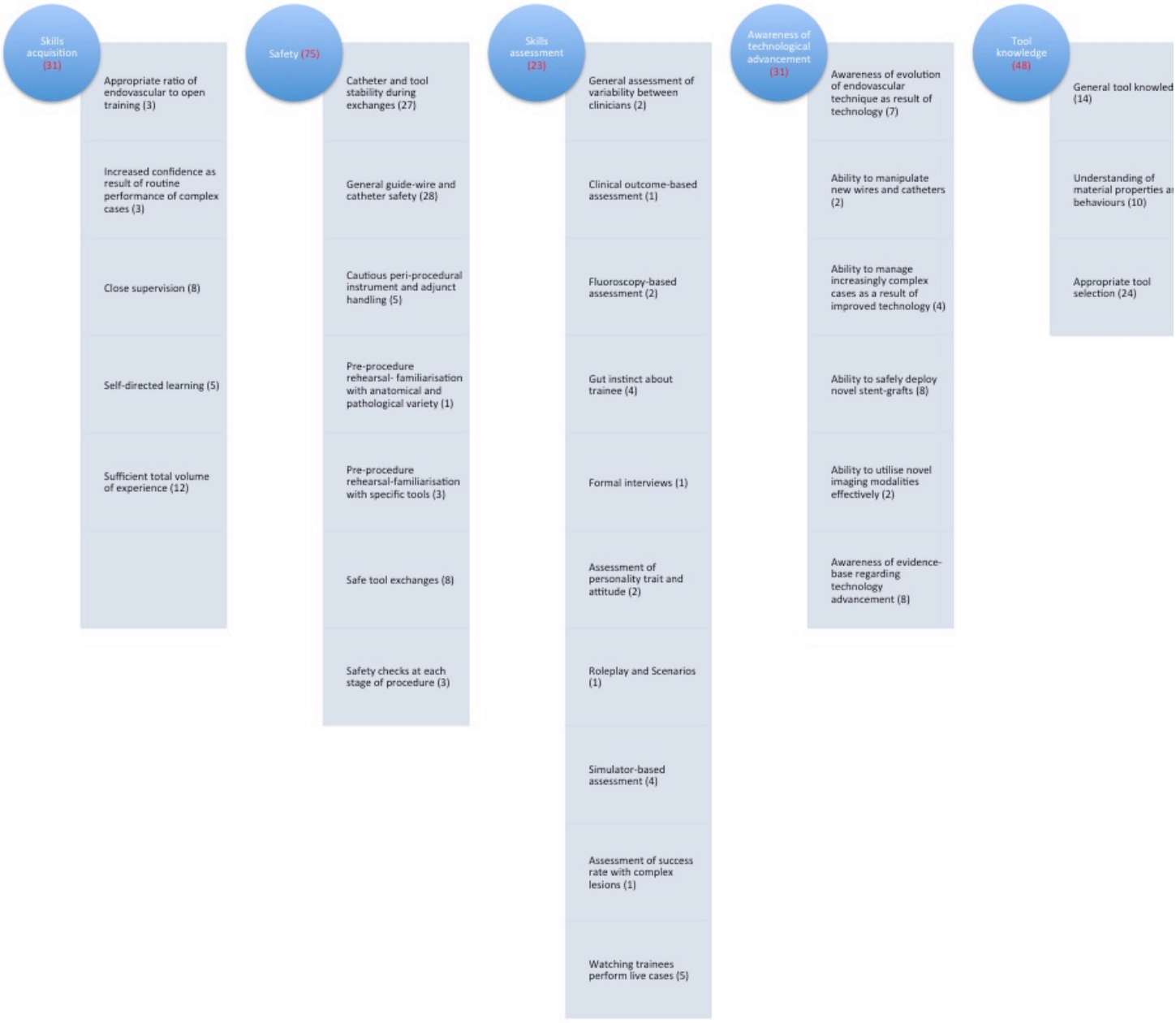
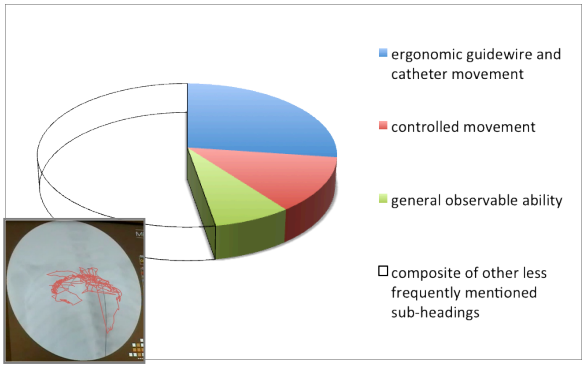
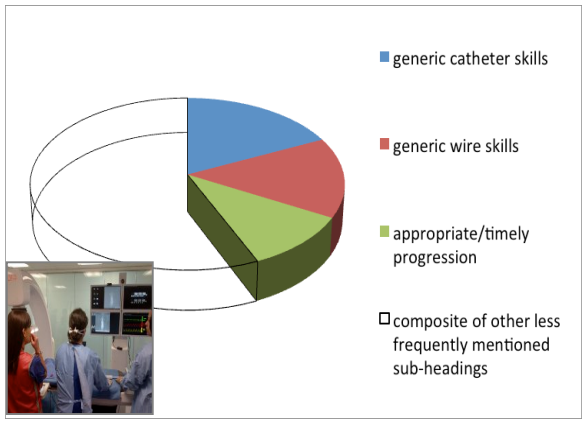


Figure 9 c). Overarching themes and sub-themes

Theme	Frequency
Catheter movements	184
Catheter manipulation	121
General ability	99
Avoiding complications	75
Safety	75
Pre-operative knowledge	48
Tool knowledge	48
Anatomical skills	46
Cognitive skills	40
Problem recognition	32
Awareness of technology	31
Skills acquisition	31
Skills assessment	23





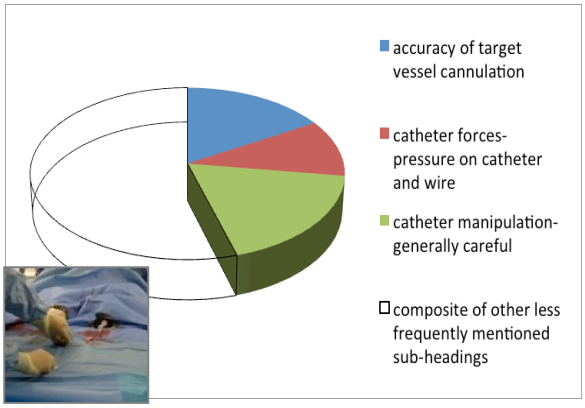


Figure 10. Overarching themes according to frequency of references

Pie-charts illustrate break-down of the top-three themes into constituent sub-themes. The top-three sub-themes are indicated in each pie-chart.

4.4. DISCUSSION

When constructing the interview pro-forma, we sought to deconstruct endovascular skill into measurable components. In doing so, we aimed to determine the finer points of endovascular technique, moving away from broad statements presented in consensus statements and qualitative rating scales. The results indicate endovascular tool manipulation as a domain of skill is more complex than previously thought, and includes a number of sub-themes which have not previously been addressed, for instance the cognitive aspect “branch-specific manipulation strategy” and maintaining an awareness of the position of the catheter and guide-wire tip. The latter is sometimes neglected in novices who are focusing their concentration on adjunct manipulation such as C-arm positioning and preparation of endovascular devices prior to deployment. A number of simulators such as the VIST record observable errors on an automated basis, for instance “moving diagnostic catheter without support of guide-wire” (Van Herzeele et al., 2008). This was addressed in the present interview study by participants as “always keeping guide-wire ahead of the catheter”. A novel concept in endovascular technique is the quantification of force and pressure when manipulating a catheter. Research into this metric has been largely driven by the recent advent of robotic catheter technology and the need to be able to accurately quantify exerted forces on the arterial wall in the absence of tactile feedback (Tercero et al., 2013; Rafii-Taril et al., 2012). The IC3ST scale discussed in the previous section addresses manipulation during cannulation specifically and describes a number of principles which were identified in this interview study, including measures of performance safety such as avoiding contact with vessel wall, respect for areas of likely embolic potential and avoiding the use of

excessive forces on the catheter (Riga et al., 2011). It does not however address the cognitive aspects of cannulation including an understanding of the catheter material properties and inherent ranges of movement, which are essential for the performance of a safe cannulation. Further, being a cannulation assessment tool it does not address other aspects of catheter manipulation for instance appropriate selection of a low-profile wire for fine manipulation when crossing a lesion; a facet of skill which was mentioned on multiple occasions during interviewing. The Generic Endovascular Rating Scale likewise covers aspects of manipulation under the domains of “handling of endovascular material” and “respect for tissue/stenosis” (Van Herzeele et al., 2009).

It is evident that observable catheter movements are a direct product of catheter manipulation. Descriptions of endovascular tool movement in the literature are very limited; Generic- and Procedure-Specific rating scales include an assessment of “time and motion” making reference to economy of movement (Van Herzeele et al., 2010; Riga et al., 2011). This study yielded a number of valuable descriptors, suggesting that interventionists are, at least, sub-consciously aware of safe movements, although these have never been formally documented. Included are a number of mechanical elements including velocity, number of movements and directional descriptors, such as avoiding excessive sideways movement. Furthermore, a number of movement sub-themes desrcibed safety of particular manoeuvres, including cautious movements in particular anatomical settings, avoiding flicking and repetitive movement. An understanding of the relationship between anatomical complexity and movement was mentioned frequently. Avoiding arterial wall-hits has

been previously treated experimentally as a surrogate marker of embolic potential (Riga et al., 2010, 2011, 2012), and the data suggests that it can differentiate between levels of endovascular experience and catheter technologies. Of note, the most prevalent sub-theme in movement was “ergonomic catheter movement”. Ten out of eleven experts mentioned the need to reach the target lesion as efficiently as possible, keeping the number of excessive movements and the total amount of movement to a minimum. This was stated both for the cannulation phase of the procedure, as well as during tool exchanges, the latter often being referred to as tool stability. A global impression of expert movement is an intervention that is performed as efficiently as possible, where the movements are controlled and smooth, velocities are constant, and attention is paid to avoiding contact with vessel walls and potentially risky anatomical areas.

In addition to providing information on tool manipulation and movement, this study yielded information on important cognitive and decision-making factors which are poorly addressed in consensus documents (Creager et al., 2004; Rosenfield et al., 2005). Whilst stated requirements include an understanding of the advantages and limitations of catheter-based intervention, as well as an understanding of the scope of endovascular intervention, the data provided in this study indicates a comprehensive spectrum of thought processes which characterise the endovascular expert. These spanned from the ability to mentally reconstruct three-dimensional structures from two-dimensional images to a thorough introspective understanding of personalised learning mechanisms and awareness of personal limitations. Of particular relevance were cognitive processes involved in avoiding complications

such as understanding how best to avoid causing embolisation, understanding and memorising the anatomical distribution of the patient's atheromatous burden, and having the self-confidence to deal with complications when they arise. A further overarching theme was the ability to anticipate problems and manage them in a collected fashion when they arose. Only one identified study to date has successfully correlated innate neuro-cognitive ability with endovascular performance (Van Herzeele et al., 2010). The investigators found that psychomotor testing of visual memory and recall, and organisational aptitude (map-planning) in novices correlated with higher generic endovascular ratings both initially and at the performance plateau on a simulator-based training course.

Potential limitations of this study include the arbitrary nature of the coding process. The coding process was initiated by generating a new "sub-theme" for every new concept or content mentioned, and subsequent statements were aligned to existing "sub-themes" if similar or identical in nature. Whilst every effort was made to adhere to this strategy and group sub-themes accurately, it was not possible to be completely certain of the accuracy of this process, potentially resulting in erroneous grouping with skewed numbers. The absolute number of references per sub-theme should therefore be treated as a rough indicator, rather than an absolute value. One might argue that this is acceptable, since the purpose of this study was merely to extract concepts regarding components of skill rather than to accurately weight or quantify their importance. Furthermore, some themes which are clearly vital to successful endovascular intervention, such as peri-operative medical care, were omitted by the expert panel, despite broad open questioning initially. Appropriate

post-operative anti-platelet and anti-coagulant therapy are important in the prevention of acute thrombosis and are particular important in procedures which expose sub-endothelial tissue such as cutting balloon angioplasty. Similarly, effective communication between endovascular team members was never mentioned.

4.5. CONCLUSION

This study has deconstructed endovascular skill into constituent components. A preliminary emphasis is placed on catheter manipulation and observable catheter movements that may represent potential targets for the development of automated skills metrics. In particular, measurement of movement and efficiency were mentioned particularly frequently, and could potentially be measured by tracking hand movements or catheter movements on the fluoroscopy screen. A heavily emphasised aspect of endovascular skills are cognitive components such as decision-making and anatomical visualisation. It is evident that endovascular competence, in its entirety, is composed of a more complex blend of fine motor capabilities and situational awareness than initially described in the literature.

CHAPTER 5.

VIDEO-MOTION ANALYSIS SOFTWARE AND BENCH-TOP VALIDATION

5.1. INTRODUCTION- VIDEO MOTION ANALYSIS (VMA)

The interview study (chapter 4) identified a number of novel potentially measureable metrics, of which ergonomic catheter movement was the most frequently mentioned descriptor of movement. In recognition of this, our department sought to develop a software package which allows for semi-automated tracking of catheter and guide-wire tips, using the fluoroscopy screen as a medium. Video-motion analysis (VMA) is an objective means of skills assessment and is relatively unexplored avenue in endovascular surgery. Motion analysis has been described in other surgical specialties, largely focusing on hand movements (Datta et al., 2001, 2002). Electromagnetic tracking systems such as the AURORA (Aurora, Northern Digital, Waterloo, ON, Canada) have been used to analyse the movements of minimally invasive instruments (Egi et al., 2008). Similarly, the Imperial College Surgical Assessment Device (ICSAD) is a well-validated hand-motion analysis tool and has been used in bench-top studies of open and laparoscopic general surgical procedures (Bann et al., 2003).

Conceptually, VMA in endovascular surgery utilises real-time fluoroscopic sequences to assess endovascular movement efficiency. This technique generates guide-wire

and catheter-tip movement data to assess the ergonomics of the surgeon's technique. This technology has the potential to provide reliable and less-time consuming option for the assessment of the surgeon's skill, assuming we hold the hypothesis, that experienced and skilled operators manipulate endovascular tools more efficiently, to be true.

5.1.1. Motion-tracking software

A novel motion-tracking software was developed in collaboration with the Department of Computing Sciences at Imperial College specifically for use in endovascular procedures. The software is presently semi-automatic and facilitates frame-by-frame tracking and analysis of fluoroscopic sequences. Following standard digital recording of the fluoroscopy screen during an interventional procedure, the sequences can be uploaded onto the software platform and segmented into constituent frames. The operator then places a tracking marker at the tip of the endovascular tool. Advancing through subsequent frames, the software then estimates the catheter-tip's position using a semi-automatic tracking scheme that probes the immediate pixel field around the tracking marker for a similar pattern of pixellation. Using Euclidean geometric principles, a total cumulative 2D path-length (PL) that is travelled by the instrument is generated and expressed in pixels of movement. On the basis of co-ordinate data, the total number of movements and average and peak instrument velocities can be calculated. The current version of the software was created in C++ code, a general-use programming language, and Open CV library, a programming function for real-time computer vision. A screenshot of

the user interface is given in figure 11. The co-odinate output data is automatically generated and saved in a separate document such as MS Notepad or Excel. In order to obtain standardised results, the camera used to record the fluoroscopy screen must be positioned consistently during each recording. The software allows the user to manually correct the position of the tracker during and after the tracking process in order to correct any errors and deviations caused by image noise, drift and video compression artefacts.

5.1.2. Calculation of Path-length

Cumulative motion of the endovascular tool being tracked is calculated using the X and Y pixel co-ordinates generated for each frame. Each frame is defined by a length of time lasting 40 milliseconds. The law of Pythagorus is used to calculate the inter-frame distance travelled by endovascular tool. It states that if the lengths of two sides of a triangle that join each other at a right angle are known, the hypotenuse is given by the square-root of the sum of the squares of the two known lengths. In the formula below, ***c*** is the hypotenuse and ***a*** and ***b*** are the two known lengths.

$$c = \sqrt{a^2 + b^2}.$$

With reference to the software, differences in horizontal (X co-ordinates) and vertical (Y co-ordinates) movement between each frame are determined, resulting in two known lengths (***a*** and ***b***) and the hypotenuse of the resulting triangle gives the

distance travelled. The data is further processed to remove movement errors caused by image noise and video compression artefacts. The sum of all the hypotenuse values equates to the total 2D path-length in pixels. Due to an inbuilt error in the software, small oscillations of 0.7 pixels in size occur occasionally. This can be remediated during processing of the raw excel data. A movement is defined arbitrarily as any displacement greater than 1 pixel. A threshold formula is applied to identify all such movements and filter out the oscillations.

The long-term goal of this stream of research is to produce a fully automated version of the tracking software for use in any 2D fluoroscopic sequence, and ultimately to integrate this analysis tool into existing angio-suite image processing systems. The use of the VMA software is limited by the stringency of standardisation measures required to maintain consistency of data output. Given that data are recorded from the fluoroscopy screen, variations in image output, for instance increasing or decreasing fluoroscopic zoom settings will affect the VMA data. For instance, increasing zoom may artefactually increase the PL value for that particular phase of a procedure. At present, the effect of C-arm angulation and zoom variation are not known, and are not automatically accounted for by the VMA software. Similarly, the reproducibility of the software, in terms of inter- and intra-observer reliability is not known. Given that this software measures movement in two dimensions only, and that the arterial tree is a three-dimensional structure, it follows that some movement data is not picked up by this tracking software.

Study aims

The primary objective of this study was to evaluate inter- and intra-observer reliability of the software in its main function; the generation of 2D path-length data. Further objectives were the following:

- To investigate the effect of varying fluoroscopy C-arm zoom settings on the output pixel data generated using the tracking software.
- To investigate the effect of varying the C-arm angulation settings on the output pixel data generated using the tracking software.
- To assess the relationship between the tracked 2D path-lengths and the real three-dimensional (3D) distances travelled within the vasculature.
- To convert pixel data into metric distance measurments (mm).

5.2. METHOD

5.2.1. 2D and 3D models

Four 2D models were designed and constructed for the purposes of this study (fig. 11), with the objective of creating fixed 2D trajectories of known metric distance through which a guide-wire could be advanced under fluoroscopic guidance. This would facilitate the conversion of the software's output pixel data into millimetres and produce standardised results for the purposes of comparison when C-arm angle and zoom settings were varied. Construction of these models involved embedding transparent flexible silastic tubing into a lightweight KAPA® foam board. Four different shapes were measured and drawn on the board. Grooves were manually carved into the board and the silastic tubing firmly embedded. Two spiral shapes of different length, a 300 mm 'S' shape and a 100 mm straight line were created. The tube lumen was just wide enough to admit a hydrophilic guide-wire, permitting strictly axial movement with no lateral deviation. When screened fluoroscopically, the foam board was radiolucent, whilst the outline of the rubber tubing could be clearly identified. The guide-wire was radio-opaque and could therefore be readily tracked. The 3D model used in this study consisted of a transparent anthropomorphic silicon phantom of a type I aortic arch (Elastrat Sàrl, Geneva, Switzerland), and was used for the assessment of the relationship between 2D and 3D path-lengths.

5.2.3. VMA data reproducibility

One of the main objectives of this study was assess the reliability of the software platform as an assessment tool. This part of the study sought to determine the test-retest and inter-observer reliability of the software when applied to a standardised trajectory of known length. For the purposes of this study, test-retest reliability was defined as the ability of the software to achieve consistent results when used by a single observer to analyse the same video at different points in time. Inter-rater reliability refers to the ability of the software to achieve consistent results when used by multiple observers to analyse the same video at different points in time.

To determine test-retest reliability, the 300 mm 'S' shape model was used (fig. 11). A guide-wire was advanced through this fixed 2D trajectory under fluoroscopic guidance (0 zoom and 0^0 angulation) and the sequence was recorded digitally. The video was uploaded onto the software and the guide-wire tip was tracked by a single observer on three separate days, five times on each day. Prior to tracking, the observer was given a 15 minute introduction to the software, comprising of a five minute demonstrations and ten minutes practice. To determine inter-observer reliability, the same fluoroscopic video-sequence was tracked by five different observers, three times each. All five observers were given the same 15-minute introductory session prior to data collection.

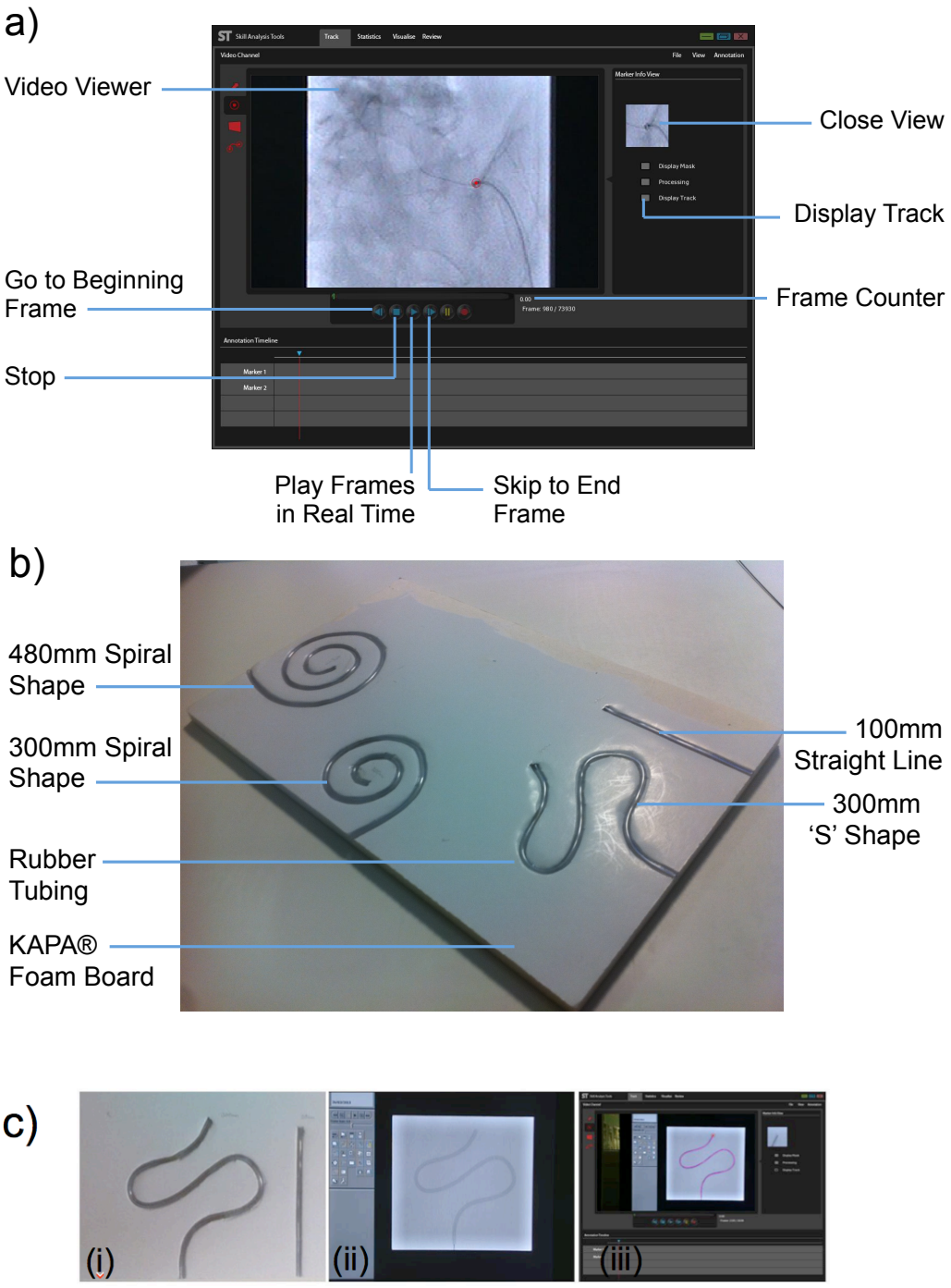


Figure 11. a) Screenshot of user interface of VMA software b) 2D models used for reliability analysis and C-arm zoom and angulation experiments c) 'S' shape model

5.2.4. Investigation of the effect of C-arm zoom settings

This part of the study sought to replicate the use of C-arm zoom settings used routinely in clinical practice. The relationship of VMA data output to magnification/zoom settings is not likely to be linear, given the multitude of factors involved in zoom generation, including flat panel detector field size and the size of the structure being imaged. It was therefore necessary to determine the effect of C-arm zoom settings in experimental conditions which reflected reality as closely as possible. In live cases, the table is often elevated, bringing the patient as close to the flat-panel detector as possible, thus minimising the radiation dose to the patient and increasing image quality. The distance from the flat-panel detector to the table is usually 20-30 cm. Increasing magnification on the fluoroscopy screen is achieved by adjusting the the flat-panel detector field size (FD setting), rather than adjusting the C-arm's physical source-to-image distance (SID setting), which is the distance between the X-ray tube to the flat-panel detector. The starting setting for most cases is an FD of 48 (no zoom), which refers to a 48 cm flat-panel detector field size. Zoom is then increased by reducing the FD setting incrementally from 48 down through standardised setting of 42, 37, 31, 27, 22, 19 and 15, the latter being the highest level of magnification. In clinical practice it is rare to see more than three levels of magnification (up to FD 31). SID was kept constant at all times.

To investigate the effect of C-arm zoom on VMA pixel output, the 300 mm spiral shape 2D model was used. The angle of the C-arm was maintained in the AP plane (0^0 rotation). Starting at FD 48, a guide-wire was advanced throught the spiral shape

under fluoroscopic guidance and the sequence captured on digital camera. The process was repeated at FD settings of 42, 37, 31, 27, 22, 19 and 15, to generate eight different path-lengths equivalent to 300 millimetres.

5.2.5. Investigation of the effect of C-arm angulation (rotation) settings

Due to the 2D nature of fluoroscopic imaging, C-arm angulation is adjusted in order to facilitate depth perception, thus allowing the interventionist to construct a 3D impression of the structure of interest mentally. The C-arm can be rotated in increments of a single degree, but the most commonly used settings are LAO (left anterior oblique) and RAO (right anterior oblique) 15^0, 30^0, and 45^0.

To investigate the effect of C-arm angulation on pixel output, the 300 mm spiral shape 2D model was used. The zoom setting was maintained at FD 48 (no zoom). A guide-wire was advanced through the shape under fluoroscopic control with the C-arm positioned at 0^0, 15^0, 25^0, 30^0, 40^0, 45^0, 55^0, 65^0, and 70^0. Since the spiral shape was not placed at the iso-centre (position half-way between the X-ray emission tube and the flat-panel detector), increasing rotation resulted in displacement of the image of the spiral away from the centre of the fluoroscopy screen. In order to maintain central positioning of the spiral on the screen, tape markers were placed around the shape on the screen and the shape shifted laterally on the table after each change in C-arm rotation/angulation. Artificial “zoom” caused by changing the position of the flat-panel detector during rotation, and movement away from the iso-centre was not adjusted for, since this occurs in reality.

5.2.6. Investigation of the relationship between 2D path-lengths and real 3D distances travelled

Endovascular intervention relies on 2D fluoroscopic imaging processing, whilst in fact endovascular navigation occurs in 3D. Whilst the authors of this study feel that this does not detract significantly from VMA as an assessment tool, given that fluoroscopy is used universally, we thought it necessary to quantify the amount of motion data lost as a result 2D analysis. An in-vitro experiment was constructed to compare 3D with 2D path-length in a standardised task.

A transparent silicone-based phantom of a type I aortic arch (Elastrat Sàrl, Geneva, Switzerland) was used. The model was constructed using patient-specific CT DICOM data. Ten endovascular novices were asked to advance around the aortic arch using a multi-purpose catheter mounted on a hydrophilic guide-wire. The start- and end-points were defined as the junction between the straight and curved portions of the descending thoracic aorta, and the aortic root, respectively. Then centre-line path-length of the phantom was estimated to be 270 mm using a length of shape-able steel wire. The wire was threaded through the phantom from the descending aorta through to the root. The wire was then suspended in the centre-line of the aorta from both ends with foreceps, whilst the second investigator measured distances radially from the wire to the arterial wall, ensuring distances were equal. An electromagnetic sensor was attached to the catheter tip to allow real time 3D path-length tracking in millilmetres using the AURORA system. Each procedure was

recorded with a camera oriented in a coronal/AP plane to allow for off-line 2D path-length analysis using the tracking software.

The experimental set-up is shown in figure 12. The camera was set up to mimic fluoroscopic screening at 0^0 rotation, whilst the electromagnetic field created by the AURORA system allowed 3D path-length to be tracked. A calibrator (50 mm scale) was fitted with the model at the level of the descending thoracic aortic orifice to allow conversion of pixel data from 2D tracking into millimetres.

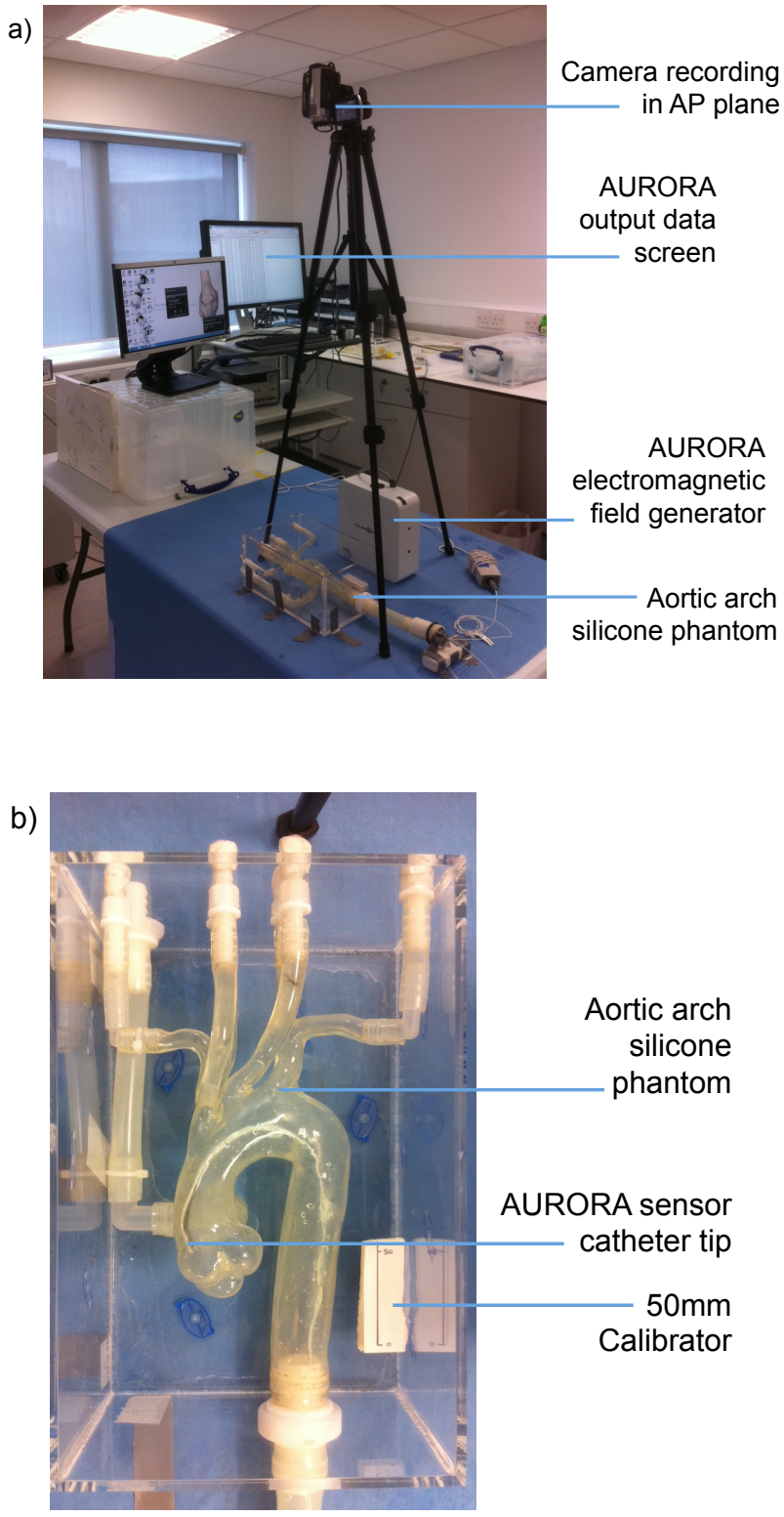


Figure 12. a) Experimental set-up demonstrating the two different tracking modalities: video-based and electromagnetic b) Coronal view of the phantom with calibrator and catheter

Statistical Analysis

SPSS version 20.0 (IBM SPSS Statistics, Armonk, NY, US) was used. Cronbach's α was was used to assess test-retest and inter-observer reliability, and was performed using the reliability scaling function on SPSS. A reliability co-efficient of 0.6 was accepted as good reliability for the purposes of this experiment. Pearson's product-moment correlation co-efficient was used to evaluate the relationship of PL with zoom and angulation. A level of $p < 0.05$ was considered to be statistically significant.

5.3. RESULTS

VMA data reproducibility

Median PL for the 300 mm 'S' shape was 855.5 pixels (IQR 837.7-881.2) for test-retest reliability assessment, and yielded a Cronbach's α of 0.979, indicating a very high degree of reliability. Absolute values are given in table 6.

	Sitting 1	***Sitting 2***	***Sitting 3***
Track 1	881.26	827.61	870.68
Track 2	855.57	883.87	832.21
Track 3	839.45	841.87	862.17
Track 4	821.22	896.15	837.71
Track 5	872.37	896.32	844.34

Table 6. Absolute PL values during test-retest reliability assessment for the 'S' shape tracking exercise

Median PL for the 300 mm 'S' shape was 839.45 pixels (IQR 837.7-851) for inter-observer reliability, and yielded a Cronbach's α of 0.983. Absolute values are given in table 7.

	Participant 1	***Participant 2***	***Participant 3***	***Participant 4***	***Participant 5***
Track 1	841.87	843.99	870.35	823.35	846.84
Track 2	839.45	816.26	888.69	825.69	849.98
Track 3	837.71	809.72	819.71	825.07	851.03

Table 7. Absolute PL values during inter-observer reliability assessment for the 300 mm 'S' shape tracking exercise

Investigation of the effect of C-arm zoom settings on PL

Path-lengths for the 300 mm spiral shape tracking with progressive C-arm zoom settings are shown in table 9.

C-arm FD Setting (cm)	*Path-Length (pixels)*
48	559.13
42	626.79
37	768.14
31	899.01
27	1054.97
22	1278.52
19	1505.62
15	1818.79

Table 8. C-arm zoom (FD) settings versus PL for a fixed 2D 300 mm trajectory

These results show that increasing C-arm zoom values increases measured path-length for the tracked 300 mm spiral. The relationship between C-arm zoom and tracked path-lengths is given in figures 13 a) and b). The graph suggests a curvilinear relationship. At the first three increments, the graph is linear.

Increasing the magnification by one standard level to FD 42 increases the path-length by a factor of 1.121, two magnifications increased the path-length by a factor of 1.374, and three magnifications increased the path-length by a factor of 1.608.

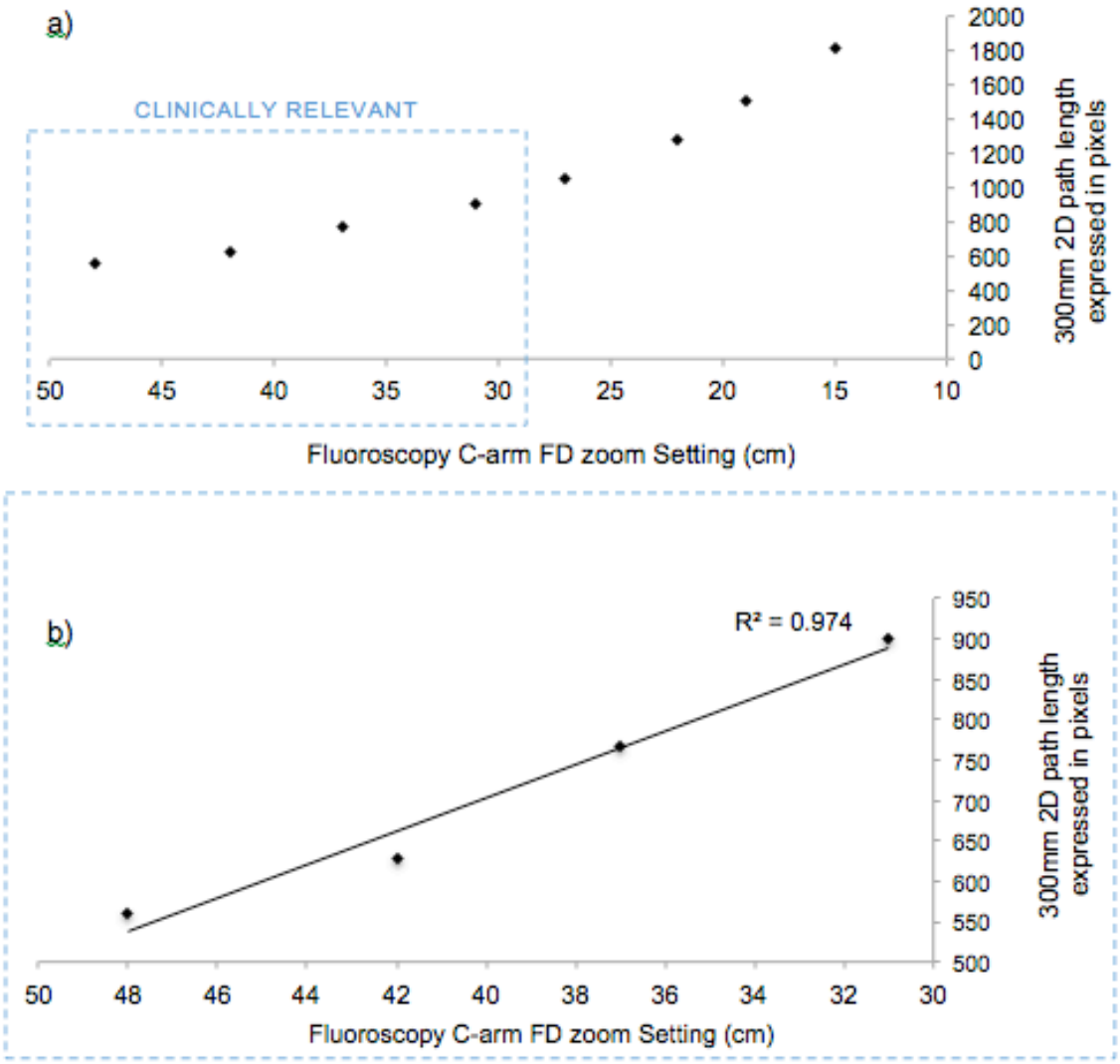


Figure 13. a) Effect of C-arm zoom (FD) settings on VMA data output b) Effect of C-arm zoom settings in the clinically relevant settings on VMA output (*p* = 0.01)

Investigation of the effect of C-arm angulation (rotation) settings

Absolute path-lengths for the 300 mm spiral shape tracking with progressive C-arm angulation are shown in table 10.

C-Arm LAO Rotation Angle (degrees)	*Path-length (pixels)*
0	542.93
10	536.44
15	533.29
25	534.43
30	526.74
40	542.92
45	547.38
55	566.04
65	665.88
70	745.75

Table 9. C-arm angulation settings and PL for a fixed 2D 300 mm trajectory

With increasing C-arm angulation up to an angle of LAO 30^0 there we observed a marginal but steady decrease in the path-length tracked for the 300 mm spiral, after LAO 40^0 onwards there was a sharp increase in path-length.

This trend is clearly demonstrated in figure 14 below. Between 0^0 and LAO 30^0 there was a decreasing linear trend in path-length with increasing rotation. At LAO 15^0 the tracked path-length decreased by a factor of 0.982 in relation the starting position at 0^0. At LAO 30^0 the tracked PL decreased by a factor of 0.970.

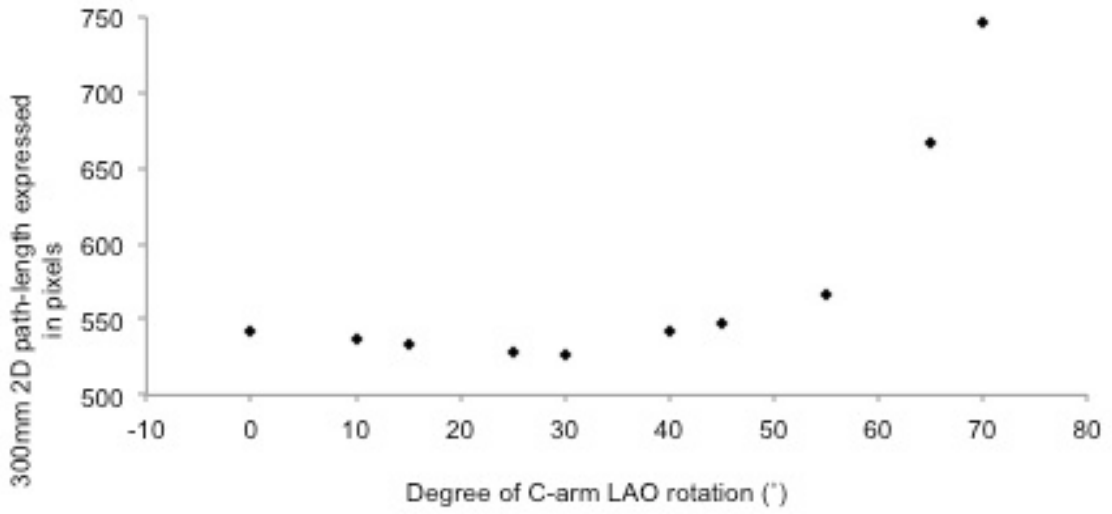


Figure 14. C-arm angulation and VMA output.

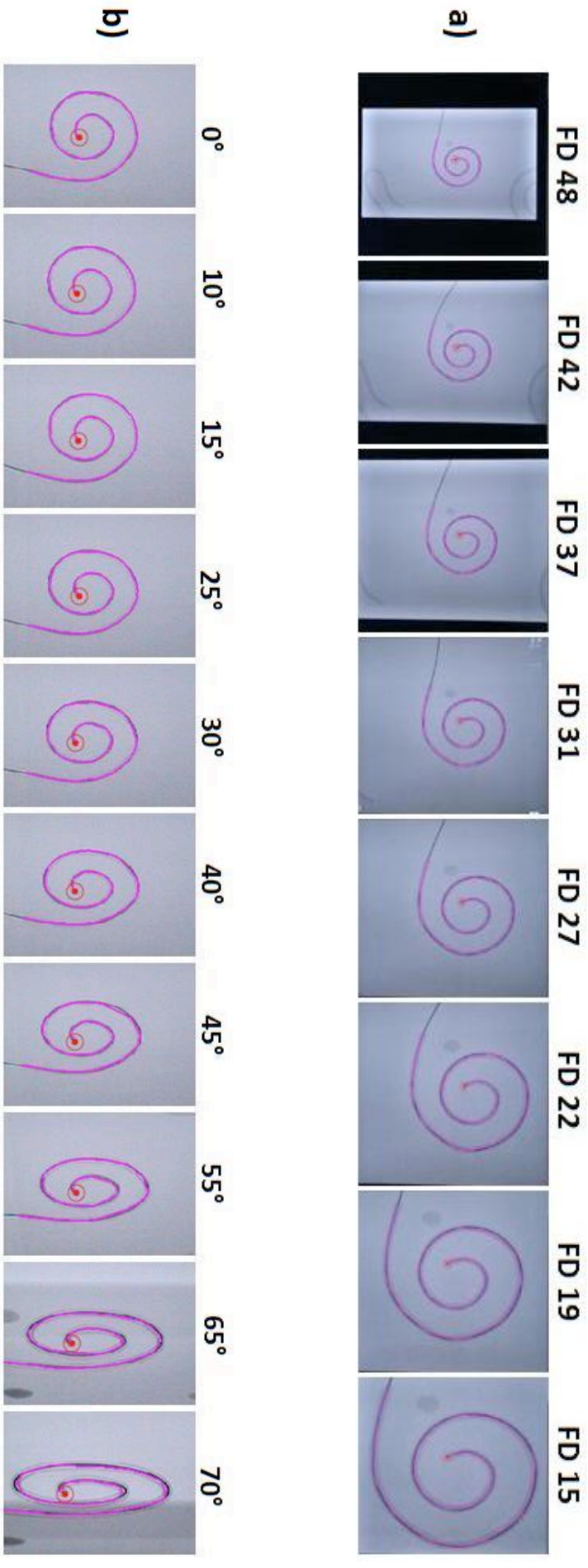


Figure 15. a) Tracked spiral trajectory with progressive C-arm zoom settings b) Tracked spiral trajectory with progressive angulation (degrees)

Investigation of the relationship between 2D fluoroscopic- and 3D electromagnetic path-lengths

2D path-lengths generated by the VMA software and the 3D path-lengths recorded by the AURORA electromagnetic tracking system for the ten novice participants are given in table 10.

Participant	*2D Track*	*3D Track*	*No. of 180° twist motions*
1	641.16	1039.65	12
2	349.39	497.01	0
3	314.46	411.53	0
4	339.99	425.23	0
5	337.00	371.90	0
6	354.01	509.25	4
7	437.38	883.48	7
8	371.17	540.44	1
9	348.28	421.27	0
10	336.19	393.36	0

Table 10. Comparison of 2D versus 3D PL (all PL measurements expressed in mm)

The 2D path-lengths were calculated using the 50 mm calibrator placed next to the phantom. At the standardised camera setting, this distance equated to 145 pixels, therefore 1 mm was the equivalent of 2.9 pixels. As an example, a tracked length of 938.99 pixels translated to 323.79 mm. Data in the table above demonstrates that PL values recorded by the software are lower than the values recorded by the AURORA system. Figure 16 b) provides a visual representation of an example of 2D versus 3D catheter trajectories. The discrepancy between 2D and 3D path-lengths was observed to increase when torqueing manoeuvres were applied. Figure 16 c) shows the relationship between the 3D and 2D path-lengths for participants who did not use torque during manipulation. Torque was defined an observable rotation of the angled catheter beyond 180^0. These manoeuvres were carefully counted for each

participant by a single observer. A linear relationship was identified between the 2D and 3D path-lengths for these participants, suggesting that the amount of motion data lost is small and predictable.

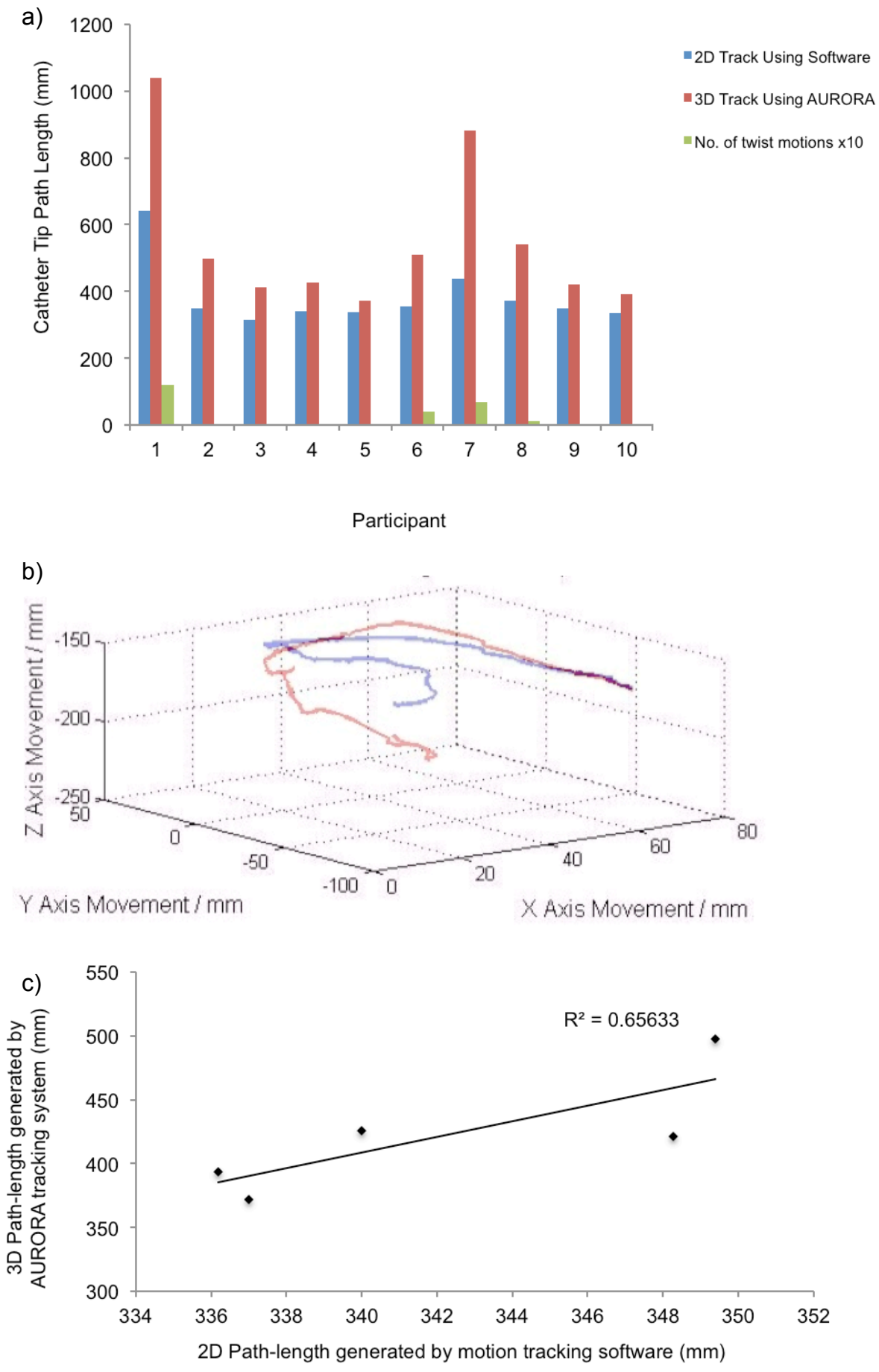


Figure 16 a) Relationship between 2D and 3D PL across all participants b) 3D line plot demonstrating discrepancy between 2D and 3D in participant 3 (c-arm perpendicular to arch) c) Scatter-plot demonstrating relationship between 2D and 3D PL for participants who did not apply torque

5.4. DISCUSSION

The primary objective of this study was to demonstrate the reproducibility of VMA in terms of test-retest and inter-observer reliability. The software demonstrated excellent reliability co-efficients of 0.979 and 0.983 for test-retest and inter-observer reliability. As a standard, Cronbach's α values greater than 0.8 are required of high-stakes testing, for instance in selection protocols for surgical trainees and post-graduate examinations (Neequaye et al., 2007; Cates and Gallagher, 2012). Despite the current version of the software being semi-automated and requiring manual corrections of the tracker position, the reliability in this study remained high.

The use of video-motion analysis in endovascular surgery has not been explored previously, so the purpose of this study was to provide an initial description of the software and to ensure requirements for test-retest and inter-observer reliability were met, as well as to evaluate the effects of zoom and angulation on data output.

There are four types of radiological zoom utilised in clinical practice, which magnify images seen on fluoroscopy screens. These are geometric, optical, digital and total zooms (Spahn et al., 2000). Geometric zoom refers to the physical distance of the patient relative to the C-arm X-ray tube and image intensifier. Standard practice is to move the C-arm intensifier as close to the patient as possible, which reduces diffraction of the x-rays. The latter can cause blurred edges on the image seen on the fluoroscopy screen (penumbra effect). This method of screening also dramatically reduces the X-ray dose absorbed by the patient (Hirshfeld et al., 2004). With geometric zoom standardised in this fashion, variation of optical is achieved by

manipulating the surface area of the flat-panel detector which is exposed to X-irradiation (FD setting). Digital zoom refers to the process of digital magnification of an image after it has formed on the fluoroscopy screen. This is rarely used as the picture quality decreases with increasing zoom.

When examining the effect of zoom we sought to replicate the settings used in clinical practice as much as possible. The C-arm image intensifier was placed 20 cm away from the 2D model to in order to represent the average distance between the image intensifier and the vasculature in common clinical scenarios. Ensuring this was kept constant, only the FD settings were changed. The table height and C-arm angulation were kept constant. The results show a clear relationship; when FD settings were adjusted to increase zoom, the PL for movement over a standardised distance also increased. The relationship is linear up to the first three levels of magnification, beyond these settings the differences become less significant clinically since FD settings beyond 31 are rarely used.

We evaluated the effect of C-arm rotation on VMA data output by maintaining constant zoom settings and table height. The FD setting was fixed at 48 (no zoom). Our initial hypothesis was that 2D PL would decrease with increasing C-arm rotation, and we were able to confirm this up to a rotation of 30^0. Beyond this degree of rotation we observed an artefactual increase in zoom. A possible reason for this is that the model was not placed at the radiological iso-centre (point half-way between the X-ray beam source and the flat-panel detector). Therefore, increasing the angulation alters the geometric relationship between the model and the X-ray

source and flat-panel detector. Consequently optical zoom changed, and therefore also the tracked path-lengths. We identified a decrease in PL with increasing rotation up to 30^0. Thereafter the radiation source was brought closer to the screened object as a result of rotation and the PL increased. A potential limitation of the rotation experiment relates to the varying width of objects being screened. For instance, the straight 300 mm object may not demonstrate any significant change in VMA data output with progressive lateral rotation, whilst an object of considerable width, for instance the 480 mm spiral will exhibit significant changes in PL when tracked. A more extensive investigation is required, beyond the scope of this study, in order to screen objects with incremental increases in width with increasing c-arm angulation, and map out the full range of VMA variation with rotation.

By using 2D fluoroscopic video sequences in the evaluation of endovascular skill, our results show that data on 3D movement is lost. Despite this, there is a significant correlation between 2D path-length and the real 3D distances moved within the vasculature. The discrepancy between 2D and 3D PL was small and predictable: high 2D path-lengths generated by the motion tracking software correlate with high 3D path-lengths generated by the AURORA tracking system. Of interest, torqueing maneouvres affected the 3D PL output, and is likely to be a consequence of movement in three dimensions. It is possible that inexperienced users are more likely to torque the catheter, which might have a bearing on results. However, given that interventional procedures are performed universally using 2D fluoroscopic guidance, we feel that 2D fluoroscopy-screen VMA is a valid means of assessment of endovascular efficiency, particularly given the findings described above.

Potential limitations of this study include the rigid standardisation of fluoroscopy settings. In reality, there are a very wide range of possible table height and image intensifier setting combinations which can be used. Repeating these experiments using all possible permutations of fluoroscopic setting is clearly beyond the scope of this experiment. Although we sought to replicate clinical settings as accurately as possible, further development of the software is required using computational modeling to predict VMA outputs across a broader range of fluoroscopic settings. Nonetheless, we feel that by trying to replicate clinical settings as accurately as possible, using real fluoroscopic guidance, we were able to identify important changes in VMA data outputs which might not have been identified using computational techniques. An example for this is the sharp increase in PL observed with increasing angulation after 30^0. This most likely occurs in real clinical settings given that most target structures are not screened at the radiological iso-centre.

5.5. CONCLUSION

Video-motion analysis is a novel method for assessment of the ergonomics of catheter and endovascular tool movement, and has the potential for further development as a reliable tool for the assessment of endovascular skill. The experiments documented above suggest that the software is highly reliable and consistent when used repeatedly. Variations in C-arm angulation and zoom settings lead to small and predictable changes in VMA data output, which can be easily adjusted for on final analysis. Furthermore, the amount of data lost due to strictly 2D analysis of movement is likewise small and predictable.

This chapter was completed in collaboration with an intercalated BSc student, Sybghat Rahim, who was directly supervised by the author of this thesis. The experiments were designed by the author of this thesis, and data collection was performed by both individuals.

CHAPTER 6.

THE USE OF VIDEO-MOTION ANALYSIS TO DIFFERENTIATE BETWEEN GROUPS OF EXPERIENCE IN SIMULATED CAS

6.1. INTRODUCTION

Simulation offers the opportunity to train in an educationally oriented environment without subjecting patients to increased risk, whilst also providing the opportunity for on-going feedback and assessment outside the demands of clinical case workload. As discussed in the review, most high-fidelity simulators, such as the VIST (Mentice, Gothenburg, Sweden), provide instantaneous and automated feedback on metrics such as total procedure and fluoroscopy times and simulator-recorded errors. The metrics recorded by a variety of simulators have demonstrated good construct validity in terms of endovascular training and experience (Van Herzeele et al., 2007, 2008; Dawson et al., 2007). However, such metrics can only be regarded as crude surrogate markers of technical skill. Several qualitative rating scales have been developed in an attempt to assess the quality of endovascular performance. Whilst many of these qualitative scoring systems demonstrate construct validity and good inter-observer reliability, they require time-consuming, video-based post-hoc analyses. Motion analysis as a tool to evaluate skill is currently unexplored in the field of endovascular surgery, the principles of which have been described extensively in the preceding chapter. A reduction of total movement (or path-length) required to successfully complete an endovascular task, may represent a reliable measure of skill. The primary objective of this study was therefore to study the novel endovascular metric in the simulated setting first- guide-wire/catheter tip path-

length (PL), in order to determine whether this constitutes an objective and sensitive discriminator of endovascular skill. The secondary objective was to correlate PL with existing simulator-derived metrics and qualitative rating scales.

6.2. METHOD

Subjects

Twenty-one interventionists participated in this study. Each had performed at least 100 general endovascular cases as primary operator. This number was arbitrarily selected to realistically reflect the minimum endovascular experience required for carotid artery stenting (CAS) training. Six interventional cardiologists (IC), eight interventional radiologists (IR) and seven vascular surgeons (VS) participated. 66% had performed at least 500 endovascular interventions as primary operator. They were sub-divided into four groups according to CAS experience: inexperienced (0 CAS cases performed, 3 IR and 3 IC participants- Group A), low-volume (1-20 CAS cases performed, 2 VS and 1 IC participants- Group B), moderate-volume (21-50 CAS cases performed, 1 VS, 2 IR and 2 IC participants- Group C) and high-volume interventionists (>50 CAS cases performed, 4 VS and 3 IR participants- Group D). The moderate- and high-volume groups had performed only 1 and 2 previous virtual-reality simulations, respectively. No one in the inexperienced or low-volume groups had previous VIST experience.

The Vascular Intervention Simulation Trainer (VIST) Simulator

The VIST simulator has been discussed extensively in the introduction, so no further elaboration will be made here. It was used to carry out all the simulations in the present study.

Task performed

All subjects received an initial didactic session on the VIST simulator and were familiarised with the system followed by a practice session of treating an ipsilateral common iliac artery stenosis. Prior to study commencement, available endovascular materials and patient's records demonstrating the target lesion were provided. All participants were asked to treat a proximal right internal carotid artery stenosis (90%) using endovascular techniques in a type 1 aortic arch. The purpose of this study was to validate metrics for endovascular skill assessment rather than knowledge, so for less experienced subjects in CAS a protocol was available explaining the different steps of the CAS procedure. Passive assistance was provided by members of the interventional team comprising of an assistant, radiographer, and a circulating nurse. The videos of these CAS simulations were kindly provided by Dr Isabelle Van Herzeele of the University of Ghent, Belgium. Recruitment of participants and task set-up are therefore attributed to her group.

Catheter Tracking Software

The software has been extensively described in the previous chapter so no further elaboration on the actual software will be made here. In this series of videos, the fluoroscopy screen was inadvertently angled with respect to the recording camera. Pre-processing of video frames was therefore performed for correction of perspective distortion due to the positioning of the camera with respect to the simulator's monitor. Affine transformation of pixel co-ordinates was used to generate a transform (T) matrix once the simulator screen corner co-ordinates were

known. The T matrix was then applied to the entire dataset of pixel co-ordinates for each video to obtain normalised results. This process was performed in conjunction with the Department of Computer Sciences. The initial tracking point was standardised and defined as the origin of the left subclavian artery. In all procedures the most distal part of the guide-wire/catheter interface was tracked (either the guide-wire or catheter tip).

Data Analysis

Post-hoc video analysis of all procedures was performed by a blinded assessor using the catheter tracking software described above. Phases of active movement were tracked, and tracking was not performed during phases of fluoroscopic image manipulation (such as C-arm rotation) in order to avoid incorporation of movement artefact into the final PL analysis.

Each case was segmented into four defined procedural phases. Arch Navigation was defined as movement from the left subclavian ostium to a resting position of guide-wire and catheter at the aortic root. Right common carotid artery cannulation (CCA) was defined as movement from the aortic root to a point 1 cm within the right CCA. External carotid artery (ECA) manipulation was defined as movement from 1 cm within the CCA to a position 2cm within the ECA. Internal carotid artery (ICA) manipulation was defined as movement from within the CCA, across the ICA stenosis to a point at the distal most bend of the ICA. For each subject the wire/catheter tip PL was calculated for the entire procedure as well as the four different procedure phases. The output measure is given in number of pixels. Additionally, we were able

to calculate peak velocities, knowing that the distance travelled per frame and that the duration of each frame was 40 milliseconds.

The VR simulator records instantly and automatically the procedure time, fluoroscopy time, contrast volume used, number of cine-loops used and simulator-defined errors. Errors are classified into catheter vessel errors (pressing catheters against the vessel wall), catheter movement errors (moving catheters without support of a guide wire), moving near a lesion (wire and catheter), moving the embolic protection device (during and after deployment), moving the stent during deployment (and deploying whilst in the guiding catheter or sheath) and inflating the balloon inside the guiding catheter. Qualitative procedural scores were obtained for comparison with PL; three blinded independent experts assessed each procedure using a validated general endovascular rating scale and a CAS-specific rating scale (Van Herzeele et al., 2008); a median score was calculated. Therefore, each performance was awarded a median CAS- and generic- endovascular rating as a result of the three assessments. As described in previous publications, the generic-endovascular rating scale was adapted from OSATS and was designed to test various aspects of basic general endovascular skills (Van Herzeele et al., 2009).

Statistical Analysis

Data were analysed with the Statistical Package for Social Sciences 20.0 (SPSS, Chicago, Ill). The data was found to be not normally distributed and therefore non-parametric tests were used. Distributions across all four groups of experience as well as groups according to specialty were compared using the Kruskal-Wallis test. Pre-

defined post-hoc comparisons of PL between each group of interventionists with similar CAS experience were performed using the Mann-Whitney U test. Correlations between PL and rating scale procedure scores, total procedure time, fluoroscopy time, contrast volume, number of cine-loops and simulator-recorded errors were performed using Spearman's rank correlation coefficient. A level of $P < 0.05$ was considered to be statistically significant.

6.3. RESULTS

It was feasible to track path length of endovascular tools using this semi-automated method with minimal manual adjustment. Typical graphical representations of path lengths can be seen overlain onto the angiographic image in figure 17.

6.3.1. Path-length Differences Between Groups of Experience

Analysis of distribution across all four groups using the Kruskal-Wallis test showed statistically significant differences between groups (p = 0.02). Except for the 0 CAS group, there was a decrease in PL with increasing experience. Post-hoc analysis demonstrated the PL was significantly reduced in the highly experienced group D when compared to other groups with CAS experience (fig. 18). Group D used 5160.3 (interquartile range- IQR) pixels of movement compared to 6856.7 (5914.4-8106.9) for group A (p = 0.046); 10905.1 (7851.1-14381.5) for group B (p = 0.017) and 9482.6 (8663.5 - 13847.6) for group C (p = 0.003). There was no significant difference between Groups A and B (p = 0.095), however Group A performed significantly better than Group C (p = 0.009). There was no significant difference in PL across groups according to specialty (p = 0.5).

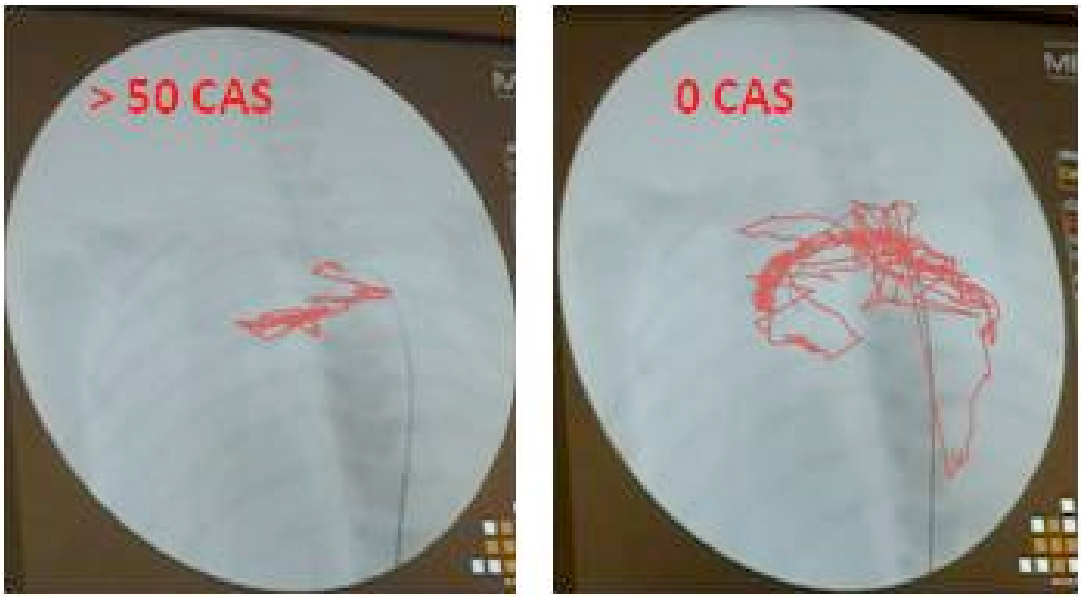


Figure 17. Graphical representation of tracked guide-wire trajectories during arch navigation in simulated carotid artery stenting (CAS). Seen in this format, the greater PL of the inexperienced interventionist (0 CAS) becomes evident

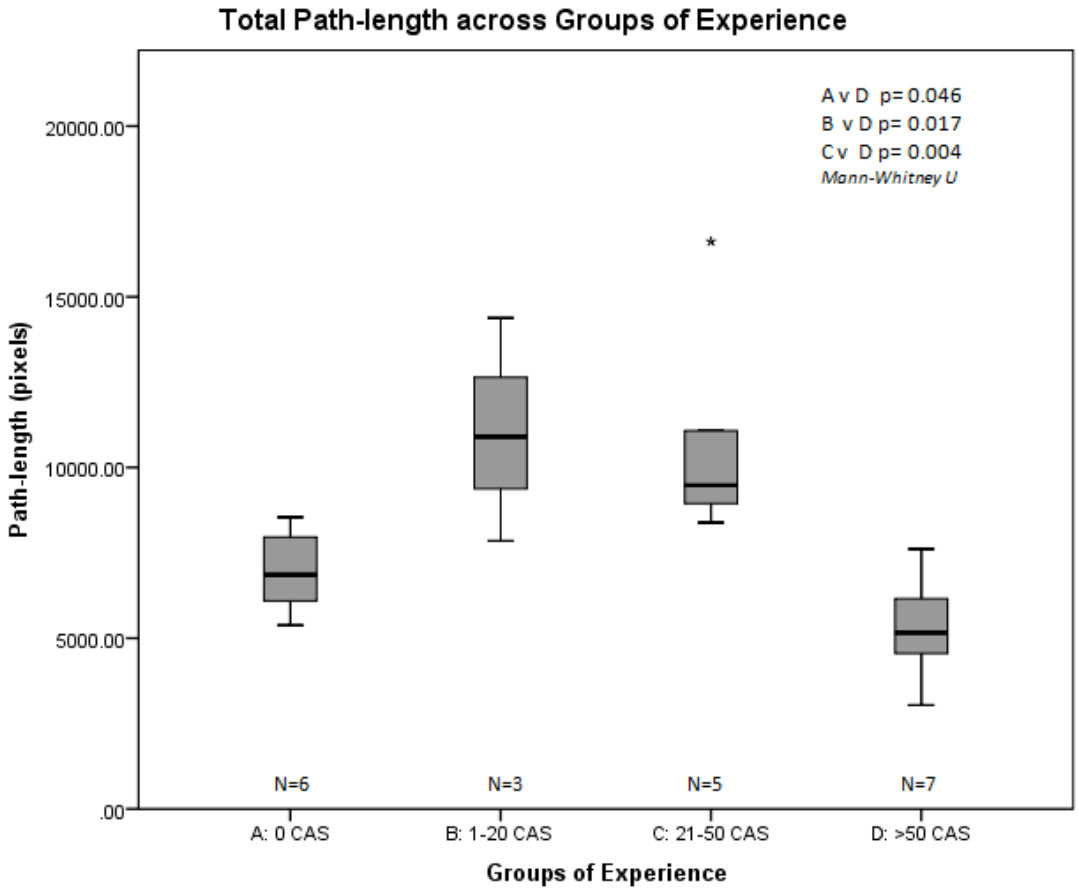


Figure 18. Box-plot representing PL (y-axis) taken to complete the carotid stenting task across groups of varying experience (x-axis) (Kruskall-Wallis *p* = 0.02). The whiskers represent extreme values and the stars the outliers

6.3.2. Path-length Differences Between Groups of Experience; Procedural Breakdown into Phases

Absolute median path-length values are given for each procedural phase according to the previously-defined groups of experience in table 11. P values are given for analysis of distributions, and where relevant following post-hoc analysis. Path-lengths for the different groups of experience are clustered according to procedural phase in figure 19.

	Group A (0 CAS)	Group B (1-20 CAS)	Group C (21-50 CAS)	Group D (>50 CAS)	(p=)
Total PL Median IQR	6856.7 5914-8107	10905.1 7851-14381	9482.6 8663-13848	5160.3 4046-7143	0.02
Arch. Nav. Median IQR	1111.7 887-1858	2178 617-5606	2841 1269-4204	864.7 764-2106	0.36
CCA Median IQR	1358 959-1587	1790 576-9238	1063 732-1545	782 648-1849	0.83
ECA Median IQR	980 591-1079	1276 956-1760	1013 670-1310	661 317-929	0.21
ICA Median IQR	245 214-292	729 279-1779	449 295-826	297 278-473	0.047 AvC: p=0.03

Table 11. PL data for each phase of the procedure according to groups oexperience

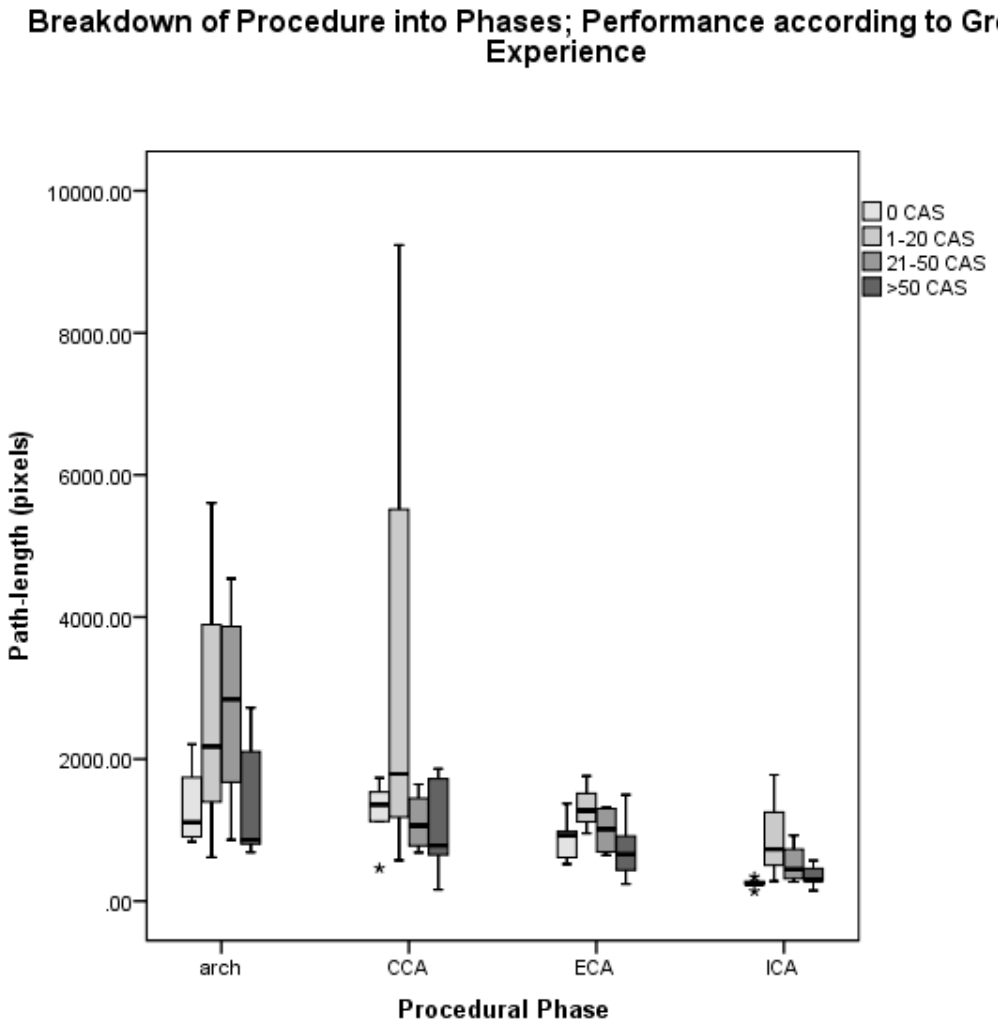


Figure 19. Cluster box-plot demonstrating procedural phase-breakdowns. Each phase given on the x-axis is divided into clusters giving PL for that phase according to experience

6.3.3. Correlation of Path-length with Rating Scales and Simulator-derived Metrics

Out of all participants, the median procedure-specific CAS score (fig. 20 a) achieved was 25/35 (13-33) and correlation with PL demonstrated a statistically significant inverse relationship (rho = -0.567, p = 0.014). Correlation of PL with the general endovascular rating scores (fig. 20 b) (median: 29/45 (20-40) also demonstrated a significant inverse relationship (rho = -0.519, p = 0.027).

Correlations of PL with simulator-recorded errors (rho = 0.403, p = 0.097), contrast volume used (rho = -0.028, p = 0.938), total procedure time (rho = 0.42, p = 0.08) total fluoroscopy time (rho = 0.463, p = 0.053), and number of cine-loops used (rho = 0.141, p = 0.578) were not found to be statistically significant.

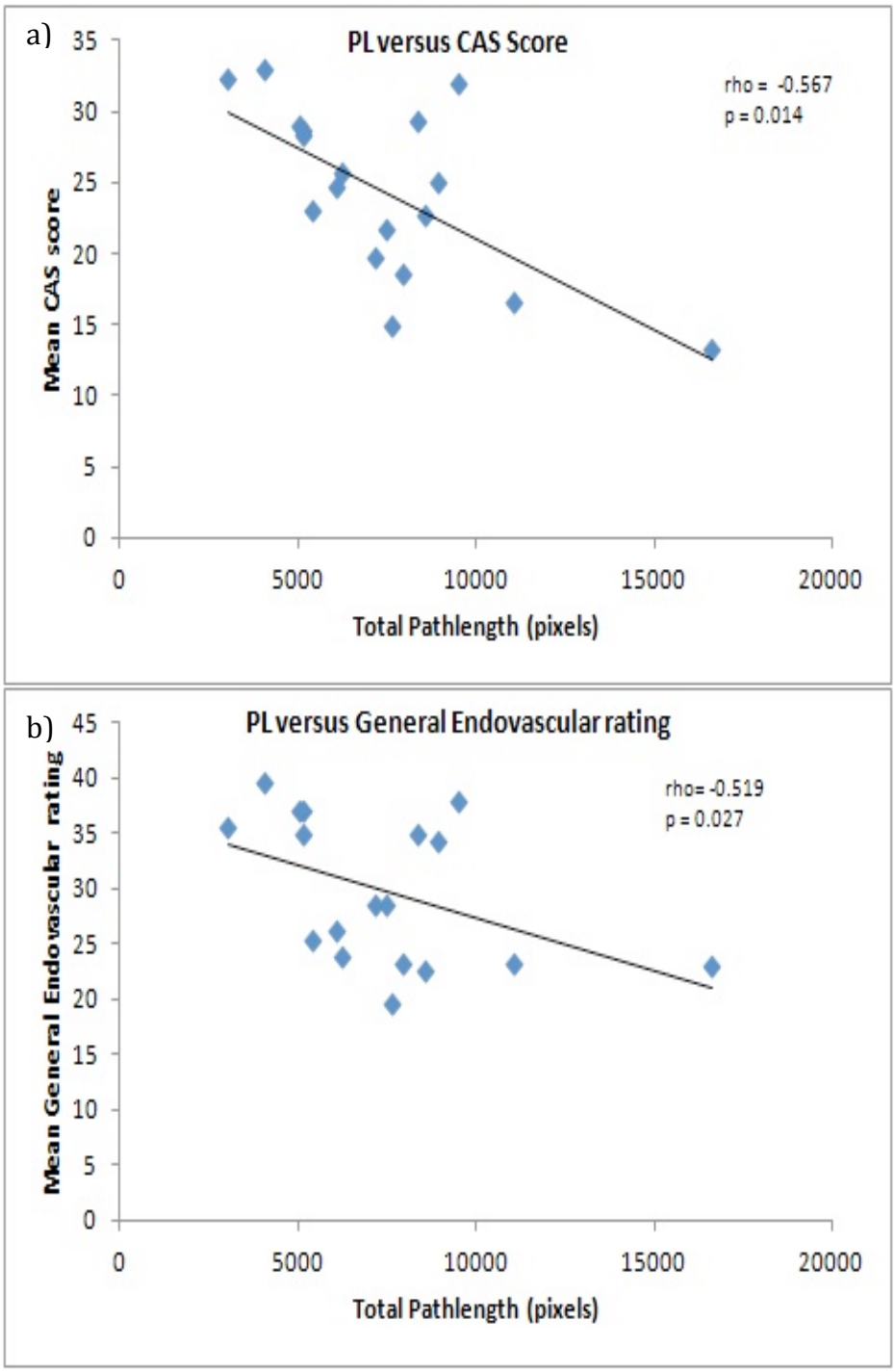


Figure 20. a) and b) Scatter plots showing PL correlations with Total CAS score and General Endovascular Rating, respectively. PL is given on the x-axis and assessment scores on the y-axis. Individual scores are indicated by the blue diamonds

6.3.4. Velocities across groups of experience

There was no significant difference between the groups for peak velocity (fig. 21): median peak velocity for group A was 1.5 pixels/ms (IQR 1.3-2.3) vs 4.09 (1.7-7.4) for group B vs 5.2 (2.4-11.4) for group C and 5.6 (1.5-8.9) for group D (p = 0.051).

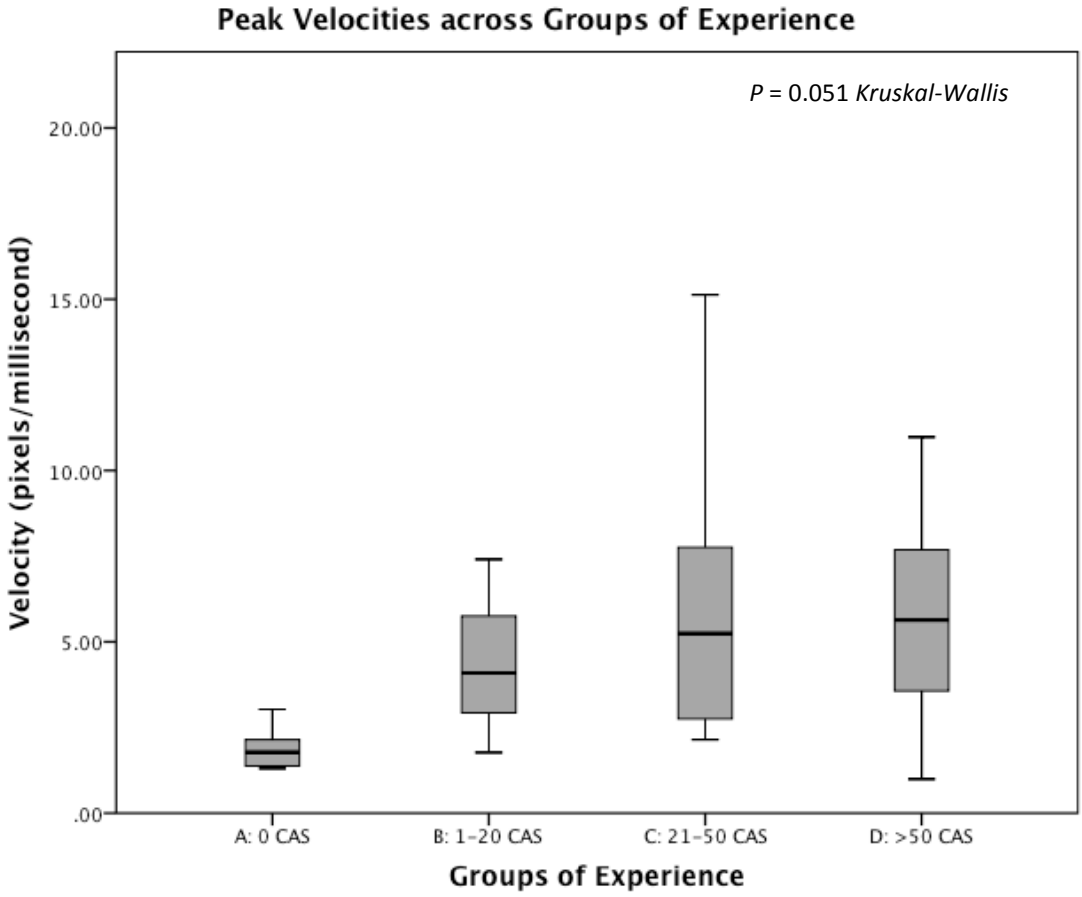


Figure 21. Peak guide-wire/catheter velocities across groups of experience

6.4. DISCUSSION

Path-length calculations have previously been employed in laparoscopic surgery and have been able to discriminate between levels of experience (Aggarwal et al., 2009]. This study has demonstrated that it is feasible to track endovascular tools on recorded angiography screens and determine PL to assess of endovascular skill. To our knowledge, this is the first study to demonstrate the feasibility of video-based guide-wire tracking using angiography images, specifically. Other tracking tools have employed the use of electro-magnetic, ultrasound and magnetic-resonance based mechanisms (Bond et al., 2009; Manstad-Hulaas et al., 2011; Kurpad and Unal, 2011). These, however require significant modification of the tip of the endovascular tool as well as the operating room/angio suite. The advantages of this technology include the ability to provide an *objective* assessment metric that may be improved to become fully automated, and potentially provide real-time feedback to trainees and assessors. Existing qualitative rating scales require time-consuming live assessment or post-hoc video analysis by experts and assignment of numerical values to statements which may introduce an element of subjectivity. It has been observed previously that edited video assessment appears to reduce the reliability of this tool and therefore a short cut to viewing entire procedures seems unreliable (Scott et al., 2000). Other methods to track endovascular tools employing position sensors require direct modification of devices in order to facilitate tracking. This may cause interference with the existing mechanical properties of catheters and wires.

This study has shown that guide-wire/ catheter tip PL differs between four groups of experienced endovascular therapists with varying CAS experience. Total procedure PL seems to be significantly reduced for the most experienced operators when compared to those who have performed less than 50 CAS cases. Path length was also able to differentiate the highly- experienced (>50 CAS) group from inexperienced (0 CAS), low-volume (1-20 CAS), and moderate-volume (21-50 CAS) groups. Of note, the low- and moderate-volume groups (B and C) exhibited the highest PL values for total procedure, arch navigation and ICA measurements. A similar pattern was observed in these groups for procedure and fluoroscopy time. These previously validated metrics are automatically given by the VIST simulator, and the same pattern has been observed in a previous publication (Van Herzeele et al., 2007). This pattern was not observed with the rating scale assessments; both the intermediate and highly experienced groups attained significantly higher scores on the generic rating scale than the inexperienced group. The proposed explanation for this observation may be that the novice group attempted to perform the simulated task as quickly as possible with few movements without necessarily appreciating the dangers of such an approach, whilst the moderately experienced groups attempted to complete the task in a more exploratory fashion, moving the guide-wire more frequently when searching for the optimal cannulation strategy. This also translates into increased fluoroscopy and longer procedure times. This theory is supported by a study which evaluated the performance of junior, intermediate and highly experienced surgeons on a virtual reality iliac stenting model before and after receiving cognitive skills training (Van Herzeele et al., 2008). The investigators found that cognitive skills training significantly increased total procedure and fluoroscopy time, but reduced

percentage of residual stenosis, suggesting that more attention was paid to quality outcomes rather than faster task completion. Interestingly, experienced operators may undertake an increased number of wire and catheter exchanges, thereby increasing PL.

In the present study, we observed statistically significant correlations between PL and general endovascular / procedure specific rating scales which strengthens the hypothesis that PL may be a useful adjunct to endovascular skills assessment. No significant correlations were seen between PL and simulator-derived metrics (total procedure and fluoroscopy time, contrast volume, errors, and number of cine-loops). It is interesting to note that there was no correlation between this new metric and simulator-derived metrics such as procedure-time. Given the findings of the review undertaken in chapter three, showing that procedure time demonstrated construct validity in most comparisons of groups of experience, one would expect to see a correlation in this study. It is possible that this reflects the nature of the CAS procedure: experts may deliberately take a long period of time in order to perform the procedure as carefully as possible.

Motion analysis during the different phases of the CAS procedure demonstrated that PL during arch navigation, CCA cannulation and ECA manipulation was lowest in the highly experienced group, however this did not achieve statistical significance, perhaps likely due to the small numbers in this sub group analysis. For CCA cannulation in particular, we observed a non-significant but step-wise reduction in PL with increasing experience, with the exception of the low-volume group who had

the longest PL. Small numbers in this group may not accurately reflect this level of experience. For ICA manipulation the most inexperienced group had the shortest PL. A possible explanation for this relates to the fact that inexperienced subjects are less aware of the potential hazards of crossing the lesion with the embolic protection device. With experience, endovascular manipulation in this phase involves careful and measured set-up in the CCA before attempting lesion crossing.

A potential limitation of this study relates to motion analysis of a three-dimensional (3D) procedure on a two-dimensional (2D) image. Aspects of the catheter motion out of the x and y planes will not be captured using our method. Whilst this clearly produces an error in calculation of PL, it is balanced by the fact that this method may be applied to live and simulated cases without the need for tool modification, but via simple recording of the angiography screen. Also one may argue, that the majority of current endovascular techniques in the clinical setting are performed utilising 2D fluoroscopy. Furthermore, the motion/PL output, at present, from the software analysis is measured in pixels. There is therefore some difficulty in interpreting these results and the real distances are not known. In addition, the current software does not account for changes in image magnification during C-arm manipulation during live cases, and ensuing errors in PL measurement have to be manually corrected. Phases during which the fluoroscopy view was changed were not tracked in an attempt to limit “non-operator dependent” PL data being captured; which may have led to the loss of valuable descriptive motion data. Our group is currently focusing on further software development to address these limitations. Simulator software errors were also evident and included unintentional endovascular tool movements,

removal of endovascular tools and occasionally tool duplication on the simulator screen. Such errors were corrected for during final analysis by removing raw pixel co-ordinate data identified as being a software-generated error. Lastly, groups were small and divided arbitrarily according to CAS experience, which may not necessarily represent actual expertise. Small numbers and the possibility of type II errors may also account for poor correlations between PL and conventional simulator-derived metrics.

While path-length measurement does not represent the entirety of endovascular skill assessment, full automation and further evaluation in a study of live cases will hopefully result in the refinement of an objective skill metric which will accurately and efficiently define expert performance in terms of movement, and will complement existing metrics. Further development of video-motion analysis in general as a medium for skills assessment has the potential for identification of additional motion-descriptive metrics.

6.5. CONCLUSION

This pilot study has demonstrated that semi-automated endovascular tool PL measurement is feasible using fluoroscopy images. The motion path length appears shorter for highly experienced operators during CAS procedures on the VIST simulator and there are significant correlations between PL and qualitative video-based rating scores. Path-length measurement may represent a useful adjunct to existing endovascular skills assessment tools. Further work to evaluate the software is described in the subsequent chapter.

The data in this chapter has also been reported in part in a previous paper using the same cohort of participants (Van Herzeele et al., J Vasc Surg. 2007;46:855-63). The novelty of this chapter lies with the presentation of a novel method of endovascular skill assessment.

CHAPTER 7.

THE USE OF VIDEO-MOTION ANALYSIS TO DIFFERENTIATE BETWEEN GROUPS OF EXPERIENCE IN LIVE CORONARY INTERVENTION

7.1. INTRODUCTION

The need for robust and reproducible assessment of endovascular skills has been discussed extensively in previous chapters, as have existing assessment tools. Briefly, endovascular skills can be quantified by means of automated metric panels which most modern simulators such as the VIST (Mentice AB, Gothenburg, Sweden) can provide. In live cases, metrics such as procedure time and fluoroscopy time are automatically derived from the imaging system, whilst at our institution contrast volume is recorded as a matter of policy by our radiographers. Qualitative rating scales have been developed in an attempt to assess endovascular performance and include generic- and procedure-specific rating scales, most of which are derived from the Reznick Scale (Van Herzeele et al., 2009). The overall objective of this chapter is to demonstrate feasibility of video-motion analysis in live intervention.

Diagnostic coronary angiography (CA) is the most frequently performed arterial procedure, with 215,575 diagnostic coronary angiographies having been performed in 91 interventional centres in a year according to the most recent UK National Coronary Angioplasty Audit (Ludman, 2006). Morbidity and mortality for this procedure vary between 0.8-4.6% and 0-0.2%, respectively according to international data (Jensen et al., 2012). Despite the large volume of these

procedures being performed annually, investigation into suitable metrics which define expertise in this procedure remain largely restricted to radiation dose-area product (DAP) and procedure-and fluoroscopy times (Hillock et al., 2006; Jensen et al., 2012; Räder et al., 2011; Shah et al., 2013). A consensus does exist regarding ideal reference levels for DAP (45 Gy cm^2), fluoroscopy time (6.5 mins) and contrast usage (100 mls) (Padovani et al., 2008; Räder et al., 2011). Recommendations are in place internationally regarding training targets prior to which a trainee can perform diagnostic coronary angiography independently; both the American College of Cardiology and the European Society of Cardiology recommend similar volumes of experience (200-300 cases as primary operator) prior to undertaking unsupervised cases (Jacobs et al., 2008; Gillebert et al., 2013), whilst the Cardiac Society of Australia and New Zealand defines competence as the attainment of 150 cases as supervised primary operator and a further 150 as an unsupervised primary operator (Hillock et al., 2006). Similar to the endovascular rating scales described previously, global- and procedure-specific qualitative rating scales have been developed for the assessment of invasive cardiology skills (Chaer et al., 2006; Bagai et al., 2012). Lipner et al have validated a scoring matrix based on cognitive decision-making processes at key points in simulated PCI which incorporates management of crisis scenarios (Lipner et al., 2010). Six PCI scenarios of varying complexity were designed by a committee of the American Board of Internal Medicine, and key decision nodes were established at various check-points which included unexpected emergencies such as failure to establish re-flow or ventricular fibrillation. Scoring for each node was weighted according to the severity of each emergency.

Video-motion analysis

We have demonstrated in the preceding chapter that VMA is able to differentiate between levels of experience in simulated carotid stenting, although there is no data describing its use in live interventional cases. The primary objective of this study was therefore to investigate the validity of VMA as a reliable and sensitive discriminator of endovascular skill in live diagnostic coronary angiography, specifically to establish construct validity across groups of experience. Secondary objectives were to correlate VMA data with previously validated quantitative markers of skill; procedure- (PT) and fluoroscopy-times (FT) and dose-area product (DAP), and to investigate the effect of access route (radial versus femoral access) and anatomy (right versus left coronary artery) on path-length. The latter was evaluated specifically in the trainee group (<4000 cases), since the trans-radial approach is thought to be technically more demanding, and demonstrates a prolonged learning curve amongst trainees in interventional cardiology trainees (Balwanz et al., 2013).

7.2. METHOD

Study Design and Participants

The fluoroscopy screens of 50 consecutive coronary angiographies performed in a single coronary catheterisation suite (Toshiba Infinix CF-i^{TM}, Tokyo, Japan) were prospectively recorded. Digital camera set-up was standardised with respect to angulation (0^0 in relation to the fluoroscopy screen) and distance (50 cm from lens of camera to fluoroscopy screen). No zoom was applied to the camera settings, and all angiographies were performed at 0 magnification factor with respect to fluoroscopy. Prior to starting any recordings, 21 participants were sub-divided into three pre-defined groups according volume of coronary angiography experience, using stages of the standard United Kingdom cardiology training program as reference: Group A {low volume, <1000 coronary angiography cases, first two years of higher specialist training}, Group B {medium volume, 1000-4000 cases, last four years of higher specialist training} and Group C {high volume, >4000 cases, all levels post-completion of training including senior fellows and consultants}. Group A (n=10) performed 24 paired (right and left coronary cannulations) and 1 unpaired (right or left coronary cannulations), Group B (n=5) performed 14 paired and two unpaired cannulations and Group C (n=6) performed 6 paired and two unpaired cannulations. Both femoral and radial access routes were included in this cohort, and all cases were elective diagnostic coronary angiographies or percutaneous coronary intervention (PCI) procedures. Cases of emergent PCI for myocardial infarction were excluded. In order to reduce anatomical heterogeneity in this series, three post-CABG internal mammary artery angiographies were excluded, leaving 47 video recordings that

were ultimately used for analysis. Of the 47 remaining video recordings, 13 were of elective PCI. Patient consent was obtained for all anonymised fluoroscopy screen recordings.

Catheter tracking software

The software has been extensively described in the previous chapter so no further elaboration on the actual software will be made here. In this study, the initial tracking point was standardised and defined as the point at which the catheter or guide-wire cross the inferior border of the head of clavicle. In all videos the distal most tip of the guide-wire/catheter interface (either the guide-wire or the catheter) was tracked. Inter-observer reliability has been investigated and is documented in chapter 5.

Task analysis and statistical evaluation

Post-hoc video analysis of all cases was performed by a blinded assessor using the catheter-tracking software described above. For the purposes of data collection, each cannulation attempt was defined by strict anatomical start- (inferior margin of the head of the clavicle) and end- points (first injection of contrast into coronary ostium). Path-length values, fluoroscopy time (FT), procedure time (PT) and dose area product (DAP) were collected for each cannulation attempt, in both radial and femoral access cases, according to this anatomical definition (fig. 22). In cases where only one vessel was cannulated by a particular individual, PT, FT and DAP were collated for that attempt only, PT effectively becoming the cannulation time for that

vessel. Phases of active movement were tracked, and tracking was not performed during phases of angiographic image manipulation (such as C-arm rotation) in order to avoid incorporation of movement artefact into the final analysis.

Data were analysed using the Statistical Package for Social Sciences 20.0 (SPSS, Chicago, Ill). Each cannulation attempt was treated as a separate data-point with regard to the variables recorded. Data was found to be not-normally distributed, so non-parametric tests were used. For instance, if a trainee started a cannulation attempt that was abandoned and the supervisor took over, the trainee's cannulation attempt was discounted and the supervisor's attempt was coded as a high-volume of experience attempt for future analysis. Consequently, some cases were counted as "unpaired"; the supervisor would cannulate a given side, and the trainee the other. Cases where both coronaries were cannulated by the same operator were counted as "paired" and total path-length was calculated by combining the PL values for each coronary vessel. Kruskal-Wallis test was used to compare distributions across all three groups of experience in terms of total PL as well as right and left coronary vessels separately. Pre-defined post-hoc comparisons between each group of cardiologists with similar CA experience were performed with Mann-Whitney U test. Correlations between PL and procedure time, fluoroscopy time and DAP were performed using Spearman's rank correlation coefficient.

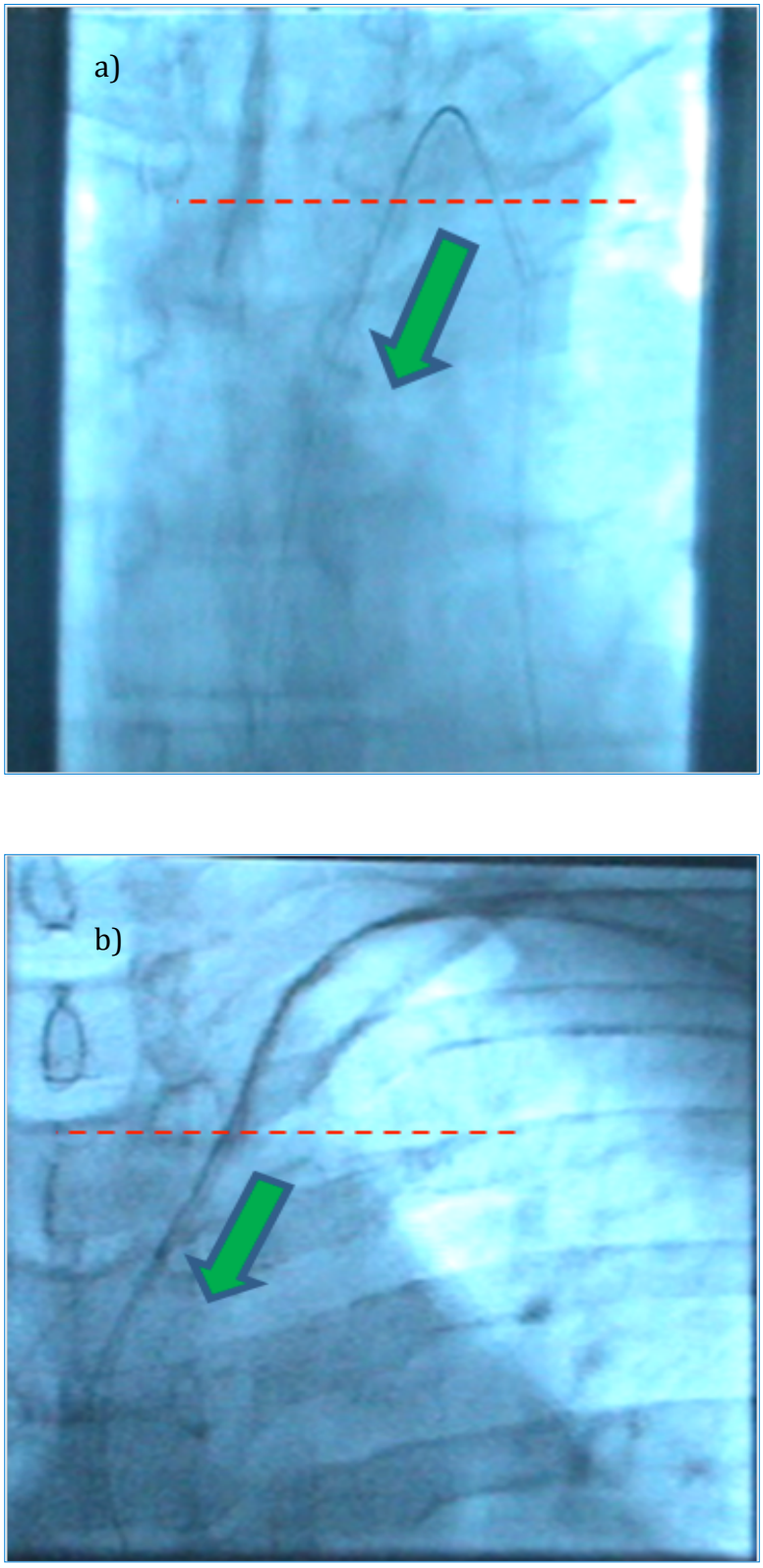


Figure 22. a) and b) Tracking start-points in femoral and radial access, respectively. The inferior margin of the head of the clavicle is indicated by the dotted red line

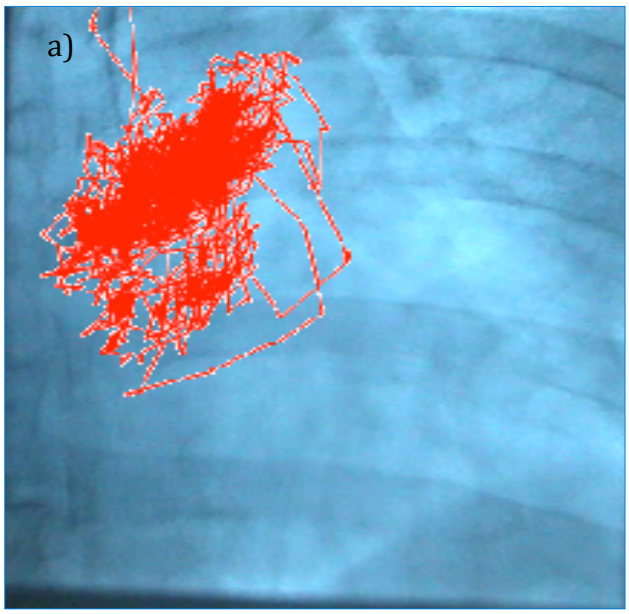
Comparisons between right and left coronary arteries were performed for the paired cannulations using Wilcoxon signed-rank test. Comparisons between femoral and radial approaches were performed using the Mann-Whitney U test.

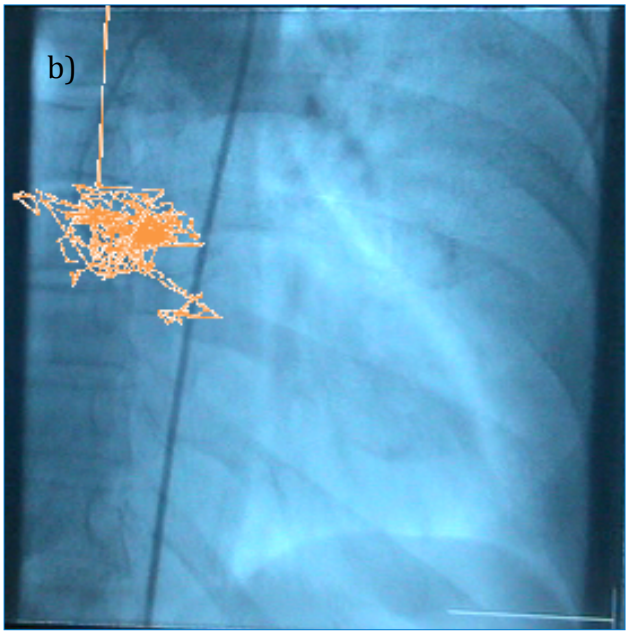
7.3. RESULTS

It was feasible to track coronary catheters and guide-wires with minimal manual adjustment of the tracking marker. Figure 23 gives typical graphical representations of catheter trajectories overlain onto the angiographic images.

7.3.1. Path-length differences between groups of experience

Groups A, B, and C performed 24, 14, and 6 paired cannulations, respectively. Analysis of distributions across all three groups of experience in terms of total PL using Kruskal-Wallis showed statistically significant differences between groups (p = 0.001). A step-wise decrease in PL, with a progressive narrowing of inter-quartile range was observed with increasing experience. Post-hoc analysis demonstrated that PL was significantly reduced in the high-volume group C in comparison to the medium-volume, and low-volume groups (fig. 24). Group C used a total of 3836 pixels of movement (IQR; 3003-4484) vs. 10556 (7242-31408) for group A (p = <0.001) and 8725 (5187-15150) for group B (p = 0.013).





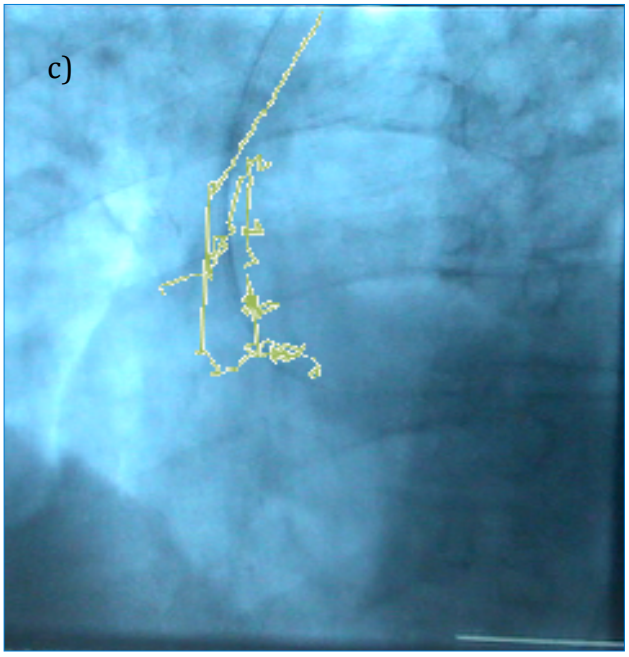


Figure 23. Graphical representation of catheter paths in right and left coronary artery cannulation, a) low-volume of experience, b) medium-volume of experience, c) high-volume of experience. Right and left cannulations can be seen as distinct clusters

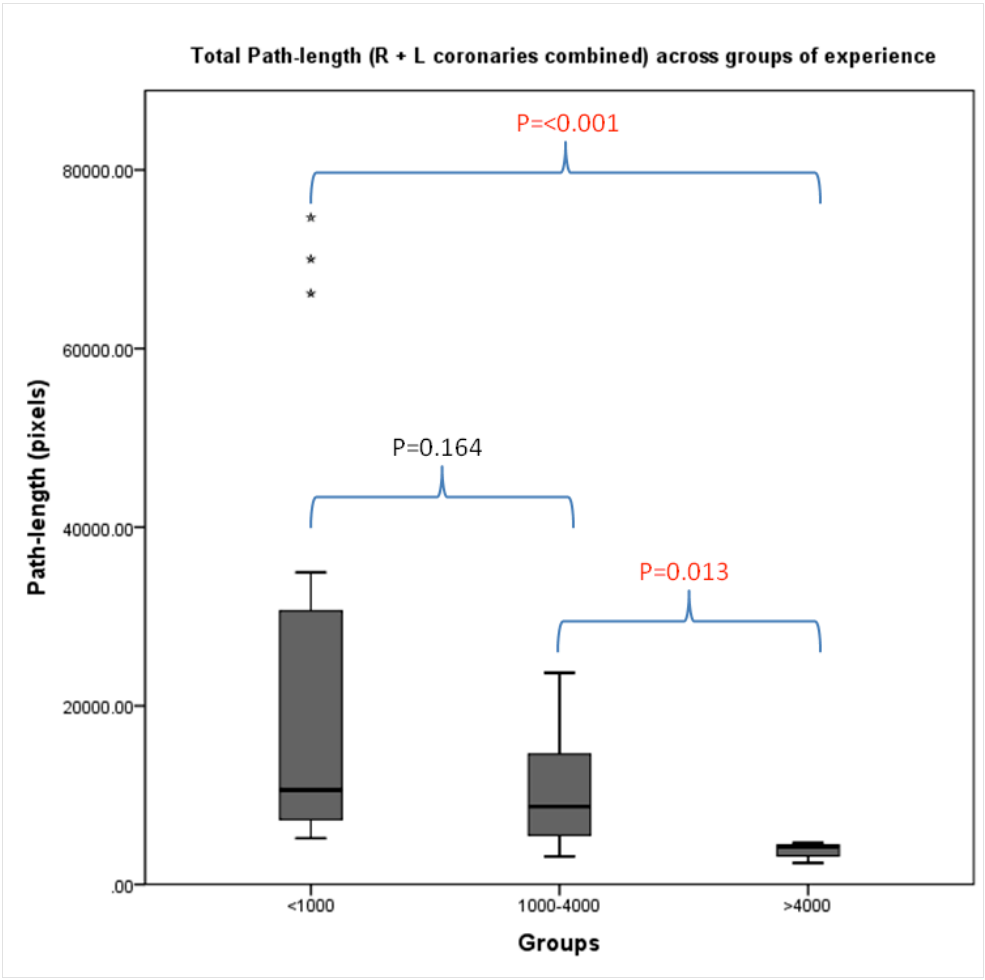


Figure 24. Box-plot representing PL taken (y-axis) to complete cannulation of bilateral coronaries. Kruskal-Wallis *p* = 0.001. The whiskers represent the range and the stars the outliers

Pooling all “paired” and individual “unpaired” cannulations, 48 left- and 45 right coronary cannulations were performed. Similarly, a step-wise reduction in PL was noted (outliers included) with increasing experience for right coronary artery cannulation (fig. 25). Median path-length for Right coronary artery cannulation was significantly reduced in group C who used 2308 (1405-2630) vs. 5591 (4004-9823) in group A (p = <0.001) and 4812 (2332-12960) for group B (p = 0.015). No significant differences were noted in path-length across the three groups for cannulation of the left coronary artery (p = 0.206).

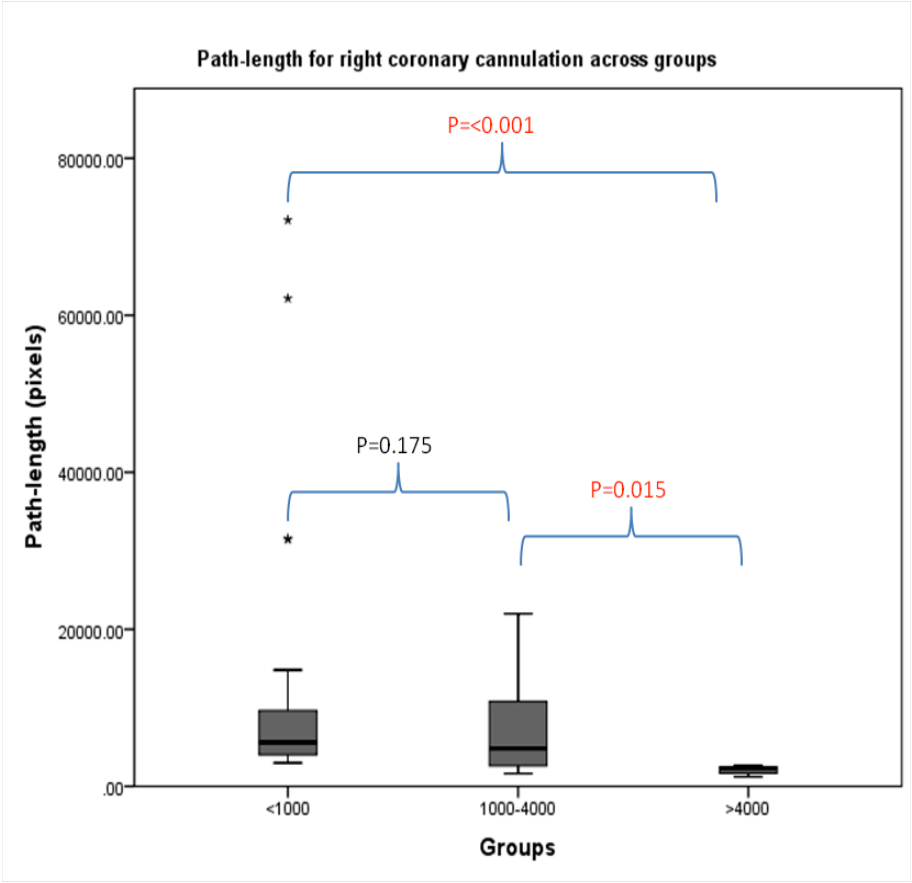


Figure 25. Box-plot representing PL taken (y-axis) to complete cannulation of the right coronaries across groups of experience (x-axis)- Kruskal-Wallis *p* = 0.001

7.3.2. Path-length differences in relation to side of coronary cannulation

Combining all operators, path-length for catheterisation of the left coronary artery was significantly shorter than the path-length to cannulate the right coronary artery , which required 2625 (1802-4755) vs. 4956 pixels (2931-9159) (p = 0.023), respectively.

7.3.3. Correlation of path-length with procedure-time, fluoroscopy-time and radiation dose (DAP)

Out of all participants, median procedure time was 6.9 minutes (IQR: 5.4-11.05 mins), fluoroscopy time; 2.6 minutes (1.7-51 mins), and DAP; 7.4 Gy cm^2 (1.7-11.7 Gy cm^2). Correlation (fig. 26) of PL with PT (*rho* = 0.827, p = <0.001) and FT (*rho* = 0.888, p = <0.001) were significant and of good strength. A correlation of moderate strength was observed with DAP (*rho* = 0.524, p = <0.001).

7.3.4. Path-length differences in relation to access route

In the trainee group (<4000 cases), median path-length for cannulation of both coronaries via the femoral access route was 9893 pixels (IQR 6385-12419) versus 19099 pixels (7166-32184) for the radial access route (p = 0.104) (fig 27).

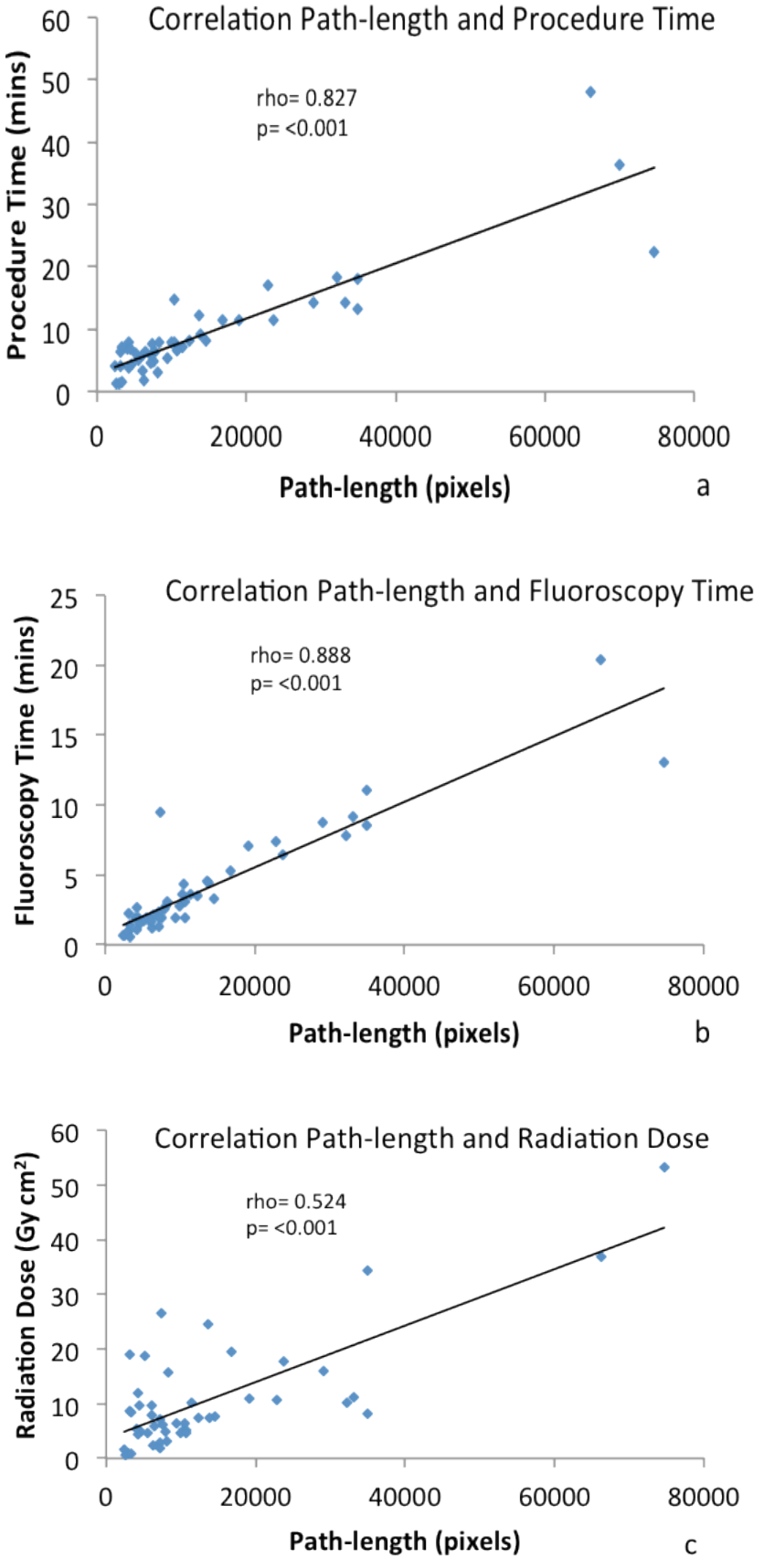


Figure 26. a), b) and c). Scatter plots showing correlation of PL with procedure-time, fluoroscopy time and radiation dose (DAP), respectively. PL is given on the x-axis and conventional metrics on the y-axis

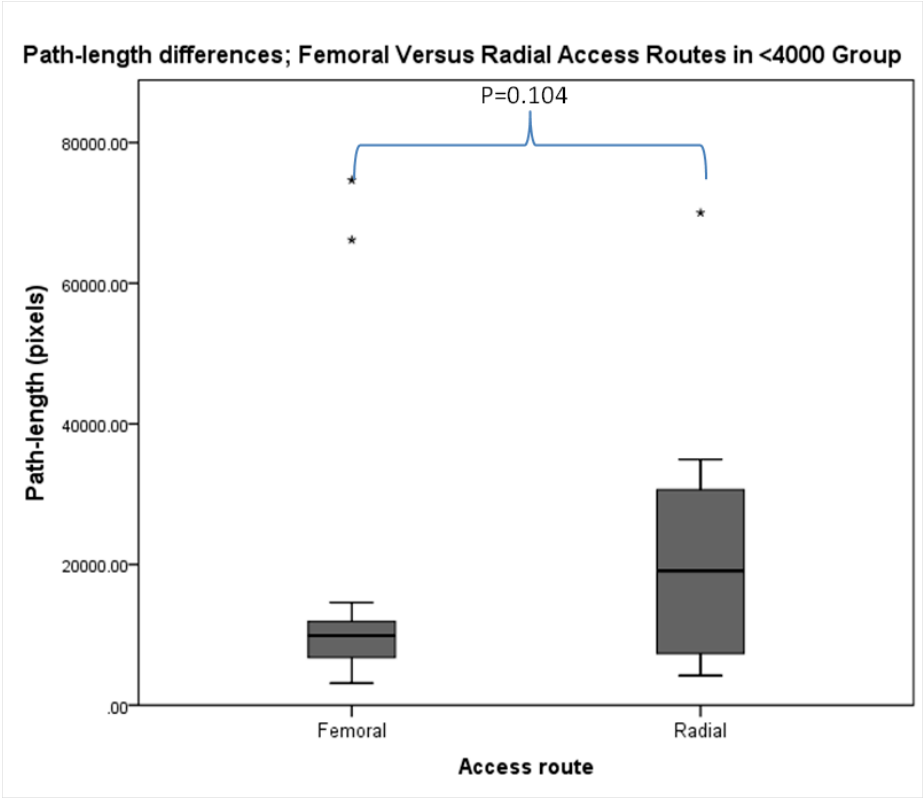


Figure 27. Box-plot comparing PL in the trainee groups for femoral versus radial access routes

7.4. DISCUSSION

Path-length calculations as a potential measure of skill have been described in the previous chapter. In that pilot study, PL was able to differentiate between groups of experience and there was a significant reduction in PL for operators with experience. The objective of this study was primarily to evaluate the potential of this software in live coronary angiography as a reliable marker of endovascular skill and to establish construct validity; this study has shown that it is possible to perform semi-automated tracking of live fluoroscopic sequences, and that PL as a metric demonstrates construct validity in coronary angiography with a clear step-wise reduction PL with progressive experience. However, the differences were significant when comparisons were made between the high-volume group and the medium- and low-volume groups.

To our knowledge, this is the first clinical study to describe video-based tracking guide-wires and catheters in live, rather than simulated, fluoroscopic sequences specifically. Other endovascular tool tracking mechanisms have been developed and include magnetic resonance-, electro-magnetic- and ultrasound-based modalities (Wood et al., 2005; Kurpad and Unal, 2011; de Lambert et al., 2012; Mung et al., 2013). Specifically in coronary angiography, Omary et al describe real-time MR-based tracking of cardiac catheters in a porcine model, although these require extensive modification of both the catheter and guide-wire in order to facilitate accurate tool registration (Omary et al., 2003). The advantages of this technology include the ability to provide an objective skills assessment metric which can potentially provide

real-time performance feedback to trainees and assessors using fluoroscopic footage as medium.

In this study PL was found to strongly correlate with procedure- and fluoroscopy-time, and a less strong correlation with radiation dose. Previous investigators have sought to evaluate these metrics in coronary angiography as potential measures of skill; Jensen and colleagues have demonstrated the relationship between fluoroscopy time and experience and identified a clear learning curve, although they did not observe this with contrast volume (Jensen et al., 2012). These observations are supported by extensive research into simulator-derived metrics which so far only identified PT and FT as construct-valid performance metrics (Van Herzeele et al., 2007, 2008, 2009). The observation of a weaker relationship between radiation dose and PL in the present series is partly corroborated Räder and colleagues who found a weak relationship between radiation dose and experience on linear regression (Räder et al., 2011). Similarly Hillcock and colleagues found that improvement in radiation dose with experience was less predictable as compared to fluoroscopy time (Hillock et al., 2006).

A strong correlation, in this series, of PL with fluoroscopy time may be readily explained by the fact that only phases of active catheter movement were tracked using the software, and tracking therefore occurred during screening periods only. In contrast, the weaker correlation of DAP experience (Räder et al., 2011), and with PL in this series may be explained by the number of variables which influence DAP readings; radiation dose is widely regarded as a product of a number of variables,

including X-ray beam quality, X-ray beam limitation devices, X-ray geometry, and fluoroscopic and acquisition imaging dose rate settings (Fetterly et al., 2011). In the present study, efforts were made to limit the influence of these variables by recording data from one particular angiography suite only.

The observation that the cannulation of the right coronary artery needed longer path-length in the entire paired cannulation cohort is potentially explained by the anatomy of coronary take-off in "normal" adults. Congenital abnormalities excluded, the right coronary artery ostium is normally oriented anteriorly as compared to the left which originates laterally, and is more variable in terms of the position of its ostium (Berger et al., 1999; Ismat et al., 2002; Mawson, 2002). We observed a step-wise reduction in PL for cannulation of the right coronary with progressive experience, however there were no differences across the groups for left coronary cannulation. The bulk of all coronary cannulations in this series occurred with the C-arm oriented at 0^0 angulation; right coronary cannulation may present a technically more challenging task for more inexperienced operators, possibly because of the requirement to torque the angled catheter anteriorly with imaging aligned in an AP plane, or because junior trainees may simply be less aware of normal coronary anatomy and the need to adapt cannulation strategy according to position of a target vessel. The data suggests that anatomical factors affect PL values and efficiency of cannulation, and that the right coronary is potentially more discriminatory in terms of skill assessment in coronary cannulation; experts are able to reduce their PL irrespective of the side cannulated.

It is interesting to note the path-length continues to decrease after 1000 cases, suggesting that the learning curve for coronary angiography may continue longer than previously thought. Most cardiological societies recommend 150-300 cases as primary operator in order attain competence for independent practice of diagnostic coronary angiography specifically. A number of groups have sought to define novice learning curves in terms of existing performance metrics such as fluoroscopy- and procedure-times and compare with mean expert levels; Räder et al retrospectively evaluated novice and expert performance in a large series of 4200 coronary angiographies and found that 300-600 cases were required, across a range of metrics (FT, PT, DAP, and contrast volume), to achieve expert levels of performance (Räder et al., 2011). Jensen et al found that 150 cases were required to reach expert performance inter-quartile ranges (Jensen et al., 2012). It is possible that due to the prospective and sequential gathering of data in this series, that smaller numbers in the high-volume of experience group may not accurately reflect this sub-population of cardiologists in terms of PL. Nonetheless, PL data in this study were found to strongly correlate with validated metrics (PL and FT) which were used in the studies described above. Therefore, the learning curve plateau for coronary angiography may not actually occur at between 300 and 600 cases, and the attainment of true expertise may require a significantly larger volume of experience. One might argue that given these strong correlations that PL simply reinforces the validity of pre-existing metrics. The authors strongly feel, however, that PL is a valuable descriptor and may correlate in future studies with adverse events such as embolisation.

Potential weaknesses in this study relate to the fact that the software records movement in 2D only, whilst advancing a catheter around the aortic arch and cannulation of coronary vessels clearly involves movement in the *x*, *y* and *z* planes. Whilst this clearly results in a deficit of recorded movement data which may have been recorded by using 3D tracking mechanisms, one might argue that this is counter-balanced by the ability to analyse live cases without having to modify endovascular tools. Furthermore, the majority of interventional cardiological cases are performed using 2D fluoroscopy. We have performed further, as yet unpublished, work that demonstrates that the 2D deficit in recorded movement data is in fact small and predictable when compared to 3D electro-magnetic tracking. Phases of fluoroscopy table or C-arm movement were not analysed in order to avoid incorporation of "non-operator dependent" PL data, which may have resulted in the loss of valuable movement data. Further work is underway to refine the software and address this limitation. Recording live cases for the purposes of skill analysis has a number of drawbacks: Firstly, it is not possible to control for anatomical variability, as is possible in simulated cases, in terms of factors such as arch tortuosity, calcification, thrombus and coronary ostial stenosis. Secondly, the performance of trainees may have been influenced by advice given from supervising cardiologists. Both of these variables may have contributed to the broad inter-quartile ranges particularly in the low-volume and medium-volume groups, but one might argue that the ability to overcome anatomical complexity is a hallmark of true expertise and is reflected by the narrow IQR in the high-volume group.

7.5. CONCLUSION

This study has demonstrated that video-motion analysis is feasible in live diagnostic coronary angiography, and that PL as a metric of endovascular performance is able to differentiate between groups of experience. VMA data also correlates well with previously validated endovascular performance metrics, and may form a valuable adjunct in endovascular skills assessment. The side of coronary cannulation affects VMA data, and may be a reflection of subtle variation in anatomical difficulty. The attainment of true expertise in this procedure may require a larger volume of experience than previously thought. The next chapter focuses on evaluating the effect of anatomy of VMA data and path-length measurements.

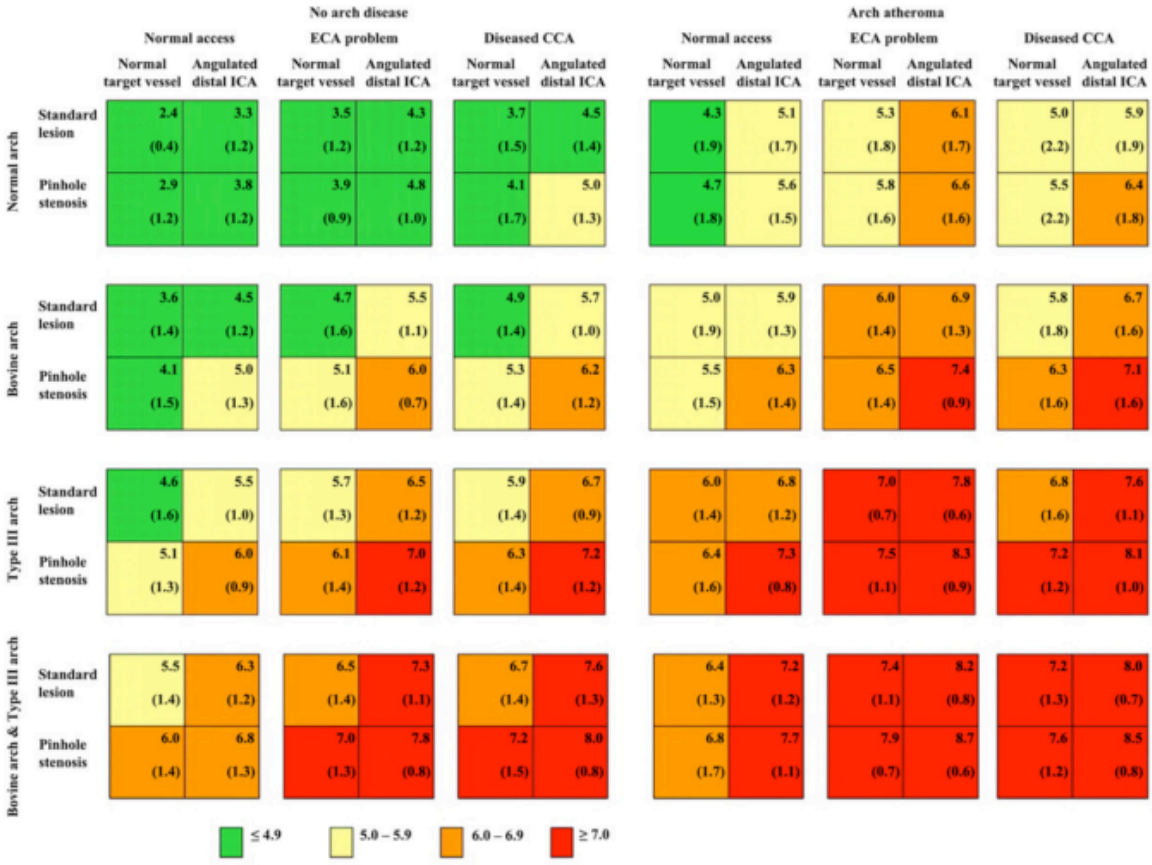
CHAPTER 8.

THE USE OF VIDEO-MOTION ANALYSIS TO ASSESS ENDOVASCULAR EFFICIENCY IN ANATOMICALLY COMPLEX SCENARIOS IN CAROTID ARTERY STENTING.

8.1. INTRODUCTION

Since the introduction of carotid artery stenting (CAS), numerous prospective RCTs have sought to compare this technique with CEA in terms of peri-operative and post-operative stroke risk. Although meta-analysis suggests that results have demonstrated satisfactory outcomes across a diverse group of studies, at least in the long-term, the risk of stroke and death in symptomatic patients undergoing CAS is significantly higher than for CEA (Touzé et al., 2009). Moreover the increased stroke risk is clustered in the peri-operative period (up to 30 days post-operatively), suggesting a strong procedural element which contributes to the overall risk of this procedure (Mas et al., 2004). Although the introduction of embolic protection devices has been shown to reduce the risk of embolisation significantly (Castriota et al., 2002; Zahn et al., 2004), a substantial amount of evidence suggest that embolisation occurs during wire and catheter manipulation in the aortic arch, and cannulation of the supra-aortic vessels prior to the deployment of a protection device; Cao and colleagues sub-divided the CAS procedure into operative phases and found that of eight disabling strokes in a series of 301 procedures, four occurred during arch navigation and four during the stent-implantation and ballooning (Cao et al., 2006). A similar pattern was noted by Verzini and colleagues who noted occurrence of major strokes in the cannulation and stenting phases (Verzini et al.,

2006): out of ten major strokes, four occurred during the cannulation phase and six during stent ballooning. Large trials such as CREST and EVA-3s have demonstrated that a number of variables influence outcomes after CAS, including age, symptom status, lesion characteristics, anatomy and operator experience (Mas et al., 2004; Brott et al., 2010; Naggara et al., 2011). Specifically, sub-group analysis of EVA-3s demonstrated that increased complications occurred when the origin of the internal carotid artery was angulated $>60^0$ in relation to the common carotid artery (Naggara et al., 2011). In an effort to score cases according to anatomical difficulty, and so improve case selection, MacDonald and colleagues developed a scoring system by asking a group of CAS experts to grade a number of anatomical features over four rounds in a Delphi survey (Macdonald et al., 2009). The survey identified and weighted 12 different anatomic features including arch configuration, target vessel and tortuosity, and vessel calcification. Each anatomical feature was assigned a score from 1 to nine, and a scoring grid was ultimately developed with 96 different anatomical combinations. Finally all combinations were stratified into green (easy cases- score: <4.9), amber (medium cases- 5-5.9), and red (hard cases- >7.0) (fig. 28).



Predicted mean level of difficulty for CAS in each specified combination anatomy from the regression model (with interactions). Standard deviations are given in parentheses. The mean cutting score differentiating a "yes" response from a "no" response across the panelists was 5 with a mean score of 7 for a "no" response and a mean score of 4 for a "yes" response. The scores in Table 4 were therefore presented as traffic light colors; red for particularly difficult anatomy, a broad amber band (pale and dark allowing for the minor degree of uncertainty amongst panelists) representing moderate difficulty and green representing lesser difficulty.

Figure 28. Anatomic scoring system for carotid stenting (Macdonald et al., 2009, Willaert et al., 2012). Anatomical complexity has been colour-coded using a traffic-light scheme: green (easy cases), amber (medium) and red (hard).

Understanding regarding how anatomical complexity affects efficiency of tool manipulation and movement remains unexplored. With increasing anatomical complexity, the hypothesis is presented that the carotid stenting procedure becomes harder, and that video-motion analysis can demonstrate this accurately. The previous chapters have investigated motion analysis as a means of analysing efficiency of performance, and found that it can differentiate between groups of experience (Rolls et al., 2013), both in simulated and live cases. VR-simulation has evolved to allow for incorporation of patient-specific CT- and MR-DICOM data into computer-based simulation devices such as the AngioMentor™ (Simbionix, Airport City, Israel), facilitating case simulations based on real anatomy and procedure-specific rehearsals (Willaert et al., 2012; Desender et al., 2013). This study combined both of these technologies to investigate the relationship between anatomical complexity and efficiency of endovascular tool movement. The primary objective was therefore to determine the effect of anatomical complexity on video-motion analysis data. Further objectives were to sub-divide the CAS procedure into operative phases and to identify how anatomical variation in each phase influences efficiency of performance as measured by video-motion analysis. Finally, we sought to correlate VMA data with Procedure Specific (PSRS) and Generic Rating Scales (GRS).

8.2. METHOD

Participants

Twenty endovascular novices from a diverse range of specialties (interventional radiology, vascular surgery and neuroradiology) participated in the study. The following inclusion criteria in terms of minimal experience were applied (Willaert et al., 2012):

-Five arch and/or visceral and/or peripheral vessel angiographies, and/or

-Five angioplasty and/or stenting procedures of extra-cranial, visceral, or peripheral arteries, and/or

-Five abdominal aortic or thoracic endovascular aneurysm repairs and/or contralateral limb cannulations

The videos of these CAS simulations were kindly provided by Dr Isabelle Van Herzeele and Dr Willem Willaert of the University of Ghent, Belgium. Recruitment of participants and task set-up are therefore attributed to their group.

AngioMentor simulation device and patient-specific reconstructions

Three-dimensional (3D) reconstructions of three real patient cases, one from each traffic-light color were created using Simbionix PROcedure rehearsal studio software (Simbionix USA Corp, Cleveland, OH, USA). A multi-disciplinary panel reviewed each case to verify that each of the three cases was scored appropriately using the anatomic scoring system (Macdonald et al., 2009). The reconstructions were based on real patient CT-angiogram DICOM data. The AngioMentor Express simulator (Simbionix USA Corp) was used to perform the training cases and three patient-

cases. The cases were acquired from a pre-existing database of 3D reconstructions stored on the Simbionix PROcedure rehearsal studio software. Clinical and radiological features were as follows:

Green case- 72-year-old man with a type I arch and an asymptomatic 90% stenosis of the left internal carotid artery (LICA). The anatomic score for this case was 2.4 (see fig. 28).

Amber case- 82-year-old man with acute aphasia and an 80% stenosis of the left ICA. The case was characterised further by an angled left common carotid artery take-off and bovine arch morphology. The anatomic score was 5.9.

Red case- 82-year-old woman with a symptomatic right-sided 80% internal carotid artery stenosis. The aortic arch was classified as having type II morphology with a very tortuous common carotid artery, although its take-off was not described as angulated.

Task performed

All subjects received an initial didactic session comprising of a 25-minute video lecture, describing the carotid disease and the key components of carotid stenting. Following this, each subject underwent technical training consisting of three 90-minute sessions on the Angiomentor simulation device. The interventionists each performed one generic CAS case to familiarise themselves with the steps of the procedure, followed by two challenging cases consisting of CAS procedures in type III and bovine arches. The last two exercises were used to familiarise the participants with various cannulation techniques and endovascular tools. After the initial didactic and cognitive training period each participant completed the green, amber, and red

cases in random order, ensuring that time between training and study exercises did not exceed five days. A five-minute interval was afforded the participant between each case. A consultant surgeon was present during each procedure, acting as the scrub nurse and radiographer, and providing passive assistance where required.

Catheter-tracking software

The catheter tracking software has been extensively described in a previous publication (Rolls et al., 2013) and in an earlier chapter of this thesis. The protocol for tracking in this experiment is given in the sub-section below.

Task analysis

Post-hoc video analysis of all procedures (n=60) was performed by a blinded assessor using the VMA software described above. Only phases of active movement were tracked, and phases of angiographic image manipulation (such as C-arm rotation and "table" movement) were not analysed in order to avoid incorporation of movement artefact into the final PL analysis. Each case was sub-divided into four pre-defined procedural phases (fig. 29). Arch Navigation was defined as movement of the guide-wire and catheter from the level of the 3rd rib to a resting position at the aortic root. Common carotid artery cannulation (CCA) was defined as movement from the aortic root to a stable position 2 cm distal to the common carotid ostium. External carotid artery manipulation (ECA) was defined as movement from 2 cm within the CCA to the distal-most tip of the ECA. Internal carotid artery manipulation (ICA)/lesion crossing was defined as movement from 2 cm within the CCA to the position at which the embolic protection device was deployed.

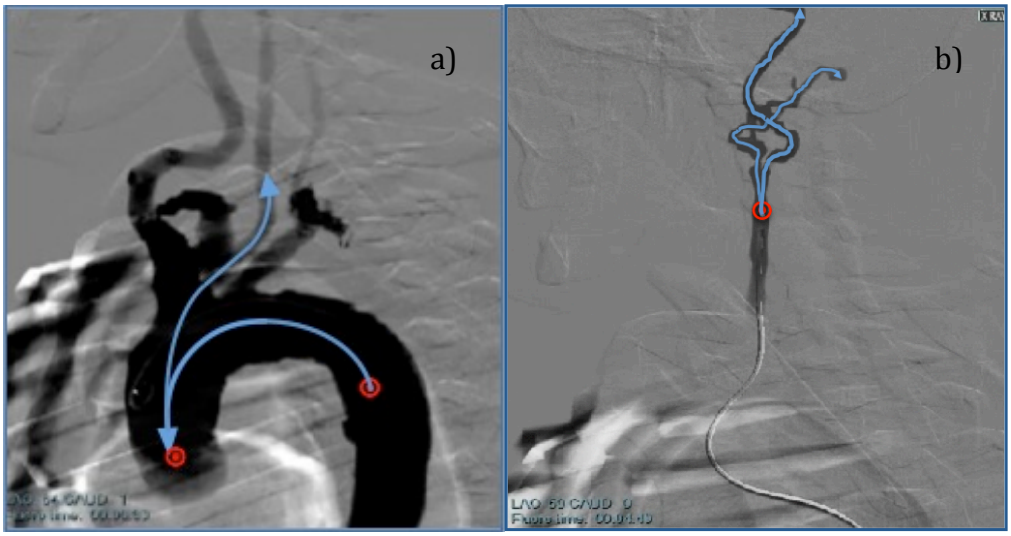


Figure 29. a) Arch navigation and CCA cannulation phases, b) ECA and ICA manipulation phases

For each simulation the wire/catheter tip PL was calculated for the entire procedure as well as each of the procedural phases, and was expressed as pixels of movement. Qualitative procedural rating scales were obtained for comparison with PL: Two blinded experts assessed each procedure with a validated Generic Endovascular Rating Scale and a Procedure-Specific CAS Rating Scale (Van Herzeele et al., 2009), and an average score was calculated. Therefore, each procedure was awarded an average CAS-specific- and Generic Endovascular Rating score. As described in the introductory chapter and in previous publications, both of these rating scales were derived from the original Reznick qualitative rating scale (Martin et al., 1997; Van Herzeele et al., 2009). Each domain of endovascular skill is scored on a Likert scale around descriptive comments which serve as anchor points for scores 1 (very poor), 3 and 5 (clearly superior). There are eight domains in the Generic Rating Scale, giving a maximum score of 40, and seven domains in the Procedure Specific Score, giving a maximum score of 35. The Procedure-Specific Rating Scale was designed to assess the key components of the CAS procedure, such as cannulation of target vessels and also allows the assessor to rate the quality of the final product and the overall performance.

Statistical analysis

Data were analysed with the Statistical Package for Social Sciences 20.0 (SPSS, Chicago, Ill). The data was not normally distributed, therefore non-parametric tests were used. *Friedman's test* was used to assess repeated (Green, Amber and Red cases) total procedural PL, and procedural phase PL measurements across the same group of interventionists. Pre-defined post-hoc comparisons of PL between the

different grades of anatomical complexity were performed, when a significant difference was identified with *Friedman's test*, using the *Wilcoxon-signed rank test*. Correlations between PL and Generic- and Procedure-Specific Rating Scales, as well as individual domains of these rating scales were performed using *Spearman's rank correlation coefficient*. In order to investigate PL as a potential *qualitative* metric, total PL was correlated with generic qualitative descriptors for the entire procedure; "respect for tissue", "flow of procedure", and "handling of endovascular instruments". PL for specific procedural phases (CCA cannulation and lesion crossing/ICA manipulation) were correlated with the domains of "catheterisation" and "lesion crossing" phases, in order to evaluate the metric as a descriptor for the quality of individual procedural phases. A level of $p < 0.05$ was considered to be statistically significant.

8.3. RESULTS

It was feasible to track path-length of endovascular tools using videos derived from the AngioMentor simulator. Typical graphical representations of path-lengths for each of the grades of anatomical difficulty can be seen overlain onto the angiographic image in figure 30.

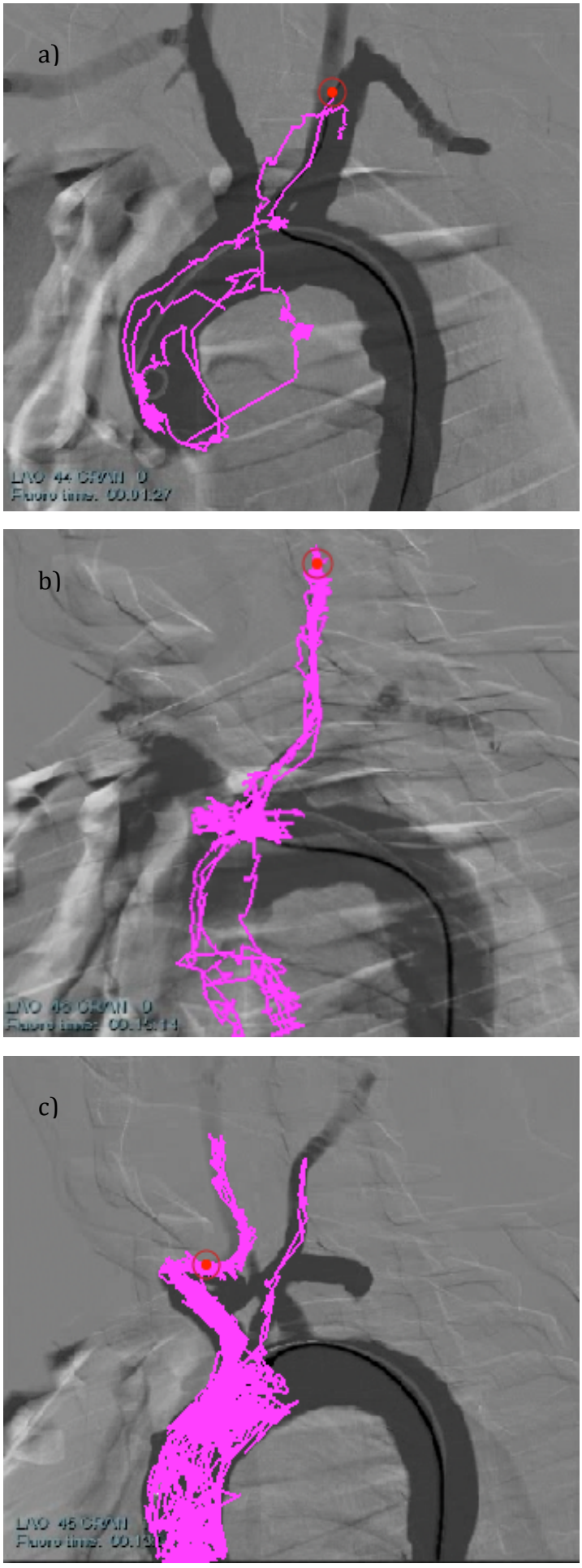


Figure 30. Graphical representations of tracked catheters during CCA cannulation in the green (a), amber (b) and red cases (c). In the hardest case, the catheter trajectory has almost completely obscured the ascending aorta. There has also been an erroneous vessel entry (LCCA)

8.3.1. Total Path-length differences between the cases of varying anatomical complexity

There were significant step-wise increases in total path-length with increasing anatomical complexity: The median PL for the green case was 5000.0 pixels (inter-quartile range (IQR) 4075-5403.2), vs 9059.8 pixels (IQR 5974-14553) vs 17372.9 pixels (IQR 11495-26594) for the amber and red cases, respectively (p = <0.001). Post-hoc analysis with the *Wilcoxon-signed rank test* demonstrated that PL was significantly reduced for green vs amber cases (p = <0.001), and amber vs red cases (p = 0.003).

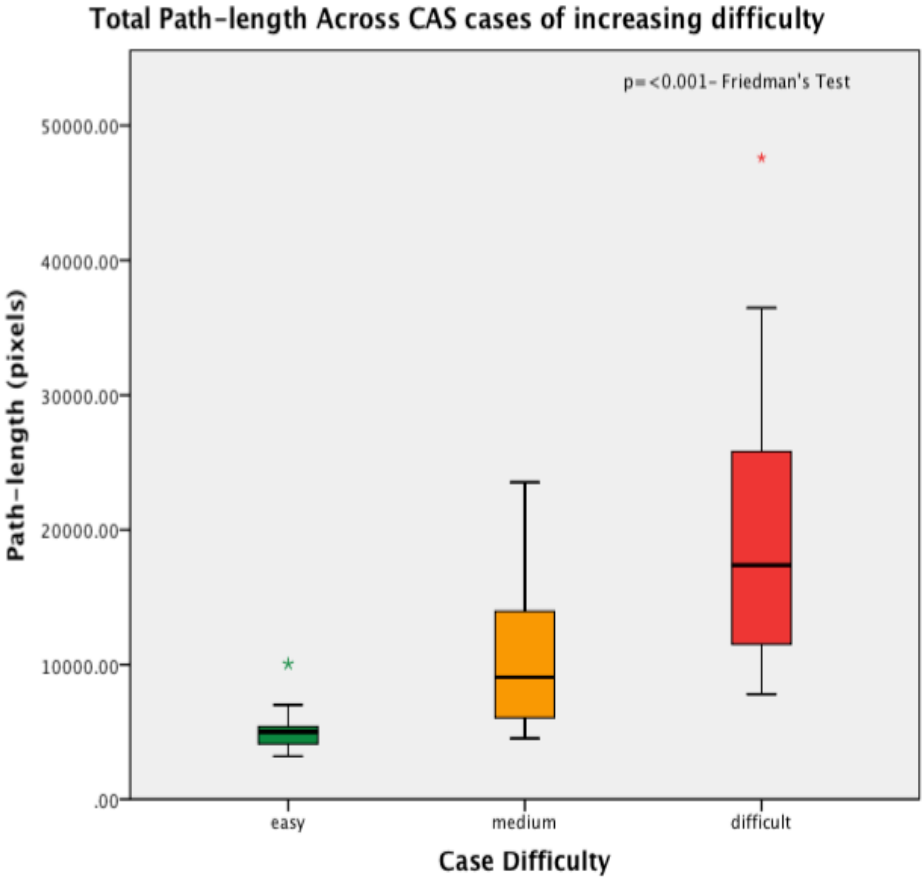


Figure 31. Box-plot representing PL (y-axis) taken to complete the CAS procedure across cases of progressive anatomic complexity (x-axis). The whiskers represent the range and the stars the outliers

8.3.2. Path-length differences between the cases of varying anatomical complexity; procedural breakdown into phases

There were significant step-wise increases in path-length with increasing anatomical complexity during CCA cannulation: The median PL for the green case was 748.67 pixels (IQR 603.4-1403.5) vs 3273.6 (IQR 1544.8-8142.4) vs 8844.7 (IQR 5954.5-15767.9) for the amber and red cases, respectively (p = <0.001). Post-hoc analysis with the *Wilcoxon-signed rank test* demonstrated that PL was significantly reduced for green vs amber cases (p = <0.001), and amber vs red cases (p = 0.033). Differences in median path-lengths during the remaining procedural phases were not found to be significant: path-lengths according to traffic-light groupings were 359.9 (green) vs 388.1 (amber) vs 382.8 (red) for arch navigation (p = 0.4), 356.7 vs 329.8 vs 736.7 for ECA manipulation (p = 0.4), and 657.1 vs 635.4 vs 863.2 for ICA manipulation/lesion crossing (p = 0.7).

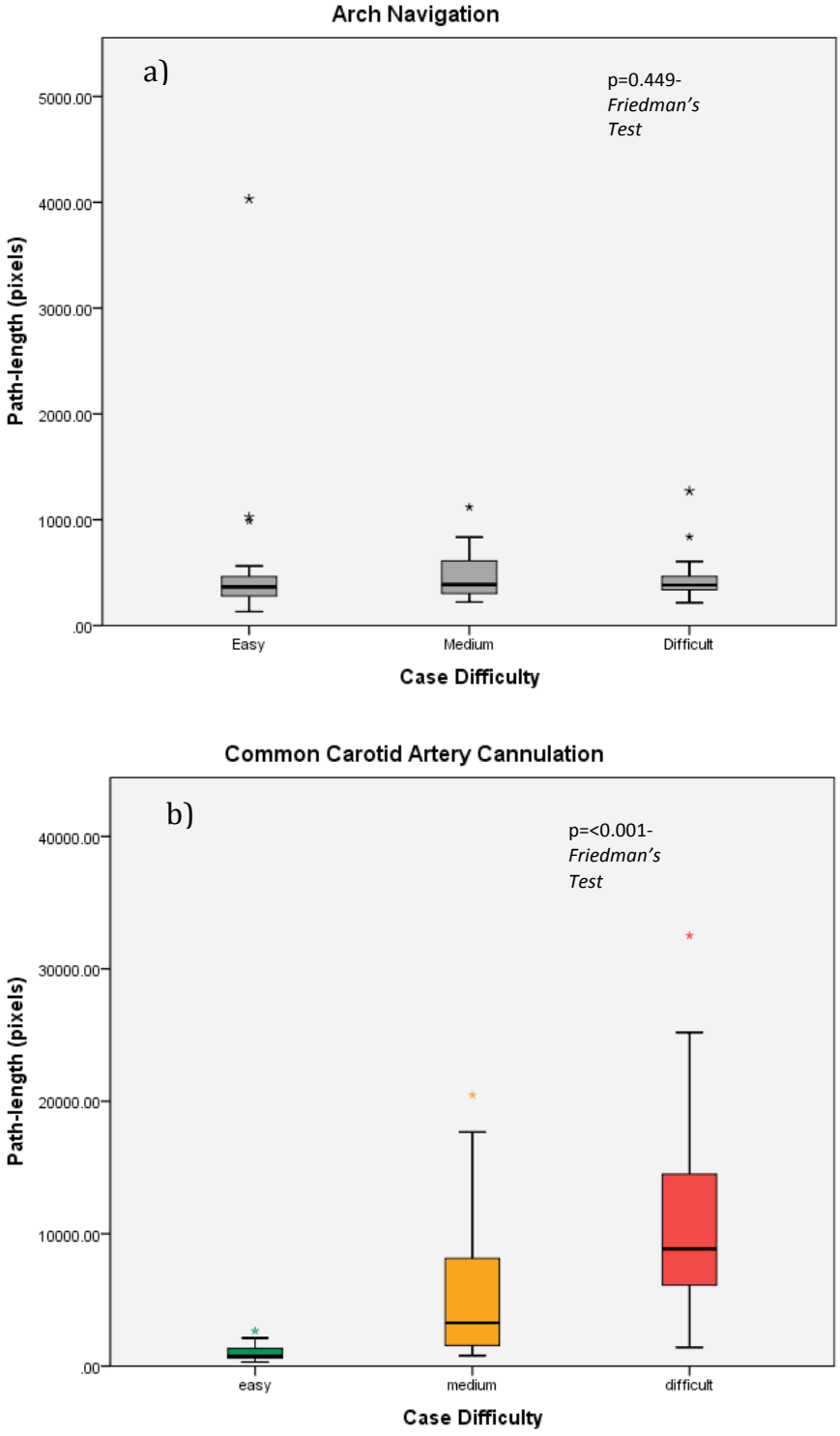


Figure 32. a) and b). Box-plot representing PL (y-axis) taken to complete the arch navigation and CCA cannulation phases in cases of progressive anatomic complexity (x-axis). The whiskers represent the range and the stars the outliers

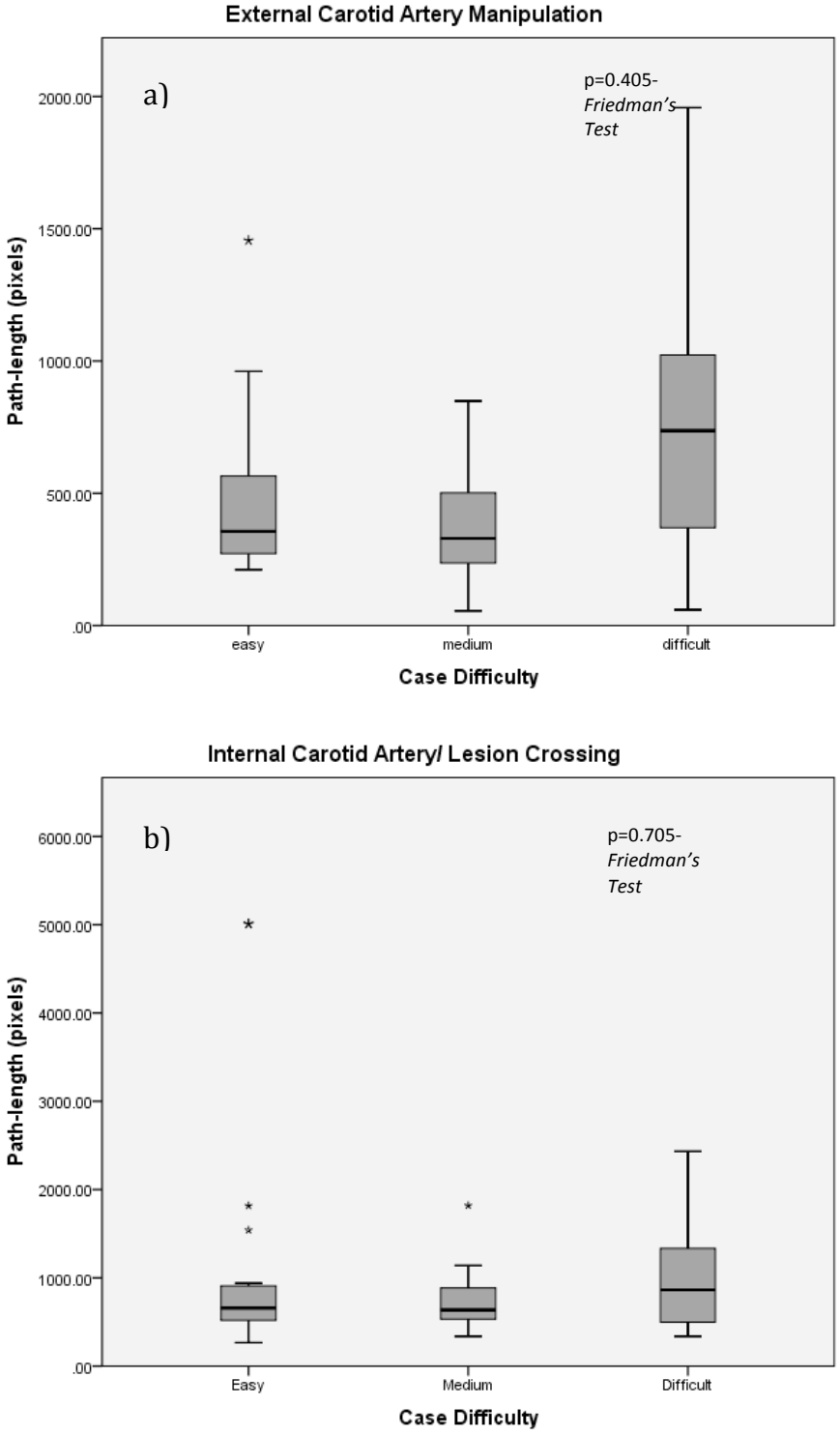


Figure 33. a) and b). Box-plot representing PL (y-axis) taken to complete the ECA and ICA cannulation phases in cases of progressive anatomic complexity (x-axis). The whiskers represent the range and the stars the outliers

8.3.3. Correlation of path-length with rating scales

For all procedures across the three grades of anatomic difficulty, the median Procedure Specific Rating Scale score achieved was 21.5/35 (18.6-24) and correlation with PL demonstrated a statistically significant inverse relationship (rho = -0.549, p = <0.001), and the median Generic Rating Scale score achieved was 28.2/40 (24.6-30). Correlation of PL with the GRS demonstrated a similar statistically significant inverse relationship (rho = -0.632, p = <0.001).

Correlation of path-length with specific domains of rating scales

Total PL was significantly and inversely correlated with the "respect for tissue" (rho = -0.510, p = <0.001), "handling of endovascular material" (rho = -0.483, p = <0.001), and "flow of procedure" (rho = -0.713, p = <0.001) domains. PL for CCA cannulation was strongly and inversely correlated with the "catheterisation phase" (rho = -0.672, p = <0.001). A weaker correlation between ICA manipulation/lesion crossing PL and "lesion crossing phase" was identified (rho = -0.273, p = 0.035).

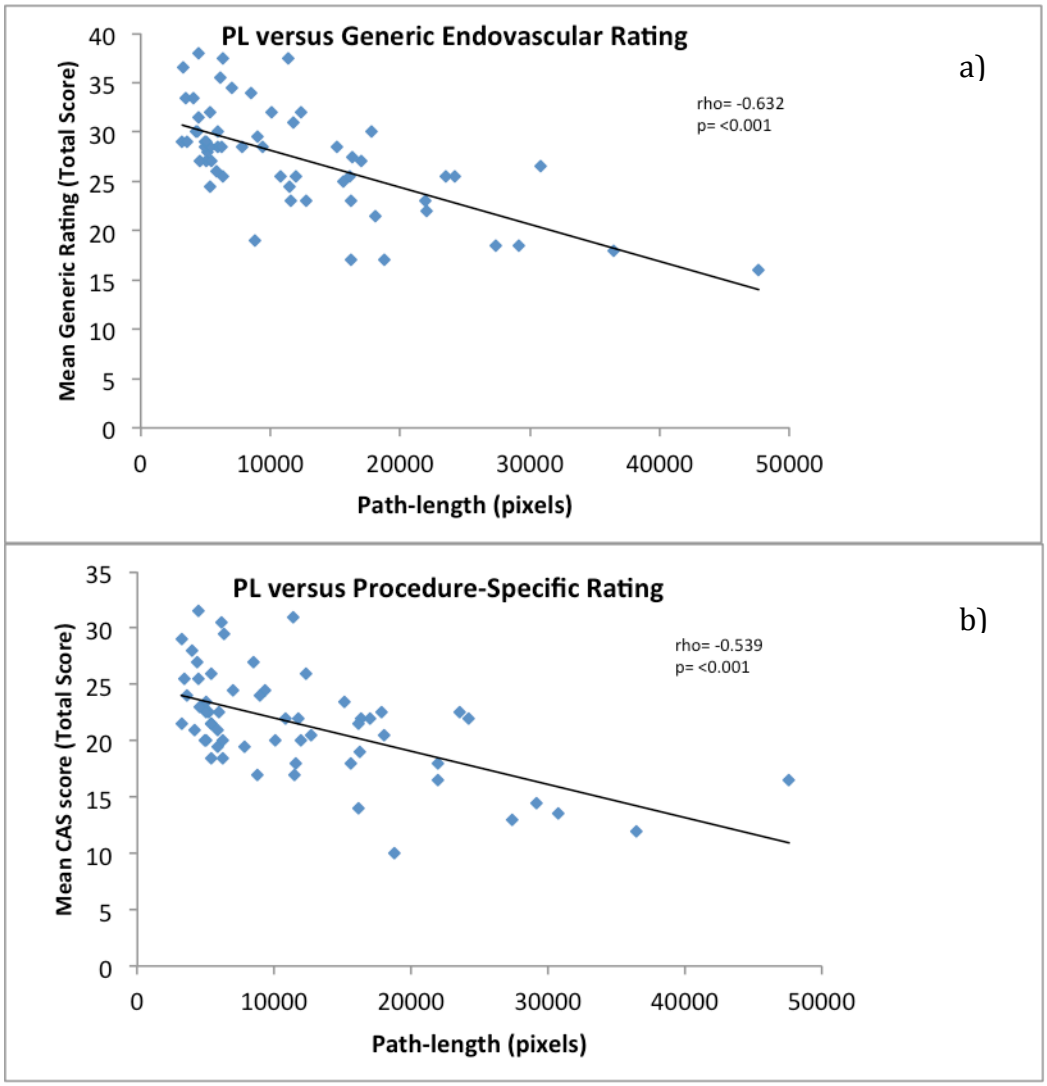


Figure 34. a) and b). Scatter plots showing PL correlations with Generic- and Procedure-Specific Rating, respectively. PL is given on the x-axis and assessment scores on the y-axis. Individual scores are indicated by the blue diamonds

8.4. DISCUSSION

This study documents the direct relationship between anatomical complexity and efficiency of catheter and guide-wire movements. Furthermore, it has provided evidence to demonstrate that challenging arch and target vessel configurations significantly impede cannulation attempts. We identified a significant step-wise increase in total path-length measurements for the entire procedure with progressive anatomical complexity, with significant differences between the case groups of differing anatomical difficulty on post-hoc analysis. Moreover, when the CAS procedure was deconstructed into a series of procedural phases, it was apparent that the CCA cannulation phase demonstrated a similar significant step-wise increase in PL with progressive anatomical complexity. The phases of arch navigation, ECA and ICA manipulation did not demonstrate any significant differences, although there was a trend towards reduced efficiency as measured by PL in the red cases for the two latter procedural phases. Figure 30 demonstrates that challenging CCA cannulation, in addition to repetitive movement at the origin of the target vessel, causes excessive movement in the ascending aorta, proximal to the target vessel. The tips of curved and re-curved catheters such as the Headhunter, Simmons and AL1 devices are oriented cranially during the cannulation attempts in order to access the ostia of the target vessels, and a low-profile guide-wire is advanced into the target vessel. In a type III arch, which is characterised by target vessel origin below the inferior curve of the aortic arch and therefore acute angulation of the target vessel with respect to the aortic arch, inadvertent and forceful advancement of the catheter in an attempt to secure access once the

catheter has already engaged the ostium can result in the catheter flicking out of the target vessel and into the ascending proximal aorta. Similarly, if the angulation of a catheter is insufficiently matched to the angulation of the target vessel, the inherent stiffness of the device can cause it to slip out of the vessel and into the proximal aorta. It is plausible that this pattern of movement contributes to embolisation during the catherisation phases of the CAS procedure (Cao et al., 2006).

Data relating rates of embolisation and anatomical configuration are fairly limited and heterogeneous in terms of anatomical factors studied. Nagarra and colleagues have evaluated the digital subtraction angiograms from the EVA-3s trial and found angulation of the ICA in relation to the CCA ($>60^0$) to be the only independent anatomical factor to significantly affect 30-day ipsilateral stroke risk (Naggara et al., 2011). A statistically non-significant trend for increased complications with type III arch configurations, sub-petrous ICA tortuosity, extensive calcification, ostial involvement, and target internal carotid artery stenosis was observed. No associations were noted with CCA tortuosity, aortic arch calcification, ipsilateral ECA stenosis (>50%), severity of target lesion stenosis (>90%), ulceration, target lesion lesion stenosis length (>10 mm), and side of carotid lesion/intervention. The same authors conducted a meta-analysis on existing trial data and found that the pooled risk for stroke or death at 30 days was increased in patients who underwent left-sided CAS, and in those patients whose lesions were heavily calcified or longer than 10 mm. Consistent with analysis of their own data, 30-day stroke risk was higher in patients with increased CCA-ICA angulation.

In contrast, Silvestro and colleagues sought to correlate their outcomes, in terms of a composite end-point stroke and death at one month, with adverse anatomical features; tortuous supra-aortic vessels, tortuous ICA, calcified target lesion and contrateral ICA occlusion, and did not identify any anatomical predictors of adverse clinical outcome (Silvestro et al., 2008).

In an extensive meta-analysis of 206 independent studies, the only independent anatomical predictor of stroke and death was re-stenosis after previous CEA (Touzé et al., 2009). Contralateral occlusion, calcification, ulceration, and laterality had no impact on outcomes. Sub-group analysis of Pro-CAS registry, which contains data on 5341 CAS interventions, similarly did not demonstrate that side of intervention or presence of a contralateral lesion had any bearing on outcome (Theiss et al., 2008). In keeping with other studies (Naggara et al., 2011), degree of target lesion stenosis, likewise, was not a predictor of outcome. In terms of lesion characteristics, Sayeed and colleagues evaluated the angiographic characteristics of 421 patients who underwent CAS found that lesion length (> 15 mm) and ostial involvement were independent predictors of peri-procedural stroke risk (Sayeed et al., 2008).

Other characteristics, including lesion calcification, ulceration, and contralateral occlusion were not associated with adverse outcomes. Age appears to be a predictor of anatomical complexity and has been documented in two recent studies: Lam et al have demonstrated that patients > 80 yrs of age have significantly higher incidences of unfavourable anatomical characteristics, including arch elongation, arch calcification, CCA ostial stenosis, CCA and ICA tortuosity, and degree of treated

lesion stenosis (Lam et al., 2007). Similar characteristics were significantly more prominent in another cohort of octogenarians, namely aortic arch elongation and calcification, CCA and ICA tortuosity, CCA stenosis and degree of target lesion stenosis (Lin et al., 2005). Although there was a non-significant trend towards increased rate of ipsilateral stroke, with 5 occurring in the > 80 group and 1 in the < 80 group, the authors could not confirm that these anatomic factors were predictors of adverse neurological events, possibly due to small patient numbers (133 and 82, respectively).

Given the small number of studies evaluating anatomic variablity and outcomes in CAS assessing diverse anatomical features, it is impossible to conclude upon definitive anatomical predictors which adversely affect outcome. There are however a few factors which appear to be significant: angulation of the ICA with respect to CCA and a trend towards increased neurological complications in type III arches. Conversely, contralateral occlusion, lesion laterality, calcification and ulceration consistently did failed to demonstrate any impact on neurological outcome following CAS.

In the present study, adverse CCA configuration appeared to be the main discriminator and is supported by the observation that path-length for CCA cannulation was significantly and strongly correlated with the “catheterisation phase” rating. Furthermore, PL distributions across case difficulty for procedural phases were significantly different only for the CCA cannulation phase, and mirrored those of PL comparison for the entire procedure. In this series, the two harder cases

were characterised by a type II arch with an acutely angled CCA take-off and a bovine arch with a tortuous CCA consisting of two > 90^0 turns, which contributed significantly to the overall PL value. Both anatomical configurations have not demonstrated a significant impact on outcome in the studies described above, however both characteristics have been shown to significantly increase procedure time (Madhwal et al., 2008). We observed that challenging CCA cannulation resulted in excessive movement within the arch. Prolonged periods of manipulation within the arch have been associated with increased rates of embolisation (Verzini et al., 2006), and avoiding excessive arch manipulation altogether appears to significantly reduce rates of embolisation (Palombo et al., 2010). Although insignificant, there was an increase in PL during ICA manipulation for the red case, which was characterised by a calcified pin-hole ostial ICA stenosis.

A potential weakness of this study in particular, are subtle variations in terms of actual vessel lengths, particularly ECA and distal to the CCA bifurcation. Given the anatomical variability of a typically tortuous structure such as the ECA, it was challenging to accurately define and standardise start- and end-points for PL measurements across the three cases. Consequently, variation in terms of PL output for this vessel and ICA may be significantly related to vessel length itself rather than impact of tortuous anatomy on efficiency of tool manipulation. One might argue therefore that variations in PL during navigation through small-diameter vessels, which allow only for axial movement up and down the length of the vessel, are more a reflection of the anatomy itself. In comparison, variation in PL during cannulation of challenging target vessels arising from a large-calibre vessel such as the aorta may

more accurately reflect the impact of skill and anatomical variation on efficiency of tool manipulation.

8.5. CONCLUSION

Increasing anatomical complexity in CAS leads to significant increases in path-length during endovascular manipulation. CCA cannulation appears to be the procedural phase that is primarily affected by anatomical complexity. Excessive, prolonged and inefficient movements during manipulation, especially during CCA cannulation, may partly reflect the increased embolisation risk associated with anatomically challenging cases.

Some of the data in this chapter has also been reported in part in a previous paper using the same cohort of participants (Willaert et al., J Vasc Surg. 2012;56:1763-70). The novelty of this chapter lies with the presentation of a novel method of endovascular skill assessment.

CHAPTER 9.

THE USE OF VIDEO-MOTION ANALYSIS IN THE EVALUATION OF TECHNOLOGY BENEFIT DURING CANNULATION IN FENESTRATED ENDOVASCULAR AORTIC REPAIR

9.1. INTRODUCTION

Increasingly, fenestrated endovascular aortic repair (FEVAR) has been advocated as a feasible alternative to open repair for complex aneurysmal morphology, including short-necked infra-renal, juxa-renal and thoraco-abdominal aortic aneurysms, having to date demonstrated lower overall mortality rates as compared to open repair (Sun et al., 2006; Verhoeven et al., 2006; British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry, 2012), with good short- and mid-term outcomes (Bicknell et al., 2009; Quiñones-Baldrich et al., 2013). Longer-term results indicate acceptable target vessel patency rates (Amiot et al., 2010; Mastracci et al., 2013). Despite advances in graft technology, allowing treatment of increasingly complex morphologies (Bungay et al., 2011; Rolls et al., 2014), and the inherent appeal as an alternative to complex open or hybrid repair, the procedure is still characterised by potentially long procedure times and associated radiation exposure (Mohapatra et al., 2013). Selective catheterisation of target fenestrations is technically demanding and can potentially prolong the procedure. In order to achieve access for deployment of target vessel stents, a combination of guide-wires and pre-shaped catheters are used. Stable positioning of the selective catheter within the target vessel is required in order for advancement of a stiff wire, over which a sheath and

ultimately a stent is introduced. Although there is little data to support the notion that anatomical complexity adversely impacts the efficiency of cannulation of visceral branches, in theory and in our experience, downward angulation of target vessels would prolong cannulation and fluoroscopy times. Similarly, increased access vessel tortuosity has been shown to lengthen cannulation times, at least in simulated bench-top procedures (Riga et al., 2012).

Robotic catheter systems represent an innovative approach to endovascular intervention, and have the potential to reduce fluoroscopy times and radiation exposure, at least to the operator, in complex arterial intervention. The Hansen Sensei and Magellan systems (Hansen Medical, Mountain View, CA, USA) are commercially available platforms and have been described in a number of previous publications (Riga et al., 2010, 2011, 2011, 2012). The prototype Hansen Sensei^{TM} demonstrated early efficacy and safety in transvenous cardiac mapping and electrophysiology (Kanagaratnam et al., 2008; Saliba et al., 2008). This system has been extensively investigated in a series of in-vitro studies (Riga et al., 2009, 2010, 2011, 2012), which demonstrated considerable benefit in terms of efficiency and stability during navigation and cannulation exercises. Initial proof-of-concept was delivered in 2009 with a clinical application in standard infra-renal EVAR (Riga et al., 2009).

Briefly, both systems are remotely steerable catheters which are controlled by a "master-slave" electromechanical mechanism (fig. 35). The newer Magellan system was designed specifically for use in the peripheral arterial tree, and represents a significant refinement of the catheter itself. The novel Northstar^{TM} catheter is smaller and more flexible and is comprised of a 6 Fr leader-catheter and 9 Fr outer-sheath, with 180^0 and 90^0 multi-directional bending capacities (7 degrees of freedom), respectively.

Following CE marking, the system was successfully deployed in FEVAR to facilitate cannulation of target renal vessels (Riga et al., 2013), and has demonstrated its utility in cannulation of diseased ilio-femoral segments in an initial trial (Bismuth et al., 2013). Other clinical applications have also been described for the Sensei system, and have included the management of kinked renal bridging stents following branched endovascular aneurysm repair (Carrell et al., 2012), and treatment of pulmonary artery anastomotic stenosis at the site of previous lung transplantation (Lumsden et al., 2010).



Figure 35. Hansen Magellan™ control console

Having demonstrated its feasibility in the assessment of skill in prior chapters as well as its ability to differentiate efficiency in cannulation across varying anatomic difficulty, the primary objective of this study is to assess the ability of video-motion analysis software to discern technology benefit during cannulation in live cases. Robotic catheter technology, as mentioned previously, has been validated extensively with the use of conventional endovascular performance metrics in bench-top studies, however limited performance data exists in live intervention. Fenestrated EVAR provides an opportunity to compare conventional versus robotic cannulation given the technically demanding nature of target vessel catheterisation. The primary aim of this study was to measure path-length, number of catheter-tip/guide-wire movements, and cannulation time for manual and robotic cannulation of fenestrations in order to examine technology benefit.

9.2. METHOD

Study Design and Participants

Between January 2012 and February 2014 the fluoroscopy screens of 10 consecutive robot-assisted fenestrated EVARs, performed in a single endovascular suite (Phillips Healthcare, Andover, Mass, USA), were prospectively recorded. Digital camera set-up was standardised with respect to angulation and distance from the fluoroscopy screen. Angiographies were performed at varying zoom factors which were recorded for the purpose of adjustment of pixel data in order to compensate for zoom artefact. For the first two cases, renal artery cannulations were randomised to either robotic or conventional techniques. After discussion at the multidisciplinary team meeting, the endovascular team elected to use the robotic catheter in the subsequent cases for the more anatomically challenging renal vessels in terms of angulation and stenosis. Coeliac and superior mesenteric artery (SMA) cannulations were performed manually in all cases and were therefore excluded from analysis. Three patients were treated with Zenith^{TM} Fenestrated (Cook Medical, Bloomington, IN, USA) and seven with Anaconda^{TM} Fenestrated (Vascutek, Inchinnan, Renfrewshire, Scotland) grafts.

Procedural Preparation Stent Graft Planning

Threshold for treating standard infra-renal aneurysms is 5.5 cm. Indications for fenestrated stenting in complex aneurysms were aneurysm size above or equal to 6 cm or growth exceeding 1 cm per year, together with unsuitable proximal necks (<1 cm, conical). In order to create three-dimensional and multi-planar reconstructions,

CTA digital imaging and communications in medicine data were imported onto a Phillips workstation (Phillips Healthcare, Andover, MA, USA) for detailed assessment and measurement of aneurysm morphology and graft planning. All reconstructions were evaluated by a single radiologist. Pre-operative work-up for all patients consisted of a full cardio-pulmonary assessment including stress-echocardiography, pulmonary function testing and MAG-III scanning. Following MDT discussion, all devices were customised to include key target vessels.

Implantation and Cannulation Technique

The following is a description of standard technique for robot-assisted fenestrated grafting. There were subtle variations in each case in terms of equipment used, depending on the endo-graft and aneurysm morphology. Full, informed consent was obtained for all procedures. Following anaesthetic induction, both common femoral arteries were exposed surgically in each case. After systemic heparinisation, the main bodies of the grafts were introduced via one of the exposed common femoral arteries over 0.035-inch stiff Meier wires (Boston Scientific Corp, Natick, MAS, USA) and deployed under fluoroscopic guidance in order to align the fenestrations with the target vessels. During deployment of the Anaconda device, the “peaks” of the graft were typically positioned laterally above the renal vessels, whilst either the SMA or coeliac arteries were positioned ventrally in the “valley” of the graft. After deployment, it is still possible to partially collapse and re-position the main body via the control collar to further align fenestrations with target vessels. The Zenith device is similarly oriented using radio-opaque markers to accommodate target vessel ostia. Sheath withdrawal causes only partial expansion of the device, allowing further

adjustment of the fenestrations with respect to the target vessels, although to a lesser degree than the Anaconda device. Fenestrations were then cannulated manually from within the graft using either a combination of selective guide-catheters, such as Sos (Angiodynamics, Queensbury, NY, USA) and Van Schie (Cook Peripheral Intervention, Bloomington, USA), over angled 0.018" Terumo wires (Terumo Medical Corporation). Robotic navigation involved introducing the catheter via the common femoral artery (CFA), driving it into the aneurysm sac and into the main body of a given graft. Control of the catheter occurred remotely from the workstation which was located outside the endovascular suite and away from the radiation source. The workstation screen provided in all cases a virtual representation of the catheter and 3D positional information. The catheter was then advanced to a resting position such that the tip of the leader catheter was positioned 2-3 cm inferior to the target fenestration, from which point the catheter was then shaped and navigated into the fenestration. A 0.014" Terumo wire (Terumo Medical Corporation, Somerset, NJ, USA) was then advanced robotically into the target vessel through the leader catheter, over which the 6 Fr leader was advanced to successfully cannulate the target vessel. Access was secured following either robotic or conventional cannulation with 0.035" stiff wires. Selective conventional catheters or robotic leader catheters were then exchanged for sheaths (e.g Ansel- Cook Medical, Bloomington, IN, USA) to facilitate advancement of covered stents into the target vessel. All stents were flared proximally to enhance sealing and moulding of the stents with the main body of the graft. Following deployment of the bifurcated piece and contralateral limbs, all junctions were

balloon moulded and check angiograms were performed. Throughout the procedures, activated clotting time was maintained at 300 seconds.

Task Analysis and Statistical Evaluation

Analysis of all cases was performed using the catheter-tracking software described in the previous chapters, and tracking of the distal-most tip of the guide-wire catheter interface was performed. For the purposes of data collection, each cannulation attempt was defined by strict start- (entry of the catheter into the main body of the graft) and end-points (positioning of guide-catheter in the target vessel sufficiently stable to advance stiff wires), and also timed according to these start- and end-points. Each cannulation attempt was treated as a separate statistical data point, whether successfully completed or not; for a given renal target, if guide-catheter access was lost as a result of advancement of the stiff wire, a new attempt was commenced and counted towards statistical analysis, as was the initial failed attempt. Similarly, if cannulation was clearly attempted, but access never achieved with a guide-catheter, this attempt was likewise counted statistically, and tracking as well as timing were stopped once the guide-catheter was removed from the main body of the graft. In order to convert pixel data into centimetres, calibration was performed in each case against a stilled fluoroscopic image of a 5 Fr pig-tail catheter at zero magnification- the only radio-opaque feature found to be constant in all recorded cases. The raw pixel co-ordinate data for each case were then segmented by zoom setting, of which there were four standard settings; Mag 0 (FD 48 cm), Mag 1 (42 cm), Mag 2 (37 cm) and Mag 3 (31 cm). Following conversion of pixel data to

centimetres, each phase of magnification was adjusted according to previously identified (see methods chapter) factors for each zoom setting in order to create an accurate, rather than apparent path-length in centimetres.

Phases of active movement were tracked, and tracking was not performed during phases of angiographic image manipulation, in order to avoid incorporation of movement artefact into the final analysis. Path-length, number of movements and cannulation times were collected for each cannulation attempt. Number of movements was calculated using the raw excel data sets: A movement was defined arbitrarily as any displacement greater than 1 pixel. A threshold formula was applied to identify all such movements and apply binaric code (I/0). All movements were ascribed (I), whilst all data less than 1 pixel was attributed to oscillations associated with the software (0). The number of movements was then calculated by summating all (I) values.

Data were analysed using the Statistical Package for Social Sciences 20.0 (SPSS, Chicago, Ill, USA). Non-parametric tests were applied, since the data was found to be not-normally distributed. Comparison of distributions across groups between robotic and conventional cannulation techniques were performed for the parameters of path-length, total number of movements and cannulation time.

Anatomical Analysis

Pre-operative CTA angiograms were analysed on Osirix (Pixmeo, Switzerland), and measurements of renal artery angulation in relation to the mid-line of the aorta, as well as percentage stenosis were obtained. Assessment of renal artery anatomy was also performed on fluoroscopic sequences obtained during cannulation of the renal targets with the fenestrated stents partially deployed, in order to obtain intra-operative anatomical data. Two measurements were taken; displacement of the centre of the target vessel ostium either cranially or caudally with in relation to the centre of the fenestration (displacement), and the degree of angulation of the target vessel in relation to the fenestration. Hand injections of contrast were used when technical difficulty cannulating the target vessel was encountered and these were used to calculate the anatomical parameters above with respect to the fenestrations.

9.3. RESULTS

A total of ten fenestrated grafts were implanted, comprising of 7 Anaconda^{TM} and 3 Cook Zenith^{TM} grafts. Twelve robotic- and twelve conventional renal cannulations were performed. Two failed conventional cannulations were completed robotically. In a further instance, robotic access was lost and the conventional attempt at the same target vessel was prolonged. Similarly, in another patient, conventional catheter access was lost, and was repeated conventionally.

9.3.1. Differences in path-length between robotic and conventional renal cannulation

There was a significant reduction in total path-length when robotic renal cannulation was performed. The median PL for the robotic group was 268.6 cm (IQR 159.6-852.4) vs 1312.3 cm (IQR 338.2-3218.3) for the conventional group (p = 0.045).

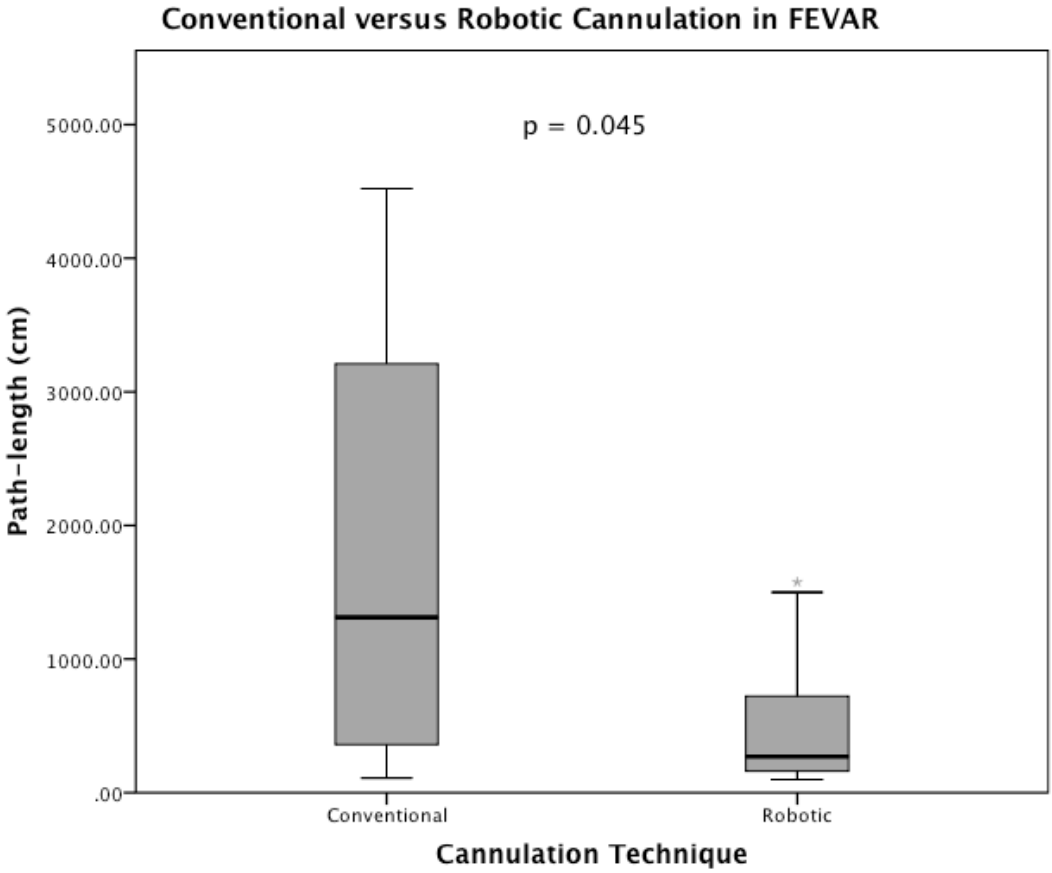


Figure 36. Box-plot representing PL (y-axis) taken to cannulate the renal arteries, against cannulation strategy used (x-axis). The whiskers represent the range and the stars the outliers

9.3.2. Differences in the number of movements between robotic and conventional renal cannulation

There was a trend towards reduction in the total number of movements required when robotic cannulation was performed, however this was not significant. Median number of movements for the robotic group was 644.5 (IQR 254.5-1905) vs 2501 (490-4208) for the conventional group (fig. 37).

9.3.3. Differences in cannulation time between robotic and conventional renal cannulation

There were no significant differences in cannulation time between the two groups. Median cannulation time for the robotic group was 16 minutes (IQR 5-27.5) vs 12 minutes (4.7-36) for the conventional group (fig. 38).

9.3.4. Target Vessel Anatomy

There was a trend towards increased use of hand injections for vessels cannulated robotically (n=6 hand injections), versus those cannulated conventionally (n=3 hand injections). No significant anatomical differences were found between robotic and conventional cannulation cases, for either degree of stenosis (p = 0.16), or angle of renal artery (p = 0.35) Two failed conventional cannulation attempts were completed robotically (table 12).

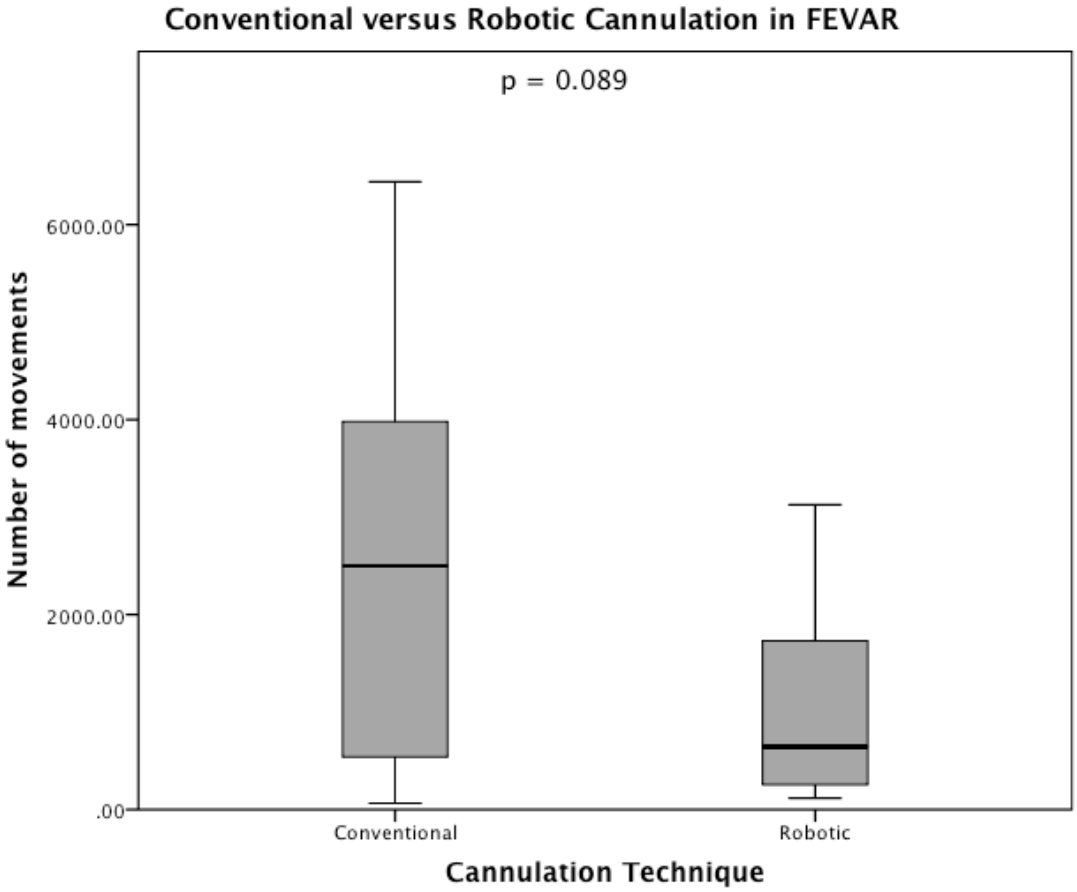


Figure 37. Box-plot representing total number of movements (y-axis) taken to cannulate the renal arteries, against cannulation strategy used (x-axis). The whiskers represent the range and the stars the outliers

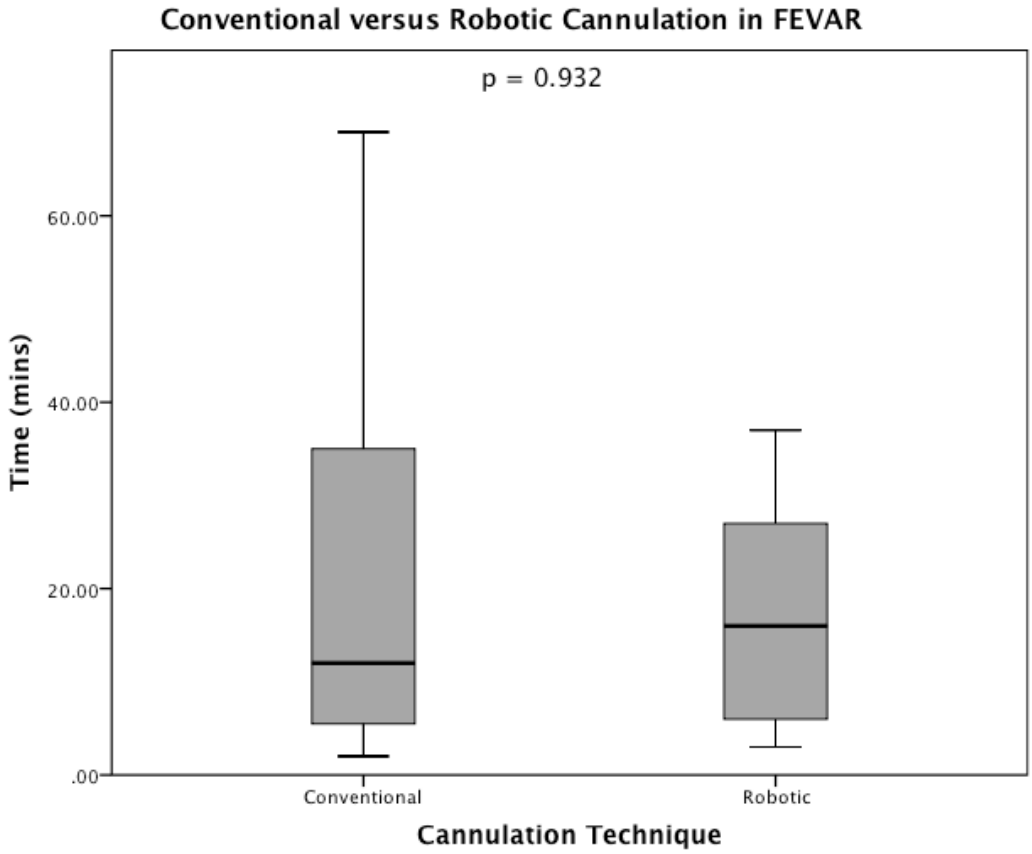


Figure 38. Box-plot representing time taken (y-axis) to cannulate the renal arteries, against cannulation strategy used (x-axis). The whiskers represent extreme values and the stars the outliers

Case	R-Angle	R-stenosis	C-Angle	C-stenosis	R-Intraop	C-Intraop
A	114^0	20%	105^0	0%	-	-
			110^0	0%		
B	116^0	0%	NA	NA	170^0, 9 mm	-
	142^0	55%			93^0, 1.6 mm	
C	95^0	67%	95^0	0%	200^0, 8 mm	110^0, 11 mm
D	142^0	50%	145^0	0%	-	-
E	141.7^0	0%	136^0	0%	-	150^0, 7 mm
F	145^0	48%	90^0	50%	80^0, 2.4 mm	-
G	73^0	0%	137^0	0%	130^0, 2 mm	-
H	114^0	0%	115^0	0%	140^0, 4 mm	110^0, 1 mm
I	135^0	0%	90^0	0%	-	-
J	95^0	0%	85^0	0%	-	85^0, 2.6 mm

Table 12. Target vessel anatomy during cannulation attempts. (R)-robotic. (C)-conventional. Intraop.- intra-operative data. The distance expressed in mm relates to the displacement of the fenestrations cranially or caudally in relation to the target vessel. Absence of anatomical data as indicated by (-) implies no contrast was administered.

9.4. DISCUSSION

To the author's knowledge, this series represents the largest series describing the use of the Magellan™ system in complex aortic intervention. Previous reports have described its use in individual cases (Riga et al., 2009, 2013), however limited data exists in terms of its performance in live aortic cases. This study also represents the first attempt to systemically evaluate endovascular robotic performance in live cases in terms of efficiency. Video-motion analysis has been validated over the course of previous chapters, and initial data from this series suggest that it is able to evaluate the benefit of novel endovascular technologies. The findings suggest that the robotic technology confers an advantage in terms of ergonomic movement; there was a non-significant trend towards reduction in the total number of movements, however the total path-length was significantly reduced. One might argue that the finding of equipoise in terms of cannulation time between the two techniques reflects favourably on the robotic technique. Although the pre-operative CTA suggests there were no differences anatomically between those vessels cannulated either robotically or conventionally, the available intra-operative data suggests that target vessel morphology of those vessels cannulated robotically was indeed challenging and a greater number of hand injections was required. Further data in the form of a much larger series is required to demonstrate this conclusively.

Evaluation of robotic efficiency during renal artery cannulation during FEVAR in previous bench-top studies using the Hansen Sensei™ yielded different results as compared to the present study: procedure time and total number of movements

were significantly reduced (Riga et al., 2010). It is possible that the difference in cannulation times between the bench-top data and the present series can be accounted for by the significant discrepancy between live and simulated cases with regard to anatomical complexity. Additionally, the robotic platforms differ significantly in terms of their profiles. In contrast to the bench-top data in which the renal targets were similar in terms of anatomy, the data in this study does not represent a like-for-like comparison between the two techniques given the morphological variety encountered in the live cases. A rigid comparison of bench-top versus live data is therefore not appropriate.

There is little data which correlates the effect of target vessel angulation and endovascular performance in FEVAR. In theory and in our experience, increased angulation would prolong cannulation and fluoroscopy times. Similarly, cannulation times of target vessels have been shown to increase incrementally with progressive iliac tortuosity in bench-top models (Riga et al., 2012). Anatomical hostility is generally recognised as a significant contributor to the technical demands in fenestrated and branched stenting (Rodd et al., 2011). As seen in the previous chapter, efficiency of cannulation of aortic arch target vessels is significantly affected angulation of vessel take-off. This may also be applicable to visceral vessels. This fenestrated series is a heterogeneous group in terms of anatomy and devices used, much unlike the silicone model described in previous studies. Although not evidenced by data provided in this study, interaction between graft and aorta adds an additional domain of complexity; fenestration misalignment can make some of the cannulations challenging even for the robotic catheter. In the bench-top studies,

fenestrations were perfectly aligned with the target vessel ostia, and catheters were removed once a target vessel was cannulated. A further contributor to the complexity of live cases is the interaction of multiple wires and catheters in the visceral segment. In theory, the presence of stiff wires could make the later cannulations more challenging.

The VMA data implies that robotic technology conferred an advantage in terms of ergonomic movement. There was a non-significant trend towards reduction in the total number of movements, however the total path-length was significantly reduced. This suggests that per individual catheter tip movement, the path-length in robotic cannulations is reduced, implying that robotic manipulations are generally more controlled. The significant reduction in PL for robotic cannulation suggests that the catheter has more efficiently engaged the target vessel, having moved a shorter distance to reach it. As identified in the semi-structured interviews in chapter 4, this efficiency may reflect a combination of movements that have led to an overall reduction in path-length: a reduction in PL also represents increased catheter stability, since repeated cannulation attempts will invariably result in increased PL.

From a clinical perspective, prolonged cannulation attempts and excessive movement in conventional FEVAR remain poorly explored, and no direct causal relationships between excessive endovascular tool manipulation and complications have been demonstrated to date. Proving that robotic technology can reduce the frequency of target vessel “events” such as acute thrombo-embolism and dissections would require a much larger cohort sufficient to prove a significant temporal

relationship between catheter manipulations and complications. Cochennec et al have sought to evaluate the impact of intra-operative adverse events during FEVAR on clinical outcome (Cochennec et al., 2014). Problems with target vessel cannulation were found to be the most frequent intra-operative problem and resulted on occasions in devastating complications such as permanent renal insufficiency and death. A larger prospective multi-centre study (Marzelle et al., 2014) sought to identify predictors of clinical outcome. Similar to the previous study, target vessel factors including number of fenestrations/branches (four) and "failure to cannulate" were identified as independent predictors of mortality and major complications. Although the data in these studies is insufficient to prove a cause-and effect relationship between efficiency of cannulation and clinical outcome, it is in theory plausible that reduced movement, particularly up-stream of the target vessel and at the ostia may result in fewer embolic events or target vessel dissections.

A number of important observations were made during this study that pointed towards potential advantages of the robotic catheter technology. Two conventional attempts at cannulation were unsuccessful: In one instance, cannulation was not achieved conventionally, due to misalignment of the fenestration with the target ostium in a case characterised a highly angulated aneurysmal neck. Cannulation was achieved robotically and was most likely aided by additional stability of the robotic catheter, which was positioned in the angulated aneurysmal neck just inferior to the fenestration. In the second instance, access to the renal target was lost during exchange for a stiff wire. The stability afforded by the robotic platform subsequently facilitated a smooth exchange of wires. Positioning of the robotic catheter within the

target vessel did not always guarantee on-going access throughout the procedure: in one case the renal target was successfully cannulated and the inner catheter and outer sheath left in a resting position within the renal artery over a soft wire only, whilst the remaining three vessels were cannulated conventionally. Unfortunately the soft wire was dislodged and access was lost. Although previous experimental work and experience in this series suggest that robotic catheters confer additional stability during cannulations and wire exchanges (Riga et al., 2010), it is worth noting that even with this technology operators should seek to secure target vessel access with at least a stiff wire prior to proceeding with further cannulations. A larger series is required in order to support these observations more robustly.

Potential drawbacks of the video-motion analysis technique in relation to this study include time-consuming analysis to convert pixel data to centimetres: as zoom settings were changed, post-processing was required in order to segment the raw data from each video according magnification and apply the appropriate adjustment factors. This is time-consuming particularly in complex endovascular cases which frequently employ multiple zoom settings. Significant further work is required to fully automate this process, and a possible solution may be to integrate the VMA software with the fluoroscopic system's video processing unit in order to automatically adjust pixel output according to zoom.

9.5. CONCLUSION

VMA can objectively differentiate robotic cannulation techniques from conventional ones, and robotic catheterisation is characterised by more controlled and restricted movements in terms of catheter-tip trajectory, without an increase in overall cannulation time, despite being used for the more challenging cannulations. Robotic technology was also able to access the target vessels in instances where conventional techniques had failed. Further studies are required to fully understand the potential benefits of this advanced technology.

CHAPTER 10.

GENERAL DISCUSSION AND FUTURE DIRECTIONS

This thesis set out to evaluate the concept of video-motion analysis (VMA) in endovascular surgery. VMA in this field had remained unexplored until now, and indeed formal evaluation of endovascular performance has not been part of routine clinical practice. However, numerous other enterprises including high-performance sport and the automobile industry have made use of this technology to enhance performance. As outlined in the introductory chapters, numerous vascular research institutions have devised a number of qualitative and quantitative assessment tools in order to formalise the evaluation of performance. These have been largely driven by the need to evaluate new simulation technologies, which in turn have been driven by the demand to improve patient safety. The shift away from the traditional apprenticeship model whereby a trainee received a time-based one-on-one surgical education from an experienced trainer has also been triggered by the inception of the European Working Time Directive, and a similar and substantive reduction in working hours in United States. In its place, the creation of focused surgical training opportunities has been augmented by the use of training simulators and structured educational days, typically away from the trainee's department. Accompanying this change is the need for formal and objective assessment of surgical technique, such that the trainee's progress can be formally demonstrated to the relevant training boards and nominated educational supervisors.

By way of introduction, ***Chapters 1*** and ***2*** sought to describe the principles of endovascular therapy and outline existing means by which endovascular technique and skills and technique are assessed. In particular, ***Chapter 1*** outlined the history and development of endovascular intervention and provided an early description of the more complex procedures to be evaluated in later experimental chapters. It is evident from examination of endovascular "history" that the scope of intervention has rapidly extended from early experiences with cerebral angiography and infra-inguinal balloon dilatation (Dotter and Judkins, 1964), to complex high-stakes interventions across multiple vascular beds including the cerebral and visceral systems. It is also evident that technology has driven the expansion of endovascular intervention, with low-profile and co-axial devices making targets in small calibre vessels more accessible. The utility of these techniques in certain vascular domains such as carotid disease remains controversial. In others, such as coronary disease, endovascular techniques have become the mainstay of treatment options and have largely superseded open surgical techniques. Aortic intervention has continued to expand, and technological advancement has led to the entirely endovascular management of complex aneurysmal disease including the visceral segment and the aortic arch. The long-term durability of these interventions, particularly where branches or fenestrations have been required to maintain end-organ perfusion, remain the subject of investigation (Mastracci et al., 2013).

Successful selective catheterisation of these target vessels requires considerable expertise, and failure to do so safely can have catastrophic consequences, including organ dysfunction and death (Marzelle et al., 2014; Cochennec et al., 2014). The

relationship between experience and outcomes in standard infra-renal EVAR as well as other endovascular procedures has been documented (Lin et al., 2005; Mullenix et al., 2005; Cao et al., 2006; Verzini et al., 2006; Forbes et al., 2007; Klompenhouwer et al., 2013). Similarly, a large volume of predominantly simulator-derived studies have been able to document learning curves across a range of procedures, and have been able to correlate levels of experience with crude markers of endovascular performance (see chapter 3). Thus, given that outcomes in endovascular procedures have been linked to experience, and by extension endovascular skill and performance, ***Chapter 2*** sought to define the *status quo* in terms of available endovascular skills assessment methods. As a prelude to this, a variety of endovascular training modalities were described, including virtual reality (VR) simulation and synthetic models. Prior to the introduction of formal assessment forms, experience and expertise were crudely assessed in the form of an operating log-book that provided little in the way of qualitative feedback. Now widely adopted, the Intercollegiate Surgical Curriculum Program (ISCP) incorporates assessment forms that provide a very basic assessment of competence on the basis of a procedural check-list. Broadly speaking, two categories of endovascular skill assessment were identified: quantitative and qualitative. The latter group broadly encompasses generic- and procedure-specific rating scales and the former is comprised largely of automated procedural metrics such as procedure- and fluoroscopy time. Although both of these categories have shown construct validity, the latter does not provide a qualitative component to the assessment other than efficiency, whilst rating scales can be time-consuming to complete. A combined approach providing quantitative metrics, qualitative ratings, and scoring of decision-

making skills has been evaluated by a number of groups who designed prototype computer-based scoring matrices or algorithms (Duncan et al., 2007; Lipner et al., 2010). The majority of published data on scoring matrices, quantitative metrics and qualitative rating scales is largely experimental and is varied in terms of its ability to differentiate between groups of expertise and demonstrate a learning curve.

In ***Chapter 3*** therefore, a literature review of all published data describing the use of all assessment methodologies in endovascular arterial intervention was performed in order to evaluate the current position of skills assessment in endovascular surgery. Specifically, the review sought to determine the validity of these scoring methodologies in terms of their ability to differentiate between groups of experience and to reliably demonstrate a learning curve. Further, this chapter sought to identify which methods were being routinely used in live intervention, and to identify potential gaps for the development of further metrics. Interestingly, the only description of metric usage in live cases stem from the field of interventional cardiology, perhaps as a result of the high throughput in terms of numbers of cases. Qualitative rating scales and scoring matrices had not been used routinely in live intervention at the time of writing the review. Whilst procedure time was the most frequently utilised metric, its relationship with expertise was not always linear, supporting the notion that speed of a procedure does not always reflect quality. Furthermore, very few studies have thus far correlated this metric with qualitative rating scales. Generic rating scales were seemingly more able to differentiate between levels of experience in comparison procedure-specific rating scales, although a larger number of studies would be required to safely conclude this. There

was a clear paucity of studies describing the mechanics endovascular tool motion, such as catheter motion and velocity, and represented a fertile area for further investigation.

Chapter 4 sought to pool expert opinion on motion descriptive metrics and identify potential targets for automated assessment of endovascular skill. In a series of semi-structured interviews, experts were first asked open questions regarding the characteristics of safe endovascular intervention. Closed questions subsequently followed on the fluoroscopic characteristics of skilled endovascular manipulation and potentially measurable metrics. Pooling all the coded answers, the most frequently mentioned statements referred to the theme of observable catheter movements, of which "ergonomic" catheter movement was the most prominent. This is understandable given our interest in video-motion analysis, and the relative weighting of the questionnaire towards this theme. Statements relating to efficiency of catheterisation attempts and reaching the desired target using the least possible movement were not prompted, suggesting that this might represent a target for video-based assessment. Although one might argue that interview studies, and qualitative research techniques in general, are subject to bias, this study was able to map the spectrum of qualities that define the skilled endovascular interventionist. There was also a significant emphasis, not simply on technical skills but cognitive abilities, including 3D conceptualisation and flexibility when dealing with complications. Although rating scales briefly touch upon catheter movements as a sub-domain for assessment (Van Herzeele et al., 2010; Riga et al., 2011), this study suggests that expert interventionists are not only aware of, but able to fully

deconstruct endovascular movement into safe and dangerous manoeuvres. The subsequent chapters focused on evaluating a novel software platform designed to evaluate endovascular tool movements using fluoroscopic footage as a medium.

Chapter 5 introduced a novel catheter-tracking software platform developed in conjunction with the Department of Computing, Imperial College London. The semi-automated tracking software was described in detail, and the principles of calculation of motion-descriptive data on the basis pixel co-ordinates explained. Inter-observer reliability was assessed and limitations of video-motion analysis in this setting addressed experimentally. The impact of C-arm variables including zoom and angulation on data output were documented, allowing for adjustment of data from recordings of live procedures in subsequent chapters. A criticism of 2D analysis is the loss of data as a result of movement in a 3D structure. The anatomical layout of the human vasculature, particularly when it is being screened with the patient lying supine, is such that the majority of the movement occurs in the coronal plane, with minimal displacement in the AP plane. Exceptions to this might include the aorto-iliac segment as the iliac arteries dip posteriorly over the sacral promontary, and the intra-cerebral circulation. When 2D video-tracking data were compared to 3D electromagnetic tracking data in the aortic arch, it was apparent that the amount of data lost in 2D was small and predictable. Future work in this area might investigate differences in data loss across a range of arterial beds.

Given that endovascular skills research has largely focused on simulation exercises, ***Chapter 6*** evaluated the use of the software in simulated carotid artery stenting

(CAS), and sought to establish construct validity across groups of varied experience. Twenty-one endovascular specialists each performed a simulated CAS procedure, and were assessed by a blinded assessor using the VMA software. Given the previously described paucity of significant metric correlations with qualitative rating scales (chapter 3), the catheter-tip path-length (PL) and velocities were correlated with a generic rating scale (GRS) and a CAS- procedure specific rating scale (PSRS), and found to have significant inverse correlations. VMA in this pilot study was feasible, and PL was able to differentiate between groups of experience, although the relationship was not linear, with the low-volume group obtaining higher PL scores than the intermediate group. This finding is corroborated by similar findings in terms of procedure time, and a proposed explanation is that intermediately experienced do not rush to complete the procedure and spend more time and use more exploratory manoeuvres when searching for the optimal cannulation strategy (Van Herzeele et al., 2008). Calculation of velocities was also feasible and a non-significant increase in velocity was observed with progressive CAS experience. Taken together, the data suggested that most experienced group were able to complete the task using rapid but controlled movements.

Chapter 7 sought to evaluate the use of VMA in live intervention. Coronary Angiography was selected, given the high throughput of cases and the broad range of experience of the operators performing these procedures. Fifty coronary angiographies, performed by a group of cardiologists at a single institution with a broad range of experience, were prospectively recorded and blindly analysed using the software. A step-wise and significant reduction in total PL was observed with

progressive experience, and was strongly correlated with metrics commonly used in live coronary intervention; procedure-time, fluoroscopy-time and radiation dose. A number of observations were noted on the basis of this data: Firstly, whilst most cardiological societies recommend 150-300 cases to be certified as competent, all performance metrics including PL continued to decrease after a 1000 cases, suggesting that true expertise in this procedure may be harder to achieve than previously thought. Secondly, PL was influenced by laterality of the coronaries and access route. In particular, the right coronary appeared to discriminate between groups of experience and when compared directly with the left coronary, and was significantly harder to cannulate. A proposed reason for this is the anteriorly oriented take-off of this vessel, making catheterisation with fluoroscopy oriented in an AP plane more challenging.

In view of this data, the objective of ***Chapter 8*** was to discern the effect of anatomical complexity on VMA data, given that expertise identified in the previous chapter as not being the only variable of importance. In order to do this, videos of 20 novice interventionists each performing an easy, medium and hard simulated CAS case in random order were analysed using the software. Anatomical complexity was scored according to a previously validated anatomic scoring system (Macdonald et al., 2009). A clear step-wise increase in PL was observed with progressive anatomical complexity, specifically, common-carotid artery cannulation (CCA) appeared to be the discriminating procedural phase, with increasing take-off angulation making this phase of the procedure more demanding. To our knowledge, this chapter is the first to describe the direct relationship between anatomical complexity and endovascular

tool manipulation. Existing evidence suggests that embolisation occurs during manipulation in the aortic arch and cannulation of target vessels prior to deployment of the embolic protection device (Cao et al., 2006; Verzini et al., 2006), and sub-group analysis of EVA-3s data would imply an increase in embolic complications with increasing internal carotid artery angulation with respect to the common carotid artery (Naggara et al., 2011). Although not formally demonstrated through statistical evaluation, plots of the catheter trajectories indicated that the majority of excessive movement during challenging CCA cannulations occurred in the ascending aorta proximal to the ostia of the supra-aortic vessels, and may represent a potential mechanism for embolic events during this phase of the procedure.

Chapter 9 combined this stream of work with another major current research stream within the department; endovascular robotic technology. The latter stages of this work coincided with the clinical robotics program, and the objective of this chapter was to apply the now-validated VMA software in the assessment of robotic catheter technology in a series of complex renal cannulations during fenestrated endovascular aortic repair (FEVAR). Ten cases were prospectively recorded, and renal arteries received either conventional or robotic cannulation with the Magellan^{TM} system. Robotic cannulations were completed with a significantly reduced PL as compared to conventional techniques, and there was a trend towards a reduction in the number of movements with this technology, although this was found to be non-significant. To our knowledge, this study represents the largest documented series of robotic aortic intervention to date, and also documents a novel systematic approach to evaluation of new endovascular technologies that

extends beyond the scope of traditional outcome-based registries. In contrast to the previous chapters, where fluoroscopic settings were not changed during procedures, data in this series required extensive post-hoc adjustment for variation in zoom using the factors identified in chapter 5. In comparison to previous bench-top work, no significant improvements in cannulation time were observed for the robotic technology, and a potential explanation of this lies in the complexity of the live cases as compared to the relatively simplistic bench-top models. Although there is limited data to directly link efficiency of target-vessel cannulation with clinical outcome, prolonged and difficult cannulations, including failure to cannulate are associated with major adverse outcomes in large prospective studies (Cochennec et al., 2014; Marzelle et al., 2014).

10.1. FUTURE PERSPECTIVES

At present, the VMA software is still semi-automatic and extensive manual correction and adjustment of the tracking point is required by the observer in order to accurately track the catheter, and can be time consuming. This is particularly the case in sequences characterised by rapid, multi-directional movement. Further funding is required to employ research fellows to develop a fully automatic tracking function. Once this has been achieved full integration of the software with standard fluoroscopic imaging systems would be desirable. Analysis presently requires video recording of fluoroscopic monitors using standardised camera settings, often in busy angiography suites, requiring the investigator to closely observe the camera in order to prevent disruption of the recording. The video is then subsequently analysed. By

achieving both of the above, fully automated and instantaneous motion analysis of endovascular performance may be feasible. Extensive post-hoc adjustment of raw data and manual calibration is required in order to account for C-arm manipulation and provide a final metric system PL value. Further refinement of the software would ideally allow for communication between the software and the imaging hardware and allow for automated acquisition of C-arm positional data and incorporation into final PL calculation. The current edition of the software does not permit active motion tracking when the screening field is being changed, since this would incorporate artefactual movement data. However this may result in the loss of movement data, and further development is required in order to adjust for such movement.

Tracking of endovascular tools during endovascular intervention has many applications beyond assessment of skills, including enhanced navigation for accurate localisation within the vasculature. Accurate positioning of the guide-wire or catheter with respect to the vasculature is required for the successful deployment of therapeutic devices such as stent grafts and balloons. Fluoroscopic image quality of the guide-wire, specifically, can be restricted by a number of factors including measures to reduce radiation dose and the use of contrast agent. Current guide-wire detection techniques reduce background information content of the fluoroscopic image, in order to improve the contrast between the image background and image elements representing the guide-wire. Furthermore, the low signal-to-noise ratio in fluoroscopic images makes it challenging to differentiate small structures like the guide-wire from other structures in the background. Improving guide-wire detection

and enhancement remains a priority and warrants the acquisition of further funding and in-depth investigation.

Although this stream of investigation has thus far documented the feasibility of video-motion analysis in simulated and live intervention, further work should ideally focus on expanding and refining a panel of motion-descriptive metrics that more comprehensively describe the expert interventionist's catheter movement. A possible method could be to ask a panel of experts to watch fluoroscopic footage and accurately document particular movements that constitute effective endovascular manipulation, followed by a series of simulated endovascular exercises in order to establish construct validity of the enhanced metrics.

Alternatively, further metrics could be extracted from the expert interview data described in ***Chapter 4*** and applied to a series of simulated tasks. For instance, motion repetition and proximity of the catheter trajectory to the vessel wall could be utilised as markers of endovascular "safety". Ideally, such metrics would consider the vessel walls and shape and geometry of the vasculature in the context of known high-risk areas such as the ostia of the supra-aortic vessels. However formal pooling of expert opinion would be required to accurately define these areas and describe appropriate endovascular manoeuvres for their safe navigation. Although excessive endovascular tool movement may result increased embolisation, no direct correlation between movement and embolisation has been documented. Trans-cranial Doppler (TCD) has been used to investigate embolic release during trans-cathetheter aortic valve implantation (TAVI) and carotid stent procedures (Kahlert et

al., 2012; Erdoes et al., 2012; Tulip et al., 2012), and provides real-time data. Synchronising video-motion analysis with TCD recordings with the objective of establishing a temporal relationship between particular endovascular tool movements and embolisation could enhance understanding of mechanisms of embolisation and further inform both endovascular surgeons and trainers in terms of optimising technique.

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PUBLICATIONS, PRESENTATIONS AND PRIZES RELATING TO THIS WORK

Publications

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Presentations

"The Use of Video-motion Analysis to determine the Impact of Anatomical Complexity on Endovascular Performance in Carotid Artery Stenting" Rolls AE, Riga C, Rahim S, Willaert W, Van Herzeele I, Stoyanov D, Hamady M, Cheshire N, Bicknell CD. Presented at Multidisciplinary European Endovascular Therapy Congress, Rome, 11/06/2013

"The use of the Anaconda Fenestrated Stent-Graft System in challenging anatomical Scenarios, early single-centre experience" Rolls AE, Hamady M, Burfitt N, Bicknell CD, Riga CV, Cheshire NJ, Jenkins M. Presented at the British Society for Endovascular Therapy, Warwickshire, 27/06/13

"The use of the Anaconda Fenestrated Stent-Graft System in challenging anatomical Scenarios, early single-centre experience" Rolls AE, Jenkins M, Burfitt N, Bicknell CD, Riga CV, Cheshire NJ, Hamady M. Presented at the British Society of Interventional Radiology, Manchester, 13/11/2013

"Expert Identification of the Components of Endovascular Skill" Rolls AE, Riga C, Van Herzeele I, Hamady M, Cheshire N, Bicknell CD. Presented at the Society for Clinical Vascular Surgery, Miami, 16/03/13

"Video-motion Analysis in Live Coronary Intervention is able to Differentiate different levelsof Experience and Provides a Novel Method of Skill Assessment" Rolls AE. Presented at the London Surgical Symposium, 06/12/12

"Motion Analysis of Catheter-based Endovascular tasks to develop re-producible, real-time skill metrics with discsriminatory potential" Rolls AE, Riga CV, Stoyanov D, Van Herzeele I, Yang GZ, Hamady M, Cheshire N, Bicknell C. Presented at the European Society for Vascular Surgery, Bologna, 19/09/12

"Catheter-tip Path-length in the assessment of Endovascular Skills" Rolls AE, Riga CV, Stoyanov D, Van Herzeele I, Yang GZ, Hamady M, Cheshire N, Bicknell C. Presented at the British Society for Endovascular Therapy, Stratford-upon-Avon, 29/06/12

"Robot-assisted Fenestrated Endovascular Aortic Repair" Rolls AE, Riga CV, Hamady M, Bicknell C, Chehsire N. Presented at Multi-disciplinary European Endovascular Therapy Congress, Rome, 09/6/12

"2D guide-wire tip Path-length; a Novel Endovascular Skill Metric" Rolls AE, Riga C, Stoyanov D, Van Herzeele I, Hamady M, Yang GZ, Cheshire N, Bicknell C. Presented at Multi-disciplinary European Endovascular Therapy Congress, Rome, 09/6/12

Prizes

"The Use of Video-motion Analysis to determine the Impact of Anatomical Complexity on Endovascular Performance in Carotid Artery Stenting" Scientific Prize, First Rank, MEET Congress, June 2013