The impact of patient-specific pre-operative rehearsals on surgical performance

by

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Declaration

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been given within candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others

Publications:

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Abbreviations

3DG	Group using 3D model
3D	Three dimensional
CAS	Carotid Artery Stenting
CAT	Competency Assessment Tool
CD	Compact Disc
CG	Control Group
CLASICC	Conventional versus Laparoscopic-Assisted Surgery In Colorectal Cancer
CNC	Computer Numerical Control
COST	Clinical Outcomes of Surgical Therapy Study
CRM	Circumferential Margin
CSU	Clinical Service Unit
CT	Computed Tomography
CTA	Computed Tomography Arteriogram
DICOM	Digital Imaging and Communication Medicine
DM	Distal Resection Margin
DTI	Diffusion Tensor Imaging
DVS	Damage to Vital Structures
EVAR	Endovascular Aneurysm Repair
LC	Laparoscopic Cholecystectomy
MDCT	Multi-detector CT
MI	Minimally Invasive
MIQ	Mental Imaging Questionnaire
MP	Mental Practice

MPO	Mental Practice Only
MRA	Magnetic Resonance Arteriogram
MRI	Magnetic Resonance Imaging
MRV	Magnetic Resonance Venogram
NA	Normal Anatomy
NCB	Non Cauterized Bleeding
NIG	No Information Given
NOM	Number of Movements
OCHRA	Observational clinical human reliability analysis
Per	Perforations
PL	Instrument tip Path Length
POC	Proof of Concept
Pre-op	Pre-operative(ly)
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
SARS	Society of Academic & Research Surgery
SCD	Short Cystic Duct
SMR	Structured Mental Rehearsal
TMJ	Temporomandibular Joint
UK	United Kingdom
US	United States
USD	United States Dollars
VR	Virtual Reality

Abstract

Background: Performing minimally invasive surgery can be technically challenging. In addition to its inherent difficulty, other factors can contribute into making cases particularly difficult. For instance, patient characteristics such as a narrow pelvis, a high BMI and a low tumour can pose an additional challenge in low anterior resections. As technical difficulty is associated with immediate oncological results and patient outcomes, it is important to explore novel methods to prepare for challenging cases, taking into account the individual patient and disease characteristics. The aim of the current project is to develop and test case specific rehearsal methods, establishing the feasibility of their application in a real clinical environment.

Methods: Patient specific virtual and physical (i.e. synthetic) anatomical models were developed using 3D reconstruction and modelling, based on MRI and CT images of patients. These were then combined with mental practice and tested in a simulated (two studies) and a clinical environment (one study). The first study compared MP to MP with virtual 3D models and to a control group; the second study compared MP to MP with 3D visual aids after a significant degree of anatomical variation was introduced; and the clinical trial compared MP with the use of three different aids (Virtual, physical models – including simulation and MRI) to routine clinical practice (control group).

Results: The first study showed performance differences across groups, with the control group performing worse (time to complete LC ($F(2,17) = 8.77$, $p = .002$, $\eta p^2 = .51$), Control group: Median (M) = 1447sec, SD = 341sec) 3D & MP group (M =

670sec, SD = 326sec) (p = .002)). The second study showed equal performance when the anatomy was “normal” [MP vs. MP and 3D Model Total CAT score – NA: 23.63 vs. 26.69 p=0.2 – SCD: 20.5 vs. 26.31 p=0.02 η^2=0.32 – DA: 24.75 vs. 30.5 p=0.03 η^2=0.28] but superior performance for the MP and 3D model group for complex anatomy. Although the clinical trial showed no difference in overall performance (Median control: 30.5, MRI: 34.25, virtual: 31.75, physical: 34, *p* = 0.75, η^2 <0.01), the time spent not performing dissection (“nothing” time) was significantly shorter for the SMR with MRI group compared to the control group (57.5 vs. 42min, *p* < 0.001, η^2 = 0.212).

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1.1 Identifying the problem

Minimally invasive surgery (MIS) requires a distinct set of skills compared to open surgery. Physical contact between the surgeon and patient is less, reducing the tactile cues that guide the surgeon during open procedures. In addition, the surgeon has to become accustomed to the “fulcrum effect”, whereby a small movement outside the abdomen translates to a larger one intra-abdominally, actuated on an inverted axis and giving rise to counter-intuitive movements(1).

In MIS, the 3D operative field is replaced by a 2D projection onto a television screen, limiting the depth of optical field for the operator and reducing visual cues that may have helped identify anatomical structures(2). Further, the range of movements is reduced to four degrees of freedom, forcing the surgeon and their assistants to undertake non-ergonomic positions, which can add to the physical burden of the operation (3) (figure 1).

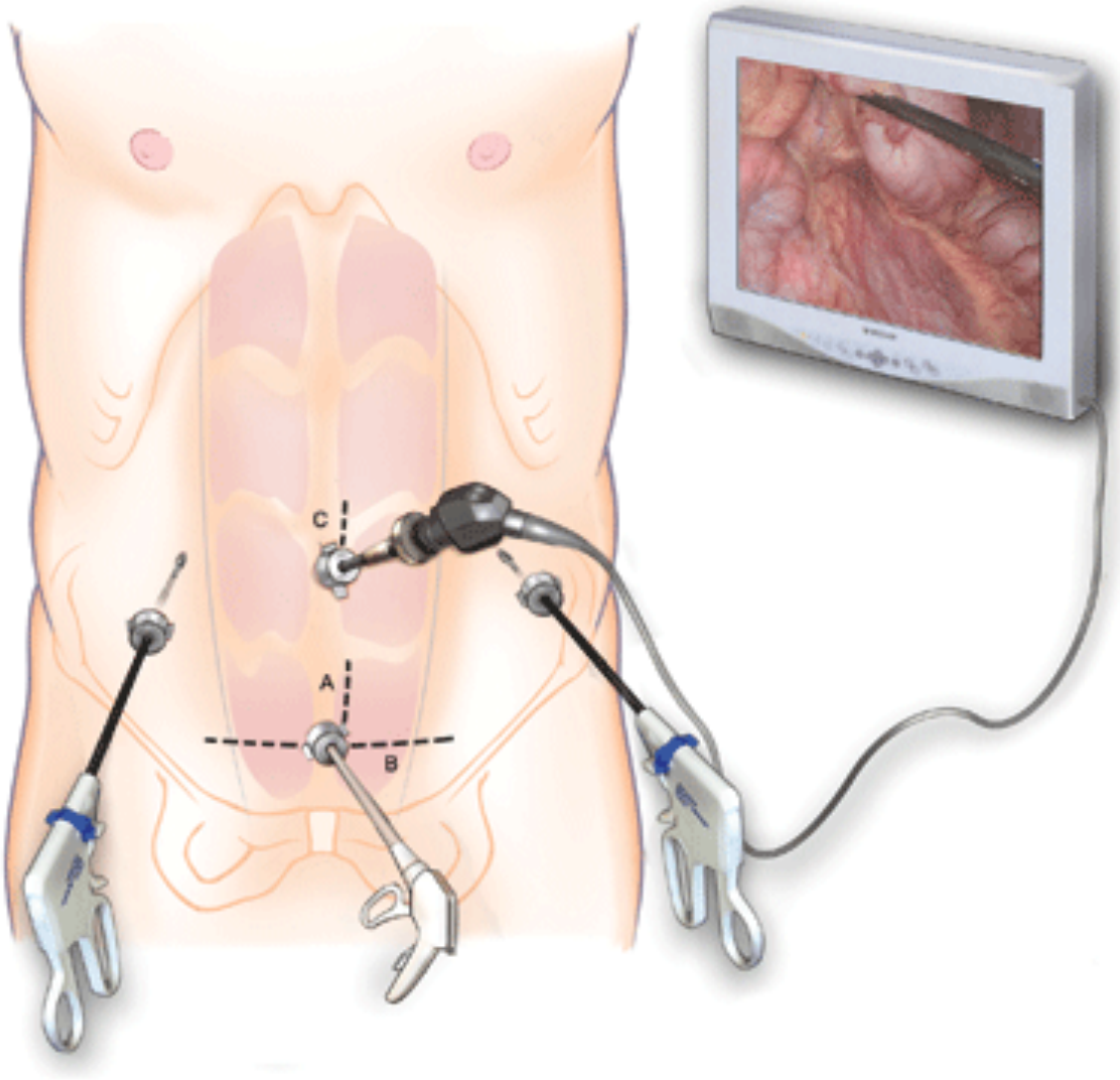


Figure 1. Minimally invasive surgery , reproduced from Columbiasurgery.org (4)

Although various training opportunities, such as courses using cadavers, animal models (5), virtual reality and physical simulators (6, 7) are available for some types of laparoscopic surgery, there is paucity of didactic methods for others (e.g. low anterior resection). Also, anatomical variability poses further difficulties (8-12), which are not reflected in existing training models. To overcome these limitations, patient-specific pre-operative planning has

been proposed (13-26). However, the methodology is rather diverse and success rates range considerably from 62.5% (25) to 100% (13). Furthermore, the majority of evidence on the clinical impact of patient-specific rehearsals originates from non-comparative studies (13-26).

Based on the current evidence, it is difficult to evaluate which technique is ideal for pre-operative planning. The most commonly used ones are virtual models, which are reconstructed into a 3D anatomical model from medical imaging such as CT or MRI, and synthetic (or physical) anatomical models, which are built through a computer process guided by how anatomical structures are depicted on medical imaging. A clinical RCT comparing different methods of preparation is necessary to identify the optimal pre-operative planning technique. Moreover, for comparison reasons, a common methodology that can accommodate the different types of anatomical models used for the surgical rehearsals should be sought.

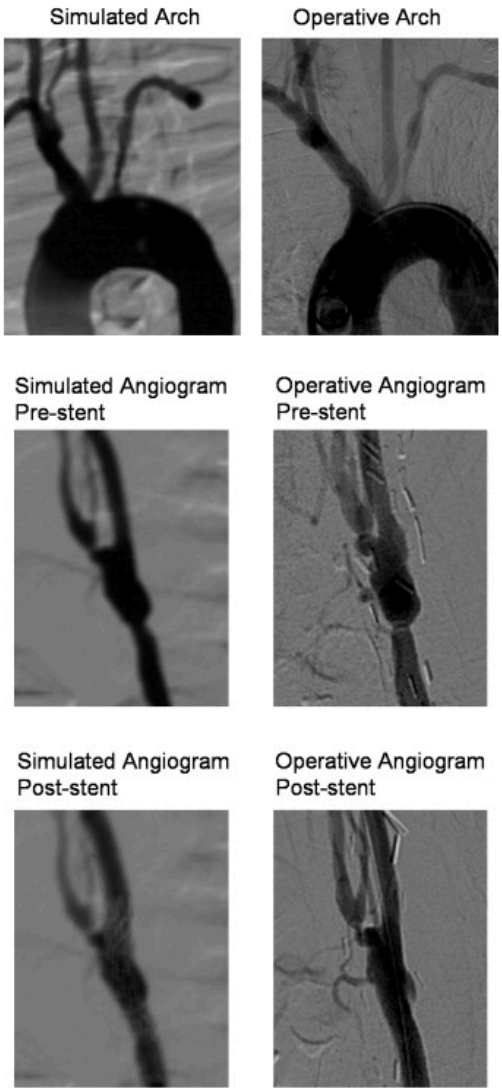


Figure 2. Patient-specific models and operative angiogram. Reproduced from Hislop *et al.* (22).

Besides rehearsals using anatomical models (16, 21-23) (Fig. 2) and VR simulators (23, 24), several studies assessed mental simulation of a surgical procedure without physical movement (known as mental practice or mental imagery) as a form of pre-operative preparation (27-30). During this technique, the surgeon is required to recreate images of the anatomical structures included in the rehearsed procedure. For this step, surgeons would usually use cognitive pictures acquired from their past surgical experience.

However, this may no longer be necessary as the technology for recreating 3D virtual and physical models from 2D medical imagery, is now readily available and more cost-effective than in the past. These anatomical models can replace the mentally produced image, offering the opportunity of patient-specific preparation. In addition, by introducing different types of anatomical models to the mental preparation, comparisons would be possible, paving the way for a randomised controlled trial.

1.2 Minimally invasive gastrointestinal surgery

While seeking a methodology to teach and prepare for complex laparoscopic procedures it is important to understand how this type of surgery has evolved and the advantages and limitations.

1.2.1. History of minimally invasive surgery – an overview

Laparoscopy is formed by the unison of two Greek words; ‘lapara’, referring to the abdominal cavity and ‘skopein,’ meaning to inspect. The term refers to the technique of using an endoscope to access and assess the abdominal cavity (31). The history of laparoscopy is lengthier that most think. As early as 460 - 375BC Hippocrates used an apparatus with structural similarities to endoscopes to examine the rectum (32), and a natural light source was incorporated to early endoscopic tools by Albukasim in 936 - 1013AD (33).

The next milestone in minimally invasive surgery was in the nineteenth century when Bozzini, a German doctor, used mirror reflected candle light to illuminate a tube-like instrument advanced into the urethra to assess the bladder (34). Segales and Fisher used similar methods in the 1800s (35). In 1853, Desormeaux designed an open tube endoscope, achieving a brighter light source by condensing light beams produced in a kerosene lamp, burning

a mixture of turpentine and alcohol. Unlike previously used reflectors or prisms, he used a lens (35).

The invention of the light bulb by Edison in 1880 gave a significant boost to endoscopic instrumentation design, making procedures like laryngoscopy, oesophagoscopy and proctoscopy rather frequent investigations from the late 1800s onwards (36). George Kelling, a surgeon in Dresden, attempted the very first laparoscopy in 1901. The technique, named Koelioscopie, entailed inserting a cystoscope through a trocar, into a dog's abdominal cavity and insufflating oxygen to establish pneumoperitoneum (36). In the same year, a Swedish surgeon Jacobaeus inserted a cystoscope into a human peritoneal cavity without establishing pneumoperitoneum (37).

Kelling reported forty-five laparoscopies describing physiological as well as pathological findings (33). These reports generated worldwide spread of laparoscopic techniques, including at the John Hopkins Hospital in 1911, when Bertram Bernheim introduced laparoscopy to the United States (37).

In 1924, Zollikofer used CO_2, instead of atmospheric air, as the infiltrating gas for creating pneumoperitoneum. The rationale was that CO_2 would reduce discomfort because it is absorbed easily by the human body, resulting to more rapid reduction of the intra-abdominal pressure after surgery. Also, CO2 is less combustible than air, making the operation less susceptible to complications when heat is used (38).

German physician Heinz Kalk instigated the next development. In 1929, he invented a new lens allowing him to view internal organs obliquely. He used this new equipment in conjunction with the dual trocar puncture technique he developed leading to improved organ visualisation and facilitating the entrance of instruments through the peritoneum. Kalk published over twenty-one papers between 1929 and 1959, reporting the outcomes of various laparoscopic operations on patients (37, 39).

In 1938, Janos Veress invented a needle, to help induce pneumothoraces as treatment for tuberculosis. This was a spring loaded blunt needle, bearing a cover which sprung forward to conceal a sharp needle in response to alteration in pressure as it entered the pleural cavity. Today, the Veress needle is used to create pneumoperitoneum in the abdominal cavity (39).

Increasing interest in laparoscopic surgery in the next decades produced rapid advancements in equipment and operative technique. The invention of the “cold light” illuminator, with the use of fibreglass in 1952 by Fourestier, Gladiu and Valmiere, eased concerns regarding laparoscopy because it eliminated intraperitoneal burns caused by previous light sources (40, 41).

By the 1960s, laparoscopic surgery was widely used in gynaecological surgery. Kurt Semm, a German gynaecologist designed an automated

insufflator to monitor intra-abdominal pressure, increasing the safety of the procedure and disposing of the need for a syringe to establish pneumoperitoneum (42). Semm also introduced thermocoagulation in laparoscopy (39) and developed his own techniques aiming to replace open with laparoscopic gynaecological surgery as well as popularised procedures such as laparoscopic omental adhesiolysis, tumour biopsy, uterine perforation repair, endometrial implant placement and bowel suturing (37). He was the first surgeon to perform laparoscopic appendicectomy in 1983 (31). He developed his own training device the “Pelvitrainer”, which he used to train his peers and juniors (40).

Meanwhile, general surgeons were far more reluctant in embracing this new type of surgery. This changed in 1986 when technological advances allowed camera images to be projected onto video screens (39). A laparoscopic cholecystectomy performed by Phillipe Mouret in 1987 was considered to be the first procedure using this technology (41).

Relatively recent developments in the field of laparoscopic surgery include Natural Orifice Transluminal Endoscopic Surgery (NOTES) and single-incision laparoscopic surgery (SILS). NOTES builds on the idea of minimally invasive surgery promoting scarless operations that do not require any skin incision. The first appendicectomy without an incision of the skin was performed transgastrically by Reddy and Rao in 2004 (43) with the first NOTES cholecystectomy being performed by Marescaux *et al*. in 2007 (44).

Although a few human cases of NOTES have been performed, the development of this technique is still in its infancy and has not gained popular acceptance . A compromise between NOTES and traditional laparoscopic practice is single incision laparoscopic surgery (SILS). 1997 saw the first ever SILS laparoscopic cholecystectomy performed by Navarra *et al*, who inserted two trocars into the umbilicus, bridged only by a small strand of fascia which was then divided to aid gallbladder removal (45). Compared to traditional laparoscopic surgery, SILS further minimises invasiveness by undertaking the operation via only one abdominal access point (46). Research continues into perfecting the technique and establishing it in routine practice.

1.2.2 History of minimally invasive colorectal surgery

Jacobs *et al.* (47) performed the first laparoscopic assisted colectomy in 1991, a procedure more technically challenging compared to others performed in a minimally invasive manner until then. It required identification of the bowel segment to be resected, dissection in more than one quadrant of the abdomen, mobilisation and transection of the bowel, identification and transection of the segmental vascular structures, specimen retrieval and formation of an anastomosis (48).

Initially, minimally invasive colorectal surgery was reserved for benign disease. Early reports of unusual metastatic spread and port site metastasis in up to 21% of cases were a deterring factor for the application of laparoscopy in colorectal cancer resections (49). Further investigation showed that rates of port site metastasis were comparable to wound and drain metastasis in open surgery, at around 1%, helping to alleviate fears about the use of laparoscopy in malignant disease (50-53). Further support for laparoscopic colorectal cancer surgery came from several well-designed, randomised controlled trials comparing the safety and efficacy of laparoscopic as compared to the open technique (54, 55). In the UK, Guillou *et al.* (55) conducted the MRC-funded CLASICC (Conventional *versus* Laparoscopic-Assisted Surgery In Colorectal Cancer) trial. This was a multi-centre randomised controlled trial recruiting 794 patients with colorectal cancer from 27 UK centres. 526 were randomised to have laparoscopic surgery and 268 open surgery. The outcomes included safety (morbidity and mortality), short and long-term oncological outcomes (circumferential resection margin positivity, local and distant recurrence, survival), quality of life and health economics. CLASICC demonstrated that laparoscopic-assisted surgery produced similar short and long-term outcomes as open surgery, with the exception of anterior resection where there were concerns regarding a higher circumferential resection margin positivity rate in the laparoscopic group, although this did not translate into a difference in local recurrence on long-term follow-up (55). Similarly, an NIH-funded multi-centre trial in the US, the COST (Clinical Outcomes of Surgical Therapy) study, showed that laparoscopic colon cancer surgery was non-inferior to open surgery (56, 57).

The consensus of both trials, and a subsequent meta-analysis, was that laparoscopic surgery was feasible and safe, offering at least similar oncological results to open surgery (54-62). It should be noted that transverse colon cancers were excluded from both CLASICC and COST, and COST recruited just colon cancer, which has implications for wider generalisability (55, 56).

A common finding of all the early studies of laparoscopic colorectal surgery was the high rate of conversion to open operation. This was attributed to the increased technical difficulty associated with the laparoscopic approach and the long learning curve to becoming proficient with a different skills set. A minimum of 20-50 procedures were required to reach basic proficiency for laparoscopic colectomy (63). Laparoscopic colorectal surgery was supported with the introduction of relevant guidelines (64) however, surgeons were cautioned that such techniques should be undertaken by experienced practitioners who have completed appropriate training (48).

As previously mentioned, rectal and transverse bowel cancer were largely excluded from studies comparing laparoscopic and open approaches. However, once confidence had been gained in laparoscopic colon cancer surgery, the next logical application was for laparoscopic total mesorectal excision (TME). Open to laparoscopic approach was compared through a number of studies (65-67). Trastulli *et al.* conducted a meta-analysis of nine RCTs including 1544 patients, 841 of whom had laparoscopic surgery and

703 open. They concluded that laparoscopic surgery for rectal cancer had several advantages, including significantly less blood loss, earlier resumption of normal diet and bowel function and shorter hospital stay. The incidence of post-operative abdominal bleeding, late adhesional obstruction and late morbidity was significantly less for patients who underwent laparoscopic rectal cancer surgery. No difference was found in short or long-term oncological results (66).

It is of note that although a recent large, multi-centre trial including 486 patients with clinical stage II or III rectal cancer, comparing open to laparoscopic surgery showed similar success rates between the two approaches (completion of resection – Circumferential Margin (CRM) >1mm and Distal Resection Margin (DM) (-)), the non-inferiority of laparoscopic surgery in regards to oncological results, was not established. The study concluded that laparoscopic surgery is not justified in stage II and III rectal cancer patients (68). Conversely, de'Angelis *et al.* who conducted a multicentre propensity score matching study including also locally advanced pT4 rectal cancers (stage II/III/IV) (n=137), showed laparoscopic cases to have good oncological results, which were comparable to open surgery (69). These conflicting results are further testament that laparoscopic rectal cancer surgery is more technically demanding that colonic surgery.

Similar to other types of gastrointenstinal surgery, techniques such as NOTES and SILS were also applied to colorectal surgery. Robotic surgery was another landmark new technique used for colorectal procedures.

1.2.3. Robotic colorectal surgery

The first robotic colectomy was performed in 2002 (70). By 2004, D'Annibale *et al.* reported 52 cases, including 10 rectal cases, concluding that similar operative and post-operative results were achieved with robotic and laparoscopic techniques (71).

In 2006, the first 6 cases of robotic TME were documented (72). Rawlings *et al.* in 2007 reported 17 robotic right hemicolectomies and 13 anterior resections, concluding that robotic surgery was feasible and safe (73). A similar outcome was reached by Spinoglio *et al.* in 2008 who compared 50 robotic resections to 161 laparoscopic operations (74).

A systematic review published in 2014 assessed robotic rectal surgery. It included 17 case series, 14 comparative studies and 1 randomised controlled trial (RCT). Robotic surgery was associated with longer operative times compared to laparoscopic surgery and no difference in regards to blood loss and oncological outcomes (positive circumferential margins and number of retrieved lymph nodes). Conversion rates (to open surgery) were found to be

lower for robotic surgery (75) (76). A number of studies show equivalence or superiority of robotic, compared to laparoscopic surgery, in regards to post-operative complications, including anastomotic leak (72, 75, 77).

A more recent review of 24 studies (2 RCTs and 22 Non RCTs), conducted by Zhang *et al*. (75), included 3318 patients, 1466 of whom had robotic and 1852 laparoscopic surgery for colorectal cancer. They found no differences in operation times, complication rates and oncological outcomes. While surgery related cost is higher for robotic surgery the total hospitalisation-related cost is similar between robotic and laparoscopic surgery (75).

Emerging evidence show that robotic surgery may have superior outcomes in preservation of sexual and bladder function compared to laparoscopic TME surgery (78, 79). The main reason for genitourinary dysfunction is injury to the hypogastric and/or to the sacral splachnic nerves. It is believed that improved visualisation which can be best accomplished with robotic surgery, contributes towards the preservation of these nerves, hence achieving better preservation of sexual and bladder function (80). Ozeki *et al*. (79) conducted a non-randomised, prospective study, recruiting fourty-five consecutive male patients who underwent open or robotic surgery. The primary outcomes of the study were urinary and sexual function post-operatively, which were found to be similar between the two groups.

A large multicentre trial is on-going assessing amongst other variables functional outcomes. The MRC/NIHR ROLARR (RObotic Versus

LAparoscopic Resection for Rectal Cancer) study is a prospective randomised controlled project assessing the safety and efficacy of robotic rectal cancer surgery, comparing it to laparoscopic surgery. The primary outcome in ROLARR is conversion to open surgery, based on the hypothesis that the robot makes anterior resection technically easier. Secondary outcomes include oncological safety (circumferential margin positivity, recurrence and survival), intra-operative and post-operative complications, 30-day post-operative mortality, sexual and bladder dysfunction, quality of life, and health economics (81). 471 patients were recruited in 29 centres in 10 countries of whom 466 completed the study. ROLARR concluded that robotic surgery does not decrease the need for conversion to open surgery and no statistical difference was found for other end points including disease free circumferential margins, complications, bladder and sexual dysfunction and 30-day mortality (82)

Figure 3. The da Vinci® surgical robotic platform (83).

1.2.4 Advantages and disadvantages of laparoscopic surgery (compared to open surgery).

Similarly to open surgery, the primary aim of laparoscopic surgery is to achieve a good oncological outcome. Potential advantages of laparoscopic surgery are reduction of surgical access trauma, diminishment of the inflammatory response to surgery (84, 85), and preservation of postoperative immune function (85). The reduction in post-operative pain, ileus and respiratory tract infection allow for earlier mobilisation and discharge from hospital (86). Patients undergoing laparoscopic surgery have quicker recovery time and return to normal activities earlier compared to open surgery. Moreover, there is less need for post-operative analgesia, less blood loss during surgery and post-operative complications (54, 87-93). When used in cancer cases, laparoscopic surgery has been shown to have equivalent short- and long-term oncological results to open surgery (74, 76, 94-96). Whilst in the early years of laparoscopic colorectal surgery multi-centre randomised controlled trials assessing the long-term oncological results were scarce (76), recent studies have addressed this showing encouraging results.

Laparoscopy sceptics would argue about increased cost (97, 98) and prolonged operative time (74, 76, 94-96). NICE addressed concerns about the

cost-effectiveness of laparoscopic surgery by appointing an assessment group to conduct a systematic review and economic evaluation of the clinical and cost effectiveness of laparoscopic colorectal surgery (98). The systematic review and meta-analysis evaluated data from studies conducted between 2000 and 2005 and was based on a balance sheet and modelling approach. In regards to clinical effectiveness, the committee acknowledged that there were differences in the short term outcomes of the two techniques - laparoscopic surgery was associated with longer theatre times and shorter hospital stay, however, the long-term outcomes, such as tumour recurrence, disease free or overall survival at three years, were similar if performed by appropriately trained surgeons. Regarding cost-effectiveness, laparoscopic surgery bore a higher cost with an estimated mean difference of 265 pounds (95% CI -3829 to 4405) compared to open surgery. In addition, case-base analyses showed favourable results for open surgery compared to laparoscopic. However, acknowledging that significant quality of life benefits associated with laparoscopic surgery (earlier return to work/normal daily activities) most likely exist but have not been captured by the evidence available at the time, the committee felt that laparoscopic surgery is cost effective and a good use of NHS resources (99).

Another concern are the physiological effects caused by patient positioning and pneumoperitoneum which can be detrimental on patients with cardiac and pulmonary co- morbidity (100-102). Increased abdominal pressure, patient positioning and absorption of $CO_{2,}$ used to establish pneumperitoneum, can

be harmful to patients (100-102). Prolonged head down position should be avoided due to fears of increasing intracranial pressure. Intra-abdominal pressure should be reduced for patients with cardiovascular and pulmonary disease to avoid respiratory acidosis due to CO_2 absorption (103) or a decrease in cardiac index due to reduced venous return, as a result of direct pressure onto the inferior vena cava (100).

Increasingly, surgeons are required to operate on elderly and frail patients with significant co-morbidities (104), which adversely influence surgical outcomes (105). There is increasing evidence that minimally invasive surgery provides improved outcomes in elderly patients in a similar manner to the younger population (30,34, 56,60). This is particularly true in frail patients whose recovery can be severely compromised if they undergo more invasive procedures (105).

1.2.5 Learning curves

A learning curve demonstrates the improvement in performance of a task conducted repeatedly. Initially, the rate of improvement is high but as the number of repetitions increases, it becomes limited until change is unnoticeable. Learning curves are usually portrayed as an exponential graph containing three main parts, a steeply increasing line (high improvement rate), a turning point and then a flat horizontal line (undetectable improvement – plateau part of the curve) (106) (Fig. 4a). Learning effect can also be

demonstrated as the horizontal mirror image of the graph described above using Wright's law [$f(x) = ax^k$ – a: first attempt result and k: log of learning rate divided by log of 2] or other mathematical models (107) (Fig. 4b).

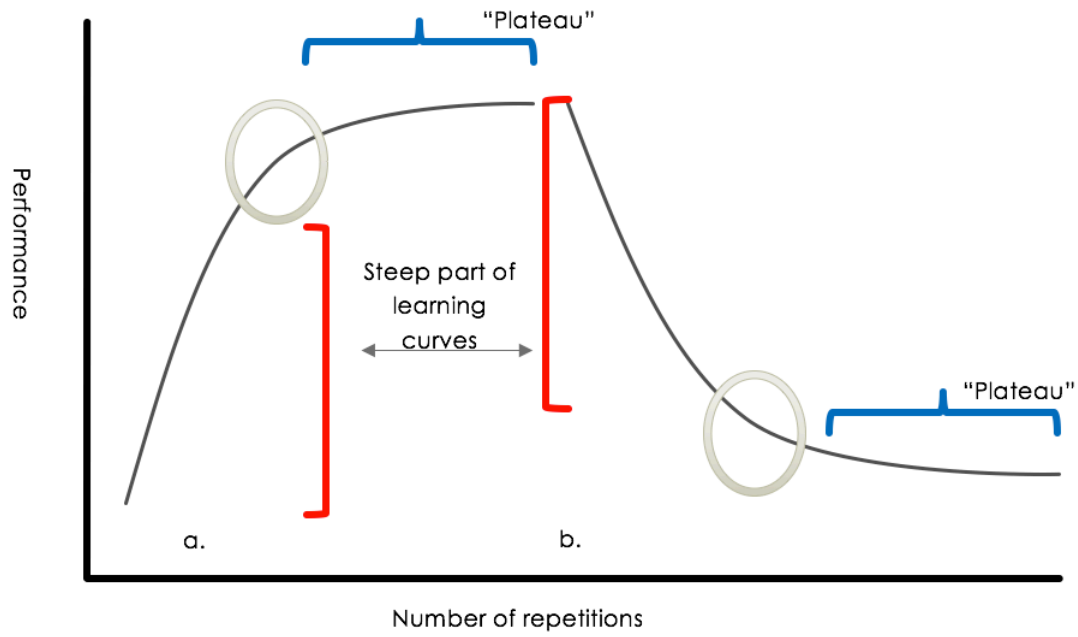


Figure 4. a. Learning curve. b. Learning curve after Wright's law is applied. Circles indicate "turning point".

The learning curves for the procedures chosen to test the novel pre-operative rehearsal techniques are discussed below. The operation of choice for the pre-clinical (simulation) studies was Laparoscopic Cholecystectomy (LC). The reasons for this choice were:

- LC simulators (LAP Mentor ®) (108) are readily available in the region
- Simulated operations with the selection of six anatomical variations are available (108).
- LC is a routinely performed procedure (109)

- The anatomy of the gallbladder and its blood supply may vary significantly (110).
- LC involves complex laparoscopic skills (111).

For the clinical trial minimally invasive (MI) Anterior resection or Total Mesorectal Excision – TME was used. The reasons for selecting this procedure were (i) at the time of commencement of this project there was no commercially available training model for this procedure (ii) technically, it is a highly demanding procedure notorious for prolonged learning curves (112), (iii) it is performed at much higher frequency than in the past (in UK laparoscopic approaches for colorectal cancers rose from 5% in 2003 to 40% in 2011 (113)), and most importantly (iv) individual anatomical and tumour characteristics have been shown to pose an additional difficulty in rectal cancer surgery (8-11)

1.2.5.a. Laparoscopic cholecystectomy

The steep part of the laparoscopic cholecystectomy learning curve has been shown to stabilise after 30-35 procedures according to a number of studies (114-117). Interestingly, Voitk *et al.* showed that there is still detectible improvement (time to complete procedure) after two hundred procedures. After three hundred procedures, no further improvement was documented. The least improvement was noticed for “easy” cases, whilst more challenging ones become easier further down the learning curve, indicating that more

experienced surgeons have the ability to recognise and promptly solve issues related to anatomical variations and more severe disease (118).

The above findings are relevant for the current projects because: (i) they illustrate the learning effect and overall room for improvement within the first three hundred procedures (ii) they demonstrate that training methods should accommodate both “easy” and “difficult” operations as these appear to have a different learning rates. Performing three hundred cholecystectomies within the time constraints of surgical training in the UK would be a difficult task, therefore training adjuncts should be introduced to accelerate the learning process, particularly for difficult procedures.

1.2.5.b. Laparoscopic rectal cancer surgery

Although the degree of difficulty may vary between different procedures, laparoscopic colorectal surgery is difficult to learn (119). A review of 4852 cases by twenty-six surgeons in seven institutions, including both cancer and benign cases, showed the average number of colorectal procedures required for a learning curve to plateau, as defined by successful completion without conversion, to be 152 procedures. Complications were significantly reduced after 143, whilst operating time was decreased after 96 procedures. Although specific analysis for laparoscopic rectal cancer surgery was not undertaken,

pelvic dissection, in male patients in particular, was identified as one of the risk factors for conversion to open surgery and complication occurrence (63), indicating increased technical difficulty.

This is in line with the findings of other studies showing the learning curve for laparoscopic total mesorectal excision (TME) to be more prolonged than colonic surgery (120), with the distal resection of the rectum posing a particular challenge (121). Son *et al.* looked at four hundred thirty one patients and found the turning point of the learning curve to be 79 for complication reduction and 75 for operating time reduction. When a combination of outcomes (conversion to laparotomy, intraoperative complications, postoperative complications, reoperations, operative time, and transfusion volumes) was considered, the effective learning effect was found to occur between 60-80 procedures (122).

It should be noted that the above studies recruited surgeons experienced in open surgery, therefore the learning curves reported may not apply to trainees. Nevertheless, the reported numbers of procedures needed to reach learning curve turning points require significant training time commitment. Furthermore, patient characteristics, such as gender, body mass index and pelvic dimensions as well as tumour characteristics [distance from the anal verge, size] can increase the technical complexity of rectal cancer surgery (8-10, 63) and further prolong the learning process.

1.3. Training methods for laparoscopic surgery

Various learning methods have been proposed for teaching laparoscopic skills. Amongst these are the use of training boot camps with a mixture of lectures and hands-on practice (123-125), cadaveric surgery workshops (126), virtual reality (108)(108)(108) and low fidelity simulators (127-132). More recently, mental practice has been proposed to augment surgical skills training (133).

Whilst both simulation embedded training courses and mental practice show promise, they were used for enhancing a generic set of skills and they are more often than not targeted at laparoscopy novices (133, 134). Although such preparation may suffice for straightforward cases it may be inadequate for complex cases (e.g. large tumours, high BMI, narrow pelvis). Therefore, a new methodology should be developed to accommodate patient-specific preparation prior to complex gastrointestinal laparoscopic surgery.

Learning points for current project:

- Laparoscopic surgery is technically demanding
- Laparoscopic techniques have prolonged learning curves
- Changing population characteristics (e.g. ageing, obesity), introduction of novel technology to laparoscopic surgery and restriction in working time have altered the training needs of contemporary surgeons
- Novel training methods are needed for laparoscopic surgery

1.4. Mental practice in surgery

Motor imagery (MI) is often defined as the cognitive simulation of an action without explicit physical movement, conducted in order to augment task-related performance (135-137). One distinction is whether the process is visual or kinaesthetic (138); the former relates to visualising, watching oneself or another individual performing a specific movement, whilst the latter involves imagining the feelings normally produced during the actual motor task (139).

Evidence from cognitive neuroscience indicates that imagined movements share similar neural networks as performed actions (140), which has led to the intriguing possibility that MI could potentially be used as a training and performance facilitation tool for technical surgery related skills. The repetition of mental imagery is defined as Mental Practice (MP) (141) and recent studies have explored the possibility of using MP for surgical training, with encouraging results (27, 28, 142, 143).

It is important whilst designing the current project, to review the relevant literature and understand the physiological pathways of MP as well as established how it was previously applied in surgery.

1.4.1. Visual imagery (VI)

MP involves the generation, maintenance, inspection and transformation (144-146) of an image. An image may be created in two distinct ways (147); from direct perceptual information and from resurfacing information previously stored in long-term memory (148). Such production may be a voluntary or an involuntary process (148) and the images generated could be generic, specific, periodic or modified by one's own personal experiences (149, 150). It is worth noting that MP is not restricted to generation of visual images, but is often also used for simulating audio (151, 152), olfactory (153), and haptic imagery (154), which could be useful in recreating not only the sights, but the sounds and smells associated with the operating theatre.

A key component for image maintenance is attention (147, 155, 156) with research indicating there are greater attentional demands than those required by typical everyday activities (157-159). Producing and retaining an image opens the door to assessing morphological and other features of the objects (148) through "image inspection", which includes identifying spatial relationships between objects (145).

Manipulation of visual images is an additional step in the process of imagery (147, 156) with examples including mental rotation, zooming and object transportation (144, 160). More complicated forms of image manipulation include restructuring, during which the perception of images can be altered in

a specific manner (161). Mental synthesis involves the blending of rotation and image restructuring. During synthesis different parts of an image are altered in order to create novel designs and explore new possibilities (156).

1.4.2. Kinaesthetic imagery (KI)

KI is the imagery of movement and muscular activity, whilst visual imagery is associated exclusively with the sense of sight (162). During KI, the motor action is internally re-enacted, and interestingly follows the constraints associated with human sensorimotor control (157-159, 163). During KI, the participant imagines the practiced task from an internal perspective (139).

Kinaesthetic and visual imagery are not mutually exclusive and can therefore occur simultaneously (164). Surgeons participating in studies involving mental preparation are often asked to experience both visual (“see” the procedure) and kinaesthetic (“feel” the procedure) stimuli (165). The ability to perform kinaesthetic imagery and the degree of engagement in cognitive tasks can be objectively evaluated (166, 167). Good imagers divert the corticomotor excitability towards the muscles involved in the actual performance of the movement whilst the distribution of potentials in bad imagers is not muscle specific (167). It should be noted, however, that the initial ability can be modified, increasing proportionally to experience of motor execution (168-170). These have implications for the application of MI in surgery, suggesting

that methodologies should be tailored based on surgeon expertise and baseline abilities.

1.4.3. Cognitive practice and motor skill acquisition

Active cognitive engagement is necessary for motor skills acquisition (171, 172). Cognitive and motor processes share common features, such as improved performance with practice and, conversely, decline with lack of practice. Moreover, initial stages of imagery practice and motor skills learning have identical objectives and feedback can play an essential role in both, with automation following repeated practice (140). MP includes reflexion, problem solving and “reality check” stages (140), whilst sensory feedback is a vital part of early associative phases of motor task learning (173). A classic motor learning theory, Schmidt's schema motor programme theory, highlighted the importance of mentally storing how a task looks, feels and sounds as a form of performance (174), modifying feedback processes that are fundamental components of visual and kinaesthetic MI. Identifying how a surgical procedure is “experienced” by experts has been a common method in preparing MP scripts to train novices (142, 143).

Further, experimental evidence indicates that the time required to perform a task mentally is proportional to the time needed for the task to be performed physically (160). Visual perception (146) and memory (145) play a significant role in mental imagery too (175, 176). Motor imagery is also subject to similar

computational models as the overt motor actions, including alterations in performance caused by sensory feedback and other movement response regulating factors (177) (157, 178-180). Common cortical and subcortical networks observed by neuroimaging studies demonstrate that mental practice engage motor-related networks, including the supplementary motor area (181, 182), the parietal cortex (183-186), the premotor cortex (182, 183, 187), the primary motor area (184, 188, 189) and the cerebellum (190).

Similarly, electroencephalography studies show substantial overlap in scalp-related electrical activity in response to real and imagined actions (191-193). Cunnington *et al.* documented movement related potentials (MRP) produced by cortical activity, usually evoked by voluntary physical movement, during the preparation of imagined movement (192). Source analysis from EEG studies also points to the primary motor structures being implicated in mental and physical task performance (193). Similarly, DC potential signals localised to the sensorimotor hand area (194)) while subjects perform or imagine various hand movements appear both quantitatively and qualitatively equivalent for imaginary and actual task performance (191).

1.4.4. MP compared against existing skill learning methods (simulation)

One of the most frequently used training tools in surgery is simulation, which has long been considered a useful adjunct to traditional training (134). However, a frequent criticism of current simulation approaches is that they are

unable to fully replicate the experience of conducting an operation (195). During MP the “reconstruction” is not limited to visual stimuli, as audio (151, 152), olfactory (153), and haptic (154) “images” can also be created and, potentially, could be used to provide a holistic representation of the theatre environment. Thus, MP offers the possibility of producing high fidelity simulation that cannot yet be matched by technology even with the advent of fully immersive VR systems.

In addition, image synthesis, manipulation and restructuring occurring during the image inspection phase of MP also make this process ideal for the diversity one may encounter during surgical procedures. For instance, mentally practicing the removal of the peritoneal covering from Callot’s triangle during laparoscopic cholecystectomy could be achieved through restructuring the initial image of the gallbladder and liver. This can “reveal” an altering image allowing the surgeon to prepare for anatomical variations (e.g. proximal bifurcation of the cystic artery) and complications (e.g. common bile duct injury). This type of fidelity is rarely available in current simulators or even in animal models.

Furthermore, simulation bears a significant cost and requires dedicated facilities. Despite the fact that it has been applied in surgery for at least the last two decades, its cost-effectiveness and impact on patient outcomes remains to be conclusively established (134). Conversely, MP has minimal expenditure and can be performed at any time, anywhere. After initial training

sessions, MP can be effectively performed without the need of supervision (142, 143), although it is worth noting that there is some evidence that unsupervised simulation training may not yield the same degree of performance (196)).

Besides learning basic surgical skills and initial stages of operations, we speculate that MP could be used for a variety of purposes. For example, expert surgeons could use it to practice technically complex operations (197). For others, it may be a cost-effective way of maintaining technical skills whilst on a career-break. It could potentially also be useful for reducing the learning curve of an operation (140), which is particularly relevant in the “no learning on patients” era where there is a need for a concerted effort to the surgical training paradigm from one of high quantity to high quality for learning.

1.4.5. Application of MP for experts and non-experts

As MP provides a route for the learning of motor skills (198), it could be utilised across all levels of training. For example, inexperienced surgeons could reflect on partial surgical tasks such as achieving access to the abdominal cavity, whilst more experienced surgeons could practice steps of the operation they have seen but not yet performed. Experts could rehearse variations that could potentially occur during technically demanding procedures (140).

A recent systematic review conducted by Rao *et al.* (133) assessing the role of mental practice in the acquisition of surgical skills which included nine randomised controlled trials and 474 participants, reported that five out of nine trials showed a favourable outcome. The RCTs that describe favourable results taught a variety of skills ranging from basic skills (e.g. cutting a circle drawn on a rubber glove in a box trainer) to full procedures (e.g. laparoscopic cholecystectomy in a box trainer using porcine liver and gallbladder) (28, 30, 142, 143, 199). The assessment tools used in these studies were equally diverse and included objective (e.g. checklists, time to complete task, number of instrumental tip movements) and other non objective measures (28, 30, 142, 143, 199). Interestingly, the studies that did not show any significant impact of mental practice on the acquisition of skills used very similar tasks and evaluation methods as the ones that did demonstrate a difference (e.g. circle cutting in a box trainer and checklists, scoring systems for assessment) (27, 29, 200, 201).

The authors of the systematic review attributed the difference in results to the duration of the mental practice sessions and the number of times these were repeated. However, the difference in duration between the studies that did and did not show a statistically significant difference was as low as five minutes (133), raising the question on whether there is a separate factor contributing to boosting the effect of mental practice.

Nevertheless, the evidence regarding the impact of MP on surgical skills of experts is non-existent as comparative studies have thus far only recruited medical students (27-29, 199-201) and surgical trainees (30, 142, 143).

As a recent systematic review was conducted by Rao *et al. (133),* it was decided that another systematic review would not provide further insights. Rao *et al.* (133) looked at 7985 studies and finally included nine RCTs which matched their inclusion criteria. In summary, four studies (27, 29, 200, 201) showed no effect of mental practice on surgical skills. The remaining five (28, 30, 143, 165, 199), showed a favourable effect of mental practice on surgical skills. The authors attributed the difference in results to the duration of the mental practice sessions. All (28, 143, 165, 199) but one (30) showing a favourable effect used thirty minute mental practice sessions. The studies' further characteristics (e.g. type of surgical skills, mental practice methodology, assessment methods etc.) are discussed below.

1.4.6. Content and duration of MP sessions

The structure and duration of mental practice sessions in surgery can vary greatly. For example, Mulla *et al.* (201) provided medical students with a 25-minute one-to-one mental training session, which comprised step-by-step descriptions of the motor skills required, relaxation techniques, as well as intrinsic and extrinsic visualisation of the chosen task for assessment. Subsequently, the students were asked to undergo 15-minute self-driven

practice sessions daily. Three randomised controlled trials (RCTs) provided a 30-minute single session to the participants. These included psychologist-led relaxation techniques, step-by-step breakdowns of procedures embedded with sensory cues and surgeon supervised mental imagery practice sessions. Of these, two showed a favourable effect of mental practice on surgical skills and one showed no difference (27, 28, 199).

Two RCTs employed several 30-minute MP sessions immediately prior to the surgical procedural. These were based on a MP script and preceded by relaxation techniques. Both of these showed the groups who underwent mental practice to have performed better to statistically significant degree, when compared to their counterparts who did not embark on mental practice (142, 143).

Immenroth *et al.* (30) offered the longest duration one-to-one mental training sessions, lasting 90 minutes overall. In contrast, some studies have had sessions lasting 5 (200) and 3 minutes (29) with participants being asked to repeat the process several times prior to assessment.

Currently, there is no established “cut-off” time for the duration of MP. What we know from previous studies is that sessions lasting 30 or more minutes produce more positive results than shorter ones (202). Importantly, it is worth noting that longer sessions may not be the solution as there is unlikely to be a linear relationship. Indeed, prolonged motor imagery sessions may have adverse effects on motor performance, due to mental fatigue (203). Alongside

delineating an optimal time, the pragmatics of conducting MP in a hospital setting with a time-poor environment also need to be considered.

During MP sessions non-expert surgeons are required to become familiar with the task they are about to perform (e.g. simulated laparoscopic cholecystectomy) (28, 200, 201, 204-206). Various training techniques have been proposed for this purpose. Eldred-Evans *et al.* (204) followed Peyton's 4-steps approach for teaching practical skills while others trained novices to proficiency before applying the MP intervention (143) or employed expert teaching (27, 28).

Once the surgeon has a relatively good understanding of the task, they are asked to physically practice it several times during supervised session(s). At the end of this process the surgeon may undergo an assessment to ensure their understanding of the task. Equally, they will receive training or instructions on how to practice mentally and then be asked to have a series of MP sessions, either supervised or self-driven (28, 142, 143, 199-201).

Surgeons may also be required to fill out a questionnaire to establish their baseline ability to practice mentally because the capability to reconstruct images mentally varies across individuals. Some frequently used scales include the Mental Imagery Questionnaire (142, 143, 207) or its revised version (Mental Imagery Questionnaire Revised Second version (MIQ-RS)) (207) as well as the Cube test, part of the Intelligence-Structure-Test 2000R

(29). The first two entail performing a task physically and then mentally and consequently assessing how difficult it was to do the latter (208).

1.4.7. Preparing an MP session

The most popular methods for designing a MP session for surgery are (i) achieving a consensus between experts on how the task should be performed (142, 143, 207), (ii) preparing physician/educator led sessions which include a breakdown of the procedure in steps in order to facilitate the visualisation process (27, 28, 199, 201) or (iii) a combination of the two (200). Consensus is usually achieved through a series of semi-structured interviews and consequent thematic analysis of their transcripts in search of visual and kinaesthetic cues. This process yields a script that requires subsequent validation (142, 143, 207).

The MP sessions described in the literature take place in a simulated environment using anaesthetised animals (27, 28) or inanimate models including box trainers (29, 199, 201), virtual reality simulators (142, 143), mannequins (200) and animal tissue (30, 207). This may be an option for one planning to run such a session in their institution. However, one should also consider that simulated environments are considerably more stress-free than clinical ones (209). The latter are highly pressurised and subject to mental

distraction and auditory stimuli, which are factors known to have detrimental effects on surgical performance (210). Hence, relevant adjustments should be made to increase the fidelity of a simulated environment, which could impact on their ability to transfer to an operating theatre.

1.4.8. Skills taught with MP

Various skills have been taught using MP, ranging from basic to procedural skills and full procedures. Some of the basic/procedural tasks include cutting out a 44mm diameter circle from a rubber glove using a box trainer or a virtual reality simulator (199, 201), opening and closing a midline incision on an anaesthetised rabbit (27, 28), or suturing during a laparoscopic Nissen fundoplication on a virtual reality simulator (29). Full tasks included a simulated laparoscopic cholecystectomy on a virtual reality simulator (142, 143), a porcine liver and gallbladder placed in a box trainer (30), and a laparoscopic jejunojejunostomy (207) and cricothyroidectomy on a mannequin (200). The diversity in difficulty and subspecialty of the chosen tasks demonstrates that MP can be a useful tool for all training grades and a variety of surgical specialties.

1.4.9. Outcome measures to assess MP impact

The most frequently used measure in studies to date is the all-encompassing overall performance metric, which may be a composite of any number of the following: time taken to complete a task, accuracy (29, 199, 201) and rating checklists (27, 28, 30, 142, 143, 200, 207). An indirect way to assess the MP sessions is questionnaires (142, 143, 207) addressed to experts or the participating trainees.

1.4.10. Outcomes of MP in surgery

Whilst MP was identified as a potential learning method for surgical skills more than a decade ago, there is a paucity of conclusive clinical evidence to support its efficacy. A mini review of the literature revealed that seven of the identified ten RCTs demonstrated a favourable effect of MP on technical skills (28, 30, 142, 143, 199, 207). One trial showed that MP with MI is equivalent to additional physical practice (27). On the contrary two RCTs (29, 201) showed MP to be inferior or have no impact compared to other types of preparation. Reduced MP duration was identified as one of the possible reasons for a lack of positive results (202). It is worth noting, however, that the majority of these studies include participants (i.e. medical students) who are not representative of the target population. The studies have certainly identified the promise of MP, but evidence of transferability to a clinical environment is practically non-existent.

1.4.11. Issues related to the application of MP in surgical training

As mentioned previously, the success of MP is associated with the expertise of the participant (168-170), therefore the duration and nature of the MP sessions should be modified according to the surgeon's stage of training. MP has been shown to increase movement accuracy (211, 212) and quality (213). However, the number of repetitions necessary for learning surgical procedures is still unknown and has to be evaluated through appropriately designed studies. The variance in baseline ability to perform MP should also be addressed perhaps with the introduction of an interactive anatomical model (virtual or real).

The implementation of MP within a busy clinical environment is subject to time restraints and increasing needs for service provision. Concrete evidence of the effectiveness of MP would be needed through the conduction of high quality, clinical, randomised controlled trials.

1.4.12. How can MP be patient-specific – a new hypothesis

Recreating mental images is a vital part of mental practice;if these are replaced by anatomical models replicating each patients' anatomy, the mental practice can be patient-specific.

For the purposes of surgical preparation, patient specific (PS) three-dimensional virtual and synthetic anatomical models can be built through the processes of 3D image reconstruction (13, 16, 18, 19, 21-24, 26, 214, 215) and additive manufacturing (14, 25) (i.e. Stereolithography (15, 216)) respectively. Moreover, physical cutting guides and implants can be designed and manufactured during the rehearsal process and then sterilised and used during the real operation (13, 16, 18, 19, 21-24, 26, 214, 215).

Several open source programmes have made 3D imaging reconstruction more accessible to the average computer user. The product of this process (i.e. virtual model) can be used for the purposes of pre-operative planning (13, 16, 18, 19, 21-24, 26, 214, 215) or can be used as a “stepping-stone” for the creation of physical models with the use of computer assisted designing and additive manufacturing (14, 25). The latter would allow the physical practice of the surgical procedure.

Additive manufacturing such as 3D printing, once considered “science fiction” is now available to academics, doctors and the general public, as desktop 3D printers are a reality (217). The term 3D printing refers to successive layers of materials placed on top of each other under computer manipulation (218). Such techniques, whereby a physical model is created using a computer aided design software are referred to using the collective term “additive manufacturing” (219).

Learning points for current project:

- Mental practice is a promising technique for the acquisition of motor skills
- Evidence about the feasibility of MP in a clinical environment are non-existent
- Evidence about the impact of MP on experts' performance are non-existent
- When tested in a simulated environment MP had favourable results for increasing surgical skills
- Clinical trials assessing the effect of MP on technical skills are needed.

1.5. Surgical rehearsals using patient-specific anatomical models

Surgical rehearsals using patient-specific anatomical models (without the addition of mental practice) were utilized in the past in various surgical specialties. Reviewing the methodology used previously could provide an insight on how anatomical models can be prepared for the current studies. Moreover, information will be received about feasibility, accuracy and clinical impact of patient-specific pre-operative preparations.

1.5.1. Methodology for patient-specific pre-operative rehearsals

The most common surgical specialities in the included studies are maxillofacial surgery (n=16) (14, 15, 20, 220-232) and orthopaedics (n=15) (13, 17, 214, 215, 233-243) (table 1) and whilst most preparation processes involved solely the surgeon, in two studies the entire surgical team was involved with the aim of achieving improved coordination (19, 244).

The methods for patient-specific preoperative preparation as described in the literature can be categorized into: i) *surgical planning*; allowing the surgeon to establish the surgical approach and dissection sequence, but not including a complete physical rehearsal of the procedure [e.g. inspection of anatomy with augmented reality environment platforms (26, 214)], or ii) *surgical rehearsal* (i.e. simulated surgery), where the surgeon had a variety of virtual surgical

tools at their disposal and performed all the physical and mental processes one would in a real theatre environment [e.g. performing surgery on a virtual reality simulator (19, 22-24)].

For the purposes of surgical preparation, Patient Specific (PS) three-dimensional virtual and synthetic anatomical models were built through the processes of 3D image reconstruction (13, 16, 18, 19, 21-24, 26, 214, 215) and additive manufacturing (14, 25) (i.e. Stereolithography (15, 216)) respectively. In some studies, physical cutting guides and implants were designed and manufactured during the rehearsal process and then sterilised and used during the real operation (13, 16, 18, 19, 21-24, 26, 214, 215).

A variety of medical imaging modalities are used for image 3D reconstruction including various types of Magnetic Resonance Imaging (MRI) (16-18), Computed Tomography (CT) (13-16, 18-20, 22-25, 214-216, 235) and more specialised imaging such as Diffusion Tensor Imaging (DTI) (26).

1.5.2. Comparators

Two types of comparisons are common: (i) results of rehearsals are compared to the ones of real operations (i.e. patients act as their own controls) (19, 22, 23) (ii) preoperative preparation methods are compared to standard treatment or computed aided surgery (i.e. two distinct groups of

patients) (17, 221, 227, 241, 245). The overall outcome in question is similarity between rehearsal and real procedure on the first occasion and assessment of possible superiority of the rehearsed procedures jcompared to non-rehearsed ones (evaluating for possible differences) in the second type of comparisons.

1.5.3. Type of outcomes

The most frequently used outcome measures in the literature are: (i) accuracy of pre-operative preparation methods (ii) clinical outcomes and (iii) surgeons' feedback.

(i) Accuracy of pre-operative preparation methods

Accuracy of the pre-operative preparation methods is reported using several outcome measures (table 1). The most frequently used are (i) number of cases in which the preoperatively formulated plan was successfully followed (13, 15, 18, 25, 214, 215, 220-222, 225, 226, 230, 232, 233, 235, 236, 238, 239, 242, 246, 247) (ii) anatomical accuracy of models compared to operative anatomy (15, 24), and/or (iii) validity of the pre-operative processes, as reported by surgeons/surgical team (19, 21-24). The results for accuracy range from 66.7-100% (table 2). Face validity [the extent to which a simulation appears similar to the real situation] (248) and content validity [validity of tests

based on detailed examination of its contents] (249) , where reported, was above 3.4/5, demonstrating good realism (Fig. 5).

(ii) Clinical outcomes

Immediate surgical outcomes, including peri-operative complications, are reported in most studies. For comparison, the number of cases that had a satisfactory outcome (e.g. anatomical reduction of a fracture) are presented as a percentage of the overall number of cases (table 2).

Author - Year – Country	Study design	Specialty	Sample size	Intervention
Perry et al. (14) 1998 - UK	CS	Max-Fax	21	Virtual planning of procedures and (for selected cases) inspection of physical models
Kockro et al. (16) 1999 - Singapore	CS	NS	21	Planning using a virtual reality platform
Lo et al.(228) 2004 - Taiwan	CS	Max-Fax	4	Rehearsals using physical models created through CAM – manufacturing of synthetic implants
Leong et al. (250) 2005- USA	CS	H&N	22	Preoperative virtual planning and 18/22 intraoperative navigation
vanSteenberghe et al. (216) 2005 - Switzerland,	CS	Oral surgery	27	Planning using virtual 3D images and construction of physical surgical guides and prostheses

Belgium, Sweden				
Radecka et al. (25) 2006 - Sweden	CS	Urology	8	Rehearsals with synthetic models manufactured using CAD
Gateno et al. (226) 2007-USA	CS	Max-Fax	5	Virtual planning and CAM of physical surgical splints and templates – intraoperative navigation for some cases
Xia et al. (232) 2007- USA	CS	Max-Fax	5	Virtual planning and CAM of physical surgical splints and templates – intraoperative navigation for some cases
Hislop et al. (22) 2009 - US	NRC	Vascular	5	Virtual operation on simulator
Lu et al. (251) 2009 - China	CS	NS	9	Virtual planning and manufacturing of navigational template through rapid prototyping
Ng et al. (18) 2009-Singapore	CS	NS	23	Planning using a virtual reality platform (Dextroscope, Volume Interactions, Singapore)
Dhanda et al. (223) 2010 - USA	CS	Max-Fax	4	Physical models manufactured from virtual models – design and manufacturing of implants and guides
Fornaro et al. (215) 2010 - Switzerland	CS	Ortho	7	Virtual surgery and virtual adaptations of implants (prebending)
Qiu et al. (26) 2010 - China	CS	NS	45	Planning using virtual reality platform (Dextroscope, Volume Interactions,Singapore)
Dong et al. (233)	CS	Ortho	5	Virtual planning

2011 - China				
Essig et al. (224) 2011 - Germany	CS	Max-Fax	3	Planning with virtual and physical models – surgical plates pre-bent during preparation
Ferrari et al. (21) 2011 - Italy	CS	General	10	Planning of cutting planes using virtual models
Hu et al. (13) 2011 - China	CS	Ortho	7	Virtual planning of procedure and plate contouring
Tepper et al. (15) 2011 - US	CS	Max-Fax	2	Virtual surgery and inspection of physical models as well as preparation of physical surgical splints and implants
Derand et al. (222) 2012 – USA, Sweden	CS	Max-Fax	4	Virtual planning of operation – design and manufacturing of plates, mesh and cutting guides
Kanzaki et al. (252) 2012 - Japan	CS	Thoracic surgery	11	Virtual planning
Kerens et al. (237) 2012 - Netherlands	CS	Ortho	10	Virtual planning – design and manufacturing of cutting guides
Nam et al. (17) 2012 - US	NRC	Ortho	Group 1 37 (41 knees) – group 2 38 (41 knees)	Computer Assisted Surgery (CAS) versus pre-operative planning and construction of Patient Specific Cutting guides (PSC)
Scolozzi et al. (230) 2012 - Switzerland	CS	Max-Fax	2	Virtual surgical planning – design and manufacturing of PS implants

Shen et al. (214) 2012 - China	CS	Ortho	6	Semi-automatic virtual surgery and construction of virtual and real implants
Willaert et al. (23) 2012 - Australia	NRC	Vascular	18 (3 excluded)	Virtual operations on simulator with the participation of the entire surgical team
Adolphs et al. (220) 2013 - Germany	CS	Max-Fax	10	Virtual surgery with two types of splints – optimal splint manufactured with rapid prototyping
Desender et al. (19) 2013 - Belgium	NRC	Vascular	10 (1 excluded)	Virtual procedures on simulator
Hsu et al. (227) 2013 - USA	NRC	Max-Fax	65	Virtual planning and CAM of physical surgical splints and templates – intraoperative navigation for some cases
Issa et al. (236) 2013 - USA	CS	Ortho	84 (89 knees)	Computer generated preoperative plan and manufacturing of PS instrumentation and cutting blocks
Mandel et al. (253) 2013 - Brazil	CS	NS	18	Virtual planning
Pietsch et al. (239) 2013 - Austria	CS	Ortho	50	Computational planning of surgery and designing of PS implants
Schweizer et al. (240) 2013 - Switzerland	CS	Ortho	6	Planning of cutting planes on virtual model – design and manufacturing of drill guides
Small et al. (241) 2013 - USA	RCT	Ortho	36	Virtual procedures on VRS – patient specific implants designed and manufactured
Victor et al.	CS	Ortho	14	Virtual planning and

(242) 2013 - Belgium				manufacturing of physical guides
Ayoub et al. (221) 2014 - Germany	RCT	Max-Fax	20	Planning using virtual and physical anatomical models – design and manufacturing of cutting guides
Franceschi et al. (234) 2014 - France	NRC	Ortho	107	CT introduced in planning software for design and manufacturing of physical cutting guides
Gander et al. (225) 2014 – Switzerland, Netherland	CS	Max-Fax	12	Virtual planning – design and manufacturing of PS implants. Intraoperative navigation for 7/12
Haq et al. (20) 2014 - UK, US	CS	Max-Fax	5	Interactive virtual surgery and construction of real cutting guides and implants
Leeuwen et al. (238) 2014 - Norway	CS	Ortho	39 (42 knees)	Virtual planning – design and manufacturing of physical guides
Makiyama et al. (24) 2014 - Japan	CS	Urology	13	Virtual operation on simulator
Fürnstahl et al. (235) 2015 - Switzerland	CS	Ortho	3	Semi-automatic virtual surgery and construction of real surgical guides
Isotani et al. (246) 2015 – Japan, USA	CS	Urology	20	Virtual surgery
Kusaka et al. (247) 2015 - Japan	CS	Urology	2	Planning with virtual and physical models
Li et al. (i) (254)	CS	NS	9	Virtual planning

2015 - China				
Li et al. (ii) (245) 2015 - China	NRC	NS	37	Group A: Preoperative planning using 3D printed models – Group B: routine practice.
Schepers et al. (229) 2015 -	CS	Max-Fax	7	Virtual planning and CAM of physical guides for introducing implants
Steinbacher et al. (231) 2015 - USA	CS	Max-Fax	6	Virtual surgery – design and 3D printing of guides, splints and implants
Vlachopoulos et al. (243) 2015 - Switzerland	NRC	Ortho	14	Virtual surgery – design and manufacturing of physical drill and cutting guides

Table 1. Characteristics of studies identified in current literature. CS: Case series, NRC: Non Randomised Controlled Studies, RCT: Randomised Controlled studies, Max-Fax: Maxillo Fascial surgery, NS: Neurosurgery, H&N: Head and Neck surgery, Ortho: orthopaedic surgery, CAS: Computer Assisted Surgery, CAM: Computer Assisted Manufacturing, PS: Patient Specific, VRS: Virtual Reality Simulators.

The majority of studies reported satisfactory immediate surgical results (60-100%). Complication reporting was sparse with two exceptions: (i) van Steenberghe *et al.* who reported 6/27 cases of bruxism (involuntary grinding of the teeth), a complication known to be associated with immediate loading of implants in fully endentulous maxillae (216), and (ii) Furnstahl *et al.* (235) who describe severe pain post operatively due to incomplete procedure [medial compartment of the knee not repaired in theatre, despite having achieved repair during rehearsal]. The number of participants was too small (n=3) to embark on further analysis (table 2).

(iii) Surgeons' feedback

Whilst authors found the preparation methods to be useful in different ways such as: (i) better understanding of patient individual anatomy and pathology (13, 16, 18, 19, 21, 22, 24-26, 215, 221, 222, 225, 233, 242, 250, 251), (ii) reducing operating time or number of procedures required (14, 15, 17, 20, 22, 25, 214, 216, 222, 224, 226, 229, 233), (iii) reducing complications or assisting in the avoidance of damage to vital structures (13-15, 18-24, 26, 214, 215), and (iv) promoting a minimally invasive approach (e.g. reduce amount of dissection needed) (15, 26, 214, 215); drawbacks were also highlighted. For instance, technical issues encountered during the application of pre-operative rehearsals, such as the reliance of the accuracy of anatomical models on the quality of imaging they were based on (14, 16-19, 23, 25). Definition can be increased by increasing the number of images or acquiring thinner slices (17, 18, 25), however, additional resources would be needed and ionisating radiation dose received by patients may increase (15). In fact, three of the included studies reported that additional imaging was required (17, 25, 235).

Study	Good clinical outcome - Major complications
Perry et al. (14).	4/5 (80%) selected cases presented had a satisfactory outcome
Kockro et al. (16)	4 illustrative cases presented Total tumour excision in 3/4 (75%) cases
Lo et al. (228)	Symmetry and normal orbital contours achieved in all cases No complications (29-55 months f/u)
Leong et al.	NIP
vanSteenberghe et al. (216)	24/27 (88.9%) implants pass one year control - Bruxism 6/27 (22.2%), 4/27 inflammation of the gingiva
Radecka et al. (25)	Complete clearance of stones 5/8 (62.5%) - Mucosal perforation 1/8 (12.5%)
Gateno et al. (226)	Deformities corrected at 6 week f/u
Xia et al. (232)	NIP
Hislop et al. (22)	Successful operations (0% residual vessel stenosis) 3/5 (60%)
Lu et al. (251)	77.8% improvement in symptoms at 9 months f/u No complications
Ng et al. (18)	Complete resection 23/23 (100%) - 4.3% had additional neurological deficit post-operatively 1/23 severely disabled due to post-operative complications
Dhanda et al. (223)	1.43 cm average improvement in mouth openining
Fornaro et al. (215)	Anatomic or satisfactory reduction of fracture 7/7

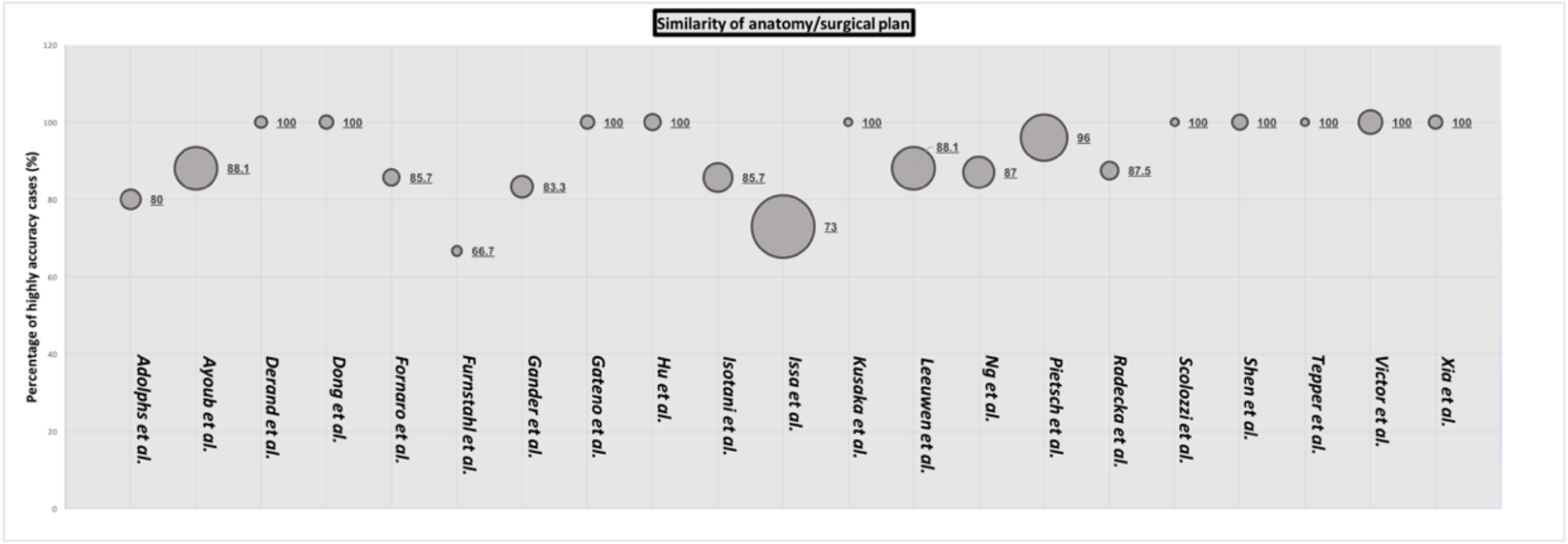
	(100%) - No serious complications
Qiu et al. (26)	Total tumour resection 33/45 (73.3%) - Decrease >10% of effective fibre of pyramidal tract 7/45 (15.6%)
Dong et al. (233)	Resection margins free of tumour in all cases
Essig et al. (224)	2/3 good results
Ferrari et al. (21)	No Information Provided (NIP)
Hu et al. (13)	NIP
Tepper et al. (15)	NIP
Derand et al. (222)	Surgeons' opinion: Good correlation of plan and surgical steps Calculated reduction in operation time 30min
Kanzaki et al. (252)	No conversion to open Margins free of cancer 3 complications – prolonged air leak, needed pleurodesis
Kerens et al. (237)	All guides fitted well during real surgery Good stability in all cases at 6 weeks f/u No complications
Nam et al. (17)	Good alignment of lower limb for: CAS: 92.7% - PCS:70.7%
Scolozzi et al. (230)	Satisfactory reconstruction 2/2 0 complications
Shen et al. (214)	Satisfactory or anatomical reduction in 5/6 (83.3%) cases - No complications (0%)
Willaert et al. (23)	NIP
Adolphs et al. (220)	NIP
Desender et al. (19)	NIP

Hsu et al. (227)	NIP
Issa et al. (236)	No complications
Mandel et al. (253)	NIP
Pietsch et al. (239)	Satisfactory outcome (overall axis within 3^{o}) 47/51 (94%)
Schweizer et al. (240)	Improvement of wrist ROM at 1 year f/u Increase of wrist strength by 10% on average No complications (no instability or crepitus)
Small et al. (241)	No differences in length of procedure or blood loss 1 complication in control group and 0 in PS preparation group
Victor et al. (242)	13/14 healed well 0 complications
Ayoub et al. (221)	2 transplants failed due to venous thrombosis
Franceschi et al. (234)	Significant improvement of WOMAC score after 1 year 3.7% (4 cases) stiffness: 1 required change of insert and 3 cases arthrolysis
Gander et al. (225)	No re-operation needed No complications (no visual impairment, no sensation of foreign body)
Haq et al. (20)	Improvement of mouth opening 3/5 (60%) - No facial nerve injury (0%) - Re-operation in 1/5 cases
Leeuwen et al. (238)	10/41 HKA angle>3^{o} from neutral axis
Makiyama et al. (24)	NIP
Fürnstahl et al. (235)	All (100%) osteotomies healed in 3-6 months - Joint effusion 1/3 (33.3%)
Isotani et al. (246)	Resection margins negative for cancerous tissue No urological complications

Kusaka et al. (247)	NIP
Li et al. (i) (254)	Surgeon's opinion: anatomy accurately represented
Li et al. (ii) (245)	Shorter op time and blood loss in intervention group No difference in complication rates
Schepers et al. (229)	6/7 flaps survived (average f/u 9.7 months) 1.2-2mm discrepancy between pre and postoperative model
Steinbacher et al. (231)	NIP
Vlachopoulos et al. (243)	All osteotomies healed after mean time of 3.6 months Increased ROM and grip strength for both groups

Table 2. Clinical outcomes

Technical troubleshooting (14, 16, 19, 23, 26), as well as unrealistic biomechanical properties, mostly concerning soft tissue, (13, 16, 18, 19, 22-24, 26) have been reported. On occasion, the contralateral, healthy side was used as a template for the repair of the diseased one (221, 224, 226, 230, 231, 242, 243), which could be troublesome in cases of bilateral pathology or asymmetry.



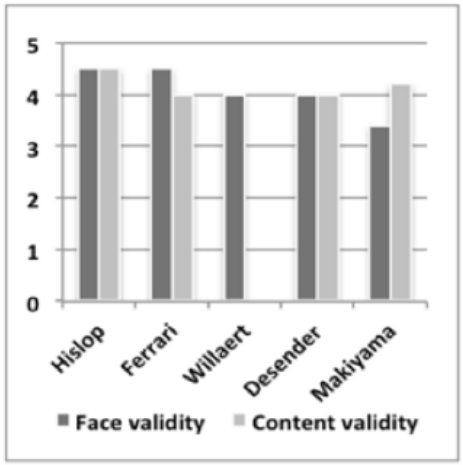


Figure 5. Above. Similarity of anatomy/surgical plan. Below. Face and content validity

It should also be noted that many authors propose PS preoperative preparation for “difficult” cases (e.g. severely comminuted fractures or skull base tumours surrounded by vital structures) (14-18, 21) and find no additional benefit in what they would traditionally consider a “straightforward” case (14, 15, 22, 24, 235).

A rather significant number of studies reports the cost of pre-operative preparation with PS anatomical models which ranges from hundreds to thousands of pounds (220, 221, 230, 240, 250). The manufacturing time is also reported ranging from hours to weeks (222, 225, 233, 251).

1.5.4. Meta-analysis

Meta-analysis was applied where permitting by similarity of research question and measured outcomes. Hislop *et al.* (22), Desender *et al.* (19) and Willaert *et al.* (23) all assessed the likeness of rehearsals to real procedures in vascular surgery and employed three common outcomes to do so (i.e. time to complete procedure, fluoroscopy time and fluoroscopy volume) (Fig. 6). The results of the meta-analysis demonstrate that although rehearsals were significantly quicker than real procedures (SMD=-1.56 [-2.19,-0.93] P<0.00001), the other two outcomes measured during the rehearsal, resembled the results of the real procedure (fluoroscopy time (min): SMD= -

0.1 [-0.63,0.42] P=0.7, fluoroscopy volume (ml): SMD= -0.43 [-0.97,0.11] P=0.12).

Li *et al.* (245) , Ayoub *et al.* (221), Small *et al.* (241), and Hsu *et al.* (227) recruited two distinct groups of patients to compare the clinical results of surgical procedures that were rehearsed to standard surgical treatment, while Nam *et al.* (17) compared the former to real time computer assisted surgery. The pre-rehearsed operations were completed in significantly less time (SMD -0.47 [-0.79, -0.16] P=0.003) but the immediate clinical outcome was similar for practiced and not practiced operations (SMD=0.03 [-0.23, 0.29] P=0.82) (Fig. 7.).

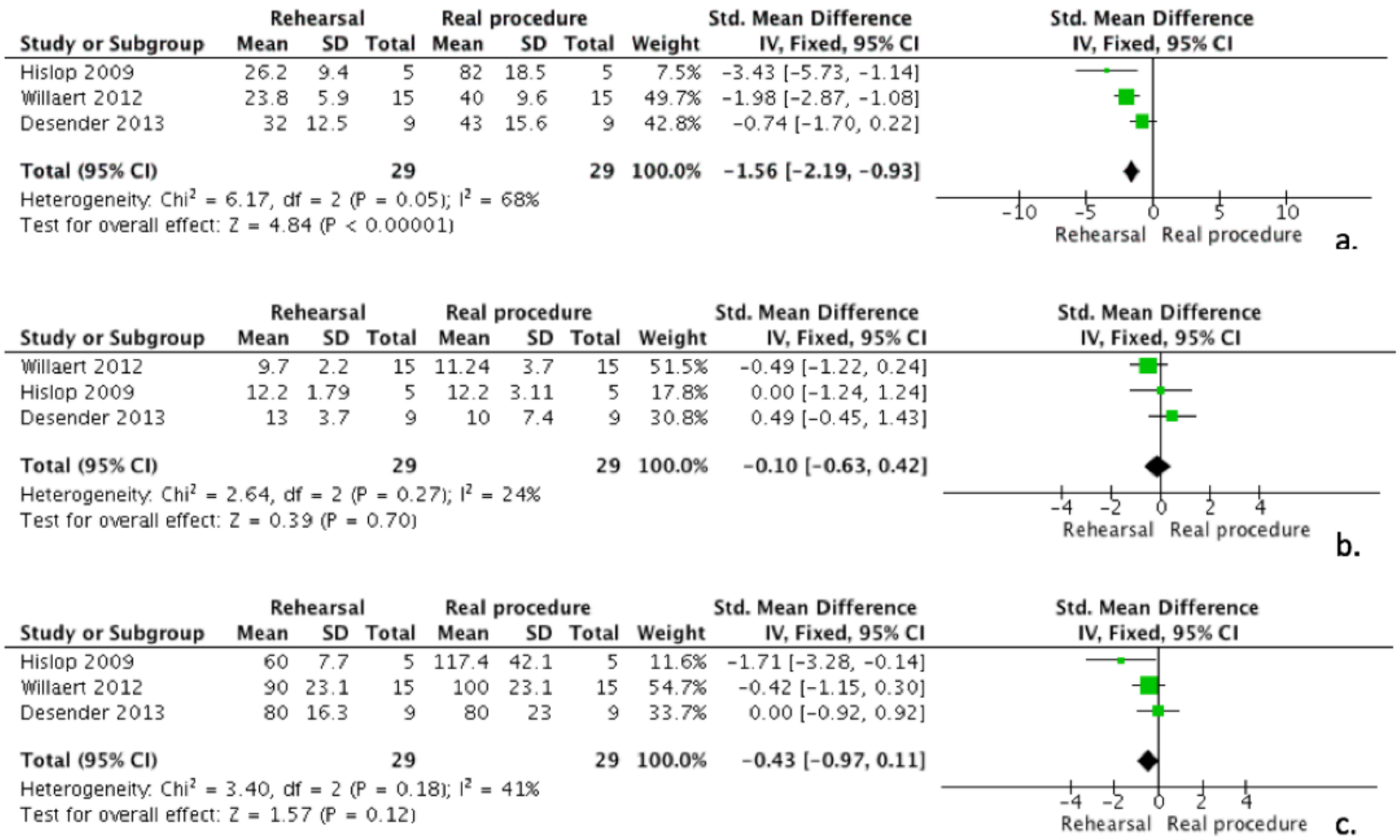


Figure 6. Meta-analysis comparing rehearsals and real procedures. a. Comparison of time to complete procedure b. Comparison of fluoroscopy time c. Comparison of fluoroscopy volume

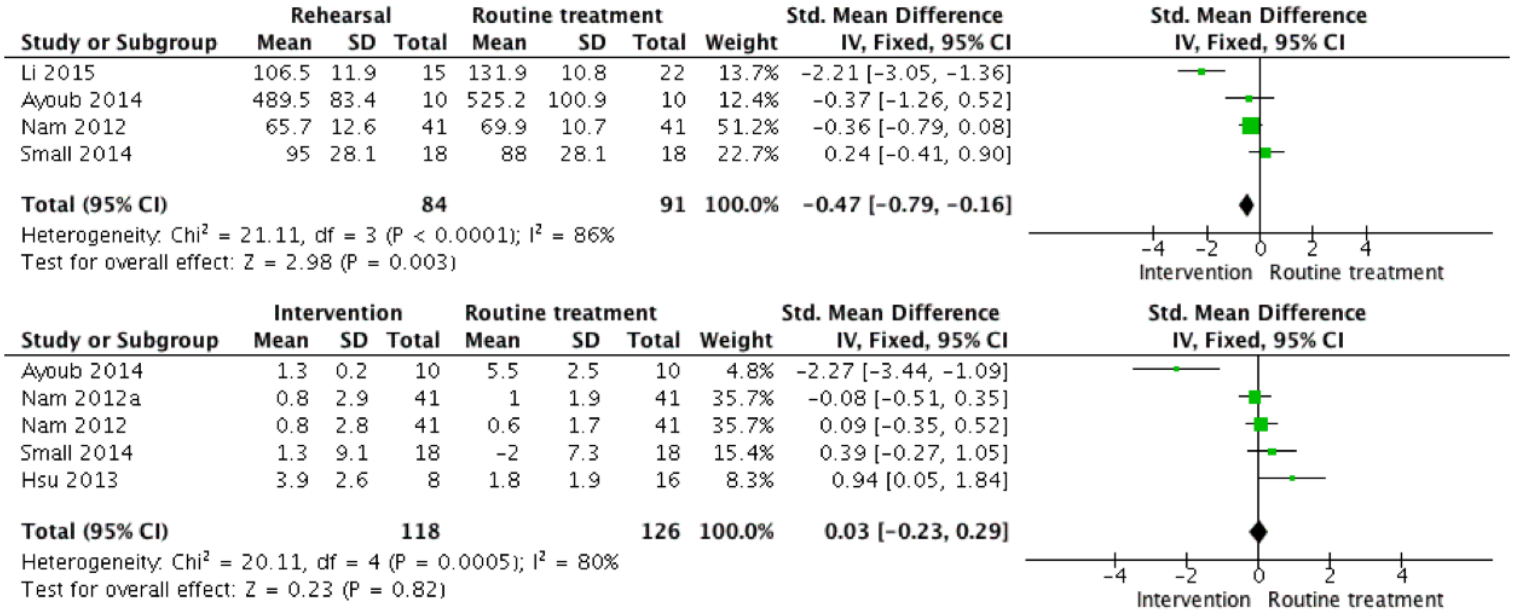


Figure 7. Meta-analysis of rehearsal compared with standard or other intervention (e.g. Nam et al patient specific preparation compared to computer assisted surgery). a. Time (min) to complete procedure. b. Linear translation (mm)-rehearsal vs. real procedure. Two different measured outcomes are included for Nam et al (for femoral and tibial compartment).

For the purposes of the meta-analysis, assumption of normal distribution of the data was made and the following mathematical equations were used to calculate Standard Deviation (SD) on different occasions (255):

(i) SD = IQR (Interquartile range) width/1.35

(ii) SD = $\sqrt{N}$ (CI (Confidence Interval) upper limit – CI lower limit)/ 4.128

(iii) SD = SE (Standard Error)/ $\sqrt{(1/N_E+1/N_c)}$, SE=Mean Difference (125)/t

N: sample size

N_E: sample size of intervention group

N_c: sample size of control group

t: ratio of difference in means to standard error of difference in means

1.5.5. Conclusions from literature review

The literature demonstrates that patient-specific pre-procedural rehearsals are feasible and safe. The accuracy of the anatomical models and the immediate clinical outcomes of the rehearsed procedures are satisfactory. Meta-analysis comparing rehearsals and real procedures showed good correlation between

the two, whilst when operations following rehearsals were compared to non-rehearsed ones the former were performed quicker and yielded the same surgical outcome.

Furthermore, it should be noted that the number of RCTs identified is rather limited. Similarly, Pratt *et al.* (256) looked into preparation prior to foetal surgery and See *et al.* (257), investigating the impact of endovascular surgery rehearsals on trainees' performance, highlighted the lack of randomised controlled trials.

The great variance in methods and measured outcomes is reflected in the results of heterogeneity tests of the meta-analysis (I^2 test 80% and 86%). When two types of interventions are compared (two distinct groups of patients), heterogeneity is more prominent. This highlights the need for the development of a common methodology that can incorporate two different anatomical models to allow for accurate comparisons to take place.

Learning points for current project:

- Pre-operative patient-specific rehearsals have good, but inconsistent, accuracy and good clinical results.
- The methodologies used to apply rehearsals with patient-specific anatomical models are diverse, which could be a contributing factor to the lack of comparative studies.
- The number of RCTs is limited.

Chapter 2

Aims and Objectives

Chapter 2: Aims and Objectives

2.1. Aim

The overall aim was to design and test a novel pre-operative preparation method for enhancing surgical performance and operative quality. This novel method should be inclusive of a patient-specific component, to assist surgeons in navigating through technically difficult operations.

2.2 Objectives

Objective 1: Establish which are the existing pre-operative preparation methods. This objective was completed through two reviews, one systematic review evaluating pre-operative preparation with the use of patient-specific anatomical models and a narrative review assessing the impact of pre-operative mental practice on surgical skills.

Objective 2: The second objective was to create a novel methodology combining mental practice and 3D anatomical models avoiding the pitfalls of previous applications. This was established with the creation of anatomical models as described in Chapter 3 preliminary work.

Objective 3: Test the feasibility of the novel combination in a simulated environment. This objective was completed with the feasibility and pilot study described in Chapters 4 and 5.

Objective 4: Test the feasibility of the novel method in a real-time surgical environment. This was completed through the clinical trial described in Chapter 6.

Chapter 3

Preliminary work

Chapter 3: Preliminary work

3.1. Preparation of patient specific models

The introduction of high definition cross-sectional imaging in medicine has allowed for the accurate visualisation of intra-abdominal structures contributing in prompt disease diagnoses (258). However, interpretation of cross-sectional images bear significant disadvantages (259). Not all clinicians are familiar with elucidation of cross-sectional images (258); depth perception and anatomical association between physiological and pathological entities are challenging for the referring physicians (i.e. non radiologists) who often lack basic training in 2D image interpretation (259).

Initial efforts at 3D reconstruction of medical images commenced in the late 70's with the development of 3D rendering software (258). While both medical imaging and 3D computer reconstruction technology have progressed immensely since, available software are not friendly for users without computer programming experience. Recognising this to be one of the main barriers for the wide spread use of three dimensional image reconstruction in medicine, the University of Leeds prepared an in-house freeware which can be used by physicians (Volume Viewer©). This was initially utilised to produce 3D histopathology images used for research purposes. The freeware is based on a generic image registration algorithm and uses parallel computing using

the OpenMP library in C++ (Microsoft, Redmond, WA). It allows for multilevel registration through which the user can manually select a region, zoom in, and register repeatedly a specific area. Data fusion techniques are then used to produce a three dimensional anatomical model which can be visualised using novel “in-build” visualization methods (260).

3.1.a. Virtual models for rectal cancer patients

MRI pelvis is performed as part of the routine staging process for all rectal cancer patients. For the purposes of our study the MRI images were exported in the form of Digital Imaging and Communications in Medicine (DICOM) on a Compact Disc (CD) and uploaded on Volume Viewer © (University of Leeds) software for visualisation and segmentation.

A novel semi-automatic algorithm, prepared in collaboration with the team who developed the original version of Volume Viewer© was added to the software, aiming to accelerate the process of image registration and 3D reconstruction. With the updated version of the software, significant surgical-anatomical structures were identified and tagged on a random image slide by a trained user. The software then automatically estimated the shape of the same structure on the subsequent slide. This semi-automatic process allows for swift and accurate segmentation of a structure throughout the whole dataset. The entire process was closely monitored and validated by a surgical expert.

For the initial models, the rectum, mesorectum, bladder, prostate, seminal vesicles, ureters, were reconstructed through the semi-automated method. The pelvic bone was reconstructed in a fully automated process, which is possible due to the discrepancy in radio-opacity between bone and the surrounding soft tissues. The completed segmentation of a three-dimensional polygonal structure was dynamically viewed in a 3D viewing software [MeshLab© (Piza, Italy), Figure 8], which allowed for interactive visualisation of the models.

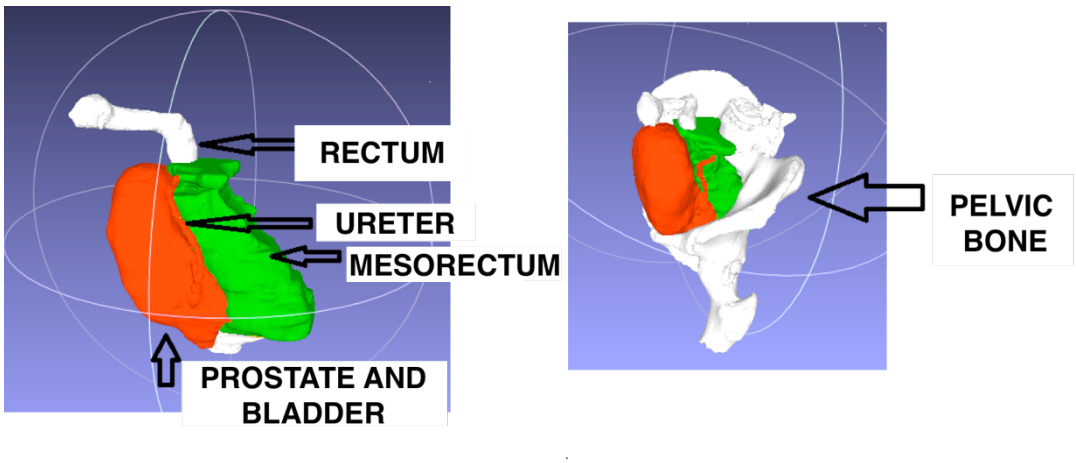


Figure 8. Prototype of virtual model

In subsequent reconstructions, during the clinical trial the urinary bladder and prostate were not reconstructed due to the discrepancy of the volumetric status between the time of the MR/CT and the time of the operation. To be more specific, patients attended MR and CT scanning with a “full” bladder while they were routinely catheterised during surgery. Therefore, reconstructing the urinary bladder at the time of the MR was unrealistic.

3.1.b. Physical model for rectal cancer patients

The physical (i.e. synthetic) models for rectal cancer patients were created through the method of Computed Assisted Design (CAD) based on their virtual counterpart. During this process the virtual models were converted and exported in an STL file and were used for the purposes of 3D printing, thus creating physical models. 3D printing is a form of CAD that can produce three dimensional objects from a digital file. This is achieved by printing successive layers of materials over each other (261). In this way, synthetic models of different parts of the skeletal and visceral pelvic anatomy were created.

After the reconstruction of the pelvic bone to a 3D virtual model, a half oval structure was added to it using SOLIDWORKS®, a 3D CAD design software (Figure 9). This feature was added for the purposes of making the pelvic model re-usable and hence more cost-effective. The final 3D virtual model was 3D printed, using Objet1000 Multi-material 3D Printer (Stratasys, MN, USA). The same process was followed for producing a physical model of the rectum and mesorectum.

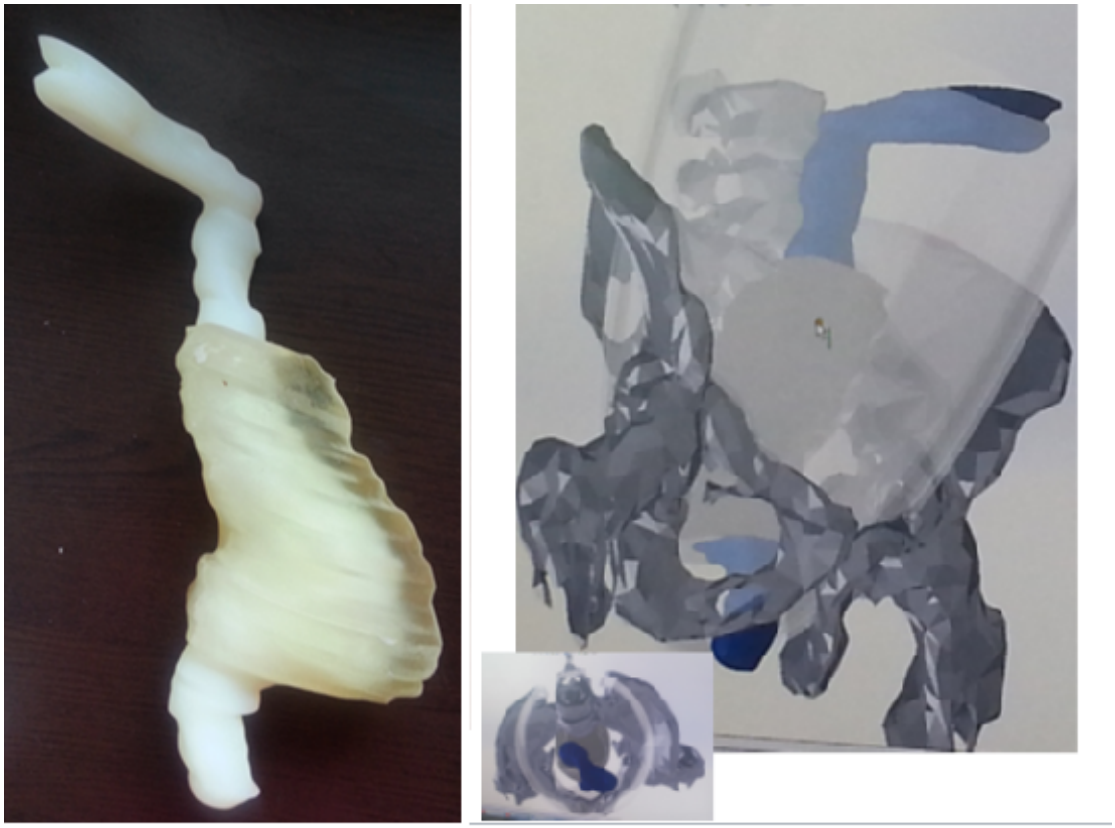


Figure 9. First prototype of physical model of rectum and mesorectum and CAD model for pelvic bone.

Although both the rectum and mesorectum were reconstructed for the prototype, in order to accelerate the manufacturing process during the clinical trial, only the mesorectum was 3D printed into a physical model. This was then used as a negative cast to create the mesorectal fascial plane where surgical dissection takes place during total mesorectal excision. Semi-liquid silicon was used to cover the solid mesorectum in such a way that when dried it provided an accurate representation of the plane. The resulting entity was then placed in the reusable pelvis. The gap between the “fascia” and the “pelvic wall” was filled in by pliable material leaving a small gap, tightly packed with polyester fibres; representing the so called “angel hairs” found in the

embryological plane separating the mesorectum from surrounding structures. After the pelvic model was prepared, it was placed into a box trainer for the surgeons to practice the pelvic dissection part of the procedure.

3.1.c. Virtual models for non-clinical trials

For the first pre-clinical study, a model of the liver and the gallbladder was used. This included a single cystic duct and a single cystic artery located posteriorly to the cystic duct. For the second pre-clinical trial three different anatomical variations of the gallbladder and biliary tract were used. The 3D models used for the pre-clinical studies were reconstructed manually from an anonymised computed tomography (CT) scan using the “in- house’’ 3D reconstruction software Volume Viewer, University of Leeds. The models were exported onto open source visualisation software (MeshLab) and were used for the purposes of the studies in a manner explained in the next two chapters.

3.2. Expert opinion on surgical simulation

The synthetic models, the construction of which was explained above, were used to simulate the pelvic dissection part of a rectal cancer operation. Prior to introducing simulation as one of the comparators in the clinical trial, the

merit of simulation as a training tool in surgery was explored through a national survey seeking the opinion of experts.

Simulation is a training tool shown to facilitate the acquisition of surgical skills (262-269), which can be transferred from a simulated to a clinical environment (134). The introduction of simulation was necessary as surgical training progressed from the Halstedian paradigm “see one, do one, teach one” (270, 271) to the “no learning curve on patient” era (195). Undoubtedly, technological advancements and increasing trainers’ expertise led to both enhancement of surgical skills acquirement and augmented patient safety (134).

For the past twenty or so years, simulation is timidly being introduced into training for various types of surgery (272), with laparoscopic surgery being no exception (83, 127, 196, 273-275). In fact, successful completion of simulation based training sessions such as the Fundamentals of Laparoscopic Surgery (FLS) course is required for career progression (276, 277).

A brief review of the literature demonstrates that simulation may be a good comparator to MP in a clinical trial, as there is evidence proving its efficiency for acquiring surgical skills. Moreover, the emerging application for enhancing non-technical skills (interaction with the surgical team, decision making) may also be suitable for inclusion into the methodology of the trial. The simulation model due to be used in the trial will be validated through assessment of the

transferability of skills to a clinical environment

Prior to the introduction of simulation as one of the comparators, considering the combination of challenges and new applications, it was imperative to explore the perceptions of experts on surgical simulation. This was done through an externally validated questionnaire, which was disseminated nationally, to the Heads of School of Surgery (247) and their deputies and regionally to the surgical Training Program Directors (TPD) and their deputies.

(i) Methods:

This is a mixed qualitative, quantitative cross-sectional study. The methodology consists of 4 stages. 1) Development of questionnaire 2) External validation of questionnaire 3) Regional and 4) National dissemination.

Questionnaire development

The steering group for this study consisting of surgical education fellows and the Head of School of Surgery (Health Education Yorkshire and the Humber, HEYH), after conducting a literature review and establishing the grounded theory, developed a draft questionnaire.

Validation:

For purposes of external validation, we undertook a series of semi-structured interviews and consequently applied thematic analysis on the transcripts. Agreement ≥80% between the emerging themes and questions on the draft questionnaire was considered to demonstrate validity (278).

Five surgeons with a national educational role and who were speakers/discussants at the Association of Surgeons of Great Britain and Ireland conference in 2014 were interviewed. They were presented with 5 “open” questions (e.g. what are your views on simulation in surgery?). The interviewer was then allowed to ask clarifying questions according to the replies they received, but these were not predetermined or leading.

Interview transcripts data

The transcripts of interviews were analysed by two independent assessors. Data extraction and categorisation was conducted for the purposes of thematic analysis. This was aimed at establishing validity of the selected questions. Transcript data was summarised to the highest degree possible.

Dissemination

The questionnaire (please see appendix) was disseminated both regionally (to Training Programme Directors - TPDs and their deputies) and nationally (to Heads of School - HoS and their deputies) through electronic mail. Overall the questionnaire was disseminated regionally (Yorkshire and the Humber) to 27 TPDs or deputies and Nationally to HoS or/and their deputies in 14 Local Education and Training Boards (LETBs) or Deaneries. Yorkshire and the Humber LETB was excluded as the HoS is the senior author of the current study.

(ii) Results:

Content validity

Thematic analysis of the semi-structured interview transcripts revealed the following themes:

(1) Advantages and shortcomings of simulation in surgery (e.g. does not fully re-enact the stressful environment of an operating theatre or it is a good training tool)

(2) Concerns about delivery of simulation

(3) Uses of simulation beyond technical skills acquisition (e.g. assessment of surgical skills, non-technical skills acquisition)

(4) To whom simulation should apply to and which simulation model is optimal (e.g. level of training, basic/procedural tasks or complete operation)

There was an 82.4% agreement between the thematic analysis of the data extracted for the interview transcripts and the questionnaire.

Survey results

The regional response rate was 78% (21 questionnaires received/27 questionnaires sent) with replies from 9/11 specialties (cardiothoracic surgery, general surgery, maxillofacial surgery, neurosurgery, trauma and orthopaedics, Ear Nose Throat (ENT) surgery, pediatric surgery, urology and vascular surgery). After national dissemination, we received responses from 11/14 Deaneries (79%). 28 questionnaires were sent to HoS and deputy HoS (2 for each Deanery) and 15 were received. However, the response rate nationally was calculated according to the region of response as the approach to surgical simulation is considered to be identical within a region.

All TPDs and HoS agreed that simulation is a good training tool (Fig. 10). They reject the notion that simulation can be used mostly for acquiring basic

surgical skills (TPDs: 18/21, HoS: 13/15) and is useful mostly to novices (TPDs: 21/21, HoS: 15/15) (Fig. 11). Regarding its face validity, 15/21 TPDs and 14/15 HoS felt that it can adequately re-enact stressful situations (Fig. 10).

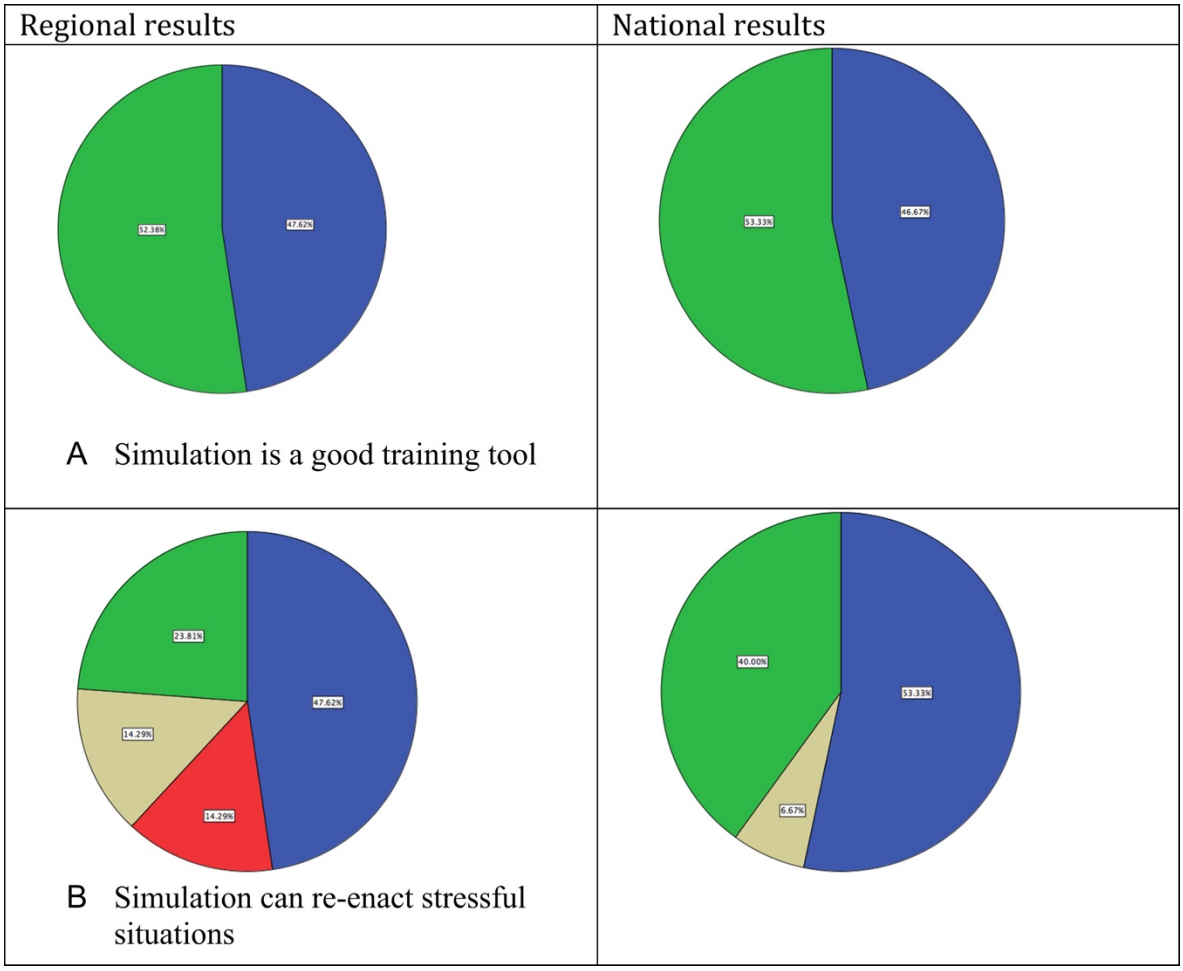


Figure 10. Survey results 1. (A) Simulation is a good training tool. (B) Simulation can re-enact stressful situations. Green: strongly agree/very important, blue: agree/ important, beige: indifferent, red: disagree/not important, and black: strongly disagree/not important at all.

There is strong support for simulation to be used for acquiring non-technical skills (20/21 TPDs and 13/15 HoS) (Fig. 12) and for supervised training (15/21 TPDs, 11/15 HoS).

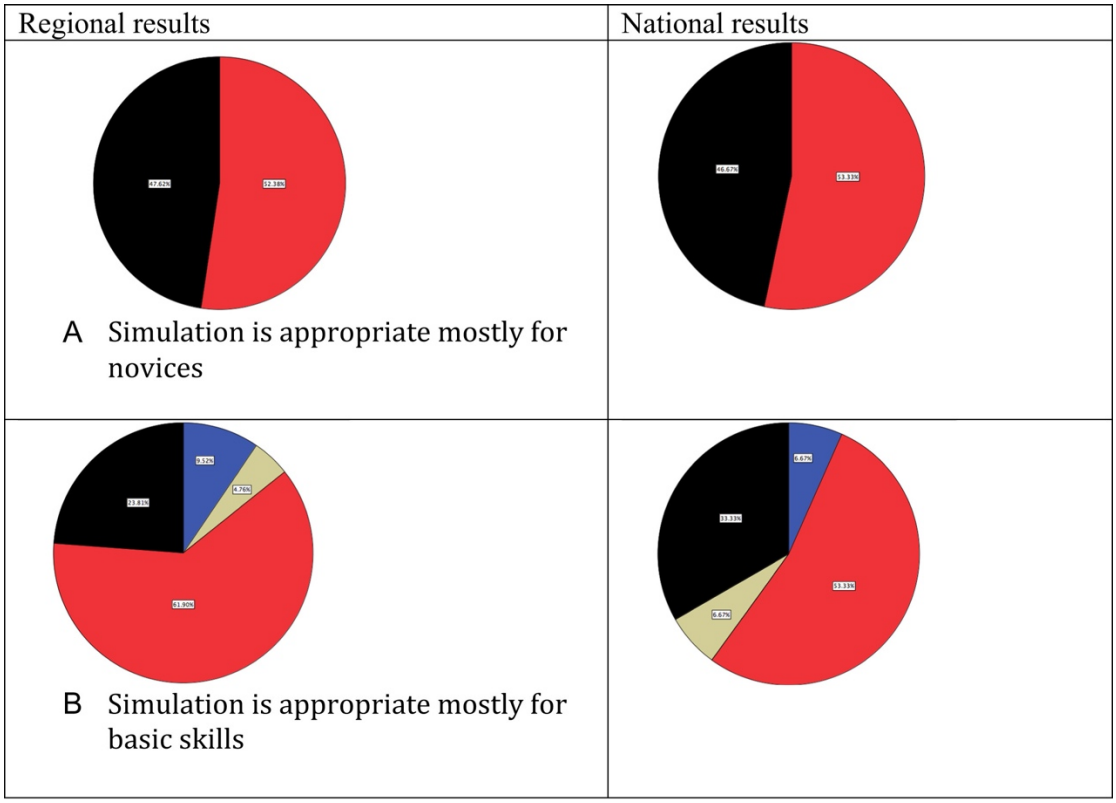


Figure 11. Survey results 2. (A) Simulation is appropriate mostly for novices. (B) Is simulation appropriate mostly for basic skills? Green: strongly agree/very important, blue: agree/important, beige: indifferent, red: disagree/not important, and black: strongly disagree/not important at all.

Fewer believed that simulation should be used for assessment of an individual's surgical skills (TPDs: 14/21, HoS: 6/15) (Figure 12) and only 8 HoS and 8 TPDs would make a decision on recruitment based on performance at a simulation session.

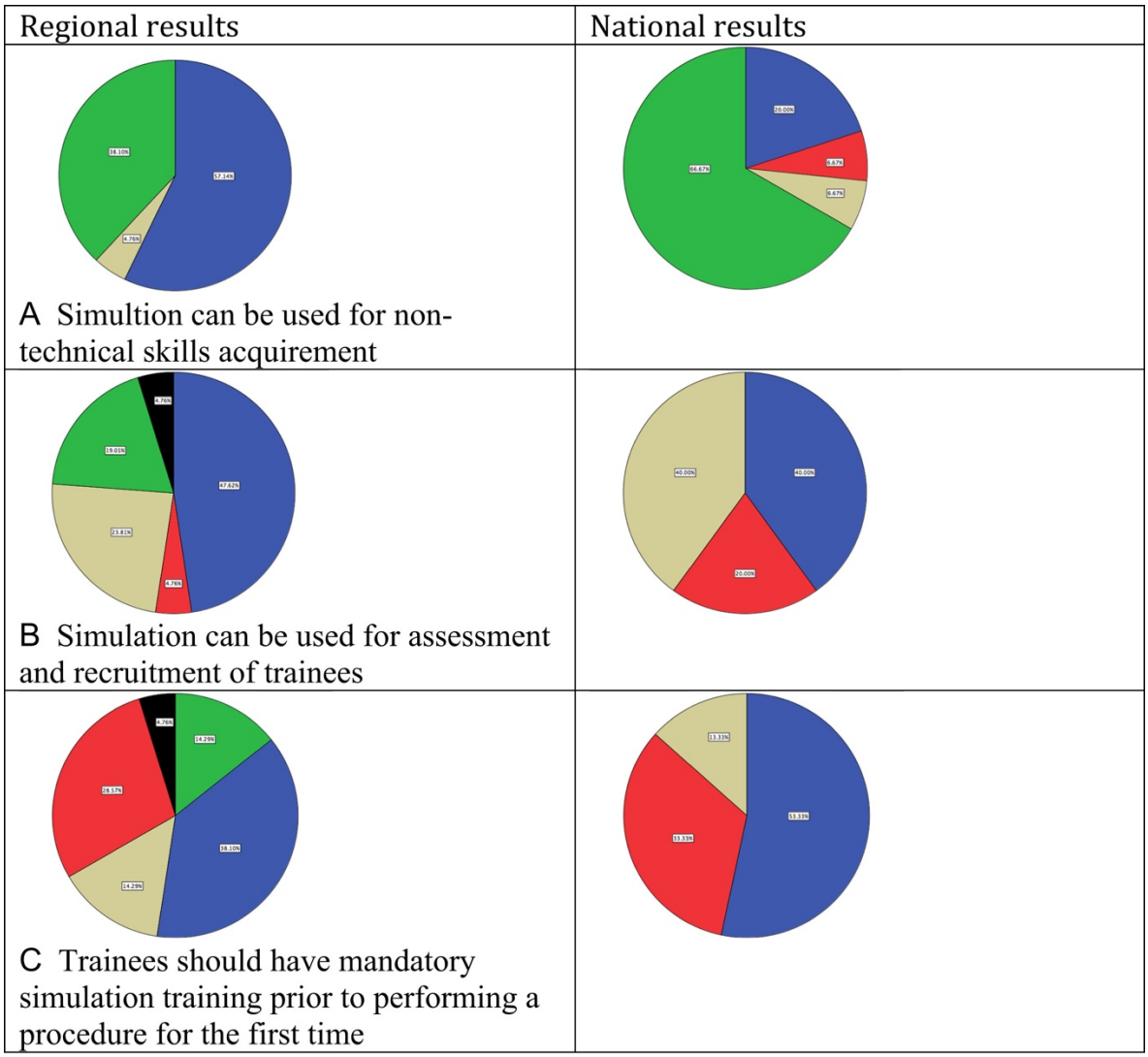


Figure 12. Survey results 3. (A) Simulation can be used for nontechnical skills acquirement. (B) Simulation can be used for assessment and recruitment of trainees. (C) Trainees should have mandatory simulation training before performing a procedure for the first time. Green: strongly agree/very important, blue: agree/important, beige: indifferent, red: disagree/not important, and black: strongly disagree/not important at all.

Opinions were conflicting about simulation becoming compulsory prior to performing a procedure for the first time (11/21 TPDs and 8/15 HoS agree) (Fig. 12) and whether “hands-on” stand-alone sessions/courses (and not as

part of a long-term curriculum) can be of educational value or not (12/21 TPDs and 8/15 HoS thought that stand alone sessions are of benefit).

Finally, regarding more practical issues, 14 TPDs and 12 HoS replied that simulators should be located in both clinical skills centers and in operating.

(iii) Discussion:

Here, we present the findings of an externally validated national survey about the present and future of simulation in surgery completed by leading surgical educators. This study provides an insight to the perceptions of experts on simulation in surgery as a whole, as well as areas which may still be considered controversial or are not fully supported (e.g. compulsory simulation). It also offers indications about how experts think simulation should be delivered (e.g. supervised) which may be an impetus for change.

Overall, there is substantial agreement nationally and regionally with some exceptions. These may be attributed to local practices. For instance, simulation is used successfully for evaluation purposes during surgical courses within the Yorkshire and Humber region, which may have led to increasing confidence in its use for that purpose.

The results of the current study show that surgical educators believe simulation to be a good training tool, the use of which should not be restricted to teaching basic surgical skills to novices. They strongly support use of simulation for non-technical skills acquisition.

Compulsory training on simulators prior to performing a procedure for the first time and use of simulation for assessing trainees' technical skills or for recruitment did not yield homogenous support. It should be noted however, that in regards to the assessment question there is a discrepancy in the results from the regional and national respondents; the majority from Yorkshire and the Humber (Y&H) believed that simulation (14/21) can be used for assessment compared to only 40% of national respondents.

In regards to the location of the simulators it was widely believed (regionally and nationally) that simulators should be found both in the operating theatres and in clinical skills centers to maximise the opportunity for both taught and self-directed training. However, there is general reluctance by trusts to locate high fidelity simulators in surgical theatres as use by trainees who have not undergone appropriate induction on the simulator is considered more likely, increasing the risk of damage to the equipment. Equally, there is likely to be a lack of technical staff in theatre who can take "ownership" of the simulator.

Although the difficulties surrounding the deployment of high-fidelity simulators could probably be overcome there is mounting evidence to suggest that low

cost / low fidelity simulators produce the same or better pedagogic result as high fidelity trainers (127, 279, 280). Such equipment can be easily transferred to theatres, their use is self-explanatory dismissing the need for an initial induction, and there are no significant maintenance costs.

The outcomes of this study are consistent with the ones of similarly themed surveys. Aydin et al. (281) surveyed both specialists and trainees and reported that both groups recommend simulation as a method of overcoming the reduced training opportunities in the operating theatre and believe it to be suitable for technical and non-technical skills learning. Forster et al. (282) assessed the opinion of TPDs, who expressed enthusiasm for surgical simulation. The respondents considered that laparoscopic simulators improved training and that simulation for trainees was desirable. Similarly to the opinion of HoS in our study, the TPDs did not feel that simulation should be used for assessment at that time of the survey (2011) but considered it a possible for the future. These findings both in the Forster et al. and the current study may reflect the paucity of high quality evidence regarding the utilisation of simulation for assessing surgical skills (283).

De Win *et al.* sought the opinion of Belgian gynaecology, urology and general surgery trainees about their training. Almost all responders found clinical skills training to be helpful and important for their future career. The majority of trainees in this survey attended extracurricular courses or freestyle stand-alone training, which they found of didactic value (284). This is consistent

with our finding that simulation outside of a long-term curriculum is also considered educational.

Further, De Win *et al.* (284) reported poor access to skills centers, due to either inconvenient hours or location. The current study indirectly assessed this issue by asking the respondents whether they thought that simulators should be located in the operating theatres (ensuring 24 hour access) or in clinical skills centers. The majority suggested that simulators should be placed in both clinical skills centers and theatres. Further data from Y&H suggests that usage in centers that are only accessible to trainees between 0900-1700 is limited (285). It is clear that simulators should be accessible for free-training 24/7, however, it should be noted that the presence of a trainer is of vital importance at least for the initial training sessions.

It should be noted that specialties of the responders vary significantly adding to the potential generalizability of the findings of this survey. Transferability of surgical skills acquired to the operating room has been demonstrated in various surgical specialties in the past (286, 287).

Although this study has not assessed trainee opinion about simulation there has been a detailed report published by the Association of Surgeons in Training (ASiT) in which trainees are calling for simulation to be included in the curriculum with appropriate quality assurance of training centers and improved access to the facilities that are available (288).

This study has some limitations. It does not provide high level evidence as it is designed to explore expert opinion (i.e. level evidence VII) (289), however as TPDs and HoS have a crucial role in shaping the delivery of surgical education, we feel it is important to be aware of their perceptions. Further, as we decided to focus on expert opinion we did not seek the opinion of trainees, however we do feel this was done extensively in previous reports (281, 290).

(iv) Conclusion

In summary, the TPDs and HoS had a positive attitude towards simulation in surgical training, and believed it to be a useful tool for acquisition of both technical and non-technical skills

Learning points for current project:

- It is widely accepted that simulation is a good training tool for surgeons and it is reasonable to consider it as a comparator (to mental practice) in a future trial.
- It can be used for various levels of training
- The presence of a trainer at least during the initial parts of training is essential
- Simulation can be used to teach both technical and non-technical skills
- The synthetic model will be validated through transferability of skills from a simulated to a clinical environment. Therefore, a clinical study is necessitated.

Chapter 4

Feasibility study

Chapter 4: Feasibility study

Following the preliminary work phase, we were able to produce patient specific models, both virtual and physical, using medical images such as MRI and CT as well as design a patient specific mental practice process. Moving on to testing the feasibility of applying mental practice in surgical practice, we completed a study in a simulated surgical environment, aiming to ensure that patient safety is preserved and there were no interruptions or delays caused to the surgical process.

4.1. Materials and Methods

Ethical approval

After consultation with the Research and Development (R&D) department of Leeds Teaching Hospitals, it was advised that approval by an NHS research ethics committee or the R&D department was not required. The study received departmental approval by the research lead of the surgical Clinical Service Unit (CSU).

Participants

Twenty junior specialty trainees (core trainees and early registrar years; postgraduate years 2-4) were recruited for this study. The surgeons were case-matched 1:1:2 (MPO: 3D&MP: Control) based on the following variables: number of real laparoscopic cholecystectomies conducted as primary surgeon and number of times they had used the same virtual reality simulator in the past (Table 3). All participants had seen and assisted in Laparoscopic Cholecystectomy (LC) operations but had not performed more than 15 as primary surgeons. Twice as many participants were allocated to the control group in order to increase statistical power (291). This is particularly desirable if the cost for including additional control is minimal (292). Specifically, asking individuals allocated to the control condition to

review a pre-prepared didactic video bears no additional cost to the study and is a method that these surgical trainees were familiar with as it is used during teaching sessions of surgical skills within the area.

Group	3D	MPO	CG
No of LC as primary surgeon (median)	7 (3-14)	4 (0-15)	5.5 (2-12)
No of times simulation was used (median)	1-5 (0 - >10)	0 (0- 6-10)	0 (0 - >10)

Table 3. Trainees' experience at baseline. LC: Laparoscopic cholecystectomy.

3D model

The 3D model was reconstructed from an anonymised Computed Tomography (CT) transferred through a Compact Disc (CD) in Digital Imaging and Communications in Medicine (DICOM) form, to "in-house" 3D reconstruction software (VolumeViewer, University of Leeds). The 3D model was created through manual reconstruction to "match" the VR simulated images of a normal anatomy gallbladder, biliary tract and

vascularity (Fig. 13). The model was then exported onto open source visualisation software (MeshLab) and underwent minor contouring.

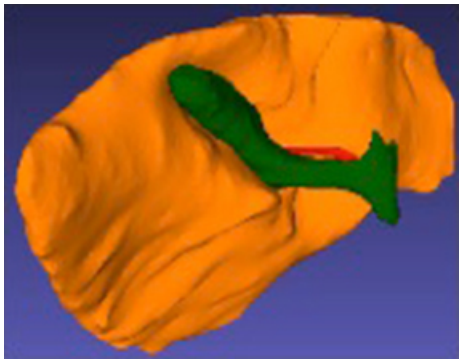


Figure 13. Interactive 3D model for laparoscopic cholecystectomy

Intervention

The Control Group (n = 10) was exposed to a didactic real time video of a LC, whilst two intervention groups (3D group; n = 5) and Mental Practice Only (MPO; n = 5) underwent a single 25 minute Mental Preparation (MP) session in the presence of a facilitator. For the 3D group, an interactive 3D model of the relevant surgical anatomy (Figure 13) was incorporated into the MP process (Figure 14).

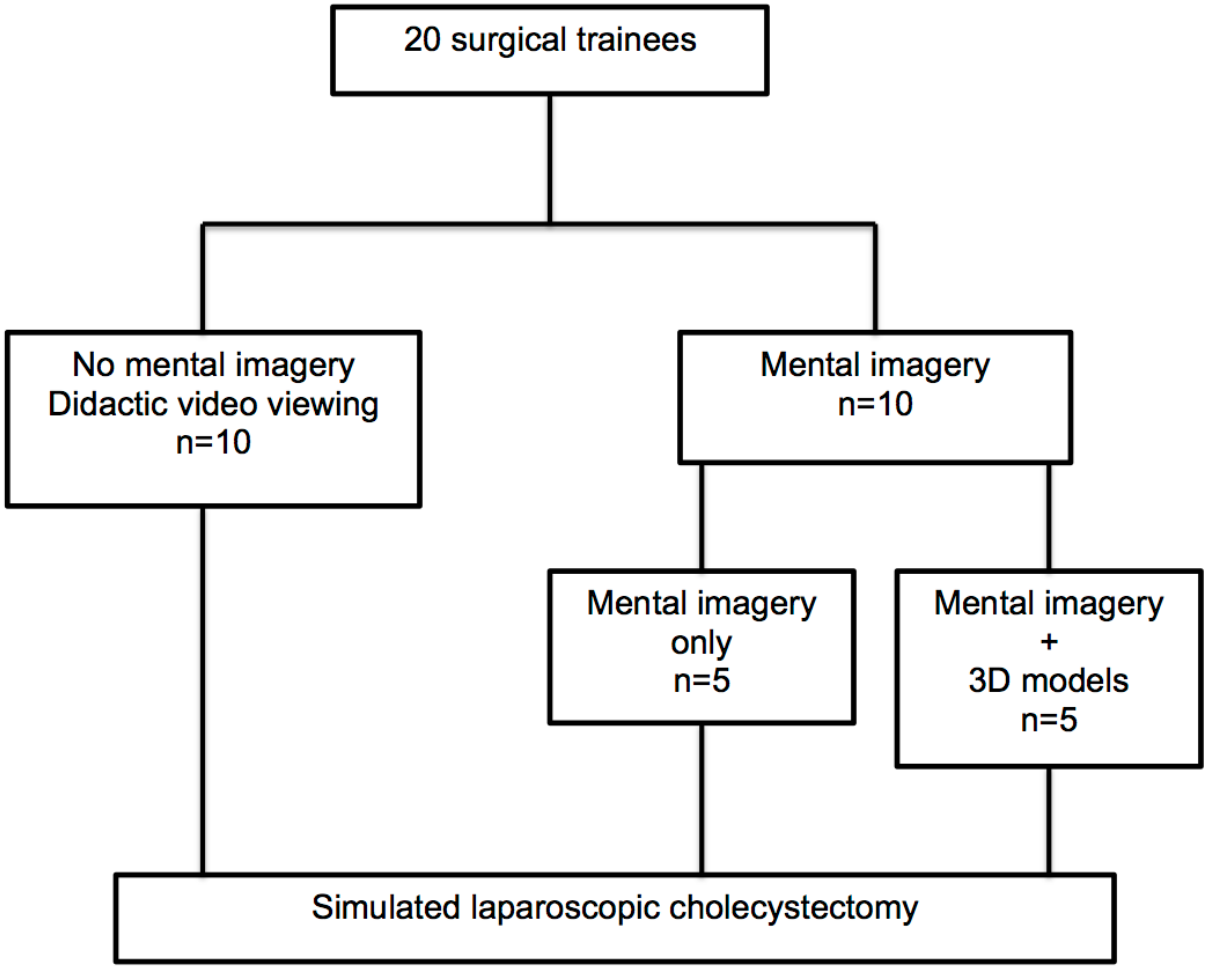


Figure 14. Flowchart of case-control allocation

Prior to the commencement of MP, the experimenter, acting as a facilitator, provided demonstrations of verbalised mental preparation to the participants. In addition, the opportunity to train on how to use the VR simulator (LAP Mentor, Simbionix, Cleveland, OH, USA) was provided. The participants were taught practical aspects of simulation usage, such as how to select a surgical tool and where the diathermy pedals are located. The trainees did not require additional training on how to perform

a laparoscopic cholecystectomy as they had previously assisted or/and performed laparoscopic cholecystectomies.

The intervention groups (MPO and 3D) were given an excerpt from a surgical textbook (293) containing a step-by-step breakdown of a LC and were asked to “visualise” and “feel” the operation. Participants allocated to the 3D group were taught how to use the rotation and zoom-in/-out tools of the visualisation software. In addition to MP, they were instructed to inspect the 3D anatomy on the virtual model for each step of the procedure.

All groups, after undergoing the appropriate preparation process, proceeded to perform a simulated laparoscopic cholecystectomy on a VR simulator. Performance (Instrumental Tip Path Length [PL], Number of Movements and Time To Extract Gallbladder [TTGB]) and safety metrics (Number of Non-Cauterised Bleedings [NCB], number of Perforations [Per], number of Damage to Vital Structures [DVS]) automatically provided by the simulator, were recorded. We chose these performance metrics because previous research has demonstrated that they have predictive validity between experts and novices (265). There was no previous validation of the safety metrics recorded in this study, however, these metrics were selected ahead of other measures on the basis that poor performance on these would have a clear impact on patient wellbeing if these operations were to be performed in a real clinical setting

Statistical Analysis

The performance and safety metrics were tested for departures from normality using the Shapiro-Wilk test before being subjected to a One-Way ANOVA or a non-parametric Kruskal-Wallis test as appropriate. The Shapiro Wilk test indicated that the performance metrics were normally distributed (Time p=0.87, NOM p=0.67, PL p=0.93). However, safety measures were demonstrated to have a non-normal distribution ($p < 0.001$). As a result of the normality testing, one-way ANOVA was used for the performance metrics and Kruskal-Wallis testing was used for the safety metrics. For the ANOVA, when a significant difference for a main effect ($p < .05$) was found, Bonferroni-corrected post hoc comparisons were performed. For brevity, only statistically significant post-hoc comparisons are reported. We report partial eta squared values (ηp^2) to indicate the effect size. An estimate of the effect size w^2 is reported (H/N). Analysis was carried out using IBM SPSS® version 22 (IBM, Armonk, NY) and GraphPad Prism 6.0 (GraphPad Software, Inc., California, USA).

4.2. Results

Performance metrics

We found that performance differences across groups (Fig. 15), showed a main effect in the amount of time taken by participants to complete the simulated LC ($F(2,17) = 8.77$, $p = .002$, $\eta p^2 = .51$), with the Control group (Median (M) = 1447sec,

SD = 341sec) taking significantly longer ($p = .002$) relative to the 3D & MP group (M = 670sec, SD = 326sec). Similarly, the Number Of Movements (NOM) was also significantly different across groups ($F(2,17) = 11.57$, $p = .001$, $\eta p^2 = .58$), with the 3D & MP groups (M = 627.2, SD = 352) making fewer movements relative to controls ($p = .001$). For PathLength (PL), a significant main effect was found ($F(2,17) = 7.57$, $p = .005$, $\eta p^2 = .47$) and we observed that the control condition (M = 2837, SD = 633) led to longer distances covered in comparison to the 3D & MP condition (M = 1540cm, SD = 957cm) and the MP only condition (M = 1800cm, SD = 370cm; $p = .038$).

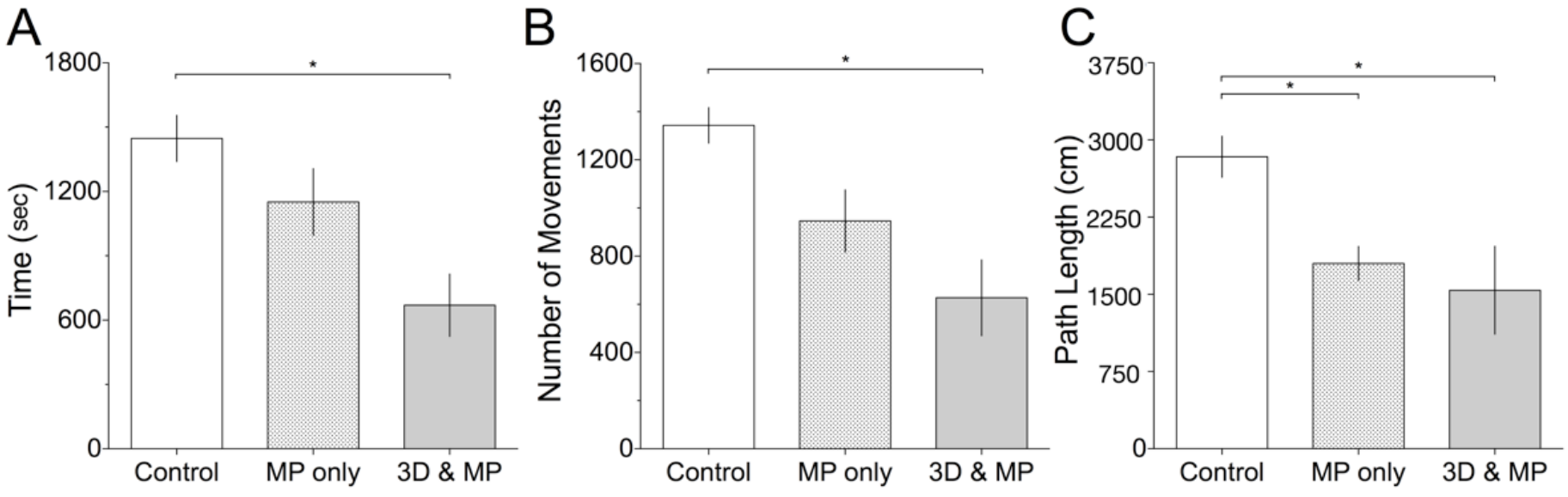


Figure 15. MP: Mental Practice only, 3D & MP: Three dimensional model and Mental Practice.

Performance metrics (error bars represent ±1 SEM).

Safety Metrics

For the safety measures (Fig. 16.), no statistically significant difference was found in the frequency of the damage to vital structures ($H(2) = .63$, $p = .68$, $\omega 2 = .03$). The comparisons for non-cauterised bleeding ($H(2) = 4.71$, $p = .13$, $\omega 2 = .24$) and number of perforations ($H(2) = 4.8$, $p = .082$, $\omega 2 = .24$) showed marginal trends but did not reach the statistical significance threshold.

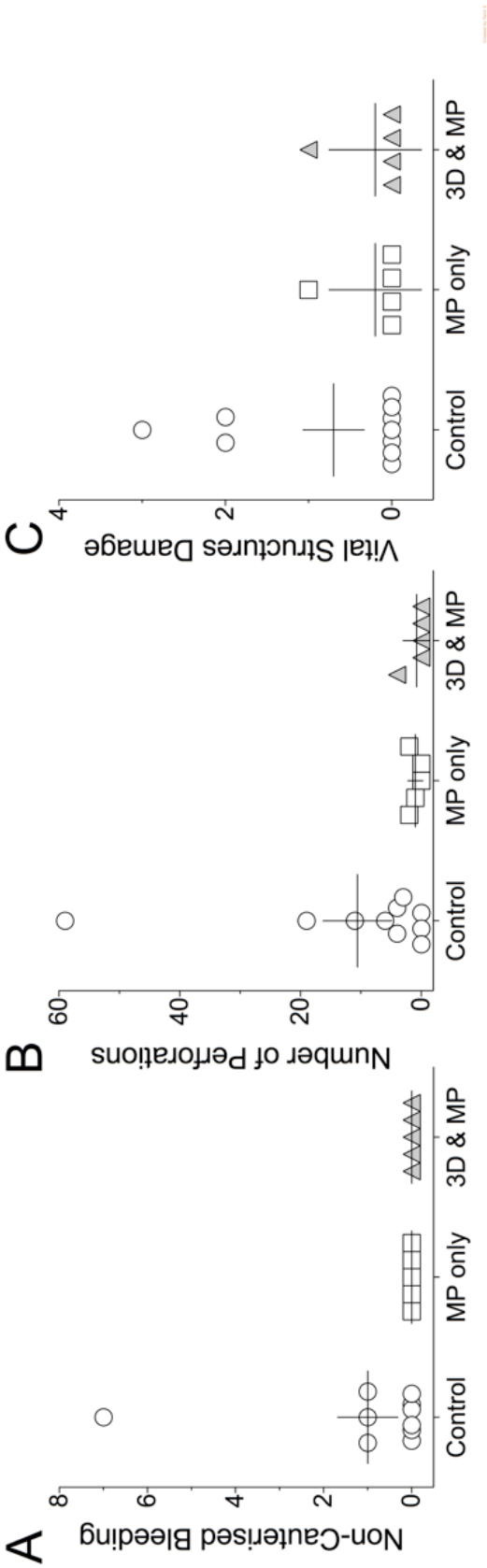


Figure 16. Safety metrics (error bars represent ±1 SEM).

4.3. Discussion

There is a long history of using mental practice to improve performance in sports and arts. Whilst recent work has suggested that this approach could be adapted for skill acquisition, evidence remains equivocal (28, 142, 143). We suggest that, because the ability to produce a mental image varies across individuals (208),this could potentially account for differences across studies. It is also known that MP is a demanding process (144, 146, 294) requiring a number of cognitive processes to work in concert (157-159). We speculated that providing support for MP might enable trainee surgeons to maximise the benefit of this approach.

The present study therefore applied a novel approach and developed interactive 3D visual models. The hypothesis was that this would alleviate the cognitive load of producing and maintaining a virtual image and standardise the quality of the image produced amongst individuals, which we hypothesised would subsequently lead to better surgical performance. When this approach was compared with pre-procedural preparation using didactic video viewing, there was an indication from our data that this may enhance the assessed surgical performance metrics. Conversely, mental imagery alone appeared to enhance only path length when the same comparison applied.

Safety metrics (damage to vital structures, non-cauterised bleedings, liver perforations) were found to be similar in the three groups. Adverse events, with the exception of two outliers, were rare occurrences (Fig. 16), which may not have been

the case if the participants recruited had been novices (i.e. have not performed the operation as a primary surgeon).

The concept of the current study is novel - no trial to date has combined a 3D model with mental practice. However, several randomised controlled trials (RCT) have assessed the effect of mental rehearsal without the use of additional aids (28, 30, 142, 143, 199) with conflicting results. The MPO group in our study improved in only one metric (PL) when compared to the control group. Other metrics, such as NOM showed a trend and a greater sample size study may have demonstrated a more conclusive enhancement of performance.

Similarities can also be found in the methodology described in the relevant literature. For instance, the duration of the MP sessions is similar with previous studies assessing the acquisition of surgical skills after MP (27, 28, 142, 143, 199). Similarly to the current study, Mulla et al. (201) and Eldred-Evans et al. (199) used a step-by-step breakdown of the procedure while Sanders et al. (28) used a textbook to facilitate the consequent MP process. Other authors have applied training sessions on how to perform a laparoscopic cholecystectomy, but this was necessary because they recruited medical students who were not familiar with the performed procedure (27-29, 199-201). The current study recruited advanced beginners who were familiar with the technique as surgical assistants or through performing the operation as primary surgeon.

It should be noted that there are limitations to this study. Firstly, this was an exploratory, case controlled (rather than randomised trial) with a small sample size of 20 participants. The limited sample size increases the possibility of making a type II error. Relatedly, the use of eta square calculation may overstate the effect size due to the small number of participants in the intervention groups (n=5). As such, the generalizability of these results may be limited due to the small sample size of this study. Nevertheless, this exploratory finding does provide an interesting avenue for a future, larger scale, statistically high powered RCT. To inform future work, using an average obtained effect size from our performance metrics ($\eta p^2 = .52$), we computed (using G*Power 3.1.9) [46] that a minimal sample size of 42 would need to be adopted to achieve 80% power (1-β error probability). We add the caveat that the eta square may be overstating the effect size in such a small sample so the sample size may need to be considerably larger. We anticipate that future studies will contribute information that will enable more accurate estimates.

It is also noteworthy that, unlike previous studies, in which medical students were recruited (27-29, 199-201), only surgical trainees participated- a more representative sample of the target population. Recruitment of inappropriate participants in education studies has previously been highlighted by the Association for Surgical Education (ASE) who concluded that recruiting medical students is not an appropriate method for validating educational methods that are targeted at surgical trainees (134).

To address the issue of individual differences in MP, some previous studies tested the baseline ability of the participants to perform MP in order to ensure equality of the comparative groups (29, 207). In our study, we adopted an alternative approach (as our priority was to facilitate group level performance rather than attenuate individual differences) and instead standardised the presentation of the visual model, the presence of a facilitator and the provision of a textbook excerpt throughout the MP session.

Specialties such as orthopaedic and vascular surgery have been using imaging 3D reconstruction to make treatment decisions (19, 22, 235). However, the anatomical model viewing process has not been employed in a systematic manner- thus providing a different experience for individual surgeons. Furthermore, three-dimensional patient-specific models have not been explored for didactic value in non-experts. Mental imagery provides an ideal platform for both a systematic approach and for boosting the potential didactic effect of anatomically variant models. This combined approach of mental imagery and anatomically variant anatomical models may be applied both in the pre-operative preparation of expert surgeons prior to complex surgical procedures or in didactic sessions for novices. For instance, minimally invasive total mesorectal excision complexity has been shown to be associated with patient (e.g. pelvic dimensions) and tumour characteristics (e.g. rectal cancer local invasion and distance from the anal verge) (10, 11, 295); hence requiring a preparation which accommodates these factors. The merger of anatomical models reconstructed from medical images and mental

preparation introduces the possibility of patient specific rehearsals for the above as well as other types of surgery.

Varying anatomy often complicates laparoscopic cholecystectomy (the procedure used in this study). Previous anatomical or radiological studies have categorised the relevant anatomical variations (296); which we can recreate in 3D anatomical models - models that can subsequently be used in combination with mental imagery to teach non-expert trainee surgeons. This is a relatively inexpensive method (3D reconstruction software is available as freeware and requires no specialist IT experience (297)), which could potentially boost surgical performance and ultimately lead to improved patient outcomes.

Chapter 5

Pilot study

Chapter 5: Pilot study

After completing a feasibility study, we proceeded to a pilot study with the introduction of anatomical variation. Also for this study the participants were trained to reach the plateau of their learning curve prior to applying the intervention, ensuring that baseline expertise is similar between groups. The methodology and results are discussed below.

5.1. Methods

Surgical procedure

For the purposes of this exploratory study, simulated laparoscopic cholecystectomy (LC) was the procedure of choice for the following reasons: (i) virtual reality LC simulators are readily available (LapMentor®, Simbionix, Israel) (112), (ii) simulated operations with anatomical variations are provided (108) (iii) LC is a commonly performed operation involving complex laparoscopic skills (109), and (iv) the anatomy of the cystic duct and artery vary significantly, demanding varying degrees of technical competency (110).

Participants

Sixteen medical students, (years two-five and intercalating), who have never seen a laparoscopic cholecystectomy or used the virtual reality simulator before, volunteered for the study after receiving email invitation using the mailing list of the University of Leeds. Sample size calculation was based on the primary outcome for the study, the Competency Assessment Tool – CAT, a validated scoring system for assessing surgical performance, specifically designed for laparoscopic cholecystectomy (196). A reduction in CAT score from 3 to 2 was assumed to be clinically meaningful, requiring 8 patients to be recruited to either Group A using a mental rehearsal checklist to prepare prior to simulated surgery or Group B using a checklist and an interactive 3D anatomical model; to determine a significant difference at 80% power (α=0.05, β=0.2, Standard Deviation of 0.7)

Subjects underwent small group teaching sessions on the clinical indications, anatomy, surgical technique and complications after a laparoscopic cholecystectomy (LC). They were shown how to use the virtual reality simulator (VRS) and taught a series of defined tasks on the simulator as well as a complete laparoscopic cholecystectomy. Subsequently, they performed 10 repetitions of the “normal anatomy” laparoscopic cholecystectomy, each at least forty-five minutes apart from the other.

Upon conclusion of the training phase, participants completed a questionnaire assessing their ability for mental imagery (MIQ-RS) (298) and performed a simulated laparoscopic cholecystectomy, which was scored using CAT. The MIQ-RS consists

of 14 tasks; trainees are initially asked to physically perform an action (e.g. raising a knee as high as possible and then lowering the knee so they are standing again on two feet) and after they are asked to visualise or to feel themselves performing the same task without overt physical movement. Subsequently, they were asked to score how easy it was to visualise or feel the task. A Likert scale (1-7, 1: Very hard to see/feel, 7: Very easy to see/feel) was used for that purpose (298). According to the results of the MIQ-RS and CAT they were paired in dyads of similar ability and then randomized to two equal groups (fig. 17) through the process of a draw consisting of eight “checklist only” tickets and eight “checklist and model” tickets. Had participants within a couple drawn the same type of ticket the process was repeated until they were randomized into two different groups. In such a manner the number of participants in each group remained equal.

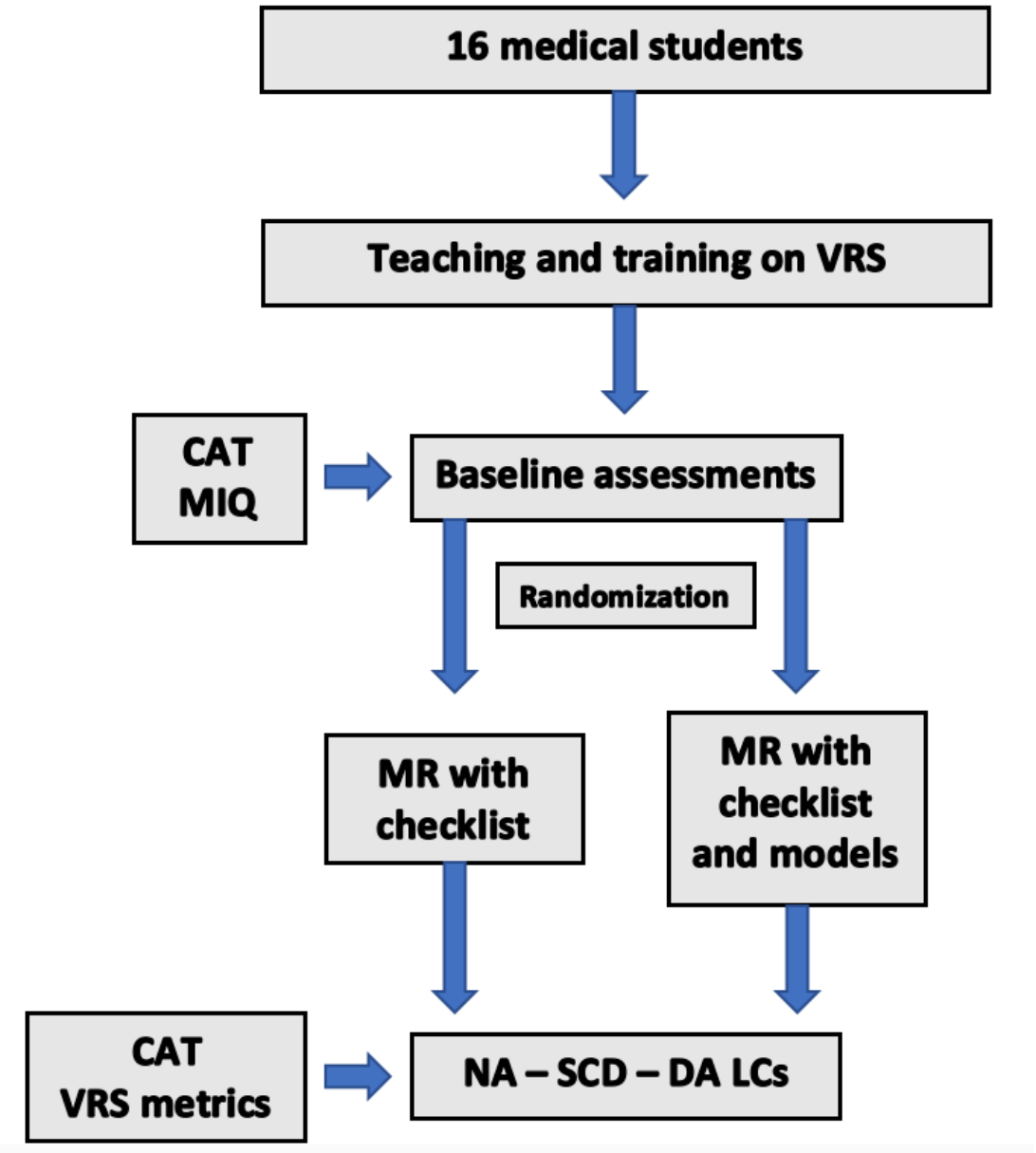


Figure 17. Study methodology for pilot study. VRS: Virtual Reality Simulator, CAT: competency assessment tool, MR: mental rehearsal, MIQ: mental imagery questionnaire, NA: normal anatomy, SCD: short cystic duct, DA: double cystic artery.

Preparation of mental rehearsal checklist

For the purposes of preparing a mental rehearsal checklist (table 4) semi-structured interviews were conducted with five specialist surgeons who regularly perform laparoscopic cholecystectomy. The concepts of mental rehearsal, and visual and kinaesthetic cues were explained and they were asked to describe how they would perform a laparoscopic cholecystectomy.

The interviews were transcribed verbatim and analysed by two of the authors, conducting descriptive synthesis and extraction of visual (e.g. “I now see Calot’s triangle”) and kinaesthetic cues (e.g. “I retract the gallbladder towards the right shoulder with moderate strength”) embedded within various steps of the procedure. The most commonly occurring cues were introduced into the checklist. These were combined with the stages of the procedure most frequently described by the surgeons in order to produce a 14 step checklist (table 4) which could be combined with visualisation of the interactive 3D models (fig. 18). This was adjusted to the stages of the procedure which can be completed on the VRS.

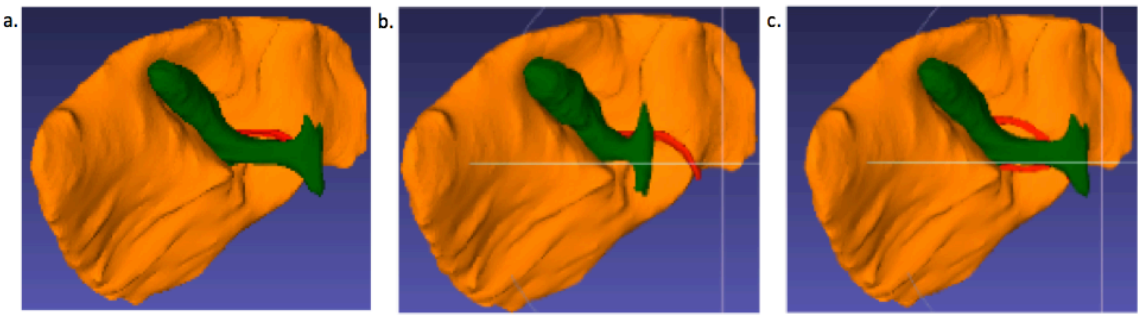


Figure 18. Virtual models a. Normal anatomy b. Short cystic duct c. Double cystic artery

3D models preparation

Three different anatomical variations were chosen for this study: “normal anatomy” (NA), “short cystic duct” (SCD) and “double cystic artery” (DA). For each anatomical variation, a 3D model was reconstructed manually from an anonymised computed tomography (CT) scan using an “in-house” 3D reconstruction software (VolumeViewer, University of Leeds). The model was exported onto open source visualisation software (MeshLab).

The NA gallbladder consisted of a normal sized cystic duct and a single cystic artery positioned posteriorly to the cystic duct. The SCD had a shorter duct and a single artery posterior to the duct. The DA gallbladder had a normal sized duct and two cystic arteries, one anterior and one posterior to the cystic duct (fig. 18).

Step	Instruction	View model
1	Visualise the retracted liver and gallbladder	*
2	Decide which instruments to use and insert them into the “abdomen” under direct vision (visualise and feel)	
3	Visualise Calot’s triangle	*
4	Retract the gallbladder (feel) in a manner that highlights Calot’s triangle (visualise the retracted gallbladder)	*
5	Decide from where and how you will commence dissection	*
6	Begin dissecting Calot’s triangle (visualise and feel)	
7	Continue the dissection carefully exposing the cystic duct and artery while adjusting the place of the retracted gb to achieve optimal view—describe the movements of both hands (visualise and feel) and what are the end points of the dissection	*
8	Visualise the skeletonised artery and duct	*
9	Insert the clip applier under direct vision (visualise). Place firmly on the cystic duct (feel), visualise both jaws of the instrument (visualise) and then place the number of clips you wish, where you choose (visualise)	*
10	Repeat step 9 with artery—visualise the end result to ensure no complications occurred	*
11	Insert the electrocautery instrument you will use for dissecting the gall bladder off the liver bed under direct vision (visualise)	
12	Retract the gallbladder as you see fit (visualise and feel) and commence the dissection of the gb off the liver bed from the point you choose (visualise)	*
13	Continue the dissection of the gallbladder from the liver bed adjusting the retraction position as you see fit (visualise and feel)—describe your movements	*
14	Ensure there is no bleeding from the liver bed either right before the completion of the dissection or at the end of it (visualise) – describe how you would deal with bleeding	

Table 4. 14 step checklist

Intervention and comparators

During the mental rehearsal session, the subjects were seated in a quiet place and given time to relax. Participants randomized to group B were taught on how to use the 3D model viewing software. All subjects were asked to read through the mental rehearsal checklist and prepare to verbalise how they would perform the procedure

whilst “viewing” and “feeling” the operation (visual and kinaesthetic cues) based on their previous experience of performing the procedure on the simulator.

The participants randomized to group A (n=8) were asked to perform a Normal Anatomy (NA) simulated LC, a Short Cystic Duct (SCD) and a Double cystic Artery (DA) simulated LC after completing a mental rehearsal session with the use of the checklist only. The students randomized to group B (n=8) were asked to do the same, but for most steps on the checklist (indicated with an asterisk – table 4) they were also asked to review the appropriate anatomical model. Group A was informed of the anatomical variation of the eminent procedure, but did not have access to the relevant anatomical model provided to group B. This process was repeated before every simulated procedure. All procedures were video-recorded for later assessment.

Measured outcomes

Performance (time, NOM and PL) and safety metrics (Number of perforations – Per, number of Non-Cauterized Bleeding - NCB and number of Damages to Vital Structures – DVS) automatically provided by the VRS were compared between the two groups for each type of anatomy. Proficiency gain curves for time to complete the procedure (time), Number Of Movements (9) and Path Length (PL) of the instrumental tip were generated by curve fitting raw data using power law [$f(x) = ax^k$ – a: first attempt result and k: log of learning rate divided by log of 2] (107).

The recordings of the procedure were judged by two blinded assessors [R.G, D.G] using the competency assessment tool designed specifically for laparoscopic cholecystectomy (196). The initial category of this score refers to the insertion of ports and as this was not part of the VRS, this category was not used for scoring.

Statistical analysis

The unpaired t-test was used to compare continuous data and the Mann-Whitney U-test for discrete data. Eta squared is reported for the statistically significant outcomes ($p<0.05$). IBM® SPSS® Statistics Vs. 24 and GraphPad Prism® 7.0b, GraphPad Software, Inc. were used for all statistical analysis and preparation of graphs. Agreement between assessors was evaluated using the Intraclass Correlation Coefficient (ICC). The two assessors were given anonymised video files of the procedure, recorded from the virtual laparoscopic camera, using Ezvid Inc (California,US) software (299), not revealing any identifiable features of the candidate, hence ensuring the assessors were blinded.

5.2. Results

The baseline ability of the two groups was similar (fig. 19). Proficiency gain curves demonstrated that medical students experienced a learning effect prior to embarking on the comparative part of the study (fig. 20).

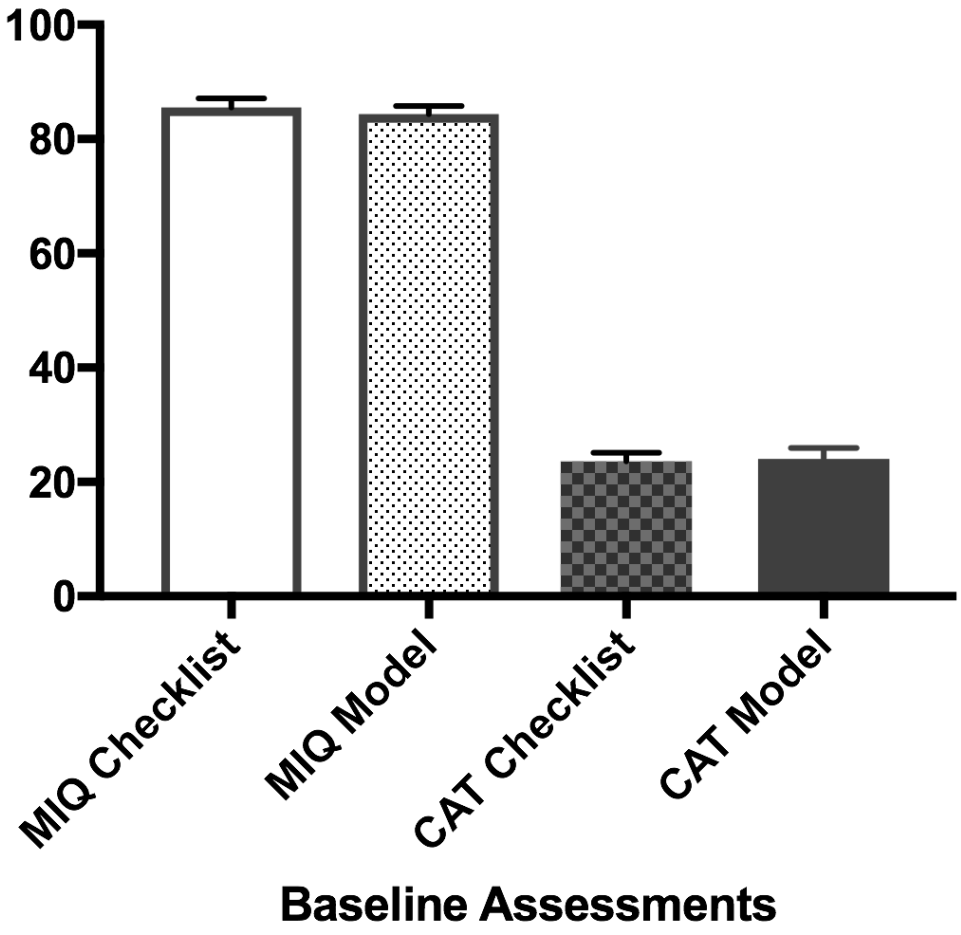


Figure 19. Baseline ability of the two groups. MIQ: Mental Imagery Questionnaire, CAT: Competency Assessment Tool. Y-axis demonstrates mean values for each variable indicated in the X-axis and error bars show SEM (standard error of mean).

VRS performance and safety metrics

a. Normal anatomy

There was no statistical difference in performance [Checklist vs. Model – time (sec): 445.5 vs. 496 p=0.64 - NOM: 437 vs. 413 p=0.88 – PL (300): 1317 vs. 1059 p=0.32] or safety metrics [Checklist vs. Model – per: 0.5 vs. 0 p=0.22 – NCB: 0 vs. 0 p=0.71 – DVS: 0 vs. 0 p=0.2] between the two groups (fig.20.).

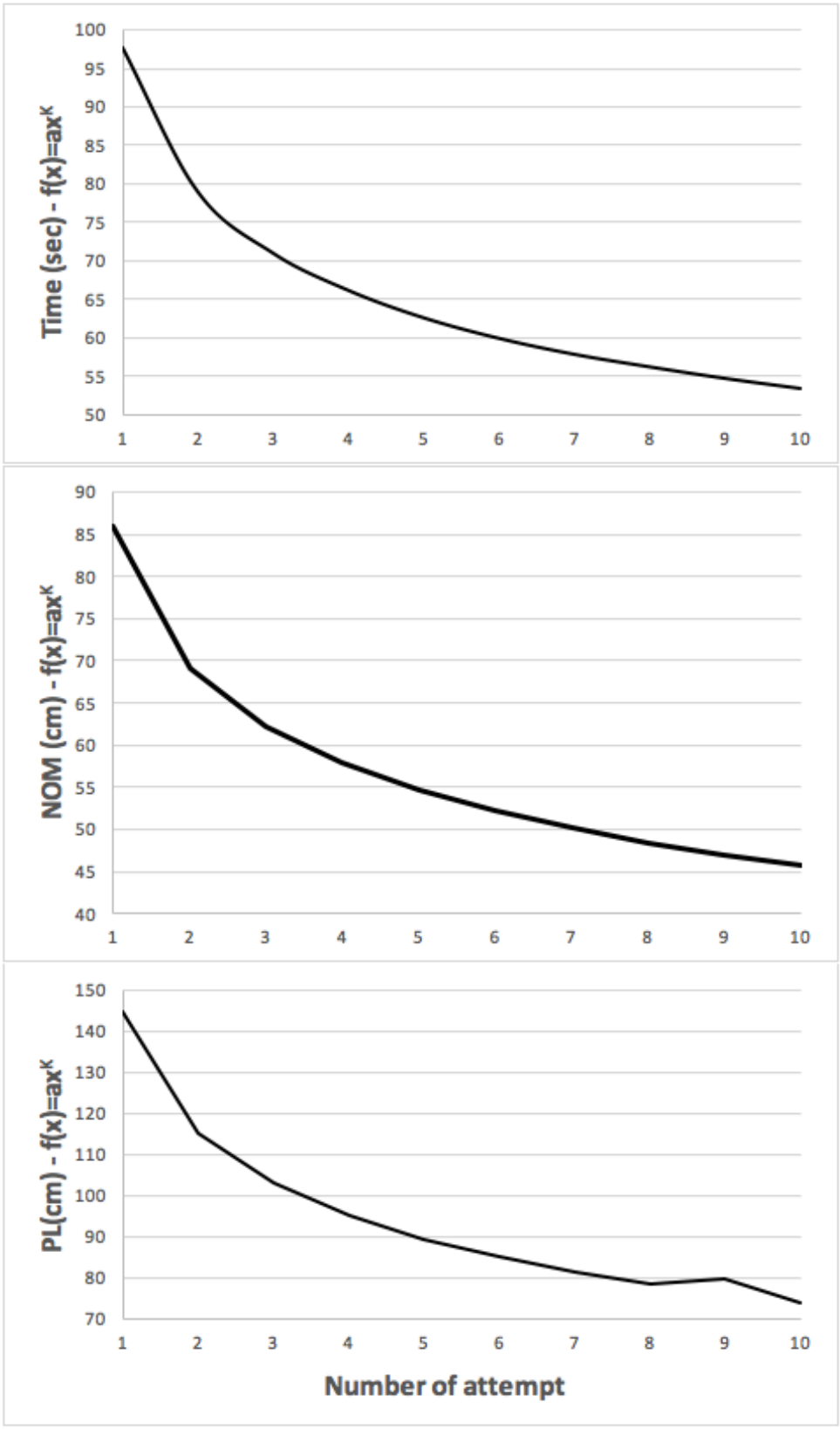


Figure 20. Learning curves for initial 10 LCs.

b. Short cystic artery

There was no statistical difference in all metrics but the number of damage to vital structures that was significantly greater in the Group A [Checklist vs. Model – time (sec): 464.3 vs. 555 p=0.2 – NOM: 506 vs. 481 p=0.86 – PL (300): 1363 vs. 1118 p=0.17 – per: 0.5 vs. 0 p=0.13 – NCB: 0 vs. 0 p=0.2 – DVS: 4 vs. 0 p=0.03 η^2= 0.34] (fig. 21.).

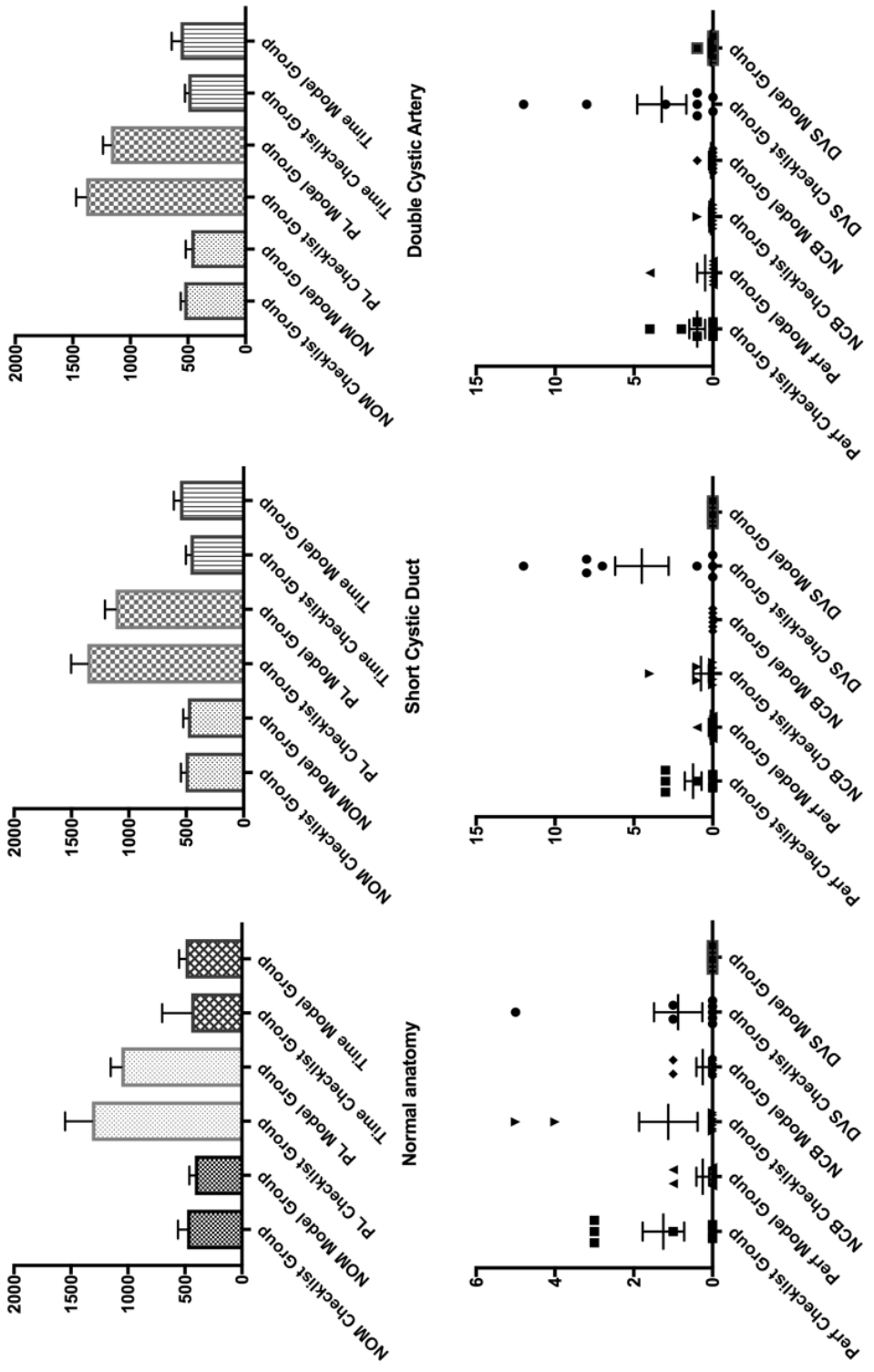


Figure 21. VRS metrics. NOM: Number Of Movements, PL: Path Length. PL is measured in cm and time in secs.

c. Double cystic artery

The only parameter that showed a significant difference was the number of damage to vital structures in Group A [Checklist vs. Model – time (sec): 498.4 vs. 565.8 p=0.43 – NOM: 541.5 vs. 514.5 p=0.4 – PL (300): 1385 vs. 1171 p=0.07 – per: 0.5 vs. 0 p=0.28 – NCB: 0 vs. 0 p>1 – DVS: 1 vs. 0 p=0.02 η^2=0.22] (fig. 21).

CAT score

The two assessors, who were blinded (blinding process explained above), of the LC videos were in good agreement (considered to be ICC> 0.8) (278) with each other [ICC: 0.81 - 95% C.I (0.66-0.89)]. According to the CAT scores, Group B performed the SCD and DA LC significantly better than the Group A, but there was no statistically significant difference in the performance of the NA LC [Checklist vs. Model Total CAT score – NA: 23.63 vs. 26.69 p=0.2 – SCD: 20.5 vs. 26.31 p=0.02 η^2=0.32 – DA: 24.75 vs. 30.5 p=0.03 η^2=0.28] (fig. 22).

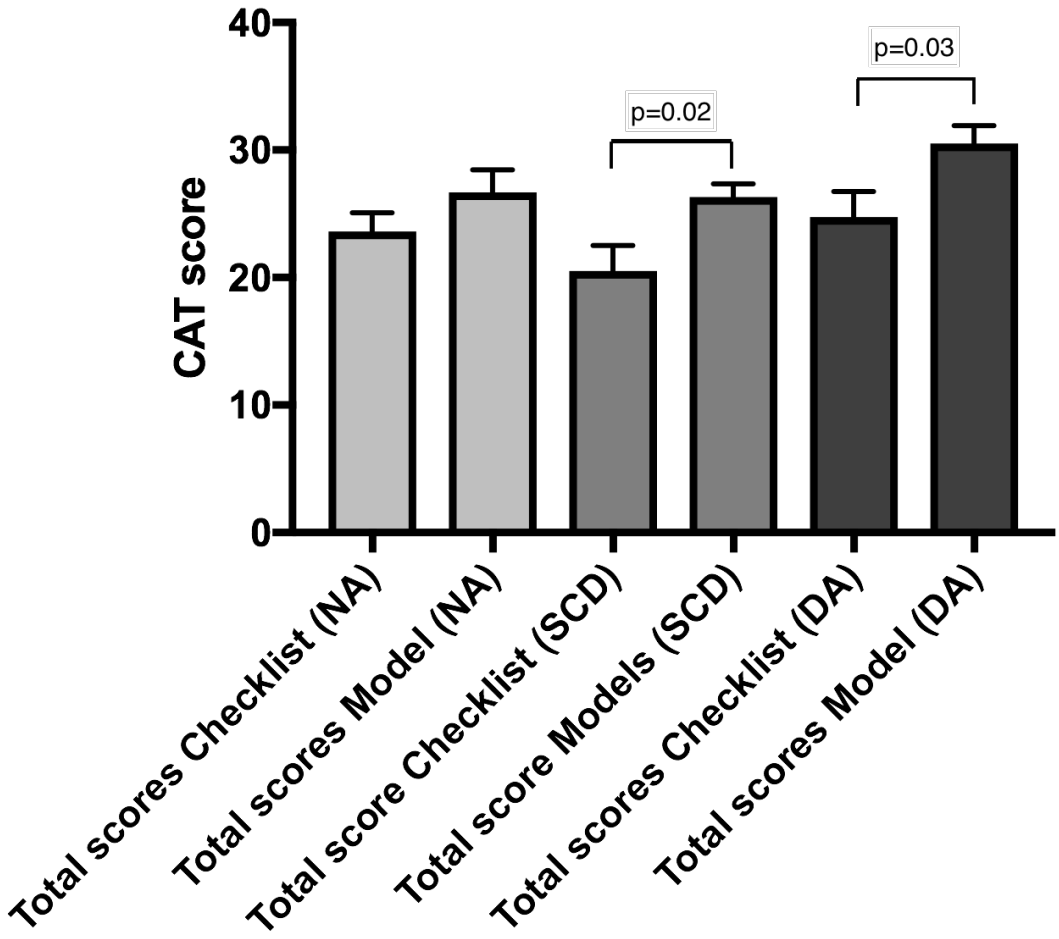


Figure 22. Competency Assessment Tool scores.

5.4. Discussion

To our knowledge this is the first study testing patient specific mental rehearsal with the use of 3D interactive visual aids. The results show that both groups performed equally well when given a “straight-forward” anatomy that they had encountered before. The group who used patient-specific anatomical models as well as the mental rehearsal checklist performed significantly better (CAT scores) and committed less errors (DVS) in cases with more challenging anatomies (i.e. short cystic duct and double cystic artery). These results support further investigation into the application of patient specific preparation with the combination of anatomical models and mental rehearsal, within a clinical environment.

The methodology used in this study is aligned to that described in the literature for mental rehearsal (27, 28, 133, 142). Experts were consulted to create a mental rehearsal checklist and an extensive step-by-step breakdown and teaching and training were provided to the participants prior to the intervention. The performance metrics have been previously validated for demonstrating surgical competency (265). However, PL and NOM are indicative of economy of movements and any difference in these values may not translate into differences in the safety aspect of the procedure (196). Similarly, time to complete a procedure is frequently associated with competency (265, 301-303), but not necessarily with quality (196). This is mirrored in the results of the study, showing completion of the SCD and DA cases in a similar amount of time, whilst Group A had significantly lower CAT score and higher number of damage to vital structures. This justifies the addition of three safety

measures (number of perforations, non-cauterized bleeding and damage to vital structures) and the CAT score evaluation as outcome measures. The assessor using CAT score has the opportunity to comment on hazardous use of instruments or detrimental tissue handling, near misses and errors as well as the fluency of the performed operation (196).

This study has some limitations. First, the participants were medical students and not surgeons, which has implications for generalisability. Due to the time commitment needed for the study, it is likely that recruitment of surgical trainees would have resulted in a high drop-out rate, a frequent problem with educational studies (304-306). Although the authors recognize that medical students are not the target group of the suggested intervention, every possible effort was made to maintain uniform experience and baseline ability of participants (fig. 19). Second, the study was not conducted in a clinical environment but in a simulation suite. Whilst the VRS used in this study has good validity (307, 308) and skills gained using such simulators are transferable to the operating room (303), there are intrinsic differences between a simulated and a real procedure (196). This is reflected in the minor modifications needed to the CAT score and mental rehearsal checklist to extract the parts of the procedure not portrayed on the simulator (e.g. insertion of ports or patient positioning). Having established a possible benefit to mental rehearsal combined with patient-specific anatomical models in a simulated environment, the next step is to test the intervention within a clinical randomized controlled trial.

5.5. Conclusion

The combination of mental rehearsal and patient-specific anatomical models reduces error occurrence and improves quality of surgery in complex procedures undertaken within a simulated environment.

Chapter 6

Clinical Trial

Chapter 6: Clinical trial

Having completed a feasibility and a pilot study in a simulated environment the next step was to conduct a clinical trial, assessing patient specific mental rehearsal and simulation in a real-time clinical environment.

Technical difficulty in rectal cancer surgery, affects both specimen quality and complication rates (10, 11) and is directly associated with anatomical and pathological characteristics (8-11). The level of difficulty is associated with tumour location, pelvic geometry and the patient's Body Mass Index (BMI) (10, 11). This suggests that the concept of individualised pre-operative planning may result in better outcomes after rectal cancer surgery.

The primary aim of this clinical trial was to test the feasibility of performing pre-operative, patient-specific, Systematic Mental Rehearsal (SMR) using virtual and physical rehearsal aids for laparoscopic rectal cancer surgery, in a real, highly time pressurised clinical environment. The secondary aim of this study was to assess the clinical impact of the two techniques described above. The outcomes used to fulfil the secondary aims of this study are: surgical performance (assessed using two previously validated tools – please see below), patient complications, length of stay in hospital and quality of tissue removed during surgery.

6.1. Materials and Methods

Participants

Patients who were diagnosed with resectable rectal cancer (distance from the anal verge 4-16cm) and were due to undergo minimally invasive (laparoscopic/ robotic, laparoscopic/transanal) rectal cancer surgery were recruited. Potential recruits were identified at the colorectal cancer MDT meeting. Patients planned for a primary Hartmann's resection (no anastomosis planned), abdominoperineal resection (APR) or primary open surgery were excluded from this study. Patients unable to represent their own interests and consent themselves for treatment were not included in the study. The operations had to be done or supervised by a consultant colorectal surgeon. The minimum requirement is an experience of >50 laparoscopic anterior resections as primary surgeons, which ensured competence in performing this procedure (309).

Sample Size

Sample size calculations were performed based on the assessment of experts and apprentices' performances conducted by Miskovic *et al.* (310). According to this

study the effect size for previous surgical experience in performing rectal cancer surgery is 1.245 (Cohen's d). As this is a significant difference (i.e. assumption that the group means will differ 1.245 standard deviations), the sample size calculations were conducted using a more modest anticipated effect size (Cohen's co-efficient d=1). Assuming four conditions (for the four groups the patients will be randomised to) between subjects, alpha at .05 and power at 80% the calculated sample size was 48 individuals. G*Power was used for the above calculations (311).

Recruitment of patients and surgeons

Surgeons: Surgeons were recruited by directly approaching them. Their eligibility was assessed through the experience questionnaire (appendix 1). All, but one surgeon recruited performed more than 250 anterior resections, the remaining one completed 151-200 procedures.

Patients: As standard practice, all rectal cancer cases are discussed at a Multidisciplinary Team Meeting (MDT), which consists of surgeons, radiologists, pathologists and oncologists. The team comes to a consensus about which treatment is most appropriate for each patient. Eligible participants awaiting surgery were then approached for inclusion to the trial. If they consented to participate in the trial they were assigned a unique trial number (UTN) that was used in place of their

identifiable data (name, date of birth) on all records created by/for them in the course of this study.

Randomisation

Randomisation was performed using covariate adoptive randomisation (minimisation). The covariates we will be adapting for are BMI (underweight, normal, overweight, obese), tumour distance from the anal verge (4-8cm, 8.1-12cm, 12.1-16), size (pT) and gender (Male, Female). An automated software algorithm was used for the purposes of the randomisation process. This algorithm has been developed by a researcher at the University of Leeds and was used successfully in previous studies.

Intervention

Design/ produce 3D virtual and physical models for the allocated patients

The aim of the clinical study was to test if already established methods - as tested in previous pilot studies – can be applied within a randomised controlled trial in a pressurised clinical environment.

Details on the preparation of the virtual and synthetic models (Fig. 23) are provided in Chapter 3.

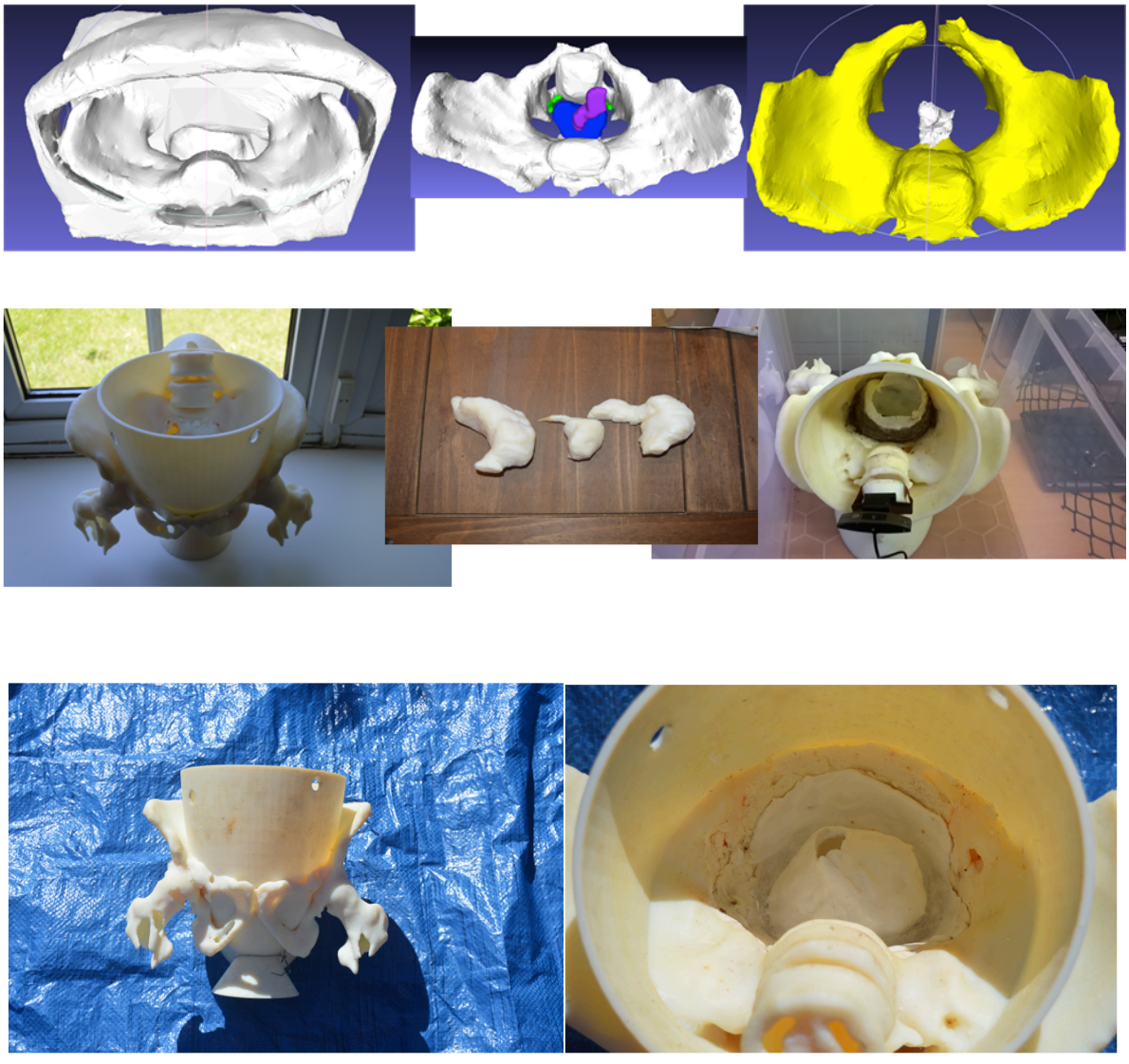


Figure 23. Virtual (above) and physical models (below).

SMR methods

Three different SMR strategies were applied for all but the control group. The variation was regarding the rehearsal aides utilised during SMR. For group 1 SMR was performed combined with MRI scans, for group 2 with interactive 3D virtual models and for group 3 with synthetic models. It should be noted that for group 3, in addition to SMR, physical practice in the form of a simulated procedure was performed.

An SMR session can take 20-40 minutes and was performed within 48 hours before the surgery at a previously agreed time. During these sessions, guided by the research fellow, the surgeons were asked to follow a protocol of mentally going through each step of the procedure. An international consensus on the technical steps was used as a guide (309) (Table 5). The SMR protocol for the three intervention groups is outlined in Table 6. The sessions were co-ordinated by the surgical research fellow (M.Y), but have been co-designed with specialist psychologists.

Step	Brief description
Posterior plane	Posterior plane is entered, the landmarks for the mesorectal plane are identified and the plane is followed as deep as possible.
Anterior plane	Identification of entry point depending on tumour location, dissection posterior to vagina/ seminal vesicles & prostate
Side walls	Identification of hypogastric nerves and dissection according to ant. and post. plane as identified in previous steps
Low pelvic dissection	Identification of pelvic floor (levator muscles), transection of Waldeyer's facia and circumferential identification of low rectal tube.
Transection of rectum	Transection of rectal tube

Table 5. Relevant TME steps according to international consensus (17).

Comparators

In this clinical trial, SMR was compared with routine pre-operative preparation practice. In addition to that, different SMR strategies were compared to each other. Different visual aides were incorporated into the standardised mental rehearsal strategy; these included (i) axial MRI scans of the pelvis, these were performed routinely for all rectal cancer patients, in order to establish the local staging of the tumour (ii) an interactive 3D virtual model reconstructed from the pre-mentioned routinely performed axial MRIs and (iii) synthetic models of the mesorectal envelope, manufactured through computer assisted designing (3D printing), based onto the reconstructed 3D virtual models.

Step	SMR theme	Group i Virtual model	Group ii Physical model	Group iii Standard scans
1	Introduction	The outline of the SMR sessions are explained by the researcher		
2	Viewing of visual aids	The participants are given opportunity to view the visual aids for 5-10 minutes		
3	Agreement on technical steps	The participants are given a summary of the steps of the procedure. They will have the opportunity to change steps according to their individual preference on how they perform the procedure		
4	Detailed TME	For each step of the procedure the surgeon will be asked to mentally go through the step and explain how he/she will do this and what possible difficulties could be encountered.		
4.1	Posterior plane	Dynamic views of the posterior plane are given	Posterior plane dissection is simulated in pelvic trainer	Posterior plane is visualised in consecutive MRI slides
4.2	Anterior plane	Dynamic views of the anterior plane are given	Anterior plane dissection is simulated in pelvic trainer	Anterior plane is visualised in consecutive MRI slides
4.3	Side walls	Dynamic views of the side walls are given	Side wall dissection is simulated in pelvic trainer	Side walls planes are visualised in consecutive MRI slides
4.4	Low pelvic dissection	Dynamic views of the low pelvic anatomy are given	Low pelvic dissection is simulated in pelvic trainer	Low pelvic planes are visualised in consecutiv

				e MRI slides
5	Strategy changes recorded	Based on the above, participants are asked if any strategic or technical changes have been made		
6	Repetition	Any of the above steps can be repeated if required by the participant		
7	Agreed plan	An operative plan is agreed and recorded		

Table 6. Framework for SMR sessions

	Posterior dissection	Anterior dissection	Lateral dissection
Retraction and Exposure (R&E)	**R&E throughout task:**	**R&E throughout task:**	**R&E throughout task:**
	4. Clearly demonstrates all landmarks. Optimal traction and tissue tension throughout.	**4**. Clearly demonstrates all landmarks. Optimal traction/counter-traction & tissue tension.	**4**. Clearly demonstrates planes. Optimal traction/counter-traction & tissue tension.
	3. Demonstrates most landmarks; appropriate traction and tension on tissue.	**3.** Demonstrates most landmarks. Appropriate	**3.** Good demonstration of planes. Appropriate traction/counter-traction & tension.
	2. Ineffective demonstration of landmarks; traction often in wrong direction. Little tension.	**2.** Ineffective demonstration of landmarks. Poor traction/counter-traction. Little tension.	**2.** Ineffective demonstration of planes. Sub-optimal traction/counter-traction. Little tension.
	1. Fails to demonstrate landmarks. Poor views & traction. Closed tissue planes. No tension.	**1.** Fails to demonstrate landmarks. Poor views & traction/counter-traction. No tension.	**1.** Fails to demonstrate correct plane. Poor views & traction/counter-traction. No tension.
	Unable to comment	Unable to comment	Unable to comment
Task Performance/ Execution	**Dissection in posterior plane:**	**Dissection in anterior TME plane:**	**Dissection in lateral TME planes:**
	4. Optimal dissection in correct plane throughout. Safe efficient instrument use.	**4**. Peritoneal reflection incised at optimal site. Correct plane followed. Efficient movements.	**4**. Dissection follows established planes. Clear bloodless plane developed safely & efficiently.
	3. Occasional loss of plane quickly corrected. Atraumatic tissue handling & instrument	**3.** Appropriate incision site. Quickly corrects loss of plane. Safe instrument use.	**3.** Appropriate plane developed safely with minimal bleeding. Quickly

	use.		corrects plane loss.
	2. Ineffective dissection. Repeated loss of plane. Inefficient, laborious instrument use.	**2.** Sub-optimal incision site. Repeated loss of plane. Inefficient, laborious instrument use.	**2.** Unclear relationship to established planes. Dissection into fat. Inefficient instrument use.
	1. Uncorrected dissection in wrong tissue plane. Blunt tissue injuries. Dangerous instrument use.	**1.** Incorrect site for incision. Mostly in wrong or unclear plane. Dangerous instrument use.	**1.** Dissection not in a defined plane or in wrong plane. No attempt to follow established planes.
	Unable to comment	Unable to comment	Unable to comment
Errors	**This task was performed with:**	**This task was performed with:**	**This task was performed with:**
	4. No bleeding/avulsion. Hypogastric nerves safeguarded. No collateral injury/perforation.	**4**. No bleeding/avulsion. Neurovascular bundles safeguarded. No collateral injury/ perforation.	**4**. No bleeding/avulsion. Inferior hypogastric plexuses safeguarded. No collateral injury.
	3. Minimal bleeding/avulsion. Risk unilateral nerve injury. No collateral injury/perforation.	**3.** Minimal bleeding/avulsion. Risk unilateral Nv bundle injury. No collateral injury/perforation.	**3.** Minimal bleeding/avulsion. Risk unilateral plexus injury. No collateral injury/perforation.
	2. Moderate bleeding/avulsion. Likely unilateral nerve injury. Risk of collateral injury.	**2.** Moderate bleeding/avulsion. Likely unilateral Nv bundle injury. Risk of collateral injury.	**2.** Moderate bleeding/avulsion. Likely unilateral plexus injury. Risk of collateral injury.
	1. Substantial bleeding/avulsion. Both nerves probably divided. Collateral injury/perforation.	**1.** Substantial bleeding/avulsion. Bilateral Nv bundle injury. Collateral injury/perforation.	**1.** Substantial bleeding/avulsion. Bilateral plexus injury. Collateral Injury/perforation.
	Unable to comment	Unable to comment	Unable to comment
End-product	**Quality of mesorectum and pelvis after task:**	**Quality of mesorectum and pelvis after task:**	**Quality of mesorectum and pelvis after task:**
	4. Smooth intact bi-lobar mesorectum. No fascial injury. No mesorectal tissue left in situ.	**4**. Smooth anterior mesorectum, +/- intact shiny Denonvillier fascia. No tissue left in situ.	**4**. Smooth lateral surface of mesorectum with no defects. No mesorectal tissue left in situ.
	3. Occasional minor mesorectal injury to fascia only. Minimal tissue left in situ in pelvis.	**3.** Occasional injury to mesorectal/ Denonvillier fascia. Minimal tissue left in situ in pelvis.	**3.** Occasional minor mesorectal injury to surface only. Minimal tissue left in situ.
	2. Sub-optimal specimen with	**2.** Sub-optimal specimen	**2.** Sub-optimal lateral

	injury into fat. Some mesorectal tissue remaining in pelvis	with injury into fat. Some mesorectal tissue remaining in pelvis.	specimen with injury into fat. Some mesorectal tissue still in pelvis.
	1. Incomplete posterior mesorectum with deep injuries into fat/to rectum. Tissue left in pelvis.	**1.** Incomplete anterior aspect to specimen. Deep fat injuries/to rectum.Tissue left in pelvis.	**1.** Incomplete lateral aspect to specimen. Deep fat injuries/to rectum. Tissue left in pelvis.
	Unable to comment	Unable to comment	Unable to comment

Table 7. CAT score for TME

Outcome measures

The primary outcome measure is feasibility of recruitment and execution of methodology without causing delays in clinical practice. Secondary outcomes include (i) surgical performance. For the purposes of assessing this, two separate, validated scoring systems were used – CAT score and OCHRA evaluation method. In order for the assessment to take place the real – time pelvic dissection was recorded through the laparoscopic theatre stack and assessed by two independent blinded experts who reviewed the video recordings (ii) clinical outcomes such as length of stay, complication rates and specimen quality.

CAT score

The CAT score consists of four categories, each representing the steps of the pelvic dissection, i.e. posterior mesorectal dissection, lateral mesorectal dissection, anterior mesorectal dissection and resection and anastomosis. For each category a score

from 1 to 4 (1: unsatisfactory performance – 4:excellent performance) was provided for evaluation according to performance in the following subcategories: a. retraction and exposure b. dissection/execution of task c. number of errors and d. quality of end product (table 7).

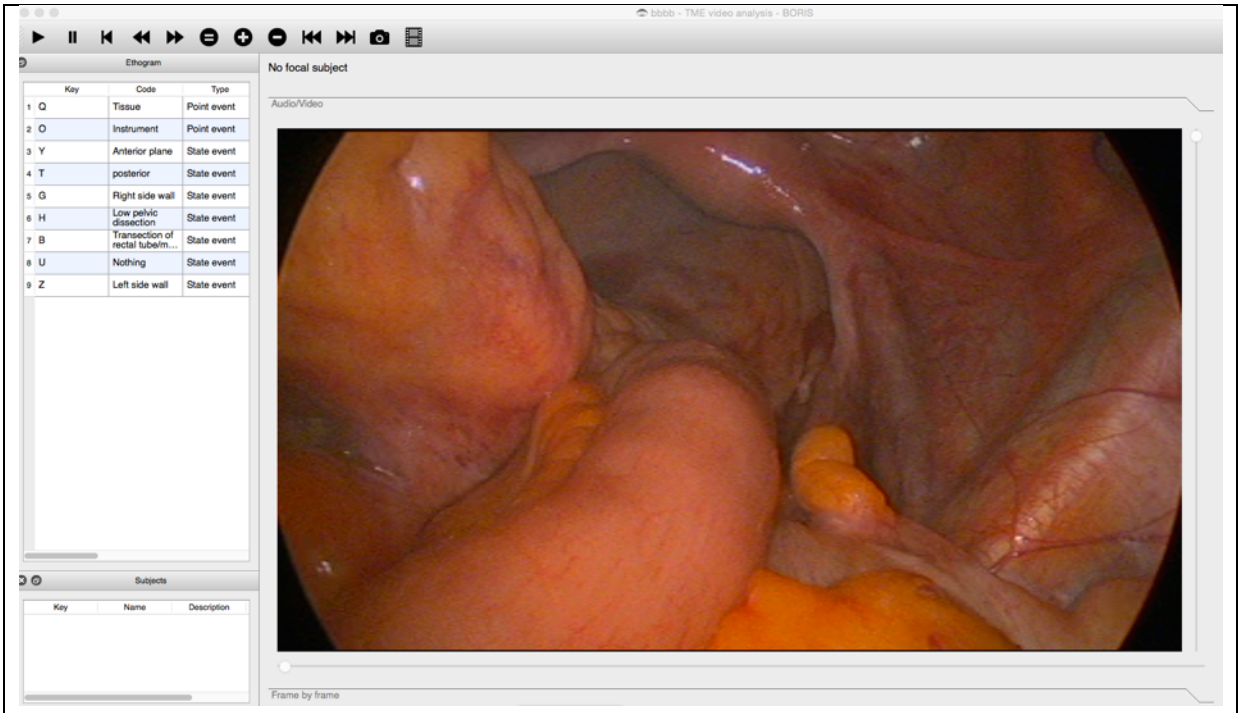
OCHRA

The second, a more objective, but labour-intense method to assess surgical performance, Objective Clinical Human Reliability Assessment (OCHRA), allows for identifying and tagging previously defined errors and near misses, using video-tagging software (19). This leads to a detailed description of performance. It has been shown previously, that a combination of CAT and OCHRA is highly specific and sensitive to reliably identify surgical competence (18).

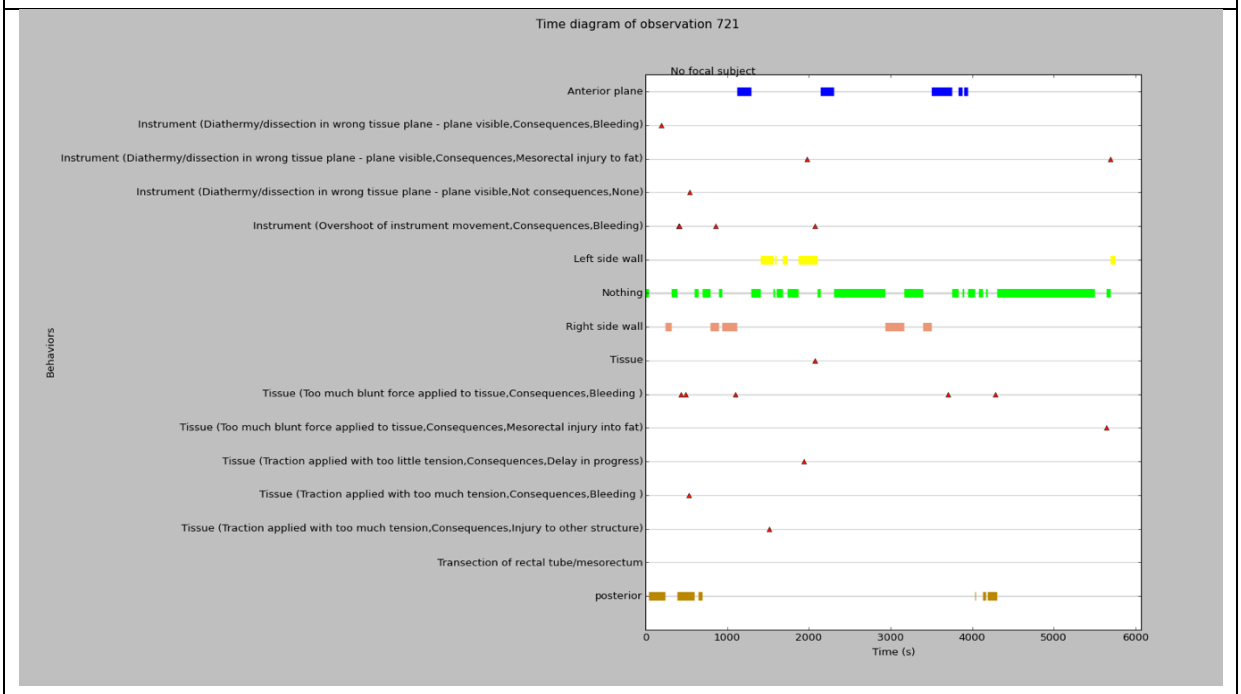
For the OCHRA evaluation process, the pelvic dissection was divided in the following steps: a. anterior plane dissection, b. posterior plane dissection, c. lateral planes dissection, d. low mesorectal dissection and e. transection. In addition to these the time spent without any dissection was recorded (under the code name: “Nothing”).

OCHRA aims to identify errors during surgery. These are divided to either errors related to (i) instrument use or (ii) tissue handling and could also be consequential or bear no consequences (Table 8) (312). All errors and time duration of each step of

the operation were recorded using BORIS, a freeware designed by the University of Pisa Italy (Fig. 24).



a.



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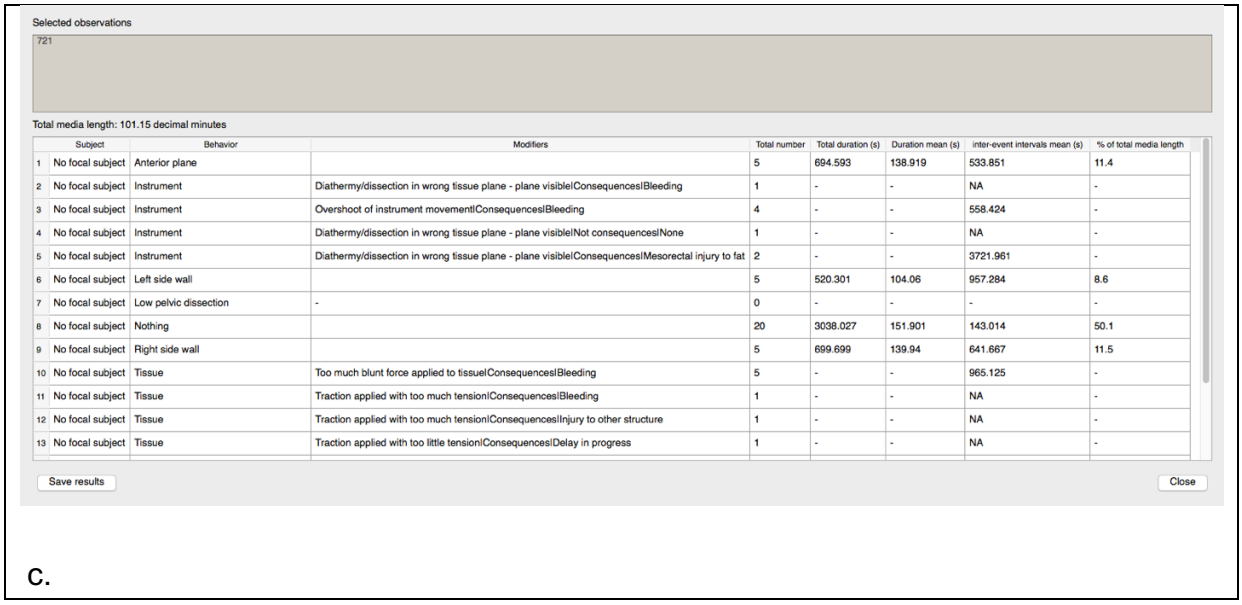
Selected observations

721

Total media length: 101.15 decimal minutes

	Subject	Behavior	Modifiers	Total number	Total duration (s)	Duration mean (s)	inter-event intervals mean (s)	% of total media length
1	No focal subject	Anterior plane		5	694.593	138.919	533.851	11.4
2	No focal subject	Instrument	Diathermy/dissection in wrong tissue plane - plane visible|Consequences|Bleeding	1	-	-	NA	-
3	No focal subject	Instrument	Overshoot of instrument movement|Consequences|Bleeding	4	-	-	558.424	-
4	No focal subject	Instrument	Diathermy/dissection in wrong tissue plane - plane visible|Not consequences|None	1	-	-	NA	-
5	No focal subject	Instrument	Diathermy/dissection in wrong tissue plane - plane visible|Consequences|Mesorectal injury to fat	2	-	-	3721.961	-
6	No focal subject	Left side wall		5	520.301	104.06	957.284	8.6
7	No focal subject	Low pelvic dissection	-	0	-	-	-	-
8	No focal subject	Nothing		20	3038.027	151.901	143.014	50.1
9	No focal subject	Right side wall		5	699.699	139.94	641.667	11.5
10	No focal subject	Tissue	Too much blunt force applied to tissue|Consequences|Bleeding	5	-	-	965.125	-
11	No focal subject	Tissue	Traction applied with too much tension|Consequences|Bleeding	1	-	-	NA	-
12	No focal subject	Tissue	Traction applied with too much tension|Consequences|Injury to other structure	1	-	-	NA	-
13	No focal subject	Tissue	Traction applied with too little tension|Consequences|Delay in progress	1	-	-	NA	-

Save results

Close

c.

Figure 24. a. OCHRA analysis software – input. b. and c. different versions of output.

Modifications to CAT and OCHRA

For the purposes of the current study two modifications were made to allow for comparisons between groups. As the cases include partial and total mesorectal excisions the duration of the partial excisions was expected to be shorter than for total mesorectal excision, therefore a smaller number of errors could be attributed to shorter duration rather than improved surgical performance. To ensure a fair comparison between partial and total mesorectal excisions, instead of comparing the crude number of errors; the rate of errors per unit of time was used as the measured outcome.

Error categories	Consequences
Instrument use errors	Bleeding
Diathermy/dissection in wrong tissue plane (plane visible)	Mesorectal fascia injury
Dissection performed in wrong direction	Mesorectal injury into fat
Too much/little energy applied with instrument	Mesorectal injury exposing muscle
Overshoot of instrument movement	Diathermy burn to viscus
Poor visualisation of instrument tip during dissection	Sharp injury to viscus
Instrument applied with too little distance to structure	Blunt bowel injury
Cutting without lifting tissues from underlying structures	Sharp injury to other structure
Inappropriate use of diathermy/cutting (tip of instrument visualised)	Traction to pelvic nerve
Use of inappropriate instrument to dissect	Injury to pelvic nerve
Retraction/tissue handling errors	Injury to ureter
Too much blunt force applied to tissue	Injury to other structure
Traction applied in wrong direction	Delay in progress
Traction applied with too little tension	Oncological compromise
Avulsion of tissue	
Use of inappropriate instrument to retract	
Inappropriate grasping/blunt handling of other structure	
Traction applied with too much tension	
Inappropriate handling of tumour	

Table 8. OCHRA error categories.

Secondary outcomes

Secondary outcomes include clinical factors such as hospital stay, complications and specimen metrics (i.e. description of specimen quality). In addition, patient demographics, comorbidities (ASA), tumour stage, BMI, age were collected.

The SMR process will be audio recorded and transcribed. This will be done after written consent is obtained by the surgeons. The reasons for audio-recording are strictly for quality evaluation and refinement of the SMR process in a future, larger study.

Statistical analysis

Statistical analysis was performed on GraphPad Prism® 7.0c (La Jolla, CA, USA), and SPSS 17© (Illinois, USA). Non-parametric tests (Kruskal – Wallis) was used for discrete, metric values. For continuous metric variable, ANOVA test was used. Finally, quality of specimen will be assessed using Chi-squared test.

Ethical approval

This study received NHS REC approval by the Leeds East Committee (Reference number: 15/YH/0134), the Leeds Teaching Hospital Research and Innovation department (reference number: GA15/070), the Mid Yorkshire NHS trust Research and Development department (reference number: JH/CSC/N:R&D(15/992)) and the HRA (IRAS identification number 165586).

Clinical Trial Registration

The current trial was registered with the ISRCTN registry data base (reference number: ISRCTN 75603704).

Funding

The clinical trial was funded by the Leeds Teaching Hospitals Charitable Foundation and was sponsored by the University of Leeds.

6.2. Results

49 patients were recruited for this clinical trial and their characteristics are demonstrated in table 9.

Group	Control	MRI	Virtual	Physical
Age (mean, range)	71.58 (63-87)	71.58 (61-84)	61.67 (37-83)	67.46 (43-84)
ASA	1x4 2x7 3x1	1x4 2x8	1x3 2x9	1x5 2x7 3x1
LOS (median, range)	7 (3-41)	7 (3-58)	7.5 (5-36)	14 (6-36)
Lymph nodes no	13.5 (8-31)	19 (12-34)	12 (8-20)	8 (5-28)

(median, range)				
Type of surgery	Lap: 7 Rob: 4 Lap/ TaTME: 1	Lap: 8 Rob: 3 Lap/TaTME: 1	Lap: 8 Rob: 3 Lap/TaTME: 1	Lap: 9 Rob: 3 Lap/TaTME: 1
Conversion (no of cases)	3	0	2	1

Table 9. Patient characteristics. ASA: American Society of Anaesthesiologists physical status score, LOS: Length of stay, Lap: Laparoscopic, Rob: Robotic, TaTME: Transanal Total Mesorectal excision, MRI: Magnetic Resonance Imaging.

Baseline comparisons

Recruited patients were randomised (minimisation) to four groups according to gender, T-stage, distance of tumour from the anal verge (AV) and Body Mass Index (BMI). To ensure that randomisation has produced four groups which are similar at baseline, the above variables were compared between the four groups. Chi-square test was used for this purpose. The results of the comparisons demonstrated that there is no statistically significant difference for the four variables between the groups (Gender p-value 0.7, BMI p-value 0.89, AV p-value 1, T-stage p-value 0.67).

Clinical indices

The most frequently occurring post- operative complications included ileus, anastomotic leak and intra-abdominal collection (table 10) and mean hospital stay

was 7,7,7.5 and 14 respectively for the control, the MRI, the virtual and the physical group. 43 operations were completed laparoscopically (including robotic) and 6 were converted to open, one of the six cases was converted to APER due to inability to complete either laparoscopic or open (table 10).

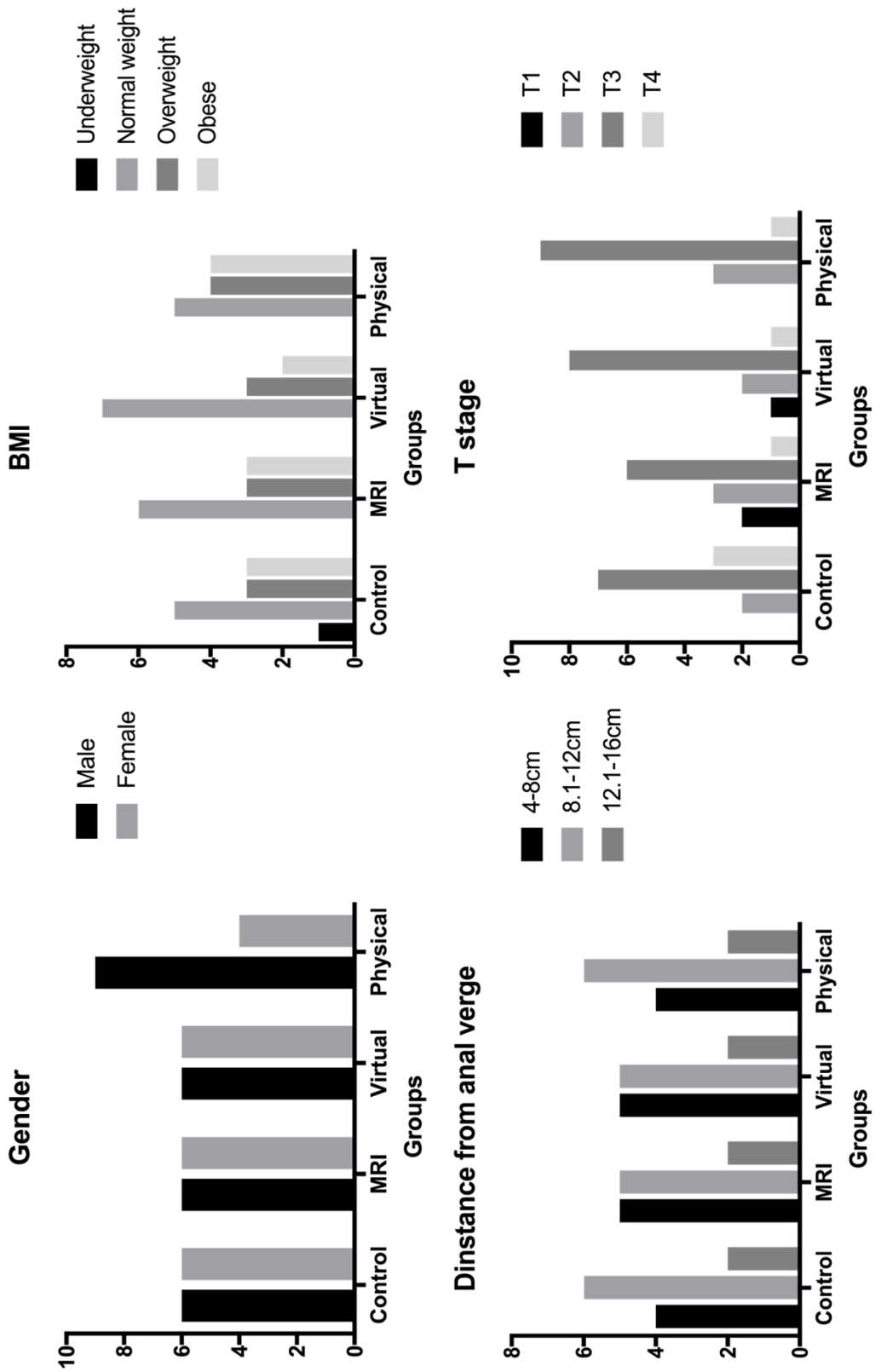

Figure 25. Patient characteristics.

	Control	MRI	Virtual	Physical
Complications	Post-op ileus: 2 Anastomotic leak: 2 Collection: 1	Post-op ileus: 1 Anastomotic leak: 1 Collection: 3	Post-op ileus and aspiration pneumonia: 1 Anastomotic leak: 1 Vaginal injury: 1	Post-op ileus: 1 Anastomotic leak: 1 Stoma retraction: 1 Necrotising fasciitis: 1
Return to theatre	1/5 – pelvic collection wash out	2/5 – wash out of intra-abdominal collection -EUA and rectal wash out of pelvic abscess	0/3	1/4 – necrotising fasciitis for debridement

Table 10. Complications and return to theatre.

Quality of specimen

The quality of specimen was defined as per Quirke *et al.* (313): good –dissection took place in mesorectal plane and mesorectum is intact with smooth surface and with defects not exceeding 5mm in depth, moderate – dissection in intramesorectal plane; the mesorectal surface has irregularities but muscularis propria is not visible and poor – dissection in muscularis propria plane with little bulk of mesorectum and defects to muscularis propria. Quality of specimen was compared between the four groups using Chi square test (fig. 26). There was no statistically significant difference in quality of specimen between the four groups (p 0.56).

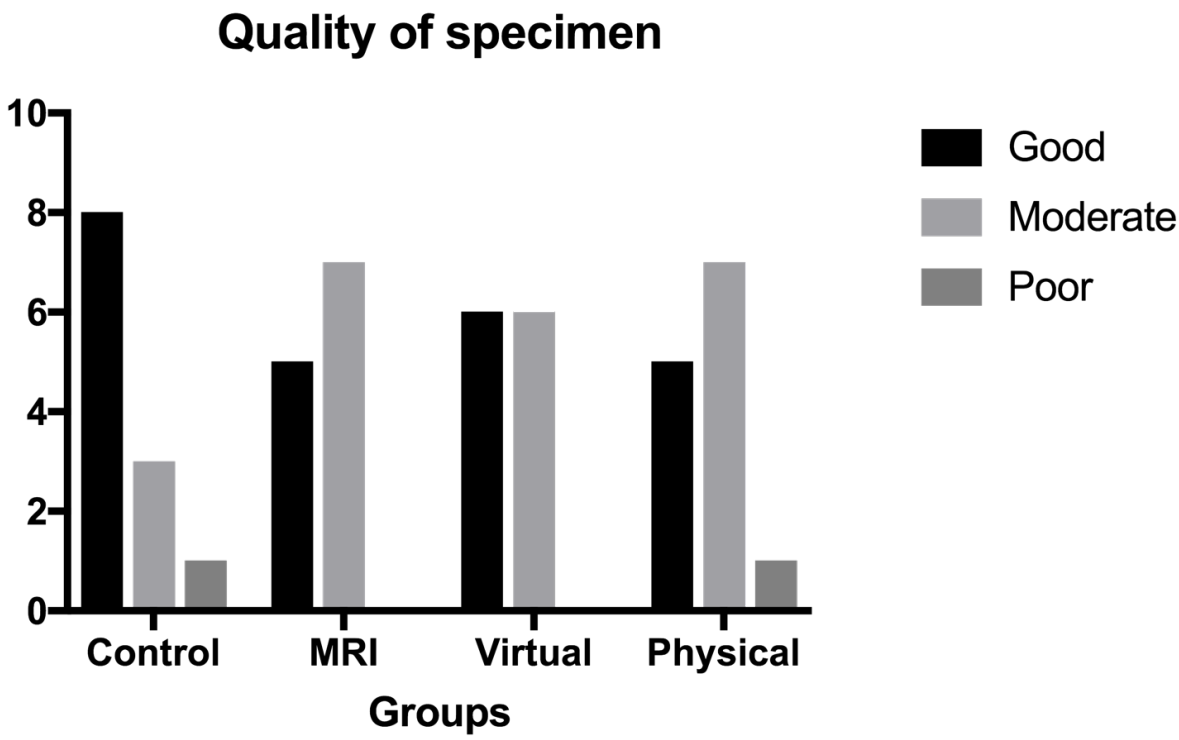

Figure 26. Distribution of quality of specimen

CAT score results

There was no statistical difference in either overall CAT scores or in CAT for individual steps (i.e. anterior, posterior and lateral dissection) between groups (median/1st–3rd IQ – control: 30.5/24.63-38.63, MRI: 34.25/30.5-40.5, virtual: 31.75/30.13-36.38, physical: 34/28.5-35, p 0.75) (Fig. 27-28).

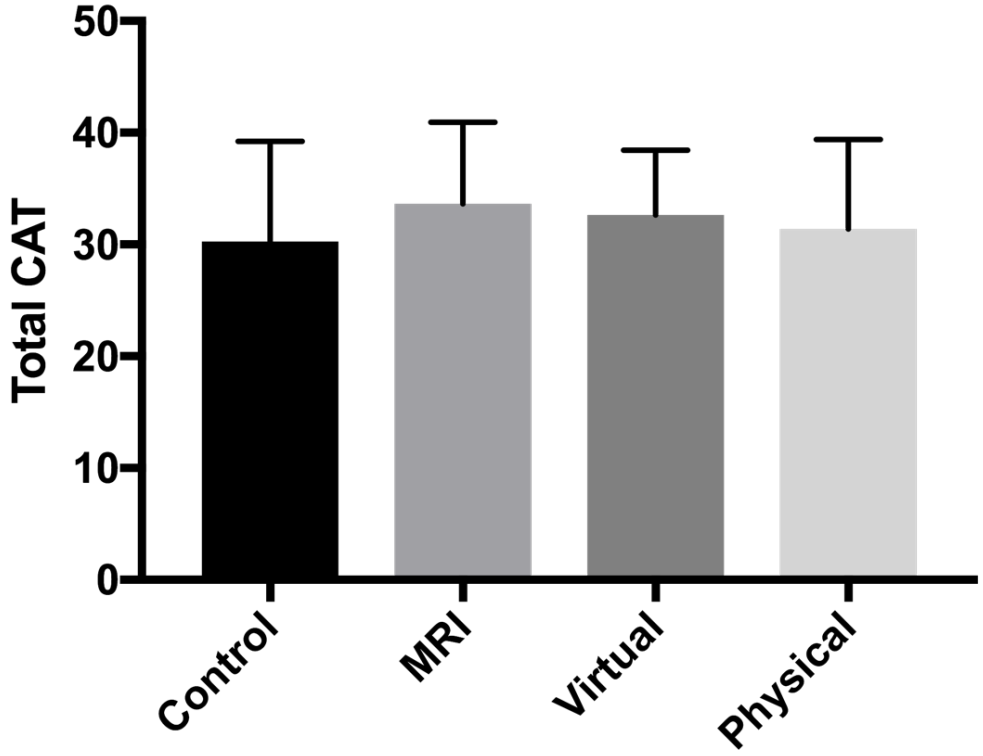

Figure 27. Total CAT scores between groups

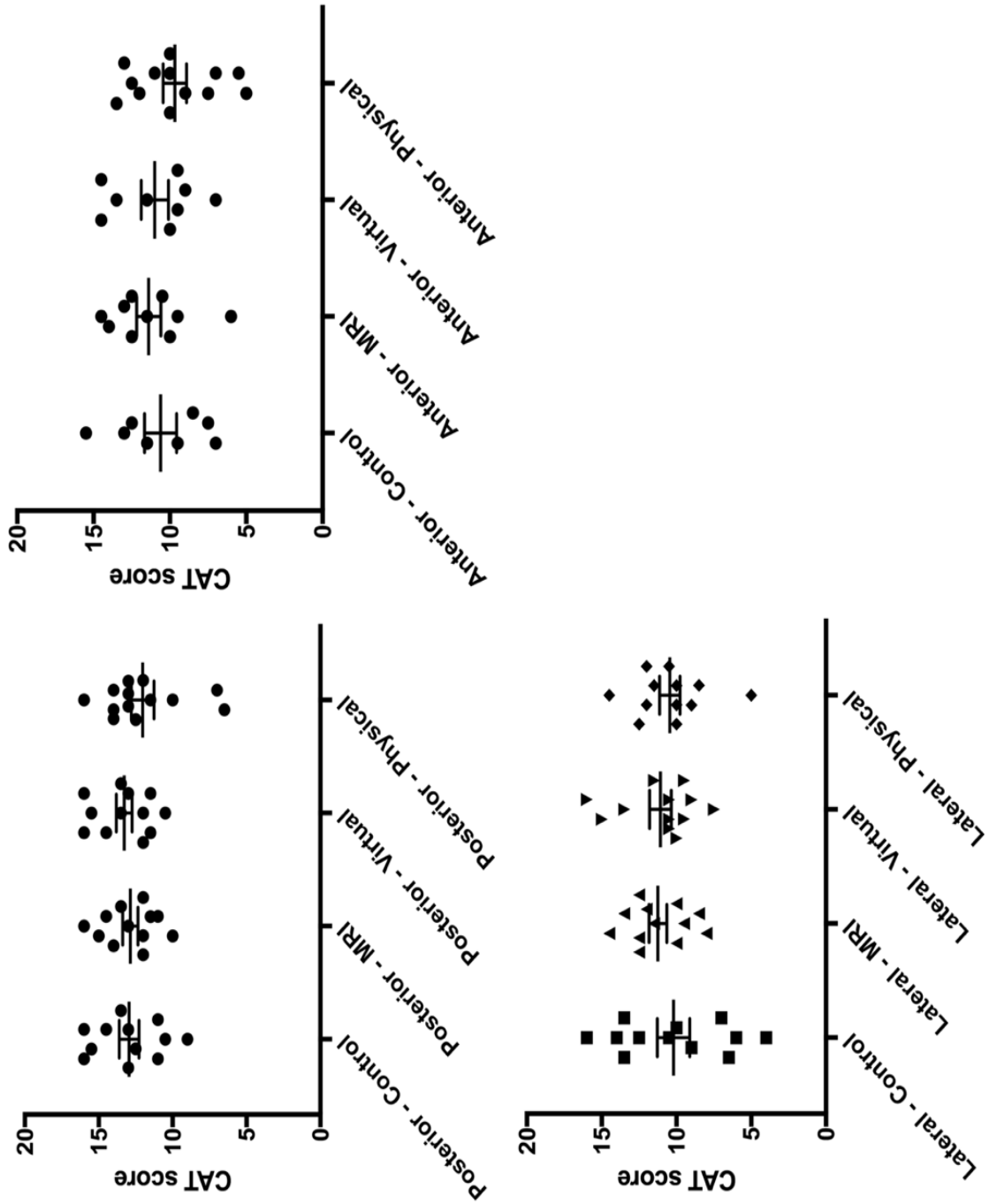

Figure 28.CAT scores for each step of TME dissection.

OCHRA evaluation

Similarly to the CAT evaluation results, OCHRA scores between groups showed no statistical difference (Table 10 – Fig. 30).

Plane	Anterior	Posterior	Right	Left	Transection
Control	0.012 0-0.02	0.015 0.01-0.023	0.012 0.003-0.039	0.013 0.006-0.023	0.004 0.001-0.026
MRI	0.003 0-0.019	0.024 0.013-0.035	0.024 0.016-0.038	0.018 0.01-0.032	0.009 0.005-0.018
Virtual	0.009 0.003-0.012	0.016 0.009-0.029	0.011 0.005-0.017	0.012 0-0.017	0.009 0-0.018
Physical	0.015 0.007-0.023	0.019 0.012-0.036	0.018 0.011-0.024	0.012 0.005-0.022	0.007 0.001-0.01
p-value	0.36	0.72	0.2	0.33	0.9

Table 11. OCHRA score results (mean and 1-3 IQR).

In addition to the error rate (number of errors/sec) for each procedural step, the amount of time spent without engaging in dissection was compared between groups. This was expressed as the rate of time spent not performing dissection divided by the overall duration of the TME dissection (i.e. “nothing” time / total time for pelvic dissection) and it was used to reflect the inefficiency of the surgical technique. The total time to complete the procedure is reported as follows (mean, first and third quartile (min)): Control group 88.35, 42.7-140.65, MRI 55.29, 33.46-63.87, Virtual 59.83, 25.70-84.89, Physical 88.31, 46.40-101.44.

The rate of time spent not performing dissection divided by the total time needed to complete the pelvic dissection, has been significantly less for cases rehearsed with SMR and MRI compared to cases that had routine preparation (Median/1st-3rd IQ (%)

- control group: 57.5/50.25-71.5, MRI group: 42/33.5-47.75; p 0.0005 – With Bonferroni correction applied level of significance is p<0.01). There was no significant difference in the rate of time spent without performing dissection between the control groups and the virtual (Median/1st-3rd IQ - virtual group: 51/38.25-61.5; p 0.13) and control and physical groups (physical group: 56/39-66; p 0.41) (fig. 29).

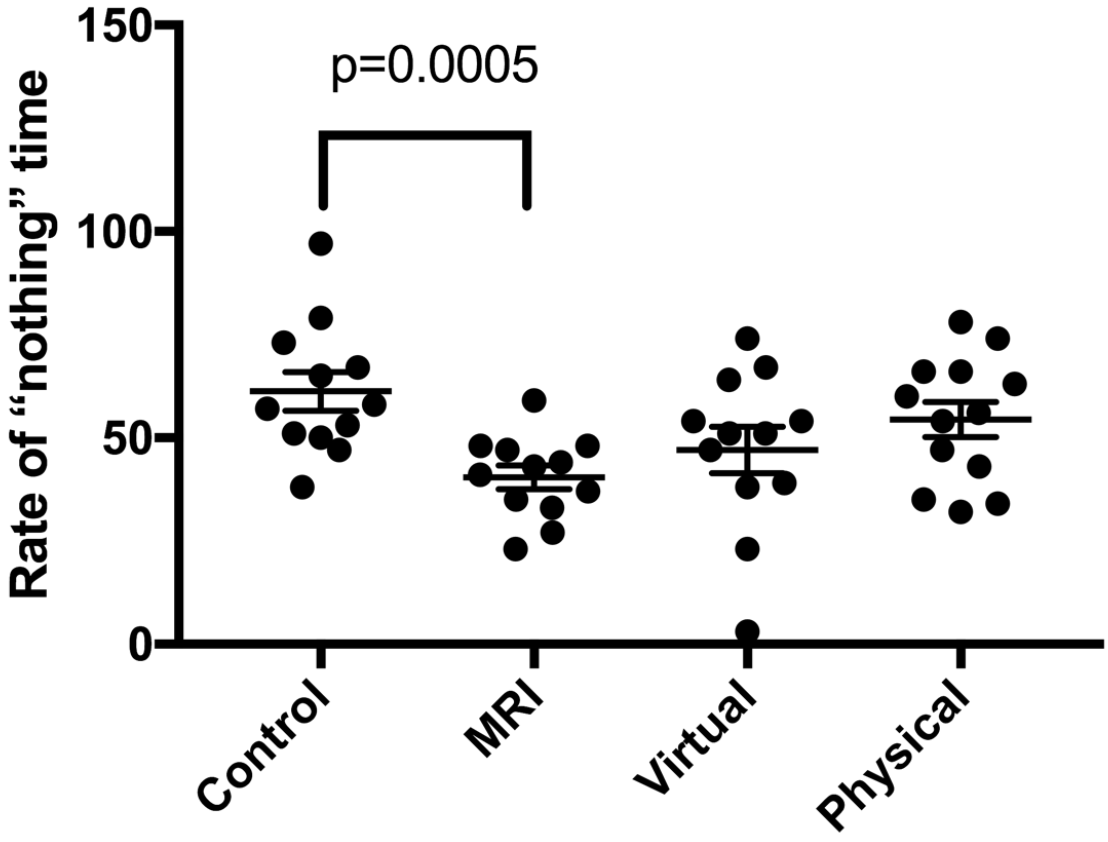

Figure 29. Rate (%) of time spent doing no dissection for each group.

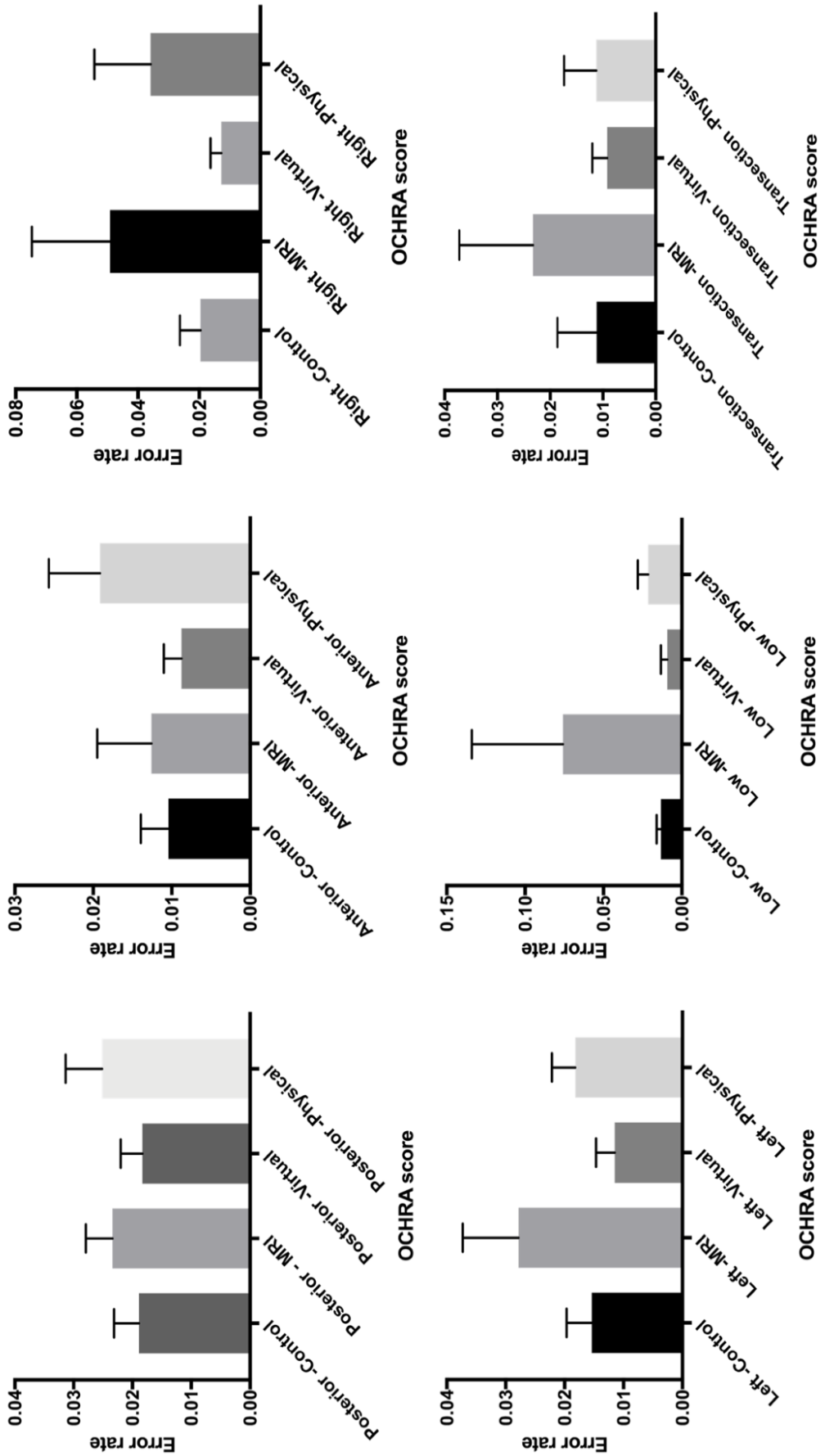

Figure 30. OCHRA – Error rate for each operative plane.

6.3. Discussion

To the knowledge of the investigators this is the first clinical trial comparing mental rehearsal and simulation in a real clinical environment. It is also one of the few randomised controlled trials employing patient-specific preparation for a complex minimally invasive procedure. The completion of this study showed that, both mental practice and patient specific simulation are feasible without causing delays in daily surgical practice. Furthermore, the process is proven to be safe, as all complications observed during this trial, were within accepted rates as these were defined in current literature (please see further below).

Three different methods of patient specific pre operative preparation were compared to routine practice. Although the majority of metrics used to assess surgical performance and quality were similar between the four groups, intra-operative efficiency (i.e. time spent performing dissection or “nothing” time) was significantly higher for surgeons that engaged in SMR using MRI were significantly more efficient in performing surgery compared to the control group. Previous studies have shown “nothing” or idle time to be correlated with surgical performance (314) and the metric reflects a combination of action selection and sensorimotor execution processes. The time required for planning and decision-making is strongly associated with task difficulty and expertise and these results indicate that augmenting the process with additional patient specific information can help reduce the demands placed on a surgeon’s cognitive and sensorimotor systems. In addition, increased idle time would

inevitably contribute to prolonged operation time, a variable repeatedly found to be associated with surgical efficiency (265, 301, 304). Moreover, although no statistical difference was established in surgical performance for different interventions, the effect size of these interventions appears to be largest for the lateral and low planes of dissection. This finding can help guide the focus of future research towards employing preparation for lateral and lower planes as surgeons appear to be coping better with superior and anterior dissection.

The combination of mental rehearsal and 3D reconstructed anatomical models (anatomy specific and non-specific) were found to be effective in enhancing surgical performance in a simulated environment when medical students and surgical trainees were recruited (315, 316). The impact on performance appears to be more limited when experts are involved. A possible reason for this is the distinct skills set that experts possess, compared to trainees (317, 318), which makes them more adaptable to unexpected events peri-operatively, hence reducing the need for patient-specific preparation. Moreover, the estimation of the sample size was based on a study reporting the difference in performance between experts and non-experts (CAT score) (310). Perhaps it was rather naïve to expect that a similar, significant impact can be accomplished by a 20-30 minute mental practice session. Therefore, it is possible that the clinical trial has been under powered and a greater sample size may have led to additional statistically significant results.

Mental rehearsal, when applied by non-experts, is a useful tool for enhancing surgical skills (133, 319). To the investigators' knowledge this is the first study examining the impact of mental rehearsal in expert surgical performance. Conversely, 3D reconstructed anatomical models have been repeatedly used by experts pre-operatively to facilitate the operative process. As previously discussed in Chapter one, the results of these applications were mixed, showing great promise on some occasions (18, 215) and less encouraging results on others (22, 26). It is also worth mentioning that the majority of current evidence on the specific topic is of low quality consisting of case series and retrospective studies (13, 16, 18, 22, 24, 26, 215, 223, 227, 228, 236, 237, 245, 247, 254). The current randomised controlled trial has failed to show superiority of 3D reconstructed anatomical models (virtual or physical) when these are compared to medical images (i.e. MRI).

Several factors such as complications, length of stay and others were documented without any comparisons between groups being undertaken as a direct association between quality of surgery and these variables could not have been established. Nevertheless, the complication rates in this cohort of patients are within acceptable rates. For instance, anastomotic leak occurred in 10.2% of patients, being treated in the vast amount of patients conservatively with antibiotics or through radiological drainage and not necessitating return to theatre. The reported anastomotic leak rates in the literature vary between 5-16% (320-324) and average conversion rate is 12.2%; in the current study is similar to the average rate reported in literature (11.9%) (325).

This study has some limitations. The estimation of the sample size was based on a difference of one standard deviation between groups which may be an overestimation of the potential impact of any educational intervention. Therefore, it is possible that had the sample size been greater a greater impact of the mental rehearsal on surgical performance would have been noted. Furthermore, there is variation in some factors such as the type of surgery (laparoscopic, robotic, laparoscopic/TaTME) and surgeons performing the procedures. However, the different types of surgery, as shown in table 9 were equally distributed between groups and the previous experience of surgeons recruited was previously established through a questionnaire (Appendix).

As demonstrated by previously conducted studies, this clinical trial also indicates that experts who reach the plateau of their learning curve (63, 114, 115, 265), consistently achieve good performance despite the varying difficulty of individual cases. However, it would be interesting for future research to explore whether mental rehearsal with use of medical images such as MRI can increase the efficiency of operations (i.e. time spent achieving progression intra-operatively) performed by experts. Moreover, the role of mental rehearsal with medical images or 3D anatomical models, in improving surgical performance of trainees should be assessed.

Chapter 7

Overall discussion

Chapter 7: Overall discussion

Minimally invasive surgery requires complex motor skills and it is often technically demanding. Anatomical variations and patient characteristics can add a significant degree of difficulty (8-11). In the current climate of restricted working hours and increasing demands for service provision, new methods should be sought to accelerate the learning curve of non experts (326) and to help experts prepare for challenging cases on a patient individualised remit.

The systematic review of the current literature and a national survey conducted at the early stages of this project, identified pre-operative patient specific preparation with anatomical models and mental practice as two of the potential techniques for improvement of surgical skills (326, 327). However, it also demonstrated that both techniques were sporadically applied with varying results (327).

Currently, simulation is well established and widely accepted as a useful adjunct to traditional surgical training (326). Therefore, comparisons between simulation and any new technique aiming to accelerate the surgical learning curve, are inevitable. Some of the drawbacks of simulation are cost and inability to portray anatomical variation (328). Recent advancements in technology such as 3D image reconstruction and additive technologies made the production of patient specific anatomical models more accessible to clinicians. It is noteworthy that some specialties (e.g. vascular surgery) have an NHS trust provided automatic rendering

software which can produce 3D reconstructed anatomical models from medical imaging such as CT and MRI. Moreover, the application of mental practice as a technique for the acquisition of motor skills in sports and performing arts brought about the possibility of application of MP in surgery. The obvious advantages are the minimal cost and repeatability – surgeons can practice as many times as they like in whichever environment without the requirement of specific equipment or the presence of a trainer/facilitator. However, the efficacy of mental practice and simulation has not been compared with an RCT in a clinical environment (327).

Within this project the aim was to compare simulation and mental practice but also to introduce a patient-specific component. As such, patient specific anatomical models were designed. For the purposes of this step a 3D rendering software was developed, with the input of two members of the overall team (MY, DM). This newer version of a pre-existing software, VolumeViewer® (University of Leeds), allowed for automation of several rendering steps. Being involved in the process of designing the new version of the software gave us the ability to make the software “fit for purpose” and navigate through the difficulties of rendering soft tissue structures (mesorectum) surrounded by other soft tissue structures (muscle, fat etc.). This is particularly difficult as most rendering software rely on the difference in radio opacity between neighbouring structures (e.g. vessels with contrast next to fatty tissue). The virtual models created through this process served the dual purpose of being used for MP and for 3D printing the physical anatomical models.

After completing the ground work of creating prototype anatomical models, both virtual and physical, and building an evidence based systematic approach to mental rehearsal, we set out to test the applicability of the novel technique. Initially, this was done in the simulation suite. The surgical procedure chosen for the models and MP testing was laparoscopic cholecystectomy. There were several reasons for this decision; LC simulators (LAP Mentor ®) (108) are readily available in the region and simulated operations with the selection of six anatomical variations (108). Moreover, LC is a routinely performed procedure (109) which involves complex laparoscopic skills (111). Also, the anatomy of the gallbladder and its blood supply may vary significantly (110), leading one to speculate that preparation using anatomy specific models may be useful for the trainee surgeon.

The initial two trials were conducted in a simulated environment. The first study compared MP alone, to MP with the use of interactive 3D anatomical models to a didactic video. The primary outcome was surgical performance measured using simulation reported metrics. This study recruited surgical trainees in the early years of their surgical career. The second study, compared MP which was specific to an anatomical variation to generic MP. The primary outcome was again surgical performance but this time in addition to the simulation provided metrics, the anonymised videos of the procedures were assessed by two blinded assessors. Although these were feasibility/pilot studies, not designed to give conclusive answers as to whether mental rehearsal and anatomical models are useful for surgical training, statistically significant differences were yielded in favour of the combination

of mental rehearsal and 3D reconstructed anatomical models, both for non-specific and specific to the simulated anatomy (315, 316).

The next step was to compare the new pre-operative preparation method combining mental rehearsal with a patient-specific component (MRI, virtual or physical model) to routine practice and to “just in time” simulation within a real-time clinical environment. The surgical procedure chosen for this RCT was minimally invasive low anterior resection for rectal cancer. Once again there were several reasons for this option. MI low anterior resection is technically demanding, with the degree of difficulty found to be associated with patient (e.g. pelvic dimensions, BMI) and tumour characteristics (e.g. distance of tumour from the anal verge and T stage) (8-11). The study was conducted in a tertiary centre for rectal cancer surgery, therefore recruiting the appropriate amount of patients would be achievable. Moreover, there is an international consensus regarding the steps of low anterior resection (309), upon which we could build on to create a procedure specific MP process.

All rectal cancer patients due to undergo curative surgery, were recruited according to the inclusion criteria as these were described in the protocol of the study (which is available on demand). A decision was made to include all forms of minimally invasive surgery as excluding one type of surgery would have prevented the inclusion of consecutive patients. Furthermore, it was noticed that particular types of surgery (robotic and TaTME) were reserved by some of the surgeons for cases they considered to be more technically challenging (e.g. male patients with narrow pelvis),

hence excluding these forms of surgery would introduce selection bias to the cohort of patients. Patients were allocated to the intervention groups using a randomisation technique (i.e. minimisation),which allowed for stratification of the cases according to BMI, gender, distance of tumour from the anal verge and local infiltration staging (T-stage). A custom made software was used for this purpose. This process ensured that each group had equal number of “difficult” cases.

The primary outcome of the clinical trial was surgical performance. This was assessed by two blinded assessors evaluating the anonymised video recordings of the pelvic dissection during the procedure. Two validated scoring systems were used (i.e. CAT and OCHRA). Although there was no statistical difference in performance between the four different groups, the time spent performing no dissection (i.e. retracting without dissecting, repositioning assistants etc.) was significantly lower for the group of surgeons who performed MP with MRI imaging prior to performing the actual procedure.

Albeit methodological limitations which were discussed in previous chapters, two out of three studies showed statistically significant improvement in surgical performance with the use of patient specific MP with the use of 3D anatomical models. The third study performed in a clinical environment did not show a significant improvement in performance, however, the results may indicate that a procedure can be accelerated (i.e. less time without dissection) with the use of MP.

There are several potential reasons for the lack of improvement of surgical performance in the clinical trial. One possible explanation was the recruitment of experts instead of trainees. The learning curve theory, suggests that once the turning point of performance towards the “plateau” of the curve is overpassed the performance remains constant (63, 114, 115, 265). By definition and as assessed by the questionnaire completed at the entry point of the clinical trial (Appendix), all participating surgeons were at the ‘plateau’ of the learning curve and therefore their performance could not be improved. Furthermore, experienced surgeons may have already developed their own preparation method which may have been undertaken by all surgeons performing surgery on patients allocated to the ‘routine practice’ group. Having had informal talks with consultants, trying to gauge their opinion on the outcomes of this study, I was told by some that they can plan the operation as they review the MRI/CT images at MDT or clinic. The process described to me, highly resembled a form of individual “mental rehearsal” based on years of experience and “trial and error” processes. As we are committed to maintaining patient safety and achieving the best possible result for our patients we could not stop surgeons from engaging in any personal preparation prior to surgery. However, this may have altered the results of the trial as ‘routine practice’ was not equivalent to no pre-operative preparation.

Overall, the results of this work have shown MP with a patient specific component to be promising in improving surgical performance. This effect may be more prominent in non-experts that have yet to reach the plateau of their learning curve, although the reduction of idle time (i.e. time spent without dissection) during expert operating

should also be searched further. In the ever changing world of surgery, with the imposed time restrictions and increasing need for service provision (329), new, “in-vitro” methods should be sought to increase the efficacy and quality of surgery. Mental practice with 3D virtual models or medical images such as MRI is an inexpensive and easily repeatable method that is worth exploring.

List of References

1. Agha R, Muir G. Does laparoscopic surgery spell the end of the open surgeon? Journal of the Royal Society of Medicine. 2003;96(11):544-6.
2. Risucci DA. Visual spatial perception and surgical competence. American Journal of Surgery. 2002;184(3):291-5.
3. Rassweiler J FT, Guillonneau B. Advanced laparoscopy. Europ Urol. 2002;2:1-12.
4. surgery C. [Available from: http://columbiasurgery.org/colorectal/minimally-invasive-laparoscopic-surgery.
5. Wyles SM, Miskovic D, Ni Z, Acheson AG, Maxwell-Armstrong C, Longman R, et al. Analysis of laboratory-based laparoscopic colorectal surgery workshops within the English National Training Programme. Surgical Endoscopy. 2011;25(5):1559-66.
6. Neary PC, Boyle E, Delaney CP, Senagore AJ, Keane FB, Gallagher AG. Construct validation of a novel hybrid virtual-reality simulator for training and assessing laparoscopic colectomy; results from the first course for experienced senior laparoscopic surgeons. Surg Endosc. 2008;22(10):2301-9.
7. LAP Mentor S. [Available from: http://simbionix.com/simulators/lap-mentor/.
8. Veenhof AA, Engel AF, van der Peet DL, Sietses C, Meijerink WJ, de Lange-de Klerk ES, et al. Technical difficulty grade score for the laparoscopic approach of rectal cancer: a single institution pilot study. Int J Colorectal Dis. 2008;23(5):469-75.
9. Akagi T, Inomata M, Etoh T, Moriyama H, Yasuda K, Shiraishi N, et al. Multivariate evaluation of the technical difficulties in performing laparoscopic anterior resection for rectal cancer. Surg Laparosc Endosc Percutan Tech. 2012;22(1):52-7.
10. Bertani E, Chiappa A, Della Vigna P, Radice D, Papis D, Cossu L, et al. The Impact of pelvimetry on anastomotic leakage in a consecutive series of open, laparoscopic and robotic low anterior resections with total mesorectal excision for rectal cancer. Hepatogastroenterology. 2014;61(134):1574-81.
11. Fernandez Ananin S, Targarona EM, Martinez C, Pernas JC, Hernandez D, Gich I, et al. Predicting the pathological features of the mesorectum before the laparoscopic approach to rectal cancer. Surgical Endoscopy. 2014;28(12):3458-66.
12. Li Y. Laparoscopic extended right hemicolectomy with D3 lymphadenectomy. Ann Transl Med. 2015;3(9):124.
13. Hu Y, Li H, Qiao G, Liu H, Ji A, Ye F. Computer-assisted virtual surgical procedure for acetabular fractures based on real CT data. Injury. 2011;42(10):1121-4.
14. Perry M, Banks P, Richards R, Friedman EP, Shaw P. The use of computer-generated three-dimensional models in orbital reconstruction. British Journal of Oral & Maxillofacial Surgery. 1998;36(4):275-84.
15. Tepper OM, Sorice S, Hershman GN, Saadeh P, Levine JP, Hirsch D. Use of virtual 3-dimensional surgery in post-traumatic craniomaxillofacial reconstruction. Journal of Oral & Maxillofacial Surgery. 2011;69(3):733-41.
16. Kockro RA, Serra L, Tseng-Tsai Y, Chan C, Yih-Yian S, Gim-Guan C, et al. Planning and simulation of neurosurgery in a virtual reality environment. Neurosurgery. 2000;46(1):118-35; discussion 35-7.

17. Nam D, Maher PA, Rebolledo BJ, Nawabi DH, McLawhorn AS, Pearle AD. Patient specific cutting guides versus an imageless, computer-assisted surgery system in total knee arthroplasty. Knee. 2013;20(4):263-7.
18. Ng I, Hwang PY, Kumar D, Lee CK, Kockro RA, Sitoh YY. Surgical planning for microsurgical excision of cerebral arterio-venous malformations using virtual reality technology. Acta Neurochir (Wien). 2009;151(5):453-63; discussion 63.
19. Desender L, Rancic Z, Aggarwal R, Duchateau J, Glenck M, Lachat M, et al. Patient-specific rehearsal prior to EVAR: a pilot study. Eur J Vasc Endovasc Surg. 2013;45(6):639-47.
20. Haq J, Patel N, Weimer K, Matthews NS. Single stage treatment of ankylosis of the temporomandibular joint using patient-specific total joint replacement and virtual surgical planning. Br J Oral Maxillofac Surg. 2014;52(4):350-5.
21. Ferrari V, Carbone M, Cappelli C, Boni L, Melfi F, Ferrari M, et al. Value of multidetector computed tomography image segmentation for preoperative planning in general surgery. Surgical Endoscopy. 2012;26(3):616-26.
22. Hislop SJ, Hedrick JH, Singh MJ, Rhodes JM, Gillespie DL, Johansson M, et al. Simulation case rehearsals for carotid artery stenting. Eur J Vasc Endovasc Surg. 2009;38(6):750-4.
23. Willaert WI, Aggarwal R, Van Herzeele I, Plessers M, Stroobant N, Nestel D, et al. Role of patient-specific virtual reality rehearsal in carotid artery stenting. Br J Surg. 2012;99(9):1304-13.
24. Makiyama K, Yamanaka H, Ueno D, Ohsaka K, Sano F, Nakaigawa N, et al. Validation of a patient-specific simulator for laparoscopic renal surgery. Int J Urol. 2015;22(6):572-6.
25. Radecka E, Brehmer M, Holmgren K, Palm G, Magnusson P, Magnusson A. Pelvicaliceal biomodeling as an aid to achieving optimal access in percutaneous nephrolithotripsy. J Endourol. 2006;20(2):92-101.
26. Qiu TM, Zhang Y, Wu JS, Tang WJ, Zhao Y, Pan ZG, et al. Virtual reality presurgical planning for cerebral gliomas adjacent to motor pathways in an integrated 3-D stereoscopic visualization of structural MRI and DTI tractography. Acta Neurochir (Wien). 2010;152(11):1847-57.
27. Sanders CW, Sadoski M, Bramson R, Wiprud R, Van Walsum K. Comparing the effects of physical practice and mental imagery rehearsal on learning basic surgical skills by medical students. American Journal of Obstetrics & Gynecology. 2004;191(5):1811-4.
28. Sanders CW, Sadoski M, van Walsum K, Bramson R, Wiprud R, Fossum TW. Learning basic surgical skills with mental imagery: using the simulation centre in the mind. Medical Education. 2008;42(6):607-12.
29. Jungmann F, Gockel I, Hecht H, Kuhr K, Rasanen J, Sihvo E, et al. Impact of perceptual ability and mental imagery training on simulated laparoscopic knot-tying in surgical novices using a Nissen fundoplication model. Scandinavian Journal of Surgery: SJS. 2011;100(2):78-85.
30. Immenroth M, Burger T, Brenner J, Nagelschmidt M, Eberspacher H, Troidl H. Mental training in surgical education: a randomized controlled trial. Annals of Surgery. 2007;245(3):385-91.
31. Manual of Laparoscopic Surgery. Klaiber C, Metzger, A., Petelin, J.B, editor. Seattle, US: Hogrefe & Huber Pub; 1993.
32. Minimal access Medicine and Surgery. D R, editor. Oxford: Radcliffe Medical Press; 1993.

33. Laparoscopic and Thoracoscopic Surgery. Frantizides CT, editor: St Louis: Mosby, 1995; 1995.
34. Ghirardini G, Golinelli F. Bozzini and the birth of endoscopy. Clin Exp Obstet Gynecol. 1992;19(1):70-2.
35. Minimally Invasive Surgery of the Foregut. Peters JH, DeMeester, T.R. , editor: St Louis: Quality Medical Publishing; 1994.
36. Lau WY, Leow CK, Li AK. History of endoscopic and laparoscopic surgery. World J Surg. 1997;21(4):444-53.
37. Mishra PDRK. History of Minimal Access Surgery [Available from: http://www.laparoscopyhospital.com/history_of_laparoscopy.htm.
38. Laparoscopic Urologic Surgery. Gomella LG, Kozminski, M., Wingield, H.N, editor. New York: Raven; 1994.
39. Gaskin TA, Isobe JH, Mathews JL, Winchester SB, Smith RJ. Laparoscopy and the general surgeon. Surg Clin North Am. 1991;71(5):1085-97.
40. Spaner SJ, Warnock GL. A brief history of endoscopy, laparoscopy, and laparoscopic surgery. J Laparoendosc Adv Surg Tech A. 1997;7(6):369-73.
41. Perissat J. Laparoscopic surgery: A pioneer's point of view. World J Surg. 1999;23(8):863-8.
42. Gomella LG, Kozminski, M., Wingield, H.N. . Laparoscopic Urologic Surgery. New York: Raven; 1994.
43. Reddy N, Rao, P. Per oral transgastric endoscopic appendicectomy in human. Abstract presented at 45th Annual Conference of the Society of Gastrointestinal Endoscopy of India. 2004.
44. Marescaux J DB, Perretta S, Wattiez A, Mutter D, Coumaros D. Surgery without scars: report of transluminal cholecystectomy in a human being. . Arch Surg. 2007;142:823-6.
45. Navarra G, Pozza E, Occhionorelli S, Carcoforo P, Donini I. One-wound laparoscopic cholecystectomy. British Journal of Surgery. 1997;84(5):695.
46. Saidy MN, Tessier M, Tessier D. Single-incision laparoscopic surgery--hype or reality: a historical control study. Perm J. 2012;16(1):47-50.
47. Jacobs M, Verdeja JC, Goldstein HS. Minimally invasive colon resection (laparoscopic colectomy). Surg Laparosc Endosc. 1991;1(3):144-50.
48. Kaiser AM. Evolution and future of laparoscopic colorectal surgery. World J Gastroenterol. 2014;20(41):15119-24.
49. Berends FJ, Kazemier G, Bonjer HJ, Lange JF. Subcutaneous metastases after laparoscopic colectomy. Lancet. 1994;344(8914):58.
50. Reilly WT, Nelson H, Schroeder G, Wieand HS, Bolton J, O'Connell MJ. Wound recurrence following conventional treatment of colorectal cancer. A rare but perhaps underestimated problem. Diseases of the Colon & Rectum. 1996;39(2):200-7.
51. Hughes ES, McDermott FT, Polglase AL, Johnson WR. Tumor recurrence in the abdominal wall scar tissue after large-bowel cancer surgery. Dis Colon Rectum. 1983;26(9):571-2.
52. Fleshman JW, Nelson H, Peters WR, Kim HC, Larach S, Boorse RR, et al. Early results of laparoscopic surgery for colorectal cancer. Retrospective analysis of 372 patients treated by Clinical Outcomes of Surgical Therapy (COST) Study Group. Dis Colon Rectum. 1996;39(10 Suppl):S53-8.

53. Allardyce RA. Is the port site really at risk? Biology, mechanisms and prevention: a critical view. Australian & New Zealand Journal of Surgery. 1999;69(7):479-85.
54. Veldkamp R, Kuhry E, Hop WC, Jeekel J, Kazemier G, Bonjer HJ, et al. Laparoscopic surgery versus open surgery for colon cancer: short-term outcomes of a randomised trial. Lancet Oncol. 2005;6(7):477-84.
55. Guillou PJ, Quirke P, Thorpe H, Walker J, Jayne DG, Smith AM, et al. Short-term endpoints of conventional versus laparoscopic-assisted surgery in patients with colorectal cancer (MRC CLASICC trial): multicentre, randomised controlled trial. Lancet. 2005;365(9472):1718-26.
56. Clinical Outcomes of Surgical Therapy Study G. A comparison of laparoscopically assisted and open colectomy for colon cancer. N Engl J Med. 2004;350(20):2050-9.
57. Weeks JC, Nelson H, Gelber S, Sargent D, Schroeder G, Clinical Outcomes of Surgical Therapy Study G. Short-term quality-of-life outcomes following laparoscopic-assisted colectomy vs open colectomy for colon cancer: a randomized trial. JAMA. 2002;287(3):321-8.
58. Leung KL, Kwok SP, Lam SC, Lee JF, Yiu RY, Ng SS, et al. Laparoscopic resection of rectosigmoid carcinoma: prospective randomised trial. Lancet. 2004;363(9416):1187-92.
59. Lacy AM, Garcia-Valdecasas JC, Delgado S, Castells A, Taura P, Pique JM, et al. Laparoscopy-assisted colectomy versus open colectomy for treatment of non-metastatic colon cancer: a randomised trial. Lancet. 2002;359(9325):2224-9.
60. Bonjer HJ, Hop WC, Nelson H, Sargent DJ, Lacy AM, Castells A, et al. Laparoscopically assisted vs open colectomy for colon cancer: a meta-analysis. Arch Surg. 2007;142(3):298-303.
61. Jackson TD, Kaplan GG, Arena G, Page JH, Rogers SO, Jr. Laparoscopic versus open resection for colorectal cancer: a metaanalysis of oncologic outcomes. J Am Coll Surg. 2007;204(3):439-46.
62. Kuhry E, Schwenk W, Gaupset R, Romild U, Bonjer J. Long-term outcome of laparoscopic surgery for colorectal cancer: a cochrane systematic review of randomised controlled trials. Cancer Treat Rev. 2008;34(6):498-504.
63. Miskovic D, Ni M, Wyles SM, Tekkis P, Hanna GB. Learning curve and case selection in laparoscopic colorectal surgery: systematic review and international multicenter analysis of 4852 cases. Dis Colon Rectum. 2012;55(12):1300-10.
64. Surgeons SoAGaE. Guidelines for Laparoscopic Resection of Curable Colon and Rectal Cancer. 2012 [Available from: www.sagescms.org.
65. van der Pas MH, Haglind E, Cuesta MA, Furst A, Lacy AM, Hop WC, et al. Laparoscopic versus open surgery for rectal cancer (COLOR II): short-term outcomes of a randomised, phase 3 trial. Lancet Oncol. 2013;14(3):210-8.
66. Trastulli S, Cirocchi R, Listorti C, Cavaliere D, Avenia N, Gulla N, et al. Laparoscopic vs open resection for rectal cancer: a meta-analysis of randomized clinical trials. Colorectal Disease. 2012;14(6):e277-96.
67. Hahn KY, Baek SJ, Joh YG, Kim SH. Laparoscopic resection of transverse colon cancer: long-term oncologic outcomes in 58 patients. J Laparoendosc Adv Surg Tech A. 2012;22(6):561-6.
68. Fleshman J, Branda M, Sargent DJ, Boller AM, George V, Abbas M, et al. Effect of Laparoscopic-Assisted Resection vs Open Resection of Stage II or III

Rectal Cancer on Pathologic Outcomes: The ACOSOG Z6051 Randomized Clinical Trial. JAMA. 2015;314(13):1346-55.
69. de'Angelis N, Landi F, Vitali GC, Memeo R, Martinez-Perez A, Solis A, et al. Multicentre propensity score-matched analysis of laparoscopic versus open surgery for T4 rectal cancer. Surg Endosc. 2017;31(8):3106-21.
70. Weber PA, Merola S, Wasielewski A, Ballantyne GH. Telerobotic-assisted laparoscopic right and sigmoid colectomies for benign disease. Dis Colon Rectum. 2002;45(12):1689-94; discussion 95-6.
71. D'Annibale A, Morpurgo E, Fiscon V, Trevisan P, Sovernigo G, Orsini C, et al. Robotic and laparoscopic surgery for treatment of colorectal diseases. Dis Colon Rectum. 2004;47(12):2162-8.
72. Pigazzi A, Ellenhorn JD, Ballantyne GH, Paz IB. Robotic-assisted laparoscopic low anterior resection with total mesorectal excision for rectal cancer. Surgical Endoscopy. 2006;20(10):1521-5.
73. Rawlings AL, Woodland JH, Crawford DL. Telerobotic surgery for right and sigmoid colectomies: 30 consecutive cases. Surg Endosc. 2006;20(11):1713-8.
74. Spinoglio G, Summa M, Priora F, Quarati R, Testa S. Robotic colorectal surgery: first 50 cases experience. Diseases of the Colon & Rectum. 2008;51(11):1627-32.
75. Zhang X, Wei Z, Bie M, Peng X, Chen C. Robot-assisted versus laparoscopic-assisted surgery for colorectal cancer: a meta-analysis. Surg Endosc. 2016;30(12):5601-14.
76. Araujo SE, Seid VE, Klajner S. Robotic surgery for rectal cancer: current immediate clinical and oncological outcomes. World Journal of Gastroenterology. 2014;20(39):14359-70.
77. Baik SH KH, Kim JS, Hur H, Sohn SK, Cho CH, Kim H. . Robotic versus laparoscopic low anterior resection of rectal cancer: short-term outcome of a prospectivecomparative study. Ann Surg Oncol. 2009;16:1480-7.
78. Kim JY, Kim NK, Lee KY, Hur H, Min BS, Kim JH. A comparative study of voiding and sexual function after total mesorectal excision with autonomic nerve preservation for rectal cancer: laparoscopic versus robotic surgery. Ann Surg Oncol. 2012;19(8):2485-93.
79. Ozeki S, Maeda K, Hanai T, Masumori K, Katsuno H, Takahashi H. Effects of robotic rectal surgery on sexual and urinary functions in male patients. Surg Today. 2016;46(4):491-500.
80. Mohd Azman ZA, Kim SH. A review on robotic surgery in rectal cancer. Transl Gastroenterol Hepatol. 2016;1:5.
81. RObotic Versus LAparoscopic Resection for Rectal Cancer (ROLARR) 2012-2015 [Available from: https://clinicaltrials.gov/ct2/show/NCT01736072.
82. Jayne D, Pigazzi A, Marshall H, Croft J, Corrigan N, Copeland J, et al. Effect of Robotic-Assisted vs Conventional Laparoscopic Surgery on Risk of Conversion to Open Laparotomy Among Patients Undergoing Resection for Rectal Cancer: The ROLARR Randomized Clinical Trial. JAMA. 2017;318(16):1569-80.
83. Vanderbilt AA, Grover AC, Pastis NJ, Feldman M, Granados DD, Murithi LK, et al. Randomized controlled trials: a systematic review of laparoscopic surgery and simulation-based training. Glob J Health Sci. 2014;7(2):310-27.
84. Busch OR, Hop WC, Marquet RL, Jeekel J. Prognostic impact of blood transfusions on disease-free survival in colorectal carcinoma. Scand J Gastroenterol Suppl. 1993;200:21-3.

85. Allendorf JD, Bessler M, Whelan RL, Trokel M, Laird DA, Terry MB, et al. Postoperative immune function varies inversely with the degree of surgical trauma in a murine model. Surg Endosc. 1997;11(5):427-30.
86. Doyle PH, Michele. Advantages and disadvantages of laparoscopic surgery. Anaesthesia & Intensive Care Medicine. 2009;10(7):328-31.
87. Biondi A, Di Stefano C, Ferrara F, Bellia A, Vacante M, Piazza L. Laparoscopic versus open appendectomy: a retrospective cohort study assessing outcomes and cost-effectiveness. World J Emerg Surg. 2016;11(1):44.
88. Gosemann JH, Lange A, Zeidler J, Blaser J, Dingemann C, Ure BM, et al. Appendectomy in the pediatric population-a German nationwide cohort analysis. Langenbecks Arch Surg. 2016;401(5):651-9.
89. Guana R, Lonati L, Garofalo S, Tommasoni N, Ferrero L, Cerrina A, et al. Laparoscopic versus Open Surgery in Complicated Appendicitis in Children Less Than 5 Years Old: A Six-Year Single-Centre Experience. Surg Res Pract. 2016;2016:4120214.
90. Segev L, Segev Y, Rayman S, Shapiro R, Nissan A, Sadot E. Appendectomy in Pregnancy: Appraisal of the Minimally Invasive Approach. J Laparoendosc Adv Surg Tech A. 2016;26(11):893-7.
91. Wei B, Qi CL, Chen TF, Zheng ZH, Huang JL, Hu BG, et al. Laparoscopic versus open appendectomy for acute appendicitis: a metaanalysis. Surg Endosc. 2011;25(4):1199-208.
92. Orsenigo E, Di Palo S, Tamburini A, Staudacher C. Laparoscopy-assisted gastrectomy versus open gastrectomy for gastric cancer: a monoinstitutional Western center experience. Surg Endosc. 2011;25(1):140-5.
93. Ruiz-Tovar J, Diez-Tabernilla M, Chames A, Morales V, Martinez-Molina E. Clinical outcome at 10 years after laparoscopic versus open Nissen fundoplication. J Laparoendosc Adv Surg Tech A. 2010;20(1):21-3.
94. Amore Bonapasta S, Guerra F, Linari C, Annecchiarico M, Boffi B, Calistri M, et al. Robot-assisted gastrectomy for cancer. Chirurg. 2017;88(Suppl 1):12-8.
95. Kostakis ID, Alexandrou A, Armeni E, Damaskos C, Kouraklis G, Diamantis T, et al. Comparison Between Minimally Invasive and Open Gastrectomy for Gastric Cancer in Europe: A Systematic Review and Meta-analysis. Scand J Surg. 2017;106(1):3-20.
96. Pearce SM, Golan S, Gorin MA, Luckenbaugh AN, Williams SB, Ward JF, et al. Safety and Early Oncologic Effectiveness of Primary Robotic Retroperitoneal Lymph Node Dissection for Nonseminomatous Germ Cell Testicular Cancer. Eur Urol. 2017;71(3):476-82.
97. de Verteuil RM, Hernandez RA, Vale L, Aberdeen Health Technology Assessment G. Economic evaluation of laparoscopic surgery for colorectal cancer. Int J Technol Assess Health Care. 2007;23(4):464-72.
98. Murray A, Lourenco T, de Verteuil R, Hernandez R, Fraser C, McKinley A, et al. Clinical effectiveness and cost-effectiveness of laparoscopic surgery for colorectal cancer: systematic reviews and economic evaluation. Health Technol Assess. 2006;10(45):1-141, iii-iv.
99. Laparoscopic surgery for colorectal cancer. Technology appraisal guidance [TA105] [23 August 2006]. Available from: https://www.nice.org.uk/guidance/ta105/chapter/1-Guidance.
100. Grabowski JE, Talamini MA. Physiological effects of pneumoperitoneum. J Gastrointest Surg. 2009;13(5):1009-16.

101. Gutt CN, Oniu T, Mehrabi A, Schemmer P, Kashfi A, Kraus T, et al. Circulatory and respiratory complications of carbon dioxide insufflation. Dig Surg. 2004;21(2):95-105.
102. Nguyen NT, Wolfe BM. The physiologic effects of pneumoperitoneum in the morbidly obese. Ann Surg. 2005;241(2):219-26.
103. Neudecker J, Sauerland S, Neugebauer E, Bergamaschi R, Bonjer HJ, Cuschieri A, et al. The European Association for Endoscopic Surgery clinical practice guideline on the pneumoperitoneum for laparoscopic surgery. Surg Endosc. 2002;16(7):1121-43.
104. Manceau G, Karoui M, Werner A, Mortensen NJ, Hannoun L. Comparative outcomes of rectal cancer surgery between elderly and non-elderly patients: a systematic review. Lancet Oncol. 2012;13(12):e525-36.
105. Lavoue V, Gotlieb W. Benefits of Minimal Access Surgery in Elderly Patients with Pelvic Cancer. Cancers (Basel). 2016;8(1).
106. Teplitz CJ. The learning curve deskbook: a reference guide to theory, calculations and applications. New York: Quorum Books; 1991.
107. Liao S. The learning curve: Wright's model vs. Crawford's model. Issues In Accounting Education (Fall). 1988:302-15.
108. Simbionix LAP MENTOR™. Laparoscopy Virtual Reality Simulator. http://www.okbmedical.com/lapmentor.html 2014 [Available from: http://www.okbmedical.com/lapmentor.html.
109. Giulea C, Enciu O, Birca T, Miron A. Selective Intraoperative Cholangiography in Laparoscopic Cholecystectomy. Chirurgia (Bucur). 2016;111(1):26-32.
110. Nagral S. Anatomy relevant to cholecystectomy. J Minim Access Surg. 2005;1(2):53-8.
111. Sarker SK, Chang A, Vincent C, Darzi AW. Technical skills errors in laparoscopic cholecystectomy by expert surgeons. Surg Endosc. 2005;19(6):832-5.
112. Reichenbach DJ, Tackett AD, Harris J, Camacho D, Graviss EA, Dewan B, et al. Laparoscopic colon resection early in the learning curve: what is the appropriate setting? Ann Surg. 2006;243(6):730-5; discussion 5-7.
113. Coleman MG, Hanna GB, Kennedy R, National Training Programme L. The National Training Programme for Laparoscopic Colorectal Surgery in England: a new training paradigm. Colorectal Dis. 2011;13(6):614-6.
114. Cagir B, Rangraj M, Maffuci L, Herz BL. The learning curve for laparoscopic cholecystectomy. Journal of Laparoendoscopic Surgery. 1994;4(6):419-27.
115. Hawasli A, Lloyd LR. Laparoscopic cholecystectomy. The learning curve: report of 50 patients. American Surgeon. 1991;57(8):542-4; discussion 5.
116. Moore MJ, Bennett CL. The learning curve for laparoscopic cholecystectomy. The Southern Surgeons Club. American Journal of Surgery. 1995;170(1):55-9.
117. Sariego J, Spitzer L, Matsumoto T. The "learning curve" in the performance of laparoscopic cholecystectomy. International Surgery. 1993;78(1):1-3.
118. Voitk AJ, Tsao SG, Ignatius S. The tail of the learning curve for laparoscopic cholecystectomy. American Journal of Surgery. 2001;182(3):250-3.
119. Martel G, Boushey RP. Laparoscopic colon surgery: past, present and future. Surg Clin North Am. 2006;86(4):867-97.
120. Siegel R, Cuesta MA, Targarona E, Bader FG, Morino M, Corcelles R, et al. Laparoscopic extraperitoneal rectal cancer surgery: the clinical practice guidelines of the European Association for Endoscopic Surgery (EAES). Surg Endosc. 2011;25(8):2423-40.

121. Bianchi PP, Petz W, Luca F, Biffi R, Spinoglio G, Montorsi M. Laparoscopic and robotic total mesorectal excision in the treatment of rectal cancer. Brief review and personal remarks. Front Oncol. 2014;4:98.
122. Son GM, Kim JG, Lee JC, Suh YJ, Cho HM, Lee YS, et al. Multidimensional analysis of the learning curve for laparoscopic rectal cancer surgery. Journal of Laparoendoscopic & Advanced Surgical Techniques Part A. 2010;20(7):609-17.
123. Fernandez GL, Page DW, Coe NP, Lee PC, Patterson LA, Skylizard L, et al. Boot cAMP: educational outcomes after 4 successive years of preparatory simulation-based training at onset of internship. Journal of Surgical Education. 2012;69(2):242-8.
124. Parent RJ, Plerhoples TA, Long EE, Zimmer DM, Teshome M, Mohr CJ, et al. Early, intermediate, and late effects of a surgical skills "boot camp" on an objective structured assessment of technical skills: a randomized controlled study. Journal of the American College of Surgeons. 2010;210(6):984-9.
125. Glassman D, Yiasemidou M, Venkateswaran B, Sivakumar R, Majumder S, Biyani CS. A multi-specialty surgical course for residents transitioning from early to intermediate training. Int J Med Educ. 2016;7:130-1.
126. Yiasemidou M, Roberts D, Glassman D, Tomlinson J, Biyani S, Miskovic D. A Multispecialty Evaluation of Thiel Cadavers for Surgical Training. World J Surg. 2017.
127. Hennessey IA, Hewett P. Virtual reality versus box laparoscopic simulators in trainee selection and aptitude testing. Surg Laparosc Endosc Percutan Tech. 2014;24(4):318-21.
128. Hiemstra E, Terveer EM, Chmarra MK, Dankelman J, Jansen FW. Virtual reality in laparoscopic skills training: is haptic feedback replaceable? Minim Invasive Ther Allied Technol. 2011;20(3):179-84.
129. Hudak SJ, Landt CL, Hernandez J, Soderdahl DW. External validation of a virtual reality transurethral resection of the prostate simulator. J Urol. 2010;184(5):2018-22.
130. Hui Y, Safir O, Dubrowski A, Carnahan H. What skills should simulation training in arthroscopy teach residents? A focus on resident input. Int J Comput Assist Radiol Surg. 2013;8(6):945-53.
131. Hull L, Kassab E, Arora S, Kneebone R. Increasing the realism of a laparoscopic box trainer: a simple, inexpensive method. J Laparoendosc Adv Surg Tech A. 2010;20(6):559-62.
132. Ikonen TS, Antikainen T, Silvennoinen M, Isojarvi J, Makinen E, Scheinin TM. Virtual reality simulator training of laparoscopic cholecystectomies - a systematic review. Scand J Surg. 2012;101(1):5-12.
133. Rao A, Tait I, Alijani A. Systematic review and meta-analysis of the role of mental training in the acquisition of technical skills in surgery. Am J Surg. 2015;210(3):545-53.
134. Stefanidis D, Sevdalis N, Paige J, Zevin B, Aggarwal R, Grantcharov T, et al. Simulation in surgery: what's needed next? Ann Surg. 2015;261(5):846-53.
135. Jackson PL, Lafleur MF, Malouin F, Richards C, Doyon J. Potential role of mental practice using motor imagery in neurologic rehabilitation. Archives of Physical Medicine & Rehabilitation. 2001;82(8):1133-41.
136. Jeannerod M. Mental imagery in the motor context. Neuropsychologia. 1995;33(11):1419-32.

137. Bernardi NF, De Buglio M, Trimarchi PD, Chielli A, Bricolo E. Mental practice promotes motor anticipation: evidence from skilled music performance. Front Hum Neurosci. 2013;7:451.
138. Lim VK, Polych MA, Hollander A, Byblow WD, Kirk IJ, Hamm JP. Kinesthetic but not visual imagery assists in normalizing the CNV in Parkinson's disease. Clinical Neurophysiology. 2006;117(10):2308-14.
139. Sirigu A, Duhamel JR. Motor and visual imagery as two complementary but neurally dissociable mental processes. Journal of Cognitive Neuroscience. 2001;13(7):910-9.
140. Hall JC. Imagery practice and the development of surgical skills. The American Journal of Surgery. 2002;184(5):465-70.
141. Driskell J. CC, Moran A. . Does mental practice enhance performance? . J Appl Psychol. 1994;79:481–92.
142. Arora S, Aggarwal R, Moran A, Sirimanna P, Crochet P, Darzi A, et al. Mental practice: effective stress management training for novice surgeons. Journal of the American College of Surgeons. 2011;212(2):225-33.
143. Arora S, Aggarwal R, Sirimanna P, Moran A, Grantcharov T, Kneebone R, et al. Mental practice enhances surgical technical skills: a randomized controlled study. Annals of Surgery. 2011;253(2):265-70.
144. Kosslyn SM. Image and mind: Harvard University Press, Cambridge, MA.; 1980.
145. Kosslyn SM. Image and brain: MIT Press, Cambridge, MA; 1994.
146. Kosslyn SM, Thompson, W. L., & Ganis, G. The case for mental imagery. New York: Oxford University Press, Inc.; 2006.
147. Pearson DG. Mental imagery and creative thought. Proceedings of the British Academy. 2007;147:187-212.
148. Pearson DG, Deeprose C, Wallace-Hadrill SM, Burnett Heyes S, Holmes EA. Assessing mental imagery in clinical psychology: a review of imagery measures and a guiding framework. Clin Psychol Rev. 2013;33(1):1-23.
149. Cornoldi C, & Rossana, D. B. Memory and imagery: A visual trace is not a men- tal image. In: A. C. Martin EGS, & C. Cesare editor. Theories of Memory. Hove: Psychology Press; 1998. p. 87-110.
150. Gardini S, Cornoldi C, De Beni R, Venneri A. Cognitive and neuronal processes involved in sequential generation of general and specific mental images. Psychological Research. 2009;73(5):633-43.
151. Betts GH. The distribution and functions of mental imagery. New York: Columbia University; 1909.
152. Tiggemann M, & Kemps, E. The phenomenology of food cravings: The role of mental imagery. Appetite,. 2005;45(3):305-13.
153. Stevenson RJ, Case TI. Olfactory imagery: a review. Psychon Bull Rev. 2005;12(2):244-64.
154. Juttner M, & Rentschler, I. . Imagery in multi-modal object learning. Behavioral and Brain Sciences. 2002;25(2):197-8.
155. Schuster C, Hilfiker R, Amft O, Scheidhauer A, Andrews B, Butler J, et al. Best practice for motor imagery: a systematic literature review on motor imagery training elements in five different disciplines. BMC Med. 2011;9:75.
156. Pearson DG, De Beni, R., & Cornoldi, C. The generation and transformation of visuo-spatial mental images. In: M. Denis RHL, C. Cornoldi, M. de Vega, & J.

Engelkamp (Eds.), editor. Imagery, language and visuo-spatial thinking Hove: Psychology press; 2001. p. 1-23.
157. Decety J, Jeannerod M, Prablanc C. The timing of mentally represented actions. Behavioural Brain Research. 1989;34(1-2):35-42.
158. Decety J, Jeannerod M. Mentally simulated movements in virtual reality: does Fitts's law hold in motor imagery? Behavioural Brain Research. 1995;72(1-2):127-34.
159. Decety J, Grezes J. Neural mechanisms subserving the perception of human actions. Trends Cogn Sci. 1999;3(5):172-8.
160. Shepard RN, Cooper, L.A. Mental images and their transformations: MIT Press/Bradford Books, Cambridge, MA.; 1982.
161. Finke RA, Pinker, S., & Farah, M. J. . Reinterpreting visual patterns in mental imagery. Cognitive Science. 1989;13(1):51-78.
162. Epstein M. The relationships of mental imagery and mental practice to performance of a motor task. Journal of sport psychology. 1980;2:211-20.
163. Rodrigues EC, Lemos T, Gouvea B, Volchan E, Imbiriba LA, Vargas CD. Kinesthetic motor imagery modulates body sway. Neuroscience. 2010;169(2):743-50.
164. McInnes K, Friesen C, Boe S. Specific Brain Lesions Impair Explicit Motor Imagery Ability: A Systematic Review of the Evidence. Arch Phys Med Rehabil. 2015.
165. Arora S AR, Sevdalis N, Moran A, Sirimanna P, Kneebone R, Darzi A. Development and validation of mental practice as a training strategy for laparoscopic surgery. Surg Endosc. 2009;24(1):179-87.
166. Roberts R, Callow N, Hardy L, Markland D, Bringer J. Movement imagery ability: development and assessment of a revised version of the vividness of movement imagery questionnaire. J Sport Exerc Psychol. 2008;30(2):200-21.
167. Lebon F, Byblow WD, Collet C, Guillot A, Stinear CM. The modulation of motor cortex excitability during motor imagery depends on imagery quality. European Journal of Neuroscience. 2012;35(2):323-31.
168. Fourkas AD, Bonavolonta V, Avenanti A, Aglioti SM. Kinesthetic imagery and tool-specific modulation of corticospinal representations in expert tennis players. Cereb Cortex. 2008;18(10):2382-90.
169. Jeannerod M, Decety J, Michel F. Impairment of grasping movements following a bilateral posterior parietal lesion. Neuropsychologia. 1994;32(4):369-80.
170. Reed CL. Chronometric comparisons of imagery to action: visualizing versus physically performing springboard dives. Mem Cognit. 2002;30(8):1169-78.
171. TJ S. Phases of meaningful learning. Rev Educ Res. 1990;60:531-47.
172. Cauraugh JH, Martin M, Martin KK. Modeling surgical expertise for motor skill acquisition. Am J Surg. 1999;177(4):331-6.
173. Fitts PM, Posner MI. Human performance. Oxford, England: Brooks/Cole; 1967.
174. Schmidt RA. A schema theory of discrete motor skill learning. Psychological Review. 1975;82(4):225-60.
175. Zimmermann-Schlatter A, Schuster C, Puhan MA, Siekierka E, Steurer J. Efficacy of motor imagery in post-stroke rehabilitation: a systematic review. J Neuroeng Rehabil. 2008;5:8.
176. Annett J. Motor imagery: perception or action? Neuropsychologia. 1995;33(11):1395-417.

177. Wolpert DM, Ghahramani Z. Computational principles of movement neuroscience. Nat Neurosci. 2000;3 Suppl:1212-7.
178. Jeannerod M, Frak V. Mental imaging of motor activity in humans. Current Opinion in Neurobiology. 1999;9(6):735-9.
179. Frak V, Paulignan Y, Jeannerod M. Orientation of the opposition axis in mentally simulated grasping. Experimental Brain Research. 2001;136(1):120-7.
180. Allami N, Brovelli A, Hamzaoui el M, Regragui F, Paulignan Y, Boussaoud D. Neurophysiological correlates of visuo-motor learning through mental and physical practice. Neuropsychologia. 2014;55:6-14.
181. Lotze M, Montoya P, Erb M, Hulsmann E, Flor H, Klose U, et al. Activation of cortical and cerebellar motor areas during executed and imagined hand movements: an fMRI study. J Cogn Neurosci. 1999;11(5):491-501.
182. Naito E, Kochiyama T, Kitada R, Nakamura S, Matsumura M, Yonekura Y, et al. Internally simulated movement sensations during motor imagery activate cortical motor areas and the cerebellum. J Neurosci. 2002;22(9):3683-91.
183. Gerardin E, Sirigu A, Lehericy S, Poline JB, Gaymard B, Marsault C, et al. Partially overlapping neural networks for real and imagined hand movements. Cereb Cortex. 2000;10(11):1093-104.
184. Nair DG, Purcott KL, Fuchs A, Steinberg F, Kelso JA. Cortical and cerebellar activity of the human brain during imagined and executed unimanual and bimanual action sequences: a functional MRI study. Brain Res Cogn Brain Res. 2003;15(3):250-60.
185. Sirigu A, Duhamel JR, Cohen L, Pillon B, Dubois B, Agid Y. The mental representation of hand movements after parietal cortex damage. Science. 1996;273(5281):1564-8.
186. Wolbers T, Weiller C, Buchel C. Contralateral coding of imagined body parts in the superior parietal lobe. Cereb Cortex. 2003;13(4):392-9.
187. Binkofski F, Amunts K, Stephan KM, Posse S, Schormann T, Freund HJ, et al. Broca's region subserves imagery of motion: a combined cytoarchitectonic and fMRI study. Human Brain Mapping. 2000;11(4):273-85.
188. Porro CA, Francescato MP, Cettolo V, Diamond ME, Baraldi P, Zuiani C, et al. Primary motor and sensory cortex activation during motor performance and motor imagery: a functional magnetic resonance imaging study. J Neurosci. 1996;16(23):7688-98.
189. Roth M, Decety J, Raybaudi M, Massarelli R, Delon-Martin C, Segebarth C, et al. Possible involvement of primary motor cortex in mentally simulated movement: a functional magnetic resonance imaging study. Neuroreport. 1996;7(7):1280-4.
190. Munzert J, Lorey B, Zentgraf K. Cognitive motor processes: the role of motor imagery in the study of motor representations. Brain Res Rev. 2009;60(2):306-26.
191. Beisteiner R, Hollinger P, Lindinger G, Lang W, Berthoz A. Mental representations of movements. Brain potentials associated with imagination of hand movements. Electroencephalogr Clin Neurophysiol. 1995;96(2):183-93.
192. Cunnington R, Iansek R, Bradshaw JL, Phillips JG. Movement-related potentials associated with movement preparation and motor imagery. Exp Brain Res. 1996;111(3):429-36.
193. Caldara R, Deiber MP, Andrey C, Michel CM, Thut G, Hauert CA. Actual and mental motor preparation and execution: a spatiotemporal ERP study. Experimental Brain Research. 2004;159(3):389-99.

194. Caspers H, Speckmann EJ, Lehmenkuhler A. DC potentials of the cerebral cortex. Seizure activity and changes in gas pressures. Reviews of Physiology Biochemistry & Pharmacology. 1987;106:127-78.
195. McCaskie AW, Kenny DT, Deshmukh S. How can surgical training benefit from theories of skilled motor development, musical skill acquisition and performance psychology? Medical Journal of Australia. 2011;194(9):463-5.
196. Cole SJ, Mackenzie H, Ha J, Hanna GB, Miskovic D. Randomized controlled trial on the effect of coaching in simulated laparoscopic training. Surg Endosc. 2014;28(3):979-86.
197. The “R-3D-2” pilot study - the impact of rehearsal strategies prior rectal cancer surgery, using patient individualised 3D models ISRCTN registry2015 [Available from: http://www.isrctn.com/ISRCTN75603704.
198. Ryan D SJ. What is learned in mental practice of motor skills: A test of the cognitive-motor hypothesis. Journal of sport psychology. 1983;5:419-26.
199. Eldred-Evans D, Grange P, Cheang A, Yamamoto H, Ayis S, Mulla M, et al. Using the mind as a simulator: a randomized controlled trial of mental training. Journal of Surgical Education. 2013;70(4):544-51.
200. Bathalon S, Dorion D, Darveau S, Martin M. Cognitive skills analysis, kinesiology, and mental imagery in the acquisition of surgical skills. Journal of Otolaryngology. 2005;34(5):328-32.
201. Mulla M, Sharma D, Moghul M, Kailani O, Dockery J, Ayis S, et al. Learning basic laparoscopic skills: a randomized controlled study comparing box trainer, virtual reality simulator, and mental training. Journal of Surgical Education. 2012;69(2):190-5.
202. Rao A, Tait I, Alijani A. Systematic review and meta-analysis of the role of mental training in the acquisition of technical skills in surgery. The American Journal of Surgery.210(3):545-53.
203. Rozand V, Lebon F, Stapley PJ, Papaxanthis C, Lepers R. A prolonged motor imagery session alter imagined and actual movement durations: Potential implications for neurorehabilitation. Behav Brain Res. 2016;297:67-75.
204. Eldred-Evans D, Grange P, Cheang A, Yamamoto H, Ayis S, Mulla M, et al. Using the Mind as a Simulator: A Randomized Controlled Trial of Mental Training. J Surg Educ.70(4):544-51.
205. Arora S, Aggarwal R, Moran A, Sirimanna P, Crochet P, Darzi A, et al. Mental Practice: Effective Stress Management Training for Novice Surgeons. Journal of the American College of Surgeons. 2011;212(2):225-33.
206. Arora S, Aggarwal R, Sirimanna P, Moran A, Grantcharov T, Kneebone R, et al. Mental practice enhances surgical technical skills: a randomized controlled study. Ann Surg. 2011;253(2):265-70.
207. Louridas M, Bonrath EM, Sinclair DA, Dedy NJ, Grantcharov TP. Randomized clinical trial to evaluate mental practice in enhancing advanced laparoscopic surgical performance. British Journal of Surgery. 2015;102(1):37-44.
208. Gregg M, Hall C, Butler A. The MIQ-RS: A Suitable Option for Examining Movement Imagery Ability. Evid Based Complement Alternat Med. 2010;7(2):249-57.
209. Brigden D, Dangerfield P. The role of simulation in medical education. The Clinical Teacher. 2008;5(3):167-70.
210. Conrad C, Konuk Y, Werner PD, Cao CG, Warshaw AL, Rattner DW, et al. A quality improvement study on avoidable stressors and countermeasures affecting surgical motor performance and learning. Ann Surg. 2012;255(6):1190-4.

211. Pascual-Leone A, Nguyet D, Cohen LG, Brasil-Neto JP, Cammarota A, Hallett M. Modulation of muscle responses evoked by transcranial magnetic stimulation during the acquisition of new fine motor skills. Journal of Neurophysiology. 1995;74(3):1037-45.
212. Yágüez L. ND, Hoffman H., Canavan A. G., Wist E., Hömberg V. . A mental route to motor learning: improving trajectorial kinematics through imagery training. . Behav Brain Res. 1998;90:95-106.
213. Vogt S. On relations between perceiving, imagining and performing in the learning of cyclical movement sequences. British Journal of Psychology. 1995;86(Pt 2):191-216.
214. Shen F, Chen B, Guo Q, Qi Y, Shen Y. Augmented reality patient-specific reconstruction plate design for pelvic and acetabular fracture surgery. Int J Comput Assist Radiol Surg. 2013;8(2):169-79.
215. Fornaro J, Keel M, Harders M, Marincek B, Szekely G, Frauenfelder T. An interactive surgical planning tool for acetabular fractures: initial results. J Orthop Surg Res. 2010;5:50.
216. van Steenberghe D, Glauser R, Blomback U, Andersson M, Schutyser F, Pettersson A, et al. A computed tomographic scan-derived customized surgical template and fixed prosthesis for flapless surgery and immediate loading of implants in fully edentulous maxillae: a prospective multicenter study. Clin Implant Dent Relat Res. 2005;7 Suppl 1:S111-20.
217. 10 Best DLP/SLA 3D Printers You can Buy in 2016 [Available from: https://all3dp.com/best-sla-3d-printers/.
218. Excell J. The rise of additive manufacturing. The Engineer. 2013.
219. AlAli AB, Griffin MF, Butler PE. Three-Dimensional Printing Surgical Applications. Eplasty. 2015;15:e37.
220. Adolphs N, Liu W, Keeve E, Hoffmeister B. RapidSplint: virtual splint generation for orthognathic surgery - results of a pilot series. Comput Aided Surg. 2014;19(1-3):20-8.
221. Ayoub N, Ghassemi A, Rana M, Gerressen M, Riediger D, Holzle F, et al. Evaluation of computer-assisted mandibular reconstruction with vascularized iliac crest bone graft compared to conventional surgery: a randomized prospective clinical trial. Trials. 2014;15:114.
222. Derand P, Rannar LE, Hirsch JM. Imaging, virtual planning, design, and production of patient-specific implants and clinical validation in craniomaxillofacial surgery. Craniomaxillofac Trauma Reconstr. 2012;5(3):137-44.
223. Dhanda J, Cooper C, Ellis D, Speculand B. Technique of temporomandibular joint replacement using a patient-specific reconstruction system in the edentulous patient. British Journal of Oral & Maxillofacial Surgery. 2011;49(8):618-22.
224. Essig H, Rana M, Kokemueller H, von See C, Ruecker M, Tavassol F, et al. Pre-operative planning for mandibular reconstruction - a full digital planning workflow resulting in a patient specific reconstruction. Head Neck Oncol. 2011;3:45.
225. Gander T, Essig H, Metzler P, Lindhorst D, Dubois L, Rucker M, et al. Patient specific implants (PSI) in reconstruction of orbital floor and wall fractures. J Craniomaxillofac Surg. 2015;43(1):126-30.
226. Gateno J, Xia JJ, Teichgraeber JF, Christensen AM, Lemoine JJ, Liebschner MA, et al. Clinical feasibility of computer-aided surgical simulation (CASS) in the treatment of complex cranio-maxillofacial deformities. J Oral Maxillofac Surg. 2007;65(4):728-34.

227. Hsu SS, Gateno J, Bell RB, Hirsch DL, Markiewicz MR, Teichgraeber JF, et al. Accuracy of a computer-aided surgical simulation protocol for orthognathic surgery: a prospective multicenter study. J Oral Maxillofac Surg. 2013;71(1):128-42.
228. Lo LJ, Chen YR, Tseng CS, Lee MY. Computer-aided reconstruction of traumatic fronto-orbital osseous defects: aesthetic considerations. Chang Gung Medical Journal. 2004;27(4):283-91.
229. Schepers RH, Raghoebar GM, Vissink A, Stenekes MW, Kraeima J, Roodenburg JL, et al. Accuracy of fibula reconstruction using patient-specific CAD/CAM reconstruction plates and dental implants: A new modality for functional reconstruction of mandibular defects. J Craniomaxillofac Surg. 2015;43(5):649-57.
230. Scolozzi P. Maxillofacial reconstruction using polyetheretherketone patient-specific implants by "mirroring" computational planning. Aesthetic Plastic Surgery. 2012;36(3):660-5.
231. Steinbacher DM. Three-Dimensional Analysis and Surgical Planning in Craniomaxillofacial Surgery. J Oral Maxillofac Surg. 2015;73(12 Suppl):S40-56.
232. Xia JJ, Gateno J, Teichgraeber JF, Christensen AM, Lasky RE, Lemoine JJ, et al. Accuracy of the computer-aided surgical simulation (CASS) system in the treatment of patients with complex craniomaxillofacial deformity: A pilot study. J Oral Maxillofac Surg. 2007;65(2):248-54.
233. Dong Y, Dong Y, Hu G, Xu Q. Three-dimensional reconstruction of extremity tumor regions by CT and MRI image data fusion for subject-specific preoperative assessment and planning. Comput Aided Surg. 2011;16(5):220-33.
234. Franceschi JP, Sbihi A, Computer Assisted Orthopedic Surgery F. 3D templating and patient-specific cutting guides (Knee-Plan) in total knee arthroplasty: postoperative CT-based assessment of implant positioning. Orthop Traumatol Surg Res. 2014;100(6 Suppl):S281-6.
235. Furnstahl P, Vlachopoulos L, Schweizer A, Fucentese SF, Koch PP. Complex Osteotomies of Tibial Plateau Malunions Using Computer-Assisted Planning and Patient-Specific Surgical Guides. J Orthop Trauma. 2015;29(8):e270-6.
236. Issa K, Rifai A, McGrath MS, Callaghan JJ, Wright C, Malkani AL, et al. Reliability of templating with patient-specific instrumentation in total knee arthroplasty. The Journal of Knee Surgery. 2013;26(6):429-33.
237. Kerens B, Boonen B, Schotanus M, Kort N. Patient-specific guide for revision of medial unicondylar knee arthroplasty to total knee arthroplasty: beneficial first results of a new operating technique performed on 10 patients. Acta Orthopaedica. 2013;84(2):165-9.
238. Leeuwen JA, Grogaard B, Nordsletten L, Rohrl SM. Comparison of planned and achieved implant position in total knee arthroplasty with patient-specific positioning guides. Acta Orthopaedica. 2015;86(2):201-7.
239. Pietsch M, Djahani O, Hochegger M, Plattner F, Hofmann S. Patient-specific total knee arthroplasty: the importance of planning by the surgeon. Knee Surg Sports Traumatol Arthrosc. 2013;21(10):2220-6.
240. Schweizer A, Furnstahl P, Nagy L. Three-dimensional correction of distal radius intra-articular malunions using patient-specific drill guides. Journal of Hand Surgery - American Volume. 2013;38(12):2339-47.
241. Small T, Krebs V, Molloy R, Bryan J, Klika AK, Barsoum WK. Comparison of acetabular shell position using patient specific instruments vs. standard surgical instruments: a randomized clinical trial. J Arthroplasty. 2014;29(5):1030-7.

242. Victor J, Premanathan A. Virtual 3D planning and patient specific surgical guides for osteotomies around the knee: a feasibility and proof-of-concept study. Bone & Joint Journal. 2013;95-B(11 Suppl A):153-8.
243. Vlachopoulos L, Schweizer A, Graf M, Nagy L, Furnstahl P. Three-dimensional postoperative accuracy of extra-articular forearm osteotomies using CT-scan based patient-specific surgical guides. BMC Musculoskelet Disord. 2015;16:336.
244. Willaert W, Aggarwal R, Harvey K, Cochennec F, Nestel D, Darzi A, et al. Efficient implementation of patient-specific simulated rehearsal for the carotid artery stenting procedure: part-task rehearsal. Eur J Vasc Endovasc Surg. 2011;42(2):158-66.
245. Li C, Yang M, Xie Y, Chen Z, Wang C, Bai Y, et al. Application of the polystyrene model made by 3-D printing rapid prototyping technology for operation planning in revision lumbar discectomy. Journal of Orthopaedic Science. 2015;20(3):475-80.
246. Isotani S, Shimoyama H, Yokota I, China T, Hisasue S, Ide H, et al. Feasibility and accuracy of computational robot-assisted partial nephrectomy planning by virtual partial nephrectomy analysis. Int J Urol. 2015;22(5):439-46.
247. Kusaka M, Sugimoto M, Fukami N, Sasaki H, Takenaka M, Anraku T, et al. Initial experience with a tailor-made simulation and navigation program using a 3-D printer model of kidney transplantation surgery. Transplantation Proceedings. 2015;47(3):596-9.
248. Carter FJ, Schijven MP, Aggarwal R, Grantcharov T, Francis NK, Hanna GB, et al. Consensus guidelines for validation of virtual reality surgical simulators. Simul Healthc. 2006;1(3):171-9.
249. Gavazzi A, Bahsoun AN, Van Haute W, Ahmed K, Elhage O, Jaye P, et al. Face, content and construct validity of a virtual reality simulator for robotic surgery (SEP Robot). Ann R Coll Surg Engl. 2011;93(2):152-6.
250. Leong JL, Batra PS, Citardi MJ. Three-dimensional computed tomography angiography of the internal carotid artery for preoperative evaluation of sinonasal lesions and intraoperative surgical navigation. Laryngoscope. 2005;115(9):1618-23.
251. Lu S, Xu YQ, Zhang YZ, Xie L, Guo H, Li DP. A novel computer-assisted drill guide template for placement of C2 laminar screws. Eur Spine J. 2009;18(9):1379-85.
252. Kanzaki M, Maeda H, Wachi N, Kikkawa T, Komine H, Isaka T, et al. Complete video-assisted thoracoscopic multi-subsegmentectomy based on patients' specific virtual 3-D pulmonary models. Asian J Endosc Surg. 2013;6(2):110-5.
253. Mandel M, Amorim R, Paiva W, Prudente M, Teixeira MJ, Andrade AF. 3D preoperative planning in the ER with OsiriX: when there is no time for neuronavigation. Sensors. 2013;13(5):6477-91.
254. Li H, Wan F, Li J, Sheng L, Li G, Chen G, et al. Flat Detector Computed Tomography-Based "Dual Vessel Fusion" Technique for Diagnosis and Surgical Planning in the Management of Dural Arteriovenous Fistula. World Neurosurg. 2015;84(2):520-7.
255. collaboration C. Cochrane collaboration's tool for assessing risk bias [Available from: http://handbook.cochrane.org/chapter_8/table_8_5_a_the_cochrane_collaborations_tool_for_assessing.htm.

256. Pratt R, Deprest J, Vercauteren T, Ourselin S, David AL. Computer-assisted surgical planning and intraoperative guidance in fetal surgery: a systematic review. Prenat Diagn. 2015;35(12):1159-66.
257. See KW, Chui KH, Chan WH, Wong KC, Chan YC. Evidence for Endovascular Simulation Training: A Systematic Review. Eur J Vasc Endovasc Surg. 2016;51(3):441-51.
258. Maher MM, Kalra MK, Sahani DV, Perumpillichira JJ, Rizzo S, Saini S, et al. Techniques, clinical applications and limitations of 3D reconstruction in CT of the abdomen. Korean J Radiol. 2004;5(1):55-67.
259. Karatas OH, Toy E. Three-dimensional imaging techniques: A literature review. Eur J Dent. 2014;8(1):132-40.
260. Roberts N, Magee D, Song Y, Brabazon K, Shires M, Crellin D, et al. Toward routine use of 3D histopathology as a research tool. Am J Pathol. 2012;180(5):1835-42.
261. History of 3D printin: The free beginner's guide [Available from: http://3dprintingindustry.com/3d-printing-basics-free-beginners-guide/history/.
262. Derossis AM, Fried GM, Abrahamowicz M, Sigman HH, Barkun JS, Meakins JL. Development of a model for training and evaluation of laparoscopic skills. Am J Surg. 1998;175(6):482-7.
263. Goova MT, Hollett LA, Tesfay ST, Gala RB, Puzziferri N, Kehdy FJ, et al. Implementation, construct validity, and benefit of a proficiency-based knot-tying and suturing curriculum. J Surg Educ. 2008;65(4):309-15.
264. Scott DJ, Goova MT, Tesfay ST. A cost-effective proficiency-based knot-tying and suturing curriculum for residency programs. J Surg Res. 2007;141(1):7-15.
265. Aggarwal R, Crochet P, Dias A, Misra A, Ziprin P, Darzi A. Development of a virtual reality training curriculum for laparoscopic cholecystectomy. British Journal of Surgery. 2009;96(9):1086-93.
266. Barsuk JH, McGaghie WC, Cohen ER, Balachandran JS, Wayne DB. Use of simulation-based mastery learning to improve the quality of central venous catheter placement in a medical intensive care unit. Journal of Hospital Medicine (Online). 2009;4(7):397-403.
267. Crochet P, Aggarwal R, Dubb SS, Ziprin P, Rajaretnam N, Grantcharov T, et al. Deliberate practice on a virtual reality laparoscopic simulator enhances the quality of surgical technical skills. Annals of Surgery. 2011;253(6):1216-22.
268. Zendejas B, Cook DA, Bingener J, Huebner M, Dunn WF, Sarr MG, et al. Simulation-based mastery learning improves patient outcomes in laparoscopic inguinal hernia repair: a randomized controlled trial. Ann Surg. 2011;254(3):502-9; discussion 9-11.
269. Zendejas B, Cook DA, Hernandez-Irizarry R, Huebner M, Farley DR. Mastery learning simulation-based curriculum for laparoscopic TEP inguinal hernia repair. J Surg Educ. 2012;69(2):208-14.
270. Kerr B, O'Leary JP. The training of the surgeon: Dr. Halsted's greatest legacy. Am Surg. 1999;65(11):1101-2.
271. Tan SY, Uyehara P. William Stewart Halsted (1852-1922): father of American surgery. Singapore Med J. 2010;51(7):530-1.
272. Kurashima Y, Hirano S. Systematic review of the implementation of simulation training in surgical residency curriculum. Surg Today. 2016.

273. Frigenza M, Tran A, Breaud J, Fournier JP, Bongain A, Delotte J. Evaluation of single incision laparoscopic surgery "low-fidelity" simulation training. J Visc Surg. 2014;151(5):335-9.
274. Lin YH, Luo YL, Lee CC, Yang SF, Yu DS. A PC-based laparoscopic surgery skills training and assessment system. Conf Proc IEEE Eng Med Biol Soc. 2014;2014:498-501.
275. Teitelbaum EN, Soper NJ, Santos BF, Rooney DM, Patel P, Nagle AP, et al. A simulator-based resident curriculum for laparoscopic common bile duct exploration. Surgery. 2014;156(4):880-7, 90-3.
276. Rosenthal ME, Ritter EM, Goova MT, Castellvi AO, Tesfay ST, Pimentel EA, et al. Proficiency-based Fundamentals of Laparoscopic Surgery skills training results in durable performance improvement and a uniform certification pass rate. Surg Endosc. 2010;24(10):2453-7.
277. Scott DJ, Ritter EM, Tesfay ST, Pimentel EA, Nagji A, Fried GM. Certification pass rate of 100% for fundamentals of laparoscopic surgery skills after proficiency-based training. Surg Endosc. 2008;22(8):1887-93.
278. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33(1):159-74.
279. Mohammadi Y, Lerner MA, Sethi AS, Sundaram CP. Comparison of laparoscopy training using the box trainer versus the virtual trainer. Journal of the Society of Laparoendoscopic Surgeons. 2010;14(2):205-12.
280. Diesen DL, Erhunmwunsee L, Bennett KM, Ben-David K, Yurcisin B, Ceppa EP, et al. Effectiveness of laparoscopic computer simulator versus usage of box trainer for endoscopic surgery training of novices. Journal of Surgical Education. 2011;68(4):282-9.
281. Aydin A, Ahmed K, Shafi AM, Khan MS, Dasgupta P. The role of simulation in urological training - A quantitative study of practice and opinions. The surgeon : journal of the Royal Colleges of Surgeons of Edinburgh and Ireland. 2015.
282. Forster JA, Browning AJ, Paul AB, Biyani CS. Surgical simulators in urological training--views of UK Training Programme Directors. BJU Int. 2012;110(6):776-8.
283. Tavakol M, Mohagheghi MA, Dennick R. Assessing the skills of surgical residents using simulation. Journal of Surgical Education. 2008;65(2):77-83.
284. De Win G, Everaerts W, De Ridder D, Peeraer G. Laparoscopy training in Belgium: results from a nationwide survey, in urology, gynecology, and general surgery residents. Adv Med Educ Pract. 2015;6:55-63.
285. Marina Yiasemidou PD, James Tomlinson, Daniel Glassman, Joanne Johnson, Michael Gough. Should simulation be compulsory for trainees in all surgical specialties? BMJ STEL 2014;1:A68-A9.
286. Boza C, Leon F, Buckel E, Riquelme A, Crovari F, Martinez J, et al. Simulation-trained junior residents perform better than general surgeons on advanced laparoscopic cases. Surgical endoscopy. 2016.
287. Celentano V. Need for simulation in laparoscopic colorectal surgery training. World journal of gastrointestinal surgery. 2015;7(9):185-9.
288. Association of Surgeons in Training. Simulation in Surgical Training. 2011 [Available from: http://www.asit.org/assets/documents/Simulation_in_Surgical_Training___ASiT_Statement.pdf.
289. Fineout-Overholt BMMaE. Evidence-based practice in nursing & healthcare: a guide to best practiceBernadette M. Melnyk and Ellen Fineout-Overholt. 2005. p. 10.

290. Cooper CE, Blannin M, Hall C, Griffin M. NIRS-detected changes in the arm during mental rehearsal of physical activity (imaginary exercise). Advances in Experimental Medicine & Biology. 2006;578:191-6.
291. Hennessy S, Bilker WB, Berlin JA, Strom BL. Factors influencing the optimal control-to-case ratio in matched case-control studies. Am J Epidemiol. 1999;149(2):195-7.
292. KJ. R. Modern epidemiology,. Little., editor. Boston: Brown and Company; 1986.
293. Skandalakis LJ SJ, Skandalakis PN. Extrahepatic Biliary Tract. Surgical Anatomy and Technique A Pocket Manual. 3rd ed. New York, USA: Springer; 2009.
294. Kosslyn SM. mage and brain: The resolution of the imagery debate. Press M, editor. Cambridge1994.
295. Targarona EM, Balague C, Pernas JC, Martinez C, Berindoague R, Gich I, et al. Can we predict immediate outcome after laparoscopic rectal surgery? Multivariate analysis of clinical, anatomic, and pathologic features after 3-dimensional reconstruction of the pelvic anatomy. Ann Surg. 2008;247(4):642-9.
296. Ding YM, Wang B, Wang WX, Wang P, Yan JS. New classification of the anatomic variations of cystic artery during laparoscopic cholecystectomy. World Journal of Gastroenterology. 2007;13(42):5629-34.
297. Yushkevich PA, Piven J, Hazlett HC, Smith RG, Ho S, Gee JC, et al. User-guided 3D active contour segmentation of anatomical structures: significantly improved efficiency and reliability. Neuroimage. 2006;31(3):1116-28.
298. Gregg M HC, Butler A. The MIQ-RS: A Suitable Option for Examining Movement Imagery Ability. Evid Based Complement Alternat Med 2010;7(2):249-57.
299. Ezvid Inc [Available from: https://www.ezvid.com/.
300. Chae MP, Rozen WM, McMenamin PG, Findlay MW, Spychal RT, Hunter-Smith DJ. Emerging Applications of Bedside 3D Printing in Plastic Surgery. Front Surg. 2015;2:25.
301. Aggarwal R, Moorthy K, Darzi A. Laparoscopic skills training and assessment. British Journal of Surgery. 2004;91(12):1549-58.
302. Loukas C, Nikiteas N, Kanakis M, Georgiou E. The contribution of simulation training in enhancing key components of laparoscopic competence. American Surgeon. 2011;77(6):708-15.
303. Sturm LP, Windsor JA, Cosman PH, Cregan P, Hewett PJ, Maddern GJ. A systematic review of skills transfer after surgical simulation training. Annals of Surgery. 2008;248(2):166-79.
304. Ahlberg G, Enochsson L, Gallagher AG, Hedman L, Hogman C, McClusky DA, 3rd, et al. Proficiency-based virtual reality training significantly reduces the error rate for residents during their first 10 laparoscopic cholecystectomies. American Journal of Surgery. 2007;193(6):797-804.
305. Grantcharov TP, Kristiansen VB, Bendix J, Bardram L, Rosenberg J, Funch-Jensen P. Randomized clinical trial of virtual reality simulation for laparoscopic skills training. British Journal of Surgery. 2004;91(2):146-50.
306. Munz Y, Kumar BD, Moorthy K, Bann S, Darzi A. Laparoscopic virtual reality and box trainers: is one superior to the other? Surgical Endoscopy. 2004;18(3):485-94.
307. Ayodeji ID, Schijven M, Jakimowicz J, Greve JW. Face validation of the Simbionix LAP Mentor virtual reality training module and its applicability in the surgical curriculum. Surg Endosc. 2007;21(9):1641-9.

308. Ayodeji ID, Schijven MP, Jakimowicz JJ. Determination of face validity for the Simbionix LAP mentor virtual reality training module. Stud Health Technol Inform. 2006;119:28-30.
309. Miskovic D, Foster J, Agha A, Delaney CP, Francis N, Hasegawa H, et al. Standardization of laparoscopic total mesorectal excision for rectal cancer: a structured international expert consensus. Ann Surg. 2015;261(4):716-22.
310. Miskovic D, Ni M, Wyles SM, Kennedy RH, Francis NK, Parvaiz A, et al. Is competency assessment at the specialist level achievable? A study for the national training programme in laparoscopic colorectal surgery in England. Annals of Surgery. 2013;257(3):476-82.
311. A. FFEELAGB. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods. 2007;39 (2):175-91.
312. Foster JD, Miskovic D, Allison AS, Conti JA, Ockrim J, Cooper EJ, et al. Application of objective clinical human reliability analysis (OCHRA) in assessment of technical performance in laparoscopic rectal cancer surgery. Tech Coloproctol. 2016;20(6):361-7.
313. Quirke P, Steele R, Monson J, Grieve R, Khanna S, Couture J, et al. Effect of the plane of surgery achieved on local recurrence in patients with operable rectal cancer: a prospective study using data from the MRC CR07 and NCIC-CTG CO16 randomised clinical trial. Lancet. 2009;373(9666):821-8.
314. D'Angelo AL, Rutherford DN, Ray RD, Laufer S, Kwan C, Cohen ER, et al. Idle time: an underdeveloped performance metric for assessing surgical skill. Am J Surg. 2015;209(4):645-51.
315. Yiasemidou M, Galli R, Glassman D, Tang M, Aziz R, Jayne D, et al. Patient-specific mental rehearsal with interactive visual aids: a path worth exploring? Surg Endosc. 2017.
316. Yiasemidou M, Glassman D, Mushtaq F, Athanasiou C, Williams MM, Jayne D, et al. Mental practice with interactive 3D visual aids enhances surgical performance. Surg Endosc. 2017;31(10):4111-7.
317. Rhee R, Fernandez G, Bush R, Seymour NE. The effects of viewing axis on laparoscopic performance: a comparison of non-expert and expert laparoscopic surgeons. Surg Endosc. 2014;28(9):2634-40.
318. Tien T, Pucher PH, Sodergren MH, Sriskandarajah K, Yang GZ, Darzi A. Differences in gaze behaviour of expert and junior surgeons performing open inguinal hernia repair. Surg Endosc. 2015;29(2):405-13.
319. Davison S, Raison N, Khan MS, Dasgupta P, Ahmed K. Mental training in surgical education: a systematic review. ANZ J Surg. 2017;87(11):873-8.
320. Konishi T, Watanabe T, Kishimoto J, Nagawa H. Risk factors for anastomotic leakage after surgery for colorectal cancer: results of prospective surveillance. J Am Coll Surg. 2006;202(3):439-44.
321. Peeters KC, Tollenaar RA, Marijnen CA, Klein Kranenbarg E, Steup WH, Wiggers T, et al. Risk factors for anastomotic failure after total mesorectal excision of rectal cancer. Br J Surg. 2005;92(2):211-6.
322. Rullier E, Laurent C, Garrelon JL, Michel P, Saric J, Parneix M. Risk factors for anastomotic leakage after resection of rectal cancer. Br J Surg. 1998;85(3):355-8.
323. Shiomi A, Ito M, Maeda K, Kinugasa Y, Ota M, Yamaue H, et al. Effects of a diverting stoma on symptomatic anastomotic leakage after low anterior resection for

rectal cancer: a propensity score matching analysis of 1,014 consecutive patients. J Am Coll Surg. 2015;220(2):186-94.
324. Vignali A, Fazio VW, Lavery IC, Milsom JW, Church JM, Hull TL, et al. Factors associated with the occurrence of leaks in stapled rectal anastomoses: a review of 1,014 patients. J Am Coll Surg. 1997;185(2):105-13.
325. Gouvas N, Georgiou PA, Agalianos C, Tzovaras G, Tekkis P, Xynos E. Does Conversion to Open of Laparoscopically Attempted Rectal Cancer Cases Affect Short- and Long-Term Outcomes? A Systematic Review and Meta-Analysis. J Laparoendosc Adv Surg Tech A. 2017.
326. Yiasemidou M, Glassman D, Tomlinson J, Song D, Gough MJ. Perceptions About the Present and Future of Surgical Simulation: A National Study of Mixed Qualitative and Quantitative Methodology. J Surg Educ. 2017;74(1):108-16.
327. Yiasemidou M, Glassman D, Jayne D, Miskovic D. Is patient-specific pre-operative preparation feasible in a clinical environment? A systematic review and meta-analysis. Comput Assist Surg (Abingdon). 2018;23(1):57-68.
328. Agha RA, Fowler AJ. The role and validity of surgical simulation. Int Surg. 2015;100(2):350-7.
329. Yiasemidou M, Gkaragkani E, Glassman D, Biyani CS. Cadaveric simulation: a review of reviews. Ir J Med Sci. 2017.

Appendix A

A.1 Patient consent form for clinical trial

PATIENT CONSENT FORM

"The "R-3D-2" pilot study - Randomised Controlled Trial On The Impact Of Surgical Rehearsal Strategies In Rectal Cancer Surgery Using 3D Models By Using 2 Methods"

Patient ID: …..……..Initials: …….. Date of Birth: ……...

Patient initial each point

1. I confirm that I have read and understand the information sheet dated **26/04/2016 (version 7)** for the above study, have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I agree to take part in the study. _

2. I understand that my medical records may be looked at by authorised individuals from the Sponsor for the study, the UK Regulatory Authority, Independent Ethics Committee or from the NHS Trust in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study and any further research that may be conducted in relation to it. I also give permission for a copy of my consent form to be sent to the Sponsor for the study. Finally, I give permission for my magnetic resonance scans (MRI) to be used for the purposes of this study (to build 3D models) and for my surgical procedure to be recorded. _

3. I understand that even if I withdraw from the above study, the data collected from my medical files, recordings of my procedure and magnetic resonance images (including 3D model based on MRI images) collected from me will be used in analysing the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous. _

4. I consent to the storage including electronic, of personal information for the purposes of this

study. I understand that any information that could identify me will be kept strictly confidential

and that no personal information will be included in the study report or other publication.

Name of the patient	Patient's signature and date
Name of the Investigator taking written consent	Investigator's signature and date

Original to be retained and filed in the site file. 1 copy to patient, 1 copy to be filed in patient's notes.

A.2 Patient information sheet

PATIENT INFORMATION SHEET

"The "R-3D-2" pilot study - Randomised Controlled Trial On The Impact Of Surgical Rehearsal Strategies In Rectal Cancer Surgery Using 3D Models By Using 2 Methods"

PART 1

1. Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

PART 1 tells you the purpose of this study and what will happen to you if you take part.

PART 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

2. What is the purpose of the study?

Our study will examine the impact of rehearsing procedures beforehand using patient individual 3D virtual and plastic models, on surgical performance and short-term patient complications. Currently surgeons use a series of scan slices to view where the various organs and the tumour are. However, it is very difficult to "translate" these images to 3D anatomy. We are using similar images (called MRI or magnetic resonance images) to produce a 3D model of the anatomy. This has been happening in other surgical specialties (bone, blood vessel surgery) for years. It is possible that providing your surgeon with a 3D "map" of your individual anatomy and asking them to practice your procedure before actually performing it, will help them to perform your surgery better and remove the cancerous tissue more effectively. It will also help them to know better where vital structures are in relation to the tumour and help to avoid injuring them.

All the surgeons participating in this study are highly experienced and have performed rectal cancer surgery many times in the past.

3. Why have I been chosen?

You have been chosen because you were diagnosed with low bowel (rectal) cancer and you are due to undergo keyhole surgery to have your tumour removed.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form

to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time, without giving a reason. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

5. What will happen to me if I take part?

Besides signing a written consent form, you will not have to do anything outside your routine standard treatment. There will be four groups of patients. You will be randomly allocated to one of them. According to which group you belong in, your surgeon will be given the following aides to help them mentally rehearse your procedure: group (i) virtual 3D models of your anatomy on a computer screen, group (ii) a plastic model of your anatomy and group (iii) routine MRI scans. If you are randomized to group (iv) your doctor will prepare for your surgery using their preferred, routine method. Group (ii) will also rehearse the procedure physically using the plastic models. Your surgeon will then proceed to perform your operation. This will be recorded only for participants in this trial for the purposes of assessing your surgeon's performance. The recording of the procedure will be done though the keyhole camera showing only your internal organs, therefore it will be impossible for anyone to identify you. We will not use personal details (DOB, hospital number, name) to identify the recording of the procedure. Instead we will use an arbitrary number which will be allocated to you after you agree to participate in the study. Finally, we will analyse the results to see if giving your surgeon patient individual models of your anatomy helped them perform better.

Only your Magnetic Resonance scans (MRI) will be used for this study. We will not be using any scans that expose you to ionizing radiation and we will not ask you to undertake any additional scans other than the ones you already had.

The models mentioned above, virtual and plastic, will be destroyed when we analyse the data we collected. This means that we will not be storing these models long term. The latest we are storing these models for is 3 months after the end of our study. The same is true for the recordings of your procedure (i.e. they will be safely destroyed the latest three months after the completion of the study).

Surgeons will be allowed to use all their standard preparation techniques prior to surgery as well as the new techniques we are proposing with this study.

6 What do I have to do?

If you decide to take part to the trial you won't have to do anything different from your standard routine care. That would include having two different types of scans and then proceeding to an operation. After that you will be transferred to a ward where you will remain until you are well enough to go home. Your treating team will pass on details of your recovery to the research team. This will happen again using the arbitrary number that was allocated to you after you agreed to participate in the study and not identifiable details such as your name and date of birth. This way the details the research team receives is anonymised and no one outside your treating team will have access to your medical files.

7. What is the procedure that is being tested?

We are testing whether rehearsing your procedure using three dimensional tools (virtual-on a computer screen and physical –plastic) of your individual anatomy can help your surgeon perform the operation better. These models portray most of the organs in your pelvis and where within the bowel the tumour is. We will use your magnetic resonance images to create these models.

8. What are the possible disadvantages and risks of taking part?

The surgeons performing these procedures are highly experienced and have performed this type of surgery many times before. You may develop complications during or after your procedure. This may be the case if you were not participating in this trial as well. Your surgeon and anaesthetist will explain what the possible complications of your procedure are.

As a rectal cancer patient due to undergo surgery you will receive two types of scans. We will be using one type of these scans called MRI to construct 3D models. This scan does not expose you to ionising radiation.

9. What are the possible benefits of taking part?

It is possible that using individualised 3D anatomical models to plan a surgical procedure will help surgeon perform your surgery better therefore reducing the risk of complications and cancer recurrence.

10. What happens when the research study stops?

When the research study stops, the data collected will be analysed. You will continue to be looked after by your doctor in the normal way.

11. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you do wish to raise a concern you may want to contact the "Patient Advice and Liaison Service" at:

<u>For Leeds Teaching Hospitals:</u>

Tel: (0113) 2066261 - Available during normal working hours only.

Tel: (0113) 2067168 - For queries outside of normal working hours, please leave a voicemail.

Fax: (0113) 2066146

E mail: patientexperience.leedsth@nhs.net

For Mid Yorkshire Hospitals Trust:

Telephoning - 01924 543686 / 543685 / 543688 / 543687 Monday – Friday: 8.30am – 5.00pm.

Faxing – 01924 543949 - 24 hours

Email - pals@midyorks.nhs.uk

12. Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

13. Contact Details

Your Doctor

Name Tel. Number:

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

14. What if new information becomes available?

Sometimes during the course of a clinical trial, new information becomes available on the processes that are being studied. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

15. What will happen if I don’t want to carry on with the study?

Your standard of care will not be affected if you decide to withdraw from the study. You can choose to do so at any part of the trial without providing a reason for your decision. If you withdraw from the study all recordings and clinical information we have obtained up to that point will continue to be used for the purposes of the study.

16. Will my part in this study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times.

The information will be held securely on paper and electronically at your treating hospital under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

If you withdraw consent from further study treatment, unless you object, your data and samples will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 3 years. Arrangements for confidential destruction will then be made.

17. Informing your General Practitioner (GP)

We will not be informing your GP of your participation in this trial.

18. What will happen to the results of this clinical trial?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be

anonymous and none of the patients involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask your study doctor.

19. Who is organising and funding this clinical trial?

This clinical trial is funded by Leeds Teaching Hospitals Charitable Trustees Foundation and

sponsored by the University of Leeds.

20. Who has reviewed the study?

This study was given favourable ethical opinion for conduct in the NHS by NHS Ethics Committee.

21. Contact for further information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Dr. Marina Yiasemidou

Email: M.Yiasemidou@leeds.ac.uk

Mob: 07975531067

Research Nurse (TBA)

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

A.3. Surgeons' consent form for clinical trial

SURGEON CONSENT FORM

"The "R-3D-2" pilot study - Randomised Controlled Trial On The Impact Of Surgical Rehearsal Strategies In Rectal Cancer Surgery Using 3D Models By Using 2 Methods"

Name: …..……..

Surgeon initial each point

4. I confirm that I have read and understand the information sheet dated **26/04/2016 (version 7)** for the above study, have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time without having to provide a reason. I agree to take part in the study. _

5. I understand that recordings of the Structured Mental Rehearsal I will be undertaking and of the procedure that I will be conducting may be looked at by authorised individuals from the Sponsor for the study, the UK Regulatory Authority, Independent Ethics Committee or from the NHS Trust in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my the previously mentioned recordings for the above study and any further research that may be conducted in relation to it. I also give permission for a copy of my consent form to be sent to the Sponsor for the study. _

6. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous. _

7. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication. _

8. I consent for the Structured Mental Rehearsal sessions that I undertake to be audio recorded and transcribed by a member of the research team. _

9. I consent for the operations I conduct to be video recorded and assessed by two independent assessors. _

10. I understand that the 3D Virtual and physical models as well as the entirety of the Structured Mental Rehearsal (SMR) process have an advisory role and the final clinical decisions are the responsibility of the operating surgeon. _

_____	_____
Name of the surgeon	Surgeon's signature and the date
_____	_____
Name of the Investigator taking written consent	Investigator's signature and date

Original to be retained and filed in the site file. 1 copy to surgeon, 1 copy to be filed in patient's notes.

A.4. Surgeons' information sheet for clinical trial

SURGEON INFORMATION SHEET

"The "R-3D-2" pilot study - Randomised Controlled Trial On The Impact Of Surgical Rehearsal Strategies In Rectal Cancer Surgery Using 3D Models By Using 2 Methods"

PART 1

1. Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

PART 1 tells you the purpose of this study and what will happen to you if you take part.

PART 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

2. What is the purpose of the study?

There have been recent evidence to indicate that patient and tumour characteristics are associated with Total Mesorectal Excision (TME) technical difficulty. With our study we would like to assess whether it is feasible to conduct pre-operative planning using patient specific anatomical models and what clinical impact this will have.

Specifically, the primary purpose of this study is to test the feasibility of recruitment of patients and surgeons who are willing to perform Structured Mental Rehearsal (SMR) using scans, virtual and physical rehearsal aides for laparoscopic TME surgery for rectal cancer. Feasibility of randomisation, data collection and analysis will also be tested.

The secondary purpose of this study is to assess the clinical impact of two novel pre-operative planning techniques; SMR with virtual 3D patient specific maps of pelvic anatomy and SMR and simulation using patient specific physical models of pelvic anatomy. For that purpose, we will use the following outcomes: Surgical performance, patient complications, and quality of tissue removed during surgery. Therefore, this project can potentially establish “Proof of Concept (PoC)” that preparing for surgery on patient-specific basis is possible and can improve both surgical performance and patient outcomes.

The hypotheses for the PoC pilot data analysis are:

Hypothesis 1: Using patient specific virtual models to mentally rehearse a procedure will improve surgical performance and reduce patient complications after keyhole rectal cancer surgery.

Hypothesis 2: Using patient specific physical (plastic) models for rehearsal procedures will improve surgical performance and reduce patient complications even further compared to mental rehearsal with virtual models only. The plastic models will include patient specific soft tissues (specimen and tumour) and a reusable generic pelvis.

3. Why have I been chosen?

You have been chosen to participate because you are an experienced laparoscopic colorectal surgeon, who has performed more than 50 laparoscopic TME procedures for rectal cancer as a primary surgeon.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

5. What will happen to me if I take part?

Overall 64 patients will be recruited and randomised to four groups. According to which group your patient is been randomised to you will either perform an SMR session using either routine MRI scans or patient specific 3D virtual tools or a physical model or you will prepare for surgery as you routinely do. For the ones using the physical model besides the SMR you will also be able to perform a simulated procedure. During this process a facilitator will be present and the session will be audio recorded. At a later data the SMR session will be transcribed and used for research purposes.

The procedure you will be performing will be partially video recorded (i.e. only the pelvic dissection will be recorded). The recordings will then be seen and assessed by two independent assessors. The recordings will be performed only through the laparoscopic camera and will therefore be impossible for the patient or for you to be identified. We will kindly ask members of your team to prospectively record the peri- and post- operative complications of the recruited patients. This is done in order to avoid exposing patient records to individuals outside the direct healthcare team.

All electronic data will be encrypted and stored in a secure, backed up University of Leeds (UoL) computer drive, housed in a lockable office in a limited access building.

6. What do I have to do?

As the consultant in charge of your patient care, you will be kindly asked to initially approach your patients and explain the study to them at out-patient colorectal clinic. The inclusion criteria are: patients with histologically confirmed cancer 4-16cm from the dentate line, due to undergo laparoscopic TME. The cases considered for inclusion in the study should have been discussed at the Multi Discipline Team meeting (MDT). The study should be explained to your patients and they should be given time to decide whether they want to participate in the study. If they are agreeable they can be consented at their next attendance in clinic.

After written consent is obtained, the patient's details will be passed on to the research team in order for a Unique Trial Number (UTN) to be allocated. The patient will then be randomly allocated to one of four groups. The patient's Magnetic Resonance (MR) scans will be obtained in order to "construct" the 3D virtual and physical models or alternatively used as an aide for the SMR sessions.

The SMR sessions will take place 24-48 hours prior to the procedure. The sessions will be audio recorded and used for research purposes. Furthermore, the pelvic dissection of the TME will be recorded through the laparoscopic camera. The recordings will be assessed by two independent assessors.

You will be kindly asked to answer a questionnaire and undergo a semi-structured interview, to let us know what you think about the SMR process and the aides.

We will kindly ask a member of your team to prospectively document patient complications.

Surgeons will be allowed to use all their standard preparation techniques prior to surgery, as well as the new techniques we are proposing with this study.

7. What is the procedure that is being tested?

As explained above we are testing patient specific 3D virtual and physical models as pre-operative planning tools.

8. What are the alternatives for diagnosis or treatment?

The alternatives for pre-operative planning are routine MRI scans.

9. What are the side effects of any treatment received when taking part?

If you do decide to take part in the study, you must report any problems you have to your study nurse or doctor. There is also a contact number given at the end of this information sheet for you to phone if you become worried at any time. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

10. What are other possible disadvantages and risks of taking part?

There will be a time commitment for the SMR sessions. They are anticipated to take on an average 30-45 minutes.

You should also be made aware that the reconstructions will be based on the axial (transverse) view of the MR images only. Each slide has a 4mm gap from the next and previous one and the MR series may or may not picture the whole of the mesorectal structure. Therefore, the models that we provide should not be used for diagnostic purposes or as the sole tool for forming an operative plan.

11. What are the possible benefits of taking part?

We believe that preparing for surgery using 3D virtual or physical tool may help pre-operative planning and consequently surgical performance.

12. What happens when the research study stops?

When the study stops we will analyse the data we have collected from the study. We will feedback the results to all surgeons participating in the study. The results will be presented in a cumulative manner, therefore no individual surgeon will be identifiable in conference presentations and journal publications.

13. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. There will be regular meetings with the research team, however if there is something of urgency you can contact the research team using the contact details below.

14. Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

15. Contact Details

Your Research/Specialist Nurse

Marina Yiasemidou

Email: M.Yiasemidou@leeds.ac.uk

Mob: 07975531067

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

16. What if new information becomes available?

Sometimes during the course of a clinical trial, new technologies becomes available. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to continue in the study you will be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If the study is stopped for any other reason, you will be told why.

17. What will happen if I don't want to carry on with the study?

If you do not wish to carry on with the study, please inform the research team using the contact details provided on this information sheet. You will not have to provide a reason why.

18. Will my part in this study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study will remain strictly confidential at all times. The information will be held securely on paper and electronically at the University of Leeds, under the provisions

of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Information will be transferred from your hospital site to the University of Leeds organizing the research, to enable analysis of the study results to be undertaken, this will be done on password protected, encrypted external hardware, however your name will only appear on your consent form, which will be sent separately to any clinical results collected for the trial. All other records will have your name removed and will only feature your trial number (Surgeon Unique Trial Number - SUTN).

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 3 years. Arrangements for confidential destruction will then be made.

19. What will happen to the recordings of procedures and audio recordings of the SMR process?

The recordings of the procedures will be destroyed after the completion of data analysis for this trial. The audio recordings will be safely destroyed after transcription.

20. What will happen to the results of this clinical trial?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the surgeons involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask a member of the research team.

According to your contribution and the authorship guidelines as these are outlined in the protocol of the study, you may be an author on the journal publications and conference presentations. If you wish to read the authorship guidelines please ask a member of the research team.

21. Who is organising and funding this clinical trial?

This study is sponsored by the University of Leeds and funded by the Leeds Teaching Hospitals Charitable Foundation.

22. Who has reviewed the study?

This study was given favourable ethical opinion for conduct in the NHS by an NHS Research Ethics Committee.

23. Contact for further information

You are encouraged to ask any questions you wish. If you have any questions about the study, please speak a member of the research team, who will be able to provide you with up to date information about the technologies involved. If you wish to read the research on which this study is based or the study protocol please ask a member of the research team. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Marina Yiasemidou

Email: M.Yiasemidou@leeds.ac.uk

Mob: 07975531067

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

Surgeon's experience

Name	

Years in practice

(Colorectal) Surgical	
(Colorectal) Laparoscopic	
(Colorectal) Robotic	

Previous laparoscopic TME/Anterior resection experience

	10-50	51-100	101-150	151-200	201-250	>250
Overall number of cases performed as primary surgeon						
No of cases performed as primary surgeon in the past 12 months						
Overall number of cases assisted						
No of cases assisted in the past 12 months						

Previous experience with 3D imaging

Yes	
No	

For what purpose (e.g. 3D surgery)

A5. National survey on the role of simulation in surgical training

1. What is your gender?
2. What us your specialty?
3. Which is your deanery?

*** 4. Please answer as appropriate, according to your opinion**

	Strongly disagree	Disagree	Indifferent	Agree	Strongly agree
Simulation is a good training tool for surgeons	○	○	○	○	○
Simulation is for novices only	○	○	○	○	○
Simulation is for acquiring basic skills only (knot tying, eye hand coordination), not for learning full surgical procedures	○	○	○	○	○
Trainees should have mandatory simulation training before doing a real surgical procedure for the first time.	○	○	○	○	○
Simulation can be used for acquiring non-technical skills (e.g communicating with theatre staff)	○	○	○	○	○
A simulated environment can re-enact a stressful situation.	○	○	○	○	○
Simulation should be used for assessment and recruitment of surgical trainees.	○	○	○	○	○
Fragmented simulation (not as part of a curriculum) is educational.	○	○	○	○	○
I would employ a trainee who failed a simulation scenario badly.	○	○	○	○	○

5. If you answered agree or strongly agree to question 4a (Simulation is a good training tool for surgeons), go to the next question.
If you answered strongly disagree, disagree or indifferent to the same question. This is because:

- ◯ Currently simulators are inefficient but there is potential for improvement
- ◯ I don't believe simulators will ever simulate surgical procedures to an acceptable degree

Other (please specify)

*** 6. Simulators should be located in**

- ◯ Other
- ◯ In theatres
- ◯ In clinical skills centres
- ◯ In both

Other (please specify)

*** 7. Please answer according to your opinion**

	Extremely not important	Not important	Indifferent	Important	Very important
How important is it for simulation centres to be formally accredited for their capacity to provide training?	◯	◯	◯	◯	◯
How important is it for trainees to have a trainer present during a simulated session?	◯	◯	◯	◯	◯
How important is it for simulation training to be driven by consultant mentors based in each trust/hospital?	◯	◯	◯	◯	◯

*** 8. Rank the following simulators according to which you think has the best educational value (1=best, 4=worse).**

- ⠿ ▲▼ Animal models
- ⠿ ▲▼ Synthetic models
- ⠿ ▲▼ Cadavers
- ⠿ ▲▼ Virtual reality simulators