DOCTOR OF PHILOSOPHY

Use of Human Reliability Analysis to evaluate surgical technique for rectal cancer

Wilson, Peter John

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USE OF HUMAN RELIABILITY ANALYSIS TO EVALUATE SURGICAL TECHNIQUE FOR RECTAL CANCER

PETER JOHN WILSON

Doctor of Philosophy

University of Dundee

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DEDICATION

Dedicated to my wife, for her unfailing support and encouragement throughout the project.

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I would like to thank Professor Robert Steele for his close supervision and careful advice on every aspect of the project, and for his patience in reviewing the many sequences of video footage.

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DECLARATION

I declare that the studies described in this thesis were completed by myself in the Department of Surgery and Molecular Oncology at the University of Dundee, and under the supervision of Professor Robert Steele and Mr George Hanna. This thesis has been composed by myself and has not been submitted previously for a higher degree.

Peter J Wilson

March 2012

STATEMENT FROM SUPERVISOR

This is to certify that Peter Wilson has completed the nine terms of clinical research, and has fulfilled the conditions of ordinances 9 and 14 of the University of Dundee and that he is qualified to submit the following thesis for the Degree of Doctor of Philosophy.

Professor Robert JC Steele

Professor George B Hanna

March 2012

PUBLICATIONS ORIGINATED FROM THESIS

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Wilson PJ, Hanna GB, Cuschieri A, Steele RJCS. Surgical technique for rectal cancer: evaluation through ergonomic principles. (Presented at the Association of Coloproctologists of Great Britain and Ireland 2005, Dublin)

Wilson PJ, Hanna GB, Cuschieri A, Steele RJCS. Adverse events observed during rectal cancer resections. (Presented at the European Society for Coloproctology 2006, Lisbon)

LIST OF ABBREVIATIONS

Surgical / Medical

ACPGBI	Association of ColoProctologists of Great Britain and Ireland
APER	Abdomino-Perineal Excision of Rectum
AR	Anterior Resection
ASA	American Society of Anesthesiology
CRM	Circumferential Resection Margin
LAR	Low Anterior Resection (of rectum)
LC	Laparoscopic Cholecystectomy
LR	Local Recurrence
PCA	Patient-Controlled Analgesia
POSSUM	Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity
QLQ	Quality of Life Questionnaires
RCR	Rectal Cancer Resection
TME	Total Mesorectal Excision

Ergonomic / Other

EEM	External Error Mode
HRA	Human Reliability Analysis
HTA	Hierarchical Task Analysis
MPEG	Motion Picture Experts Group
TA	Task Analysis
TTE	Tool-Tissue Error

SUMMARY

Outcomes from surgery are dependent upon technical performance, as demonstrated by the variability that exists in outcomes achieved by different surgeons following surgery for rectal cancer. It is possible to improve such outcomes by focused training and the adoption of specific surgical techniques, such as the total mesorectal excision (TME) training programme in Stockholm which reduced local recurrence rates of cancer by 50%.[1]

It is generally accepted that good surgical technique is the enactment of a series of positive surgical actions, and the avoidance of errors. However, the constituents of good surgical technique for rectal cancer have not yet been studied in sufficient detail to identify the specific associations between individual steps and their consequences.

In this study the ergonomic principles of human reliability analysis (HRA) were applied to video recordings of rectal cancer surgery. A system of error definition and identification was developed, utilising a bespoke software solution designed for the project. Calculation of optimal camera angles and position was determined in a virtual operating theatre. Analysis of synchronised footage from multiple camera views was performed, through which over 6,000 errors were identified across 14 procedural tasks. The sequences of events contributing to these errors are reported, and a series of error reduction mechanisms formulated for rectal cancer surgery.

Chapter 1

INTRODUCTION

1 Introduction

1.1 Introduction

Colorectal cancer is the third most common malignancy in the UK, and accounts for over 16,000 deaths per annum.[2] During the past 10 years, there has been an increase in the incidence of the disease in the UK, but this is mirrored by an increase in 5-year survival. The single most common site for colorectal cancer is the rectum, accounting for nearly 40% of cases. Not only has there been an improvement in survival in rectal cancer, but also in many other measures of quality of care, including local recurrence rates[3] and the proportion of sphincter-saving procedures.[4] There have been advances in the early identification of disease,[5] in the pre-operative assessment and imaging of patients,[6 7] in defining the role of adjuvant therapy,[8] and in refining surgical technique.[9]

It is to the latter of these advances, the refinement of surgical technique, that many of the improvements in outcome may be attributed. Although adjuvant therapy has a role in improving survival, the magnitude of its effect is far less than that of surgery.[10] Much of the improvement in surgical technique may be attributed to the introduction and widespread adoption of total mesorectal excision (TME), to largely replace traditional blunt dissection around the rectum. Local recurrence (LR) rates were typically between 15-20% after traditional surgery;[11] with TME these have been reduced to less than 3% in the hands of some surgeons.[12 13] However, this improvement is not uniform, such that LR rates in excess of 15% are reported, despite the application of TME.[14 15] Conversely, a LR rate of 5.2% has been achieved following principally blunt dissection, in contrast to the sharp dissection advocated in TME.[16]

Thus, although surgical technique is an important determinant of improved outcomes, the nature of this relationship is by no means straightforward. The variability in observed outcomes suggests that even amongst those claiming to perform TME, there is inconsistency in surgical technique, and it appears that the label of 'TME' is applied to a variety of operative techniques. Studies which make no mention of technique, yet achieve excellent results may be performing more anatomically correct dissections than those that claim to use TME, but attain inferior outcomes. Consequently, categorising studies according to adoption of TME is less useful than examining the detail of the technique employed.

The purpose of this chapter is twofold: to review those outcomes that are associated with surgery for rectal cancer and to investigate the relationship between surgical technique and outcome.

1.2 Outcomes in TME Surgery

1.2.1 Local recurrence

TME was developed primarily as a technique for sphincter-preservation for low rectal tumours.[17] The fact that the dissection was developed along clearly-defined embryological planes, resulted in a second benefit, which is now one of the most compelling reasons for adoption of this technique: that of decreased LR, as described above.

The impact of surgical technique upon LR rates has been clearly and repeatedly demonstrated, both through implication and through intervention. The individual surgeon has been identified as an independent predictor of outcome in several studies: Philips,[18] McArdle,[19] Porter[20] and Holm[21] have all published on the variability in local recurrence rates observed between different surgeons. Both a special interest in colorectal surgery and a large caseload of resections are associated with a decrease in the incidence of LR.[20, 18] However, none of these studies documented the detail of operative technique, although the need for such documentation was recognised:

> "…specific operative techniques in rectal cancer surgery are responsible for the improvement seen in specific groups of surgeons... However, the ability to retrospectively identify specific operative factors is difficult, if not impossible. The identification of these factors would best be done in a comprehensive prospective fashion."[20]

One of the most compelling demonstrations of good surgical technique resulting in low rates of LR comes from Heald's own series of 519 patients with rectal cancer.[9]

Anterior resections were performed in 465 of these patients (89.6%), 380 (81.7%) of which were deemed to be curative at the time of operation. Following anterior resection, overall LR at 5 years was found to be 5%, and in the group deemed to be curative LR was only 2%.

The hypothesis that local recurrence is dependent on technique has been borne out in two large-scale interventional studies: the Dutch TME trial and the Swedish TME project.[1 22] Patient outcomes from the control arm of the Dutch TME trial (no neoadjuvant radiotherapy given) were compared with those from a previous trial, in which conventional surgery was performed.[22] Following the introduction of TME, LR rates fell from 16% to 9% at two years (P=0.02).[22] The Swedish TME project also demonstrated a fall in LR rates when compared to historical control groups, from 14% to 6% (P<0.001).[1]

Some details of surgical technique are given in these two papers. Both studies utilised workshops, videos and instructor-surgeons to teach the new technique and to ensure quality control of technique. Allusion is made to earlier papers which give a fuller description of the technique,[11 12] but it is impossible to state how and to what extent the specifics of these descriptions were applied, and certainly not on a case-by-case basis.

1.2.2 Survival

Inter-individual variability exists in survival rates, just as for LR. In McArdle's study of 13 surgeons in a single hospital, curative resection for colorectal cancer resulted in 10-year survival ranging from 24% to 63%.[19] Surgeon experience, training and case-volume are all positively associated with survival,[20-24] although inter-surgeon variability also exists amongst high-volume surgeons.[21]

The same studies that demonstrated improvements in LR following TME have also described an increase in survival. In the Dutch TME trial, survival at 2 years after surgery alone rose from 77% to 86% compared to historical controls (P=0.02);[22] in the Swedish project, death from rectal cancer fell from over 15% to 9% with the introduction of TME (P=0.002).[1]

Although there is a trend for high-volume surgery to be associated with greater survival, this does not mean that high-volume *per se* leads to improved outcomes. Several of the papers cited above suggested that the common denominator in the relationship between volume and outcome is superiority in surgical technique.[20 21 23 24]

Survival following rectal cancer surgery is therefore dependent upon surgeon-volume, experience and training, but only to the extent that these variables are reflected in enhanced technique. These papers have stressed the need for analysis of the practice-patterns and surgical technique of high-volume surgeons with high rates of survival. Despite this continuing need for the investigation of surgical technique, such studies have yet to be conducted.[24]

1.2.3 Pathological – adequacy of tumour clearance

In both traditional surgery and TME, involvement of the circumferential resection margins (CRM) is a powerful predictor of outcome, both for local recurrence and for survival.[25-30] In some studies in which TME was performed, CRM involvement was not demonstrated to impact upon LR:[31] it was suggested that TME allows sufficient clearance of tumour from the pelvis, such that patients with involved margins succumb to distant metastases before LR is detected. However, subsequent studies [29,30] have reported that CRM status is strongly associated with LR, development of metastases and survival, and is the principal pathological predictor of outcome that may be altered through intervention.

In addition to microscopic evaluation of the CRM, macroscopic assessment of the resected specimen has been proposed as a means of quality control of surgical technique.[32,33] A complete or nearly complete mesorectum is associated with an overall recurrence rate of 20.3%, compared to 36.1% in the presence of an incomplete mesorectum (P=0.02).[33] Furthermore, gauging the quality of the resected specimen can establish the cause of CRM involvement, and reflects on the adequacy of surgical technique.[33]

However, utilising pathological data to comment on the adequacy of surgical technique is still an assessment of outcome rather than process. The fact that this assessment occurs closer to the point of interest than long-term outcomes (such as LR and survival) undoubtedly facilitates reflection on technique, but it does not permit direct analysis of technique. Identification of a focal mesorectal defect may reveal *where* an error occurred, but not *how* or *why* it did so.

To date, no such studies analysing the process of surgical technique and its impact on pathological assessment have been performed. Although it is evident that technical performance has a direct bearing on the appearance of the specimen, the progression from *in vivo* to *in vitro* has not yet been investigated.

1.2.4 Rate of curative resection

Whilst it is acknowledged that the ability to achieve a curative resection will depend in part on the stage at which the disease presents, the Association of Coloproctologists of Great Britain & Ireland (ACPGBI) recommends a curative procedure rate of 60% or more.[34]

In addition to a purely pathological assessment, a curative resection is one which is also believed by the surgeon to have removed all macroscopic disease. A proposed definition is, “removal of all macroscopic disease at the time of operation, backed up by histological evidence that the resection margins of the specimen submitted to the pathologist are clear of tumour”.[18]

In practice, the definitions of both the numerator (surgical and / or pathological opinion of ‘curative resection’) and the denominator (total number of referrals *vs* laparotomies *vs* resections *vs* intention to cure) are so variable, that any meaningful comparison is extremely difficult. The significant differences in the usage of the term ‘curative resection’ are associated with significant differences in apparent outcomes.[35]

Indeed, it has been recommended that “the term ‘curative resection’, based on intra-operative judgement as used by many surgeons, should be abandoned and replaced by the residual tumour classification of the TNM system”.[36 37] Until such definitions are standardised, it remains unclear to what extent the adequacy of resection depends on surgical technique, and how the latter may be optimised to ensure the highest possible rate of cure.

1.2.5 Rate of sphincter preservation

Prior to the adoption of TME by the surgical community, it was widely held that a distal resection margin greater than 5cm was required. Furthermore, there was a belief that the more radical the operation, the greater the chance of cure.[12] As a result, many patients with mid- and low-rectal tumours underwent abdominoperineal resection (APR) – in one study the rate of APR was as high as 57%, with rates for individual surgeons greater than 80%.[21]

With the advent of TME came the realisation that an intact mesorectal ‘package’ is of greater importance than extensive distal resection margins, allowing APR rates to be reduced dramatically. The ACPGBI recommends that the rate of APR should be less than 40%, although rates as low as 7% have been achieved.[9 34] Indeed, low rates of local recurrence have been maintained even when the distal resection margin is within 1cm of the tumour,[38-40] although such practices are not universally accepted.[41] Some studies have shown an increased rate of local recurrence with margins less than 2cm,[20] and even those who advocate the safety of this practice emphasise that margins greater than 1cm should be obtained whenever possible, albeit not necessarily at the expense of the anal sphincter.[42]

A recent study which investigated the effect of type of resection (anterior resection *vs* APR) found no effect on LR or survival, once other factors such as height of tumour, intra-operative perforation and CRM involvement had been adjusted for.[43] Therefore, it appears that if a low anastomosis is possible, it may be performed without compromising the oncological quality of the resection. According to the above study,[43] it seems there are no patient- or tumour-characteristics that account for high rates of APR, and a high rate of APR may be attributed to the poor technical skill or choice of the surgeon. The precise nature of this skill, and the components of this choice have not yet been studied.

In addition to the issue of sphincter preservation, APR is associated with other adverse outcomes including poor mesorectal dissection, high rates of CRM involvement, and five times the rate of perforation compared to anterior resections.[44] For these reasons, the surgeon should aim to achieve sphincter preservation wherever possible; in those instances in which a clear distal resection margin cannot be achieved with anterior resection, a cylindrical dissection plane is advocated in which the levators are removed *en bloc*.[45]

1.2.6 Quality of life

Physical well-being is difficult to define. In accordance with the WHO definition of health, it is more than the absence of disease or infirmity.[46] Numerous measures and scales have been used in an attempt to quantify well-being in rectal cancer, ranging from Global Quality of life scores[47-49] to more symptom- or system-specific problems such as faecal incontinence or erectile dysfunction.[50 51] Patient focus groups have identified those attributes of outcome which are perceived by patients as most important (Table 1a),[52] and it has been noted that the greatest components of short- and long-term morbidity are those associated with the treatment of disease, rather than caused by the disease itself. In turn, the treatment administered is largely dependent on the location and stage of disease.

Attributes 1 – 9 are all increasingly prevalent with advancing disease state A – G

	Attribute
1	Fatigue
2	Diarrhoea
3	Faecal urgency
4	Faecal incontinence
5	Sexual dysfunction
6	Pain
7	Cognitive problems
8	Social interaction
9	Fear of recurrence

Table 1a – Attributes of outcome

	Disease State
A	Stage I rectal or I/II colon cancer with resection only
B	Stage III colon cancer treated with resection and chemotherapy, no side-effects
C	Stage III colon cancer treated with resection and chemo, significant side effects
D	Stage II/III rectal cancer treated with resection/chemo-/radiotherapy
E	Stage II/III rectal cancer treated with resection/chemo-/radiotherapy/ostomy
F	Stage IV colorectal cancer without ostomy
G	Stage IV colorectal cancer with ostomy

Table 1b – Disease states in colorectal cancer [52]

Using these two descriptions of the disease state (location/stage of disease, and treatment administered) a clear pattern emerges of decreasing quality of life with advancing disease state (Table 1b).

Until recently, many institutions adopted questionnaires which were constructed locally, and thus were not validated or tested for reliability across other centres. Although many of the issues addressed are similar (e.g. number and timing of bowel movements, stool consistency, and patient satisfaction with bowel function,[53-55]) the comparisons which may be made between studies are limited. Indeed, in some instances it appears no questionnaire was used, but a reference is made to 'clinical assessment' as the tool for gathering these data.

An instrument which has proved valuable in assessing quality of life in cancer patients is that developed by the European Organisation for Research and Treatment of Cancer (EORTC). The QLQ-C30 is a core questionnaire which has been demonstrated to be reliable and valid, even across different cultures.[56] This questionnaire examines all the major areas of function (physical, emotional, cognitive, social and role) as well as evaluating the patient's health status at a global level. More recently a supplementary module (QLQ-CR38) has been developed for use with the QLQ-C30, which specifically addresses quality of life related to colorectal disease.[57] Within this module, questions are targeted at 2 main areas: function and symptoms. The 'function' scale focuses on body image, sexual function and future perspective; the 'symptom' scale assesses problems experienced in micturition, side-effects of chemotherapy, gastrointestinal symptoms (urge ± incontinence and stoma problems), sexual problems and weight loss.[57]

A number of studies have demonstrated psychological disturbance in a significant number of patients following abdominoperineal resection. This is manifested through depression, loneliness, suicidal thoughts, low self esteem and feelings of rejection.[58] However, such disturbances are much less pronounced in patients who have undergone a sphincter-preserving operation. This variable appears to be one of the main determinants of psychological well-being, and therefore in order to optimise psychological outcome, one should – as far as is feasible – minimise the number of abdominoperineal resections.

The role of surgical choice and technique in determining sphincter-preservation remains unclear, as discussed above.

In the context of rectal cancer surgery, global functional status must be considered a fundamental component of well-being, and as such, has been addressed above. Furthermore, anorectal function – as assessed by questionnaire – has also been covered within the same section. However, the area of physiological assessment of anorectal function may add further valuable information, and has been subject to many studies.[47 53 59-63]

Although there are many components to faecal continence, the factors which are thought to be most significant following rectal surgery are rectal volume and compliance. Many of the other measures are not significantly different between patients and controls, and – more importantly – between groups of patients categorised according to continence.[60]

The observation that – following rectal extirpation – patients experience a desire to defecate at lower rectal volume, but similar pressure, suggests that desire to defecate occurs earlier due to reduced compliance and / or reduced volume. Patients in whom a J-pouch is formed have rectal compliance and volume which approaches normality, and so experience less faecal urgency and frequency of defecation. However, the difference in clinical function between these two groups reduces with time, perhaps due to adaptation of the straight anastomosis as a reservoir, such that there is no significant disparity at 2 years.[64] Therefore, there remains considerable diversity of opinion as to the extent of the role of the J-pouch in rectal surgery.

1.2.7 Intra-operative bleeding

After the introduction of TME, Nesbakken *et* al[65] noted significant intra-operative blood losses of up to 8,500ml, with a median of 800ml. This was attributed in part to "difficulties in mastering the new technique", and six years after the introduction of TME, blood loss was significantly lower for anterior resection (although not for APR), with a maximum of 2,500ml, and a median of 700ml.

A similar trend was identified in a later study, in which a higher blood loss is noted for TME over conventional surgery (1,000ml v 900ml), although the difference bordered on significance (p=0.06).[22] Intra-operative blood loss is directly associated with other adverse outcomes. One paper reported a fourfold increase in major surgical complications, such as anastomotic leak, abscess or intestinal obstruction, for patients with blood loss exceeding 1,000ml.[65] Another study has demonstrated that blood loss more than 1,000ml impairs identification of the pelvic nerves, which in turn is associated with postoperative voiding difficulties.[66]

Many studies have examined the effect of blood transfusion on outcome in colorectal cancer, and two meta-analyses indicate that transfusion is associated with an increased risk of local recurrence and decreased survival.[67 68] There has been much speculation regarding this relationship between these factors, and it has been proposed that the immunomodulatory effects of transfusion enhance tumour growth.[69 70] However, non-causal mechanisms have also been suggested;[71] blood transfusion may only be a marker for greater blood loss consequent on poor dissection.

1.2.8 Perforation

Spillage of intestinal contents during operation is a common but undesirable occurrence, noted by the surgeon in approximately 20% of APR's, and by the pathologist alone in a further 3-4% of cases.[72]

Spillage poses two main risks: those of infection and of tumour seeding. Indeed, because of the consequences of tumour seeding, such procedures have been deemed palliative, with outcomes similar to advanced disease. In a study of inadvertent perforation during APR, Porter *et al*[72] found that this increased the risk of local recurrence to 54% (a hazard ratio of 4), and lowered 5-year survival to 29% (a hazard ratio of 3.4).

However, in a more recent study of rectal cancer surgery, tumour spillage was differentiated into 2 groups: those with minimal localised spillage or perforation, and those with generalised peritoneal contamination.[73] Although the rate of early complications did not differ between these two groups, survival was markedly different: those with localised perforation demonstrated similar survival trends to stage-matched patients undergoing curative surgery; those with generalised perforation had a survival curve comparable to patients with metastatic disease.

1.2.9 Wound infection / Sepsis

The prognostic significance of septic complications following surgery for rectal cancer extend beyond the immediate postoperative period. Data from the Veteran's Affairs study indicates that a deep wound infection is an independent factor in postoperative mortality, with a relative risk of 2.98. However, a superficial wound infection is much less significant, conferring a relative risk of only 1.04.[74] A smaller study examined the effect of perineal and intra-abdominal infection following radical surgery for rectal cancer, and identified an increased recurrence rate only in the subgroup with perineal infection.[75] However, the control (non-infected) group in this study was dissimilar in composition to the 'infected' group, with a much lower proportion of AP resections (34 *vs* 57%). No mention is made of abdominal wound infections – where present, these appear to have been incorporated into the 'non-infected' group.

Regardless of the potential sequelae of wound infection, it constitutes significant morbidity as an isolated entity, and should be minimised. One important factor in reducing the rate of wound infection is the usage of prophylactic antibiotics. A review of antibiotic prophylaxis in colorectal surgery indicated that failure to use any prophylaxis led to a wound infection rate of 40%, compared to 13% in the antibiotic groups.[76] Of those groups to whom antibiotics were administered, a single dose with broad spectrum cover appeared sufficient. Appropriate combinations include metronidazole with one of cefotaxime, cefuroxime or gentamicin; single agents are less effective.

Few studies have examined the role that surgical technique plays in the development of wound infection. Although evidence exists that infection rates vary between surgeons,[19] the detail to explain this association is lacking.

1.2.10 Anastomotic leakage

Anastomotic leakage is poorly defined. In most studies 'anastomotic leakage' is identified upon clinical grounds, with radiological confirmation where necessary, although these terms are rarely described explicitly,[19 22 77-79] with quoted rates between 3 and 19%.[80] Nonetheless, leakage following anterior resection is potentially serious, and may result in a permanent stoma (10 – 100%)[79] or death, with mortality rates between 6-22%.[81] Long-term consequences include increased local recurrence and poorer survival.[60 82 83]

For these reasons, there is great interest in identifying causes of anastomotic leak; several studies using analysis of variance have found factors that are significantly related to anastomotic leak (Table 2).[13 65 80 84]

One important factor linking surgical technique with anastomotic leakage is the adoption of TME for rectal cancer. Several studies have shown that this leads to higher rates of anastomotic leak when compared to traditional surgery.[22 85] It is thought that part of the cause of anastomotic leakage following the introduction of TME may be the difficulties encountered during the learning curve of mastering a new technique. Nesbakken et al found that the rate of anastomotic leakage was 9% for conventional surgery and 23% soon after the introduction of TME ($p=0.01$).[65] However, once time for competence with TME was allowed, the rate of leakage fell to 8%. An alternative explanation[86] is that in some of the studies which reported a high rate of leakage, it was normal practice to retain a skeletalised tube of rectum.[13] When a J-pouch is performed it obviates the need for a significant rectal remnant, and the anastomosis is less likely to break down.[87] These observations may be helpful in understanding how leaks occur, and which aspects of surgical technique influence this outcome.

Risk Factor	Study	Groups Compared	Leak rate (%)
Low resection	Enker [84]	Low anterior resection (LAR)	5
		LAR with coloanal anastomosis	1
	Nesbakken [65]	Anastomosis > 6cm	7
		Anastomosis 3-6cm	25
Anastomotic tension*	Karanjia [13]	No	9
		Yes	22
Gender	Rullier [80]	Female	7
		Male	15
Obesity†	Rullier [80]	No	15
		Yes	33
Operating time	Rullier [80]	≤ 4h	7
		> 4h	17
Intra-operative bleeding	Nesbakken [65]	< 1,000 ml	6
		≥ 1,000 ml	29
	Nesbakken [65]	No blood transfusion given	4
		Blood transfusion given	27
Type of excision	Nesbakken [65]	Partial mesorectal excision	6
		Total mesorectal excision	24
Type of anastomosis	Peeters[88]	Pouch	8.4
		Side-to-end	12.4
		End-to-end	15.9
Diverting stoma	Peeters[88]	No	16.0
		Yes	8.2
Pelvic drainage	Peeters[88]	No	23.5
		Yes	9.6

Table 2 – Risk factors for anastomotic leakage. *Evidenced through mobilisation of the splenic flexure †Only significant for subgroup of patients with low anastomosis.

Whilst some studies indicate that a protective stoma reduces the rate of anastomotic leakage,[80 88] this is not a universal finding.[65 81 85] It does, however, minimise the severity of the complications of a leak, and reduces the need for emergency re-operation, as demonstrated in a multicentre analysis.[81] The principal disadvantage of a temporary stoma is that it requires a second operation to reverse the stoma, and so there are those who advocate a protective stoma only in those patients most at risk of anastomotic leak, namely those with tumours less than 8cm[80] or 6cm[13] from the anal verge.

1.2.11 Ileus and obstruction

The combination of surgical stress, increased sympathetic activity, handling of bowel and abdominal pain all contribute to an inhibition of motility or ileus.[89] The degree and duration of ileus is variable, with normal passage of flatus usually observed within 72 hours of operation, and defecation by the 4th or 5th postoperative day.[90] Ileus has been defined as pathological if it lasts beyond the 5th postoperative day,[74] although this is not a universally adopted definition.

Mechanical obstruction is another important complication, and can be difficult to distinguish from ileus, particularly if there has been no clear recovery of normal function before the obstruction develops.[91]

The major adverse results of these two complications are delayed discharge and – in the case of obstruction – re-operation in approximately 18% of cases. The rate of ileus reported varies significantly between studies, and appears to be dependent upon a number of factors, including level of anastomosis, mode of access (laparoscopy *vs* laparotomy) and mode of analgesia (epidural *vs* PCA).[89-91]

1.2.12 Medical complications

This term encompasses a wide range of potential complications, and although each typically has an incidence of less than 5%, the total complication rate may be as high as 25%.[74] It has been suggested that such complications are not related to surgical technique,[21] and this is borne out by the lack of frequency with which they are reported in studies of rectal cancer surgery.[21 22 92-94]

Although these complications may have a more complex and multifactorial aetiology than their surgical counterparts, there is often a contributing surgical element. For example, it has been shown that transverse abdominal incisions for major laparotomies are associated with better respiratory function than traditional vertical incisions.[95 96] The advantage of a transverse incision following cholecystectomy is also demonstrated through fewer respiratory complications,[97] although these findings have not been confirmed for major laparotomies.[98 99]

Review of patient series of rectal cancer surgery reveals a similar association between surgical technique and medical complications. In the ‘early’ period of TME, when surgeons were gaining experience with the technique, Nesbakken et al noted a higher rate of pneumonia (11% *vs* 5%), although this did not achieve significance.[65] Similarly one surgeon reports from his own experience that low anastomoses are associated with a higher rate of DVT than high anastomoses (1.5% *vs* 0.8%), and with a higher rate of pulmonary embolism (2.6% *vs* 1.2%), the latter bordering on significance ($p=0.057$).[91]

1.2.13 Mortality

The ACPGBI Guidelines state that surgeons should achieve a 30 day mortality of 3 – 7% for elective resections for colorectal cancer, and 15 – 25% for emergency surgery. More recent studies indicate that lower mortalities are possible, and are even to be expected: many centres are reporting mortalities lower than 3% for elective surgery[20 22 65 79 91] with mortality as low as 0.6% in a series of 681 patients in a specialist service.[84]

Mortality for rectal cancer surgery is highly dependent upon several pre-operative characteristics of both the patient and the disease itself (Table 3). Mortality is also increased if a patient has a higher preoperative Goldman class (an index of cardiac risk),[20] and POSSUM or P-POSSUM score,[100-103] although the latter tends to over-estimate the likelihood of mortality, particularly in laparoscopic resections.[104]

Characteristic	Reference	Study	Variable	OR*	P
Dukes' stage	Dukes' A	Smith[94]	B	1.61	0.07
			C	1.74	0.04
			D	4.46	<0.001
Urgency of operation	Emergency	Tekkis[100]	Elective	0.14	–
	Emergency	Smith[94]	Elective	0.53	<0.001
Age of patient	0 – 50 years	Tekkis[100]	50 – 59	5.4	–
			60 – 69	10.6	–
			70 – 79	17.2	–
			80+	44.0	–
	0 – 64 years	Smith[94]	65 – 74 years	1.90	0.001
			75+ years	4.41	<0.001
	0 – 69 years	Killingback[91]	70+ years	6.50†	<0.0001
Blood urea level	–	Longo[74]	–	1.05	0.03
Impaired sensorium‡	Absent	Longo[74]	Present	8.13	0.004
Blood albumin level	–	Longo[74]	–	0.35	0.02
PTT	<25 secs	Longo[74]	>25 secs	0.34	0.03

Table 3 – Pre-operative factors influencing operative mortality from rectal cancer. (*Odds ratio of mortality versus reference category); †Includes resections for colonic cancer. ‡Mental status changes or delirium in the context of the current illness.

After surgery, a number of adverse events relate strongly to death. A prospective study of 591 patients undergoing proctectomy from the Veterans' Affairs Program identified 20 variables which were associated with increased mortality, some of which are listed below (Table 4).[74]

Complication	Incidence (%)	Mortality (%)	Relative risk
Cardiac arrest	1.02	100.0	45.05
DVT	0.51	100.0	36.76
Acute renal failure	1.35	62.5	26.04
CVA	0.85	60.0	21.98
PE	0.68	50.0	17.24
MI	0.51	33.3	10.88
Bleeding requiring transfusion	4.23	28.0	13.21
Pneumonia	5.92	25.71	14.83
Prolonged ileus	9.31	12.73	5.68
Deep wound infection	5.92	8.57	2.98

Table 4 – Incidence of postoperative complications and association with 30-day mortality[74]

In addition to all the above patient-related factors, the surgeon is also a significant variable in mortality following rectal resection. Several studies have identified a wide range of post-operative 30-day mortality between different surgeons, allowing for confounding factors such as case-mix and peri-operative setting. Factors contributing to this variation include level of experience of the surgeon (relative risk 0.8 for those surgeons with more than 10 years experience as a specialist),[21] registration as a specialist (odds ratio 0.67 for those registered),[94] and volume of surgery (relative risk 0.70 for high volume compared to very low volume surgeons).[23] Comparison of individual surgeons reveals an even greater level of variability, and mortality hazard ratios ranging from 0.56 to 2.03 amongst 13 surgeons in McArdle's study,[19] although the surgeon characteristics contributing to these differences were not explored.

1.3 Surgical Process and Outcome

Adverse outcomes for rectal cancer surgery are diverse in nature, from the immediate (such as blood loss and perforation) to the very late (for example local recurrence). For each of these types of outcome, there is also diversity of the quality of outcome achieved.

Much of the variation in quality of outcome is dependent upon the individual surgeon, and reflects differences in surgical technique, although non-surgical 'inputs' such as stage of disease and co-morbidity must be taken into account (Figure 1). Other significant influences include wider aspects of patient care, from pre-operative preparation to post-operative management. In addition, there are many 'system factors' such as the institutional case volume, operating environment, communication and the role of other health professionals both in the operating theatre and beyond.[105-107] However, the impact of these influences is beyond the scope of this study, which will concentrate on the surgical technique, whilst acknowledging the significance of these other factors.

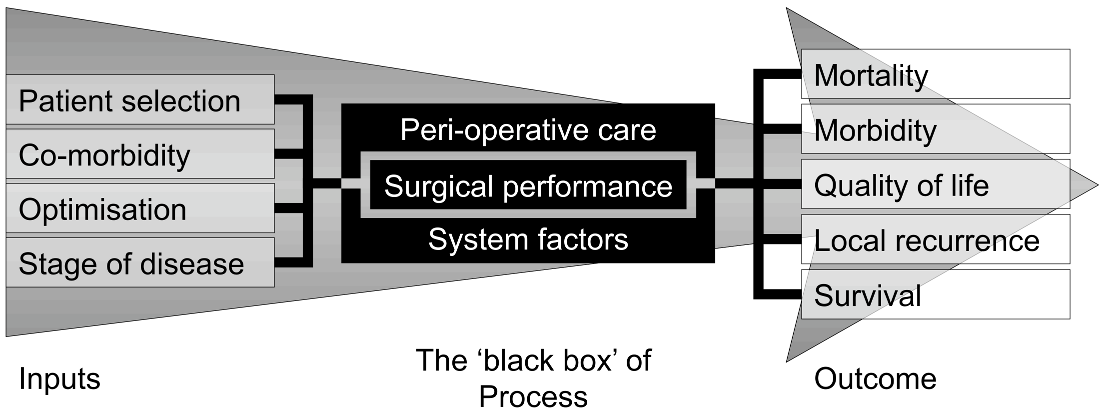


Figure 1 – The relationship between inputs, surgical process, and outcome

The details of surgical technique are often lacking, and the way in which they relate to outcome are poorly understood. The fullest descriptions of TME originate from Basingstoke,[12 17 108 109] although it has also been described elsewhere.[110] Even these detailed descriptions permit a certain ambiguity, so that although different surgeons may believe they are following the same protocol, the dissections may not be identical. For example, it has been demonstrated that identification of the pelvic nerves greatly reduces the risk of post-operative bladder dysfunction.[66] However, even for those patients in whom nerve identification was complete, 5.6% experienced post-operative voiding disturbance. This implies that the nerves were not completely preserved, contrary to the opinion of the operating surgeon. Therefore, an independent and objective opinion of the operative process is required.

The difficulties inherent in studying the operative process are well recognised, such that it has been considered “virtually impossible to objectively assess the quality of surgery”.[111] One approach which has been used is that of direct observation by an expert, as in the Dutch and Swedish TME trials mentioned above.[1 22] This has the merit of direct and synchronous feedback to the operator, and facilitates standardisation of an operating technique. However, this method is neither comprehensive, nor validated, and does not serve to identify the value of the component steps which are taught.

Other methods in use include checklists and scoring systems,[112 113] motion analysis and virtual reality.[114] Whilst each of the above has its own merits, all have significant limitations in their ability to access the operative process, often through the subjectivity of the method, or the technical difficulty in applying the technology to an operation – particularly open surgery – without considerably influencing the target variables in question.

1.4 An Ergonomic Approach to Surgical Technique

There is a discipline that is devoted to the study of human work, and has already been used to contribute to the understanding of surgical technique. Ergonomics is "the application of scientific information concerning humans to the design of objects, systems and environment for human use."[115] In order to improve safety in high-risk industries, tools have been developed that allow the evaluation of human work and error. These incorporate elements from the fields of ergonomics, engineering and psychology and form a range of methodologies that collectively are termed Human Reliability Analysis (HRA). Whilst these methodologies vary in their strengths and format, they share a common set of aims: to describe the component steps of a task; to identify the ways in which errors may allow deviation from the task; to quantify the frequency and impact of these errors; and to devise and implement means of error reduction and avoidance. Although it has traditionally belonged to the sphere of industry, HRA is now being adopted by other domains, including surgery.

Investigation of human work in the operating theatre is not new. Studies on operative efficiency were conducted in the first half of the 19th century;[116 117] research into technical efficacy, however, has only flourished more recently.

Studies in surgical skills laboratories have demonstrated that certain components of a surgical manoeuvre can have quite stringent requirements if errors are to be minimised. For example, Joice et al studied endoscopic suturing and found that if the needle approaches the tissue outwith the angles of 80 – 100^{o}, the rate of failure of suture completion rises threefold.[118]

Ergonomic principles have also been applied to surgical procedures in the operating theatre, particularly laparoscopic cholecystectomy (LC).[119-122] LC is a natural candidate for initial experimental application of these ergonomic principles – it is a frequently-performed operation, is routinely carried out by non-consultant surgeons[123] and precise video capture of the procedure facilitates repeated review and analysis.

From these studies, recurrent and consistent errors have been noted independently, particularly associated with dissection around the cystic artery and duct. Whilst the majority of these errors passed without complication,[119] where complication did occur the form was predictable: misidentifying or dissecting too close to the common bile duct or right hepatic duct.[122] Consequently, it has been possible to identify the points at which errors are more likely to occur, and suggest ways in which adverse outcomes may be avoided.

Given the success of preliminary applications of ergonomics to surgery, this work has been continued in other operations, including colorectal surgery,[124] but to date there have been no studies that evaluate rectal cancer surgery in sufficient detail to explain the differences in observed outcomes.

1.5 Conclusions from Literature Review

It has been demonstrated that the nature and quality of outcomes from rectal cancer surgery are as diverse as the surgeons themselves. Those who have investigated surgical outcomes have made repeated appeals for an evaluation of the path that leads from surgical process to outcome,[19 20 24 125] although to date no such studies have been performed.

Whilst there can be no doubt that other factors such as co-morbidity and surgical environment play a significant role in determining outcomes, it is also evident that surgical technique is one of the single most important improvable variables in determining outcome. At present there exists no system that identifies and then addresses the 'specific operative factors' involved.

A few surgical fields have already benefited from the application of ergonomic principles and techniques, and have demonstrated how errors occur, and how they may be avoided. The introduction of such a system for rectal cancer surgery is imperative if surgical skills and clinical outcomes throughout the surgical community are to be elevated to the level currently reported only by the minority. This system must be capable of documenting and describing the detail of surgical technique – both good and bad – as observed in actual operations. It must also demonstrate how variations in technique directly impact upon immediate, short- and long-term outcomes, so that technique may be modified to optimise these outcomes. The benefits of this method are manifold: it will enable the refinement of an individual's performance; it will facilitate focused and standardised training of surgical trainees; and it will provide a means of assessment of surgical performance. The ultimate aim of this approach, however, is to achieve in surgery what has been achieved in industry: safe and reliable practice in a high-risk environment, and the saving of lives through avoidance of error.

1.6 Hypothesis and Aims

It is hypothesised that errors in rectal cancer surgery contribute to adverse outcomes, and that these errors are observable and amenable to study, utilising ergonomic tools such as HRA.

The aims of this study are / were to apply a system of HRA to a series of rectal cancer resections in order to identify the errors that occur during these procedures, to evaluate the aetiology and impact of these errors, and to propose a series of error-reduction mechanisms. These aims are discussed under the headings of the key steps of HRA.

1.6.1 Identification of the problem

The problems that this project addresses are those outlined in the literature review, namely the variability of surgical technique for rectal cancer, and the adverse events associated with surgical error.

1.6.2 Task analysis

Task analysis for rectal cancer surgery involved the collation of material from a variety of sources into a systematic representation of the operative process. This was then validated through the input of a panel of experts in the fields of rectal cancer and surgical ergonomics.

1.6.3 Error analysis

Through a series of pilot procedures, a methodology was developed for data capture, review and analysis. The error framework was further refined through collaboration with experts in surgical ergonomics. A software platform was created that facilitated review of the video footage, and incorporated the error framework in a custom-designed scoring system.

1.6.4 Error identification and quantification

The above system for error analysis was applied to a series of recordings of rectal cancer resections. The circumstance, nature and consequence of all observed errors were documented and categorised according to the error framework.

1.6.5 Impact assessment

The impact of errors was determined both from the observed frequency and the severity of their consequences. Any error that was frequent and / or serious was explored in more detail, and potential causes identified.

1.6.6 Error reduction

Those errors that had been identified as frequent and / or serious were reviewed, and the circumstances contributing to the errors documented. A series of error-reduction mechanisms were then proposed that would operate through modification of the active and / or latent errors identified.

Chapter 2

TASK ANALYSIS FOR RECTAL CANCER SURGERY

2 Task Analysis for Rectal Cancer Surgery

2.1 Development of Task Analysis

2.1.1 Approach to study

It has been demonstrated that rectal cancer surgery would benefit from a systematic study according to ergonomic techniques. In order to conduct such a study, it was essential to define ideal and existing technique in an ergonomic format, and then develop a method of recording and analysis of surgical technique from actual procedures.

2.1.2 Introduction to task analysis

A task analysis (TA) is an essential element of HRA. It has been defined as “the study of what an operator is required to do, in terms of actions and/or cognitive processes, to achieve a system goal”.[126] The TA must have defined start- and end-points, which – for the purpose of this study – were deemed to be the commencement and conclusion of the operative procedure. It is recognised that this excludes all of the diagnostic process and all pre- and post-operative elements of the treatment process; however, as the focus of the study is surgical technique, the demarcation points are selected to contain this element alone.

Applying this methodology to a given task can have several purposes, including collection of data, description or simulation of the task, evaluation of the resources required, and identification of actual or potential errors.[126] The type of TA selected will depend upon many factors, including the documentation available, the nature of the task, the procedural environment and the purpose for which the task analysis is being developed.

2.1.3 Development of task analysis

In order to develop the task analysis, training in ergonomic principles and techniques was required. This was obtained through reference to literature from the fields of engineering, psychology and human factors, with particular attention to the cause and nature of human error, and how such errors could be recorded and classified. Further instruction in human factors was obtained through consultation with academics who have published in this field, and conducted similar studies of surgical technique.[119 127]

Following this training, it was decided that of the variety of approaches to task analysis, a hierarchical task analysis (HTA) would be adopted, as it achieves several goals: it facilitates classification of the procedure into major tasks with defined start and endpoints; it allows recurrent decomposition of tasks in increasing detail to the level required of the analysis; it allows for a variety of accepted techniques to be used, and classified as valid steps, not as errors. The methodology for development of the HTA followed that published by Joice et al.[119]

The material which contributed to the HTA was collected from existing descriptions of operative technique and observational data from actual procedures. Data sources included articles in journals and surgical textbooks,[110 128] video-taped surgical tutorials,[129] and video-recordings of operations performed locally. The descriptions of operative technique derived from these sources were compiled into a preliminary HTA, which was refined through discussion with a local expert in surgery, and as more data was obtained from the sources described.

Once the preliminary HTA has been constructed, it was subjected for approval through a panel of established experts (Appendix 1). These experts in the fields of surgery, pathology and human factors were identified through peer selection, and invited to attend an Expert Group Meeting. Although there is no formal consensus on the identification of such experts, to obtain a consensus from the surgical community would have been beyond the scope of the study. It was felt that the experience and skill mix of the participants justified their inclusion in the group, and allowed development of an opinion that could reasonably be termed “expert”.

Those that responded positively received a copy of the HTA which they were asked to review and comment upon prior to the meeting. At the meeting, the HTA was discussed in detail in its entirety, and all present invited to contribute so that the variation in opinion might be adequately represented.

Comprehensive audiovisual recording of the meeting enabled a full transcript of the discussion to be made, which was used as the basis for developing the definitive HTA. Those that had attended the meeting were sent two documents for their review. The first document was a summary of all comments made during the course of the meeting, and labelled according to the originator of that statement, to allow each member of the group the opportunity to confirm that his opinions had been correctly understood.

The second document represented the combined statements of all members of the group, and required that each member indicate whether the step was an essential step, an optional step, or to be avoided altogether (Appendix 3). The replies from these documents were implemented into the definitive HTA (Appendices 1 and 2, summarised in Table 5), which was applied in the assessment of surgical technique through human reliability analysis (HRA).

Task	Tasks in Anterior Resection	Tasks in APER
1.	Access abdomen	Access abdomen
2.	Identify advanced disease or complicating factor	Identify advanced disease or complicating factor
3.	Optimise access & exposure	Optimise access & exposure
4.	Dissect around sigmoid and descending colon	Dissect around sigmoid and descending colon
5.	Dissect around splenic flexure	Dissect around splenic flexure
6.	Divide vessels in sigmoid mesocolon	Divide vessels in sigmoid mesocolon
7.	Divide colon at optimal site	Divide colon at optimal site
8.	Mobilise rectum down to pelvic floor	Mobilise rectum down to pelvic floor
9.	Excise rectum with adequate margins	Perineal dissection
10.	Create colopouch or simple colotomy	Close perineal wound
11.	Anastomose colon to rectal stump	Exteriorise loop of colon
12.	Exteriorise loop of ileum	Close midline wound
13.	Close midline wound	Complete colostomy
14.	Complete ileostomy	Additional procedure (optional)
15.	Additional procedure (optional)	

Table 5 – Summary of major tasks in anterior resection and abdominoperineal resection (APER)

2.2 Development of analytical framework

It was recognised that in order to accurately describe the nature of any observed deviations from the Task Analysis, an analytical framework was required. Through a pilot analysis of 20 procedures, reference to ergonomic textbooks and papers, and consultation with a registered ergonomist (George Hanna), an event classification based upon four error categories and one recovery category was developed (Table 6).

Any event that fell outwith the description or sequence of the Task Analysis was recorded as a deviation or error, and a classification made according to any of the five categories that were relevant. Occasionally, a single event merited more than one entry in any given category, although – at the time of data extraction from the file – this was recorded as a single event.

Implicit in the scoring of the recovery mechanisms is the concept that a higher score indicates a greater change in the procedure, and therefore signifies the occurrence of a more substantial error. In addition to the five Error Categories, an additional two categories were developed in order to represent events that either did not impact directly upon tissues, or fell outwith the task analysis but were not scored as errors. The first category was labelled as ‘preparatory’ steps, and typically consisted of manoeuvres in which the arrangement of tissues were altered in order to improve future dissection. This category is similar to the ‘failure’ category, which was utilised in the event of such steps being omitted. The second category comprised a variety of techniques employed by individual surgeons in order to achieve a number of desirable goals (such as improving patient safety, minimising waste, and reducing risk of infection), but not accounted for by the task analysis (Table 7).

Error Category	Errors or Elements within Category
External Error Mode	1. Step is not done / partially completed 2. Step is done in addition (unnecessary step) 3. Step is done late 4. Step is done with too much (speed, force, distance, depth) 5. Step is done with too little (speed, force, distance, depth) 6. Step is done in wrong (orientation, direction, point in space) 7. Step is done on / with the wrong object 8. Other
Failure to Prepare Operative Field	1. Adjust hold to improve visualization 2. Adjust hold to improve traction 3. Adjust hold to separate structures 4. Search for structure to dissect / divide / clamp 5. Search for structure to avoid 6. Other
Tool-Tissue Errors	1. Poor camera views in open surgery 2. Non-visualization of instrument tip during diathermy 3. Non-visualization of instrument tip during sharp dissection 4. Non-visualization of instrument tip during other action 5. Inappropriate diathermy (tip visualized) 6. Inappropriate cutting (tip visualized) 7. Avulsion of tissue 8. Inappropriate blunt handling of tissues (tip visualized) 9. Diathermy in wrong tissue planes 10. Sharp dissection in wrong tissue planes 11. Error in use of other instrument 12. Instrument error 13. Overshooting of instrument movement 14. Suture / tie poorly-placed 15. Suture / tie poorly-tied 16. Incorrect use of stapling device 17. Inter-Step error 18. Other 19. Non-surgical error
Consequences	1. Bleeding from major vessel 2. Bleeding from small vessels 3. Bleeding (source unidentified) 4. Perforation of / injury to viscus 5. Bleeding from viscus 6. Diathermy burn to viscus 7. Diathermy burn to other structure 8. Injury to nerve 9. Mesorectal injury 10. Incorrect dissection plane 11. Compromise other oncological principle 12. Delay in procedure 13. Risk of anastomotic leak 14. Risk of infection 15. Other 16. Risk of bleeding 17. Risk of injury to viscus 18. Risk of injury to nerve 19. Risk of mesorectal injury

Table 6 – Error mechanisms applied to Task Analysis

Non-Error Category	Elements within Category
Preparatory Step	1. Adjust hold to improve visualization 2. Adjust hold to improve traction 3. Adjust hold to separate structures 4. Search for structure to dissect / divide / clamp 5. Search for structure to avoid 6. Other
Recovery mechanisms	1. Continue uninterrupted or convert to correct action 2. Perform step previously omitted 3. Requires repetition of step (e.g. regrasp) 4. Corrective action within subtask 5. Change in subtask or sequence 6. Change in major task or sequence 7. Change operation performed 8. Other
Individual Techniques	1. Management of difficult planes 2. Management of difficult bleeding 3. Time-saving devices & techniques 4. Improvement of access 5. Improve oncological safety 6. Reduce risk of infection 7. Reduce risk of injury to patient 8. Safety check 9. Other

Table 7 – Non-Error Categories utilised in analysis of procedures

In this thesis, all events from Table 6 *except* Tool-tissue error category 1 (poor camera view) will be referred to as "errors"; those from Table 7 as "non-error events". The collective term for both types of incidents will be "events". Those instances in which an "error" contains a recovery mechanism will still be referred to as "errors". Tables 6 and 7 are reprinted on a foldout sheet at the end of the thesis, in order to facilitate interpretation of error codes.

As the study progressed, the error mechanisms were refined, such that some of the procedures analysed required revision to ensure that the coding remained accurate. One additional development was the subclassification of mesorectal injury (consequence 9) as documented in Table 8. This was too dependent upon real-time observation to allow retrospective recoding, and was therefore only applied to later cases.

Mesorectal injury	Description
9a.	Fascial defect
9b.	Fat exposed
9c.	Rectal adventitia exposed
9d.	Into rectal muscle
9e.	Perforation
9f.	Transection too close to tumour

Table 8 – Subclasses of mesorectal injury

Chapter 3

DEVELOPMENT OF FACILITIES FOR VIDEO CAPTURE AND ANALYSIS

3 Development of Facilities for Video Capture and Analysis

3.1 Development of System for Video Recording

3.1.1 System requirements and restraints

In order to analyse rectal cancer resections in a way that was amenable to validation by independent assessors, it was deemed necessary to develop a video-based recording system that would record each operative procedure in its entirety. The system was to record as much as possible of the interactions between surgeons, instruments and tissues of the patient, whilst conforming to the constraints imposed by budget, and the need for minimal intrusion and maximal portability.

3.1.2 The virtual theatre

The ideal placement of cameras within the operating theatre was assisted through the creation of a virtual operating theatre, using scaled measurements from the operating theatre at Ninewells Hospital in Dundee. The virtual theatre was modelled using Amapi Version 5 (Eovia Corporation, California). The virtual theatre permitted realistic positioning of the patient, surgeons and operating lights, as well as creation of the viscera visible within a laparotomy (Figure 2a). By changing the location, angle and field of view of a camera it was possible to predict which elements of the abdomen and its contents would be visible, the level of zoom / magnification that would result from a given lens, and which items of the operating environment might be encroach upon or obscure the view of the target instruments and organs.

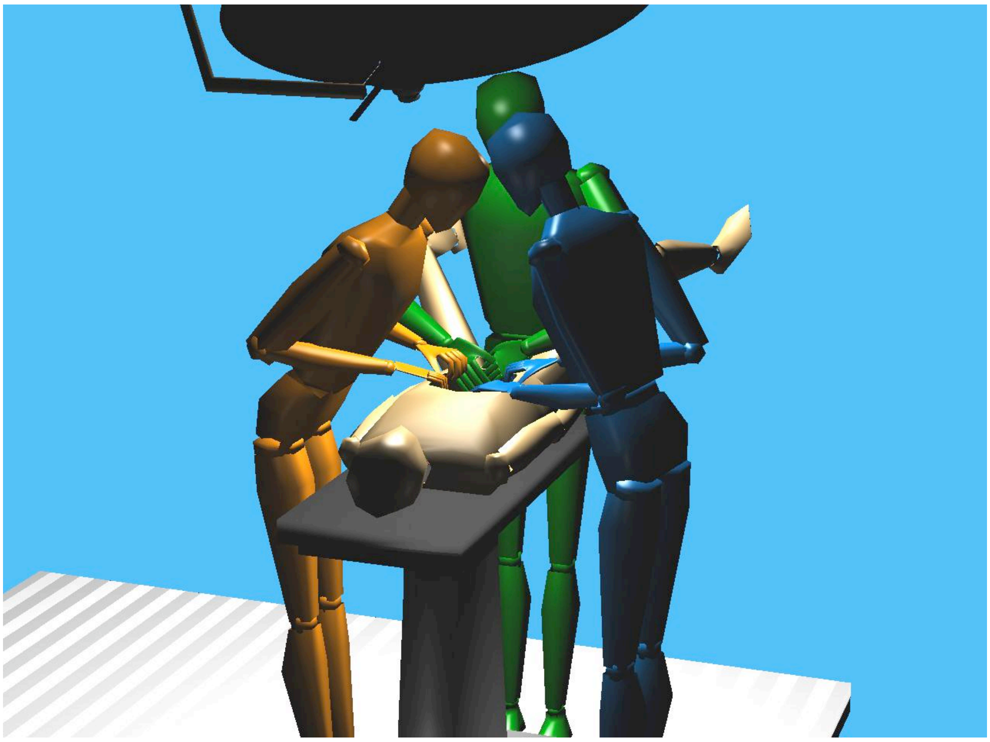


Figure 2a – The virtual theatre

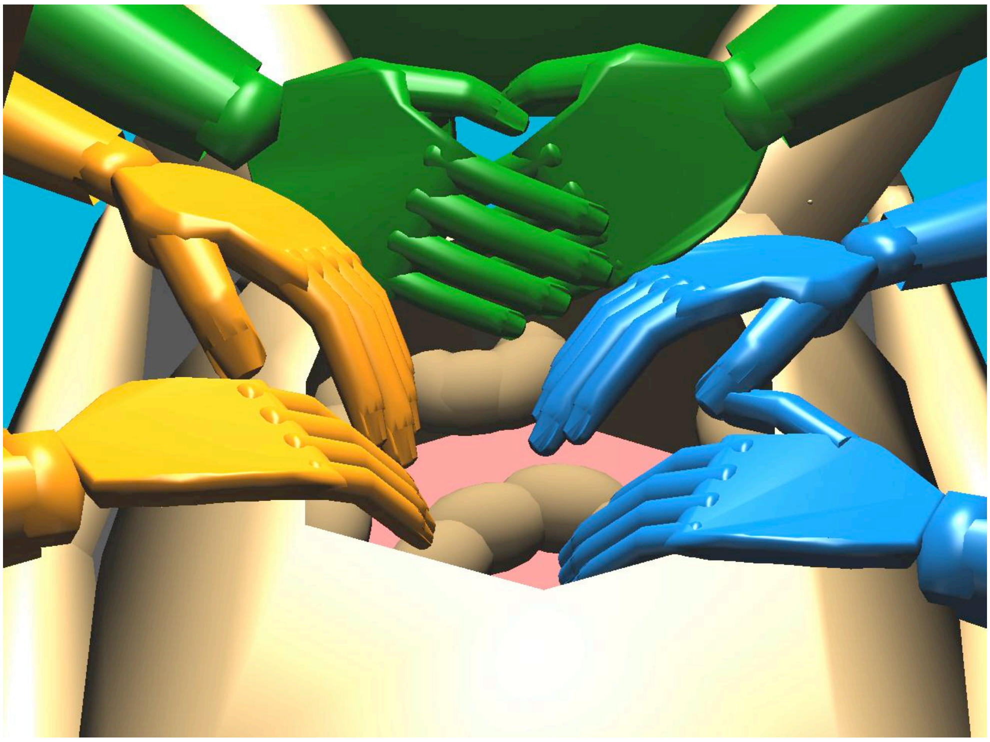


Figure 2b –View when camera positioned above patient’s head in virtual theatre

From this virtual environment, it was possible to determine some of the optimal angles for obtaining video recordings of the procedure. It was observed that positioning of a camera with a high focal length above the patient’s head would allow visual access to the pelvis, whereas a wider view of the abdomen would be obtained with a wide angle lens in the same position (Figure 2b). Cameras mounted on the operating lights would obtain better views of the abdomen, in particular the upper abdomen which would be crucial for mobilisation of the splenic flexure. However, both of these viewpoints were limited by the probability of frequent obstruction to view from the bodies and heads of the operating surgeons. Indeed, any camera that was located further from the operating field than the surgeon's head would become obstructed as the surgeon positioned him-/herself for an optimal view of the operating field.

Therefore, it became apparent that head-mounted cameras would be required in addition to fixed cameras, so that views of the operative field would not become obscured by the operating team. A lens with a long focal length would be necessary to capture the detail of the fine dissection required during the operation, but – due to the small angle of view of such a lens – might be difficult to direct accurately to the site of dissection (Figure 2c). A lens with a shorter focal length would overcome this problem, but would not capture adequate detail for all of the dissection (Figure 2d).

The conclusion drawn from study of the virtual operating theatre was that two head-mounted cameras of differing focal lengths would be required, in addition to one or more cameras mounted in an overhead position.

3.1.3 Visit to Basingstoke

Basingstoke is regarded as the home of total mesorectal excision, as described by Heald in 1993.[9 11] Through its state of the art Pelican Centre, the hospital at Basingstoke runs courses on surgical technique for rectal cancer. These are centred upon high-quality live video feeds from the operating theatre that are viewed by the course participants. A visit was made to Basingstoke in order to view the facilities and equipment available at the site, with a view to replicating any of these that might be applicable in the centres that would be involved in the current study.

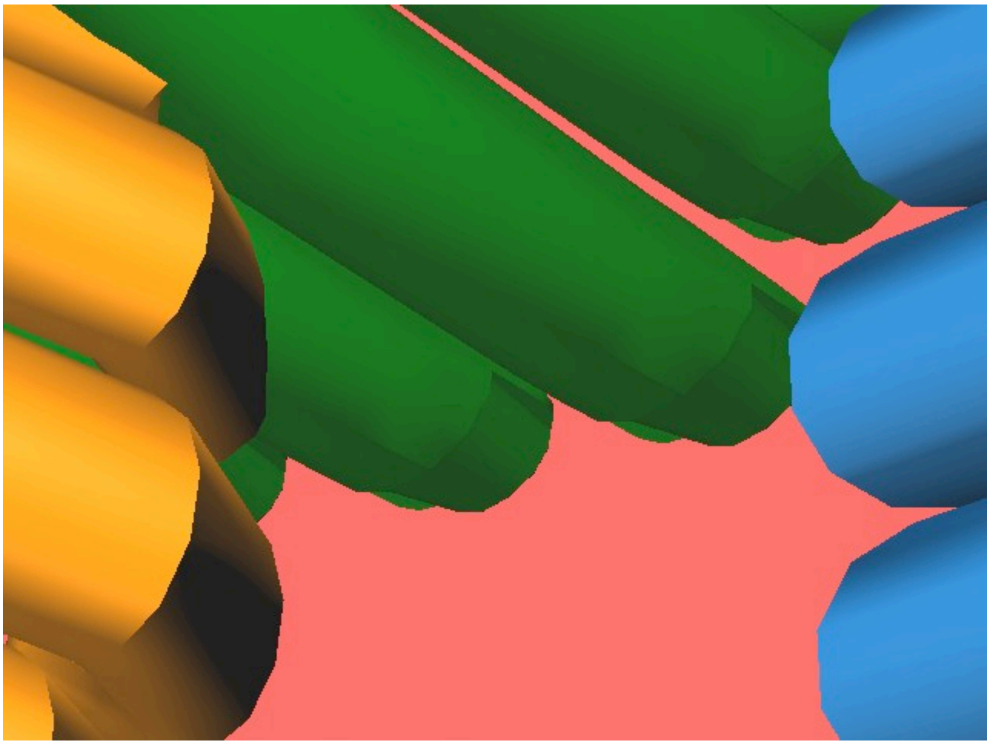


Figure 2c – View obtained from head-mounted camera with long focal length

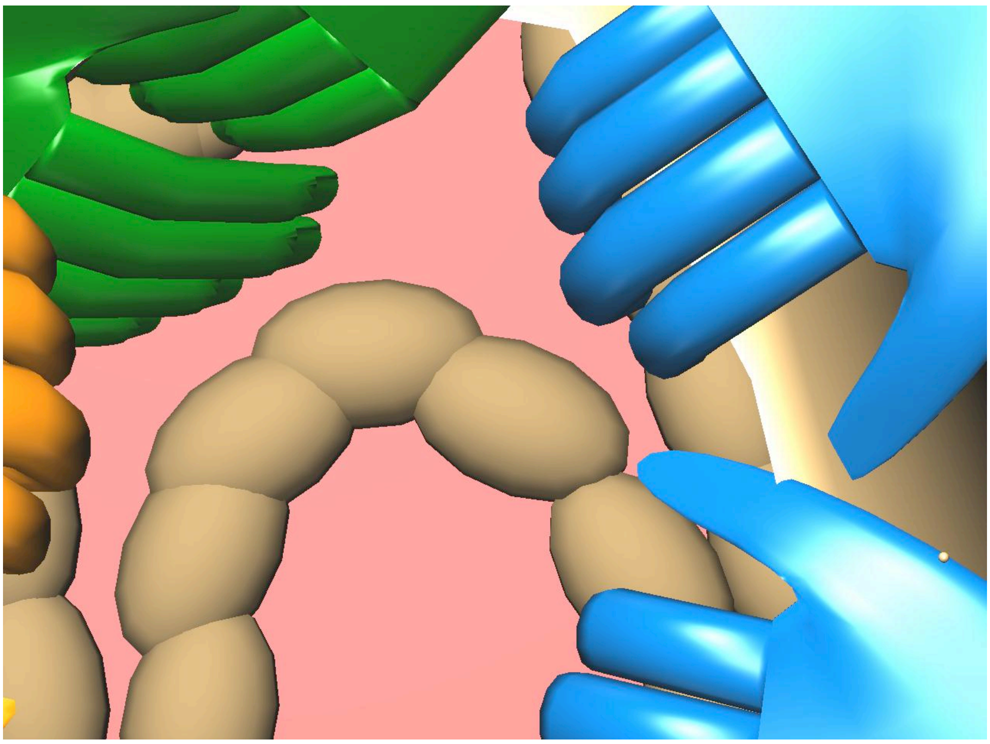


Figure 2d – View obtained from head-mounted camera with shorter focal length

It became apparent that a single high-quality camcorder sufficed for the video link in Basingstoke, and that this maintained a largely uninterrupted view of the pelvic dissection. However, such a solution was not applicable in this project, for several reasons. Firstly, the positioning of the camera was typically where the surgeon wished to place his head, and the surgeons would reposition themselves accordingly, yet would nonetheless find themselves clashing with the camera. Secondly, the position of retraction, instruments, viscera, and even the operating table would all be adjusted in order to maintain views into the pelvis. And lastly, if the surgeon operating from one side could not help but impede the view of the camera, the surgeon from the other side would take over. Therefore it became evident that in a surgical setting in which a single senior operator was present, and minimal intrusion required, such a system would not be tolerated. Nonetheless, helpful advice was obtained on the characteristics of video equipment which would secure recordings of the highest quality, and guidance received on how to manage and avoid pitfalls during these recordings.

3.1.4 Cameras

As described above, it was decided that a combination of cameras would be necessary in order to capture as much of the surgical activity as possible. The first of these would be the head-mounted camera with long focal length and magnified field of view. A camera with a co-axial light source was required in order to overcome the difficulties of accurately directing a camera with a narrow viewing angle. The MicroLux camera system (LuxTec, Massachusetts) was selected, as it incorporated one of the smallest cameras available with high resolution.

The second head-mounted camera was the subject of significant design, trial and redesign. Once initial recordings were made in the operating theatre, it became apparent that should both surgeons be attached to wired cameras, this could pose problems as the surgeons changed places around the operating table during the course of the procedure. In order to overcome this problem, the possibility of a wireless camera was investigated. At first, an inexpensive low resolution system (Wireless Spycam, Swann Communications, Victoria) was trialled, and mounted upon a headframe from a laboratory mask and following initial success, was upgraded to a higher resolution system (Wireless Stealthcam, Swann Communications, Victoria). These cameras utilise wide-angle lenses with a customised mounting. In order to achieve the desired angle of view, a micro lens was taken from another system, and a new mount built for it by the Surgical Technology Group, Dundee.

Despite preliminary success with this system, significant difficulties were encountered in the form of interference in the transmission of the audiovisual signal in the operating theatre. After experimentation with position of camera and receiver, and discussion with local experts in physics and radio signals, it was determined that the cause of this interference was due to a multi-path effect, and could not be managed with simple shielding or repositioning. The solution to this problem would have required design and manufacture of a customised polarising antenna, tuned to the frequency of the transmitting camera. As such an undertaking lay outwith the scope of this project, the wireless system was abandoned in favour of a high resolution wired camera, the IKS50 (Toshiba Corporation, Tokyo), which could be configured with a 12m cable, which would permit sufficient length to allow movement of the surgeons around the operating table. This was mounted on the same headframe as the previous cameras.

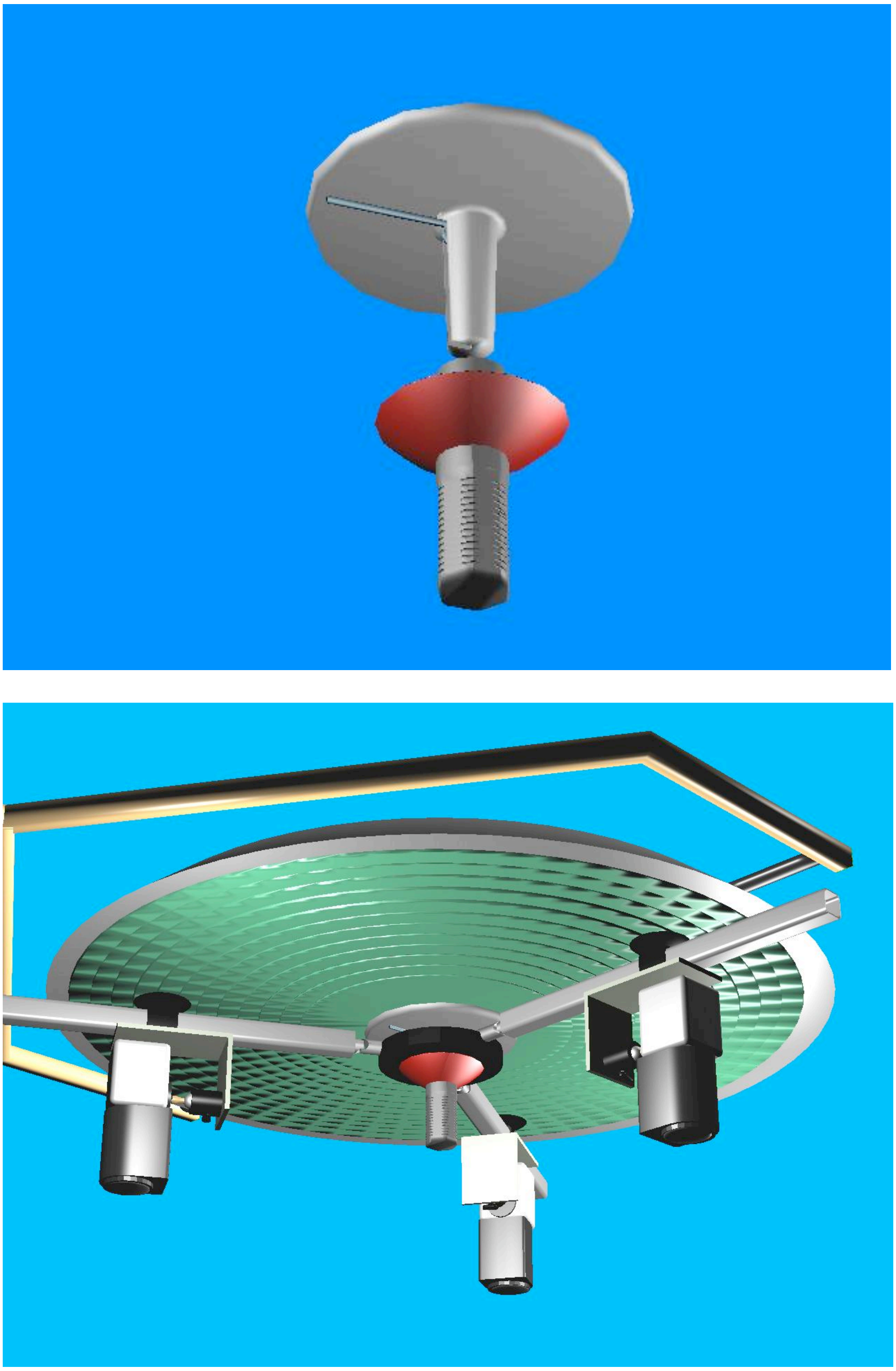


Figure 3 – Light handle used in operating theatre lighting system; with overhead camera system

An overhead camera system was designed that could be mounted on to the main operating light, ensuring that any camera mounted on it would be directed at the site of interest (Figure 3). Once this had been constructed and trialled it became apparent that the hinge joint on the operating light and the means for generating friction was worn out, such that it could not hold the weight of the light, with or without the camera system. Therefore it was not possible to mount any camera on the operating light, and an independent mounting was designed. This consisted of a modified microphone boom that stood by the anaesthetic equipment, with the camera positioned above the patient’s head.

In this position, there were fewer constraints on size and weight of the camera, and therefore a larger and very high resolution camera was selected. The Hitachi HV-D30, (Hitachi Denshi Technosystems Limited, Tokyo) contains 3 separate charge-coupled devices, enabling more accurate colour representation, and is capable of 800 lines of resolution. A small microphone was also placed in this location to record conversation between members of the surgical team. The video equipment utilised in the study is demonstrated in Figure 4.

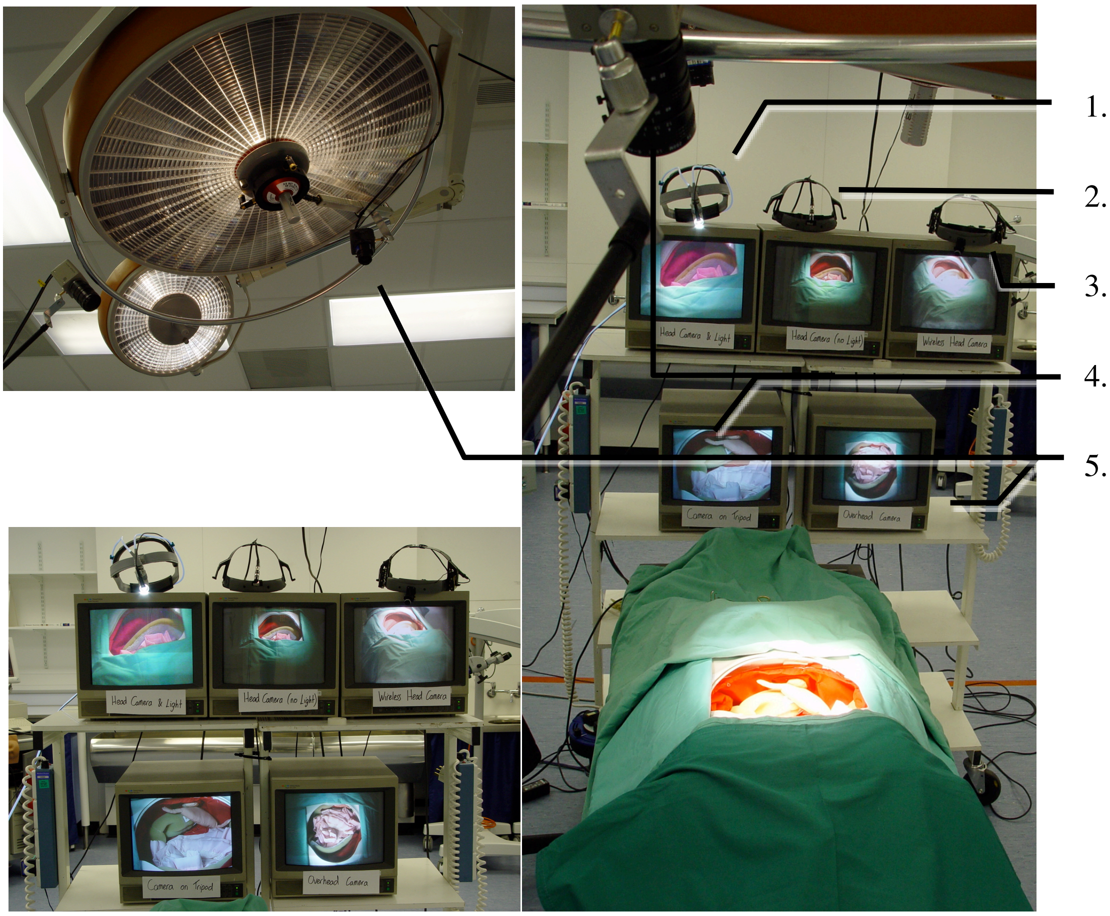


Figure 4 – Camera equipment utilised in the study. 1. Microlux camera system; 2. Toshiba IKS50 camera; 3. Wireless ‘SpyCam’ system; 4. Tripod-mounted Hitachi HV-D30; 5. Sanyo VC-5775 mounted on operating light.

3.1.5 Video transmission

The video signals were conducted from cameras to recording devices via S-Video cables, as this was the highest quality of video format supported by the cameras and video recorders. Component video transmission would have been possible from the Hitachi camera, but the marginal gain in video quality was not considered justified by the markedly increased cost of recording that this would have entailed. Radiofrequency interference from the diathermy equipment resulted in poor picture quality and even aborted video recording in a number of procedures. This was overcome through use of more modern diathermy sources (Valleylab Force FX, Tyco Healthcare Group, Colorado) and shielded cables.

3.1.6 Video recorders

A variety of recording media were used in a way that reflected the need for optimal quality and for computer-based control of the recorded video material. As the head camera with light source was felt to be the most critical, recordings were made onto DV-Cam tapes (Sony PDV-184N, Sony Corporation, Tokyo), recorded in DV format, which allowed 4 hours 40 minutes of footage on a 3 hour tape. DV recording does not employ any inter-frame compression, and applies only a mild intra-frame compression of 5:1, and is the highest quality possible within the scope of this project. The recording unit selected was the BR-DV3000 (JVC Limited, Yokohama) as an entry-level DV-capable tape deck.

The output from the second head camera was converted into a digital signal (Director's Cut Take 2 converter, Miglia Technology Limited, Tring) and recorded onto a 160GB Firewire external hard drive (LaCie Limited, Oregon) in DV format. After review of the footage, this was archived in MPEG-2 (Motion Picture Experts Group version 2) format in standardised VIDEO_TS folders on DVD's, allowing 2 hours of material for each 4.7GB DVD. The footage from the overhead camera was recorded onto a DVR-5100H unit (Pioneer Corporation, Tokyo), which combined an 80GB hard drive with a DVD recorder. Video was recorded directly onto the hard drive, split into 2-hour segments and then copied onto 4.7GB DVD's as above.

3.2 Development of System for Video Analysis

3.2.1 Need for system for analysis

Although application of a task analysis to recorded video may be performed manually, a computer-based system for analysis was deemed preferable, due to the need to synchronise multiple video streams, extract time codes, input data in shorthand, and avoid duplication of input. Therefore a search was made for suitable systems that would facilitate this process. A number of programs were found that had been developed for analysis of animal behaviour, for example 'JWatcher' from Macquarie University in Sydney. However, these did not perform synchronisation of multiple video streams, and were customisable only to a limited extent.

In consultation with staff from the Department of Applied Computing, an appropriate platform of hardware & software was selected which would allow construction of such software.

3.2.2 Selection of hardware

The Quicktime video format and Quicktime Player (Apple Incorporated, California) have become industry standards for the recording and playback of computer-based video. The player is capable of playing multiple video streams simultaneously, which was a requirement of the analysis. Quicktime is native to the Apple MacIntosh platform, and Quicktime Player is scriptable using Applescript, which is a high-level scripting language for Apple MacIntosh. As portability between operating departments was essential, a Powerbook G4 (Apple Incorporated, California) was selected for recording of procedures. For analysis of the procedures, an Intel-based dual-processor iMac (Apple Incorporated, California) was obtained. Video performance was optimised at factory with incorporation of 2GB of RAM, and 256MB of video graphics memory, and enabled the system to handle multiple video files with smooth playback. Screen resolution of 1650 x 1050 pixels permitted viewing of video streams in maximum size, so that details of tissues could be perceived.

3.2.3 Development of Software

Through consultation of Applescript documentation and example files, and from review of Applescript forums,[130-132] the elements of the program were assembled and refined (Table 8). Additional functionality was added as the need became apparent, until the program attained its final state (see Appendix 5). This was used for all video analysis.

The software performed functions including location and display of video and data files; data extraction from any previous analysis; synchronisation, playback and navigation through video files; collection and interpretation of data entry by user; recording of video analysis to text file; playback of video and corresponding analysis in validation mode (Figure 5).

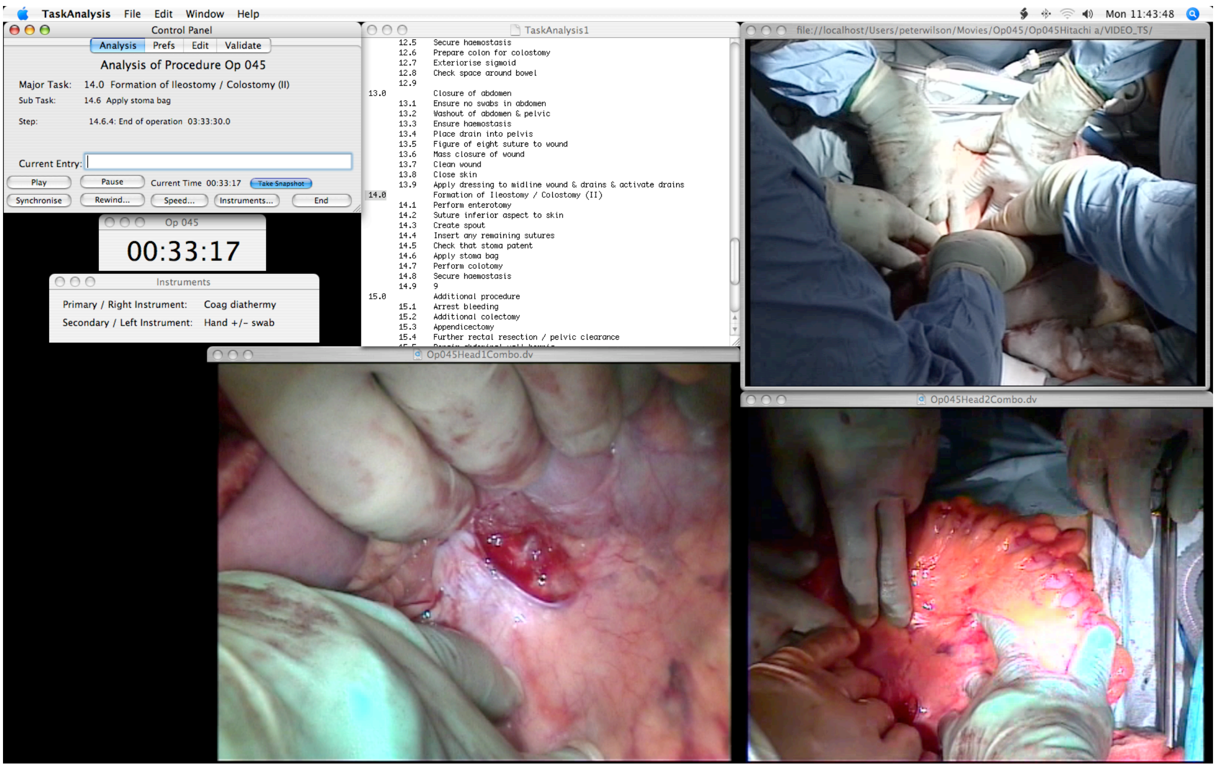


Figure 5 – Screenshot of video analysis and software

Analysis of an operation resulted in the production of a formatted text file, detailing Task, Subtask and Step numbers for every event, identification of any errors observed, and the time point of the event. Extraction of data from this file was automated with additional software developed in the same way as above (see Appendix 6).

Subroutines	Functions
Hideboxes, DisplayIOV, DisplayPanel	Display or conceal elements of user interface as required
CheckDirectories	Define paths and folders in which files are to be found and stored
ReadPreferences, WriteNewPrefs	Extract data from the user preferences file, and adjust the variables used in the program accordingly. Write new file if none exists
DefineErrorMechanisms	Extract descriptions of error terms from the error files and dictionary, and allocate these to the lists of terms that will be used in the program
CheckOperation	Prompt the user to select a procedure name / number to analyse
SetVariables	Define the variables that will be used throughout the program
OpenFile	Opens and arranges files containing task analysis and lists of error types
ReadLastTask, ReadSyncLine	Extracts data from any analysis performed by the user at a previous sitting
CheckForDVD, CheckForQT, CountVLC, DVDStats, QTStats, VLCStats	Queries all available video players to determine video tracks available, and statistics for any tracks identified
CST, CTS	Converts time in seconds to time in HH:MM:SS format, and vice versa
PlayMovies, PauseRoutine, SpeedRoutine, RewindRoutine	Instructs all active video streams to play / pause / change speed of playback / or go directly to a specified timepoint
SyncRoutine, SyncQTRout, SyncDVDRout, SyncVLCRout	Synchronises or realigns all active video streams
CollectData, Abbreviations	Extracts data from user entry, and interprets any abbreviations used
OperativeStep, LookUpTask, ErrorSafe	Identifies any user input coding for change in task or subtask, or recording an error event
AddTaskNumbers, AddToData	Automatically prefixes a task / subtask / step number to the user data, and writes this to a file
EditLast, EditAbbreviations, EditErrors	Allows user to alter a previous entry, or modify the lists used in defining errors and abbreviations
ReadIOVFile, IOV, StartIOV	Randomly selects sequences from the analysis file to be played back in Demonstration mode for inter-observer validation
Clicked the object	Detects user activation of a button or text entry
HelpRoutine	Opens a document to assist and instruct the user
SwapSides, SizeWindow, ChangeTextSize	Resize and rearrange the video and text windows
WriteTextBox	Update the user interface panel according to most recent entry
WriteMovieTime, Overwrite, CloseFile	Write and save video information to analysis file, and close the program

Table 9 – Subroutines and functions in analysis program

3.3 Collection of Data

3.3.1 Surgeon selection and recruitment

In order to achieve the desired numbers of cases from a number of different surgeons, it was necessary to extend the study outwith Dundee. Primarily from a logistical perspective, centres in Perth, Dunfermline and Inverness were selected, and surgeons from these centres were sent information about the study and invited to participate. Two of the external centres accepted the invitation and received a brief presentation concerning the purpose and nature of the study, following which they agreed to continue participation.

3.3.2 Submission to committees for ethics and research and innovation

Submission was made to all relevant committees for ethics and for research and development (Tayside, Fife and Highland), and approval obtained prior to commencing the study. All information sheets, consent forms and record forms used were approved by these committees.

3.3.3 Patient selection and recruitment

Inclusion criteria for this study were primary rectal adenocarcinoma within 15cm of the anal verge, for which elective curative rectal resection was intended. The operations of interest were anterior resection of the rectum and abdomino-perineal resection of the rectum. and were identified from elective waiting lists in the participating hospitals. Where any doubt existed about the nature of the pathology or the intended procedure, the casenotes would be consulted and the case discussed with surgeon. Where doubt remained, the patient was included in the study. Patients were invited to participate through the patient information sheet, which would either be sent to the home address, or – if admission to hospital was more than 24 hours prior to the procedure – through direct approach. Signed consent to participate was obtained for each video recording.

3.3.4 Operative record forms

Detailed pre-, intra- and post-operative data was gathered for every patient, and entered on a standardised form. The pre-operative data included mode of presentation, previous medical history, and results of investigations. During the operation, American Society of Anaesthesiology (ASA) and Physiological and Operative Severity Score for enUmeration Of Mortality and Morbidity (POSSUM)[133] scores were determined, and a measure was kept of blood loss against time. Immediately following the operation, a debriefing questionnaire was conducted with the surgeon to determine his / her perception of difficulties and errors encountered during the procedure. Additional outcome measures recorded included complications, time to discharge, local recurrence and survival.

3.3.5 Project database

All data from the operative records forms were transcribed into a database custom-built for this project, utilising Microsoft Access 1998 (Microsoft Corporation, Redmond). POSSUM scores were automatically used to predict individual risk for morbidity and mortality.

3.4 Pathological scoring of resected specimens

3.4.1 Imaging of specimens

Review of the literature on surgical technique revealed that one of the measures most proximal to the operation is the assessment of the macroscopic appearance of the resected specimen. Therefore, high-quality still images of the fresh specimen were taken with a digital camera (Sony DSC-F717, Sony Corporation, Tokyo), mounted on a tripod.

3.4.2 Scoring of specimens

The mesorectal grade introduced by Quirke is now incorporated into the minimum dataset collected by pathologists for rectal cancer specimens.[32 134] Although it is a valuable measure of adequacy of dissection, a score of 1 to 3 does not sufficiently represent the variety of appearances for the purpose of this study. Therefore, a more detailed scoring system was developed, as a modification of the Quirke system, and that proposed by Abercrombie et al.[135] During imaging of the fresh specimen, each quadrant (anterior, left lateral, posterior, and right lateral) was examined in turn, and any defects found were indicated in the photograph and scored (Table 9). This resulted in a mesorectal score for each quadrant, which could be compared with the errors identified during dissection in that quadrant.

Defect identified	Score
No defect	5
Fascial defects only	4
Entry into mesorectal fat	3
Rectal adventitia visible	2
Defect in muscle of rectal wall	1
Perforation into rectal lumen	0

Table 10 – Mesorectal scoring system

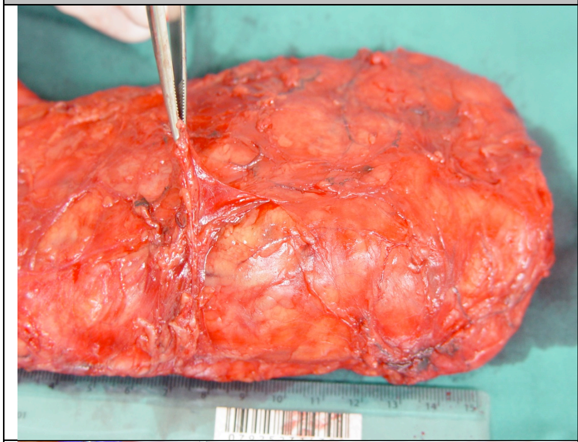
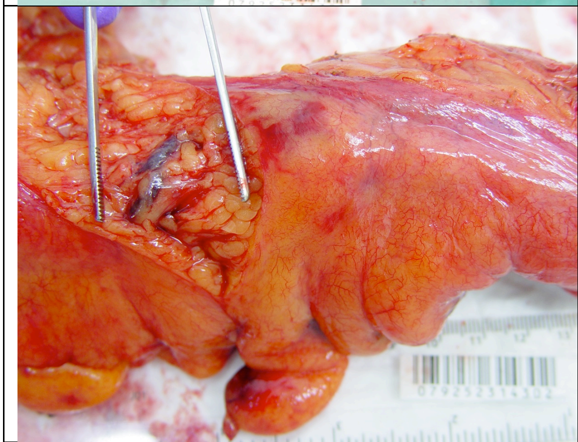
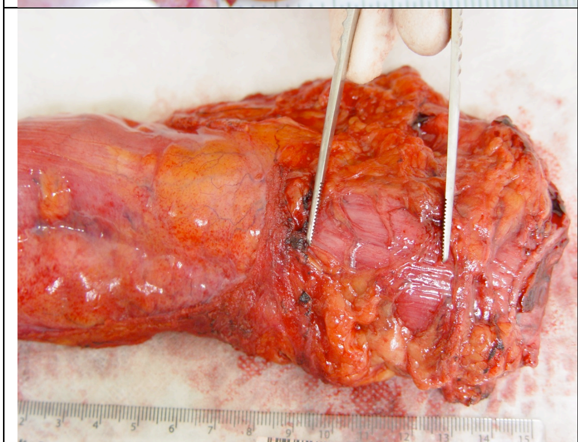
	Grade of Specimen
	4
	3
	2
	0

Figure 6 - Mesorectal scoring of specimens.

3.5 Analysis of data

3.5.1 Validation of error analysis

Coding a surgical error requires two forms of interpretation: firstly, that relating to the surgical events as they unfold on-screen; and secondly, the interpretation by which these events are correctly coded. As both of these are specialised tasks, validation was obtained from two separate sources. For the first, samples of the videos were reviewed by an expert in colorectal surgical technique (RJCS), and the associated descriptions of the events verified. For the second, the text files were reviewed by an expert in surgical ergonomics (GBH) to determine whether the coding of the text-based error descriptors was correct.

3.5.2 Verification of data

Data verification was performed at several levels. These included a function built into the software to ensure that data were correctly coded at the time of capture; automated validation of text files to ascertain that the codes matched the descriptive text with which they were associated; and random sampling and manual review of text files to determine that the coding system was correctly entered.

3.5.3 Extraction of data

The record of surgical errors was kept in prose in a text file, with standardised error codes embedded into the data, including details of the task, subtask, and time at which the event was recorded. These files varied between 500 and 1,000 lines in length, requiring automated data extraction utilising the software developed above. Queries were made of the data regarding numbers and types of errors and error-combinations, and how these were distributed throughout the tasks of the procedures.

3.5.4 Statistical Analysis

The summarised data from the above queries was reviewed on spreadsheets (Microsoft Excel for Mac 2001, Microsoft, Redmond) and reformatted for statistical analysis in Microsoft Excel and SPSS (SPSS Inc., Chicago, Illinois). Significance was determined through tests of correlation and linear regression.

Chapter 4

RESULTS

4 Results

4.1 Layout of results section

The results of the development of the task analysis, the virtual theatre and the system for recording and analysis have already been presented. In this section, the description of the demographics of the patients will be followed by brief comments on the operating times and on episodes of suboptimal camera views. Thereafter, a systematic prospective review of the errors encountered during individual tasks will be presented: by necessity, not every error encountered may be fully described, but broad patterns of error types will be identified and discussed.

In the next section, a retrospective analysis of errors will be presented, considering the adverse outcomes that were encountered, and attempting to account for some of these from the analyses of the procedures.

The penultimate section will address individual cases that are particularly worthy of more detailed examination. In the final section, novel methods of describing and evaluating error events will be explored.

4.2 Demographics of patients and tumours

One hundred and eleven patients were approached and invited to participate in the study, of whom 108 agreed. The remaining three indicated that they were too preoccupied with concerns about the operation to consider enrolling in research. Procedures were analysed sequentially, commencing with the procedure most recently recorded. In this way, the last procedure to be analysed was amongst the first to have been recorded. After fifty-nine procedures had been analysed it became evident that video quality from the early procedures was too poor to permit accurate analysis and consistent comparison with the latter procedures, and was therefore abandoned.

The demographics of the patients, pathologies and procedures are indicated in Table 11.

		All Patients	59 Patients
Gender	Male Female	64 (59%) 44 (41%)	32 (55%) 27 (45%)
Age of patient		67.3+/-10.4 (range 43 –87)	67.0+/- 10.9 (range 43 – 87)
Number of surgeons		8	8
Operations per surgeon		11.6+/- 7.7 (range 1 – 23)	7.0+/-5.2 (range 1-14)
	High AR Mid AR Low AR APER	17 (17.5%) 20 (20.6%) 26 (26.8%) 24 (24.7%)	7 (11.9%) 14 (23.7%) 21 (35.6%) 12 (20.3%)
Procedure deemed curative at time of operation	Yes No	70 (72.1%) 27 (27.8%)	46 (78.0%) 13 (22.0%)
Clinical estimate of TNM stage	T0 T1 T2 T3 T4 N0 N1 N2 M0 M1	17 (17.5%) 6 (6.2%) 30 (30.9%) 24 (24.7%) 20 (20.6%) 89 (91.8%) (5.2%) 3 (3.1%) 91 (93.8%) 6 (6.2%)	9 (15.3%) 4 (6.8%) 19 (32.2%) 17 (28.8%) 10 (17.0%) 51 (86.4%) 5 (8.5%) 3 (5.1%) 55 (93.2%) 4 (6.8%)
Blood loss		1052 ml +/- 1134 (range 0 – 5900)	1263 ml +/- 1200 (range 0 - 5900)
Anastomotic leak	Yes/No/Missing	9 / 72 / 27	7 / 38 / 14
Return to theatre	Yes/No/Missing	6 / 75 / 27	5 / 40 / 14
Local recurrence	Yes/No/Missing	2 / 76 / 28*	2 / 41 / 14*
Mortality	Yes/No/Missing (Mean days to death)	21 / 59 / 28 (613.8)	11 / 34 / 13 (608.3)

Table 11 – Demographics of patients in the study (+/- standard deviation). *An additional 2 patients were deemed 'likely' to have developed local recurrence

4.3 Operating times

Fifty-nine procedures were analysed, with an average operating time of 190.3 +/- 46.7 (range 100.0 – 330.0 minutes). The time shown for different types of procedures is shown in Figure 7. The terms 'low', 'medium' and 'high' anterior resection were at the discretion of the operating surgeon. Stricter definitions were not possible due to lack of availability of relevant data such as tumour height at colonoscopy.

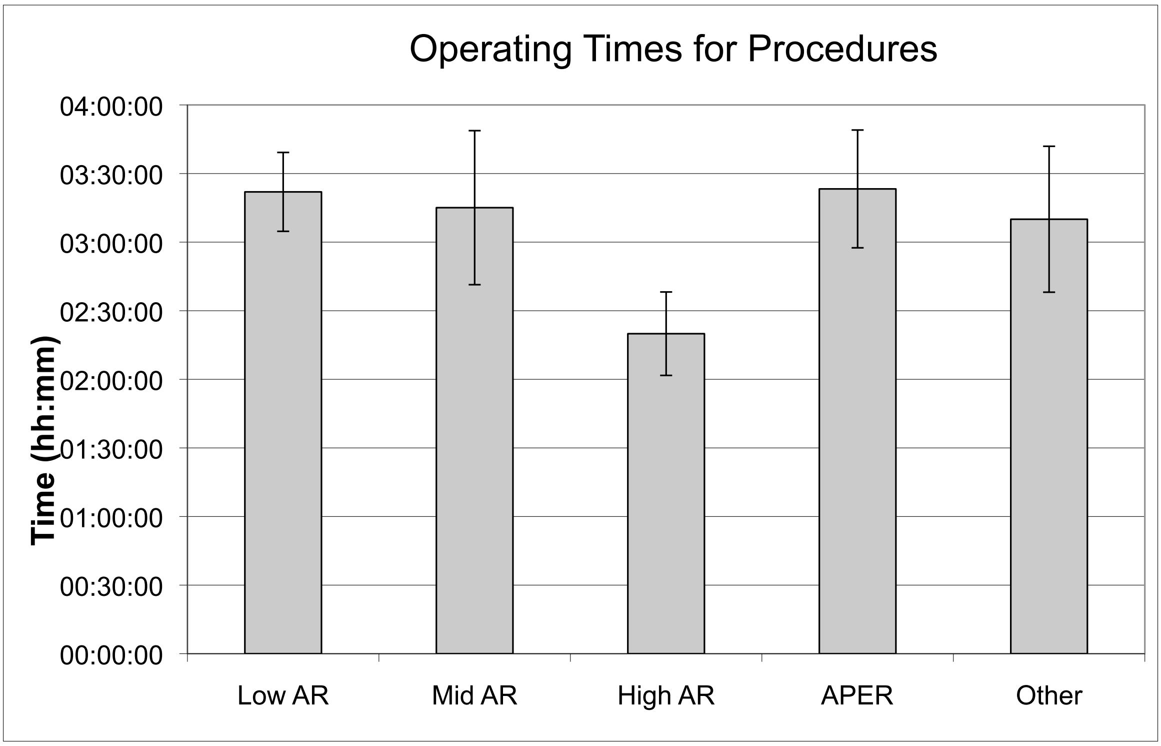


Figure 7 – Operating times for different procedures. APER = abdomino-perineal excision of rectum; AR = anterior resection (mean ± 95%CI)

The time taken to complete procedural tasks varied from a mean of just over 4 minutes for exploration of the abdomen at laparotomy, to nearly 34 minutes for rectal dissection. The range of times taken for each of these tasks also varied widely. For example, Task 8 (rectal dissection) took an average of over 39 minutes in low anterior resections, but just over 16 minutes in high anterior resections (Figure 8). Tasks 1 – 8 are considered together, as they are common to all procedures. Tasks 9 – 14 (or in some cases, 16) differ between anterior resections and APER's, and so tasks for these two groups must be analysed separately.

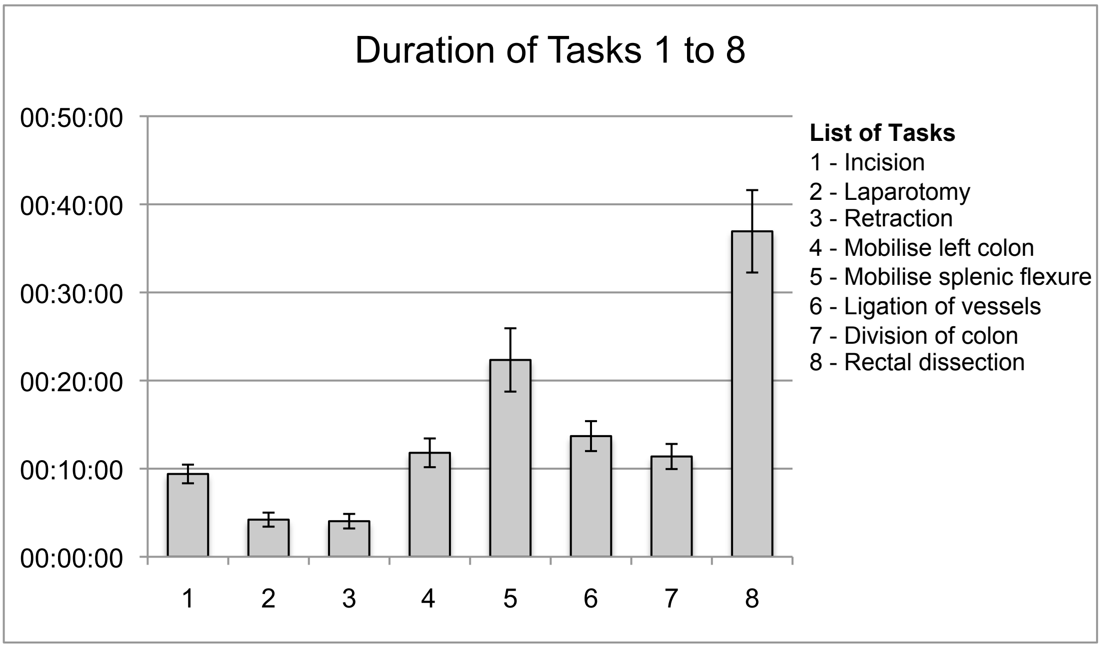


Figure 8a – Operating time by Task. APER = abdomino-perineal excision of rectum; AR = anterior resection (mean±95%CI)

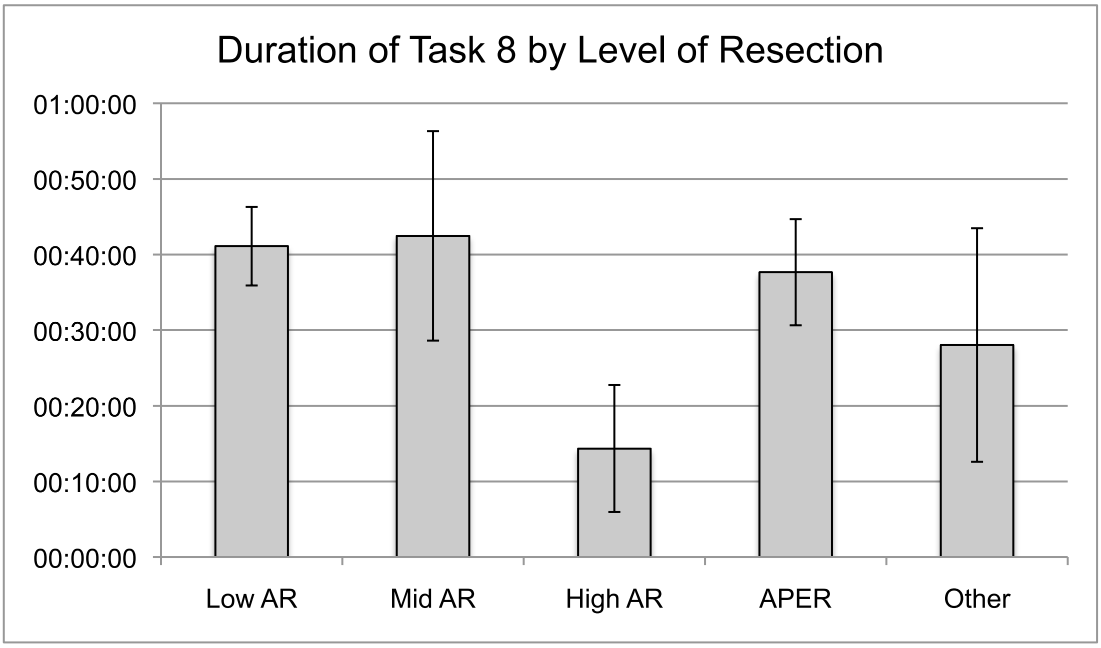


Figure 8b – Task 8 shown in detail for different procedures. APER = abdomino-perineal excision of rectum; AR = anterior resection (mean±95%CI)

4.4 Suboptimal camera views

Despite every effort to ensure uninterrupted visualisation of the operative field from at least one camera, there were times when this was not achieved. For the duration that the recorded views were too poor to allow analysis of the procedure, an entry of

"Poor camera view" was made in the text file. This enabled accurate calculation of the proportion of the procedure and of each task that was deemed impossible to analyse. This is represented in Figure 9. The tasks in which most difficulties of visualisation were encountered were Task 4 (mobilisation of left colon), and Task 8 (rectal dissection). It was deemed that if greater than 25% of any task was not visualised, then analysis of the remainder of the task was to be interpreted with caution. Seven such cases were encountered during task 4, and three during task 8.

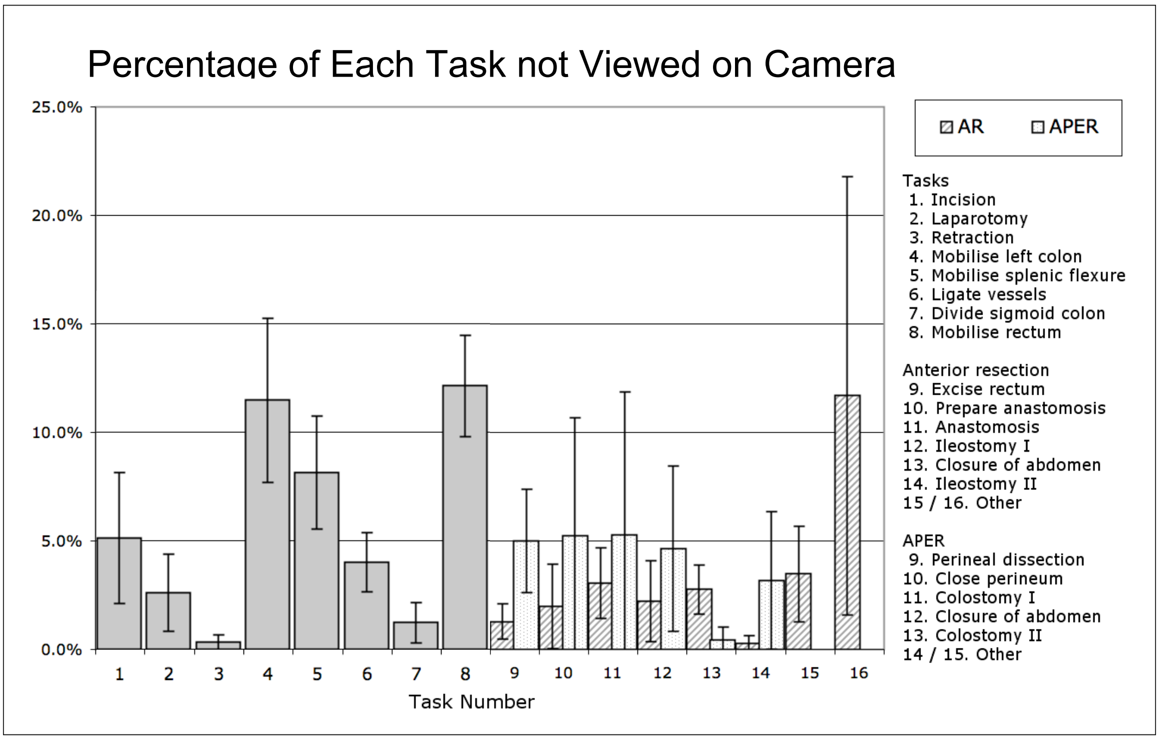


Figure 9 – Percentage of Task not viewed on Camera

4.5 Prospective Error Identification

A total of 7,562 events were identified in 59 procedures, although 1,404 of these coded for poor views obtained from the cameras. The remaining 6,158 events comprised 3,365 errors and 2,793 non-error events. Each of these events is multi-dimensional, containing up to 4 dimensions corresponding to each of the Error Categories described in Table 6, and 3 dimensions of the Non-Error Events in Table

7. The potential number of combinations of error combinations exceeds 138,000 (8 External error modes x 6 Failure modes x 19 Tool-tissue interactions x 19 Consequences x 8 Recovery mechanisms), and therefore it is not practical to consider each combination for each task. However, of the 138,000 possible combinations, only 690 were encountered during the analysis, and of these only 314 were identified on more than one occasion.

The rate of occurrence of errors and events was also calculated as a frequency per minute, to allow comparison across tasks of varying duration (Figure 10).

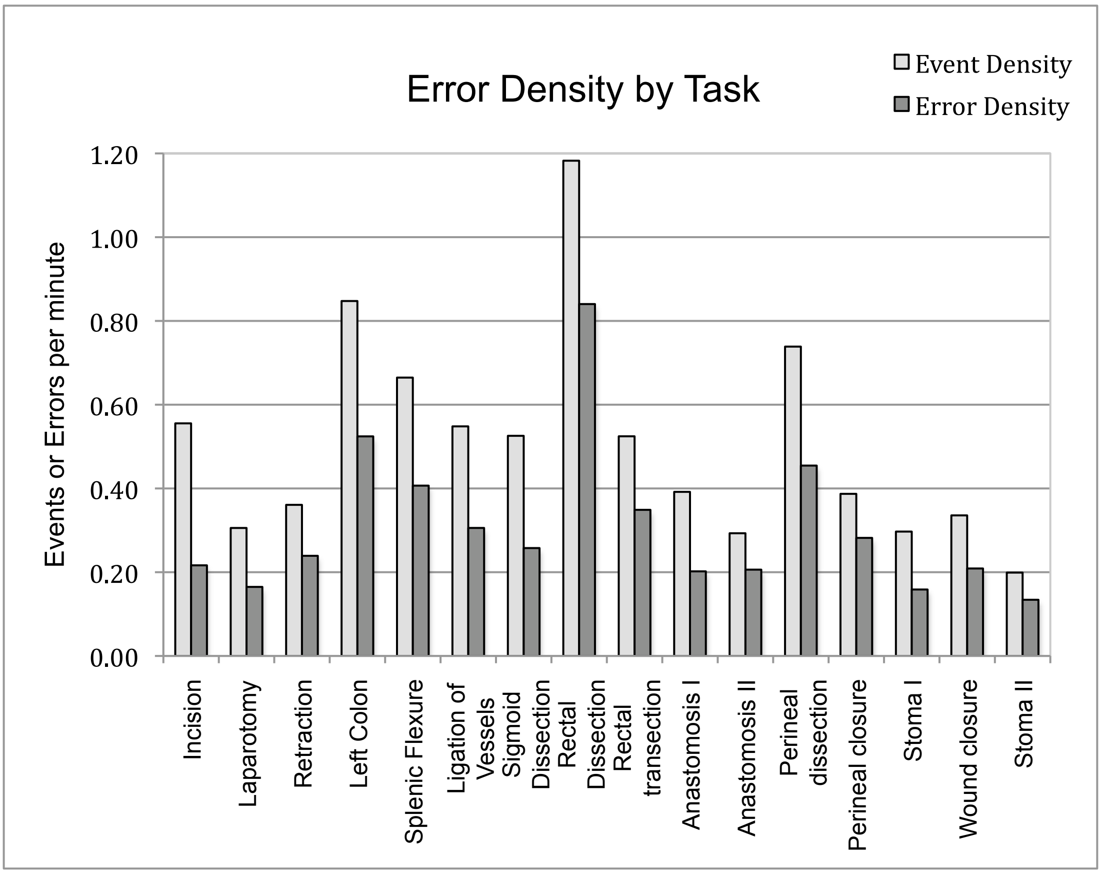


Figure 10 – Error density by task, expressed in events or errors per minute. "Events" includes all errors, recovery mechanisms and preparatory steps, whereas errors are those outlined in Table 6 (page 37).

Although "Error density" might preferably be expressed as Number of errors ÷ Number of component steps, the complexity of movement from multiple surgeons and tools renders this approach impossible.

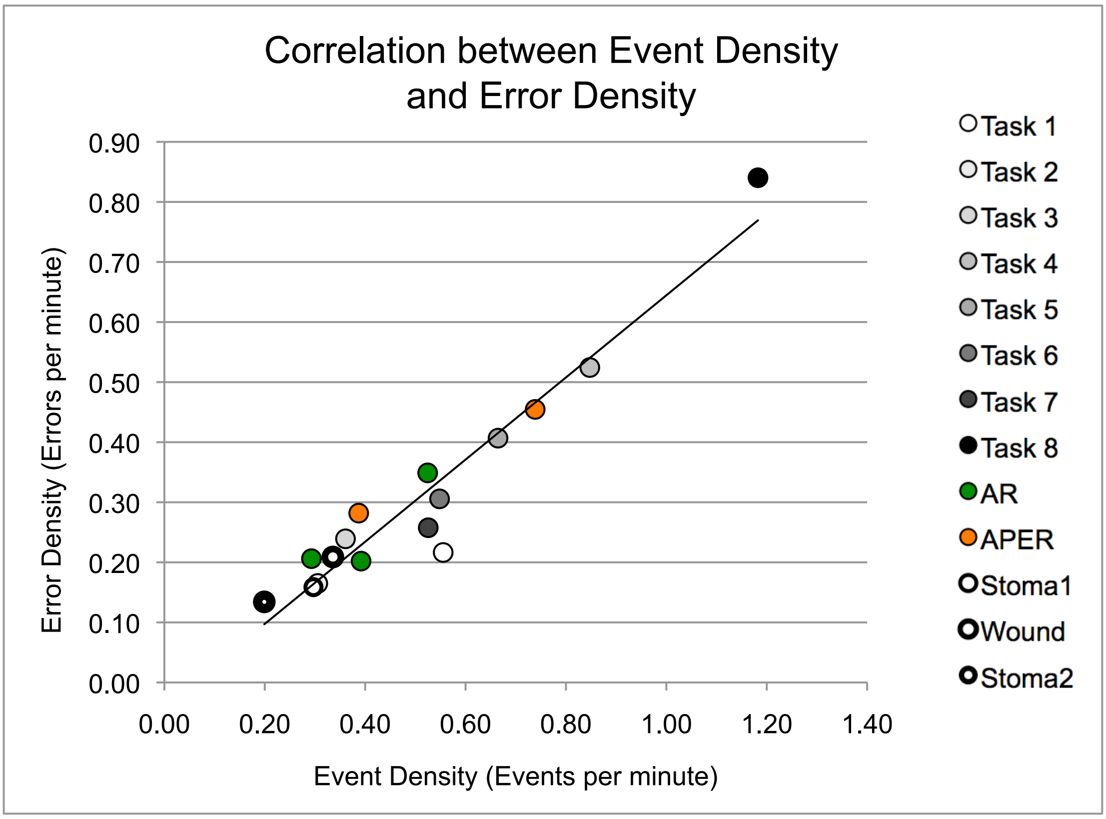


Figure 11 – Correlation between event density and error density, r = 0.96, p<0.001. Tasks common to all procedures are shown in monochrome; tasks unique to AR & APER are shaded in green and orange respectively.

There was a close correlation between event density and error density (Figure 11), indicating that tasks that contain a higher number of steps per unit time also contain a greater frequency of errors.

The number and range of error combinations for each task will now be considered. In addition, those errors that occurred occasionally, but with more serious consequences will also be reviewed. A graphical overview of TTE's and Consequential errors is presented for each task, to facilitate comparison of quantity and distribution of errors between different tasks.

4.5.1 Task 1 – Incision of abdominal wall

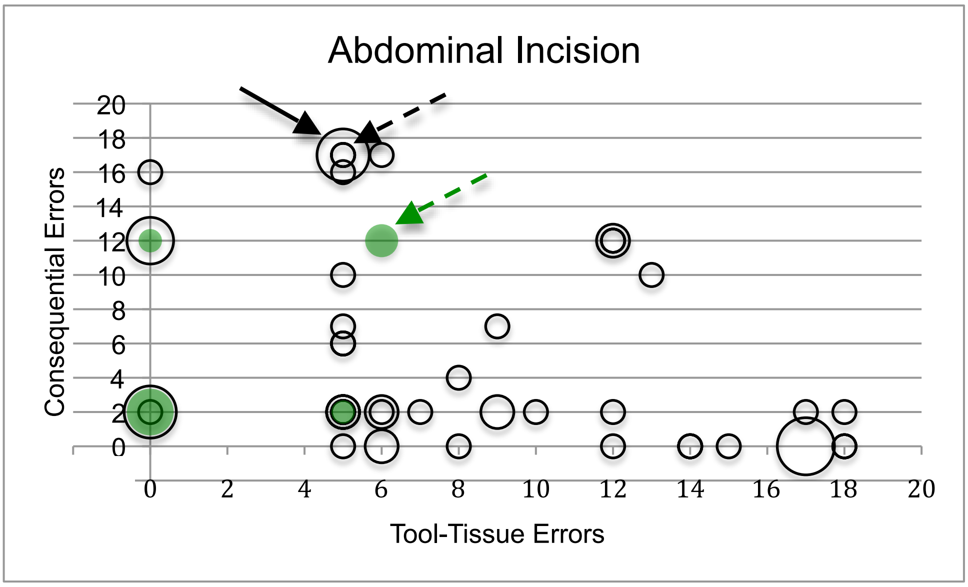


Figure 12 – TTE's vs Consequences in Task 1, Abdominal Incision. See text for details.

The first of the graphical overviews, Figure 12, may be understood as follows: along the horizontal axis are the 19 Tool-tissue error categories, and the vertical represents the 19 Consequential Errors (see Table 6). Those events that are without consequence have a consequence value of zero, and lie along the horizontal axis; consequences that occur without an associated TTE lie on the vertical axis. The area of each circle is proportional to the number of events. Combinations with different EEM's will each have separate points. For example, the combination TTE 5, Consequence 17 & EEM 7 occurs 5 times (outer circle, solid arrow), whereas TTE 5, Consequence 17 & EEM 4 occurs only once (inner circle, dashed arrow). A green circle indicates a TTE-Consequence combination in which a Recovery mechanism has been implemented. For example, TTE 6 and Consequence 12 occurred twice with a Recovery step (green arrow).

During incision of the abdominal wall, a total of 308 events were identified. Of these, 39 were related to poor camera views, and 188 were non-error events (see page 38 for definitions). Sixty-two of these were recovery events, typically to deal with bleeding from vessels encountered during entry into the abdominal cavity. Most of these were classified as recovery type 4 (action within subtask) or 3 (repetition of step), although one of these represented inspection of diathermy injury to small bowel. Recovery mode 2 (perform step previously omitted) was encountered when a vessel had not been managed correctly, and the surgeon then arrested or prevented bleeding appropriately.

A total of 81 errors were documented, only 14 of which occurred more than once. In four instances, the combination of External Error Mode (EEM) 7 (step is done on / with the wrong object) was observed with Tool-tissue Error (TTE) 12 (instrument error), all of which were related to usage of recently introduced diathermy machines. In all instances, the settings had not been optimised for a blend of cutting and coagulation, and led either to slow progress through the layers of the abdominal wall, or to excessive bleeding from vessels in which haemostasis had not been secured.

Other groups of errors were identified: inappropriate diathermy (TTE 5) was observed 21 times, 8 of which were associated with bleeding from small vessels (Consequence 2). Seven times there was a risk of injury to viscus (Consequence 17) associated with TTE 5, and one observed injury to viscus (Consequence 6).

When incision was made with scissors or scalpel instead of diathermy, only one instance of risk of injury to viscus was observed; conversely, the operator tended to err on the side of caution, with consequent minor delays in the procedure. Another event in which a consequence was observed was delayed exploration (EEM 3, TTE 17) for source of bleeding, when only one end of a cut vessel was secured, and the other end not sought until the bleeding became apparent (Consequence 2).

4.5.2 Task 2 – Laparotomy

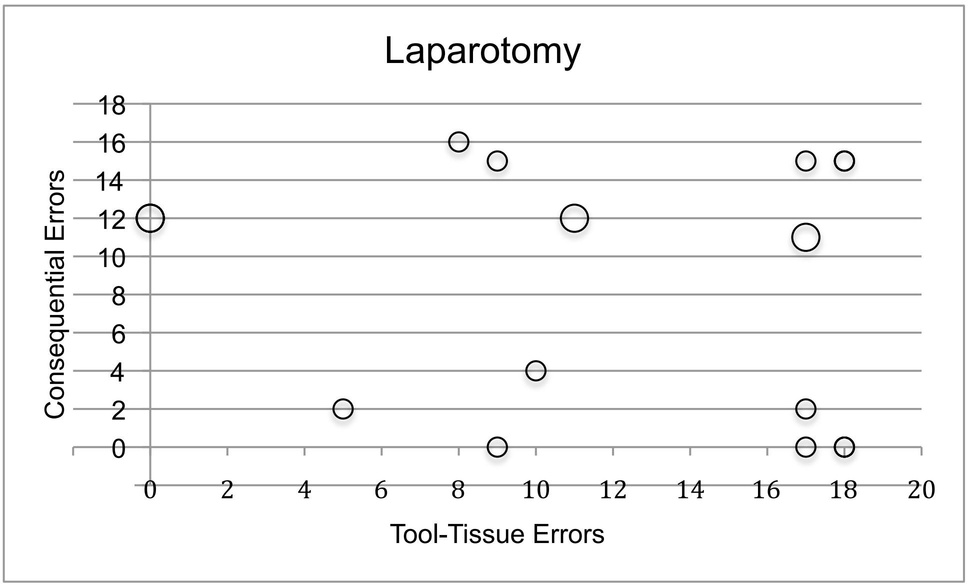


Figure 13 – TTE's vs Consequences in Task 2, Laparotomy. See page 70 for explanation.

Task 2 (Laparotomy) was one of the briefest tasks observed, taking less than 5 minutes on average to complete. As anticipated, the event count within this task is low, with only 76 events recorded (average of 1.29 events per procedure), and therefore, not only is the absolute error count low, but Task 2 also contains one of the lowest error densities of the procedure, with only 0.16 error events per minute. Of the 76 events observed, 17 indicated poor camera views (TTE 1), and 15 related to recovery events, all of which pertained to application of diathermy to small bleeding vessels. Four of the events were preparatory, and therefore non-error events.

Few errors were observed more than once, including two instances of EEM 7 (step done with wrong object), TTE 11 (error in use of other instrument) and Consequence 12 (Delay in procedure). Both of these related to incorrect selection of an instrument (one retractor, one wound drape), and the delay that followed as this was corrected.

Inter-step errors (TTE 17) were noted 5 times, usually as a failure to perform a step (such as packing small bowel, checking for bleeding points), but once with EEM 2 (step done in addition), when the skin incision was extended when not required, and then not exploited fully.

Of the remaining events, all were unique. EEM 1 (step not done) was observed three times, two of which were associated with Consequence 2 (bleeding from small vessels): failure to control vessel whilst dividing adhesions; and failure to examine the operative field for bleeding vessels.

EEM 6 (step done in wrong orientation) was identified in two instances, both during dissection through adhesions. On these occasions, the surgeon strayed away from the abdominal wall and towards the adherent viscera. In one of these cases, the serosa was stripped from adherent small bowel, and required repair later in the procedure.

4.5.3 Task 3 – Placing retraction system

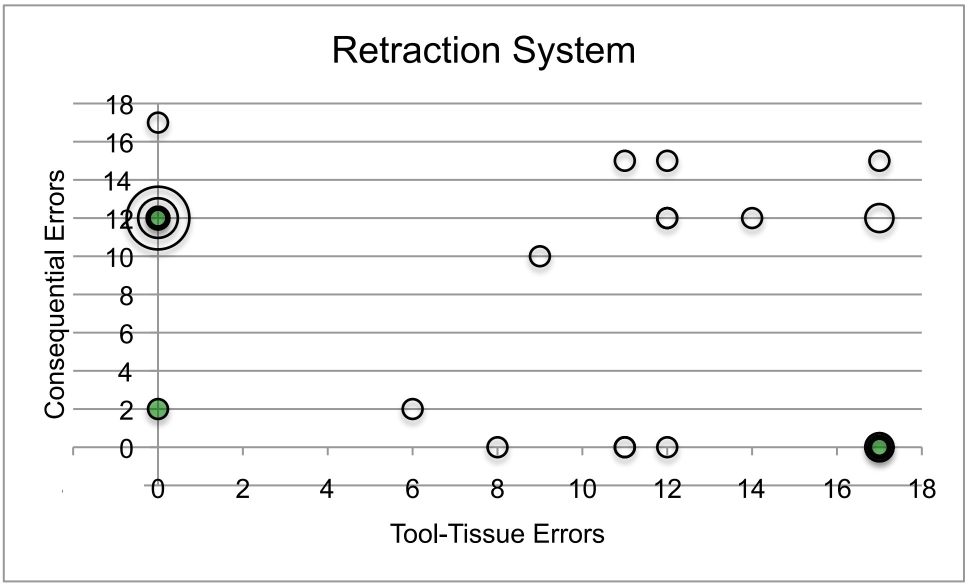


Figure 14 – TTE's vs Consequences in Task 3, Retraction System. See page 70 for explanation.

Relatively few errors were encountered during task 3, in part due to the brevity of the task (less than 4 minutes on average), but also due to the low error density (0.24

errors per minute). Of the 86 events observed, 17 denoted poor view, and 53 were error events. Fifteen of these errors pertained to failure to adequately pack the small bowel to the right upper quadrant, seven of which caused delays during task 3. In all 15 cases there was also the potential for delays throughout the remainder of the procedure, as well as the risk of injury to small bowel that encroached upon the operating field.

Three error events were due to poor positioning of the Omnitract system (Omni-tract Surgical, Minnesota), or poor fitting of the retraction blades onto the system. Two error events related to adjustment of position of the Omnitract system. The remaining two events were due to late introduction of a retraction system, and failure to perform a full laparotomy.

4.5.4 Task 4 – Mobilisation of left colon

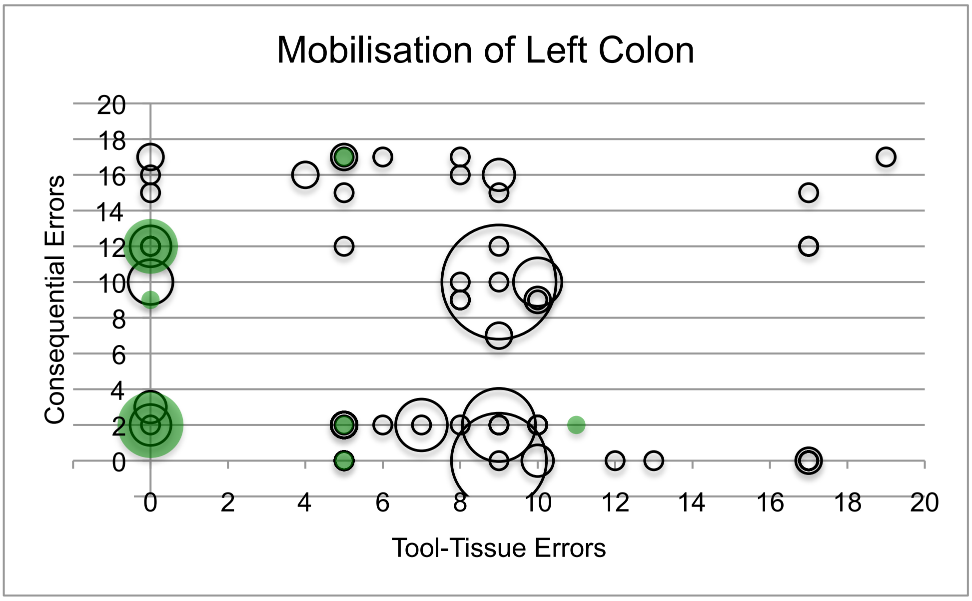


Figure 15 – TTE's vs Consequences in Task 4, Mobilisation of Left Colon. See page 70 for explanation.

In task 4, 590 events were identified, with an error density of 0.52 errors per minute. Of these events, 141 related to poor camera views, and 134 to non-error events. Forty-five of the non-error events were comments on helpful techniques employed by the surgeon, most of which concerned good management of difficult planes. Adjusting hold to improve traction accounted for 25 of these. Other beneficial manoeuvres in task 4 included changing approach when dissection is difficult; employing sweeping action of instrument tip to develop plane; and use of other instruments (scissors, pledget, forceps) to open difficult planes.

Forty-one error events were isolated recovery events (i.e. no EEM/TTE / Consequence was scored at the time of the recovery), 30 of which were type 4 (corrective action within subtask); all of the 30 Recovery type 4 errors involved swabbing or applying diathermy to bleeding vessels. The remainder of recovery events were distributed evenly between types 1, 2, 3 and 5. The majority of these constituted repetition of diathermy for bleeding vessels. However, Recovery type 5 (change in subtask or sequence) occurred three times, associated with suture to repair a serosal bowel defect, or arrest persistent bleeding.

Of the remaining 124 error events, 63 were associated with a combination of EEM 6 (step in wrong orientation) and TTE 9 (diathermy in wrong area / tissue plane). Nineteen of these were without consequence, 29 resulted in an incorrect dissection plane, 11 caused bleeding from small vessels, and 2 led to burns to greater omentum or to the fat around the colon (consequence 7). Twenty-two error events with Failure types were identified, 18 of which (types 1 to 3) consisted of compromised access due to failure to pack viscera in task 3, or suboptimal dissection due to inadequate traction. Failure type 4 (search for structure to dissect) was noted when a vessel crossing the dissection space was not ligated or coagulated, and in both instances led to bleeding from this vessel. Failure type 5 (search for structure to avoid) was associated with dissection too close to the iliac vessels or the ureter, although injury to these structures was not observed.

4.5.5 Task 5 – Mobilisation of Splenic Flexure

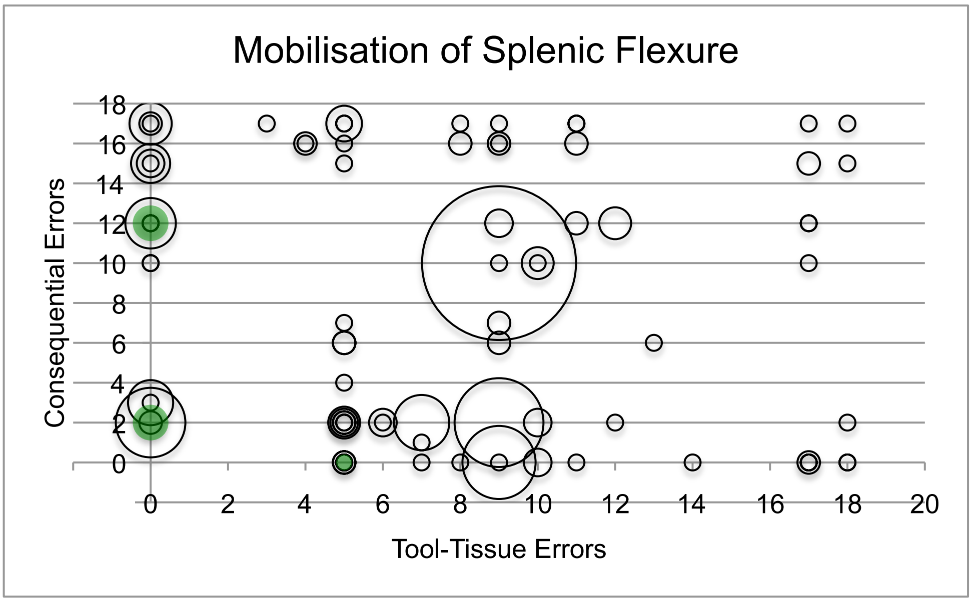


Figure 16 – TTE's vs Consequences in Task 5, Mobilisation of Splenic Flexure. See page 70 for explanation.

Task five yielded both a high absolute number of errors (903) and error density, with 0.85 errors per minute. One-hundred and forty nine of these errors pertained to poor camera views, and 177 to non-error events. Of the non-error events, 73 described preparatory steps (50 of these to improve traction), and 41 to beneficial techniques (38 of these type 1, management of difficult planes).

One-hundred and ninety four recovery events were observed, 3 of which were of type 5 (change in subtask or sequence). Two of the type 5 recoveries were extension of the wound to access the splenic flexure; one was a repair of a colonic serosal defect. The remainder of recovery events were of type 4 or lower, 92 of which described managing bleeding from small vessels.

The number of error events observed was 726, 93 of which were of the combination EEM 6 (step is done in wrong direction), TTE 9 (diathermy in wrong area / tissue plane), and Consequence 10 (incorrect dissection plane). In 35 cases, dissection strayed into greater omentum, with delays and increased bleeding; in 12 instances dissection entered fat around the colon, with associated risk of devascularisation or injury to colon; twice entry into retroperitoneal fat was observed, and in 21 cases it was not clear which incorrect plane was entered.

Consequent to entry into incorrect planes, the combination of EEM 6, TTE 9 and Consequence 2 (bleeding from small vessels) was observed 24 times, and usually arose from vessels in the greater omenutm. In an additional 16 cases, a note of Consequence 2 alone was made, and often reflected bleeding arising from a preceding combination of EEM6 / TTE 9.

The combination of EEM 4 (step is done with too much), TTE 7 (avulsion of tissue) and consequence 2 (bleeding from small vessels) was recorded 10 times, and was due to excessive traction on tissues. In one instance the avulsion occurred due to contraction of tissues during diathermy, and failure to relieve tension to allow for this contraction.

Failure to adjust hold to separate structures (EEM 1, failure type 3) was noted 20 times, 8 of which were without consequence, but 12 times were associated with risk of injury to viscus encroaching upon the operating field or other consequence (consequences 17 and 15).

EEM 7 (step done on / with wrong object) and TTE 12 (instrument error) occurred five times, all of which represented problems encountered with new diathermy systems or settings, four of which resulted in bleeding from small vessels (consequence 2).

Other errors observed included EEM 2, TTE 11 and Consequence 17 (Risk of diathermy arc to suction), and Consequence 16 (Risk of bleeding from pack to spleen). There were many other single errors.

4.5.6 Task 6 – Ligation of vessels

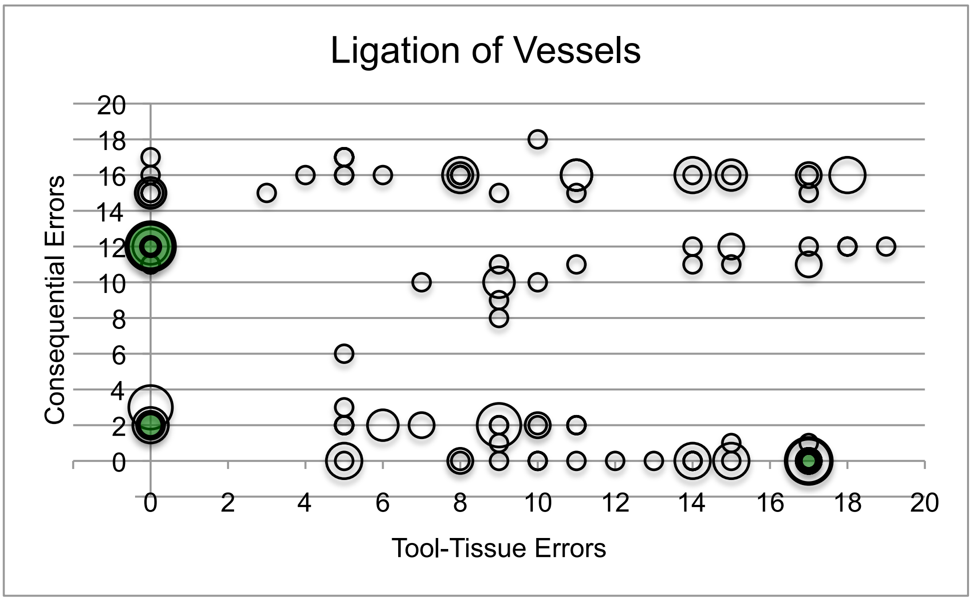


Figure 17 – TTE's vs Consequences in Task 6, Ligation of Vessels. See page 70 for explanation.

A total of 448 events were observed in task 6, with an error-density of 0.67 errors per minute. Poor camera views accounted for 58 events, non-error events for 127, and isolated recovery events for 72. Two of the recovery events were of type 5, i.e. a change of subtask: one of these was the repair of a serosal defect; the other was to divide vessels more distally due to potential compromise of blood supply earlier in the procedure. The remainder of recovery events were of type 4 or less, the majority of which were directed at arresting small bleeding vessels.

Ninety-eight error events were identified. Although few of these events were identical, some patterns of errors were evident. Error event EEM 6 (step is done in wrong direction), TTE 9 (diathermy in wrong area / tissue plane), and Consequence 2 (bleeding from small vessels) was observed 6 times. 'Failure' was a component of 17 error events, 13 of which were related to failure to institute adequate retraction in task 3. In most instances, this simply required re-packing, but in 6 cases it was associated with a consequence such as risk of diathermy injury to bowel, bleeding from vessels or injury to nerves around the origin of the IMA.

The combination of EEM 5 (step is done with too little) and TTE 15 (Suture / tie poorly tied) was observed 8 times, 6 of which were due to inadequate tension during ligation of a vessel, with associated risk of slippage of the tie and bleeding from the vessel. Fourteen instances of TTE type 17 (inter-step error) were detected, 5 of which involved incomplete dissection of the inferior mesenteric vessels from their surrounding fat. In 3 of the Errors of type 17, the vessels were not ligated prior to proceeding with dissection, which does not allow adequate assessment of the vascularity of the colon.

On 9 occasions TTE type 5 (inappropriate diathermy) was witnessed, including arcing of current to other instruments, activation close to bowel, and usage in the wrong mode. The only consequence observed in this situation was bleeding from small vessels, although the chance of occult injury was high.

4.5.7 Task 7 – Division of sigmoid colon

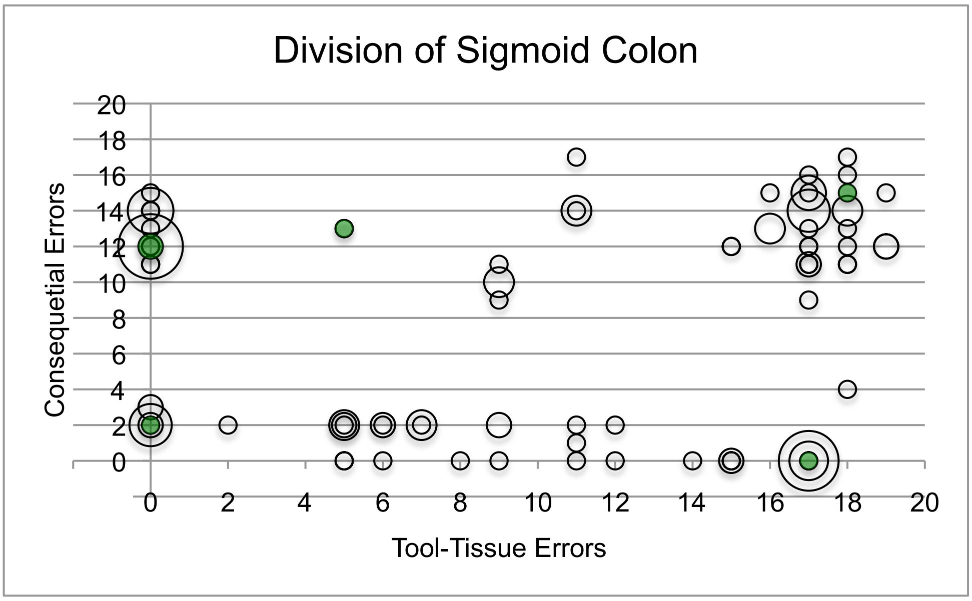


Figure 18 – TTE’s vs Consequences in Task 7, Division of Sigmoid Colon. See page 70 for explanation.

A total of 356 events were identified in Task 7, with a density of 0.49 events per minute. Only 21 of these described poor camera views, as division of the colon is a manoeuvre performed in the centre of the wound, and often above the wound, and is easily seen on all cameras: the average time spent off-camera in task 7 was 0.8%. One-hundred and twenty six non-error events were documented: 48 preparatory steps, and 75 observations on technique. Twenty-seven of the preparation events were of type 4 (search for structure to dissect), often characterised by careful palpation of the sigmoid mesocolon for vessels. Twenty-four of the techniques were of type 8 (safety check), most of which were either to leave the purse-string on the anvil long (to allow confirmation of firing of the anastomosis stapler) or temporary release of the clamp on the proximal end of the marginal artery (to check for adequacy of perfusion). However, in many of these cases, task 7 had been deferred until after task 8, and therefore omitted a better test of vascularity: appearance of the distal colon after division. Technique type 6 (reduce risk of infection) accounted for 18 of the events observed, and usually took one of two forms: applying a betadine swab to the cut end of colon, or draping packs over the other viscera during division of the bowel. Other techniques observed included wrapping a sterile glove around the distal end of colon prior to proceeding to task 8; massaging air from proximal to distal colon to enable manipulation of the anvil; and tucking a pack to the left side of the root of the colon to protect retroperitoneal structures.

Thirty-two recovery events were recorded, all of type 4 or less. Of these events, 26 concerned managing vessels or bleeding areas, typically by applying diathermy or a haemostat.

Two hundred and thirty error events were identified, no individual combination being identified more than 9 times. However, TTE type 17 (inter-step error) was observed 27 times, 24 of which was either with EEM 1 (step is not done) or EEM 3 (step is done late). All of those with EEM 3 (10 times) represented performing task 7 after task 8. Five of those with EEM 1 denoted failure to apply a bowel clamp to open colon, with associated risk of infection (consequence 14) or tumour spillage (consequence 11). In 6 instances, the inferior mesenteric vessels were not tied prior to commencing mesocolic division, with a risk of transecting the vessels distal to their origin.

Other error events included excess handling of cut bowel (EEM 2, TTE 18, Consequence 11), and failure to change gloves or instruments after handling the cut bowel (EEM 1 or 7, TTE 18, Consequence 11 or 14).

4.5.8 Task 8 – Rectal dissection

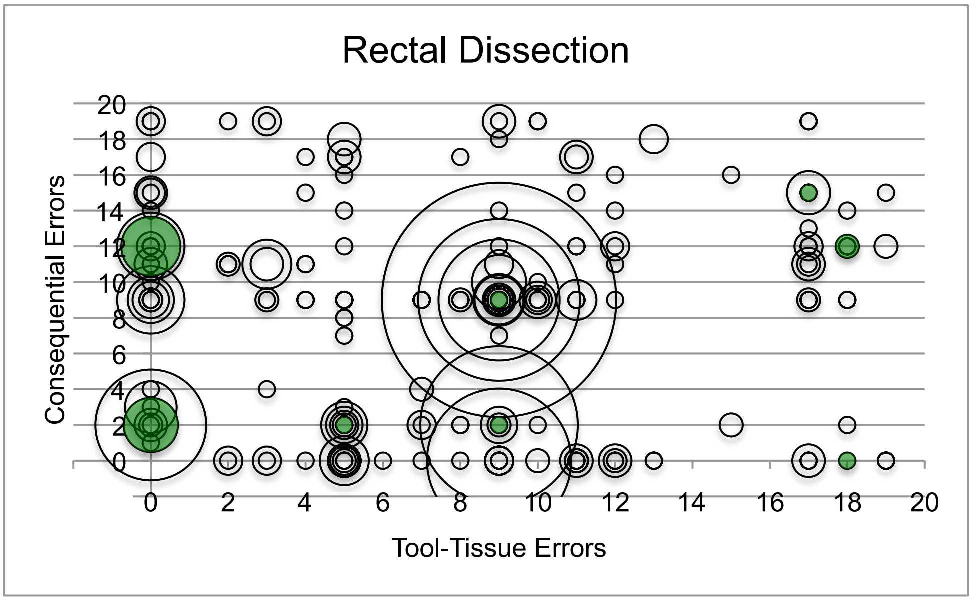


Figure 19 – TTE's vs Consequences in Task 8, Rectal Dissection. See page 70 for explanation.

Task 8 contained the highest event count (2,615) and event density (1.31 events per minute) of any task. Non-error events accounted for 369 of these, recovery events for 396, poor camera views for 650, and error events for 2246. Of the 369 non-error events, there were 231 preparatory steps (93 of which were of type 2, adjust hold to improve traction) and 62 observations on technique (49 of which were type 1, management of difficult planes).

Of the 179 Preparation type 2 events (adjust hold to improve traction), the instruments used in achieving traction were St. Mark's retractor (32), hand alone (28), hand with swab (25), other retractor (8), suction (7), De Bakey's forceps (5), not specified (29). Additional techniques employed to aid dissection (Technique type 1) included use of St. Mark's retractor not only to expose but also to develop planes; use of a pledget to sweep tissues aside; angling the tip of the diathermy, and extending the peritoneal incisions to facilitate traction around the rectum.

The most frequently observed error event was EEM 6 (step is done wrong orientation), TTE 9 (diathermy in wrong tissue planes) and Consequence 9 (mesorectal injury), which was observed 394 times. One-hundred and seventy five of these events were classified further into depth of mesorectal injury: 60 were fascial, 102 into fat, 9 to rectal adventitia, and 3 into rectal muscle. As subtasks 1 to 4 corresponded to dissection in posterior / left lateral / right lateral and anterior planes, it was possible to identify where these errors occurred. There were 50 errors in the posterior quadrant, 83 in the left lateral, 98 in the right lateral, and 155 in the anterior quadrant. There were 5 occurrences of this error combination in subtask 6, all associated with transection of the mesorectum at a level that was too high.

Mesorectal injury was observed an additional 98 times: 17 of these were with EEM 6 (6 with TTE 11 (use of other instrument), and the remainder with TTE's 1, 5 and 10). Forty-seven instances with other EEM's were noted: there were 17 in which no EEM or Error was entered, often when a consequence followed soon after a recent error event. Consequence 9 occurred with TTE 9, but without EEM 6 a total of 15 times: with EEM 1, this reflected either a failure to apply suction, or to apply optimal traction; with EEM 4 (step not done) this was due to excess force with the diathermy, so that the tip proceeded beyond the intended target; with EEM 5 (step is done with too little), this was always associated with inadequate force being applied to a retractor; when with EEM 7 (step is done on / with wrong object), this was often due to use of an incorrect retractor, but was also observed with incorrect settings of the diathermy, and with failure to protect the bowel during traction, which led to tearing of the mesorectal fat.

4.5.9 Task 9 in Anterior Resection – Transection of the Rectum

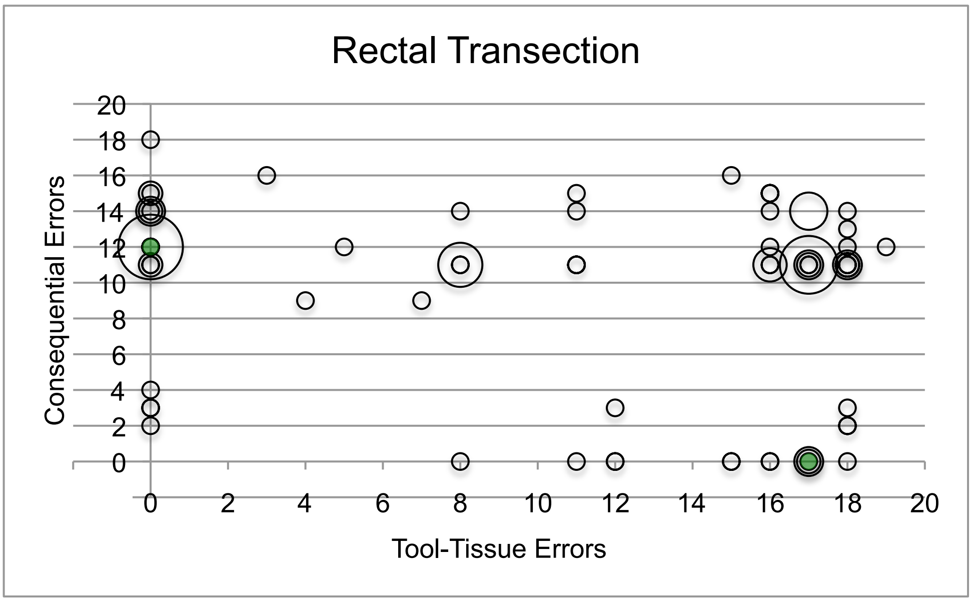


Figure 20 – TTE's vs Consequences in Task 9 in AR, Rectal Transection. See page 70 for explanation.

At Task 9, the task analysis for anterior resection and abdomino-perineal resection diverges to describe rectal transection or perineal dissection respectively. Rectal transection contained 233 events, with an average of 4.6 events per procedure, and an event density of 0.69 events per minute. These events were composed of 41 non-error events, 42 isolated recovery episodes, 18 recordings of poor camera views and 192 error events.

The 41 non-error events included the use of a Betadine swab behind the rectum during transection (Techniques type 5 and 6); packing fluffed swabs to the pelvis (Technique type 2), and manoeuvres to manipulate the stapling gun into position (Technique type 9). The 42 recovery events included optimising retraction (Recovery type 2), the use of Betadine washout to manage potential pelvic contaminations (Recovery types 3 and 4), and excision of rectal remnant (Recovery type 5).

Few error events were replicated identically, but certain patterns of error were evident: approximately half of the errors included TTE types 16 to 18 (error in use of stapling device, inter-step error and other type of error). TTE 16 included use of wrong size of stapler; failure to advance stapler down rectum; and failing to check that the stapler completely encircled rectum or was free of other structures. Twenty-four inter-step errors were observed, 14 of which were with EEM 1 (step not done). These comprised failure to perform washout, failure to apply 2nd stapler or clamping device, and failure to change gloves after handling the transected bowel. TTE type 18 (other) described a miscellaneous group of errors ranging from excess handling of transected bowel to transection of rectum at wrong level, most of which were associated with consequence 11 (compromise other oncological outcome).

4.5.10 Task 9 in APER – Perineal dissection

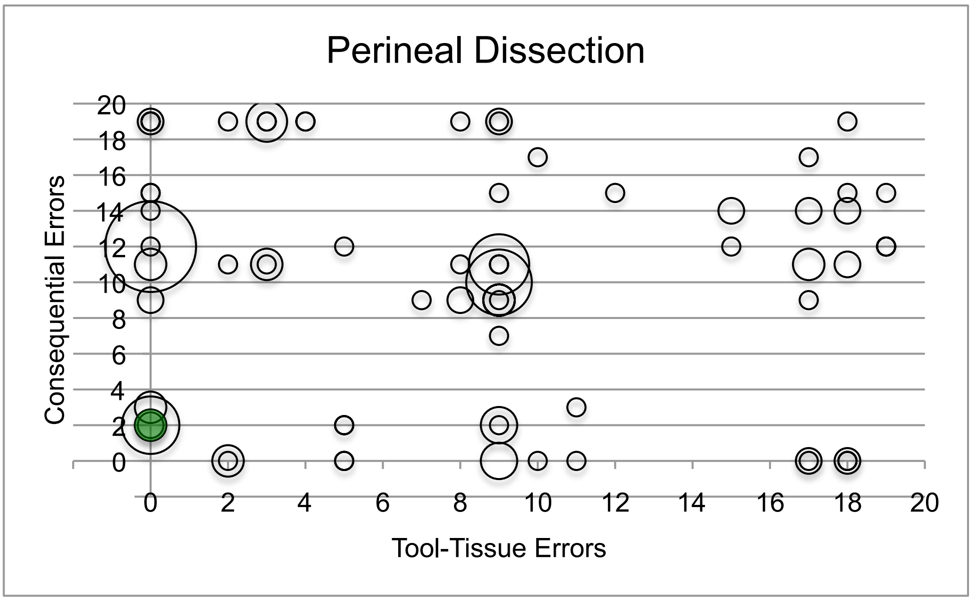


Figure 21 – TTE's vs Consequences in Task 9 in APER, Perineal Dissection. See page 70 for explanation.

There were a total of 430 events during perineal dissection, an average count of 33.08 events per procedure, and an event density of 0.85 events per minute. These consisted of 110 non-error events, 55 recovery events, 71 poor camera views, and 320 error events. Of the 110 non-error events, 61 described helpful techniques employed by individual surgeons. Thirty-four of these concerned Technique type 1 (management of difficult planes), which reflects the difficulties and uncertainties encountered during perineal dissection. As there are no planes comparable to those of peri-rectal dissection, it is necessary to develop other means of determining landmarks and position, including careful marking of skin prior to dissection, directing diathermy towards coccyx, palpation in the vagina, and the use of deep tissue retractors. The remainder of the non-error events described preparatory steps, such as good use of retraction (types 1 and 2) and careful palpation for urethra (type 5).

The 320 errors observed were evenly distributed around most of the EEM and TTE categories, although there was a clustering of events with the combination of EEM 6 (step is done in wrong orientation) and TTE 9 (Diathermy in wrong tissue planes) that accounted for 50 events. Twenty-eight of these were due to dissection too close to the anal canal or rectum, such that the fat was stripped from around the anorectum, giving no protection from locally invasive tumour. In two instances, this error combination led to bleeding from or entry into the vagina. TTE type 9 was observed in an additional two instances: EEM 1 (step is not done), in which blood was not cleared away to enable visualisation of the target, and EEM 5 (step is done with too little), in which the traction applied was insufficient to open the tissue planes.

4.5.11 Task 10 in Anterior Resection – Preparation of colon for anastomosis

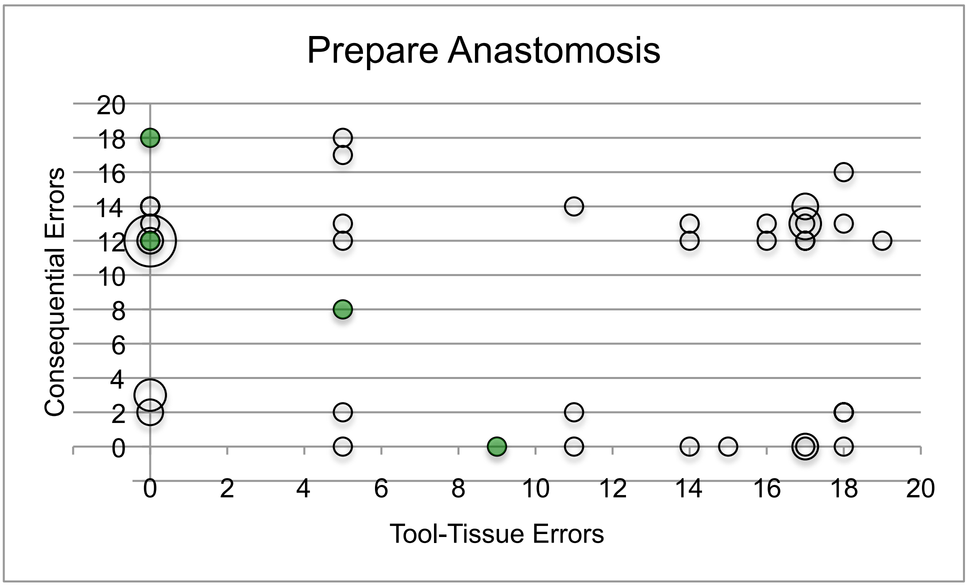


Figure 22 – TTE's vs Consequences in Task 10 in AR, Preparation for Anastomosis. See page 70 for explanation.

Task 10 took an average of approximately 6 minutes to complete, and contained a total of 161 events, resulting in an event density of 0.46 events per minute. Of these, 37 were non-error events, 45 were recovery events and 23 denoted poor views; only 124 were error events, and the error density for this task was only 0.32 errors per minute. The majority of non-error events were similar to those in task 9, and concerned the use of Betadine swabs or packs to minimise the risk of infection (Technique 6) or improving visualisation through traction (Preparation 1).

Of the 124 errors recorded, no EEM / TTE combinations were noted more than twice, although TTE 5 (inappropriate diathermy) was found 7 times, including diathermy close to a nerve or bowel, contact with a pack overlying bowel, or activation of diathermy without contact.

4.5.12 Task 10 in APER – Closure of perineum

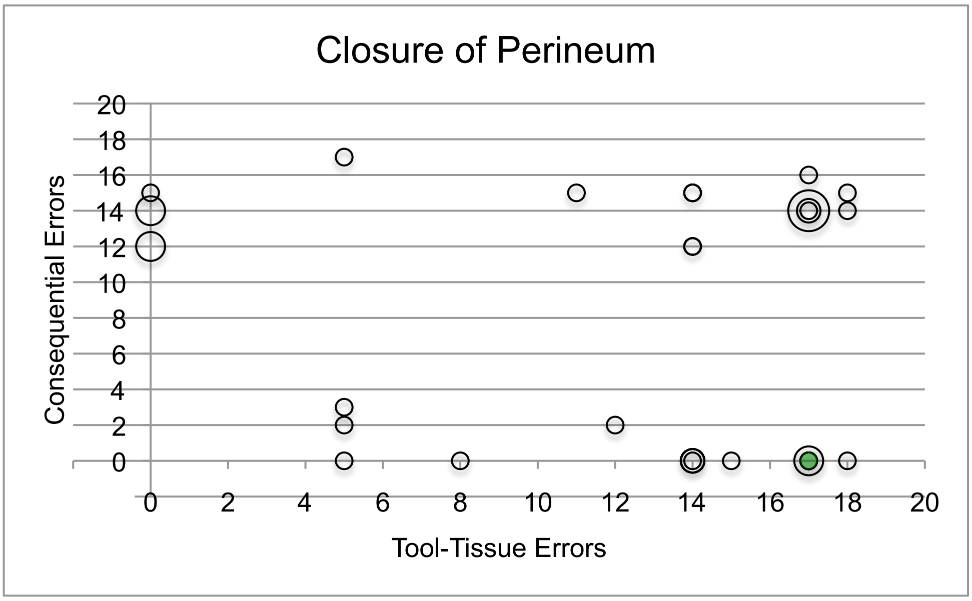


Figure 23 – TTE's vs Consequences in Task 10 in APER, Closure of Perineum. See page 70 for explanation.

Closure of perineum was performed in an average of less than 17 minutes, and held a total of 92 events, with an event density of 0.42 events per minute. Non-error events accounted for 13 of these, recovery events for 14, and poor views for 17, with 79 error events observed. Sixteen of the error events incorporated TTE 17 (inter-step error), and were associated with either failure to perform (or delay of) wash of perineal wound, or closure of perineal skin with the risk of preventing drainage of wound (EEM 2, Consequence 14). TTE type 14 (suture poorly placed) was noted 11 times, due to variation in techniques of closure, such as a continuous suture to levator ani, wide spacing of sutures, or mattress closure to wound; none of these were associated with observed consequences.

4.5.13 Task 11 in Anterior Resection – Anastomosis

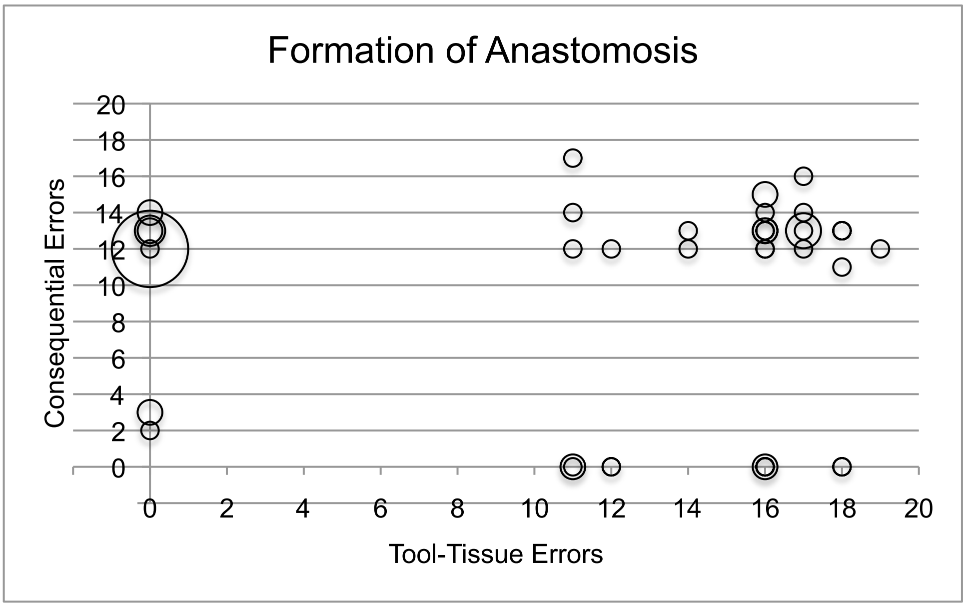


Figure 24 – TTE's vs Consequences in Task 11 in AR, Formation of Anastomosis. See page 70 for explanation.

Formation of the anastomosis was completed in 42 of the 48 anterior resections recorded; in the remaining 6, a colostomy or end ileostomy was fashioned. In the 42 procedures in which an anastomosis was made, the task lasted an average of 12 minutes, contained 3.8 events, with an event density of 0.3 events per minute. Of the 158 events observed, there were 32 non-error events, 19 recoveries, 23 episodes of poor camera view, and 124 errors.

The techniques included measures to reduce the risk of infection (washout of pelvis with antibiotics, and Betadine-soaked swab under anastomosis), and to assist in the insertion of the stapling gun (rectal examination or mounted swab to determine direction and length of rectal stump).

Most of the preparatory measures were of type 3 (adjust hold to separate structures) and 5 (search for structure to avoid), and consisted of manoeuvres to ensure no material was trapped in the stapler during the anastomosis.

4.5.14 Task 12 in Anterior Resection – Formation of Ileostomy / Colostomy Part I

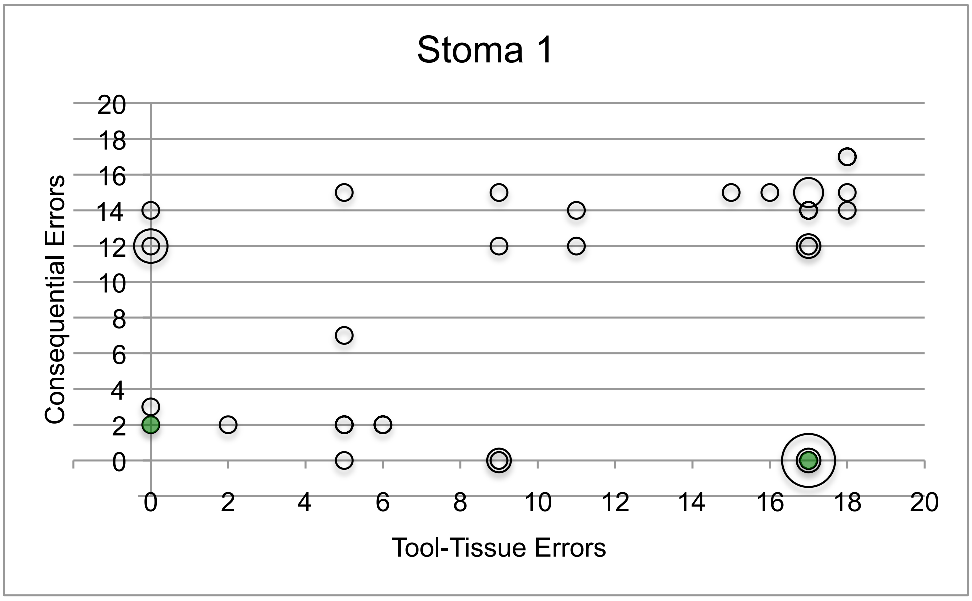


Figure 25 – TTE's vs Consequences in Task 12 in AR and Task 11 in APER, Formation of Stoma, Part I. See page 70 for explanation.

Due to the similarities in Task 12 of anterior resection and task 11 of APER (formation of colostomy I), the two will be considered together in this section. A stoma was formed in all of the APER's and in 26 of the 48 anterior resections. Both took an average of approximately 6 minutes, with a total event count of 146, and an event density of 0.64 events per minute. Of these, there were 46 non-error events, 25 recovery events, 22 episodes of poor camera view, and 100 errors.

The non-error events included measures to reduce infection (changing gloves prior to proceeding, or packing the stoma site with a Betadine swab); measures to reduce the risk of injury (the use of anti-adhesive products, or manipulating the bowel with a catheter), and preparatory measures 4 (search for structure to dissect) and 5 (search for structure to avoid) during manipulation and dissection of the stoma site.

Recovery measures were aimed either at arresting bleeding vessels (types 3, 4 and 5) or to enlarging the stoma site. This was scored as recovery type 3 (requires repetition of step) when performed during the skin incision, but as type 6 (change in major task or sequence) when it required the surgeon return to task 12 from another task.

Of the 100 error events, 22 concerned TTE type 17 (inter-step error), often due to failure to mark ileum prior to exteriorisation, but also associated with un-necessary resection of colon, which resulted in the need for additional mobilisation. TTE type 9 (diathermy in wrong tissue planes) was observed 4 times in association with EEM 5 (step is done with too little), when making the stoma site too narrow or too shallow, and once with EEM 6 (step is done in wrong orientation), when the stoma was placed too close to the inferior epigastric vessels.

4.5.15 Task 13 in Anterior Resection – Closure of abdomen

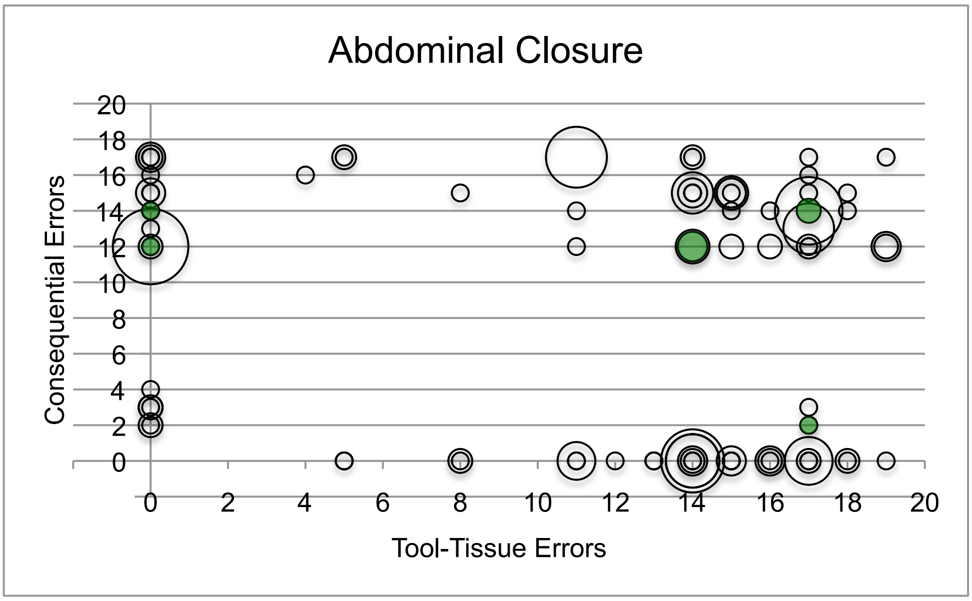


Figure 26 – TTE's vs Consequences in Task 13 in AR and Task 12 in APER, Closure of Abdomen. See page 70 for explanation.

Closure of the abdomen is labelled as Task 13 in anterior resection, but as Task 12 in APER. As above, the similarities between these tasks justify a combined analysis. Abdominal closure took an average of 28 minutes to complete, with a total of 343 events identified and a mean error density of 0.27 errors per minute. Of these, 102 were non-error events, 33 were recovery events, 44 were recordings of poor camera view and 164 denoted error events. Common techniques employed included the use of a plastic insert during suturing of the wound, to protect the viscera from injury, and haemostats applied to fascial edges to assist placement of sutures. Preparation types 5 and 3 were associated with the use of hand or other instrument to separate the wound from the underlying viscera during abdominal closure, in order to avoid inadvertent injury.

Few error combinations were repeated exactly, although TTE types 14, 15 and 17 accounted for 88 of the error events observed. TTE type 14 (suture / tie poorly-placed) was observed 48 times: with EEM 6 (step is done in wrong orientation) to indicate incorrect placement associated with puckering of skin or taking bites of muscle in addition to fascia; with EEM 1 (step is not done) when viscera not protected during suturing or failure to check that wound completely closed; with EEM 3 (step is done late) when drain secured after dressing had been applied, or when subcuticular suture could not be tightened due to being left slack for too long; or with EEM 5 (step is done with too little) when bites taken of tissue were too small.

TTE type 17 (inter-step error) was observed in a variety of situations: with EEM 1 when the wound had not been cleaned prior to closure, or when no covering stoma had been placed, sometimes in the presence of a demonstrated anastomotic leak. TTE type 17 was also recorded with EEM 2 (when the retraction system was dismantled before access to abdomen was completed) and EEM 3 (associated with failure to secure haemostasis, or to check swab counts).

4.5.16 Task 14 in Anterior Resection – Completion of ileostomy

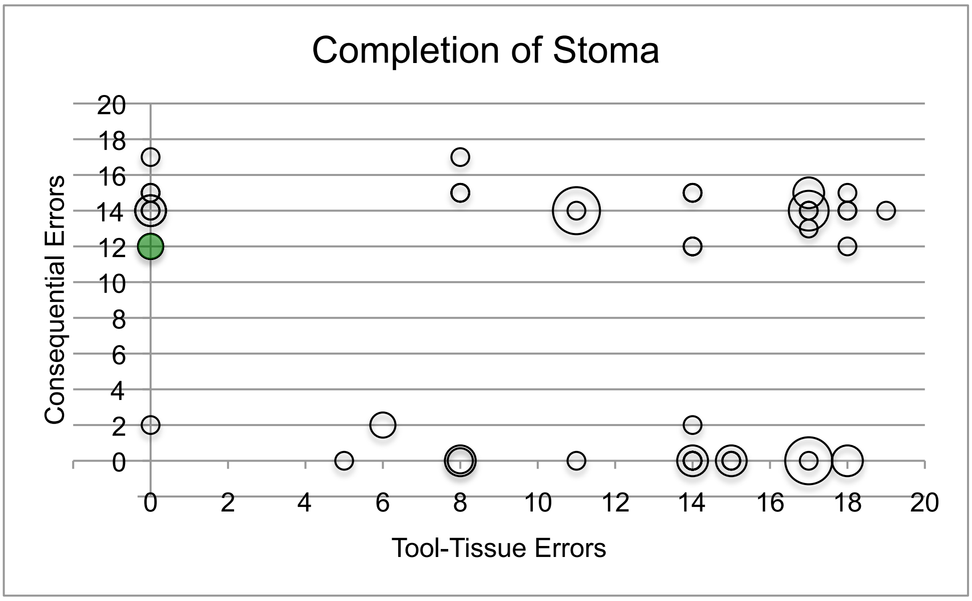


Figure 27 – TTE's vs Consequences in Task 14 in AR and Task 13 in APER, Completion of Stoma. See page 70 for explanation.

Once again, this shall be considered with Task 13 of APER (completion of colostomy) due to the similarities between the tasks. Completion of ileostomy / colostomy took an average of 11 minutes to complete, during which time a total of 85 events were observed. Fifteen of these were non-error events, 12 were recovery events, and only 1 was due to poor camera view, as this was a task performed entirely on the surface of the abdomen, and more amenable to visual access.

Of the 57 error events, TTE type 14 (suture / tie poorly placed) was recorded a total of 14 times, associated with failure to place sutures in correct sequence, with resulting formation of poor stoma. Other errors included inappropriate grasping of the stoma with Babcock's forceps (TTE type 8), failure to prepare suction at time of bowel incision (EEM1, TTE 11, Consequence 14), and failure to apply stoma bag, with associated risk of infection (TTE 17, Consequence 14).

4.6 Consequences of Errors

The consequences will be examined according to the codes assigned to them, from 1 to 19 (as per table 5), firstly throughout the procedure, and – where applicable – to individual tasks. For each consequence, patterns of preceding events shall be sought.

4.6.1 Global frequency of consequences

Consequence 1 (Bleeding from major vessel) was only encountered in 10 instances across 9 procedures. There was little duplication of tool-tissue errors that led to this consequence, as it was observed following diathermy, avulsion, poor placement or tying of sutures, and in the use of other instruments.

The second category of consequence (Bleeding from small vessels) was identified 522 times. The most frequently-specified error resulting in bleeding from small vessels was diathermy in wrong tissue planes (171 instances), followed by inappropriate diathermy (65 instances). Inappropriate use of sharp dissection (20) and sharp dissection in wrong tissue planes (20), although a less common cause of bleeding, are disproportionately represented, given their infrequent use during these procedures, reflecting the fact that diathermy seals vessels at the same time as division of tissue. Avulsion of tissue was the cause of bleeding in 33 instances. All other types of error occurred less than 10 times each.

The third type of consequence (bleeding from an unidentified source) occurred 67 times. In 46 cases, this was an isolated entry, indicating that no causative action was associated with that observation. In some instances this was due to temporal separation (i.e. the precipitating action had been performed some time earlier) and in others the cause could not be identified because the source of bleeding had not yet been identified. Nonetheless, on 21 occasions a contributing factor was identified, including failure to search for a structure to dissect or ligate (7 times), inappropriate diathermy (3 times) and inter-step error (2 times).

Consequence type 4 (perforation of / injury to viscus) was noted a total of 12 times. These injuries included devascularisation of the left colon, dissection into seminal vesicles, and a number of serosal injuries to small and large bowel caused by diathermy.

The fifth type of consequence (bleeding from viscus) was not noted in any instances. This is because wherever possible an attempt was made to identify the type of vessel from which bleeding occurred, and was thus categorised as either consequence type 1 or 2.

Consequence type 6 (diathermy burn to viscus) occurred in 12 instances. This category shares significant overlap with consequence type 4, but tended to represent isolated burn injuries without additional mechanisms of injury. Of the 12 cases, 7 were due to inappropriate diathermy, and 5 to diathermy in incorrect tissue planes. Interestingly, none were due to TTE type 2 (non-visualisation of instrument tip), but this is most likely because since the instrument tip was not visualised on camera, then neither could the consequence be observed.

Consequence type 7 (diathermy burn to other structure) occurred 16 times, and demonstrated a similar association with errors type 9 (diathermy in wrong tissue planes) and type 5 (inappropriate use of diathermy). All such instances of ‘inappropriate diathermy’ involved the application of diathermy to other organs (for example diaphragm or greater omentum) through failure to secure control of tissues or instruments (e.g. failing to secure tissues in retraction), or through unobserved contact of diathermy with a second tissue area. In some instances it was noted that use of insulated forceps would have prevented the injury.

The eighth category of consequence (injury to nerve) was observed only four times. In addition, the risk of nerve injury (consequence 18) was recorded 12 times. The actions related to nerve injury included inappropriate use of diathermy (8 cases), diathermy in wrong tissue planes (2 cases) and overshooting of instrument tip (3 cases).

Mesorectal injury is the 9th category of consequence, and one of the most frequently observed, having been recorded 292 times. Nearly all of these (251) were associated with TTE type 9 (diathermy in wrong tissue planes), a relationship that will be explored more fully in section 4.6.9. On the other hand, the risk of mesorectal injury (consequence 19) was related to a diverse range of errors, including non-visualisation of instrument tip during sharp dissection (9 instances), non-visualisation of instrument tip during diathermy or other action (4 instances) and inappropriate grasping of tissues (2 instances).

The tenth type of consequence is incorrect dissection plane, and represents a similar type of dissection injury to ‘mesorectal injury’, but outwith the pelvis. The associated errors are therefore similar to those identified with mesorectal injury, and the 207 occurrences are predominated by errors of diathermy in wrong tissue planes (174 times) and sharp dissection in wrong tissue planes (15 times).

Consequence type 11 (compromise other oncological principle) is another diverse category, with 168 events spread over 5 main types of error: non-visualisation of instrument tip during sharp dissection (19 times), inappropriate grasping / blunt handling of tissue (14 times), diathermy in wrong tissue planes (23 times), suture poorly-placed (11 times), and inter-step error (38 times). The remainder of error types included errors in the handling of contaminated or tumour-related tissue (6 times), and transection of rectum too close to tumour (3 times).

Consequence 12 (delay in procedure) occurred 405 times, 181 of which were recorded as isolated events, i.e. without accompanying EEM or other TTE types. The majority of these errors were due to periods of waiting for additional materials such as sutures or instruments. The remainder of the causes of delays are sufficiently diverse to warrant a separate review for each task in the procedure (see sections 4.6.2 – 4.6.10).

The remainder of categories of consequence pertained to *risks* of events rather than observed consequences. Categories 18 (risk of nerve injury) and 19 (risk of mesorectal injury) have already been discussed. Consequence 13 (risk of anastomotic leak) was identified 59 times, 21 of which pertained to inter-step errors, in particular the failure to fashion a covering stoma (11 instances), to strip colonic fat from around anvil (4 instances), or to evaluate the anastomosis or ‘donuts’ from anastomotic stapler (1 instance).

Consequence type 14 (risk of infection) shares some overlap with consequence 11 (compromise other oncological principle). It was observed 129 times, 39 of which were recorded as isolated events, often because the associated EEM / TTE types had already been recorded with consequence 11. The TTE types most frequently associated were errors in use of other instrument (17 occurrences) and inter-step errors (48 occurrences). Of these inter-step errors, 22 described failure to clean the wound prior to closure, 9 pertained to failure to apply bowel clamps to open bowel, 4 to failure to protect wound by covering stoma with bag, and 3 to failure to perform washout of pelvis with saline.

Consequence 16 (risk of bleeding) was documented 73 times, and was associated with almost every TTE type. These included inappropriate grasping / blunt handling of tissues (14 instances), non-visualisation of instrument tip (10 instances), sutures poorly-placed or poorly tied (10 instances), and inappropriate diathermy (5 instances).

4.6.2 Consequential errors in Task 1 (Incision)

Fifty-six consequential errors were identified in task 1, 28 of which described bleeding from minor vessels. The causes of bleeding most frequently identified was diathermy (8 instances) and sharp dissection (3 instances), associated with 3 categories of EEM: step is not done (e.g. failure to coagulate a vessel before dividing); step is done with too much (e.g. dissection too deep, injuring concealed vessel); and step is done on / with wrong object (e.g. incision made with blade rather than with diathermy). Additional causes of bleeding during incision included failure of new diathermy machine to coagulate (2 instances).

Injury to a viscus or other structure was observed 5 times during task 1. On 2 occasions this was involved diathermy burn to small bowel as a consequence of using diathermy to incise the peritoneum. Risk of similar injury was observed 8 times, although on these occasions no actual injury resulted. In one instance haemostats that were used to lift the peritoneum grasped too much tissue, resulting in a crush injury to small bowel.

4.6.3 Consequential errors in Task 2 (Laparotomy)

Of the 76 errors recorded in task 2 (laparotomy) only 16 were consequential, reflecting the observational nature of the task. Six of these described delays in the procedure, including non-surgical errors such as waiting for instruments to be provided. Other causes of delays included poor packing of small bowel, necessitating repetition of packing several times; inappropriate use of surgical materials (for example wrong size of drape) led to ineffective use of both time and resources.

In 4 instances, Task 2 was not fully performed, or was omitted altogether. In the latter instances, this was recorded as an error within Task 3, since there was no Task 2 within which to code the error. In one instance in which laparotomy revealed advanced metastatic disease, no wound protection was applied, exposing the patient to high risk of wound metastasis.

Injuries observed during Task 2 included bleeding from small vessels through failure to identify and control blood vessels during exploration of the abdomen (2 instances). In addition, excessive traction applied to the left upper quadrant risked an avulsion injury to the spleen (1 instance). The remaining category of consequence, 'Other' was utilised 4 times: 3 of these described errors in extension of the wound, and the 4th described an error in performing sigmoidoscopy. The wound extension errors were failure to make use of the full length of the wound; unnecessary extension of the wound to xiphoid; and ragged wound extension. Sigmoidoscopy was performed as part of a separate study, and because no bowel clamps were applied, colonic insufflation impeded intra-operative control of the colon.

4.6.4 Consequential Errors in Task 3 (Establishing retraction)

The most frequently observed error relating to placement of the retraction system was failure to place a system adequately or at all (49 instances in 17 procedures). These errors were rarely identified within Task 3 itself, either because no retraction system was placed (and therefore there was no Task 3 within which to record the error), or because the consequences impacted upon subsequent tasks. Although failure to establish good retraction does not directly lead to tissue damage, its contribution to significant errors should not be underestimated. Its impact may be demonstrated through the frequent combination of EEM (step not done) with failure types 1 or 3 (adjust hold to improve visualisation / adjust hold to separate structures). Of 273 such combinations, 168 were associated with consequences: 65 delays in procedure, often to revise suboptimal retraction; 26 ‘other’ consequences, typically describing difficulty in access and dissection due to lack of retraction; 24 episodes of risk of injury to viscus, and 3 actual injuries, as bowel encroached upon the field of dissection; 23 episodes of compromised oncological principle or risk of mesorectal injury, most often reflecting low rectal dissection being performed blindly.

Despite placement of a retraction system, small bowel was often poorly controlled, with attempts to drape packs over small bowel rather than tuck it securely to the right upper quadrant. Such measures were often ineffective and required multiple repetitions, as well causing delays in the procedure, and the associated risks described above (38 occasions).

4.6.5 Consequential Errors in Task 4 (Mobilisation of left colon)

In task 4, 170 consequential errors were recorded. The most frequent of these was bleeding from small vessels (62 cases). Twenty of these were recorded without any associated aetiological factors, often because the bleeding would often follow another error, but not occur simultaneously. Of the identified causes of bleeding, diathermy in wrong tissue planes was recorded most frequently (18 times), followed by avulsion of tissue (9 times), and then inappropriate diathermy with tip visualised (8 times).

Incorrect dissection plane was the identified consequence in 54 instances, 40 of which were due to diathermy in wrong planes, and 7 due to sharp dissection in incorrect tissue planes. This ratio may reflect not that diathermy is more likely to cause such an error, but to the more frequent use of diathermy as the primary dissection tool in this task.

Delay in the procedure was recorded 22 times in task 4, 11 of which were due to re-packing of small bowel to the right upper quadrant, which in turn was due to failure to adequately pack the small bowel during task 3. Other causes of delay included inefficient dissection technique (either abandoning a plane too soon, or persevering too long in a difficult plane), ineffective methods of retraction (failure to use a swab to grasp bowel), or difficulties in use of the assistant, either through poor communication, or because an assistant was absent for this task.

Ten instances of 'risk of injury to viscus' were recorded in task 4, 5 of which pertained to retroperitoneal structures. These errors included inappropriate handling of the ureter with forceps, and the application of diathermy close to ureter or gonadal vessels without first ensuring their safety. Unsafe use of diathermy was often related to attempts to arrest bleeding from small vessels: the surgeon would apply diathermy via a pair of forceps to a bleeding point without ensuring that vulnerable structures were not at risk. In another instance, the surgical assistant picked up the ureter in a pair of forceps, in a motion which the scrub nurse interpreted as requesting diathermy to be applied to the forceps holding the ureter. Fortunately this misunderstanding was corrected before any current was delivered to the ureter.

Failure to install adequate retraction also impacted upon task 4: failure to control abdominal viscera resulted in encroachment upon the operating field, and inadvertent diathermy injury to the greater omentum on one occasion, and 2 further instances of risk of injury to uncontrolled bowel.

4.6.6 Consequential Errors in Task 5 (Mobilisation of splenic flexure)

The consequence most frequently observed in task 5 was haemorrhage, which was observed in 108 instances. Ninety-eight of these recorded bleeding from small vessels, 9 from an unidentified source, and one from a large vessel. The procedure leading up to the latter event contained frequent episodes of poor camera views, and therefore the cause of the haemorrhage is difficult to ascertain. Nonetheless, it appears that the dissection plane strayed posteriorly near the left kidney; upon attempting to recover the correct plane, the assistant surgeon applied too much traction, avulsing the left gonadal vein. This was managed through the application of a Satinsky clamp, and suturing with 4/0 Prolene.

Of the 98 episodes of bleeding from small vessels, 31 were due to diathermy in incorrect planes; 12 were due to inappropriate use of diathermy; and 30 were not associated with any tool-tissue error. The explanation for the latter is that the bleeding was due to a preceding error, but occurred shortly afterwards, and therefore the association with the error cannot be extracted from the dataset. Other causes of bleeding from small vessels included sharp dissection in incorrect planes (5 instances), inappropriate use of sharp dissection (4 instances), and avulsion of tissue (12 instances). In all instances, avulsion of small vessels was caused by excess traction or counter-traction being applied, resulting in bleeding from mesocolon, retroperitoneal vessels, or greater omentum.

Diathermy injury to bowel and other organs was observed 11 times in task 5. In 4 cases this was simply due to failure to define the correct plane during dissection. In the remainder, unsafe use of diathermy resulted in injury: activation of diathermy whilst adjusting the grip; failure to move adjacent bowel out of the operating field; inadequate traction to adjacent structures; and overshooting of the diathermy tip.

Splenectomy was required in two operations – these are discussed within the context of Task 15, 'Additional Procedure'.

4.6.7 Consequential Errors in Task 6 (Division of inferior mesenteric vessels)

One hundred and thirty consequential events were described in task 6, the most frequent of which was the risk of bleeding (35 instances). Eleven of these were due to division of the inferior mesenteric vein between clamps, rather than tying in continuity; 5 were associated with failure to completely strip the fat from around the inferior mesenteric vessels prior to division; in 4 instances, the error was transfixion of the inferior mesenteric vein, rather than tying. Other errors associated with risk of bleeding included inadequate length of vessel for securing a tie; clamps or forceps manipulated blindly or with too much force; and grasping the inferior mesenteric vein with too much force.

In addition to risk of bleeding, actual bleeding was identified on 41 occasions: 31 occurrences of bleeding from small vessels, 7 from an unidentified source, and 3 from major vessels. These latter 3 events described 3 different mechanisms of bleeding from a large vessel: failure to hold tension on the IMA with the first throw of the transfixion suture; tie partially cutting through the IMV due to bulk of fat remaining on IMV; and diathermy incising a branch of the IMA whilst creating window around IMA. Of the 31 episodes of bleeding from small vessels, 8 were due to diathermy in incorrect planes; 4 were due to inappropriate use of diathermy (for example using diathermy in cutting mode, or failure to coagulate vessels prior to division); 3 were from sharp dissection in incorrect planes; 3 were from inappropriate use of sharp dissection (typically use of sharp dissection when diathermy would have prevented bleeding); and 2 due to avulsion of vessels caused by excessive traction.

On 9 occasions, a compromise of oncological principle was recorded. These were most often due to division of the inferior mesenteric vessels at a distal point, sometimes beyond their bifurcation. In another instance, the tie on the distal aspect of the IMA was cut short, potentially hindering the ability of the pathologist to identify the apex lymph node.

Of the 21 episodes of procedural delay were identified, only 2 involved waiting for the circulating nurse to obtain instruments or other materials. Most were due to re-packing of small bowel to the right upper quadrant, following inadequate packing in Task 3. Five were associated with inefficient handling of instruments by the assistant surgeon. These errors included dropping of a suture and frequent swapping of instruments.

Other consequences witnessed during task 6 included diathermy burn to colon due to use of non-insulated forceps, and diathermy to nerves at the origin of the inferior mesenteric artery.

4.6.8 Consequential Errors in Task 7 (Division of sigmoid colon)

In task 7, 116 consequential errors were identified, 28 of which were procedural delays. In contrast to task 6, many of these were due to errors by the scrub nurse or circulating nurse (15 cases). Most of these were failure to identify, prepare and provide the appropriate instrument(s), and in particular to lubricate and supply the anvil of the circular stapler. Such an error was more likely to occur if the scrub nurse was inexperienced, or was unable to anticipate the request for other reasons. In an additional 3 cases, the surgeon had failed to communicate his/her choice of stapling gun to the scrub nurse with adequate notice to allow preparation of the instrument.

Bleeding from small vessels occurred 27 times, with a similar range of causes as those previously documented in other tasks.

Unique to task 7 was the high incidence of 'risk of infection', which was recorded 22 times. Twelve of these pertained to failure to protect the operating field with large packs whilst the sigmoid colon was being divided; in 2 cases unclamped bowel was left in the operating field whilst another step was performed; and in 3 cases the suction tip was applied to the abdomen or pelvis after being used to aspirate bowel contents.

Consequence type 4 (injury to viscus) was noted only once, but was associated with a major complication requiring a change of procedure. During the course of division of the mesocolon, the marginal artery was divided in an attempt to mobilise more colon, although it was not realised at the time that this was the marginal artery. As a result, the distal colon became devascularised, and anastomosis was not possible.

Compromise of oncological principle was recorded 9 times in task 7. In 4 instances, this was due to distal division of the mesocolon; in 3 cases it was due to failure to protect the abdomen and pelvis following division of the bowel and/or handling of the specimen. In one case, a lymph node was excised and sent separately, potentially compromising the ability of the pathologist to comment on the status of the apical node.

Risk of anastomotic leak occurred 8 times, 3 of which were due to suboptimal orientation of a recently-introduced stapling device. Other causes included failure to assess orientation of bowel prior to stapling; dividing colon just prior to anastomosis (and therefore not allowing time to assess vascularity of the divided colon); and application of diathermy to a bleeding vessel on the bowel surface.

'Other' consequences were recorded 9 times during task 7, and included failure to identify polyposis coli pre-operatively; late division of sigmoid compromising access to pelvis; incorrect size of stapling gun used due to lack of suitable alternative; and failure to mark stoma sites pre-operatively.

4.6.9 Consequential Errors in Task 8 (Mobilisation of rectum)

During task 8, 892 consequential errors were identified. Over three-quarters of these were attributable either to mesorectal injuries (492 cases) or bleeding from small vessels (197 cases). The most prevalent cause of mesorectal injury was diathermy in incorrect tissue planes (411 cases). This could be subdivided into injury to fascial layer (70 cases), defect in mesorectal fat (130 cases), defect down to adventitial layer (20 cases), dissection into rectal muscle (4 cases) and perforation into lumen (1 case). In 267 cases, the depth of dissection could not be determined with certainty, either because of poor views, or because the layers were not sufficiently clear to make the necessary distinction.

There were many factors that contributed to the creation of mesorectal defects, only some of which are portrayed in the moment that the error occurred. In many instances, preceding events contributed to the injury, for example inadequate traction, poor visualisation, incomplete control of bleeding, and previous deviation from the correct dissection plane. The difficulties associated with quantifying the contribution of these factors to any event will be addressed in section 4.8; in this section, only those events observed at the time of injury will be described.

Of the 411 cases in which diathermy in the incorrect plane was the immediately preceding tool-tissue error, there were a variety of EEM and failures recorded. The most frequently observed EEM associated with diathermy causing mesorectal injury was ‘step is done in the wrong orientation / direction’ (394 times), and described the surgeon positioning the diathermy tip incorrectly for optimal mesorectal dissection. Sometimes this was an error of one or two millimetres, but at other times it reflected poor selection of the quadrant of mesorectum to be dissected. As indicated above, the underlying cause for applying diathermy to the incorrect area was often multifactorial; in addition there were elements of the decision-action sequence that were not accessible to evaluation through simple observation, and too specific to be identified in the post-operative interview.

Thirty instances of failure to perform preparatory steps were recorded within the 411 cases of diathermy-induced mesorectal injury. These were failure to adjust hold to improve visualisation (10 cases) and failure to adjust hold to improve traction (20 cases).

Other EEM types associated with diathermy-induced mesorectal injury included performing actions with too little (force, etc.) (5 cases), performing actions on the wrong object (5 cases), and action omitted (3 cases). In all cases of performing an action with too little (force, etc.), the error described was inadequate traction, typically with the toe of the St. Mark’s retractor failing to open the tissue plane adequately, or even obscuring the dissection plane. In one instance, inadequate traction was applied because the first surgeon was attempting to wield the diathermy as well as the retractor. Of the 5 instances of performing actions on/with the wrong object, 4 described poor retraction due to either inadequate dimensions or style of retractors, and 1 recorded difficulties in securing sufficient traction with gloves alone instead of using a swab to improve traction. There were a variety of omission of steps recorded with diathermy-induced mesorectal injury, including failure to insert an appropriate retractor, failure to clear the operating field of blood, and failure to complete the anterior peritoneal incision.

Other errors associated with mesorectal injury included sharp dissection in wrong tissue planes (12 cases), error in the use of other instruments (7 cases), inappropriate diathermy (5 cases), avulsion of tissue (4 cases) and inappropriate blunt handling of tissue (4 cases). Although only 11 cases of mesorectal injury were associated with sharp dissection, it was used quite infrequently for rectal dissection. In one operation in which sharp dissection was the primary instrument for this task, 7 instances were recorded of scissors causing mesorectal injury, 1 of which created a defect down to the rectal adventitia. The other instruments involved in creating mesorectal defects were often Lahey's and Overholt-Geissendorf forceps used in dividing small areas of mesorectum between clamps. Often these were used correctly, but in 6 instances division was performed too proximally, dividing mesorectum that the surgeon had previously taken pains to preserve, and risking spillage of tumour cells from the mesorectum. Poor positioning of the St. Mark's retractor often compromised access and visualisation to the pelvis; in one additional instance inadequate traction allowed slippage of the retractor, which forced the diathermy into the fat of the mesorectum.

The recording of inappropriate diathermy described a variety of errors. These included transection of mesorectum during a low anterior resection, diathermy through a field obscured by blood, and proximal application of diathermy, which resulted in stripping of the mesorectum from the rectum. Avulsion injuries to the mesorectum were recorded 4 times in task 8, typically as the surgeon attempted to achieve sufficient traction and counter-traction to complete the distal dissection. The propensity of such traction to propagate traction tears was increased through application of traction remote to the site of dissection, and failing to protect the mesorectum with a covering such as a swab or pack. This type of injury also caused damage to the sigmoid colon in 2 instances, resulting in deep tears to the mesosigmoid. Other modes of mesorectal injury included excessive force in the use of the suction probe was observed to strip fascia from the surface of the mesorectum; and grasping of the mesorectum with Babcock's forceps caused mesorectal defects, almost to the point of tearing the mesorectum apart.

In 18 cases, the risk of mesorectal injury was recorded, associated with many of the circumstances described above. One scenario that was over-represented in these 18 cases was the use of bipolar scissors to dissect deeply within the pelvis without adequate visualisation, perhaps due to a false sense of assurance that the risk of injury was low.

Following mesorectal injury, the second most common consequence observed during rectal dissection was bleeding from small vessels (197 cases). The cause of such bleeding was most often dissection with diathermy in incorrect planes (95 instances), followed by unspecified causes (45 instances). In the cases of unspecified cause of bleeding, this also was often due to dissection outwith the correct plane, but priority was given to any mesorectal injury associated with this type of error, and therefore bleeding from small vessels was recorded separately.

On 20 occasions, bleeding from small vessels was caused by the use of inappropriate diathermy, which fell into 3 categories: failure to coagulate a vessel prior to its division; application of diathermy directly to a bleeding point when diathermy via forceps was required; and application of diathermy via forceps when ligation was required. Blunt handling and avulsion accounted for a further 6 instances of bleeding from small vessels, from actions such as applying too much traction, or applying traction with an inappropriate instrument (for example forceps instead of a swab). The risk of injury to viscus was recorded in an additional 17 instances, 9 of which pertained to diathermy being activated precariously close to other organs (including conduction of diathermy through other instruments), 7 to blind or inappropriate use of suction, and 1 instance of bowel being caught between the handles of a bowel clamp.

Procedural delays were described in 58 instances, with a wide range of associated causes. These included re-packing of small bowel to the right upper quadrant (14 cases), inefficient dissection techniques (10 cases), lack of preparation by circulating theatre staff (6 cases), instrument failures (4 cases) and dropping instruments to the floor (4 cases).

Compromise of oncological principle was noted on 36 occasions, including inadequate visualisation during dissection (24 cases), which was often itself caused by poor traction / counter-traction, and premature transection of the mesorectum (4 cases), and blunt digital dissection of the mesorectum (1 case).

Diathermy injuries to other structures were recorded only twice, although many similar injuries were entered in the category of consequence, 'bleeding from small vessels'. The organs injured were the seminal vesicles, with resulting leakage of seminal fluid into the pelvis, and the pelvic sidewall in the vicinity of the hypogastric nerve. Diathermy injury to pelvic nerves was recorded in another 2 cases, with risk of injury to the nerves in an additional 8 cases; in some of the latter there may have been actual injury, although this was obscured by other tissues or lack of definition in the video footage.

4.6.10 Consequential Errors in Task 9 of AR (Rectal transection)

The most frequently-observed consequence in task 9 was compromise of oncological principle, a total of 53 times. This was often associated with inter-step errors (20 occasions): failure to apply a clamp or row of staples proximal at the point of transection (10 occasions), failure to wash the rectum out at the time of transection (6 cases), and excessive handling of the divided rectum (3 cases). In one additional case, although a clamp was applied proximal to the level of transection, it was not close enough to this point, thereby compromising its potential effectiveness. Incorrect use of stapling device was a cause of compromise of oncological principle in 7 cases. Six of these pertained to early transection of the rectum, before an adequate distal resection margin had been obtained; the other described activation of the Contour curved cutter stapler (Ethicon Endo-Surgery, Cincinnati, Ohio) prematurely, before rectal washout had been performed. This was due to a failure to appreciate that the device would staple and divide upon activation.

The risk of infection was recorded 15 times, 9 of which were associated with the compromise of oncological principle, as both categories of consequence shared similar aetiologies. These included failure to apply a clamp or 2nd row of staples (7 cases), failure to change gloves after handling of contaminated material (4 cases), and failure to adequately cover transected bowel (3 cases).

Delay in the procedure was described 23 times, 17 of which related to waiting for materials and instruments to be provided, 4 to inefficient technique (including awkward positioning of the stapling device), and 1 re-packing of small bowel to the right upper quadrant (the latter occurring 3.5 hours into the procedure).

Mesorectal injury occurred twice in task 9, once involving excessive force in the application of the stapling gun, resulting in a badly-torn mesorectum (followed shortly afterwards by perforation of the tumour).

The risk of anastomotic leak was observed twice, both involving the trapping of peri-colic fat at the site of the anastomosis. Two instances of the risk of bleeding were described, both relating to poor visualisation of the pelvis: in one case the surgeon was transecting the rectum through a pool of blood (followed shortly by a problematic bleeding vessel from the pelvic sidewall), and in the second case the crowding of bowel into the pelvis impaired the ability of the surgeon to ligate a bleeding vessel.

Haemorrhage from small vessels and from unidentified sources was a problem in 7 cases, one of which is described above. Other errors in this category included suction rather than arrest of bleeding; removal of packs before haemostatic suture available; difficulty in accessing pelvis to arrest bleeding points; and failure to seek out source of haemorrhage.

Other consequential errors observed included the use of a purse-string device as clamp at the point of transection; small bowel encroaching into the pelvis; ineffective ring retraction system compromising access to the pelvis; risking nerve injury by taking large bites of tissue around a bleeding vessel; and the use of a 2nd stapler for the 2nd staple line, applied after removal of the first stapler (all single instance examples).

4.6.11 Consequential Errors in Task 9 of APER (Perineal dissection)

During the perineal compononent of APER's, 152 consequential errors were identified, the most repeated being the compromise of oncological principle, which was observed a total of 34 times. The commonest form of this type of error was the failure to include a cuff of fat on the distal end of the specimen, the dissection often proceeding directly on the surface of the sphincter complex. Other ways in which oncological principles were compromised included peri-rectal dissection without direct vision (8 times) and being inappropriately guided by an assistant directing the surgery from the abdominal aspect of the dissection (6 times).

Procedural delay occurred 31 times during perineal dissection, 9 of which related to delays waiting for surgical equipment to be made available, 4 to changing gloves, and 2 each to waiting for a 2nd scrub nurse, re-scrubbing of the assistant surgeon, and review of the casenotes.

Mesorectal injury and incorrect dissection plane each accounted for 15 errors in this task, the majority of which either dissected into the peri-rectal fat, or stripped it away altogether. In one instance a sequence of events including inappropriate guidance from the assistant and excess use of blunt force with forceps resulted in perforation and then full transection of the specimen at the level of the levator complex.

4.6.12 Consequential Errors in Task 10 (Preparation for anastomosis)

The consequence most frequently observed in Task 10 was procedural delay (17 times). Five of these episodes related to the re-packing of small bowel to the right upper quadrant, and five to inefficient surgical technique (for example, incorrect positioning of the anvil, followed by excision and re-insertion; untying a knot in a suture; and performing ineffective searches for bleeding points that would have been revealed with a saline washout). Waiting for instruments to be prepared accounted for a further 5 delays. These included errors on the part of the scrub nurse, the circulating staff, and late requests made by the surgeon.

The risk of anastomotic leak was recorded 10 times, 4 of which were associated with failure to strip the fat from around the anvil. Other errors in this category included bunching of colon with the purse-string suture; incorrect placement of the Contour curved cutter stapler, resulting in a concavity of the distal colon; and failure to release sufficient tension at the splenic flexure.

Bleeding from small vessels occurred on only 7 occasions, due to there being relatively little dissection during this stage of the procedure. Three of these episodes occurred within a single patient, in whom there existed a degree of coagulopathy caused by the combination of aspirin and recent chemotherapy. Ineffective use of diathermy (either too brief or at an incorrect position) failed to arrest bleeding on 2 occasions. Although packing of the pelvis with fluffed swabs was not stipulated in the task analysis, it appeared that this practice resulted in less bleeding at this stage, and less time spent managing bleeding points. Bleeding from an unidentified source was noted 3 times, each related to failure to adequately seek out the source of continued bleeding. Twice, this was due to non-systematic removal of packs from the pelvis, rather than careful inspection for bleeding points with the removal of each pack. In one instance, in an attempt to arrest bleeding the hypogastric nerve was injured through the application of diathermy via a pair of forceps. The risk of nerve injury was observed in similar circumstances on an additional two occasions. Application of diathermy whilst in contact with an abdominal pack risked causing injury to the underlying bowel on one occasion.

The risk of infection was observed 6 times, 4 describing the failure to use abdominal packs to protect abdominal contents from open bowel, and 2 relating a failure to prepare suction, such that the abdomen was exposed to faecal fluid.

4.6.13 Consequential Errors in Task 11 (Formation of anastomosis)

A total of 58 consequential events were observed in Task 11, 27 of which described delays in the procedure. On 9 occasions, the delay was caused by waiting for an instrument to be prepared or made available; on 6 occasions the delay was due to waiting for an assistant surgeon to perform an air leak test of the anastomosis; 4 instances of delay related to lack of familiarity with the anastomotic stapling gun, and difficulties in assembly, positioning or dismantling; on 2 occasions incorrect positioning of a rectal tube resulted in delay whilst it was repositioned; and lack of an anal dilator caused delay in the introduction of the stapling gun in 1 case.

The risk of anastomotic leak was recorded on 21 occasions. In 4 instances, there was risk of or actual interposition of tissue between the two elements of the anastomosis, for example peri-colic fat or non-observation during closure of the stapling gun. On 4 occasions there were errors in operation of the anastomotic stapling device, including opening the gun prior to activation, and partial incorporation of the anal sphincter into the anastomosis. On one occasion, a leak observed during a test of the anastomosis (tested by insufflating the neo-rectum with air via the anus) was not managed with reinforcement of the anastomosis, nor with a covering stoma. On another occasion, an attempt to reinforce an anastomosis failed to cover the staple line, and therefore did not succeed in containing any potential anastomotic leakage. Other errors contributing to the risk of anastomotic leak included failure to alleviate tension on the anastomosis; failure to fashion a covering stoma; and failure to evacuate the air from a distended rectum.

The risk of infection was recorded 5 times, through errors such as uncontained bowel spillage from failure to use packs; contamination of the suction probe with faecal material which was then used in the pelvic cavity; failure to washout the rectum such that the gun introduced faecal material to the pelvis; and failure to clean the stem of the anvil, even though macroscopically contaminated with faecal material.

The risk of bleeding was recorded on one occasion, relating to the completion of the anastomosis before all bleeding points had been assessed and arrested.

4.6.14 Consequential Errors in Task 12 (Formation of ileostomy / colostomy Part I)

In task 12, a total of 33 consequential errors were recorded, 10 of which were due to procedural delays. Three of these described the performance of additional steps (such as mobilising more colon than was necessary, or resecting too much colon, thus requiring further mobilisation). Three instances of delay involved waiting for materials or instruments from circulating theatre staff. The remainder of delays comprised events such as: failure to strip fat from the bowel, resulting in difficulties in exteriorising the stoma; use of scissors in creation of the stoma, causing slow progress in dissection through the muscles of the abdominal wall; and slow piecemeal removal of fat from the subcutaneous tissue of the abdominal wall.

Seven instances of bleeding from small vessels were identified, resulting from failure to palpate for small mesenteric vessels, and cutting too deeply into the mesentery with scissors, knife or diathermy. The risk of infection (identified 5 times) was most often associated with failure to protect the stoma site from open bowel, either through premature removal of the staple line at the distal end of bowel, or through failure to close the bowel at all.

Failure to mark either the ileum or the skin (with the potential for poor orientation or siting of the stoma) was recorded 4 times. Other errors encountered during exteriorisation of colon or ileum included twisting of the mesocolon, failure to dilate a tight stomal passage (3 times), and excessive stripping of mesocolon away from distal colon, with associated risk of ischaemia.

4.6.15 Consequential Errors in Task 13 (Wound closure)

Task 13 contained 151 consequential errors, the commonest of which was procedural delay (46 occurrences). Twenty-two of these delays related to those caused by waiting for instruments and materials to be made available to the operating team, or for the suction disposal units to be changed. Poor control of sutures accounted for 6 episodes of delay, such as accidental formation of knots and loops that required time to undo. Poor placement of sutures during mass closure caused delays on 3 occasions, once it became apparent that the sutures were unsatisfactory and needed replaced. Inaccurate positioning of staples during skin closure (exacerbated by omitting to utilise Littlewood's forceps to appose the skin edges), resulted in removal of staples on 3 occasions.

Errors in placement and securing of drains resulted in procedural delays 3 times. These errors included failing to secure the drain prior to the application of a dressing; difficulties in directing the drain towards the pelvis; and placing additional unnecessary sutures to secure the drain. These delays are in addition to those caused by placing drains that are contra-indicated according to recent directives, as described below.

Injury to viscus was described once, and the risk of such injury an additional 26 times. The actual injury was the precipitation of ischaemia of the colon, following inappropriate diathermy and suturing to a bleeding point at the splenic flexure. Risk of injury was most often related to the placement of suction drains in the pelvis, and theoretical risk of associated bowel injury and anastomotic breakdown. Other errors included failure to ensure that the viscera were not caught in the internal aspect of the suture used for mass closure (4 times), omitting to draw the greater omentum over the small bowel, excessive use of suction directly onto small bowel; and exteriorisation of viscera due to shallow anaesthesia and patient movement (all 1 occurrence each).

4.6.16 Consequential Errors in Task 14 (Formation of ileostomy / colostomy Part II)

Of the 110 errors observed in task 14, 50 were consequential; 26 of these related to the risk of infection. Most of the risks of infection (22 errors) were due to one of three error types: failure to prepare the suction for use or change the suction disposal units; failure to cover or dress the wound; and delays in applying a stoma bag to the completed stoma. In several instances, there was not only the risk of infection, but actual contamination of the wound. For example, delayed application of the stoma bag resulted in the abdominal wound being covered in profuse diarrhoea that issued from the stoma; attempts to clean the stoma with suction resulted in smearing of faeces around the stoma site; and failure to prepare the suction led to spillage of enteric fluid at the time of enterotomy.

Procedural delay was encountered 7 times, usually due to poor placement of sutures duration formation of the stoma. Bleeding from small vessels occurred 4 times, from a variety of causes including excision of staple line with scissors, removal of an incorrectly-placed suture, and failure to arrest bleeding points before continuing with stoma formation. Other errors encountered during completion of ileostomy included trauma to the ileum caused by manipulation of the mucosal surface with Babcock's forceps; malformation of the stoma due to failure to follow the correct placement and sequence of sutures; and failure to secure the exteriorised bowel, associated with significant risk of open bowel falling back into the abdominal cavity.

4.6.17 Consequential Errors in Task 15 (Additional Procedure)

An additional procedure was required 84 times in 36 operations. The most frequent type of procedure was to address excessive haemorrhage. Whilst control of haemorrhage was a part of every procedure, it was classed as an ‘additional procedure’ if it interrupted the normal flow of the operation. This was required 24 times in 14 operations, most often for haemorrhage from the left upper quadrant (see ‘Splenectomy’ below), but also from the left gonadal vessel, and particularly troublesome haemorrhage from the pre-sacral veins. In one instance, haemorrhage from an unidentified source caused difficulties throughout the procedure, and it was not until abdominal closure that it was found to originate from the wound edge.

An additional colectomy was performed in 5 procedures. Three were for distal ischaemia, usually associated with injury to the marginal artery; one was planned for a second caecal tumour; and one total colectomy was required due to extensive polyposis that had not been identified pre-operatively.

Anti-adhesive products such as Icodextrin were utilised on 9 occasions, often purely through surgeon preference, but sometimes influenced by patient-related factors such as pre-existing adhesions, or surgery-related factors such as complex surgery with long or difficult dissections.

Additional rectal resection was performed 5 times, either because the surgeon was dissatisfied with the initial circumferential or distal resection margins, or – on 2 occasions – because of transection or avulsion through the tumour. In all cases, the remaining dissection was attempted in continuity with the previous dissection, but often performed piecemeal.

Splenectomy was required in two procedures. The first splenic injury was due to dissection straying from the correct plane, exacerbated by a short abdominal wound, culminating in a cycle of dissection and retraction with increasing haemorrhage and decreasing visibility. The second procedure requiring a splenectomy was initially performed without any form of retraction system; a retractor was only placed once haemorrhage from the left upper quadrant was apparent. Lack of a retraction system meant that both the view of the surgeon and the video camera were limited, and therefore the precise moment and nature of the injury was not recorded. Poor views resulted in poorly-controlled utilisation of handheld retractors, often requiring force without visualisation to provide some access. It seems likely that injury to the spleen occurred as a result of this manipulation.

4.7 Association between Types of Errors

In addition to the validation inherent in the methodology of the study (review of the error scores by experts in surgical technique and in surgical ergonomics), the error scoring system was also validated through statistical means. By demonstrating that the number of non-consequential errors correlates with the incidence of observed mesorectal injuries (consequence 9), it may be concluded that even those events without immediate repercussion signify an operation that is more likely to lead to adverse outcomes (Figure 28).

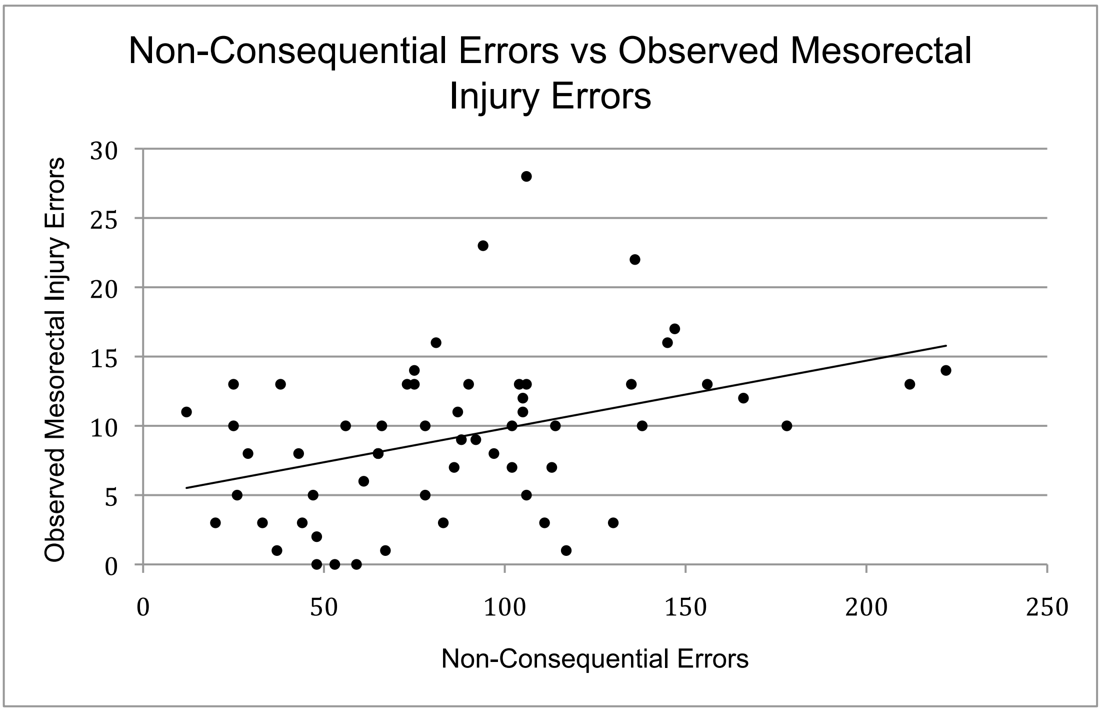


Figure 28 – Association between errors and mesorectal injuries, r=0.40, p=0.002

4.8 Association between Errors and Outcome

The primary aim of this study was to establish a methodology that would bridge the gap between surgical process and outcome. The means by which this was achieved was through correlation of surgical errors with the appearance of the mesorectal specimen. Those errors which described any mesorectal injury were tabulated against average mesorectal grade. The mesorectal injuries were separated into the subclasses of injury from fascia to perforation as described in section 2.2. Utilising a linear regression analysis, a model was developed that described the relationship between the weighted error score (using the coefficients of each subclass of injury) and the score from the mesorectal specimen. As may be seen in Figure 29, the correlation between the weighted error score and the mesorectal score is very high, even if outliers are excluded.

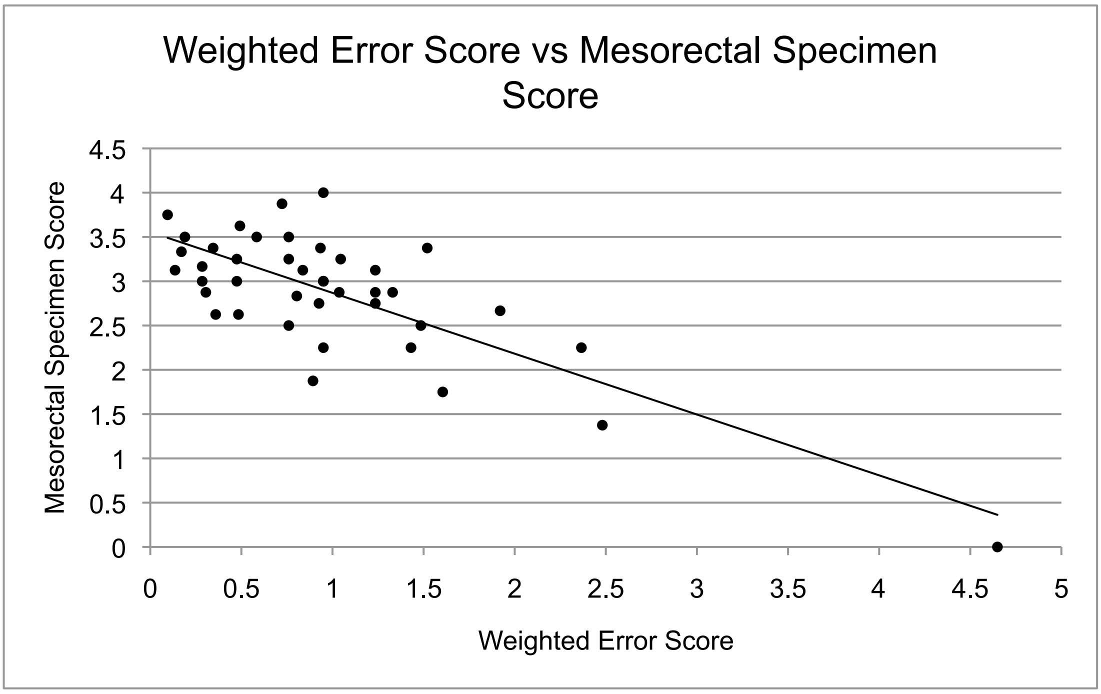


Figure 29 – Association between weighted errors and mesorectal score, r=0.904 (0.818 excluding outlier), p=0.001 (0.041 excluding outlier)

4.9 Novel Methods of Error Description and Analysis

One of the greatest difficulties in assessing and presenting the data is the vast number of individual errors and of types of errors identified during the course of the analysis. Some errors are represented hundreds of times, although 250 of the errors identified were unique. Some grouping of non-identical errors is possible, for example, restricting the group to all errors of type EEM 6 and Consequence 9 within Task 8. However, even this does not differentiate the more significant errors from those that are less significant, and equally does not describe the variety of factors that will have contributed to the error, yet lie outwith the immediate enacting of that event.

Another dimension that may be difficult to account for is that of time. The previous analysis does not reveal the temporal relationships of any of the errors identified. To this end, plotting error types against time for each of the procedures yields a form of 'fingerprinting' for each operation (Figure 30). This allows the rapid identification of error clusters (indicated by yellow bars), the relationship of these errors to individual tasks, and probing of the operation for specific error types (shown in red).

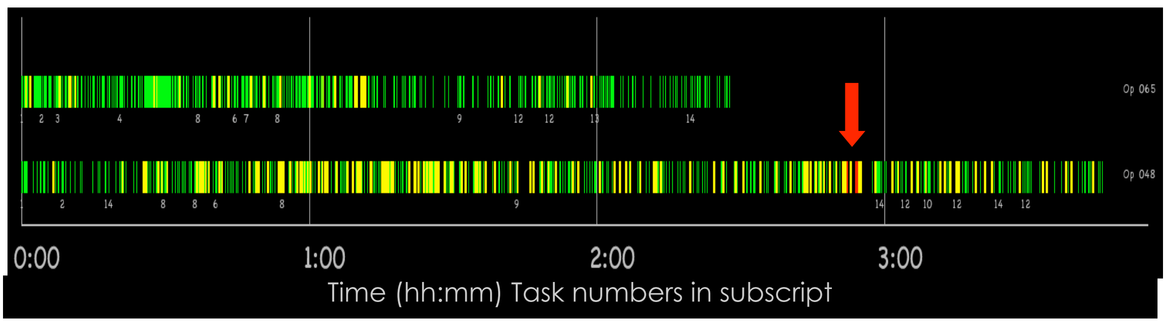


Figure 30 – 'Fingerprinting' of the tasks and errors of a procedure

In this figure, two operations are compared: one in which few errors were encountered, and a good mesorectal specimen was achieved, and the other in which a series of errors resulted in perforation of the specimen (red arrow).

Chapter 5

DISCUSSION

5 Discussion

The aim of this study has been to identify the nature and frequency of the errors enacted during rectal cancer resections, as well as the consequences associated with these errors. If such errors may be identified, then mechanisms may be proposed by which the errors, and therefore adverse outcomes, may be avoided. Having demonstrated both the most frequent as well as the most severe combinations of errors and consequences, it is now possible to begin proposing error-resistant modes of conducting these procedures. These propositions will follow the previous pattern of addressing the procedure according to its component tasks.

5.1 Pre-operative Error Reduction

During the course of the procedure, errors were encountered that reflected failures in pre-operative assessment and preparation, and will be addressed here. Inadequate pre-operative investigation allowed other colonic pathology, such as colonic polyposis, to pass undetected. This resulted in the intiation of an inappropriate procedure, performing anterior resection instead of subtotal colectomy, and risking infection and seeding of tumour from an unnecessary division of the sigmoid colon.

Anticipation and correction of coagulopathy may prevent refractive bleeding during the course of the procedure. Surgeons may become indifferent to the impact of individual anti-platelet and anti-coagulant medications, but must remain attentive to the synergistic effect of multiple products, and where required, must ensure omission of medication in advance of the operation, to allow sufficient time for reversal of effects. This requires not only review of routine medications, but also cognizance of any chemotherapy administered to the patient.

Open communication with the entire operating team both before and during the procedure is vital for patient safety and efficient conduct of the operation. Issues to be addressed include patient positioning, and any changes of position anticipated intra-operatively; supplementary instruments and materials likely to be required; clear communication in circumstances that might present any doubt regarding the intended action (for example instructing the assistant when tissue between the forceps is to receive diathermy, and when it is to be preserved – Note section 4.6.5).

It is also incumbent upon the surgeon to ascertain that all instruments to be requested during the procedure are available, in order to avoid compromising dissection or reconstruction through lack of retractors or stapling guns. The surgeon must ensure that s/he is familiar with the device, how it is to be handled, its mode of action, and how to proceed in the event that the device should fail.

Finally, the surgeon must ensure that other members of the multi-disciplinary team are involved to the extent that is necessary for each patient. This may require assessment by a colorectal specialist nurse and siting of any potential stoma; detailed anaesthetic review including cardio-respiratory investigations; and review by an occupational health practitioner regarding domestic circumstances that may need modification.

5.2 Task 1 – Incision of the abdomen

Although vertical incision for rectal resection was the unanimous opinion of the expert group, 23 procedures were conducted through a transverse incision.

The most frequent consequence observed during incision was bleeding from small vessels, which relates to the errors identified in prospective analysis. Therefore, in order to minimise bleeding during incision, a series of error-reduction mechanisms are proposed. Firstly, the diathermy machine should have been properly installed and set up by trained personnel, and theatre staff (both nursing and surgical) trained in the correct operation of the machine. All staff should be satisfied that the machine performs to requirements prior to its use in a surgical procedure.

Secondly, diathermy rather than sharp dissection should be employed for progress through dermis, fat, fascia and, where relevant, muscular layers. Thirdly, diathermy should be used in progressive layers in order to be able to identify and prospectively coagulate small vessels encountered during the dissection. In many instances deep and prolonged strokes caused bleeding from small vessels which could have been identified without bleeding. And lastly, if bleeding does occur, the surgeon must ensure that both ends of the vessel are adequately coagulated before proceeding.

One of the more significant consequences observed during task 1 was injury to small bowel, in addition to a considerable number of scenarios of potential injury to small bowel. Such injuries may be avoided by lifting the peritoneum with haemostats, and ensuring that sufficiently small bites of peritoneum are taken that small bowel will not be caught in the haemostats. The peritoneum must be incised with sharp dissection in order to avoid diathermy injury to small bowel.

5.3 Task 2 – Laparotomy

The most critical element to be addressed during task 2 is to ensure that it is performed thoroughly and with understanding. The surgeon must examine each of the relevant areas of the abdomen, giving consideration as to how the findings from each evaluation might influence the course of the procedure. The assessment must incorporate inspection and palpation of the rectum and liver, estimation of the mobility of the sigmoid colon and splenic flexure, complemented with examination per rectum where indicated, all contributing to the data already gleaned from pre-operative investigations. Once a thorough assessment has been performed, the surgeon will be able to evaluate the adequacy of the incision, and whether extension will be required to allow sufficient access to the splenic flexure. It is essential to create a length of wound that optimises access to the abdomen, whilst avoiding an excessive size of wound that may impair post-operative respiratory function, and to utilise the full extent of the wound that has been created.

It is also appropriate at this point in the procedure to establish that no inadvertent injury has occurred during the course of the incision, and to arrest any bleeding points from the wound edges. Omission of this step may cause continued unnecessary bleeding throughout the procedure, harmful in its own right, as well as obscuring future dissection.

5.4 Task 3 – Placement of Retraction System

It appears to be routine practice for some surgeons not to place a retraction system at this stage or at all, or to use ineffective modes of retraction. The disadvantages of such practice are manifold: frequent delays to adjust access to the abdomen, risk of and actual injury to viscus, difficulty in progressing the plane of dissection, trauma to the wound and viscera from blind and forceful hand-held retractors, and ineffective use of the surgical assistants. In particular, the careful and systematic packing of small bowel to the right upper quadrant at this time will save repeated delays later on in the procedure. Therefore, it is impossible to over-emphasise the need to establish good retraction at this point in the procedure, using a system with which the surgeon is familiar, and for which all the relevant parts and attachments are available. This appears to be one of the most important steps in the procedure, the impact of which resonates throughout each of the tasks that follow.

5.5 Task 4 – Mobilisation of the Left Colon

In mobilisation of the left colon, there are a number of positive steps that may be taken to facilitate progress. Optimisation of traction and counter-traction is essential if the correct plane of dissection is to be identified and developed effectively. Maintenance of traction is not simply a question of force, but of evaluating how the tissues will best open in response to traction, using swabs or other means to distribute the force along the tissues, adjusting one's hold on the tissues as required, specific instruction to the assistant surgeon, and a keen awareness of tactile feedback and of the threshold at which avulsion injuries might occur. In the development of good dissection planes, other factors demonstrated to be important were the establishment of a retraction system, and careful and appropriate use of the diathermy, ensuring the tip remains visualised at all times. Bleeding and straying from the dissection plane occurred much more frequently when the tip was not visualised, or when the surgeon attempted to probe for a plane with active diathermy. Such probing should be performed through blunt dissection and with varying traction until the correct plane may be demonstrated with confidence.

Maintenance of good dissection planes will ensure minimal bleeding, avoidance of damage to the colon, mesocolon and retroperitoneal structures, and swift progress through this stage of the procedure.

In order to avoid injury to retroperitoneal organs, the surgeon must develop a 'mental map' of the relevant anatomy, in which s/he remains orientated whilst focusing on the detail of the dissection at hand. Failure to safeguard the ureter and gonadal vessels caused several instances of near injury and one actual injury to the gonadal vein. There is a tendency for the surgeon to focus so intently on the task of dissection or of arresting minor haemorrhage that the significant risk to other structures may be overlooked.

5.6 Task 5 – Mobilisation of the Splenic Flexure

The cardinal errors in task 5 are those that lead to haemorrhage, both the frequently-observed bleeding from small vessels, and the rare haemorrhage from large vessels. The former are avoided through continued application of the principles outlined above, namely adequate retraction with good visualisation, careful traction within the limits of tissue avulsion, and precise application of diathermy to the areolar tissue of the relevant plane. Bleeding from large vessels requires not only close adherence to these same principles, but also an awareness of the special causes of bleeding related to dissection around the splenic flexure. The risk of injury to the gonadal vessels has already been mentioned, but merits additional attention due to the potentially catastrophic nature of any injury, as described in section 4.6.6. Should the dissection proceed too far posteriorly, the dangers to these vessels are multiplied both from the proximity of diathermy, and the lack of covering tissue to disperse any dangerous traction. In these circumstances, the surgeon must ensure that the assistant is aware of the risk of injury, and handles the tissues with appropriate care.

The other potentially serious source of bleeding during task 5 is from the spleen itself, which is most at risk from avulsion of the capsule through forces transmitted along its ligaments and attachments. This risk is minimised through good access and lighting to the left upper quadrant, so that the surgeon is not inclined to pull the splenic flexure down into view. Other measures to be taken include only careful application of a retractor to the left upper quadrant, and only performed by an experienced assistant; freeing the splenic flexure relatively early, so that other manipulations do not exert unnecessary forces on the spleen; and extension of the wound as required to maintain access to the splenic flexure.

It may be worth noting that both splenectomies occurred within the context of transverse abdominal incisions. Whilst this is insufficient evidence to suggest that the risk of splenic injury is significantly higher with such incisions, surgeons should be aware that selection of wound type has many potential consequences, beyond ease of access, including postoperative pain and complications.[136]

5.7 Task 6 – Division of the Inferior Mesenteric Vessels

Ligation and division of the inferior mesenteric vessels requires careful handling and preparation of the vessels, to avoid any risk of avulsion and to ensure secure ligation. Division of the inferior mesenteric vein between clamps was a practice frequently observed, and although no avulsion was witnessed as a result, a relatively small error with a clamp in situ could lead to a serious tear of the vein and a catastrophic haemorrhage. Therefore, ligation of the inferior mesenteric vein in continuity is recommended, as per the consensus of the expert group. Similarly, transfixion of the vein may create a defect in the vein that is difficult to repair, and therefore simple ligation is to be performed instead.

Preparation of the inferior mesenteric artery must include stripping of the fat from close to its origin in order to provide a tie or suture with a secure purchase, but not so close to the origin that the hypogatric plexus is at risk of injury. A sufficient length of artery must be stripped to allow a generous cuff of vessel between ligature and point of transection, so that the ligature will not slip off the vessel.

The three observed occurrences of bleeding from the inferior mesenteric vessels (loose ligature, cutting through vessel with suture, and diathermy to branch of vessel) may have been avoided through the placement of a double hitch on the first throw; adequate stripping of fat from the vessel; and assessment of anatomy through careful inspection and palpation of the vessels prior to dissection. Bleeding from small vessels may be largely avoided through the measures described in section 5.6, namely maintenance of correct planes, avoidance of excessive traction, and coagulation of vessels prior to division.

Adherence to oncological principles requires high division of the inferior mesenteric vessels (approximately 1cm from the origin of the inferior mesenteric artery), rolling the apical node onto the resected portion of the artery, as described in the expert group meeting. The reasons for surgeons failing to divide the vessels at this level are not clear from observation, but may reflect concerns over mobility or vascularity of the descending colon, or perhaps a degree of confidence that the apical node will not be involved if the tumour is small.

Since only 2 of the 21 episodes of procedural delay were caused by waiting for the scrub or circulating nurses, most of these are attributable to inefficiencies of the operating team. Once again, re-packing of small bowel to the right upper quadrant was the primary cause of delays in this task, a fault that must be resolved through careful preparation in task 3. Other inefficiencies such as dropping sutures or poor handling of instruments are training issues for surgical trainees, to be addressed through practice both in the operating theatre and in the practice laboratory.

Injuries to abdominal organs may be avoided through the correct use of instruments (for example insulated forceps for the application of diathermy) and preservation of autonomic nerves at the origin of the inferior mesenteric artery.

5.8 Task 7 – Division of the Sigmoid Colon

As stipulated in section 4.6.5, clear communication between the members of the operating team pre- and intra-operatively may avert many potential adverse events. This is particularly true during division of the colon, in which the surgeon is dependent upon the timely preparation and presentation of a variety of instruments and other materials. In order to avoid the delays and frustration caused by poor communication, the surgeon must indicate clearly which stapling gun(s), purse-string devices and sutures are to be used, sufficiently ahead of time to allow the circulating and scrub nurses to obtain and prepare the devices. An experienced scrub nurse may anticipate many such requests, so that a surgeon is not required to mentally prepare for the next stage of the procedure. However, such experience cannot be taken for granted, and does not remove the responsibility of preparation from the operating surgeon.

The high rate of risk of infection in task 7 is associated with a variety of errors, all of which share a common failure to maintain adequate separation between those instruments and tissues that are ‘clean’ and those that are contaminated. The surgeon must therefore remain vigilant in the distinction between these tissues, and take adequate measures to avoid contamination of clean areas. The principles to be adhered to include minimisation of contaminated tissue, for example using staplers that seal and divide. If division is to be performed without staples the risk of contamination must be minimised, i.e. the divided colon is clamped to ensure no gross spillage, it is segregated from the rest of the abdomen with the generous use of abdominal packs, and it is left without anastomosis for a minimal period of time. It may be because of this latter reason that in several instances division of the sigmoid colon was deferred until after rectal mobilisation had been completed. However, this is associated with its own risks, namely difficulties in mobilising the rectum, and inability to ascertain the viability of the colon prior to anastomosis. Therefore it is recommended that staplers that seal and divide should be used routinely for division of the sigmoid colon. If tissue or instrument should become contaminated, it should be removed from the operating field and cleaned or disposed of, or if this is not possible, thoroughly cleaned within the operating field, taking care not to disseminate the contamination any further.

Close adherence to the principles of non-contamination will also serve to avoid some of the errors associated with compromise of oncological principle, specifically those relating to risk of seeding of tumour cells in the abdominal cavity. Other modes of this error could be avoided through high division of the sigmoid mesocolon and mesenteric vessels, and resisting the temptation to excise palpable lymph nodes to be sent separately from the rectal specimen.

In order to minimise the risk of anastomotic leak, the surgeon must avoid all insult to the distal colon, such as the application of diathermy to any bleeding points on the bowel surface, and careful orientation of the bowel prior to stapling, and particularly at the time of assembly of the anastomosis. Although there may be reasons for deferring division of the sigmoid colon if seal and divide staplers are not used, this practice is associated with its own risks, namely inability to evaluate vascularity of the distal colon as described above.

Familiarity with the stapler is essential not only to ensure smooth progression of the procedure, but most importantly to ensure that the anastomosis is not compromised by incorrect use of any of the devices used in its construction. If the Contour curved cutter stapler (Ethicon Endo-Surgery, Cincinnati, Ohio) is used at this juncture, it should be orientated such that a convexity and not a concavity is fashioned in the cut end of the distal colon.

5.9 Task 8 – Mobilisation of the Rectum

Task 8 was associated with the greatest number of errors observed, and also with the highest number of errors directly pertaining to the principle outcome measure of the procedure, that is the resection of rectal tumour in intact mesorectal coverings. There appears to be no simple formula that will ensure that such errors are avoided, as there were many types of errors leading to mesorectal injury, and each of these errors were often associated with a complex catalogue of preceding factors that contributed to the actual injury. Nonetheless, some of these injuries may have been avoided through application of the guidelines that are suggested below.

The type of error most proximal to the moment of injury is that which describes incorrect use or placement of the diathermy tip with respect to the desired plane of dissection of the mesorectum. Careful inspection of the 'trough' between mesorectum and pelvic sidewall should reveal the strands of loose areolar tissue that are the guide to the correct plane. It is possible that this plane was sometimes more apparent on the video recording than to the surgeon due to the magnified nature of the viewing field from the camera (2x to 3x magnification). In these circumstances, deviation from the plane of dissection cannot readily be attributed to poor lighting due to the powerful light that illuminated the entire field of view of capture from the primary head camera. It may be that in these instances the demands of this surgery are exceeding the limits of visual perception of the surgeon. If this is the case, then there may be a role for visual aids during mesorectal dissection, for example operating loupes or laparoscopic cameras.

In other cases of mesorectal injury the correct plane was not apparent on the video recording, and therefore the injury was attributed to continued dissection without appropriate visual cues to guide the development of the plane. In these circumstances adjustments must be made prior to further dissection, either in improving traction and visualisation of the dissection 'trough', or by selection of another approach in another quadrant of the mesorectum. Simple failures to adjust the angle or force of retraction were directly implicated in many instances of mesorectal injury, a type of error that may be avoided with adequate instrumentation, a sufficient number of operating assistants, good lighting, access and visualisation of the operating field, and clear communication or anticipation of surgical instruction.

In addition to these general principles, there were several specific forms of technical error that resulted in mesorectal injury. Dissection in the anterior quadrant must include incision of the full extent of the peritoneum just anterior to the recto-vesical or recto-uterine pouch, in order to allow posterior traction on the rectum to open this most difficult of mesorectal planes. Another common technical error was low mesorectal dissection followed by a relatively proximal transection of the mesorectum. In several instances, this resulted in distal resection margins that were considerably less than 5cm, thereby potentially compromising the oncological clearance of the resection, and increasing the risk of local recurrence of the tumour. Even in those instances for which sufficient distal resection margin remained, proximal transection represents a significant waste of operating time, and the bearing of unnecessary risks of haemorrhage and rectal perforation associated with low mesorectal dissection that was not utilised to its full extent. Therefore, the surgeon must ensure either that a total mesorectal excision is conducted, or that a distal resection margin of at least 5cm remains. If there is any doubt regarding the adequacy of the distal resection margin, additional assessments such as sigmoidoscopy should be performed by the surgeon or an experienced assistant. Once a sufficient distal resection margin has been achieved by mesorectal dissection, the surgeon must then ensure that the full extent of this margin is preserved during mesorectal and rectal transection.

Although it is not known if tearing the mesorectum after it has been dissected is associated with poor outcomes, it should be avoided for several reasons. Firstly, it may increase the risk of seeding from tumour within the mesorectum; secondly, it may impede the ability of the pathologist to give a true assessment of the stage of the tumour; and thirdly, the preservation of an intact specimen remains a hallmark of good surgical technique during this task. In order to ensure that the mesorectum is preserved intact, traction should be applied close to the point of dissection, so that the vector of the force applied will approach perpendicular to the plane being developed, and so that force will not be applied to potentially weak areas in the mesorectum that has already been dissected. Traction forces on the mesorectum should be distributed evenly with the assistance of a swab, and the use of traumatic instruments such as Babcock's forceps avoided altogether.

Heald has astutely described mesorectal dissection as the careful navigation between Scylla and Charybdis,[108] and thus the surgeon must avoid injury to the pelvic nerves and organs in the attempt to preserve the mesorectum. Although such injuries were infrequently observed in this study, they may have catastrophic consequences, such as massive haemorrhage from pelvic veins, or postoperative genitourinary dysfunction from injury to the pelvic nerves. In order to avoid injury to these structures, the surgeon must remain constantly aware of their location when they are visible, and even more conscious of their position when they have not yet been exposed. Following the mesorectal plane as described above is one of the best ways to ensure that the pelvic organs are not injured, although there remain specific danger zones in which the point of the diathermy must not stray, for example deep posteriorly over the sacral venous plexus, and anterolaterally as the autonomic nerve plexuses course around the pelvic sidewall towards the prostate.

Whilst the focus during this task is on the mesorectum and the pelvis, the surgeon must also remain aware of the wider field of the procedure, and to control any loop of bowel that might encroach upon the operating field. Adequate control of small bowel during task 3 will minimise the need to attend to such distractions during pelvic dissection. The surgeon must also be aware of the potential effects any action might have beyond that which is intended, for example the conduction of diathermy through an alternative pathway, or the bowel that might be crushed between the handles of a bowel clamp, as well as between the jaws.

Bleeding during the course of mesorectal dissection may be largely avoided by maintaining dissection within the correct plane, as described above. Any small vessel that is likely to be divided during the course of dissection, should be proactively coagulated prior to division. Once haemorrhage has occurred, it should be managed through the application of the 'treatment ladder' for haemorrhage, i.e. assessment of the nature and severity of the haemorrhage, complemented as necessary by saline washout to clear the operating field and reveal the source of bleeding, and determination of the most appropriate treatment, ranging from direct or indirect diathermy, to transfixion, packing and additional local and systemic haemostatic measures. Inappropriate selection of or persistence in a given 'rung' on this ladder will waste time, allow unnecessary haemorrhage, and risk causing additional injury to other organs or vessels.

5.10 Task 9 in AR – Transection of the Rectum

Given that the consequence most frequently observed during rectal transection is the compromise of oncological principle, it is this aspect that requires the closest attention. In this regard, adherence to the correct steps in the procedure and avoidance of inter-step errors would have almost halved the rate of these errors. The surgeon must ensure that the length of bowel that contains the tumour is a closed unit before the transection is performed, otherwise there is a real risk of spillage of tumour and faecal material into the pelvis. Either a bowel clamp or a stapling device will suffice, although the latter allows greater manoeuvrability during transection. Regardless of the choice of device, it must be applied sufficiently close to the point of future transection that rectal washout will ensure that the rectum between anus and clamp is completely free of faecal material.

Some surgeons appeared to prefer performing rectal washout pre-operatively instead of immediately prior to transection. This may allow the procedure to be conducted without interruption, but risks contamination and tumour implantation from faecal material that has moved distally during the course of the operation. Therefore rectal washout must be performed immediately prior to transection, and the surgeon must ensure that the clamp or stapling device does not prevent washout circulating to the area that will be stapled. In practial terms, this means performing washout before the distal stapling device has been applied. In the case of devices that seal and divide such as the Contour curved cutter stapler, the device should be applied but not activated, then washout performed, and then the device advanced further distally before it is finally applied and activated.

Procedural delay during this task may once again be largely averted through clear and timely communication to the scrub and circulating staff regarding the stapling devices and other instruments that are to be requested. An experienced surgical team may be able to anticipate many such requests, but the surgeon must continually ascertain that adequate preparations for the next stage have been made.

Failure to handle stapling devices correctly resulted in serious consequences during rectal transection, including perforation of the tumour. For this reason, a good range of stapling devices and clamps must be available so that the surgeon does not attempt to force a poorly-fitting device around a bulky tumour in a narrow pelvis. The surgeon must assess the anatomy of the pelvis and rectum carefully in order to be able to select the device most appropriate for the task. If the device does not fit, it must not be forced around the rectum, but an alternative approach devised.

5.11 Task 9 in APER – Perineal Dissection

In contrast to rectal dissection (Task 8), the landmarks and endpoint of perineal dissection are not clearly defined. The absence of a clear plane and 'mesorectal package' means that the surgeon will tend to stray either towards the pelvic wall or towards the tumour. In this series, the apple core appearance of the APER specimens suggested that surgeons are inclined to the latter type of error.

In an attempt to overcome this tendency, a group in Sweden promoted the concept of cylindrical perineal dissection, in which the mesorectum and levator complex are excised *en bloc*, often turning the patient into the prone position for completion of the procedure.[137] Such an approach yields safer tumour margins, and achieves lower rates of CRM involvement and perforation.[138] This technique may have additional benefits in overcoming other consequential errors observed at this stage of the operation: as visualisation is greatly improved in the prone position, and even further with removal of the coccyx, blind dissection is not required; furthermore the surgeon does not have to rely upon tactile guidance from an assistant at the pelvic end of the specimen.

5.12 Task 10 – Preparation for Anastomosis

Most of the errors observed during task 10 have been discussed in relation to other tasks, and could be avoided by adherence to general principles such as effective communication, appropriate management of haemorrhage, maintenance of the sterile field, and use of an adequate retraction system. It is interesting to note that failure to pack the small bowel to the right upper quadrant continues to have an impact on the procedure, even during this late stage.

The position of the anvil in the distal colon must be selected carefully. It must be sufficiently distal to avoid placing tension on the anastomosis, but a short distance from the extreme end to allow a side-to-end anastomosis to be fashioned. Incorrect positioning may be remedied by removal and re-insertion, but this is associated with additional delays in the procedure, unnecessary defects in the distal colon that must be repaired, and the risk of infection from handling a contaminated anvil. Once the anvil is in place, the surgeon must strip any peri-colic fat that might otherwise be incorporated into the anastomosis. Although it was not possible to demonstrate the occurrence of anastomotic leak as a direct consequence of failure to strip such fat from around the anvil, other forms of tissue interposition were associated with anastomotic leak in task 11.

5.13 Task 11 – Formation of Anastomosis

The aim of task 11 is the formation of a secure anastomosis whilst minimising trauma to the anal sphincter. There are a variety of errors that may compromise either of these objectives, and a range of mechanisms that may be employed to avert such errors. On commencement of this task, the surgeon should ensure that a generous length of colon is available, and that it can reach the pelvis without any tension. This may require additional mobilisation of the left colon or splenic flexure, continuing to protect the vascularity of the colon during this mobilisation.

As indicated in section 5.1, the surgeon should be familiar with all the instruments to be used during the course of the procedure, not only to reduce unnecessary delay in the operation, but more importantly to minimise potential harm or injury to the patient or the tissues as a result of inappropriate use of an instrument. Such familiarisation with instruments must include hands-on experience with the anastomotic stapling gun to be used, an experience that should initially be gained by simple examination and handling of the instrument in a non-patient related context. During insertion of the gun, a series of anal dilators should be available for the introduction of the gun through a tight sphincter. The surgeon should ensure that the gun is advanced beyond the anal sphincter complex and that only a thin covering of distal ano-rectum remains at the future staple line. Indeed, the tissue at this point is usually so thin that it is nearly translucent, and the outline of the stapling gun is clearly seen. Once inserted, the gun should not be removed until the anastomosis is complete.

The distal colon should be carefully orientated to eliminate any axial twisting of the colon that could potentially compromise the blood supply to the anastomosis. The anvil should be firmly inserted into the gun such that a distinct ‘click’ is both heard and felt. No doubt must remain regarding the security of this union before proceeding to closure of the gun. During closure and activation, the surgeon at the abdominal end must remain vigilant to ensure that no fat or any other tissue becomes interposed between the jaws of the gun. Tissue may accidentally become incorporated from the pelvic floor, the pelvic sidewalls or the distal colon, and therefore the anastomosis must be fashioned with as much clearance from all these structures as is feasible. This requires careful inspection of the anastomosis from all angles during approximation of the tissue, and may necessitate the accurate use of forceps to move or remove any tissue at risk.

Once the anastomosis has been constructed, the stapling gun should be removed and the 'donuts' examined for their integrity. The donut corresponding to distal colon is found on the stem of the anvil, and its retrieval is usually straightforward. The donut originating from the rectal stump is often buried within the distal end of the shaft of the gun, and is more difficult to extract: simple traction will frequently result in disruption of the donut, and inability to comment on the integrity of the anastomosis. Therefore a pair of haemostatic forceps may be useful in first removing the white plastic ring found at the distal end of the stapling gun; the second donut should then follow more easily.

Additional testing of anastomotic integrity may be performed, but was not stipulated by the Expert Group recommendations. Such testing may include palpation per anus, external inspection of the anastomosis, or air leak testing. The latter involves occlusion proximal to the anastomosis with a soft clamp, filling the pelvis with saline, and the insufflation of air per anus via a catheter-tip syringe. The presence of air bubbles escaping into the pelvis signifies a positive test.

The action to be taken in the presence of a suspected or demonstrated anastomotic leak was also unspecified at the Expert Group meeting. Measures observed in the course of this study included the oversewing of the anastomosis and the use of a large-bore catheter inserted per anus. The value of such measures remains unproven, and their evaluation is beyond the scope of this study. On the other hand, the value of a covering ileostomy is widely recognised in reducing the severity if not the incidence of anastomotic leak rates. This is discussed further in the following section.

5.14 Task 12 – Formation of Ileostomy / Colostomy Part I

In meeting the objective of this task, namely the exteriorisation of ileum or colon, the surgeon aims to bring out the correct length of bowel in the correct site, without twisting or other unnecessary trauma to the bowel or abdominal wall. The importance of pre-operative assessment in ensuring the correct siting of the stoma has already been discussed in section 5.1. If a colostomy is being fashioned, the distance from the stoma site to the anchoring point of the bowel must be estimated, and additional dissection performed if the length of colon available is insufficient. The colon must also be prepared by stripping of excess peri-colic fat, being careful to ensure that vascularity of the distal colon is preserved. During this dissection vessels are best identified through continuous inspection and palpation of the mesentery; hidden vessels may be avoided through the use of shallow strokes of the diathermy.

Formation of the stoma site in the abdominal wall should commence with a circular scalpel incision with the blade held perpendicular to the skin. Attempts to create the skin incision by pulling anteriorly with forceps and slicing with the blade held parallel to the abdominal wall tended to result in shallow, ragged wounds and more bleeding from the dermis. Such techniques are to be avoided. The remainder of the dissection through the abdominal wall is most effective with diathermy, both for rapidity of progress, and to minimise blood loss from the wound. Traction and visualisation is best assisted through the application of Littlewood's forceps to the disc of skin and small Lahey style retractors to the skin edges. There is a tendency to stray towards the centre of the disc of skin, thereby creating a cone of subcutaneous fat rather than a cylinder.

Once the muscle layer is reached, the fascia is incised with diathermy in a cruciate fashion. Dissection through the muscle is then best performed with a pair of blunt-nosed scissors, to spread rather than cut the muscle fibres. This minimises trauma to the abdominal wall, and assists in preserving support around the stoma, thus reducing the risk of herniation. The stoma site is then stretched to a degree that will allow the bowel to be exteriorised. The amount of stretch exerted will depend upon the habitus of the patient, the bulk of the stoma, and the size and strength of the surgeon's fingers – the necessary combination of these factors can only be learned through practice.

Once the surgeon is ready to exteriorise the bowel, the orientation of the bowel should be checked, and the bowel marked to ensure that there can be no confusion once it has been brought out of the stoma. Useful techniques employed in this regard include a pattern of diathermy marks on the serosa, or temporary sutures placed superficially in the bowel. As the bowel is eased through the stoma site, the surgeon should continue to assess the adequacy of fit, and be prepared to return the bowel to the abdomen and enlarge the site if necessary. It is essential to protect the stoma from bowel content during this procedure, a task made much more difficult if the bowel has been clamped rather than sealed with staples. The bowel should not be opened at this stage, but simply secured in place until the surgeon is ready to complete the stoma. Failure to secure the bowel may result in its return to the abdominal cavity, and the potential for spillage of faecal material into the peritoneal cavity.

5.15 Task 13 – Closure of the abdomen

As task 13 is approached, the surgeon should consider the instruments and materials that will be required, and request these in advance so that the remainder of the operating team can make the necessary preparations. Other measures that will facilitate the smooth flow of the procedure include timely changes of suction disposal units (a step easily anticipated following the use of saline for abdominal washout), and accurate placement of sutures and staples, thereby avoiding the need to repeat these.

During mass closure of the abdomen the key to safe and accurate wound closure is visualisation of the deep wound edges, and keeping viscera clear of the suture. Accuracy of skin closure is assisted by careful alignment of the wound edges which may require the use of Littlewood's or similar forceps.

The role of intra-abdominal drains remains uncertain. Their benefits (such as drainage of haemoserous fluid and early warning of haemorrhage) must be weighed against potential disadvantages, including the introduction of infection and trauma to the anastomosis. If drains are to be used, they should be placed at an appropriate point on the abdominal wall (respecting the inferior epigastric vessels), and directed to dependent positions in the abdomen and pelvis. The drain should then be secured promptly, so that it may not become accidentally dislodged. Common sense would dictate that the surgeon should have a lower threshold for using drains in procedures involving problematic haemorrhage.

In this regard, the surgeon should perform a careful inspection of the abdomen and pelvis to ensure haemostasis. Washout of the abdomen with copious volumes of warm saline assists not only in clearing the abdomen of blood and reducing any microbial peritoneal load, but also in the rapid identification of sites of continued bleeding. Nonetheless, in an endeavour to establish a dry operating field, the surgeon must not compromise the bowel so carefully dissected and anastomosed in the preceding tasks. Over-zealous haemostasis may cause significant injury, such as ischaemia of the anastomosis as documented in one of the procedures.

5.16 Task 14 – Formation of ileostomy / colostomy Part II

The errors most frequently observed during task 14 are those associated with the risk of infection. Adherence to three error reduction mechanisms at this stage would eliminate most of these errors. The abdominal wound should be covered or dressed before fashioning of the stoma; the surgeon should therefore ensure that suction is ready and on-hand prior to creation of the enterotomy or colostomy; and the stoma bag should be applied as soon as the stoma is completed.

A fixed sequence of suture placement should be followed to ensure that the stoma is correctly fashioned. Incorrect sequencing will lead to difficulties in stoma management for the patient, or the need to remove and re-insert sutures with the associated risk of bleeding and stomal haematoma. During formation of the stoma, accurate placement of everting sutures will obviate the need for traumatic means of eversion such as Babcock's forceps.

5.17 Quantitative analysis

In correlating errors and outcomes, this study has also demonstrated that it is possible to record, document and analyse surgical process in a way that allows modelling of outcome. As has been proven, surgical technique is a quantifiable entity, the measure of which correlates directly with the end result. With the correct tools for analysis of technique, it should be possible to model for other outcomes such as blood loss, wound infection and local recurrence. In order to model for these outcomes, it may be helpful to consider the interplay between process and outcome in more detail (Figure 31).

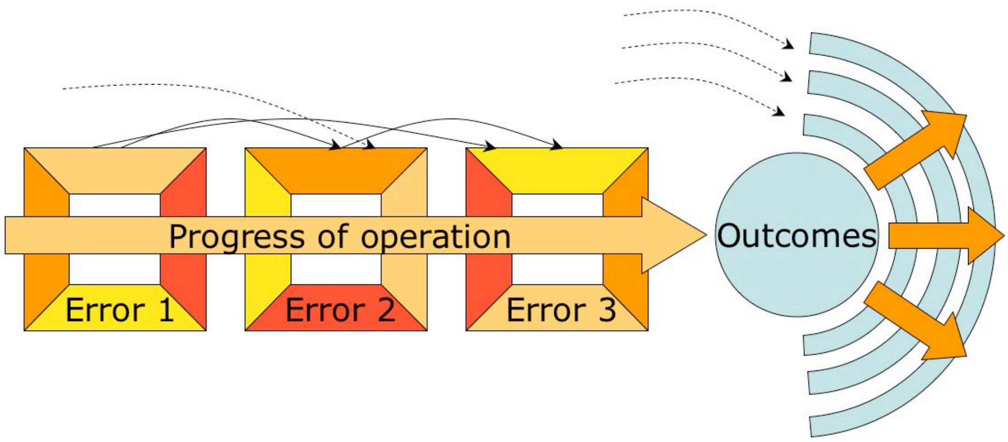


Figure 31 – Interplay between process and outcome. → Direct relationships; --→ Indirect relationships. Errors are depicted as multidimensional events, described in terms of tissue, tool, surgeon and system interactions. Each error is dependent upon preceding steps and errors, as well as external events. The consequences or outcomes that immediately follow errors are more apparent, whereas those that are further removed will also be affected by other factors, and will be less directly influenced by any given error.

In Figure 1, we considered surgical process as a 'black box'. In conducting this study, the contents of the box were described as discrete albeit inter-related error events. Each error event is a multi-dimensional action, depicting the interaction between surgeon, instrument and tissue, and the immediate effect thereof. These errors accumulate not simply in a linear fashion, but with complex dependencies upon preceding errors, and upon external factors such as patient pathophysiology and stage of disease.

At the immediate conclusion of the operation, the status of the patient and of the tissues is most directly related to the inputs of the operation and per-operative care. It is for these immediate outcomes that we should expect surgical technique to correlate most simply with outcome. Therefore it is not surprising that observed mesorectal injury is related so closely to the appearance of the specimen (R = 0.904), as there are few external factors to disturb this direct relationship.

However, the question of *how* these injuries occur is more complex. Although it is straightforward to demonstrate that procedures with a high error count also contain high rates of observed tissue damage, it is difficult to identify the specific operative factors involved. Individual hypotheses may be tested, for example that poor retraction, limited visibility and excess bleeding lead to more difficult dissections. However, the range of other potential contributing factors is so vast that traditional statistical analyses cannot identify all relevant inputs.

Similarly, more distal outcomes such as wound infection and local recurrence are more difficult to model because they are dependent not only upon the operation, but also upon external factors. Such data were gathered for the purpose of this study, but the statistical models that allow their analysis are yet to be developed.

5.18 Strengths of HRA

The approach adopted in this study has, for the first time, allowed the detailed demonstration and documentation of the processes that determine outcome in a complex surgical procedure. Utilising a multi-dimensional human error identification tool, and through prospective analysis, many error combinations were identified. Categorisation of each dimension of these errors allowed compound actions and their consequences to be evaluated and compared between different tasks, and between operations.

The development of a mobile video recording unit, allowed the recruitment of multiple centres, resulting in the capture of a wide variety of surgical techniques. This variety demonstrated both the diversity of acceptable and safe techniques, and those instances in which deviating from established technique may lead to adverse consequences.

The task analysis upon which this study was based was the result of an expert group meeting. World leaders in the fields of rectal surgery and surgical ergonomics contributed to the document through a consensus process, providing an authoritative standard against which the recordings could be compared in meticulous detail. The potential for maximal yield in data analysis was ensured through iterative development of the task analysis and the error coding system.

Recording of multi-angle synchronised video streams delivered high-resolution detail of the surgical process, and also wider views of the operating field. This combination guaranteed the greatest chance of capturing all relevant surgical activity, and kept the proportion of a procedure that could not be analysed to a minimum.

The software used for data analysis and extraction was tailored to the exacting demands of the study. Review of the recorded material was played on multiple screens, each window synchronised to a central control panel, for frame-by-frame playback if required. Customised shorthand codes improved efficiency of data entry, with automatic confirmation of code definitions to avoid errors in transcription. Formatting of entries with task and subtask numbers, as well as error codes, time stamp and free text maximised the volume of data that could be gathered, organised in such a way that facilitated post-analysis extraction. HRA coding of surgical procedures was validated in a two-step process, with sampled review of video footage by an expert colorectal surgeon (Robert Steele), followed by review of the ergonomic coding applied to the footage (George Hanna).

The result of this methodology was a study that bridges the gap between surgical process and outcome, identifying ‘error prone’ techniques. This risk reduction approach allows modification of surgical technique without waiting for adverse outcomes as indicators of suboptimal performance.

5.19 Weaknesses of HRA

Some of the strengths of this approach may also be seen as weaknesses. The meticulous nature of data analysis that allowed identification of thousands of errors comes at a price. This work is extremely time consuming, and therefore expensive. It is also impractical to apply this analytical technique throughout the health service, as the resources required are not available. Therefore this methodology is not compatible with the 'real world', and cannot be used as an audit or revalidation of surgical technique.

The intensive nature of the work also limited the number of patients that could be recruited to the study, limiting the generalisability of the findings. To achieve statistical correlation between process and distal outcomes such as local recurrence, thousands of operations would need to be analysed, a task not possible even in the research setting. The prospective character of this research also resulted in many false recruitments, recording surgical procedures that could not be utilised, for example, those operations in which no tumour was found, or no resection was possible.

Formal kappa studies and measures of agreement were not performed, partly due to time limitations of external experts, and partly due to the specialised skills required. For this study, expertise was required not only in rectal surgery, but also in ergonomics, and also training and expertise in the use of the error codes and software developed for the study. Such a combination of expertise was feasible only for the primary researcher, and not for any of the other contributing experts.

Although observation of error sequences permitted the formulation of logical and evidence-based error reduction mechanisms, these recommendations have yet to be validated in a future cycle. Indeed, such a cycle of analysis, intervention and re-analysis may not be feasible in the real world for the reasons outlined above. Instead, the recommendations must be applied in a generalised fashion, not tailored to individual error-types. Nonetheless, the impact of such error-reduction mechanisms may be measurable through traditional methods such as audit of surgical morbidity and pathological specimens.

5.20 Future work

To this end, the next step required is dissemination of the lessons learned from this study. Presentations to this effect have already been given at local, national and international levels, but the key messages must be more widely propagated. This will be achieved through peer-reviewed publication, but also needs to be adopted by the surgical colleges and tutors for incorporation in training programmes.

If the impact of this training is to be quantified, measures of operative performance must be taken prior to and at intervals after its introduction. Such measures would ideally consist of intra-operative error identification, but audits of surgical morbidity may have to suffice in practice.

The exception to this compromise may be within the research setting. In trials of surgical procedures, standardisation of operative technique is fundamental to inter-group comparisons. The methodology outlined in this thesis delivers standardisation, and provides mechanisms to achieve a uniform and safe procedure.

Although this study has considered surgical technique in isolation, the reality is that this ‘black box’ is embedded within that of peri-operative care, and the two should be considered in tandem. Standardisation of the surgical procedure will not lead to standardisation or optimisation of outcomes unless the same processes are applied to peri-operative care. Critical evaluation of every aspect of the patient journey is required in order to achieve this goal, although the resource requirements may be prohibitive in routine care. Nonetheless, the lessons learned from such a comprehensive approach, even if confined to the research setting, would be applicable across all practices, and to a wide range of procedures.

Chapter 6

CONCLUSION

6 Conclusion

This study has developed the application of HRA to complex surgical procedures and demonstrated the utility of such methods in error identification and reduction for surgery. Through the systematic deconstruction of a procedure (task analysis), evaluation of deviations from the task analysis (error identification) and methods whereby these errors may be avoided (error reduction mechanisms), a detailed blueprint has been developed that should prove valuable in the teaching and refining of this procedure.

The value and proof of this work will lie in the adoption and use of the blueprint, and by evaluation of additional procedures to determine the magnitude of error reduction that results from the implementation of these measures.

Now that HRA has been successfully applied to a complex surgical procedure that is associated with significant difficulties in obtaining adequate views, there should be few procedures that remain outwith the scope of this methodology. It is my hope that HRA and other similar techniques of analysis will be implemented across a wide range of procedures, and that surgeons and patients may benefit from improved standards of surgical technique that may follow.

Chapter 7

BIBLIOGRAPHY

7 Bibliography

1. Martling AL, Holm T, Rutqvist LE, Moran BJ, Heald RJ, Cedermark B. Effect of a surgical training programme on outcome of rectal cancer in the County of Stockholm. Stockholm Colorectal cancer study group, Basingstoke Bowel Cancer Research Project. *Lancet* 2000;356(9224):93–96.
2. Cancer Stats / Mortality - UK: Cancer Research U.K., 2003.
3. Kapiteijn E, van de Velde CJ. Developments and quality assurance in rectal cancer surgery. *Eur J Cancer* 2002;38(7):919–36.
4. Finn-Faivre C, Maurel J, Benhamiche AM, Herbert C, Mitry E, Launoy G, et al. Evidence of improving survival of patients with rectal cancer in France: a population based study. *Gut* 1999;44(3):377–81.
5. Walsh JME, Terdiman JP. Colorectal cancer screening: scientific review. *JAMA* 2003;289:1288–96.
6. Dachman AH, Yoshida H. Virtual colonoscopy: past, present, and future. *Radiol Clin* 2003;41(2):377–93.
7. Townsend DW, Beyer T. A combined PET/CT scanner: the path to true image fusion. *Br J Radiol* 2002;75:S24–S30.
8. Gibbs P, Chao MW, Tjandra JJ. Optimizing the outcome for patients with rectal cancer. *Dis Colon Rectum* 2003;46:389–402.
9. Heald RJ, Moran BJ, Ryall RD, Sexton R, MacFarlane JK. Rectal cancer: the Basingstoke experience of total mesorectal excision, 1978 - 1997. *Arch Surg* 1998;133:894–99.
10. Heald RJ. Rectal cancer: the surgical options. *Eur J Cancer* 1995;31:1189–92.
11. MacFarlane JK, Ryall RD, Heald RJ. Mesorectal excision for rectal cancer. *Lancet* 1993;341(8843):457–60.
12. Heald RJ, Ryall RD. Recurrence and survival after total mesorectal excision for rectal cancer. *Lancet* 1986;1:1479–82.
13. Karanjia ND, Corder AP, Bearn P, Heald RJ. Leakage from stapled low anastomosis after total mesorectal excision for carcinoma of the rectum. *Br J Surg* 1994;81:1224–26.
14. Hainsworth PJ, Egan MJ, Cunliffe WJ. Evaluation of a policy of total mesorectal excision for rectal and rectosigmoid cancers. *Br J Surg* 1997;84(5):652–56.
15. Tagliacozzo S, Accordino M. Pelvic recurrence after surgical treatment of rectal and sigmoid cancer. A prospective clinical trial on 274 patients. *Int J Colorectal Dis* 1992;7:135–40.
16. Polglase AL, McMurrick PJ, Tremayne AB, Bhathal PS. Local recurrence after curative anterior resection with principally blunt dissection for carcinoma of the rectum and rectosigmoid. *Dis Colon Rectum* 2001;44(7):947–54.
17. Heald RJ. The surgical aspects of total mesorectal excision: The Pelican Cancer Foundation, 2003.
18. Phillips RK, Hittinger R, Blesovsky L, Fry JS, Fielding LP. Local recurrence following 'curative' surgery for large bowel cancer: I. The overall picture. *Br J Surg* 1984;71:Dec–16.
19. McArdle CS, Hole D. Impact of variability among surgeons on postoperative morbidity and ultimate survival. *BMJ* 1991;302(6791):1501–05.
20. Porter GA, Soskolne CL, Yakimets WW, Newman SC. Surgeon-related factors and outcome in rectal cancer. *Ann Surg* 1998;227(2):157–67.

21. Holm T, Johansson H, Cedermark B, Ekelmund G, Rutqvist LE. Influence of hospital- and surgeon-related factors on outcome after treatment of rectal cancer with or without preoperative radiotherapy. *Br J Surg* 1997;84(5):657–63.
22. Kapiteijn E, Putter H, van de Velde CJH, and cooperative investigators of the Dutch ColoRectal Group. Impact of the introduction and training of total mesorectal excision on recurrence and survival in rectal cancer in the Netherlands. *Br J Surg* 2002;89:1142–49.
23. Schrag D, Pangeas KS, Riedel E, Cramer LD, Guillem JG, Bach PB, et al. Hospital and surgeon procedure volume as predictors of outcome following rectal cancer resection. *Ann Surg* 2002;236(5):583–92.
24. Hermanek P. Impact of surgeon's technique on outcome after treatment of rectal carcinoma. *Dis Colon Rectum* 1999;42(5):559–662.
25. Quirke P, Durdey P, Dixon MF, Williams NS. Local recurrence of rectal adenocarcinoma due to inadequate surgical resection. Histopathological study of lateral tumour spread and surgical excision. *Lancet* 1986;2(8514):996–9.
26. De Haas-Kock DF, Baeten CG, Jager JJ, Langendijk JA, Schouten LJ, Volovics A, et al. Prognostic significance of radial margins of clearance in rectal cancer. *Br J Surg* 1996;83(6):781-5.
27. Adam IJ, Mohamdee MO, Martin IG, Scott N, Finan PJ, Johnston D, et al. Role of circumferential margin involvement in the local recurrence of rectal cancer. *Lancet* 1994;344(8924):707–11.
28. Cawthorn SJ, Parums DV, Gibbs NM, A'Hern RP, Caffarey SM, Broughton CI, et al. Extent of mesorectal spread and involvement of lateral resection margin as prognostic factors after surgery for rectal cancer. *Lancet* 1990;335(8697):1055–9.
29. Birbeck KF, Macklin CP, Tiffin NJ, Parsons W, Dixon MF, Mapstone NP, et al. Rates of circumferential resection margin involvement vary between surgeons and predict outcomes in rectal cancer surgery. *Ann Surg* 2002;235(4):449-57.
30. Wibe A, Rendedal PR, Svensson E, Norstein J, Eide TJ, Myrvold HE, et al. Prognostic significance of the circumferential resection margin following total mesorectal excision for rectal cancer. *Br J Surg* 2002;89(3):327-34.
31. Hall NR, Finan PJ, al Jaberi T, Tsang CS, Brown SR, Dixon MF, et al. Circumferential margin involvement after mesorectal excision of rectal cancer with curative intent. Predictor of survival but not local recurrence. *Dis Colon Rectum* 1998;41(8):979–83.
32. Quirke P. Limitations of existing systems of staging for rectal cancer. In: Soreide O, Norstein J, editors. *Rectal Cancer Surgery: Optimisation, Standardisation, Documentation*. Berlin: Springer-Verlag, 1997:63-81.
33. Nagtegaal ID, van de Velde CJ, van der Worp E, Kapiteijn E, Quirke P, van Krieken JH, et al. Macroscopic evaluation of rectal cancer resection specimen: clinical significance of the pathologist in quality control. *J Clin Oncol* 2002;20(7):1729–34.
34. Guidelines for the management of colorectal cancer. London: Association of ColoProctology of Great Britain & Ireland, 2001.
35. Anwar RM, Britton A, Stevens W. Curative resection for rectal carcinoma: definition influences outcome in terms of local recurrence. *Colorectal Dis* 2001;3:312–17.

36. Soreide O, Norstein J. Local recurrence after operative treatment of rectal carcinoma: a strategy for change. *J Am Coll Surg* 1997;184:84–92.
37. Hermanek P, Sobin LH, eds. *TNM classification of malignant tumours*. UICC, 4th ed. Berlin: New York: Springer-Verlag, 1987.
38. Williams NS, Dixon MF, Johnston D. Reappraisal of the 5 centimetre rule of distal excision for carcinoma of the rectum: a study of distal intramural spread and of patients' survival. *Br J Surg* 1983;70:150–54.
39. Chia KS, Du WB, Sankaranarayanan R, Sankila R, Seow A, Lee HP. Population-based cancer survival in Singapore. *Int J Cancer* 2001;93(1):142–47.
40. Karanjia ND, Schache DJ, North WR, Heald RJ. 'Close shave' in anterior resection. *Br J Surg* 1990;77(5):510–12.
41. Smidt ML, Wegdam JA, Bremers AJA, Bleichrodt RP. Missing evidence for the adequacy of a 1-cm distal margin in resected rectal cancer. *Ann Surg Oncol* 2003;10(7):823–24.
42. Guillem JG, Moore HG, Paty PB, Cohen AM, Wong WD. Adequacy of distal resection margin following preoperative combined modality therapy for rectal cancer. *Ann Surg Oncol* 2003;10(7):824.
43. Wibe A, Syse A, Andersen E, Tretli S, Myrvold HE, Soreide O, et al. Oncological outcomes after total mesorectal excision for cure for cancer of the lower rectum: anterior vs. abdominoperineal resection. *Dis Colon Rectum* 2004;47(1):48–58.
44. Nagtegaal ID, van de Velde C, Marijnen C, van Krieken JH, Quirke P, Group DCC, et al. Low rectal cancer: a call for a change of approach in abdominoperineal resection. *J Clin Oncol* 2005;23(36):9257-64.
45. Nicholls RJ. Surgery for rectal carcinoma. In: Nicholls RJ, Dozois RR, editors. *Surgery of the colon and rectum*. London: Churchill Livingston, 1997.
46. World Health Organization. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York.19–22 June, 1946; signed on 22 July 46 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p100) and entered into force on 7 April 48.
47. Sailer M, Fuchs KH, Fein M, Thiede A. Randomized clinical trial comparing quality of life after straight and pouch coloanal reconstruction. *Br J Surg* 2002;89(9):1108–17.
48. Whynes DK, Neilson AR. Symptoms before and after surgery for colorectal cancer. *Qual Life Res* 1997;6:61–66.
49. Brennan TA, Leape LL, Laird NM. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study. *N Engl J Med* 1991;324:370–76.
50. Jess P, Christiansen J, Bech P. Quality of life after anterior resection versus abdominoperineal extirpation for rectal cancer. *Scand J Gastroenterol* 2002;37(10):1201–04.
51. Kim DG, Madoff RD. Transanal treatment of rectal cancer: ablative methods and open resection. *Semin Surg Oncol* 1998;15:101–13.
52. Ness RM, Holmes A, Kleine R, Greene J, Dittus R. Outcome states of colorectal cancer: identification and description using patient focus groups. *Am J Gastroenterol* 1998;93(9):1491–97.
53. van Duijvendijk P, Slors F, Taat CW, Heisterkamp SH, Obertop H, Boeckxstaens GE. A prospective evaluation of anorectal function after total

mesorectal excision in patients with a rectal carcinoma. *Surgery* 2003;133:56–65.
54. Mannaerts GH, Rutten HJ, Martijn H, Hanssens PEJ, Wiggers T. Effects on functional outcome after IORT-containing multimodality treatment for locally advanced primary and locally recurrent rectal cancer. *Int J Radiat Oncol Biol Phys* 2002;54:1082–88.
55. Graf W, Ekstrom K, Glimelius B, Pahlman L. A pilot study of factors influencing bowel function after colorectal anastomosis. *Dis Colon Rectum* 1996;39:744–49.
56. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993;85(5):365–76.
57. Sprangers MAG, te Velde A, Aaronson NK. The construction and testing of the EORTC colorectal cancer-specific quality of life questionnaire module (QLQ-CR38). European Organization for Research and Treatment of Cancer Study Group on Quality of Life. *Eur J Cancer* 1999;35:238–47.
58. Camilleri-Brennan J, Steele RJC. Quality of life after treatment for rectal cancer. *Br J Surg* 1998;85:1036–43.
59. Azpiroz F, Enck P, Whitehead WE. Anorectal functional testing: review of collective experience. *Am J Gastroenterol* 2002;97(2):232–40.
60. Petersen S, Freitag M, Hellmich G, Ludwig K. Anastomotic leakage: impact on local recurrence and survival in surgery of colorectal cancer. *Int J Colorectal Dis* 1998;13:160–63.
61. Alstrup N, Ronholt C, Fu C, Rasmussen O, Sorensen M, Christiansen J. Viscous fluid expulsion in the evaluation of the constipated patient. *Dis Colon Rectum* 1997;40(5):580–84.
62. Hallbook O, Nystrom PO, Sjodahl R. Physiologic characteristics of straight and colonic J-pouch anastomoses after rectal excision for cancer. *Dis Colon Rectum* 1997;40(3):332–38.
63. Wang JY, You YT, Chen HH, Chiang JM, Yeh CY, Tang R. Stapled colonic J-pouch anal anastomosis without a diverting colostomy for rectal cancer. *Dis Colon Rectum* 1997;40:30–34.
64. Joo JS, Latulippe JF, Alabaz O, Weiss EG, Nogueras JJ, Wexner SD. Long-term functional evaluation of straight coloanal anastomosis and colonic J-pouch: is the functional superiority of colon J-pouch sustained? *Dis Colon Rectum* 1998;41:740–46.
65. Nesbakken A, Nygaard K, Westerheim O, Lunde OC, Mala T. Audit of intraoperative and early postoperative complications after introduction of mesorectal excision for rectal cancer. *Eur J Surg* 2002;168(4):229–35.
66. Junginger T, Kneist W, Heintz A. Influence of identification and preservation of pelvic autonomic nerves in rectal cancer surgery on bladder dysfunction after total mesorectal excision. *Dis Colon Rectum* 2003;46(5):621–28.
67. Amato AC, Pescatori M. Effect of perioperative blood transfusions on recurrence of colorectal cancer: meta-analysis stratified on risk factors. *Dis Colon Rectum* 1998;41:570–85.
68. Chung M, Steinmetz OK, Gordon PH. Perioperative blood transfusion and outcome after resection for colorectal cancer. *Br J Surg* 1993;80:427–32.

69. Quigley RL. The effect of leukocytes on adhesion molecules. An explanation of blood transfusion enhancement of tumor growth. *Arch Surg* 1996;131:438–41.
70. Blajchman MA. Immunomodulatory effects of allogeneic blood transfusions: clinical manifestations and mechanisms. *Vox Sang* 1998;74:315–19.
71. Busch OR, Hop WC, Marquet RL, Jeekel J. Blood transfusions and local tumour recurrence in colorectal cancer. Evidence of a noncausal relationship. *Ann Surg* 1994;220:791–97.
72. Porter GA, O'Keefe GE, Yakimets WW. Inadvertent perforation of the rectum during abdominoperineal resection. *Am J Surg* 1996;172:324–27.
73. Kagda FH, Nyam DC, Ho YH, Eu KW, Leong AF, Seow-Choen F. Surgery may be curative for patients with a localized perforation of rectal carcinoma. *Br J Surg* 1999;86(11):1448–50.
74. Longo WE, Virgo KS, Johnson FE, Wade TP, Vernava AM, Phelan MA, et al. Outcome after proctectomy for rectal cancer in Department of Veterans Affairs Hospitals: a report from the National Surgical Quality Improvement Program. *Ann Surg* 1998;228(1):64–70.
75. Kressner U, Graf W, Mahteme H, Pahlman L, Glimelius B. Septic complications and prognosis after surgery for rectal cancer. *Dis Colon Rectum* 2002;45(3):316–21.
76. Song F, Glenny AM. Antimicrobial prophylaxis in colorectal surgery: a systematic review of randomized controlled trials. *Br J Surg* 1998;85(9):1232-41.
77. Arbman G, Nilsson E, Hallbook O, Sjodahl R. Local recurrence following total mesorectal excision for rectal cancer. *Br J Surg* 1996;83:375–79.
78. Saha S, Booth MI, Dehn TC. The results of total mesorectal excision for rectal carcinoma in a district general hospital before the era of surgical specialization. *Colorectal Dis* 2002;4(1):36–40.
79. Puig-La Calle J, Quayle J, Thaler HT, Shi W, Paty PB, Quan SHQ, et al. Favorable short-term and long-term outcome after elective radical rectal cancer resection in patients 75 years of age or older. *Dis Colon Rectum* 2000;43:1704–09.
80. 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):355–58.
81. Marusch F, Koch A, Schmidt U, Geiler S, Dralle H, Saeger HD, et al. Value of a protective stoma in low anterior resections for rectal cancer. *Dis Colon Rectum* 2002;45(9):1164–71.
82. Fujita S, Teramoto T, Watanabe M, Kodaira S, Kitajima M. Anastomotic leakage after colorectal cancer surgery: a risk factor for recurrence and poor prognosis. *Jpn J Clin Oncol* 1993;23:229–302.
83. Akyol AM, McGregor JR, Galloway DJ, Murray GD, George WD. Anastomotic leaks in colorectal cancer surgery: a risk factor for local recurrence. *Int J Colorectal Dis* 1991;6:179–83.
84. Enker WE, Merchant N, Cohen AM, Lanouette NM, Swallow C, Guillem J, et al. Safety and efficacy of low anterior resection for rectal cancer: 681 consecutive cases from a specialty service. *Ann Surg* 1999;230(4):544–52.
85. Carlsen E, Schlichting E, Guldvog I, Johnson E, Heald R. Effect of the introduction of total mesorectal excision for carcinoma of the rectum. *Br J Surg* 1998;85:526–29.

86. McCall JL. Total mesorectal excision: evaluating the evidence. *Aus N Z J Surg* 1997;67(9):599–602.
87. Hallbook O, Pahlman L, Krog M, Wexner SD, Sjodahl R. Randomized comparison of straight and colonic J pouch anastomosis after low anterior resection. *Ann Surg* 1996;224:58–65.
88. 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.
89. Carli F, Trudel JL, Belliveau P. The effect of intraoperative thoracic epidural anesthesia and postoperative analgesia on bowel function after colorectal surgery: a prospective, randomized trial. *Dis Colon Rectum* 2001;44(8):1083–89.
90. Danelli G, Berti M, Perotti V, Albertin A, Baccari P, Deni F, et al. Temperature control and recovery of bowel function after laparoscopic or laparotomic colorectal surgery in patients receiving combined epidural/general anesthesia and postoperative epidural analgesia. *Anesth Analg* 2002;95(2):467–71.
91. Killingback M, Barron P, Dent O. Elective resection and anastomosis for colorectal cancer: a prospective audit of mortality and morbidity 1976-1998. *ANZ J Surg* 2002;72(10):689–98.
92. Gunnarsson U, Seligsohn E, Jestin P, Pahlman L. Registration and validity of surgical complications in colorectal cancer surgery. *Br J Surg* 2003;90(4):454–59.
93. Semmens JB, Platell C, Threlfall TJ, Homan CD. A population based study of the incidence, mortality and outcomes in patients following surgery for colorectal cancer in Western Australia. *Aust N Z J Surg* 2000;70(1):43405.
94. Smith JA, King PM, Lane RH, Thompson MR. Evidence of the effect of 'specialization' on the management, surgical outcome and survival from colorectal cancer in Wessex. *Br J Surg* 2003;90(5):583–92.
95. Garcia-Valdecasas JC, Almenara R, Cabrer C, de Lacy AM, Sust M, Taura P, et al. Subcostal incision versus midline laparotomy in gallstone surgery: a prospective and randomised trial. *Br J Surg* 1988;75(5):473–75.
96. Massucci M, Lauri D, Faraglia V, Speziale F, De Santis F, Taurino M, et al. Approach to the abdominal aorta: impairment of respiratory function after supraumbilical transverse and midline laparotomy. *Ital J Surg Sci* 1989;19(3):247-53.
97. Halasz NA, Calif T. Vertical Vs Horizontal Laparotomies. I. Early Postoperative Comparisons. *Arch Surg* 1964;88:911–14.
98. Greenall MJ, Evans M, Pollock AV. Midline or transverse laparotomy? A random controlled clinical trial. Part II: Influence on postoperative pulmonary complications. *Br J Surg* 1980;67:191–94.
99. Lacy PD, Burke PE, O'Regan M, Cross S, Sheehan SJ, Hehir D, et al. The comparison of type of incision for transperitoneal abdominal aortic surgery based on postoperative respiratory complications and morbidity. *Eur J Vasc Surg* 1994;8(1):52–5.
100. Tekkis PP, Kessaris N, Kocher HM, Poloniecki JD, Lyttle J, Windsor AC. Evaluation of POSSUM and P-POSSUM scoring systems in patients undergoing colorectal surgery. *Br J Surg* 2003;90(3):340–5.
101. Isbister WH, Al Sanea N. POSSUM: a re-evaluation in patients undergoing surgery for rectal cancer. The Physiological and Operative Severity Score for Enumeration of Mortality and Morbidity. *ANZ J Surg* 2002;72:421–25.

102. Uddin FJ, Burke D. The use of POSSUM scores for morbidity and mortality in rectal cancer. *Br J Surg* 2003;90 (S1):84.
103. Menon KV, Farouk R. An analysis of the accuracy of P-POSSUM scoring for mortality risk assessment after surgery for colorectal cancer. *Colorectal Dis* 2002;4(3):197–200.
104. Senagore AJ, Delaney CP, Duepree HJ, Brady KM, Fazio VW. Evaluation of POSSUM and P-POSSUM scoring systems in assessing outcome after laparoscopic colectomy. *Br J Surg* 2003;90(10):1280–84.
105. Schrag D. Surgeon volume compared to hospital volume as a predictor of outcome following primary colon cancer resection. *J Surg Oncol* 2003;83(2):68–78.
106. Calland JF, Guerlain S, Adams RB, Tribble CG, Foley E, Chekan EG. A systems approach to surgical safety. *Surg Endosc* 2002;16(6):1005-14.
107. Lyons M, Adams S, Woloshynowych M, Vincent C. Human reliability analysis in healthcare: a review of techniques. *International Journal of Risk & Safety in Medicine* 2004;16:223-37.
108. Heald RJ. The 'Holy Plane' of rectal surgery. *J R Soc Med* 1988;81:503–08.
109. Heald RJ, Husband EM, Ryall RD. The mesorectum in rectal cancer surgery - the clue to pelvic recurrence. *Br J Surg* 1982;69:613–16.
110. Steele RJC. Anterior resection with total mesorectal excision. *J R Coll Surg Edinb* 1999;44(1):40–45.
111. Landheer ML, Therasse P, van de Velde CJH. The importance of quality assurance in surgical oncology in the treatment of colorectal cancer. *Surg Oncol Clin N Am* 2001;10(4):885–914.
112. Reznick R, Regehr G, MacRae H, Martin J, McCulloch W. Testing technical skill via an innovative "bench station" examination. *Am J Surg* 1997;173:226–30.
113. Regehr G, MacRae H, Reznick RK, Szalay D. Comparing the psychometric properties of checklists and global rating scales for assessing performance on an OSCE-format examination. *Acad Med* 1998;73:993–97.
114. Moorthy K, Munz Y, Sarker SK, Darzi A. Objective assessment of technical skills in surgery. *BMJ* 2003;327:1032–37.
115. Ergonomics: definition. Loughborough: The Ergonomics Society, 2004.
116. Gilbreth FB. Motion study in surgery. *Can J Med Surg* 1916;40:22–31.
117. Lawrence WH, Berry CH. Arrangement of the operating room. *Am J Surg* 1939;43:669–74.
118. Joice P, Hanna GB, Cuschieri A. Ergonomic evaluation of laparoscopic bowel suturing. *Am J Surg* 1998;176(4):373–78.
119. Joice P, Hanna GB, Cuschieri A. Errors enacted during endoscopic surgery - a human reliability analysis. *Appl Ergon* 1998;29(6):409–14.
120. Satava RM, Fried MP. A methodology for objective assessment of errors: an example using an endoscopic sinus surgery simulator. *Otolaryngol Clin North Am* 2002;85(6):1289–301.
121. Cao CG, MacKenzie CL, Ibbotson JA, Turner LJ, Blair NP, Nagy AG. Hierarchical decomposition of laparoscopic procedures. *Stud Health Technol Inform* 1999;62:83-9.
122. Way LW, Stewart L, Gantert W, Liu K, Lee CM, Whang K, et al. Causes and prevention of laparoscopic bile duct injuries: analysis of 252 cases from a human factors and cognitive psychology perspective. *Ann Surg* 2003;237(4):460–69.

123. Botha AJ, Elton C, Moore EE, Sauven P. Laparoscopic appendicectomy: a trainee's perspective. *Ann R Coll Surg Engl* 1996;78(1):71–72.
124. Sjoerdsma W, Meijer DW, Jansen A, den Boer KT, Grimbergen CA. Comparison of efficiencies of three techniques for colon surgery. *J Lap Adv Surg Tech* 2000;10:47–53.
125. Landheer ML, Therasse P, van de Velde CJ. Quality assurance in surgical oncology (QASO) within the European Organization for Research and Treatment of Cancer (EORTC): current status and future prospects. *Eur J Cancer* 2001;37(12):1450–62.
126. Kirwan B, Ainsworth LK. *A Guide to Task Analysis*: London: Taylor & Francis, 1992.
127. Tang B, Hanna GB, Joice P, Cuschieri A. Identification and categorization of technical errors by Observational Clinical Human Reliability Assessment (OCHRA) during laparoscopic cholecystectomy. *Arch Surg* 2004;139(11):1215-20.
128. Heald RJ, Goligher JC. Anterior resection of the rectum. In: Fielding LP, Goldberg SM, editors. *Surgery of the colon, rectum and anus*. 5th ed. London: Butterworth-Heinemann Ltd., 1993:456–71.
129. Heald RJ. Total mesorectal excision [Video presentation]. Basingstoke: The Pelican Centre, North Hampshire Hospital, 1995.
130. Applescript Language Guide. Cupertino, California: Apple Computer, Incorporated, 1999.
131. Introduction to AppleScript Studio Programming Guide: Apple Computer, Incorporated, 2005.
132. Andersson R. MacScripter, 2005.
133. Copeland GP, Jones D, Walters M. POSSUM: a scoring system for surgical audit. *Br J Surg* 1991;78:355–60.
134. Quirke P, Williams GT. Minimum dataset for the histological reporting of colorectal carcinoma. London: Royal College of Pathologists, 1998.
135. Abercrombie JF, Jameson J, Richards C, Robinson MH, Armitage NC. A novel method of photographic audit of quality of rectal cancer surgical specimens: assessment of inter-observer variability. *Colorectal Dis* 2004;6(S1):27.
136. Seiler CM, Deckert A, Diener MK, Knaebel HP, Weigand MA, Victor N, et al. Midline versus transverse incision in major abdominal surgery: a randomized, double-blind equivalence trial (POVATI: ISRCTN60734227). *Ann Surg* 2009;249(6):913-20.
137. Holm T, Ljung A, Haggmark T, Jurell G, Lagergren J. Extended abdominoperineal resection with gluteus maximus flap reconstruction of the pelvic floor for rectal cancer. *Br J Surg* 2007;94(2):232-8.
138. West NP, Finan PJ, Anderin C, Lindholm J, Holm T, Quirke P. Evidence of the oncologic superiority of cylindrical abdominoperineal excision for low rectal cancer. *J Clin Oncol* 2008;26(21):3517-22.

Chapter 8

APPENDICES

Appendix 1

Task Analysis for Anterior Resection

Anterior Resection of the Rectum

Task Analysis – Summary in Brief

Instruction

Perform sections (**1 – 14**) in series

Perform steps (1 – 2 – 3, etc) as instructed at the end of each section

1. Access abdomen

1. Cutting diathermy or knife to length of intended wound
2. Retract on both sides of wound
3. Deepen with diathermy
4. Incise linea alba or muscular-fascial layer
5. Incise peritoneum
6. Lengthen through all layers with coagulation diathermy or scissors
7. Arrest bleeding points

Do 1 – 6 In series

Do 7 Throughout

Endpoint: When able to access all quadrants and pelvis without difficulty

2. Identify advanced disease or complicating factor

1. Explore all quadrants systematically for advanced disease

2. Assess mobility of sigmoid and rectum

3. Assess for and control any bleeding

Do 1 – 2 In series

Do 3 Throughout

Endpoint: When satisfied that disease not locally advanced or disseminated

Else exit protocol

3. Optimise access & exposure

1. Place and position Omnitract

2. Place hand-held retractors as appropriate

Do 1 *Or* Do 2

Endpoint: When descending and sigmoid colon adequately exposed

4. Dissect around sigmoid and descending colon

1. Retract sigmoid colon

2. Divide adhesions between sigmoid and lateral wall

3. Dissect mesocolon to free sigmoid colon

4. Dissect mesocolon to free descending colon

5. Arrest bleeding points

Do 1 – 2 – 3 In series

If colon not yet reaching easily to pelvis Do 4

Do 5 Throughout

Endpoint: When colon reaches easily to pelvis

In which case Omit Section 5

Or When descending colon freed to root of mesentery

If APER intended Omit Section 5

5. Dissect around splenic flexure

1. Divide adhesions between omentum & splenic capsule
2. Divide peritoneum between splenic flexure and lateral abdominal wall
3. Develop plane between transverse colon and greater omentum
4. Arrest bleeding points

Do 1 – 2 – 3 In series

Do 4 Throughout

Endpoint: When splenic flexure fully mobilised

6. Divide vessels in sigmoid mesocolon

1. Divide peritoneum to the right of sigmoid colon up to origin of IMA
2. Ligate and divide IMA

3. Dissect up to IMV

4. Ligate and divide IMV

5. Examine colon and divide any remaining adhesions

6. Arrest bleeding points

Do 1 – 5 In series

Do 6 Throughout

Endpoint: When IMA and IMV divided

And When sigmoid free in pelvis

7. Divide colon at optimal site

1. Divide mesocolon

2. Divide colon

3. Arrest bleeding points

Do 1 – 2 In series

Do 3 Throughout

Endpoint: When sigmoid colon and mesentery divided

Note: *If* surgeon preference *and* APER excluded, can insert head of stapler before Step 2

8. Mobilise rectum down to pelvic floor, avoiding damage to mesorectum or adjacent structures

1. Dissect posteriorly
2. Dissect laterally
3. Dissect anteriorly
4. Complete lateral dissection
5. Arrest bleeding points

Do 1 – 2 – 3 In series / Any order / As planes develop?

Do 4

Do 5 Throughout

Endpoint: When rectum exposed as denuded muscular tube down to pelvic floor

And satisfied that will be able to place stapler below tumour

Else transfer to abdomino-perineal excision (APER) protocol

9. Excise rectum with adequate margins

1. Place first row of staples

2. Perform rectal washout

3. Place second row of staples

4. Divide rectum with knife and release stapler

Do 1 – 4 In series

Endpoint: When rectum excised

10. Create colopouch or simple colotomy

1. Decide if colopouch required

2. Create colopouch

3. Create colotomy

Do 1 *If* rectum excised at pelvic floor Do 2

If head of stapler not yet inserted Do 3

Else proceed to Section 11 at step 3

Endpoint: When colopouch formed

Or When colotomy of sufficient size to admit head of stapler

11. Anastomose colon to rectal stump

1. Choose appropriate stapler

2. Insert head of stapler

3. Insert stapler into rectal stump and assemble gun

4. Activate and remove gun

5. Check integrity of anastomosis

Do 1 – 5 In series

Endpoint: When integrity of anastomosis ascertained

12. Exteriorise loop of ileum

1. Excise disc of skin

2. Complete hole for ileostomy

3. Select, orientate and mark ileum

4. Exteriorise ileum & secure

Do 1

Do 2 *Until* Ileostomy site of adequate size

Do 3 At any point before 4

Do 4

Endpoint: When loop of ileum exteriorised in correct orientation

13. Close midline wound

1. Ensure no swabs or instruments remain in abdomen
2. Washout pelvis and abdomen
3. Ensure haemostasis
4. Place drain into pelvis
5. Figure-of-eight suture to wound
6. Mass closure of wound
7. Clean wound
8. Close skin with staples
9. Apply dressing to midline wound
10. Apply dressing to drain site and activate drain

Do 1 – 2 – 3 In any order

If surgeon preference Do 4

If surgeon preference Do 5

Do 6 – 9 In series

If drain present Do 10

Endpoint: When dressing(s) in situ

14. Complete ileostomy

1. Perform enterotomy

2. Suture inferior aspect to skin

3. Create spout

4. Insert any remaining sutures

5. Check that stoma patent

6. Apply stoma bag

Do 1 – 6 In series

Endpoint: When stoma bag in situ

Appendix 2

Task Analysis for Abdominoperineal Resection

Abdomino-perineal Excision of the Rectum

Task Analysis – Summary in Brief

Instruction

Sections 1 – 8 completed above

Perform sections (**9 – 13**) in series

Perform steps (1 – 2 – 3, etc) as instructed at the end of each section

9. Excise rectum with adequate margins

1. Prepare perineal skin with Betadine
2. Place stay suture through anus
3. Cutting diathermy or knife to create elliptical incision around circumference of peri-anal skin (long axis of ellipse in AP direction)
4. Apply skin hooks around wound ('Lone Star' retainer)
5. Insert self-retaining retractor
6. Assistant places hand in pelvis, and extends fingers alongside rectum
7. Continue with coagulation diathermy outside external anal sphincter, towards assistant's fingers

8. Palpate wound to assess progress

9. Complete dissection with diathermy

10. Divide connective tissue bands with scissors

11. Remove and inspect rectum

12. Arrest bleeding points

Do 1 *If* surgeon preference Do 2

Do 3 *If* surgeon preference Do 4

Else Do 5

Do 6

Do 7 – 8 Posteriorly: alternately, until Waldeyer's fascia breached anterior to coccyx

Anteriorly: alternately, until recto-urethralis muscle divided

Postero-laterally: alternately, until pubo-rectalis muscle divided

Do 8 – 9 Alternately, until rectum freed *Or* no progress possible with diathermy

If connective tissue bands identified by palpation, and too deep for diathermy Do 10

If rectum not yet freed return to start of 8

Do 11

Do 12 Throughout

Endpoint: When rectum removed

10. Close perineal wound

1. Insert interrupted Vicryl sutures to opposing walls of anal canal
2. Close deep fascia with continuous running suture
3. Remove skin hooks or self-retainer from wound
4. Close superficial fascia with continuous running suture

Do 1 – 4 In series

Endpoint: When superficial fascia closed

11. Exteriorise loop of colon

1. Excise disc of skin
2. Complete hole for colostomy & assess size
3. Ensure colon not twisted
4. Exteriorise colon & secure

Do 1

Do 2 *Until* colostomy site of adequate size

Do 3 – 4 In series

Endpoint: When end of colon exteriorised

12. Close midline wound

1. Ensure no swabs or instruments remain in abdomen

2. Washout pelvis and abdomen

3. Ensure haemostasis

4. Place drain into pelvis

5. Figure-of-eight suture to wound

6. Mass closure of wound

7. Clean wound

8. Close skin with staples

9. Apply dressing to midline wound

10. Apply dressing to drain site and activate drain

Do 1 – 2 – 3 In any order

If surgeon preference Do 4

If surgeon preference Do 5

Do 6 – 9 In series

If drain present Do 10

Endpoint: When dressing(s) in situ

13. Complete colostomy

1. Grasp colon in Babcocks forceps

2. Remove staple line with diathermy or knife

3. Place 2 or 3 stay sutures from skin to sero-submucosal layer and hold with clips
4. Remove Babcocks forceps
5. Tie stay sutures
6. Insert and tie any remaining necessary sutures
7. Check that stoma patent
8. Apply stoma bag

Do 1 – 8 In series

Endpoint: When stoma bag in situ

Appendix 3

Expert Group Meeting

Task Analysis Expert Group Meeting

Date 24 Feb 2004

Chair Professor Sir A Cuschieri, Professor of Surgery, Dundee (AC)

Present Professor RJC Steele, Professor of Surgery & Head of Department, Dundee (RS)

Professor RJ Heald, Professor of Surgery, Basingstoke (BH)

Professor A Munro, Professor of Surgery, Inverness (AM)

Professor P Quirke, Professor of Pathology, Leeds (PQ)

Mr RH Diament, Consultant Surgeon, Kilmarnock (BD)

Mr GB Hanna, Consultant Surgeon and Ergonomist, London (GH)

Dr PJ Wilson, Clinical Research Fellow, Dundee (PW)

For full transcript of Expert Group Meeting, please see enclosed CD.

Appendix 4

Template for commentary on Task Analysis

	Essential step Agree	Optional step Accept	Condemned step Refute
Anterior Resection			
0. Pre-operative Preparation			
Recommendations			
1) Ensure adequate bowel preparation to avoid risk of peritonitis from leak.			
2) For female: needs examination of rectum and vagina in OR to establish relationship of tumour to posterior vaginal wall.			
3) X-rays & scans displayed in OR.			
4) Review colonoscopy report, look for synchronous tumours.			
5) Positioning of the patient – yet to be described in detail			
6) For APER need urethral catheter in place			
7) Rigid sigmoidoscopy in theatre useful for quality control of procedure.			
8) Does intermittent compression affect rate of compartment syndrome?			
9) Keep patient more on the level, and legs not so high up.			
10) Position of legs could be changed during procedure.			
11) Use of calf compression a) At low pressure settings (30mmHg)			

		Agree	Accept	Refute
	b) 40mmHg, as per box.			
12)	Compartment syndrome more common in AR than other types of surgery.			
13)	Compartment syndrome probably more common in pouch surgery and colitis.			
14)	Angles of joints guessed, but no real certainty.			
1.	**Incision of Abdomen**			
Recommendations				
15)	Midline preferred to transverse.			
16)	Important to extend incision to symphysis – down to bone.			
17)	TME should not be performed unless surgeon has accessed 50-100 abdomens independently.			
18)	Make incision in stepwise fashion – complete each layer (skin, fascia, muscle) before proceeding.			
19)	Length of initial incision a) Place initial incision to umbilicus, then extend up as required.			
	b) "I make a huge incision; Don't stint on incision".			
	c) Splenic flexure variable, so cannot predict upper limit of incision. Should extend upper limit halfway between umbilicus and xiphisternum			
20)	Use of wound protector a) Always			
	b) Optional			

	Agree	Accept	Refute
Observations			
21) If upper aspect opened un-necessarily, bowel bulges out and gets in the way.			
22) Lack of exposure risks damaging spleen through mis-placed / inappropriate traction.			
2. Laparotomy			
Recommendations			
23) Explore all quadrants systematically for advanced disease (unless excess adhesions preventing exploration).			
24) Manually assess mobility of rectum & sigmoid to gauge need for extended dissection / possibility of using sigmoid for anastomosis			
25) Mobilisation of splenic flexure Agree Accept Refute a) In 5-10% of cases, sigmoid colon may be long enough that mobilisation of the splenic flexure not required			
b) Always mobilise splenic flexure			
26) Defusing spleen a) Need to defuse the spleen early, almost as soon as in the abdomen, in order to reduce the incidence of splenic injury			
b) But should not do this if mass of adhesions present above the spleen			
Observations			
27) If mobilisation of splenic flexure not necessary, then avoidance might reduce risk of splenic injury.			

	Agree	Accept	Refute
3. Set up Retraction			
Recommendations			
28) Use omnitract or equivalent			
4. Mobilise Sigmoid & Descending Colon			
Recommendations			
29) 2 assistants in addition to the principal operator required.			
30) Indication of depth of dissection: if psoas is seen, dissection is too deep.			
31) Need to identify ureter, gonadal vessels and autonomic nerves.			
32) Visualising the white line of Toldt is the key to this stage.			
33) Make incision ~2mm below retract sigmoid colon with counter-traction, and identify loose areolar tissue.			
34) "Gentle lifting forward of the sigmoid colon to open up the viscero-parietal plane".			
35) Woollen over-gloves used in Italy: Should introduce similar gloves here, and socks for St. Mark's retractors.			
36) Preferably, the first assistant should be at level of senior SpR or above.			
37) 2 people familiar with procedure as a bare minimum.			
38) Need to identify landmarks and planes in Task Analysis and during operation.			
39) Step should be described as "lifting out of the integral visceral sigmoid with the mesentery with the hindgut, the ureters the gonadal vessels, the autonomic nerves behind it". Need to identify point at which these cross the left common iliac artery.			

		Agree	Accept	Refute
40)	Must see and positively identify ureter.			
41)	Other landmarks: sympathetic nerves and hypogastrics.			
42)	Need to lift whole mesocolon so it lies vertically off the front of the aorta.			
43)	Divide vein at lower border of pancreas.			
44)	Should define this as a rectangle, and illustrate with colour diagram.			
45)	Sequence of steps in mobilising left colon a) "Sequence is important for this"			
	b) "I don't think order matters hugely"			
46)	Position of surgeons a) Principal operator on the left			
	b) Principal operator on the right			
47)	How to hold sigmoid colon a) With 2 hands & avoid sticking fingers into mesocolon to avoid bleeding			
	b) Protect the piece of bowel with a large swab, to avoid bleeding			
48)	Landmarks for mobilisation of left colon a) Consider as a rectangular space behind left colon. Left margin = point of division of peritoneum; Right margin = mesocolon of left colon, where comes off aorta; Superior margin = at level of splenic flexure (although not the splenic flexure itself); Inferior margin = iliac vessels or sacral promontory.			
	b) Superior margin = inferior border of pancreas.			
	c) One should see the duodenum superiorly.			

		Agree	Accept	Refute
49)	Division of vessels a) Divide artery first			
	b) But "no reason why can't divide vein first." (see item 50)			
50)	Superior aspect of dissection: "mobilise the DJ flexure, go down onto the vein (IMV), divide it, and from there to the pre-aortic plane to find the artery. As soon as air enters behind the DJ flexure, the whole plane opens up, and brings you in front of the nerves, to the artery."			
51)	Depth of exposure: should always see the common iliac vessels.			
52)	Dissect very close to, but shouldn't see the aortic bifurcation			
53)	From top → down – follow loose areolar plane as far down as possible; from left → right – mobilise as far medially as possible, until 'at the midline beneath it' [the transverse colon]			
54)	Completion of mobilisation is achieved when all of the colon over to the midline, as a straight line vs "Sometimes even when plane followed to root of mesocolon, a curve remains."			
5.	**Mobilise Splenic Flexure**			
Recommendations				
55)	Have to allow for peritoneal folds and adhesions, and divide both: all connections to spleen which are relevant for mobilisation of splenic flexure.			
56)	Need to be able to differentiate omental fat from that in the transverse colon, in order to dissect between them and avoid damage to vessels in mesocolon.			

	Agree	Accept	Refute
57) Approach to splenic flexure a) Start dividing adhesions in left para-colic gutter, and move up towards splenic flexure. Then go “up across the top”, to dissect the omentum off the transverse colon. Can move from one aspect to the other, gradually approaching the splenic flexure, which is left until last.			
b) To think of it as dissecting the colon out from behind the greater omentum.			
c) Start from mid-point of transverse colon, open the lesser sac from the level of the middle colic artery. Proceed along lesser sac, dividing adhesions between back wall of stomach and spleen, as far as possible. Then switch to left para-colic gutter, and move towards splenic flexure. Can move from one aspect to the other as above.			
Observations			
58) This (whole of section 5) is a hazard zone. There are inconsistencies in nomenclature (adhesions / ligaments / bands)			
59) Some patients have a fibrous connection between omentum & splenic wall – traction on this causes bleeding.			
60) Beware 2 congenital splenic adhesions: one between lower pole and splenic flexure; other from greater curvature of stomach to spleen.			
Managing splenic bleeding			
Recommendations – multiple contrasting views			
61) Pack it off, leave it, do nothing until the end of the operation. Amount of bleeding is proportional to ‘how much you fiddle about with it’			
62) Deal with splenic injury at an early stage. a) Suction around the bleeding area, apply some Surgicel for 5-10 minutes.			

		Agree	Accept	Refute
	b) If still not stopped, try diathermy with wide forceps			
	c) ‘That would make it bleed more’			
63)	Put a 5/0 stitch into capsule if still bleeding.			
64)	Try sealant and argon plasma.			
65)	Ensure critical part of mobilisation finished. Suction blood, place Surgicel, a swab and come back to it later.			
66)	Mobilise the spleen with a view to clips or Argon beam.			
67)	When to perform splenectomy a) If considerable blood loss (1,000mls), and no sign of stopping			
	b) “Difficult to prescribe absolute cut-off figures”			
	c) 500 – 1,000mls			
	d) If anticipating a loss >1,000mls.			
68)	Transfusion & cancer a) Need to consider the risk of transfusing a patient with colon cancer			
	b) “That is highly debatable.”			
6.	**Divide Inferior Mesenteric Vessels**			
Recommendations				
69)	Need to identify fascial-covered pedicle of rectum and sigmoid around posterior aspect, to avoid dissecting into lymphatic field.			
70)	Look for plane which is an extension of the mesorectum.			

	Agree	Accept	Refute
71) Ligating the vein & coming down from above permits identification of the nerves, but sometimes is misleading if IMA bifurcates early.			
72) If nodes present around origin of IMA a) Would sacrifice nerves			
b) Would roll nodes down artery			
Observations			
73) If nodes involved = C2 disease = very poor prognosis.			
74) Should know risk of nodal involvement from pre-operative imaging.			
75) Effect of sacrificing those nerves uncertain.			
Dissection around the Inferior Mesenteric Vessels			
Recommendations			
76) Proceed from behind, placing left index finger as retractor on opposite side of mesentery, and dissecting down onto finger with bipolar scissors. Lifting artery forward and to the left allows a good view of the artery and of the nerves.			
77) Ligate IMA above take-off point of ascending left colic artery, but 1.5cm from Aorta, in order to preserve pre-aortic nerves.			
78) Marking of specimen by leaving high-tie long may be helpful to less experienced pathologists.			
79) Ligate artery a) With 2/0 silk			
b) With Vicryl. Single, 0			

	Agree	Accept	Refute
80) Division of IMV a) Performed just below pancreas			
b) "Needs to be divided above the highest tributary"			
81) IMV ligated and divided, but not necessarily removed.			
82) If further mobilisation of colon required a) Can sacrifice marginal arch of Riolan			
b) But try to avoid sacrificing artery if possible			
Observations			
83) Leaving segment of vein (IMV) in place not considered harmful.			
7. Divide Colon at Optimal Site			
Recommendations			
84) Site of division is irrelevant of tumour location.			
85) Site for division a) Generally junction of descending colon and sigmoid, if mobilisation full			
b) "Always at junction of descending and sigmoid colon"			
c) "When confident that the chosen site will reach several centimetres beyond the pubic symphysis"			
Viability of bowel			
Recommendations			
86) Determine viability			

		Agree	Accept	Refute
	a) By visible pulsation of vessels			
	b) Look at colour of bowel			
	c) Cut vessels and observe for squirt of blood.			
87)	If vascularity of bowel looks poor a) "Check with anaesthetist that patient saturating properly"			
	b) Ensure no twisting, pack away in the upper abdomen, and proceed with the remainder of the operation			
	c) … "so put it away and come back to it, and be ready to admit it's not feasible"			
	d) May be necessary to consider using the right side			
	e) "Check if any further mobilisation feasible, but past experience indicates bringing hepatic flexure down never successful"			
88)	Abandoning anastomosis and proceeding to stoma formation a) Trying an anastomosis with right-sided colon – needs to be a clinical judgement.			
	b) If indications are that vascularity is poor, should not take a chance with the anastomosis. Right side has been used successfully in past, but one has got to be happy with vascularity.			
	c) Cannot make any recommendation			
	d) Even if surgeon is competent, and bowel is back-blacking (i.e. becoming progressively dark from distal to proximal), should cut losses and create stoma.			
8.	**Mobilisation of the Rectum**			
Recommendations – posterior dissection				

		Agree	Accept	Refute
89)	Objective = perfect, untorn mesorectum.			
90)	Start posteriorly.			
91)	Apply a swab to the posterior rectum, and draw it anteriorly; and draw proximally on the pre-aortic tissues. Develop areolar plane with monopolar or scissor dissection.			
92)	Continue for ‘quite a long way’ at the back, dividing the recto-sacral ligament, then to develop it round the sides, as a rotary process. Ease hypogastric nerves away from posterior surface.			
93)	If bleeding vessel encountered near to nerve, should pack it away and proceed elsewhere.			
94)	Dissection at the front not performed until much of the mid-pelvic dissection completed at back and sides.			
95)	Once posterior dissection carried far distally, traction on the recto-sigmoid makes tissues containing the middle rectal vessels stand out better. Can then slip fingers to right and left of rectum, which clarifies where lateral dissection should be performed.			
96)	To ensure mesorectum not damaged – use 2 main branches of autonomic plexus as a guide. Cut with bipolar scissors.			
97)	Needs to be done sensitively and as a slow process. Anteriorly is where most errors are seen, as difficult to access and little fat covering – most dangerous area.			
Recommendations – Anterior dissection				
98)	Divide peritoneum & ensure no bleeding. Use Lloyd-Davis or bipolar scissors to develop plane. Identify seminal vesicles early.			
99)	Place tip of Lloyd-Davis retractor behind seminal vesicles and lift forward, whilst placing posterior traction on the rectum to expose areolar plane.			
100)	If large anterior tumour in a female, should take part of the vaginal wall.			

	Agree	Accept	Refute
101) Best to consider this operation as being not on the rectum, but at the back and side it is an operation on the nerves, and at the front on the prostate.			
102) Identify vessel entering centre of seminal vesicle and divide with bipolar scissors.			
103) Dissect anterior to Denonvillier's fascia. Will need to cut through it at some point, before it becomes adherent to the prostate, usually in a U-shape, identifying and 'respecting the converging nerves'.			
104) If tumour lifted up safely out of the way, can afford to dissect closer to rectum anteriorly.			
105) After above dissection completed - 'Eyeball' where important structures lie (nerves, seminal vesicles), then visualise where these are running, and dissect 'as close to them as you dare'.			
106) Incision in anterior peritoneum a) If cancer big and/or anterior, divide peritoneum anterior to 'trough'; otherwise divide in trough			
b) "Make peritoneal incision anterior, towards the top of the prostate."			
Observations			
107) Suspects parasympathetic damage occurs in dissecting out the seminal vesicles and prostate.			
108) Sometimes small vessel – branch of internal iliacs – encountered near seminal vesicles. Bleeding from this often requires a Prolene suture.			
109) After above dissection completed, tissue remaining is at 10 and 2 o'clock – difficult to remain orientated at that point.			

		Agree	Accept	Refute
110)	Marginal involvement much higher in AP resections, due to thinning out of mesorectum towards anal canal. Reflected in lower survival rates. So should minimise ‘coning in’ and decide well before the ‘coning area’ whether an AP will be necessary. Goes on to describe Swedish version of AP resection, with wide dissection at lower end, and bringing flaps across.			
111)	Current British operation attempts to avoid nerve damage, but as a result does not give such wide clearance of tumour as it did ~30 years ago, and is probably less radical.			
Recommendations – if tumour perforated				
112)	If tumour perforated during dissection, need to give good washout with undiluted Betadine.			
113)	Also stitch up the hole, if possible, and add antibiotic to the lavage.			
114)	Also keep instruments separate to avoid further implanting.			
115)	If perforation goes through tumour, rather than healthy wall, should add adjuvant therapy.			
116)	Frozen section is helpful in very low AR			
9.	**Excision of Rectum**			
Recommendations				
117)	Tumours within 4cm of the anal verge must be treated by APER.			
118)	Washout of rectum after first stapler – use povidone iodine.			
119)	Lower palpable margin is almost always the microscopic lower edge, and therefore it is usually safe to place finger and thumb around tumour, and stapler just beyond that.			

		Agree	Accept	Refute
120)	If placing stapler very low, should leave first one on in order to use it to place traction on the anorectum without pulling on the tumour.			
121)	If in doubt, send experienced colleague to look at first staple line before firing, to check if tumour sticking through.			
122)	Ultra low anastomosis a) Should be described in Task Analysis			
	b) Concerns voiced regarding their recommendation in the Task Analysis			
123)	Should then have a working limit of 4-5cm from the anal verge; 2cm from the dentate line. Lower than this needs APER. a) Agreement with above, given riders such as patient choice and local excision.			
124)	Pre-operative radiotherapy a) Should everyone going for APER receive pre-operative radiotherapy?			
	b) Short-course pre-operative radiotherapy confers no benefit.			
Observations				
125)	Mucoid and poorly-differentiated tumours have much higher rates of margin involvement.			
10.	**Create Colopouch or Simple Colotomy**			
Recommendations				
126)	If colopouch not formed, should use most dependent part of bowel, creating a side-to end with the anti-mesenteric border.			

		Agree	Accept	Refute
127)	Formation of a colopouch – form ‘J’ loop by stitching anti-mesenteric border of stapled end to colon, ~5-6cm proximal to most dependent part. Make incision at most dependent part, and insert 60mm GIA stapler. Ensure anti-mesenteric borders are aligned, then fire stapler.			
128)	Need to ensure not bleeding after stapler fired.			
129)	Should use blue stapler for most cases, but white if colonic wall very thin.			
130)	Level at which colopouch should be used a) Only when anastomosing at level of pelvic floor – if true TME performed			
	b) Colopouch for anastomosis below 5cm. (But note item 122 – if lower than 4-5cm needs APER).			
131)	Might consider performing a coloplasty.			
132)	Suggestion to create an omega loop instead of a colopouch or side-to-end anastomosis.			
133)	Make colotomy for GIA a) Transversely			
	b) Longitudinally along teniae			
11.	**Anastomose Colon to Rectal Stump**			
Recommendations				
134)	Gun inserted by principal surgeon, not by assistant.			
135)	Become familiar with staple gun before usage.			
136)	Should not perforate rectal stump through staple line; in female prefer posteriorly.			
137)	Ensure vagina free from stapler – may need to peel it back.			

		Agree	Accept	Refute
138)	Ensure sphincter complex not being pushed up in front of stapler.			
139)	Can be difficult and dangerous to insert a gun up a long rectal stump, so handsewing may be preferable in some instances.			
140)	Use of sizer / size of gun used a) Sizer not used. Almost always uses CEA-31			
	b) Use as big a stapler as possible, e.g. 34, as may result in lower leakage rates.			
	c) Sizer only used if anal canal tight, and should perhaps be applied several steps earlier.			
141)	Hand-sewn anastomosis a) Need to add section on hand-sewn anastomosis to task analysis			
	b) Would use single layer, extra-mucosal anastomosis.			
	c) For back layer of stitches, use Gambi-type stitch.			
142)	Integrity of anastomosis a) Check digitally			
	b) Check with Foley catheter & insufflation of air. May need oversewing			
	c) Often does not test anastomosis			
12.	**Formation of Ileostomy**			
Recommendations				
143)	Ileostomy should be closed between 5-8 weeks, and not deferred.			

	Agree	Accept	Refute
144) Defunctioning an anastomosis a) If below 5cm, allowing for patient refusal			
b) "Almost always after TME."			
145) Type of defunctioning stoma a) Prefers transverse colostomy, as it defunctions better, and has a lower incidence of serious complications.			
b) Prefers ileostomy – bring loop of bowel out on a catheter, make proximal spout and distal flush. Could also consider making small distal spout to reduce skin irritation.			
146) Creating & maintaining stoma a) Draw stoma out of abdomen on catheter which is then removed			
b) Use 22 PVC whistle tip catheter, stitched to skin, and left for 7-10 days.			
13. Closure of Abdomen			
Recommendations			
147) Ensure no instruments, needles or swabs retained.			
148) Washout – saline + cephalosporin			
149) Soft dressings – Mepore.			
150) Drains a) 2 drains & squeezy bag for 48 hours.			
b) Rarely uses drains, as they remove any Adept which has been used.			
c) Single drain.			
151) Closure			

		Agree	Accept	Refute
	a) Single PDS, mass closure, sharp needle.			
	b) Nylon loop.			
152)	Approximate skin edges with Agree Accept Refute			
	a) Staples			
	b) Subcuticular PDS			
	c) Subcuticular Monocryl			
	d) Subcuticular nylon			

Abdomino-perineal Resection

9.	**Excise Rectum**			
Recommendations				
153)	Use a perineal retractor of a St. Marks' pattern.			
154)	In the Task analysis: Assistant places hand alongside rectum to guide perineal surgeon. a) Considered a dangerous practice. Condemned.			
155)	Concept of synchronous combined APER from top & bottom condemned.			
156)	Dissection – one or two centimetres of ischiorectal fat left on specimen. Dissect on one side, almost up to levator, then change to the other side and do the same.			
157)	Anterior dissection – continue until Transversus perinei reached. Go around circumference of dissection at level of levators.			

		Agree	Accept	Refute
158)	Cut through levator complex posteriorly until washout obtained. Push finger through hole. Use diathermy or scissors to take ~2cm of the levator complex from the rectum, and advance anteriorly in a 'U' shape. Puborectalis not taken at this stage.			
159)	If inferior haemorrhoidal artery or other bleeding encountered, apply a clip and leave.			
160)	Then dissect behind the Transversus perinei. Slip finger in front of rectum, behind apex of prostate, then divide puborectalis on both sides.			
161)	Type of retractor used on skin a) Use a Travers' self retainer initially, then a St. Marks' retractor.			
	b) Use Lone Star retractor. (Resolved through item 152 (see above))			
162)	Anal stay suture a) Place stay suture through anus to close it			
	b) "Place circum-anal purse-string suture. Leave it a few centimetres long and apply artery forceps to end to allow traction."			
	c) Use tissue forceps to manipulate anal canal.			
163)	Size of peri-anal incision a) Make long axis of ellipse 4-6cm long, ensuring purse string not cut out.			
	b) "Minimum of 5cm all the way round, 10cm diameter."			
	c) Difficult to measure this distance as the skin is so floppy.			
164)	Prolapsing the rectum			

		Agree	Accept	Refute
	a) Following division of puborectalis – if rectum not bulky – invert the upper rectum so it lies outside the pelvis. Turn specimen sideways and use diathermy to take the remains of the puborectalis sling on both sides.			
	b) Don’t prolapse rectum, as this distorts the anatomy.			
10.	**Closure of Perineal Wound**			
Recommendations				
165)	Consensus is for 2 drains.			
166)	Brings together fascial layers, but sometimes this is only ‘globules of fat’			
167)	No attempt to bring levators together. Fascia closed with continuous stitch.			
168)	Skin closure – subcuticular.			
169)	Wash perineal wound with saline.			
170)	Usage of drains			
	a) Two drains, for sacral hollow & ischiorectal fossa, one exteriorised through each buttock.			
	b) Drains brought out from above.			
171)	Expect to see ~500mls of haemo-serous fluid in 48h.			
172)	Closure of wound a) Close pelvic peritoneum			
	b) Don’t close pelvic peritoneum – concerned with partial closure allowing gaps for small bowel to herniate through			
11.	**Exteriorise Loop of Colon**			

Recommendations		Agree	Accept	Refute
173)	Splenic flexure not mobilised in this instance.			
174)	Rectus sheath opened with cruciate incision.			
175)	Lateral space left open.			
176)	Skin-to-bowel direction of needle not important to remember.			
177)	Route of colostomy a) Routinely perform extra-peritoneal colostomy, as leads to a lower incidence of prolapse and herniation.			
	b) Make trans-peritoneal colostomy.			
178)	Sutures used in colostomy a) Monocryl, taking full-thickness bites of colon, and good bites of skin. Usually requires 8 sutures in total.			
	b) Suggestion of Polysorb or Biosin for stoma.			
179)	Make a small eversion of the stoma to protect against diarrhoea.			

Appendix 5

Applescript Code for Analysis of Procedures

See CD enclosed with thesis.

Appendix 6

Applescript Code for Extraction of Data from Text File

See CD enclosed with thesis.

Appendix 7

Information, Consent & Record Forms

Use of Human Reliability Analysis to Evaluate Operative Technique for Bowel Surgery

Patient Information Sheet

Invitation

We invite you to participate in a research project. We believe it to be of potential importance. However, before you decide whether or not you wish to participate, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Read it carefully and be sure to ask any questions you have, and, if you want, discuss it with outsiders. We will do our best to explain and to provide any further information you may ask for now or later. You do not have to make an immediate decision.

Background

You have been asked to participate in this research as you will be undergoing surgery of the large bowel. Although the operation is carried out according to best known practice, surgeons are constantly trying to improve on this.

This research aims to identify which aspects of the operation are important in ensuring its success. This will be achieved through detailed analysis of video-recordings of operations. These analyses will be linked to information on outcome from the operation, obtained through review of case notes and of follow-up in clinic.

What the study involves

If you agree to participate in this study, your operation will be video-taped on cameras in the operating theatre. After the operation, the researcher will examine the video tapes in detail in order to analyse the technique of your surgeon.

The researcher will obtain further information from discussing the operation with your surgeon, and from reviewing your hospital notes after the operation, both whilst you are in hospital, and also following clinic attendances.

In addition, if you are agreeable, you may receive a telephone call at approximately 6-8 weeks after the operation regarding your recovery and overall state of health. Any problems or difficulties you have encountered since the operation will also be noted.

Participating in this study will not alter your treatment in any way. Regardless of your involvement in the study, you will undergo the same operation, receive the same care after the operation, and be followed up in the same clinic.

What about confidentiality?

You will not be identified in any of the video recordings, and all video tapes will be kept in secure storage. Any other information gathered will be kept in coded form.

What are my rights?

Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical staff looking after you.

The Tayside Committee on Medical Research Ethics, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Tayside and the Regulatory Authorities.

Any questions?

If you have any questions or concerns regarding this project, please do not hesitate to contact:

Peter Wilson

Clinical Research Fellow

Tel 01382 632567

Use of Human Reliability Analysis to Evaluate Operative Techniques for Bowel Surgery

CONSENT FORM

NB. ***This form must be completed and signed by the research subject in the presence of someone with knowledge of the research designated by the Principal Investigator. This may be a doctor, nurse, clinical research assistant or other member of the research team who must countersign the form as witness to the subject's signature***

Please tick (✓) appropriate box

Have you read and understood the Patient Information Sheet? Yes ☐ No ☐

Have you been given an opportunity to ask questions
and further discuss this study? Yes ☐ No ☐

Have you received satisfactory answers to all of your questions? Yes ☐ No ☐

Have you now received enough information about this study? Yes ☐ No ☐

Who have you spoken to? Dr/Mr/Mrs/Miss ....

Do you understand that your participation is entirely voluntary? Yes ☐ No ☐

Do you understand that you are free to withdraw from this study:

At any time? Yes ☐ No ☐

Without having to give a reason for withdrawing? Yes ☐ No ☐

Without this affecting your present of future medical care? Yes ☐ No ☐

Do you agree that your records in this research and supporting medical records be made available for inspection by monitors from:

NHS Tayside monitors? Yes ☐ No ☐

Regulatory authorities? Yes ☐ No ☐

Do you agree to take part in this study? Yes ☐ No ☐

Subject's signature .... Date ....

Subject's name in block capital letters ....

Telephone contact (Subject)....................................... (Home) .... (Work)

Signature witnessed by... Date ....

Witness name in block capital letters ....

Date:_______________

HRA Study – Record Sheet

Pre-operative Details

Initials ___________________ Sex____________ DOB ___________________ CHI ____________________
Consultant ________________ Ward __________ Admission date ___________ Weight________ Ht_____
Date of diagnosis ___________ Age at op _______ Date of op _______________ Date of discharge _________
Mode of diagnosis ____________________________

Previous Medical Hx

Hx _________________ Rx ____________________
____________________ ______________________
____________________ ______________________
____________________ Alc______ Smoke_______

Hb ________ Na^+ _______
WBC ______ K^+ ________
Plt ________ Ur ________
Coag ______ Cr ________

Investigations

ALT _________ CRP _____
Bil ___________ Max Ur___
AlkP _________ _________
Alb __________ _________

POSSUM Details – Physiological Score

ASA : ________

Score	1	2	4	8
Age	≤60	61-70	≥71	
Cardiac signs CXR	No failure –	Diuretic, digoxin, antianginal *or* anti-BP Rx –	Peripheral oedema; warfarin Borderline cardiomegaly	Raised JVP Cardiomegaly
Resp Hx CXR	No dyspnoea	Dyspnoea on exertion Mild COAD	Limiting dyspnoea (1 flight) Moderate COAD	Dyspnoea at rest (≥30/min) Fibrosis *or* consolidation
BP (systolic)	110-130	131-170 *or* 100-109	≥171 *or* 90 – 99	≤89
Pulse (HR)	50-80	81 – 100 *or* 40-49	101-120	≥121 *or* ≤39
GCS	15	12-14	9-11	≤8
Hb (g/100ml)	13-16	11.5-12.9 *or* 16.1 – 17.0	10.0-11.4 *or* 17.1 – 18.0	≤9.9 *or* ≥18.1
WBC ($x10^{12}$/l)	4-10	10.1 – 20.0 *or* 3.1 – 4.0	≥20.1 *or* ≤3.0	
Urea (mmol/l)	≤7.5	7.6 – 10.0	10.1-15.0	≥15.1
Na^+ (mmol/l)	≥136	131-135	126-130	≤125
K^+ (mmol/l)	3.5 – 5.0	3.2 – 3.4 *or* 5.1 – 5.3	2.9 – 3.1 *or* 5.4 – 5.9	≤2.8 *or* ≥6.0
ECG	Normal	–	AF (rate 60-90)	Any other abnormal rhythm *or* ≥5 ectopics/min, Q waves or ST/T wave changes
Total				

Total Pre-op Score: ___________________

Anaesthetic Data

Time	Swabs	Suction	Washout	Time	IVI

Epidural Y / N
Ab's given _________________________
Post-op Temp ______________________
Analgesia__________________________
Oxygen ___________________________
1st flatus__________________________
1st BO ____________________________
Nutrition __________________________
____

Operative / Tumour Details

Surgeons___________________________ Adjuvant Tx ____________________
Tumour location (Sig) ______ At operation ____________
Type of resection __________ Operating time __________
Deemed curative? _________ TNM stage _____________
Blood loss _______________Transfusion ______________
Unusual findings ____
Complications / difficulties ____________________________________
Errors ____

Operative difficulty
Build: NA/Thin/Mod/Obese/Obese+
Pelvis: NA/Wide/Mod/Narr/Narrow+
Adhesion: None/Mild/Mod/Severe
Tumour: Small/Med/Large/Adherent
Score (2-14): ______________________
Fixation______________________

Date:______________

POSSUM Details – Operative Severity Score

Score	1	2	4	8
Operative severity	Minor	Moderate	Major	Major+
Multiple procedures	1	–	2	>2
Total blood loss (ml)	≤100	101-500	501-999	≥1000
Peritoneal soiling	None	Minor (serous fluid)	Local pus	Free bowel content, pus or blood
Presence of malignancy	None	Primary only	Nodal metastases	Distant metastases
Mode of surgery	Elective	–	Emergency resuscitation of >2h possible; Operation <24h after admission	Emergency (immediate surgery <2h needed)
Total				

Total Operative Severity Score: ____________

Outcome — Date

Haemorrhage — Wound / Deep / Other ________________
Infection — Chest / Wound / UTI / Deep / __________
Septicaemia / PUO / Other ____________
Wound dehiscence — Superficial / Deep ________________
Anastomotic leak — Internal / External / Theatre?__________
Thrombosis — DVT / PE / Other / CVA / MI __________
Cardiac failure ________________

Date

Impaired RF (Urea ≥5) ______________
↓BP (Systolic <90 for 2h) ______________
Resp failure ______________
Any other complication ______________
In the event of death give date ______________
Post-mortem findings ______________

Post-op Care

Date H/W Events BP(min/freq/h) T°(max/freq/h) Hb

Day 0 ________________
Day 1 ________________
Day 2 ________________
Day 3 ________________
Day 4 ________________
Day 5 ________________
Day 6 ________________
Day 7 ________________
Day 8 ________________
Day 9 ________________
Day 10 ________________
Day 11 ________________
Day 12 ________________
Following care ________________

Pathological assessment

Macro

Spec size ____________ Tumour location ________ Mesorectal grade ______ Tumour size_________
Distance to distal margin __ Tumour perforated Y/N Tumour through wall Y/N

Micro

Tumour type___________ Tumour grade __________ Margin type __________
Distance beyond wall_____ Peritoneum involved Y/N CRM clear Y/N Distance to CRM______
Positive nodes _________ Total nodes ____________ Apical node involved Y/N
Resection complete Y/N __ Dukes________________ TNM________________

Comments

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Appendix 8

Foldout Sheet of Error Categories

See text in section 2.2, page 35 for details.

Error Category	Errors or Elements within Category	
External Error Mode	1. Step is not done / partially completed 2. Step is done in addition (unnecessary step) 3. Step is done late 4. Step is done with too much (speed, force, distance, depth)	5. Step is done with too little (speed, force, distance, depth) 6. Step is done in wrong (orientation, direction, point in space) 7. Step is done on / with the wrong object 8. Other
Failure to Prepare Field	1. Adjust hold to improve visualization 2. Adjust hold to improve traction 3. Adjust hold to separate structures	4. Search for structure to dissect / divide / clamp 5. Search for structure to avoid 6. Other
Tool-Tissue Errors	1. Poor camera views in open surgery 2. Non-visualization of instrument tip during diathermy 3. Non-visualization of instrument tip during sharp dissection 4. Non-visualization of instrument tip during other action 5. Inappropriate diathermy (tip visualized) 6. Inappropriate cutting (tip visualized) 7. Avulsion of tissue 8. Inappropriate blunt handling of tissues (tip visualized)	9. Diathermy in wrong tissue planes 10. Sharp dissection in wrong tissue planes 11. Error in use of other instrument 12. Instrument error 13. Overshooting of instrument movement 14. Suture / tie poorly-placed 15. Suture / tie poorly-tied 16. Incorrect use of stapling device 17. Inter-Step error 18. Other 19. Non-surgical error
Consequences	1. Bleeding from major vessel 2. Bleeding from small vessels 3. Bleeding (source unidentified) 4. Perforation of / injury to viscus 5. Bleeding from viscus 6. Diathermy burn to viscus 7. Diathermy burn to other structure 8. Injury to nerve 9. Mesorectal injury 10. Incorrect dissection plane	11. Compromise other oncological principle 12. Delay in procedure 13. Risk of anastomotic leak 14. Risk of infection 15. Other 16. Risk of bleeding 17. Risk of injury to viscus 18. Risk of injury to nerve 19. Risk of mesorectal injury

Non-Error Category	Elements within Category	
Preparatory Step	1. Adjust hold to improve visualization 2. Adjust hold to improve traction 3. Adjust hold to separate structures	4. Search for structure to dissect / divide / clamp 5. Search for structure to avoid 6. Other
Recovery mechanisms	1. Continue uninterrupted or convert to correct action 2. Perform step previously omitted 3. Requires repetition of step (e.g. regrasp)	4. Corrective action within subtask 5. Change in subtask or sequence 6. Change in major task or sequence 7. Change operation performed 8. Other
Individual Techniques	1. Management of difficult planes 2. Management of difficult bleeding 3. Time-saving devices & techniques 4. Improvement of access 5. Improve oncological safety	6. Reduce risk of infection 7. Reduce risk of injury to patient 8. Safety check 9. Other