CLINICAL STUDIES COMPARING LAPAROSCOPIC AND OPEN INGUINAL HERNIA REPAIR

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A thesis submitted in April 2001
to the University of Glasgow
for the degree of Doctor of Medicine

from the University Department of Surgery,
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Contents

List of Tables and Figures

Tables

Figures

Acknowledgements

I would like to gratefully record my thanks to the following people, without whose support the work described in this thesis would not have been possible:

Professor Patrick J. O'Dwyer (University Department of Surgery, Western Infirmary, Glasgow) who supervised the work for this thesis and whose patients were used for the 'single surgeon sub-group' analysis. I would like to thank him for giving me the opportunity to perform this study, and for his constant support, advice and encouragement throughout.

All of the surgeons who entered patients in the Medical Research Council Trial of Laparoscopic Inguinal Hernia Repair. In particular I would like to acknowledge the contribution of those surgeons from the West of Scotland who allowed their early patients to be used for assessment of the learning curve for laparoscopic repair.

Caron Paterson, Research Assistant, University Department of Surgery, Western Infirmary, Glasgow who co-ordinated the long term follow-up of patients in the West of Scotland after I had left the position of Research Fellow in the department.

The staff at the Health Services Research Unit, Forresterhill, Aberdeen for their management of patient randomisation, co-ordination of follow-up questionnaires and monitoring of clinical follow-up appointments throughout the centres within the UK. In particular I would like to acknowledge the contribution of Professor Adrian Grant, Director of the HSRU and Andrew Kennedy for advice on statistical matters. The HSRU also provided translations of papers from the originals in German for which I am very grateful.

Cam Donaldson and Emma McIntosh from the Health Economics Research Unit, Forresterhill, Aberdeen for their input and advice on the economic assessment described in this thesis.

Dr Mick Serpell, Consultant Anaesthetist, Western Infirmary, Glasgow for his advice, enthusiasm and co-operation which was invaluable in performing the sub-studies described in chapter four and the blood gas analyses described in chapter five.

Professor Andrew Bradley and Dr Eleanor Bolton, formerly of the University Department of Surgery, Western Infirmary, Glasgow who provided invaluable advice and also allowed me access to the equipment and computers in the Transplant Research Laboratory to perform the ELISA assay for interleukin-6.

Dr Denis O'Reilly, Consultant Clinical Biochemist, Glasgow Royal Infirmary who arranged the analysis of blood samples for C-reactive protein, albumin and glucose.

Dr Mike Hall, Bio-engineer, formerly of the Department of Physiology, Glasgow University for his help in setting up the computer program to assess driver reaction times.

The Medical Illustration Department, Western Infirmary, Glasgow who produced all of the slides and posters used in the various presentations arising from this work.

The majority of work described in this thesis was performed while I was employed as a Research Fellow in the University Department of Surgery, Western Infirmary, Glasgow. During this period I was fully funded by a grant from the Medical Research Council.

Statement of Collaboration

The randomised trial to compare laparoscopic and open inguinal hernia repair was conceived by Professor Patrick J. O'Dwyer. However, I was involved from an early stage in the trial design. The post-operative follow-up questionnaires were developed in conjunction with the Health Services Research Unit, Forresterhill, Aberdeen. Patient randomisation was also co-ordinated from the Health Services Research Unit. Initially this was done using a sealed envelope technique, but was subsequently changed to a centralised telephone based system. With the help of a research assistant, I was responsible for randomisation, post-operative review and yearly follow-up of all patients randomised from hospitals within Glasgow (418 cases). A research nurse was responsible for patient randomisation and follow-up in the Edinburgh area. In other areas throughout the United Kingdom and Ireland patient recruitment and follow-up was performed by the contributing surgeons. I personally entered in to the database the information from the peri-operative data collection forms and yearly follow-up for all West of Scotland patients. Data entry for the follow-up questionnaires was performed at the Health Services Research Unit. Statistical analysis of the data presented in this thesis was performed by myself, with advice given by the statisticians at the Health Services Research Unit. Analysis of health economics issues was performed by myself in conjunction with the Health Economics Research Unit, Foresterhill, Aberdeen.

Analysis of the learning curve was performed using patients from three surgeons from the Glasgow area. I was therefore responsible for the recruitment and follow-up of all of these patients.

I was personally responsible for the measurement of all post-operative pain scores and respiratory function tests for these sub-studies. Post-operative oximetry was recorded and analysed by myself. All blood samples for the assays performed were taken, centrifuged and frozen by myself. I performed the ELISA assays for interleukin-6 using equipment and computers in the Transplant Research Laboratory, Western Infirmary, Glasgow. Assays of C-reactive protein, albumin and glucose were performed by Dr Denis O'Reilly, Consultant Clinical Biochemist, Glasgow Royal Infirmary.

The driver reaction time study was conceived, designed and performed by myself. The apparatus used to perform the study was constructed by myself and the computer programming was performed by Dr Mike Hall, Department of Physiology, Glasgow University.

All of the patients examined in the comparison of intraperitoneal and extraperitoneal carbon dioxide insufflation were anaesthetised by Dr Mick Serpell, Consultant Anaesthetist, Western Infirmary, Glasgow. All intra-operative blood gas samples were taken and analysed by myself.

The composition of this thesis was entirely my own work and it has not been submitted previously for another degree. The entire contents of the thesis were typed by myself using Microsoft Word 97. Statistical analysis was performed, and graphs drawn, using the SPSS 7.5 statistics package for Windows. Reference Manager 7 was used to collate all references. I consulted all references cited personally, unless indicated otherwise in the References section of this thesis. The Health Services Research Unit obtained translations of papers cited from the original version in German.

List of Work Presented and Published

Oral Presentations (with published abstracts)

Wright DM, O'Dwyer PJ. "A randomised trial to evaluate laparoscopic extraperitoneal hernia repair."
Presented to the West of Scotland Surgical Association. Glasgow, October 1994.

Wright DM, Serpell MG, Baxter JN, O'Dwyer PJ. "Effect of intraperitoneal and extraperitoneal CO_2 insufflation on intraoperative blood gas changes."
Presented to the Surgical Research Society. London, January 1995.
(*British Journal of Surgery* 1995; 82: 692.)

Wright DM, Kennedy A, Baxter JN, Fife L, O'Dwyer PJ. "Open versus endoscopic tension-free hernioplasty - a randomised clinical trial."
Presented to the Association of Surgeons of Great Britain and Ireland. London, June 1995.

Wright DM, O'Dwyer PJ. "Laparoscopic or open tension-free hernia repair?"
Presented to the Grey-Turner Surgical Club. Glasgow, October 1995.

Wright DM, O'Dwyer PJ. "The trial evidence."
Presented to a symposium on Advances in Groin Hernia Repair. Clinical and Scientific Meeting of the Royal College of Surgeons of Edinburgh, May 1996.

Wright DM, Serpell MG, O'Dwyer PJ. "Open versus endoscopic tension-free hernioplasty: A comparison of post-operative pulmonary function, oximetry and pain scores."
Presented to the European Association of Endoscopic Surgeons. Trondheim, Norway, June 1996. (*Surgical Endoscopy* 1996; 10: 548)

Wright DM, Hall M, O'Dwyer PJ. "A comparison of driver reflex times following open and endoscopic 'tension-free' hernia repair."
Presented to the European Association of Endoscopic Surgeons. Trondheim, Norway, June 1996. (*Surgical Endoscopy* 1996; 10: 576)

Wright DM, Paterson CR, O'Dwyer PJ. "Early outcome following open and endoscopic tension-free hernia repair."
Presented to the Association of Endoscopic Surgeons of Great Britain and Ireland. Bournemouth, April 1997. (*Gastroenterology* 1997; 112: A49)

Wright DM, O'Dwyer PJ. "The MRC trial of laparoscopic inguinal hernia repair."
Presented to the Nordic and West of Scotland Advanced Laparoscopic Surgery Course. Glasgow, September 1997.

Wright DM, Hall MG, Paterson CR, O'Dwyer PJ. "Driver reflex times following open and endoscopic tension-free hernia repair."
Presented to the West of Scotland Surgical Association. Glasgow, November 1997.

Wright DM, O'Dwyer PJ. "The MRC Trial of endoscopic inguinal hernia repair – West of Scotland results."
Presented to the West of Scotland Surgical Association. Hairmyres Hospital, East Kilbride, April 1998.

Wright DM, Hall MG, Paterson CR, O'Dwyer PJ. "Driver reflex times following open and endoscopic tension-free hernia repair."
Presented to the Association of Surgeons of Great Britain and Ireland. Edinburgh, May 1998. (*British Journal of Surgery* 1998; 85 Supplement 1: 34-5).

Wright DM, Hall MG, Paterson CR, O'Dwyer PJ. "Driver reflex times following open and endoscopic tension-free hernia repair."
Presented to the World Congress of Endoscopic Surgeons. Rome, Italy, June 1998. (*Surgical Endoscopy* 1998; 12: 599).

Paterson CR, Wright DM, O'Dwyer PJ. "Chronic pain following tension-free hernioplasty."
Presented to the European Hernia Society. Cologne, Germany, June 1998.
(*Hernia* 1998; 2 Supplement 2: 532).

Poster Presentations (with published abstracts)

Wright DM, Serpell MG, O'Dwyer PJ. "Open versus endoscopic tension-free hernioplasty. A comparison of post-operative pulmonary function, oximetry and pain scores."
Presented to the Association of Endoscopic Surgeons of Great Britain and Ireland. Glasgow, May 1996.

Wright DM, Hall MG, O'Dwyer PJ. "A comparison of driver reflex times following open and endoscopic 'tension-free' hernia repair."
Presented to the Association of Endoscopic Surgeons of Great Britain and Ireland. Glasgow, May 1996.

Paterson CR, Wright DM, O'Dwyer PJ. "Chronic groin pain following tension-free hernioplasty."
Presented to the Association of Surgeons of Great Britain and Ireland. Edinburgh, June 1998. (*British Journal of Surgery* 1998; 85 Supplement 1: 74)

Paterson CR, Wright DM, O'Dwyer PJ. "Does mesh require fixation following TEP laparoscopic hernia repair."
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June 1998. (*Hernia* 1998; 2 supplement 2: S31-S32).

Wright DM, Hall MG, Paterson CR, O'Dwyer PJ. "Driver reflex times following open and endoscopic tension-free hernia repair."
Presented at European Hernia Society. Cologne, Germany. June 1998.
(*Hernia* 1998; 2 Supplement 2: S32)
This presentation won the prize for the best poster at the meeting.

Publications

Wright DM, Serpell MG, Baxter JN, O'Dwyer PJ Effect of extraperitoneal carbon dioxide insufflation on intraoperative blood gas and haemodynamic changes. *Surgical Endoscopy* 1995; 11: 1169-72.

Wright DM, Kennedy A, Baxter JN, Fullarton GM, Fife LM, Sunderland GT, O'Dwyer PJ. Early outcome following open versus extraperitoneal endoscopic tension-free hernioplasty. A randomised clinical trial. *Surgery* 1996; 119: 552-7.

Wright DM, O'Dwyer PJ. "Totally extraperitoneal laparoscopic hernia repair." *Seminars in Laparoscopic Surgery* 1998; 5: 217-23.

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The MRC Laparoscopic Groin Hernia Trial Group. "Laparoscopic versus open repair of groin hernia: A randomised comparison." *Lancet* 1999; 354: 185-90.

Letters

Wright D, O'Dwyer PJ, Baxter J. Hernia repair. *Lancet* 1994; 343: 1164.

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The Nyhus Classification

A classification system for groin hernias is required firstly, to facilitate the decision as to which type of repair should be used, and secondly, to allow comparison of different reports on hernia repair. Nyhus has emphasised the need to classify groin hernias by complete assessment of the internal inguinal ring and the condition of the posterior wall of the inguinal canal. This led to his description of the 'Nyhus classification':

Type 1 - Indirect inguinal hernia in which the internal ring is of normal size and Hesselbach's triangle is normal.

Type 2 - Indirect inguinal hernia with enlargement of the internal ring. Hesselbach's triangle is normal.

Type 3a - Direct inguinal hernia.

Type 3b - Large indirect hernias with an expanded internal ring that has encroached on the posterior wall of the inguinal canal (including the sliding hernia), and hernias with both a direct and indirect component (pantaloon hernia).

Type 3c - Femoral hernia.

Type 4 - Recurrent hernia. These may be direct (type 4a), indirect (type 4b), femoral (type 4c) or a combination of these types (type 4d).

(Nyhus LM. Individualisation of hernia repair: a new era. *Surgery* (1993); 114:1-2.)

This classification system is commonly used in the current literature on inguinal hernia repair and has been used to standardise the description of groin hernias within the Medical Research Council Trial of Laparoscopic Groin Hernia. The same system has therefore been used for description of groin hernias in this thesis.

SUMMARY

Groin hernia repair is one of the most common elective operations performed in general surgery. Long term follow–up shows that more than 15% of conventional sutured repairs may fail. Tension-free prosthetic repair has been introduced with reported recurrence rates of less than 1%. Preperitoneal prosthetic repair has been particularly recommended for bilateral and recurrent hernias. Laparoscopic hernia repair is similar to the open preperitoneal approach and can be performed via a transabdominal or totally extraperitoneal route. Laparoscopic hernia repair has, however, been slow to gain acceptance.

An important factor influencing the uptake of a new surgical procedure is the ease with which the technique can be learned. The operation times, conversion rates and early recurrence rates were assessed for the initial cases of three separate surgeons. A reduction was found in all three parameters assessed over the first thirty cases, suggesting that the learning curve for the laparoscopic repair is at least this long.

Twenty-seven consultants from the UK and Ireland contributed 928 patients to a multicentre randomised trial to compare laparoscopic hernia repair with currently used open repairs. As multicentre trials can create artificial differences, or mask real differences, a sub-group of 300 patients randomised by a single surgeon experienced in laparoscopic repair was also analysed separately. Perioperative data was collected on a standard profroma. Patients were reviewed clinically at one week and then on a yearly basis at the clinic. All patients completed a questionnaire including the 'Short Form 36' health assessment instrument at three months. In addition the single surgeon sub-group of patients completed the same questionnaire at one week and one month after surgery. The laparoscopic group developed less wound haematomas (7.6% vs. 15.7%; 99% CI: –14.3 to –2.0), but there was no difference in the incidence of wound infection or general complications such as urinary retention. The laparoscopic group reported lower levels of post-operative pain and this was reflected in significantly better 'Short Form 36' functional scores at one week. By one month the only significant difference between groups was a better score for physical function in the laparoscopic group, and by three months there was no significant difference in any of the 'Short Form 36' domains. The early functional advantages for the laparoscopic repair were reflected in an earlier return to normal activities (10 days vs. 14 days; $p<0.01$) and work (28 days vs. 42 days; $p=0.001$). A simulator was constructed to

measure the ability to perform an emergency stop following totally extraperitoneal or open prosthetic inguinal hernia repair. Measurements were made pre-operatively and at one, three and six days post-operatively. The laparoscopic group did not demonstrate any increase in reaction times following hernia repair. The open group had significantly prolonged reaction times on days one and three, but had returned to pre-operative levels by day six. Therefore, laparoscopic repair does not impair driver reaction times, and open prosthetic repair appears to allow an earlier return to driving than the ten days previously recommended for open sutured repair.

Linear analogue pain scores and respiratory function tests were performed at six and twenty-four hours after surgery for a subgroup of 120 patients. Pain scores and analgesic use were significantly greater in the open group at both times. Hernia repair has previously been shown to impair respiratory function and this is associated with the development of post-operative respiratory complications. In both group s there was a significant reduction in pulmonary function at six and twenty-four hours after surgery, but no significant difference between the groups. This corresponded with a similar recorded incidence of chest infection in the laparoscopic and open repair groups (laparoscopic 1.4%, open 3.1%; 99% CI: –4.6 to 1.2). Inflammatory and metabolic markers were measured in twenty patients who had a totally extraperitoneal laparoscopic repair and twenty patients who had an open prosthetic repair. Significant rises occurred in interleukin-6 and C-reactive protein, and there was a significant fall in albumin in both groups, but there was no significant difference between groups. No significant changes were recorded in glucose levels.

The laparoscopic repair is associated with greater marginal hospital costs (£278). A large proportion of this cost is due to equipment costs, which vary according to the use of reusable or disposable instruments. Even with a totally reusable instrument policy the marginal hospital costs are greater for the laparoscopic repair (£93). Additional costs occur due to a greater theatre time, although the significance of this in terms of opportunity cost is questionable. Assessment of society costs following surgery is complex and there does not appear to be any reliable method to perform this. Therefore, the overall societal costs of the procedures were not compared.

Review at one year for the main trial showed a significantly greater recurrence rate for the laparoscopic group (1.9% vs. 0%; 95% CI: 0.5 to 3.4). This may have been related to a learning curve effect as no significant difference was seen in the single surgeon sub-group of patients (laparoscopic 0.7% vs. open 0%). After a median follow-up of five years in this sub-group, there was no significant difference in recurrence rates between the laparoscopic and open groups (2.0% vs. 2.0%; 95% CI: –3.6 to 3.6). Notably, there were no recurrences found following the Lichtenstein repair. With relatively low recurrence rates following prosthetic hernia repair other long-term outcome measures may have greater significance when comparing different types of repair. This study demonstrated a similar incidence of chronic pain at one year follow-up after open and laparoscopic inguinal hernia repair.

There is conflicting evidence in the literature with regards to the relative physiological effects of CO_2 pneumoperitoneum, as used for the transabdominal laparoscopic repair, and totally extraperitoneal insufflation. Intraoperative assessment during each type of insufflation demonstrated a slower rate of accumulation of carbon dioxide and less increase in mean arterial blood pressure using the extraperitoneal approach. This approach may therefore be safer than the transabdominal technique, particularly in those patients with pre-existing cardio-respiratory disease.

The laparoscopic inguinal hernia repair has advantages for several early outcome measures, but this is counterbalanced by an apparently greater technical difficulty in performing the procedure and greater hospital costs. The long term recurrence rates following open or laparoscopic prosthetic repair are low for an experienced surgeon. It is notable that no recurrences were identified following the Lichtenstein repair. It may therefore be argued that, despite some disadvantages in early outcome measures, the Lichtenstein repair is the procedure of choice for primary, unilateral inguinal hernias as it is relatively straightforward to perform and has good long-term outcome. There may, however, be an economic argument for the laparoscopic repair to allow an earlier return to work in those patients who are part of the workforce. The preperitoneal approach has been advocated for the repair of recurrent and bilateral hernias. This being the case, there may be an argument for laparoscopic repair in these patients.

CHAPTER ONE

REVIEW OF RELEVANT LITERATURE

1.1 The Contributions of Marcy, Bassini, and Halsted

The principles governing the modern techniques of inguinal herniorrhaphy were first described in the latter decades of the nineteenth century. There has been considerable debate over the years as to whether Henry Marcy or Eduardo Bassini should have precedence in the claim that they developed these principles. In 1871, Marcy published a description of inguinal hernia repair entitled "A new use of carbolised catgut ligatures".[1] Later, in 1892, he claimed to be the first surgeon to have repaired the deep ring.[2] This claim has been supported by several authors who maintained that Marcy developed the principles of ligating the sac at the deep ring, transplanting the cord and reconstructing the inguinal canal many years before Bassini's description.[3-5] In his original paper Marcy described two cases of emergency repair of an incarcerated direct inguinal hernia.[1] These repairs involved returning the unopened sac to the abdominal cavity and suturing together 'the deep pillars of the ring'. In a review of Marcy's claim to precedence Read contended that the deep ring would not have been closed in these patients as the hernias were direct.[6] Furthermore, Marcy indicated that a repair described by Steele was precisely the same as his own repair. In this paper Steele clearly described suturing the pillars of the superficial inguinal ring.[7] In 1892, Marcy exhaustively reviewed the anatomy of the inguinal region and, like other surgeons of the day, he used the expression 'pillars of the ring' to describe only the superficial ring.[2] The deep ring was considered to be merely a hole in the transversalis fascia. Griffith, has argued for Marcy's precedence in his description of the 'Marcy repair'.[8] As part of this argument Griffith reproduced a drawing from Marcy's second book on hernia repair which clearly shows the transversalis fascia being sutured at the level of the deep ring. However Marcy, who spoke Italian, had previously translated Bassini's 1887 paper ('Casi di cure radicale dell'ernia inguinale operata col metodo dell-autore.') for his own first book published in 1889 (A treatise on hernia. A radical cure by the use of buried antiseptic animal suture.). Marcy was therefore already aware of Bassini's work before his description of opening the canal and suturing the transversalis fascia in 1892. It is only after this time that Marcy's description included opening the canal, removal of the sac and restoration of the obliquity of the canal. There is therefore considerable evidence that, despite the claims for Marcy's precedence, Bassini was the first surgeon to describe the principles which were to dominate inguinal hernia repair for the following century.

Bassini first performed his procedure in 1884 and subsequently presented his results to the Italian Society of Surgery in 1887.[9] The following year he presented the results of 122 repairs in ninety-two patients to the Italian Surgical Society. In 1889, Bassini produced a book describing his repair, and then in 1890 he described the results of 206 operations. Thirty-five of these repairs were for bilateral hernias and the age range of the patients was from thirteen months to sixty-nine years. Eleven repairs were for strangulation with no operative but three post-operative deaths. Eleven wounds became infected, and eight recurrences were found in six patients after a follow-up of four and a half years.[10]

Attilio Catterina, who assisted Bassini at the time of his greatest activity, felt that Bassini's repair was being performed incorrectly, criticised unjustly, and was poorly described in surgical texts. He conceded that this was partly the fault of Bassini because his descriptions were too short and meagre, and the illustrations were insufficient in number and detail. Catterina therefore published a book in 1932 entitled "The Operation of Bassini" in which he described each step of the original technique in precise detail.[11] Bassini's repair, as described by Catterina, involved an incision of 7-10 centimetres which was placed with reference to the anterior superior iliac spine, the pubic symphysis and the pubic tubercle. The external oblique aponeurosis was incised at the upper border of the superficial ring, which allowed it to be separated from the internal oblique by blunt dissection. The lower flap and inner border of the inguinal ligament were separated from the cord using blunt dissection. The cord and cremaster were then mobilised 'en masse' at the pubic tubercle and a finger was passed up behind the cord towards the deep ring to allow full mobilisation. The cremaster muscle was separated from the cord close to the deep ring, divided and ligated. Separation of an indirect sac from the cord was commenced close to the deep ring. Drawing the cord downward and the sac outwards, to stretch it over the inferior epigastric vessels, exposed the edge of the transversalis fascia. The fascia was divided from the deep ring to the pubic tubercle and separated from the underlying preperitoneal tissues. An indirect sac was opened and the contents reduced, then the sac was transfixed and excised. A direct inguinal sac was inverted. The first suture in the repair of the posterior wall was placed medially through the threefold layer of internal oblique muscle, transversus abdominis muscle and transversalis fascia plus the edge of the rectus muscle. The suture was passed in and out of these structures

twice then through the periosteum of the pubis. A second suture was placed through the same structures about one centimetre lateral to the first. Further sutures included only the threefold layer and the posterior border of the inguinal ligament. A total of six to eight sutures were required to complete the repair. The cord was placed on the reconstructed posterior wall and the external oblique flaps approximated to reconstruct the superficial ring. Interrupted sutures were then used to approximate the subcutaneous tissues.

Bassini has been attributed with a number of advances in inguinal hernia repair.[9] These include: dissection and isolation of the spermatic cord, ligation of the indirect sac flush with the peritoneum, complete division of the transversalis fascia, construction of a new floor for the inguinal canal using the 'triple layer', restoration of the obliquity of the canal, and early ambulation. However, it has been claimed that the first surgeon to use a high ligature of the sac at the deep ring was not Bassini but Lucas-Championniere in 1881.[12] Lucas-Championniere did not publish this technique until 1892 and so Bassini has precedence in the published literature. In addition, although Bassini is attributed with the first description of division of the transversalis fascia, it is not apparent from his publications between 1887 and 1894 that this was done. In his description of Bassini's procedure Catterina did describe incision of the transversalis fascia from the deep ring to the pubic tubercle before reconstructing the posterior wall of the canal. In Bassini's paper of 1890 there was no direct mention of whether or not the transversalis fascia was deliberately incised before repair of the posterior wall. This however may have been implied as Bassini states that the transversalis fascia should be separated from the preperitoneal fat. If the fascia was not divided this separation would only be possible in patients with a very large dilated deep ring. Andrews visited Bassini on three occasions and in 1899 described in detail the procedure he had learned.[13] His description was very similar to Catterina's with one notable exception - he does not describe incision of the transversalis fascia. It therefore appears that initially Bassini did not intentionally divide the transversalis fascia, rather he freed the triple layer through a dilated deep ring from which the cord was completely detached. Deliberate incision of the floor of the canal appears to have been incorporated by Bassini after 1899. This may have become necessary as the popularity of the repair grew and patients sought repair of smaller hernias with less dilatation of the deep ring.[11] In 1893, William Halsted described division of the

transversalis fascia which resulted in the neck of the hernia sac 'vanishing'.[14] If, as it appears, Bassini did not introduce formal division of the transversalis fascia until after 1899 then this important step may have first been described by Halsted.

The original repair described by Halsted involved the placement of six or eight mattress sutures which incorporated the external oblique aponeurosis, the internal oblique and transversus abdominis muscles, and transversalis fascia on the medial side. The stitch was then passed behind the cord and incorporated the transversalis fascia, inguinal ligament and the external oblique aponeurosis, which transplanted the cord to a subcutaneous position. This practice was later abandoned due to a 10% incidence of testicular atrophy.[15]

Around the turn of the century a number of modifications of Bassini's original procedure were described. The high incidence of testicular atrophy after skeletonisation of the cord led to a vogue for leaving it unmobilised on the posterior wall of the canal.[16,17] Ferguson described a repair which involved suturing the transversalis fascia lateral to the deep ring followed by plication of the internal oblique muscle to the inguinal ligament in front of the cord.[17] High ligation of the indirect sac at the deep ring, and proper assessment of the posterior wall of the canal, were therefore not possible with this procedure. The technique of imbrication of the external oblique aponeurosis was described by Lucas-Championnière in 1892 and subsequently promoted by Andrews.[18] Andrews first plicated the internal oblique muscle and transversalis fascia to the inguinal ligament. The posterior wall of the canal was further reinforced by suturing the upper flap of the external oblique aponeurosis to the inguinal ligament behind the cord. The lower flap was then sutured to the upper flap in front of the cord. Influenced by his high incidence of testicular atrophy Halsted adopted Ferguson's technique of leaving the cord in situ. He also incorporated imbrication of the external oblique aponeurosis into his repair, although this was performed anterior to the cord. This procedure became known as the Halsted II or Ferguson–Andrews procedure. More recently Lipton and colleagues have described the use of the external oblique aponeurosis to reinforce the posterior wall of the inguinal canal.[19] These authors argued that the tissue necrosis produced by undue suture line tension predisposed to failure of the plication types of repair. In a study to compare suture line tension they found less tension in their aponeurotic repair and

this was claimed to reduce the risk of hernia recurrence.[19] However, there have been no reports in the published literature on follow-up following this type of repair.

1.2 Relaxing incisions and the Tanner slide technique

The use of an anterior relaxing incision was first described by Wolfler in 1892, and subsequently also reported by Halsted.[9] This technique involved the use of an incision in the rectus sheath to allow the fibres of the internal oblique to be lined up with the inguinal ligament at the medial end of the repair. This procedure was thought to reduce the risk of medial recurrence. Halsted also claimed to have developed the use of a flap of rectus sheath to reinforce the posterior wall of the canal in 1896.[15] This technique, which was only use in certain cases, involved the use of a relaxing incision to raise a flap of rectus sheath, which was then sutured to the inguinal ligament. Berger described a similar technique in 1902 where the defect in the rectus sheath was repaired,[9] but McVay and Anson subsequently argued that this repair was unnecessary as the rectus fascia was strong enough to prevent hernia formation.[20]

Tanner observed that suturing the conjoined tendon to the inguinal ligament involved pulling the muscles out of their normal line of contraction.[21] He also felt that the sutures were put under tension when the patient strained, with resulting dehiscence of the repair. In order to address these concerns Tanner advocated the 'slide technique'. This was claimed to displace the line of insertion of the lower fibres of the internal oblique to a position parallel to the inguinal ligament, such that when lightly tied they would neither atrophy nor tear out. In the Tanner technique the cord was mobilised and the transversalis fascia inspected. If a deficiency was identified the lower part of the fascia was excised, and the free edge of the upper leaf was sutured to the inguinal ligament. The upper leaf of the external oblique aponeurosis was raised off the underlying internal oblique aponeurosis to about the medial third of the rectus abdominis muscle. An incision was then made through the fused aponeuroses of the internal oblique and transversus abdominis muscles. The incision extended upwards from the level of the pubis, as far medially as possible, for approximately a hands breadth. It was then curved laterally to end two centimetres from the lateral edge of the rectus muscle. This allowed the lower fibres of the internal oblique (conjoined tendon) to lie parallel with the inguinal ligament. Interrupted silk sutures were then

used to plicate the conjoined tendon to the inguinal ligament. For some direct inguinal hernias the suture through the conjoined tendon was also used to pick up the transversalis fascia, rather than placing two separate rows of sutures in the inguinal ligament. Tanner reported the use of the 'slide repair' in 116 cases with good results but, as he readily admitted, the follow-up was poor.[21]

1.3 The darn repair

In 1948, Moloney, Gill and Barclay published a description of inguinal hernia repair using a nylon darn.[22] These authors claimed that the darn formed a 'mesh' which was invariably filled by fibrous tissue. A number of requirements for the ideal lattice were described including that it be: tailored to the individual, of small mesh size, well anchored to the surrounding tissues, pliant, productive of minimal tissue reaction, technically simple to introduce, and permanent. Nylon was thought to be the best material available to meet these criteria. In the Moloney darn repair the inguinal canal was approached anteriorly and the hernia sacs dealt with in the usual fashion. The deep ring was then carefully examined and, if the edges were well defined, it was tightened with interrupted sutures placed medial to the cord. For larger hernias, a suture was passed through the posterior aspect of the internal oblique muscle and then picked up both free edges of the transversalis fascia at the deep ring. The suture was then passed through the inguinal ligament and back through the tissues again in a similar fashion to tighten the deep ring around the cord. Passing a suture through the dense fibrous tissue in the medial aspect of the pubic tubercle then commenced the first layer of the darn. A continuous suture was placed between the lower edge of the internal oblique muscle and the inguinal ligament as far as the deep ring. No attempt was made to appose the internal oblique muscle to the inguinal ligament. A second layer was then started in the same way as the first. The sutures passed through the rectus sheath medially and then the aponeurotic part of the internal oblique muscle as the darn moved laterally. On the inguinal ligament the sutures were placed between those of the first layer. When the darn reached the deep ring a few sutures were placed lateral to the cord. It was emphasised that all sutures were placed without tension. When the darn was completed the cord was returned to its normal position and the external oblique aponeurosis repaired.

Moloney et al. reported that the use of nylon resulted in a low incidence of sepsis and, in the absence of sepsis, there was no instances of extrusion of the suture.[22] There was also no reported incidence of late mesh extrusion or sinus formation. These results contrasted with Edwards study on the use of silk sutures for inguinal hernia repair where sinus formation occurred frequently.[23] In a subsequent report ten years later Moloney described superficial sepsis in 0.9% cases and deep sepsis (immediate and delayed) in 1.1% cases.[24] 0.7% of the repairs required removal of the nylon due to sepsis. Moloney reported that braided nylon was more likely to cause problems than monofilament nylon. Of 253 hernias repaired between five and ten years before, followed up by postal questionnaire and case note review, Moloney reported only two recurrences (0.8%). He emphasised that permanence was a requirement of the material used in the darn and subsequently reported that nylon retains at least two-thirds of its original strength after ten years in situ.[25]

Shuttleworth and Davies reported a follow-up of between four and twelve years on seventy-two patients who had a nylon darn repair for primary inguinal hernia.[26] All of these patients were clinically examined and a recurrence rate of 8.3% was reported. This compared favourably with the recurrence rate found with other repairs in the study including herniotomy with or without plication of the transversalis fascia (15.7%), Bassini repair (28.9%) and the Tanner slide (20%). Leacock and Rawley reported an average follow-up of 3.8 years in 326 nylon darn repairs for primary inguinal hernias.[27] All of the patients were examined with five (1.5%) recurrences and three (0.9%) sinuses being recorded.

While some authors have advocated the placement of sutures lateral to the deep ring during plication types of repair,[22] Lichtenstein and Shore have argued that this may be detrimental. Sutures placed lateral to the cord are likely to cut out during contraction of the muscle and it was argued that this leaves an enlarged deep ring, which predisposes to recurrence.[28] Lichtenstein and Shore commented that, in their experience, the majority of indirect recurrences occurred following placement of a lateral suture at the original repair.

1.4 The Shouldice repair

In 1920, Downes described a repair which involved excision of the direct inguinal sac and closure of the resulting defect in the posterior inguinal wall with a continuous suture.[29] Harrison recognised that adult inguinal herniation was due to failure of the transversalis fascia to withstand the intra-abdominal pressure to which it was subjected.[30] He therefore modified Downes repair by overlapping the incised transversalis fascia layer and then reinforcing it with a fascia lata graft. Earl Shouldice has been credited with the refinement of the technique of double breasting the transversalis fascia. In his original publication in 1945 Shouldice advised against any 'interference' with the transversalis fascia,[31] however the 'Shouldice technique' was then developed between 1945 and 1950. In 1953, Shouldice published a paper in which he clearly illustrated division of the transversalis fascia and described overlapping of the tissue layers using a total of six continuous sutures.[32] Welsh and Alexander claimed that it was Ryan, who joined the Shouldice clinic in 1950, that introduced the technique of division of the transversalis fascia.[33] Prior to this time the posterior wall was not routinely examined and, when it was inspected, the fascia had simply been plicated.[34] Glassow, who published extensive results from the Shouldice Clinic, emphasised the importance of freeing the peritoneal sac of an indirect hernia to the level of the deep ring. At this level the sac should be separated from the transversalis fascia.[35,36] This concept, which was attributed to Shouldice himself, was thought to be more important in preventing indirect recurrence than high ligation per se. Until 1948, a silk suture was used for the repair but after this time the use of stainless steel wire was introduced.[34] In 1953, Shouldice reviewed his results for the preceding eight years and demonstrated an improvement in recurrence rates (2.1% at 3 years for repairs performed in 1943-5, and 0.01% at 3 years for repairs performed in 1950).[32] The basis for the 'classic' Shouldice repair therefore appears to have been developed during this period with a corresponding improvement in recurrence rates. Glassow, who described the Shouldice repair as a modification of the Bassini repair,[37] stated that the technique was not standardised until 1951.[38]

It was not until after Shouldice's death in 1965 that the first full descriptions of the 'Shouldice repair' were in published. These publications were made by American surgeons who had visited the Shouldice Clinic,[39,40] and Glassow subsequently

described aspects of the repair in a series of reports of outcome following the repair.[36,38] The majority of Shouldice repairs were performed under local anaesthesia. The skin incision was made along the line of the inguinal canal and the external oblique aponeurosis was then divided along the same line with the upper and lower flaps being completely mobilised. The cremaster muscle was divided along the line of the cord and excised to allow an adequate view of the posterior wall of the canal. The cord was then freed from all attachments to the transversalis fascia at the level of the deep ring. In the absence of an indirect hernia sac a small crescent of peritoneum was visible on the cord and this was mobilised to prevent an indirect hernia being overlooked. If present, an indirect sac was completely freed from the cord down to the deep ring and excised. The strength of the posterior wall of the canal was then assessed. The technique of repair was essentially the same whether or not a direct defect was present. The transversalis fascia was divided starting at the deep ring and progressing along the line of the canal to the pubic bone. The basis of the repair was an overlapping technique using four continuous lines of stainless steel wire. The first suture line was started at the pubic bone and picked up the free edge of the lower flap of transversalis fascia. This was sutured to the undersurface of the medial flap at the level of the edge of the rectus abdominis, and more laterally at the level of the posterior aspect of the internal oblique. This suture was continued to reconstruct the deep ring and then turned to return as the second suture line, which picked up the free edge of the upper flap and attached it to the free edge of the inguinal ligament. The third and fourth suture lines were then placed using a second length of wire. The third line commenced at the deep ring and united the internal oblique/conjoint tendon to the posterior aspect of the external oblique aponeurosis just above the level of the second suture line in the free edge of the inguinal ligament. This line was turned at the pubic tubercle and returned as the fourth layer to reinforce the third line of sutures. The cord was then replaced in the inguinal canal and the external oblique aponeurosis was closed over it, again with a slight overlap.

Ryan reported the outcome following 369 recurrent groin hernias repaired at the Shouldice Clinic between 1941 and 1951, although only twelve repairs were performed in the first four years of this period.[41] A recurrence rate of 1.3% at two years was reported, but it should be noted that only 58% of the patients were

examined. Both Ryan and Glassow emphasised that early recurrence occurred as a consequence of poor surgery.[34,41]

In 1970, Glassow published a review of fifty thousand inguinal and femoral hernias repaired at the Shouldice Clinic between 1945 and 1967.[42] From the period 1945-50 there were 192 recurrences from five thousand repairs (3.8%). From 1951-67 the rate was 172 recurrences from forty-five thousand repairs (0.4%). The high early recurrence rate coincided the period when the repair was being refined. Glassow subsequently published his own personal experience with the Shouldice repair between 1954 and 1974.[38] From over thirteen thousand primary inguinal hernia repairs he reported seventy-three recurrences (0.6%), and from over eighteen hundred recurrent hernia repairs he identified eighteen recurrences (1.0%). Of the ninety-one recurrences identified, forty were inguinal hernias and fifty-one were femoral hernias. Glassow suggested that the 'recurrent' femoral hernias might have been missed at the original operation, despite routine inspection for them. Alternatively he thought that there may have been a technical error in dealing with the lower flap near the femoral vein, or there could have been tension in the repair which opened the femoral canal.

Other surgeons have also reported low recurrence rates for the Shouldice repair. Devlin reported a recurrence rate of 1.2% at five years,[43] and Wantz reported a recurrence rate of 1.3% for 3,454 primary groin hernia repairs performed between 1970 and 1985.[44] Wantz also reported a 4.9% recurrence rate for first time recurrent hernias, but for patients with more than one previous recurrence the rate was 40%. A preperitoneal mesh repair was therefore recommended for the latter group.[44]

Berliner noted that effective wound healing requires a fibroblastic response and adequate oxygenation.[45] An on-going balance of collagen synthesis and enzymatic lysis occurs for approximately one year after repair, until a stable aponeurotic structure is formed. Berliner argued that simple plication of the posterior wall of the inguinal canal is inadequate to stimulate fibroplasia, and therefore incision in the posterior wall is necessary for an effective repair. Fibroblasts are mobile in tissue culture and migrate to a smooth surface to which they can adhere. The overlapping layers in the Shouldice repair provide this surface. Absence of tension in the repair is also necessary to allow adequate oxygenation. Knolmayer and co-workers have

compared wound strength following imbrication versus excision and closure in the anterior rectus sheath of rats.[46] They found that at seven, fourteen and twenty-eight days excision and closure provided significantly stronger result than imbrication. A collagen cross-linking analysis was also performed and this suggested that the strength advantage increased over time. It was therefore concluded that excision and closure was preferable to imbrication for fascial tightening procedures.

Berliner adopted the Shouldice repair in 1972, but rapidly decided that the fourth suture line was superfluous.[45] He therefore developed a repair using three suture lines. The first two suture lines were placed in the same way as for the Shouldice repair. The third layer then united the transversus abdominis aponeurosis superiorly with the posterior aspect of the external oblique aponeurosis inferiorly. At a mean follow-up of 80.8 months in 1,804 repairs using this technique Berliner recorded a recurrence rate of 1.3% for primary inguinal hernias. The repair was also used for 272 recurrent inguinal hernias with a recurrence rate of 5.9%. Berliner then hypothesised that, as the transversalis fascia layer is the main barrier to direct herniation, a simple two-layered repair of the posterior wall should be adequate.[45] He performed a trial to compare the two-layered technique with the modified Shouldice repair using three lines of sutures (Table 1.1). There was no significant difference in early recurrence rates between the two groups. Although Berliner recognised that longer follow-up was required, no subsequent follow-up has been reported in the literature. Within a large randomised trial Kux and co-workers included a group that had a conventional Shouldice repair and a further group that had a two-layer Shouldice repair (Table 1.1).[47] Each type of repair was performed using a polypropylene suture. The recurrence rates for the two groups were not significantly different at two years follow-up. Varshney et al. have also performed a randomised trial comparing the traditional four-layer Shouldice repair with the two-layered technique using nylon (Table 1.1).[48] No significant difference in recurrence rates was found between the groups. Hilgert and co-workers have performed a randomised trial of Shouldice repair using non-absorbable polypropylene or reabsorbable polydioxanone (PDS).[49] At a mean follow-up of thirty-one months there was a total recurrence rate of 5% and no difference between the two groups.

Table 1.1: Trials comparing different techniques of the Shouldice repair

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Recurrence
Berliner (1984)[45]	Adult male with primary inguinal hernia	3-layer (509) 2-layer (508)	Mean 21.7 months (97.9%)	Clinical exam	3-layer – 1.0% 2-layer – 1.2%
Kux et al. (1994)[47]	Adults with primary or recurrent hernia	4-layer (200) 2-layer (200)	2 years (94.5%)	Clinical exam	4-layer – 3.6% 2-layer – 2.3%
Varshney et al. (1995)[48]	All elective adult inguinal hernias	4-layer (42) 2-layer (53)	1 year (81.3%)	Clinical exam	4-layer – 0% 2-layer – 1.9%

* number of repairs given in brackets
** percentage follow-up given in brackets

1.5 Repairs involving Cooper's ligament

Annandale is often reported as the first surgeon to use Cooper's ligament for a hernia repair in 1876.[50] However, Koontz has demonstrated that Annandale used neither the inguinal ligament nor Cooper's ligament in his repair of a combined inguinal and femoral defect.[51] The first published report on the use of Cooper's ligament was therefore that of Lotheissen in 1898, who recommended the internal oblique and transversus abdominis muscles be sutured to Cooper's ligament for the repair of femoral hernias.[12] McVay has strongly advocated the use of Cooper's ligament for inguinal hernia repair, and the technique is now known in many quarters as 'the McVay repair'.[52-57] McVay argued that, as the inguinal ligament forms neither the origin nor insertion of the transversus abdominis and internal oblique layers, there is no anatomical justification for suturing them to it.[52] He contended that Cooper's ligament should be used in repair of the posterior inguinal wall as it forms the normal insertion for these muscles. In 1942, McVay and Anson described the Cooper's ligament repair, and emphasised that this technique should only be used for hernias with a significant posterior wall defect.[53] A herniotomy with plication of the deep ring was performed for patients with indirect hernias and no significant encroachment onto the posterior inguinal wall. In the McVay repair the hernia sac was dealt with in the same way as for other anterior repairs. The attenuated area of the transversalis fascia was then excised and the free edge was separated from the underlying preperitoneal tissue. A series of interrupted silk sutures were then used to attach the transversalis fascia to Cooper's ligament along a line from the pubic tubercle to the medial border of the femoral vein. The repair was then continued laterally by suturing the fascia to the anterior portion of the femoral sheath. By 1948, use of a relaxing incision appears to have become routine and McVay recommended a sliding technique.[54]

McVay and Anson subsequently reported a series of fifty-six Cooper's ligament repairs with no recurrence, although the follow-up was relatively short for the final twenty-five patients in the series.[55] Nine years later McVay and Chapp reported a 1% recurrence rate from 197 patients who had undergone Cooper's ligament repair between one and eleven years beforehand.[56] In 1970, Halvessen and McVay reported a series of hernioplasties that had been followed up for between one and twenty-two

years.[58] Of the 442 Cooper's ligament repairs performed for posterior inguinal wall defects sixteen had recurred (3.6%). These reports demonstrated the increasing recurrence rate found when patients are followed up over a prolonged period of time.

In arguing the case for the Cooper's ligament repair McVay emphasises that the inguinal ligament is not a fixed structure, but rather is anchored only at its two extremities. Zimmerman stated that, although this observation is anatomically correct, the relatively low incidence of recurrence below the inguinal ligament (ie. femoral hernias) meant that the practical significance was questionable.[59] He also argued that use of Cooper's ligament was technically more difficult and that there was a greater risk of injury to the femoral vein. Zimmerman therefore stated that any improvement in outcome should be balanced against the added difficulties and hazards of the repair. Similarly, Lichtenstein and Shore have argued that, despite the strength of Cooper's ligament, the inguinal ligament offers many advantages for hernia repair.[28,60] While McVay contended that the lack of fixation of the inguinal ligament was a disadvantage, Lichtenstein and Shore claimed that this mobility imparted resilience to the suture line during use of the abdominal musculature.[28] It was therefore argued that sutures were more likely to cut out from Cooper's ligament than from the inguinal ligament.

More recently Rutledge has reported a twenty-five year experience of the Cooper's ligament repair[61] Unlike McVay, Rutledge used the same repair for all types of inguinal and femoral hernias, arguing that this should reduce recurrence rates as all possible defects are repaired at the original operation. The report covered 906 repairs followed up for an average of nine years. A total of eighteen recurrences (2%) were identified in surviving patients. In the earlier years of this series the cord had been transplanted to a subcutaneous position and seventeen of the recurrences were from these patients. This group therefore had a recurrence rate of 11.6% with an average follow-up of 17.4 years. Subsequently the cord was returned to its normal anatomical position and, after an average follow-up of 7.1 years, there was one recurrence in 572 repairs (0.2%).

1.6 The open transabdominal approach

The transabdominal approach to inguinal hernia repair was considered by a number of surgeons in the latter years of the nineteenth century. In 1873, Annandale described the repair of an umbilical hernia via this approach and commented that it could also be used in the management of large inguinal hernias.[62] Hutchison, in 1878, then used a transabdominal approach via a lower midline incision to treat a strangulated inguinal hernia.[62] In 1883, Lawson Tait repaired a femoral hernia found incidentally during laparotomy for an ovarian cystectomy.[62] At that time he postulated that it was possible to treat all abdominal wall hernias in this way. In 1891, Lawson Tait defined the main principles for the management of hernias via 'median abdominal section'.[63] These included that strangulation must be relieved without enlargement of the tendinous aperture through which the viscera protrudes, and the elements of the tendinous aperture must be closed during the repair. In 1913, Bates described transabdominal repair of the hernia defect using transversalis fascia.[64] In this approach a two-inch long incision was made one inch above the deep ring and parallel to the inguinal ligament. The external oblique aponeurosis and internal oblique muscle were opened along the line of their fibres, then the transversalis fascia and peritoneum were opened. This allowed the deep ring including the neck of the sac to be closed using a pursestring suture.

Laroque described a combined anterior and posterior method to deal with a hernia sac then repair the inguinal canal.[65-67] He made a standard anterior approach to the inguinal canal and, on dividing the external oblique aponeurosis, separated the fibres of the internal oblique and transversus abdominis muscles an inch above their lower margin. The peritoneum was then opened to allow reduction and excision of the hernia sac. LaRoque commented that at this point the internal orifice of the canal could be sutured, but he had not done so. Instead the peritoneal incision was closed and repair of the inguinal canal was performed using an anterior approach. LaRoque was not specific as to which technique should be used. This lack of detail reflects LaRoque's belief that total removal of the hernial sac was the essential part of hernia repair and his uncertainty about the importance of the plastic repair of the abdominal wall. Several other surgeons have subsequently advocated the use of a transabdominal approach for strangulated,[68-70] sliding,[68-71] and congenital hernias.[68]

1.7 Preperitoneal herniorrhaphy

Annandale has been attributed with an early description of the preperitoneal approach to groin hernias.[9] However, in a review of Annandale's paper, Koontz found that he had actually used an anterior approach to the inguinal canal in a somewhat esoteric combined repair of inguinal and femoral defects.[51] In 1920, Cheatle described a preperitoneal approach to the groin via a paramedian incision with longitudinal splitting of the rectus abdominus.[72] The inguinal hernia sac was ligated at the peritoneal surface. The part extending in to the canal was then drawn up as far as possible, ligated and allowed to slip back into the canal. It is not clear whether or nor Cheatle tightened the deep ring as he stated 'there is nothing to stop a surgeon occluding the internal ring by suture should he desire'. The same approach was used for the repair of femoral hernias. Cheatle subsequently described the use of a Pfannenstiel incision to approach the groin.[73] In 1936, Henry 'rediscovered' the extraperitoneal approach to groin hernias in a report that made no reference to Cheatle's work.[74] Henry was familiar with the midline extraperitoneal approach to the pelvic ureter and was impressed by the excellent view obtained of the posterior inguinal region. This allowed the true neck of the hernia sac to be identified more easily than with the anterior approach. Henry reported the repair of bilateral femoral hernias in a fourteen-year-old girl. In this patient the hernia sacs were reduced and excised then the femoral canals were covered with fascial flaps. Cadaveric dissection was then used to refine the preperitoneal approach, and inguinal defects were repaired by suturing transversalis fascia such that the deep ring was snug around the cord. In addition, Henry reported the repair of bilateral direct inguinal hernias via a preperitoneal route.[74] Jennings et al. also published a description of the preperitoneal approach via a midline incision.[75] Indirect inguinal hernias were then managed by high ligation and removal of the sac followed by tightening of the deep ring. In conditions where the sac extended into the scrotum, or was associated with dense adhesions, it was divided and the distal portion left in situ. This technique was claimed to avoid distortion of the canal and allow the formation of a scar to protect against recurrence. It was also thought to be relatively simple, with low risk of injury to the ilioinguinal nerve or cord structures. The perceived disadvantages were that the repair was unsuitable for direct hernias and large indirect hernias where the deep ring was dilated to such an extent that it overlapped the superficial ring.[75,76]

McEvedy was critical of the midline preperitoneal approach to femoral hernias.[77] His reasons for this included the requirement for a second groin incision in large hernias, a risk of splitting the peritoneum while reducing the sac, and inadequacy of the repair. McEvedy advocated an approach via a vertical incision from just over the crural canal, and associated hernia sac, to a point three inches above the inguinal ligament. The preperitoneal space was then entered via an incision in the rectus sheath parallel to the lateral border of the rectus abdominis muscle, which was retracted medially. The hernia sac was opened, to deal with the contents, then reduced. If necessary the peritoneum was opened and a bowel resection performed. The sac was excised and a repair performed by placing two or three non-absorbable sutures between the conjoint tendon and Cooper's ligament, which tightened the femoral canal. Mouzas and Diggory reported a modification of McEvedy's approach whereby an oblique skin incision was made along Langer's lines.[78] This approach was claimed to improve exposure and also facilitate inguinal hernia repair through the same incision.

In 1959, Nyhus and colleagues published a preliminary report of fifty groin hernia repairs via a lower midline incision with the divided peritoneal sac being left in situ.[79] A Cooper's ligament repair was then used for both direct and indirect inguinal hernias. One year later Nyhus, Condon and Harkins published a further paper on their clinical experience with the preperitoneal approach to all types of groin hernia.[80] They stated that the tissue available with this approach was adequate to repair each of the types of groin hernia. The approach used had been modified to a transverse incision with the lateral border carried about four centimetres into the lateral abdominal muscles, and for bilateral repairs the incision was extended across the midline. The rectus abdominis muscle was then retracted medially to develop the preperitoneal space. A true high ligation of the sac was performed in all cases. For indirect inguinal defects three or four silk sutures were placed lateral to the cord to snug the deep ring around it. To repair a direct inguinal hernia silk sutures were placed between the thickened transversalis fascia at the upper border of the defect and the iliopubic tract inferiorly. Cooper's ligament was only used if the iliopubic tract was deficient. Nyhus et al. reported 213 repairs, thirty-three of which were recurrent.[80] A total of five (2.3%) recurrences occurred between one and eighteen months after repair. Four of these were indirect recurrences, and all of them had been repaired using the methods described in the original 1959 paper. No indirect

recurrences were observed following adoption of the later technique, although follow-up for these repairs was much shorter. In 1989, Nyhus reported recurrence rates of 3% for indirect hernias and 6% for direct hernias from 1,200 primary repairs.[81] Nyhus et al. commented that the preperitoneal approach was advantageous for recurrent hernias, and also reported less testicular atrophy and neuropathy using this route.[80]

Read has also described a preperitoneal approach to inguinal hernias with a sutured repair involving the inguinal ligament.[82,83] Read agreed with McVay that the iliopubic tract was not a true anatomical structure that could be used for repair. However, he argued that bringing the transversalis fascia down to Cooper's ligament produced too much tension in the repair, even with a relaxing incision. Read reported the outcomes of 1,420 preperitoneal inguinal hernia repairs with a mean follow-up of forty-one months.[83] The recurrence rate for indirect hernias was 3.8%, and for direct hernias it was 8.2%. Read concluded from these figures that the preperitoneal approach allowed satisfactory repair of all types of groin hernia.

The use of a preperitoneal approach has been advocated for the management of acute inguinal hernias.[84,85] It was stated that this approach fulfilled three operative goals for such conditions. These are: removal of trapped abdominal contents with minimal risk of contamination or perforation, easy resection of non-viable viscus without the need for a second incision, and access for repair of the hernia defect. Malangoni and Condon claimed that petechiae in the fascial structures of the hernia defect always indicated that the viscus was strangulated.[85] In these situations they advocated resection of the involved viscus before mobilising the hernia to reduce the risk of bacteraemia via the mesenteric circulation.

Not all comments on preperitoneal herniorrhaphy have been favourable. Sonneland compared the results from conventional anterior repairs of the time and the preperitoneal repair.[86] His conclusion was that the only role for the preperitoneal approach was as an adjunct to laparotomy for other conditions. Several other reports showed much higher recurrence rates for direct inguinal hernia repair than for indirect hernia repair performed via the preperitoneal route.[87-89] Having reviewed the results from their own data and other reports, Gaspar and Casberg concluded that preperitoneal herniorrhaphy should not be used for direct inguinal defects.[89] McVay

contended that the high recurrence rate with the preperitoneal repair of direct inguinal hernias was due to the use of the iliopubic tract to effect the repair.[90] He also stated that there was undue tension in these repairs. Lindholm et al. reported relatively low recurrence rates for primary hernias, but found a re-recurrence rate of 27% at up to four years follow-up for recurrent hernia repairs.[91] The use of preperitoneal herniorrhaphy for recurrent hernias was therefore questioned. In 1971, Margoles and Braun found a much higher recurrence rate for preperitoneal repair compared with that for anterior sutured repair.[92] They also reported poorer results in the preperitoneal repair group for other outcome measures such as post-operative pain and hospital stay.[92] However, this study was not randomised and there was a greater proportion of recurrent hernias in the preperitoneal group.

1.8 Prosthetic repair via an anterior approach

The ideal implantable soft-tissue prosthesis should remain inert and stable, should not be modified by the body after implantation, should not stimulate a chemical or biological reaction, should not undergo physical change, and should remain flexible.[93] A number of biological prostheses have been tried for the repair of inguinal hernia,[94-96] including skin which produced complications such as dermoid cysts and squamous carcinoma.[97] Fascia lata appeared to provide an acceptable tissue for repair, but there were complications from the donor site.[98]

In the past fifty years a number of man-made prostheses have been used for inguinal hernia repair. In 1948, Thompson reported the use of a sheet of polyethylene which was placed in the preperitoneal space via an anterior approach.[99] With a maximum follow-up of less than two years no recurrences were identified following this repair, but some patients did complain of stiffness in the abdominal wall. The use of tantalum gauze in inguinal hernia repair was reported independently by Throckmorton and by Douglas in 1948.[100,101] This mesh was thought to act as a biologically inert framework for the ingrowth of fibrous tissue. Throckmorton advocated that the mesh should be used for direct and large indirect inguinal defects. He emphasised that it should be of sufficient size to allow placement without tension and that the tantalum sutures used should be placed into strong fascia or periosteum. The cord structures were passed through an opening high on the lateral border of the implant. Throckmorton produced radiological evidence that within twelve months the

mesh had fractured and so the long-term strength of the repair was dependent on the ingrowth of fibrous tissue.[100] This observation was reinforced by Mitchell-Heggs who performed a ten-year survey on thirty-nine patients with a tantalum gauze repair.[102] In the majority of cases mesh fragmentation was identifiable by two years after the operation. The repair described by Douglas involved a different technique as he felt that making a hole in the mesh for the passage of the cord introduced a point of weakness.[101] Douglas mobilised the testis from the scrotum and created a new deep ring by passing the cord through the internal oblique four centimetres above its lower border (the Schmieden manoeuvre). The internal oblique muscle/conjoined tendon were then plicated to the inguinal ligament and a half moon shaped piece of mesh was fixed over the canal with interrupted sutures. Douglas subsequently reported thirty-six abdominal wall hernia repairs including thirteen repairs of large or recurrent inguinal hernias.[103] After an average follow-up of five years there was no sinus formation, but two inguinal hernias had recurred. Douglas concluded that this method of inguinal hernia repair was of little value due to problems with fitting the prosthesis around the cord and, in the case of recurrent hernias, difficulty in finding tissue to anchor the prosthesis inferiorly. In 1950, McNealy and Glassman reported the repair of inguinal hernias using a Vitallium plate.[104] The plate was constructed with an opening for the cord and also perforations at the margin for placement of sutures. Like the technique used by Douglas, the internal oblique muscle was plicated to the inguinal ligament and the plate was then sutured over the repair. From ten patients who had undergone this repair in the preceding two to three and a half years one recurrence occurred, in a patient who had already recurred on five previous occasions.[104] All of the other patients had returned to work or normal activities. Recently Weitzel at al. reported a colocutaneous fistula caused by the migration of a metallic mesh.[105] This mesh had been placed over twenty years earlier for the repair of bilateral inguinal hernias.

Several other prostheses for inguinal hernia repair were also described. Schofield reported the use of polyvinyl alcohol sponge in hernia repair.[106] He showed that the mesh was invaded by granulation tissue that subsequently matured to fibrous tissue. Six large inguinal hernias were repaired using this technique with no recurrences at a maximum follow-up of twelve months. Wolstenholme used Dacron fabric for the repair of inguinal hernias and large abdominal wall defects.[107] In this repair the Dacron, which was split to accommodate the cord, was sutured inferiorly to the

inguinal ligament and superiorly to the margin of the defect in the transversalis fascia. In a subsequent post-mortem, for a patient who died from gastric carcinoma, fibrous tissue was found to be growing through the interstices of the fabric. There was no evidence of inflammatory or foreign body reaction. Horwich used open weave nylon tricot, which also allowed granulation tissue to grow through the prosthesis.[108] In this repair the defect in the transversalis fascia was closed, and, if possible, the conjoined tendon was plicated to the inguinal ligament including a Tanner slide.[21] A continuous braided nylon suture was used to attach a five by three inch piece of mesh to the inguinal ligament. A second continuous suture was then used to attach the upper border of the mesh between the pubic tubercle and the upper aspect of the internal oblique aponeurosis to cover the area of the Tanner slide. A longitudinal slit was made in the lateral end of the mesh to create two tails, which sat snugly around the deep ring. Horwich commented that the mesh should be 'quite taught'. One recurrence was identified from fifty-eight cases followed up for one year or more.[108] Three patients suffered a wound infection, but all had settled after opening of the wound. Horwich noted that, as recurrence following prosthetic repair usually occurred at a point around the edge of the implant, the mesh should widely overlap the deficiency to be repaired. Doran and co-workers reported the use of three different types of nylon net with different strand thickness and pore size.[109] A high recurrence rate was found with the thin net, but only one case developed a chronic sinus. With the thicker net a high incidence of non-healing wounds occurred and over half the cases required removal of the mesh. The medium sized net was more successful with only six of 212 repairs developing sepsis which required removal of the mesh, and four other patients developing recurrence by two years follow-up. Doran et al. concluded that, as nylon was a slightly irritant foreign body, there was a limit to the quantity that could be safely implanted.

In 1959, Usher introduced Marlex (single strand polypropylene) mesh for the repair of incisional and inguinal hernias.[110-112] Usher claimed that this mesh provided a weave that was porous enough to allow fibrous tissue in-growth without compromising the tensile strength of the prosthesis.[111] Marlex mesh had a much higher tensile strength than that for prostheses such as nylon, Dacron or Teflon (polytetrafluoroethylene).[111] The foreign body reaction to Marlex mesh was similar to that of Teflon, and was much less than the reaction to nylon or Dacron.[111] Teflon,

however, was found to allow very little fibrous tissue ingrowth while Marlex allowed uniform infiltration of the mesh. Six months after implantation Marlex showed no evidence of fragmentation and its tensile strength was maintained.[111] Marlex was also found to perform much more favourably that most other prostheses in the presence of infection. This claim has been substantiated in studies performed by Koontz and Kimberley.[113]

For direct and recurrent inguinal hernias Usher performed a conventional plication repair of the inguinal floor and then reinforced this with a mesh onlay technique.[110,112] Using silk sutures, a strip of Marlex (2.5 x 7 cm) was sutured to the inguinal ligament and pubic tubercle inferiorly, and to the rectus sheath/internal oblique muscle superiorly. A notch was cut in the mesh laterally to allow passage of the cord. The external oblique aponeurosis was closed over the mesh with the cord either returned to its normal position or transplanted to a subcutaneous position. After favourable experiences with incisional hernia repair Usher modified his repair of inguinal hernias.[110] The transversalis fascia was divided from the deep ring to the pubic tubercle and a preperitoneal space developed behind the upper flap. Using interrupted mattress sutures the upper border of the mesh was fixed behind the conjoined tendon and transversalis fascia. The lower border was then sutured to the inguinal ligament without making any attempt to perform a plication repair. Placing a few sutures lateral to the cord, between the internal oblique muscle and inguinal ligament, tightened the deep ring. Usher noted that these patients suffered less post-operative pain, which he attributed to the absence of tension in the repair.[110] In 1962, Usher reported that of eighty-four cases reviewed at one year there were five recurrences (5.9%).[114] In two of these cases, exploration showed that the mesh had pulled away from the pubic tubercle resulting in a medial recurrence. In 1970, Usher subsequently reported a recurrence rate of 3% from 286 patients.[115] Kaufmann, Weissberg and Bider have used a technique similar to that of Usher for the repair recurrent hernias with polypropylene mesh.[116] The repair differed, however, in that the mesh was split laterally and then re-sutured around the cord to fashion a new deep ring. Kaufmann et al. reported low rates of infection and recurrence using this technique.[116] Barnes also reported good results with the use of polypropylene mesh.[117]

Polypropylene mesh is now available in several forms including Marlex (woven from single strands), Prolene (woven from double strands), and Surgipro (woven from multiple filaments). It has been claimed that the greater the number of strands, the softer and more pliable the mesh.[118] Polytetrafluoroethylene (PTFE) has also been used in inguinal hernia repair. This was initially available as a 'non-expanded' mesh (Teflon),[119] but was subsequently replaced by expanded PTFE.[120] The fibrous ingrowth into a PTFE mesh is less than that observed with a polypropylene mesh,[121,122] and the tensile strength of the PTFE mesh repair is therefore less than that of the polypropylene mesh at ninety days.[122] Polypropylene, however, is associated with a greater incidence of adhesion formation when compared with expanded PTFE.[118]

1.9 The Lichtenstein repair

In 1987, Lichtenstein published a report on his personal experience with over 6,000 inguinal hernia repairs.[60] In this paper he described the routine use of polypropylene mesh to reinforce a plication repair for all direct and recurrent hernias. The external oblique aponeurosis was then sutured behind the cord, which transplanted it to a subcutaneous position. After a follow-up of between two and fourteen years forty-three (0.7%) recurrences were reported, the majority of which were attributed to excessive tension in the repair. Lichtenstein therefore refined his repair to avoid suture line tension.[123-125] Using a conventional anterior approach to the inguinal canal the direct or indirect sac would be mobilised and reduced. A piece of polypropylene mesh (16 x 8cm) was trimmed, with the medial end rounded to fit the inguinal canal. Fixation of the mesh was commenced medially with a continuous prolene suture. The mesh overlapped the pubic tubercle by two centimetres to protect against medial recurrence, and was sutured along the free edge of the inguinal ligament to a point one to two centimetres lateral to the deep ring. Medially the suture avoided the periostium of the pubic tubercle as its involvement can cause chronic periostitis. The lateral end of the mesh was divided at the junction of the middle and lower thirds to the level of the deep ring, which created two tails in the mesh. The upper tail was then passed around the cord as it emerges from the deep ring. The lower borders of both tails were anchored to the inguinal ligament using a prolene suture, and the tails were tucked beneath the external oblique aponeurosis. The upper border of the mesh was

tacked to the rectus sheath and internal oblique aponeurosis using interrupted sutures. Absorbable sutures were used in this area as the ilio-hypogastric nerve may be accidentally caught up in the suture. Lichtenstein stipulated that, once sutured in place, the mesh should not be under tension. The cord was then placed in its normal position, overlying the mesh and the external oblique aponeurosis reconstituted. In 1993, Lichtenstein et al. reported follow-up of one to eight years for 3,125 repairs performed using this technique.[125] Four patients, all from early in the series, developed a recurrence. Three of these patients had medial recurrence and in the fourth the mesh, which was thought to be too small and therefore under tension, had separated from the inguinal ligament.[125,126] No case of mesh rejection was reported and the infection rate was 0.5%. Amid and Lichtenstein subsequently reported the outcome from 5,360 inguinal hernia repairs performed at the Lichtenstein Hernia Institute.[126] This series included 1,000 patients who had simultaneous bilateral inguinal hernia repairs performed under local anaesthesia, and 360 recurrent hernias. In addition to the four previously described recurrences one further recurrence was reported. It was reported that following this type of repair the patients required oral analgesics for one to four days and had returned to work in two to fourteen days. The Lichtenstein group also collated the outcomes of 22,300 repairs performed by seventy surgeons and found similar outcomes.[125] The surgeons from the Lichtenstein clinic stated that they prefer local anaesthesia for reducible adult inguinal hernias as it is safe, effective and does not have post-anaesthetic side effects.[127] Furthermore it was argued that the pre-emptive effect of local anaesthetic administration before the incision is made results in less post-operative analgesic use. It was also claimed that bilateral defects could be repaired simultaneously using this technique with low post-operative morbidity and recurrence rates.[126,128]

Wantz reported 1,252 prosthetic repairs that had been followed up for between one and six years.[129] 97% of these repairs were performed under local anaesthetic and involved either a Lichtenstein procedure or, in the case of indirect hernias, a combination of mesh plug and a reinforcing prosthetic patch. Wantz reported six recurrences (0.5%), all of which occurred early in the series and within a few months of the initial repair. It was therefore concluded that these repairs were likely to be related to technical errors. Other authors have also reported recurrence rates of less than 1% for the Lichtenstein repair.[130,131] The outcome following Lichtenstein repair

for recurrent inguinal hernias has recently been reported by different authors as 1.8% after one year follow-up,[132] and 7.0% after two years follow-up.[133]

1.10 Modifications of the Lichtenstein repair

Capozzi et al. reported the use of prosthetic repair for all adult inguinal hernias excluding Nyhus type I.[134] In this series the posterior wall of the canal was reinforced using prolene mesh, which was fixed in place using a continuous prolene suture around the entire margin of the prosthesis. Laterally the mesh was split and sutured around the cord to reconstitute the deep ring. In this series two patients (0.3%) developed mesh infection and both settled with conservative treatment. Four recurrences (0.6%) were recorded from 651 patients followed up for an average of five years.

Vara-Thorbeck and colleagues described a modification of the Lichtenstein patch repair which they called the 'Thovara repair'.[135] Essentially this repair only differed from that of the Lichtenstein Clinic in that the external oblique aponeurosis was sutured behind the cord, which was therefore transposed to a subcutaneous position. Transposition was thought to prevent raised intra-abdominal pressure being directed along the line of the cord. The recurrence rate at one year (0.8%) was no better than that reported for the Lichtenstein repair and in addition this repair had a 1% incidence of testicular atrophy.

Valentini et al. have also described a modification of the anterior mesh repair, which they have called 'the dynamic self-regulating prosthesis'.[136] This technique involved placing two layers of mesh over each other, with the cord passing between them. The deep mesh was sutured to the rectus sheath superiorly and the more superficial mesh to the inguinal ligament inferiorly. The two meshes therefore covered the defect but could move over each other, allowing for movement of the aponeurotic and muscular structures without tension. Valenti et al. reported 585 repairs with no evidence of early recurrence.[136]

1.11 The mesh plug technique

Lichtenstein and Shore observed that recurrent inguinal hernias often consisted of a single punched out defect in an otherwise intact inguinal floor.[137] This observation was supported by Greenburg, who found multiple defects in only 2.8% of direct recurrences and observed that most defects were less than four centimetres in diameter.[138] It was argued that while taking down the entire former repair would be superfluous, and possibly detrimental, simple sutured closure of the defect would be unlikely to give a lasting repair. Lichtenstein and Shore therefore described a technique for repair of femoral and recurrent inguinal hernias using a plug of polypropylene mesh.[137] The plug was fashioned from a strip of mesh (20 x 2cm) which was rolled to form a cylinder and, where large defects were encountered, a further piece of mesh was wrapped around the first one. When placed in the defect the outer end of the plug lay flush with the surrounding tissues. It was then secured by four or five sutures, which approximated the plug to the margins of the defect. Shulman, Amid and Lichtenstein subsequently reported a twenty-year experience with this type of repair in 1,402 patients with recurrent inguinal hernia.[139] With a 91% follow-up of between three and twenty-one years they reported twenty-one recurrences (1.6%). The reasons for these recurrences were identified as insufficient plug size, an unrecognised secondary defect, infection, and insufficient sutures in a case where only two were used. In 1994, the Lichtenstein group indicated that the patch repair should be used for indirect inguinal hernias with a normal or dilated deep ring and an intact posterior wall (Nyhus types I and II).[140] It was also stated the patch prosthesis was ideally suited for repair of Nyhus type IIIa/b defects. For recurrent direct or indirect hernias less than 3.5cm diameter the plug repair was advocated, as application of a patch would involve greater dissection and an increased risk of testicular ischaemia. The patch repair was considered the best method for larger direct and indirect recurrent hernias. Shulman et al. recognised that the anterior approach to recurrent inguinal hernias carried a risk of testicular ischaemia but commented that the preperitoneal approach should only be used in circumstances such as multiple bilateral recurrences or where the patient already had one atrophic testicle.[140] However, having previously advocated the plug technique, the surgeons from the Lichtenstein clinic have now stopped using it for any type of hernia.[126] This step has been taken due to a number of concerns. Firstly, they felt that there was a risk of

missing a concurrent hernia due to inadequate dissection. Secondly, there was concern that shrinkage of the plug may result in failure of the repair. Finally, it was thought that there was a significant risk of complications including migration of the plug into the inguinal canal, scrotum, bladder, intestine or iliac vessels.

Gilbert has also described a 'sutureless' plug repair for indirect inguinal hernias that involved placement of a prosthesis into the preperitoneal space via an inguinal route.[141,142] This repair was recommended for indirect hernias where the deep ring did not exceed one fingers-breadth. Having reduced the indirect sac a six centimetre square piece of prolene mesh was cut to shape and folded into an 'umbrella plug'. The plug was inserted through the deep ring using a forceps and, when released, it unfolded behind the transversalis fascia. The posterior wall of the canal was then reinforced with a second sheet of prolene mesh. Neither of the pieces of mesh was fixed with sutures. From a series of 412 repairs, with a maximum follow-up of thirty-six months, Gilbert reported only one recurrence.[142] In subsequent repairs the second piece of mesh was omitted without any evidence of subsequent direct hernia formation.[143] This change reduced the incidence of wound seroma requiring aspiration from 5% to 1%. The use of the modified repair was then extended to indirect hernias with a deep ring greater then one fingers-breadth. In these cases a suture was placed lateral to the cord to reduce the width of the deep ring.

Rutkow and Robbins have also published extensively on the plug repair of inguinal hernias.[144-146] These authors initially used the repair for small to moderate sized indirect defects, but subsequently stated that the plug repair was indicated for the repair of all primary and recurrent inguinal hernias.[144] In Rutkow and Robbins repair the mesh plug was initially fashioned from a flat piece of polypropylene mesh, but a commercially available Marlex plug was subsequently developed ('PerFix', CR Bard, Cranston, RI).[145] The original cone of mesh had been criticised because it was unlikely to maintain its shape in vivo.[140] The commercially available plug was claimed to retain its shape as eight 'petals' of mesh supported its fluted outer layer.[145] For smaller hernias some of these 'petals' could be excised to allow the prosthesis to fit the defect.[145] All of the repairs, irrespective of hernia type, were then reinforced with an onlay of a polypropylene mesh patch (a 'plug and patch' repair). The patch, which was split laterally to fit around the cord and was not sutured in place, was not

viewed an integral part of the repair but rather as a form of 'prophylaxis' against recurrence.[145] Patients were advised that virtually all 'reasonable' activities could be recommenced by the end of the second post-operative week. Of 2,333 primary hernias repaired using this technique, with an average follow-up of four years, Rutkow and Robbins reported six recurrences (0.26%).[146] They also reported a 2.5% re-recurrence rate for recurrent hernia repair, a low incidence of post-operative complications and a rapid return to normal activity.[146] Bringman and co-workers reported a median operation time of thirty-five minutes for the plug and patch repair.[147] Sedentary workers returned to their normal occupation in a mean of seven days and manual workers in a mean of fifteen days. With a median follow-up of nine months two recurrences (1.4%) were identified. Palot et al described the use of a 'Perfix' plug technique for small to medium indirect hernias but did not advocate it for larger indirect or direct defects.[148] In two-thirds of cases an onlay patch was also sutured in place. With a median follow-up of thirty-four months for 140 patients one recurrence was found. This study did not report any cases of mesh migration, but the authors did comment that the long-term tolerance of the mesh plug required further evaluation. In the only randomised comparison Kingsnorth et al. concluded that the Lichtenstein repair was superior to the plug and patch type of repairs (Appendix A.3).[149]

1.12 Development of preperitoneal prosthetic repair

In 1962, Mahorner and Goss introduced the concept of placing a graft in the preperitoneal space to repair recurrent hernias.[150] A dermal graft was used as an 'internal buttress' for two patients where multiple previous repairs had destroyed both the inguinal ligament and Cooper's ligament, leaving nothing with which to anchor a repair. The graft was sutured to the iliopsoas fascia, the fascia either side of the iliac vessels and to the periosteum of the pubis. The anterior aspect was then sutured to the transversalis fascia. A further layer of sutures was tacked at the lower margin of the transversalis fascia. Estrin, Lipton and Block stated that the preperitoneal space was more favourable than sites anterior to the hernia defect for the placement of prosthetic material.[151] It was argued that in the preperitoneal position a rise in intra-abdominal pressure would tend to oppose the prosthesis to the abdominal wall rather than raise it off the defect. In the case of direct or recurrent hernias polyester (Mersilene) mesh or

Marlex mesh was advocated for reinforcement of a single layer sutured repair of the transversalis fascia. The mesh was sutured to Cooper's ligament, the iliacus fascia and the transversalis fascia with interrupted silk sutures. No recurrences were found in 100 patients followed up for a minimum follow-up of eighteen months.[151]

During the same period Calne developed a technique for placing polyester mesh behind the rectus muscle for the repair of bilateral groin hernias.[152] In this repair both inguinal canals were opened via a transverse suprapubic incision then indirect sacs were excised and direct sacs reduced. Dissection was continued in the extraperitoneal plane on both sides with the internal oblique and transversus abdominis muscles being displaced upwards. A piece of Mersilene mesh (10 x 20cm) was placed behind the rectus muscles then tacked to the anterior superior iliac spine and the pubis tubercle on each side. A continuous Mersilene suture was used to attach the mesh to the inguinal ligament, with a small opening left for the cord. Medially the suture was continued along the posterior border of the rectus sheath and then the conjoined tendon and internal oblique/transversus abdominis muscles superiorly. The external oblique aponeuroses were then repaired. Twenty-six patients were subsequently reported to have been followed up for more than one year after this type of repair and a total of seven (13.5%) hernias were known to have recurred.[153] Several patients complained of an initial paraesthesia in the distribution of the lateral cutaneous nerve of the thigh. This was thought to be due to trapping of the nerve by the suture along the inguinal ligament. There was also evidence of reduced compliance of the lower abdominal wall following this type of repair.

The term 'preperitoneal prosthetic herniorrhaphy' appears to have been coined by Tinckler in 1968.[154] He argued that, as the transversalis fascia was the layer that became deficient, it was this layer to which the repair should be directed. Tinckler was doubtful about the merits of a sutured repair of the transversalis fascia and so he advocated a prosthetic repair using Marlex mesh. The mesh was placed via a lower midline incision and sutured at the pubic tubercle, the superior pubic ramus, the iliopubic tract lateral to the deep ring and to the anterior rectus sheath in the midline. Three years after his original publication Tinckler produced a follow-up report that included 217 inguinal hernia repairs, twenty-seven of which were recurrent hernias.[155] There were four (1.8%) recurrences, all of which occurred at an early stage in the

series and may therefore have been related to a learning curve. Tinckler stated that this type of repair was applicable to all types of inguinal hernia repair.

In 1975, Read reported a sutured repair with a relaxing incision via the preperitoneal approach for all recurrent and direct hernias, plus some larger indirect hernias.[83] The 'bucket handle' relaxing incision was made across the width of the anterior rectus sheath, five centimetres above the level of the skin incision. McVay stated that this relaxing incision was inadequate as it was made at a level above the linea semicircularis, where the posterior rectus sheath prevented adequate translocation.[156,157] In addressing this criticism Read developed a prosthetic preperitoneal repair in which a Marlex mesh was 'substituted' for the relaxing incision.[157] He reported a total of 194 preperitoneal repairs using Marlex mesh, the majority of these repairs (72%) being for direct or recurrent defects. From this group four recurrences (0.7%) were identified, occurring between five and thirteen months after the repair. Two of the recurrences occurred after repair of a recurrent hernia. Read subsequently reported the use of Marlex mesh, via a preperitoneal approach, in the repair of eighty-three recurrent inguinal hernias.[158] With a mean follow-up of four years he found a recurrence rate of 7%. This compared favourably with his previous sutured repair with relaxing incision for which the recurrence rate was 24%, although follow-up was longer with a mean of nine years.[158] Read therefore recommended the use of the preperitoneal Marlex repair for repair of large recurrent inguinal hernias.[158]

1.13 The Stoppa repair

Stoppa was aware of Fruchard's observation that, whatever the superficial emergence of a groin hernia, they all pass through the inguinal wall within the myopectineal orifice.[159] At the weakest area of this opening the transversalis fascia represents the only structure resistant to the intra-abdominal pressure. Like Tinckler,[154] Stoppa decided that this was the best layer for repair of inguinal hernias, and he believed that permanent cure could be assured by the use of synthetic mesh. Stoppa divided groin hernias into two groups: congenital, caused by a persistent processus vaginalis, and those caused by failure of the transversalis fascia. He argued that in the latter type an irremediable loss of substance might necessitate the use of a prosthetic repair. This situation was thought to be most apparent for patients with multiply recurrent hernias.

Stoppa perceived his repair as an interposition of mesh that was able to adhere to the neighbouring layers of the abdominal wall and provide permanent support for the inguinal region.[160] In order to do this the mesh must extend broadly beyond the margins of the hernia defect in all directions. It was stated that, in keeping with Pascal's hydrostatic principle, if the mesh was large enough it would be held in place by the abdominal pressures and therefore did not require fixation. In the repair first developed by Stoppa the preperitoneal space was entered via a lower midline incision.[159] Small easily mobilised sacs were reduced, but larger and/or adherent sacs were transected and the peritoneal defect repaired. The preperitoneal space was opened widely to the level of the anterior superior iliac spines and the elements of the cord were left on the pelvic wall. There was therefore no requirement to split the mesh for their passage and this was thought to reduce the possibility of developing a recurrence through the mesh. No attempt was made to repair the orifice of the defect. Mersilene mesh was trimmed such that its width was the distance between the anterior superior iliac spines minus two centimetres. The height of the mesh was equal to the distance between the umbilicus and the pubis. The mesh was shaped like a chevron which allowed the lower inferior angles to cover the obturator foramina, and the superior convex border to fit the line of Douglas. The mesh was placed such that it generously covered the margins of the hernial orifices and also protected the midline incision. Stoppa referred to this repair as the 'giant prosthetic reinforcement of the visceral sac' (GPRVS).

Stoppa stated that the preperitoneal approach to the groin had a number of advantages. These included avoidance of scar tissue in recurrent hernia repair, avoidance of superficial nerves and vessels with a resultant reduction in the incidence of testicular atrophy and chronic pain, and no disturbance of the physiological mechanisms protecting the inguinal canal.[160] Stoppa approached the preperitoneal space through a lower midline incision, which allows simultaneous access to both groins. He stated that the Pfannenstiel incision was time consuming and offered only cosmetic advantages. Rignault, however, has argued that in addition to cosmesis the Pfannenstiel incision gave better access to both inguinal regions and produced less post-operative discomfort.[161] Stoppa was acutely aware of the potentially serious consequences of septic complications in the GPRVS. He therefore felt that it should not be used for all hernia repairs, but rather reserved for particular indications.[160]

These indications included patients older than fifty years, bilateral and recurrent hernias, and complicated defects such as large inguino-scrotal hernias. Stoppa initially advocated the routine use of this repair for patients over fifty years of age due to the high incidence of subsequent contralateral hernia formation in this group. However, in later discussions of the indications for the repair he was less emphatic on this point and estimated that the GPRVS repair was only indicated in 20–25% of inguinal hernias.[162] Initially Stoppa used antibiotic prophylaxis for the repair but subsequently stopped this with no increase in infection rates.[162] In a report on 604 preperitoneal prosthetic repairs Stoppa recorded a sepsis rate of 2.1% and a haematoma rate of 3.2%.[160] With follow-up ranging between one and ten years he reported a recurrence rate of 1.4% and no incidence of testicular atrophy. Stoppa subsequently stated that the recurrence rate for the GPRVS in his unit fell with increasing experience of the technique and by 1986 the recurrence rate was 0.56%.[163] Recurrences after prosthetic repair were considered to be due to technical errors and therefore would appear during the early post-operative period. In keeping with this Stoppa reported that all recurrences following GPRVS in his unit occurred within the first year of the repair. A number of other surgeons have reported recurrence rates ranging between 0% and 4% following the GPRVS repair.[162,164,165]

The Stoppa repair has the disadvantage that it requires general or spinal anaesthesia, and is much easier when the patient has been given muscle relaxants. For this reason an anterior approach to the groin is still preferable when loco-regional anaesthesia is compulsory.[166] Recurrence following a Stoppa repair is also easier to manage via an anterior approach.[165,166] In addition, Stoppa reported that re-operation for other pelvic pathology is complicated by the presence of extensive scarring around the mesh.[167] It was therefore suggested that prudent patient selection for GPRVS should exclude those with urological or vascular pathology that may require an open pelvic procedure.

1.14 Other methods of preperitoneal mesh repair

Rives described a unilateral preperitoneal prosthetic repair which involved a lower midline approach and reduction or division of the hernial sacs as appropriate.[162] A Mersilene mesh (10 x 10cm) was split and placed around the cord which, it was

claimed, helped to secure the mesh in place. The prosthesis was then tacked to the psoas muscle, the posterior aspect of rectus abdominis muscle and the pectineal ligament. A suction drain was placed adjacent to the mesh. In the case of bilateral hernias the same procedure was carried out on both sides. In 1983, Rives reported five recurrences in eighty-four repairs (6%), and subsequently reported a further series with one recurrence from twenty-seven repairs (3.7%).[162] Stoppa criticised this repair as he felt that fixation of the mesh increased the risk of damage to adjacent structures and opening the mesh increased the risk of a recurrence through the resulting defect.[162]

Wantz has also described a unilateral preperitoneal prosthetic repair.[168] This repair was developed to allow out-patient preperitoneal repair and was intended for recurrent hernias, primary hernias in the presence of collagen disease (eg. Ehlers-Danlos syndrome, Marfan's syndrome), and for situations where abdominal distension was present (eg. ascites). The preperitoneal space was approached through a transverse incision placed two to three centimetres below the level of the iliac crest. The rectus sheath was then divided transversely to allow entry into the preperitoneal space. A mesh (14 x 14cm) was placed in the space to cover the inguinal region, and the upper border was tacked to the abdominal muscles above the level of the incision. Of 358 repairs using this technique Wantz reported sixteen recurrences (4.4%).[162] Most of these recurrences were attributed to technical problems which were addressed by extending the inferolateral margin of the mesh.

A further technique to allow the insertion of a unilateral mesh (10 x 15cm) into the preperitoneal space via a three to four centimetre gridiron type incision has been described by Ugahary and Simmermacher.[169] A randomised trial involving this repair has been commenced but as yet there are no results available. Kugel has also described a similar technique using a double layer of mesh and reported a recurrence rate of 0.6% after a follow-up ranging between eleven and sixty-five months.[170] It was argued that these techniques offered the advantages of a minimally invasive repair but did not require a general anaesthetic and had lower costs.

Repairs involving placement of prosthetic material in the preperitoneal space via an inguinal approach have also been described. In the repair described by Rives the

transversalis fascia was opened along the length of the inguinal canal and the preperitoneal space was then developed.[171] A notch was cut in the inferolateral edge of a mesh (10 x 10cm) to allow passage of the external iliac vessels. The mesh was then sutured to the pectineal ligament and to the deep aspect of the broad muscles using mattress sutures tied deep to the external oblique aponeurosis. A slit was created laterally and the two limbs of mesh passed around the spermatic cord then sutured laterally. The prosthesis was fixed inferiorly to the vascular sheath and inguinal ligament to avoid leaving a vascular defect. The transversalis fascia was closed in front of the prosthesis using a continuous suture and the external oblique aponeurosis repaired in front of the cord. This repair was recommended for direct and recurrent hernias. In a series of 720 Rives reported an infection rate of 1.6%, but none of the infections required removal of the mesh. The overall recurrence rate was 1.9%, with a rate of 1.3% for primary hernias.[171] Several other series have also reported recurrence rates between 1 and 2% for this repair.[171] Horton and Florence reported performing this repair under local anaesthesia with no early recurrence after an average follow-up of fifteen months.[172] Stoppa criticised the repair as it required dissection of the cord and inguinal layers, which may be particularly difficult in recurrent hernias. The prosthesis used was also felt to be of inadequate size. Stoppa's own experience with this repair was less consistent that that reported by Rives.[160]

Another technique to place preperitoneal mesh via an inguinal incision has recently been described by Trabucco and Trabucco.[173] This repair involves the placement of a pre-shaped flat mesh through the deep ring. The mesh has a diameter of four centimetres with a notch in one side and a central hole of one centimetre diameter to sit around the cord. This repair has been used for small indirect inguinal hernias.

1.15 The development of laparoscopic repair

In 1977, with the laparoscopic management of indirect inguinal and femoral hernias in mind, Ger began a study in which abdominal wall hernias were closed incidentally during laparotomy for other intra-abdominal pathology.[174] He subsequently published a series of twelve patients, of which nine had inguinal hernias, two had umbilical hernias and one had a femoral hernia.[175] In each of these repairs the peritoneal sac was left in situ and the neck closed with between two and ten stainless steel Michel

clips. With a follow-up of eighteen to twenty-four months Ger reported one recurrence in a patient with a direct inguinal hernia. He therefore stated that this method was not appropriate for direct inguinal or large umbilical hernias. In 1979 a special forceps was developed to allow placement of clips through a laparoscopic port and, in 1982, Ger reported a patient who had 'clipping' of an indirect inguinal hernia using these forceps.[175] This was considered to be the first laparoscopic inguinal hernia repair in a human and had not recurred after eight years follow-up.[176] During the following decade Ger was involved in developing a multi-stapling device that could be inserted via a 12mm laparoscopic cannula.[174] When this stapler was fired the staple points were crossed and this resulted in fibrosis of the involved tissue, which helped in fixation of the repair. A study was then undertaken to assess the stapling device in fifteen Beagle dogs with indirect inguinal hernias.[176] In the first three dogs the clips were applied at open operation and then the following twelve dogs had clips applied laparoscopically. The clips approximated the margins of the defect while leaving a gap posteromedially for passage of the cord. In fourteen animals the hernias were clinically repaired. Laparoscopic and histological assessment after several weeks showed that, when properly placed, the clips migrated below the peritoneal surface where they induced fibrosis. A smooth peritoneal surface was therefore left at the site of the repair. In 1990, a clinical study was commenced which initially only involved patients with small, primary indirect inguinal hernias, but with further experience Ger also included patients with direct and recurrent hernias.[177] In these repairs a mesh plug was inserted and the clips were then used to approximate the margins of the defect over it. Ger reported thirty-one repairs in twenty-four patients with four technical failures (retained hernias) and two recurrences, one of which occurred within five months.[174] Due to failure of the stapling device, which never reached the production phase of development, Ger was forced to stop recruiting patients after twenty months.[174]

Ger stated that his technique had the advantages of requiring small wounds, no dissection, and therefore less risk of injury to cord structures, and providing the ability to perform the highest possible ligation of the sac.[176] There was also less post-operative discomfort and a faster return to normal activity, and the technique allowed simultaneous repair of bilateral hernias.[176] Ger also initially stated that there would be

a lower risk of nerve injury, but subsequently recognised that there was a high incidence of neuropathies following laparoscopic repair.[174]

Bogojavalensky has been credited with the first presentation of laparoscopic hernia repair at a scientific meeting.[178] In 1989 he presented a video to the American Association of Gynecological Laparoscopists which demonstrated the introduction of a polypropylene mesh plug into an indirect inguinal sac, followed by oversewing of the deep ring. Bogojavalensky later reported a recurrence rate of 13% at two years for this repair.[179] Laparoscopic plug techniques were further developed by other surgeons with poor results. Schultz et al. described a transabdominal approach to enter the preperitoneal space and place polypropylene mesh into the hernial defect.[180] The edges of the peritoneum were then re-approximated. High recurrence rates led to this technique being abandoned.[181] Corbitt also described a laparoscopic plug and patch repair,[182] but later abandoned this having found recurrence rates of greater than 20% at 2 years.[183] Many of these recurrences were attributed to concomitant hernias being missed due to limited dissection.

Gazayerli described a laparoscopic version of the iliopubic tract repair of Nyhus et al.[184] Initially this involved the placement of mesh within the hernial defect and then approximation of the transversalis fascia to the iliopubic tract over it. Later, the sutured repair was performed first and this was then reinforced with a patch of mesh.[181] Criticism of this repair was made because it involved placing the tissues under tension.[181]

Rosin described a procedure for Nyhus type I and II defects in which the sac was inverted and ligated with a PDS endoloop.[185] Rather than being excised the sac was left to obstruct the deep ring. In type II defects sutures were placed lateral to the inverted sac to tighten the deep ring. Rosin reported the results of seventy-five type I hernias repaired in this way and, with a mean follow-up of sixteen months, no recurrences were observed.[185] Repair of type II defects with this technique was quickly abandoned due to high early recurrence rates. Closure of the deep ring using a laparoscopic suturing technique was described by Geraghty et al in 1994.[186] In this repair a hollow J-needle was introduced percutaneously and used to place three sutures lateral to the cord to tighten the deep ring. No recurrences were reported from

twenty-five patients, although average follow-up was only 8.5 months and the size of the defects repaired was not recorded.[186]

1.16 The intraperitoneal onlay mesh technique

In 1991, Toy and Smoot described an intraperitoneal onlay mesh (IPOM) technique in which a pneumoperitoneum was created and the laparoscope used to identify the hernia defect(s) present.[187] Having reduced the contents of the hernia into the peritoneal cavity, an expanded PTFE mesh was placed over the defect and fixed in position using staples. Toy and Smoot found that recurrences occurred due to disruption of the repair in the area of Cooper's ligament. They therefore routinely opened the peritoneum at the medial umbilical ligament to expose Cooper's ligament and the pubic tubercle.[188] This manoeuvre allowed more accurate placement of staples in Cooper's ligament. A review of 441 repairs using this technique reported a recurrence rate of 3.8%, but follow-up was relatively short as only 21% of the repairs had reached more than two years.[189] The authors also reported a learning curve effect as the recurrence rate after the surgeons had performed twenty-five repairs was reduced to 0.39%.[189] In 1994, Chan and co-workers reported forty-six IPOM repairs for direct and indirect inguinal hernias using a polypropylene mesh (8 x 10cm).[190] Two recurrences (4.3%) were reported, although follow-up was again short with a maximum of fifteen months. A multicentre review reported a recurrence rate for the IPOM repair of 5.1% after a mean follow-up of twenty-three months.[191]

In a randomised study comparing IPOM repair with conventional sutured repair Vogt et al. reported less analgesic use and a faster return to normal activity in the laparoscopic group.[192] They also reported one recurrence from thirty repairs after a mean follow-up of eight months. However, in a subsequent paper on the same group of patients, Kingley et al. reported that the recurrence rate had risen to 43% at a mean follow-up of forty-one months.[193] This report concluded that the IPOM repair should not be used for the repair of inguinal hernias.

Concern has also been expressed that intraperitoneal mesh will cause adhesion formation, with subsequent bowel obstruction.[181] In their repairs Toy and Smoot used expanded PTFE, which induces less tissue reaction than polypropylene.[188] However,

Fitzgibbons et al. claimed that this may be a disadvantage as less inflammatory reaction and fibrosis may impair the long term durability of the repair.[194] They demonstrated that laparoscopic placement of polypropylene mesh produced less adhesion formation than that placed at open laparotomy. Nevertheless, the use of laparoscopy did not completely eliminate the formation of adhesions, and so the risk of bowel obstruction remained. Attwood et al. compared the incidence of adhesion formation from intraperitoneal and transabdominally placed extraperitoneal polypropylene mesh in a porcine model.[195] They described a greater incidence of adhesion formation in the intraperitoneal group, but the results did not reach statistical significance. Vadar et al. have also reported a similar study in which they showed that the incidence of adhesion formation was much greater in the intraperitoneal group for three different types of mesh.[196]

1.17 The transabdominal preperitoneal laparoscopic repair

Popp reported a small series of groin hernia repairs using a transabdominal approach in women having laparoscopic procedures for gynaecological disease.[197-199] In this repair a patch of absorbable mesh was placed in the preperitoneal space to cover the defect. Popp claimed that the mesh was held firm by the re-approximation of the peritoneum and so he did not fix it in place. However, other surgeons expressed concern over the risk of recurrence with this technique.[200]

In 1992, Arregui et al. reported the laparoscopic repair of sixty-one hernias using a transabdominal preperitoneal (TAPP) technique.[200] In this repair, having created a pneumoperitoneum, excision of the hernia sac allowed entry into the preperitoneal space. The space was then developed using blunt dissection to expose the transversalis fascia. For direct and recurrent hernias the defect in the transversalis fascia was closed with a purse-string or running suture "without tension". For indirect hernias the deep ring was tightened with a single suture. A polypropylene mesh (6 x 11cm) was then trimmed to fit over the inguinal floor such that it covered all the potential sites for inguinal or femoral hernia formation. Vicryl sutures were used to tack the mesh laterally and supero-medially to the transversalis fascia/transversus abdominus aponeurosis, and inferiorly to Cooper's ligament. Arregui stated that control of fixation depth and anchoring into Cooper's ligament was more certain with

suturing rather than stapling.[181] He did, however, recognise that suturing was more cumbersome and time consuming than stapling, especially until a surgeon's suturing technique had been refined. Having fixed the mesh, the peritoneum was re-approximated over the repair and the pneumoperitoneum released. Arregui and co-workers claimed that this repair reduced post-operative pain and allowed an earlier return to normal activity.[200]

Dion reported a series of sixty-three transabdominal repairs in which the peritoneum was incised transversely above the inguinal defect.[201,202] In the case of indirect inguinal hernias the sac was transected to avoid trauma to the cord. The deep ring was then tightened with prolene sutures and the peritoneum closed with clips. For direct and recurrent hernias the peritoneal sac was reduced and a polypropylene mesh (12 x 7cm) was placed to cover the myopectineal orifice, with a lateral slit to accommodate the cord. The mesh was fixed to Cooper's ligament, the pubic tubercle and the transversus abdominus aponeurosis/transversalis fascia. Staples were then used to close the peritoneum. Dion noted that, when fixing the mesh lateral to the cord, the staples should not be placed below the iliopubic tract to avoid causing neuralgia. Corbitt also reported two patients who developed transient neuralgia in the distribution of the lateral cutaneous nerve of thigh following TAPP repair.[203] Both of these patients symptoms resolved within a few weeks, but Corbitt again emphasised that staples should not be placed below the iliopubic tract in the area lateral to the deep ring. A number of series of TAPP repair for all types of inguinal and femoral hernia subsequently appeared in the literature and the recurrence rates from these studies are shown in Table 1.2. These series all involved the use of a single piece of mesh to cover all of the potential areas of inguinal and femoral hernia formation.

In 1993, Felix reported a modification of the TAPP repair using a double layer of polypropylene mesh.[230] Having developed the preperitoneal space, the direct or indirect sac was reduced and a mesh (10 x 15cm) was trimmed to an oval shape with a slit made medially to accommodate the cord structures. Having passed the split part of the mesh around the cord the wings were stapled to the iliopubic tract and Cooper's ligament. The upper part of the mesh was stapled to the transversalis fascia and the lower part to the iliopubic tract. A second larger mesh was then placed over

Table 1.2: Prospective non-randomised studies reporting the TAPP repair

Author	Number Of Repairs	Follow-Up	Recurrence
Arregui et al. (1992)[200]	61	Mean 2.3 months	0
Corbitt (1993)[183]	98	Mean 18 months	0
Geis et al.(1993)[204]	365	Range 6m to 30m	0.8%
Newman et al. (1993)[205]	102	Not stated	1.0%
Wheeler (1993)[206]	104	Median 10 months	0
Winchester et al. (1993)[207]	40	Median 6 months	0
Brooks (1994)[208]	43	Not stated	7.0%
Cornell et al. (1994)[179]	69	Median 9m (Range 2-28m)	1.7%
Darzi et al. (1994)[209]	126	Median 7m (Range 1-18m)	1.6%
Goodall (1994)[210]	60	Not stated	1.7%
Millikan et al. (1994)[211]	75	Mean 15 months	2.7%
Panton et al. (1994)[212]	85	Range 1m to 12m	0
Deans et al. (1995)[213]	800	Mean 14.1m (Ran. 6-14m)	1.2%
Davies et al. (1995)[214]	300	Range 1yr to 3yr	1.7%
Fitzgibbons et al. (1995)[191]	562	Median 23m (Ran. 15 –34m)	5.0%
Goodwin et al. (1995)[215]	137	Mean 20 months	1.5%
Kald et al. (1995)[216]	200	Median 12 months	3.5%
Kavic (1995)[217]	164	Mean 24 months	1.2%
Wilson et al. (1995)[218]	142	Not stated	0
Birth et al. (1996)[219]	1000	Range 2m to 36m	1.1%

TABLE 1.2 (cont): Prospective Non-Randomised Studies Of The TAPP Repair

Author	Number Of Repairs	Follow-Up	Recurrence
Marappan et al. (1996)[220]	107	Mean 8 months	3.8%
Sandbichler et al. (1996)[221]	200	Mean 18.4m (Ran. 9-31m)	0.5%
Velasco et al. (1996)[222]	50	12 months	6.0%
Cooper et al. (1997)[223]	72	Mean 21m (ran. 6-42m)	13.8%
Leroy et al. (1997)[224]	920	Minimum 4 years	1.4%
Litwin et al. (1997)[225]	554	Mean 14 months	0
Zeidan et al. (1997)[226]	103	Mean 18.3 months	1.0%
Kiruparan et al. (1998)[227]	215	Median 2.5yr (Ran. 1-4yr)	1.4%
Liebl et al. (1998)[228]	2700	Median 26m (ran. 11-58m)	1.0%
Hernandez-Richter et al. (1999)[229]	1000	Mean 12 months	0.7%

the first to cover Hesselbach's triangle and form a flap over the deep ring. This was intended to prevent recurrence through the split in the first mesh. The second mesh was also stapled in place and the peritoneum was closed with a continuous suture. After Felix's first 100 repairs, fourteen of which were a plug and patch repair and eighty-six the 'double buttress' repair, there were no early recurrences.[230] The same surgeons subsequently reported low recurrence rates (<1%) for recurrent hernias using either this transabdominal technique or a totally extraperitoneal approach.[231,232] In a review of their first 1,336 preperitoneal repairs using the TAPP (60%) or TEP (40%) procedures Felix et al. reported five recurrences (0.37%).[232] All of these recurrences presented within six months of repair and were thought to be due to technical errors. 2.4% of patients had required further surgery following their initial repair. Five of these were for recurrence, and other indications included organised seroma, hydrocoele, chronic groin pain, small bowel obstruction, small bowel injury and port site hernia.

Newman et al. used a visual analogue scale to record pain following their first 102 consecutive TAPP repairs.[205] They found that 51% of patients reported 'minimal' pain or 'no pain' at twenty-four hours, and by one week 93% of patients were pain free. One early recurrence was recorded, which was identified within seven days of surgery. In this case the mesh had become detached from Cooper's ligament. Kald et al. described 200 TAPP repairs for groin hernia in which the mesh was initially tailored according to the size of the hernia orifice.[216] They found a relatively high early recurrence rate (3.5% at twelve months) which was attributed to the dimensions of the mesh being too small. Having modified the technique to use a standard 7cm x 12cm mesh for all repairs Kald et al. found a reduction in early recurrences. The same authors subsequently published their results for the repair of 100 consecutive recurrent inguinal hernias.[233] Eighty-two of these patients had a TAPP repair using 7x12cm polypropylene mesh, and eighteen a totally extraperitoneal repair using a 10x15cm mesh. In this series there were two early recurrences at a median follow-up of 20 months.

1.18 The totally extraperitoneal laparoscopic repair

The totally extraperitoneal (TEP) laparoscopic repair is based on the principles of the open preperitoneal mesh repair. The procedure is performed entirely within the preperitoneal space and is therefore thought to reduce the risk of intraoperative vascular and visceral injury. The risk of adhesion formation is also thought to be less following this type of repair although there is experimental[234] and clinical evidence[235,236] that adhesion formation may still occur following totally extraperitoneal dissection. The TEP repair was popularised in France by Dulucq and Begin,[237] and was subsequently described in the USA by Ferzli et al.[238] and by McKernan and Laws.[239,240] Following this there have been a number of reports of TEP repair in the literature (Table 1.3).

The technique of the TEP repair is described in Chapter Two. Although insufflation of the preperitoneal space may be performed using a Veress needle, open dissection of the preperitoneal space below the umbilicus followed by insertion of a blunt port is considered to have less risk of visceral or vascular injury.[240,253] Before insertion of the port the extraperitoneal space may be further developed by blunt dissection using a finger or other instrument such as a metal rod.[254] It is also possible to develop the preperitoneal space using a commercially available balloon dissection device,[242,244,255] or a modification of this technique such as using a Foley catheter.[256] Use of the balloon dissection device has, however, been associated with a number of potential complications. Damage to small vessels in the preperitoneal space may cause bleeding, with significant impairment of the view obtained with the laparoscope. Tearing of the peritoneum has also been reported[242,257] and the resulting pneumoperitoneum often leads to loss of the working space and conversion to another type of repair.[238,240,258] Pneumoperitoneum also causes severe pain for patients having TEP repair under epidural anaesthesia.[248] Ramshaw's group have described small bowel injury and bladder injury while using the balloon dissection device.[248,259] Use of a commercial balloon dissection device also increases theatre costs for the TEP repair.[260]

Stoppa emphasised that a large interposition of prosthetic mesh should be used in the GPRVS repair.[160] This allowed the mesh to hold against the neighbouring tissue

Table 1.3: Prospective non-randomised studies reporting the TEP repair

Author	Number Of Repairs	Follow-Up	Recurrence
Begin (1993)[237]	200	Maximum 22 months	0.5%
Cable et al. (1994)[241]	40	Not stated	0
Kieturakis et al. (1994)[242]	150	Mean 6.3 months	2.0%
McKernan (1995)[243]	250	Mean 18 months	0.4%
Voeller (1995)[244]	300	Not stated	0
Dulucq (1996)[245]	864	Not stated	0.3%
Kakkis et al. (1996)[246]	67	Mean 6 months	0
Vanclooster et al. (1996)[247]	195	Minimum 6 months	0
Heithold, et al. (1997)[248]	503	Not stated	0.4%
Topal et al. (1997)[249]	632	12 months	0.3%
Ferzli et al. (1998)[250]	512	Mean 38m (Ran. 6-66m)	1.7%
Knook et al. (1999)[251]	221	Mean 40.4 months	5.9%
Aeberhard et al. (1999)[252]	1605	12 months	1.6%

layers and provided immediate support of the inguinal wall. There was therefore no requirement for fixation of the mesh. Early laparoscopic hernia repairs involved the use of a relatively small mesh, which was stapled to the surrounding tissues to prevent migration or prolapse into the hernial defect. In a study of iatrogenic abdominal wall defects created in the dog model, Dion et al. demonstrated that the bursting strength was greater at two days, two weeks and two months using sixteen compared with four staples.[261] However, a number of problems were associated with the use of a relatively small mesh staples in early laparoscopic repairs. Deans et al. described their findings on re-operation in ten patients who had a recurrence following laparoscopic repair.[213] In each case the medial edge of the mesh had rolled laterally and it was concluded that a larger area of mesh should be used (9cm x 13cm). It was also recommended that the surgeon should ensure that the medial edge of the mesh covered at least to the midline, and that the mesh be stapled to the pubic ramus. Lowham et al. also analysed the cause of recurrence following laparoscopic repair and recommended the use of a larger mesh size (10-15cm x 10-15cm), which should be adequately fixed in place.[262] Lowham et al. also recommended that the mesh should overlap the margins of the defect by at least two centimetres if stapled, and three centimetres if it is not fixed in place. Therefore use of a larger mesh size would reduce the number of repairs that required to be stapled. Leibl et al. have also recommended that the mesh should measure at least 10cm x 15cm, and that it should overlap the margins of the defect by at least three centimetres.[263] Stapling of the mesh was a source of significant morbidity in early laparoscopic inguinal hernia repair and a large number of reports have described nerve injury caused by the use of staples.[190,205,206,209,212,217,221,224,227,231,242,249,259,264-267] In addition, the use of a stapler significantly increases the equipment costs of the procedure.[215] Dunn described the use of a single suture to fix a the mesh to Cooper's ligament, which eliminated the cost of a stapler from the procedure.[268] From fifty-three repairs using this technique only one recurrence, which presented immediately, occurred within the first year. Knook et al. have reported the results of 221 primary and recurrent inguinal hernias repaired with a 10cm x 15 cm mesh that was not fixed in place.[251] With a mean follow-up of 40.4 months the recurrence rate for primary hernia repair was 3.2%, and that for recurrent hernia repair was 20%. In all six patients who were re-operated the mesh had rolled laterally. Knook et al. stated that, in recurrent hernia repair, fixation of the mesh might reduce the incidence of further recurrence. However, as stapling is

associated with a risk of neurovascular injury, they suggested that use of a larger size of prosthesis for recurrent hernia repair may be preferable.[251] Topal and Hourlay have described the use of an un-fixed 17cm x 12cm mesh with no recurrences after twelve months follow-up.[249] However, as pointed out by MacIntyre, not every groin will accommodate such a large piece of mesh, and accurate placement of a mesh of this size increases the technical challenge of the procedure.[269] Ferzli et al. have reported a randomised comparison of fifty patients with a primary inguinal hernia having TEP repair with or without staple fixation of the mesh.[270] In the stapled group, a total of four staples were placed at the symphysis pubis, Cooper's ligament and the transversus abdominus. With a mean follow-up of eight months there were no recurrences or complications recorded in either group.

The use of two separate pieces of mesh in the repair of bilateral hernias has been thought to increase the risk of medial recurrence.[213] Deans et al. reported the use of a single mesh (28 x 10cm) for laparoscopic repair of bilateral inguinal hernias – the 'bikini mesh' repair.[271] This repair was modelled on the open preperitoneal mesh repair described by Calne.[152] The mesh was stapled to the pubic ramus on either side to prevent it rolling upwards as it crossed the midline. The median operation time in this series was forty-three minutes and median hospital stay was one day. At a median follow-up of eighteen months no recurrences had been identified. Knook et al. reported a retrospective study of their experience with the TEP repair for bilateral inguinal hernias.[272] In the first seventeen patients a 30cm x 10cm polypropylene mesh was used with a relatively high early recurrence rate (17.6%), most of which occurred medially. For the next eighty-one patients in the series a 'slip mesh' was used with a reduction in the incidence of early recurrence (1.2%). This mesh was cut such that it was 10cm in breadth laterally and 15cm in breadth in the medial area of the repair. For this series the median operation time was sixty minutes and the median hospital stay was one day.

1.19 Laparoscopic re-operation for recurrent laparoscopic repair

Several groups have reported successful laparoscopic re-operation for recurrence following previous laparoscopic repair of a groin hernia, although it has been recommended that this can only be done using the TAPP technique.[213,263,273] Deans et

al. reported the repair of ten recurrences that were all direct.[213] In each case a further mesh was placed over the original one and fixed with staples to the pubic ramus medially and to the original mesh laterally. Knook et al. also reported thirty-four laparoscopic repairs of laparoscopic recurrence with a mean operation time of sixty-nine minutes.[273] Liebl and co-workers reported a different technique for the TAPP repair of indirect recurrences.[263] For direct recurrences they used the same technique as described by Deans et al.,[213] with a minimum overlap of the defect of three centimetres and staple fixation of the mesh. For lateral recurrences an en-bloc mobilisation of the peritoneum and prosthesis was performed to expose the deep ring. The new mesh was then placed anterior to the original one. From forty-six procedures there were two patients who suffered bladder injury and one patient who developed testicular atrophy. At a median follow-up of twenty-six months no recurrences had been identified.

1.20 Non-randomised comparisons of laparoscopic repairs

There have been several reports of non-randomised series to compare the outcome following TAPP and TEP repair (Table 1.4). Sayad et al., in a review of the reported literature from non-randomised trials, found a lower incidence of morbidity and recurrence following the TEP repair compared with the TAPP repair.[279] However, the value of these comparisons is debatable as, in most of the series, the TAPP and TEP repairs were performed sequentially. The surgeon's experience of laparoscopic hernia repair was therefore greater when commencing the TEP repairs. The length of follow-up was also usually shorter for the TEP repair group. Several of the reported multicentre series also appear to include the same patients.[191,274,275] Khoury reported that patients recorded significantly lower pain scores and were discharged earlier following TEP repair compared with TAPP repair.[276]

Table 1.4: Non-randomised studies comparing different methods of laparoscopic repair

Author	Repair	Number	Conversion To Other Repair	Complications	Follow-Up	Recurrence
Tetik et al. (1994)[274]	TAPP	553	Overall rate 0.8%	11.0%	Overall mean 13 months	0.7%
	TEP	457		19.6%		0.4%
	IPOM	320		13.4%		2.2%
	Ring Closure	102		1.0%		3.0%
	Plug & Patch	82		13.4%		22.0%
Phillips et al. (1995)[275]	TAPP	1944	Not stated	7.3%	Overall mean 22 months	1.0%
	TEP	578		10.4%		0
	IPOM	345		13.6%		2.0%
	Ring Closure	76		13.2%		2.6%
	Plug & Patch	286		8.4%		9.1%
Fitzgibbons et al. (1995)[191]	TAPP	562	Not stated	Not stated by repair	Overall mean 23 months (Range 15-34m)	5.0%
	TEP	87				0
	IPOM	217				5.1%
Felix et al. (1995)[231]	TAPP	738	0	Not stated	Median 24 months	0.3%
	TEP	382	1.8%		Median 9 months	0.3%

TABLE 1.4 (cont): Non-Randomised Studies Comparing Methods Of Laparoscopic Groin Hernia Repair

Author	Repair	Number	Conversion To Other Repair	Complications	Follow-Up	Recurrence
Fielding (1995)[267]	TAPP	386	Not stated	7.0%	Overall mean 20.5m	0.8%
	TEP	54		0	(Ran. 1-38 months)	0
Khoury (1995)[276]	TAPP	60	0	6.9%	Mean 18 months	3.4%
	TEP	60	0	6.9%	Mean 10 months	0
Ramshaw et al. (1996)[259]	TAPP	300	0.7%	10.7%	Mean 29m (Ran. 20-45m)	2.0%
	TEP	300	3.0%	3.7%	Mean 12m (Ran. 5-19m)	0.3%
Cohen et al. (1998)[277]	TAPP	108	0	20.5%	Overall maximum	1.8%
	TEP	100	4.0%	13.0%	40 months	0
Felix et al. (1998)[278]	TAPP	5163	Not stated	Not stated	Overall median	0.5%
	TEP	4890			36 months	0.2%

1.21 The learning curve for laparoscopic surgery

Laparoscopic procedures may be a simple modification of the open procedure whereby the principles of the operation remain the same, but are achieved using laparoscopic techniques. The most common procedure of this type is laparoscopic cholecystectomy, which has rapidly become the technique of choice for cholelithiasis. In contrast, other laparoscopic procedures may involve approach with which the surgeon is not entirely familiar. This is often the case with inguinal hernia repair because surgeons have generally used an anterior inguinal approach for the majority, if not all, of their open repairs. Therefore, the pre-peritoneal anatomy encountered while performing the common laparoscopic types of repair may initially be unfamiliar to the surgeon. In addition, the fact that a surgeon has ample experience in one particular area of laparoscopic surgery does not mean that they will be able to operate in other areas without appropriate training.[280]

Following the advent of laparoscopic cholecystectomy[281,282] surgeons found themselves under pressure from both the popular press and their patients to take up laparoscopic techniques. Formal teaching often took the form of intensive courses over one or two days, after which time the surgeons took up the procedures within their own practice. See et al. recognised that anecdotal evidence suggested a relatively high rate of complications in the early period after these courses.[283] A study was therefore performed to identify the predictors of surgical complications following a course in urological laparoscopic surgery. At three months there was a significant inverse correlation between a surgeons complication rate and the number of laparoscopic procedures performed. Of several other independent variables examined only further post-course training was a significant predictor of lower complication rates in the first three months. At twelve months there was again a significant inverse correlation between the number of procedures performed and the incidence of complications. At this stage analysis of the other independent variables demonstrated that attendance at the course alone (vs. with a colleague), practice setting (solo vs. group) and the type of surgical assistant (variable vs. same) were all significantly correlated with a higher rate of complications. Post-course training and sub-specialisation did not correlate with increased complication rates at twelve months. See et al. suggested that the effect of additional training was to move the individual

surgeon's position along the learning curve.[283] This effect is most pronounced in the early clinical period following training and by twelve months the benefit is obviated by the additional clinical experience that had been gained by those surgeons who had not sought further training. The other risk factors identified at twelve months were thought to suggest that an association with other surgeons skilled in laparoscopic techniques is important in decreasing risk.

The effect of the learning curve has been demonstrated for a large number of laparoscopic procedures performed in general surgery. Review of the literature on bile duct injury following open cholecystectomy showed an incidence between 0% and 0.5%.[284] With the introduction of laparoscopic cholecystectomy there was an increase in the incidence of bile duct injuries. This was perhaps most dramatically illustrated by the increased number of referrals to specialist hepato-biliary units for management of bile duct injuries.[285,286] In the Southern Surgeons Club series the bile duct injury rate in each groups first thirteen patients 2.2%, compared with 0.1% for subsequent patients.[287] The national survey of hospitals in the USA showed that the average bile duct injury rate was 0.65% in institutions that performed less than 100 cases per year, compared with 0.42% at hospitals where more than 100 cases were performed per year.[288] Watson and colleagues have analysed the overall learning curve for laparoscopic fundoplication for a group of eleven surgeons, and also the curve for each individual surgeon.[289] They found that the complication rate, number of re-operations and conversion rate were all higher in the first fifty cases done by the group as a whole. These rates were also higher for each individual surgeon in their first twenty cases. Watson et al. also reported that the incidence of adverse outcomes was lower for surgeons who began fundoplication later in the overall experience of the group.[289] This is presumably because experienced supervision was available and is in keeping with the observations of See et al.[283] The learning curve for laparoscopic colonic surgery has been assessed by a number of groups who have demonstrated a reduction in operation time, complication rates and hospital stay as the surgeon progresses along the learning curve.[290-293] The consensus from these studies is that the learning curve for laparoscopic colon resection is between thirty-five and fifty cases.

1.22 The learning curve for laparoscopic hernia repair

The Conventional Anterior versus Laparoscopic Hernia Repair (COALA) Trial from the Netherlands has examined the TEP repair for inguinal hernias.[294-296] This trial studied the learning curve for four surgeons who were introduced to the TEP repair under the guidance of surgeons already familiar with the technique.[258] Supervision continued until both the trainer and trainee felt that they were competent to perform the procedure alone. The four surgeons performed a total of thirty consecutive inguinal hernia repairs each. There was a reduction in the median operation time of twenty minutes between cases 1-10 and cases 21-30. Similarly, in a randomised trial of open versus TAPP repair, Stoker et al. reported a reduction in median operating time from sixty minutes for cases 1-20 to thirty minutes for cases 56-75.[297]

Within the COALA trial there was a total of ten conversions (8%), three being converted to a TAPP repair and the other seven to an open procedure.[258] The most common reason for conversion was the creation of a peritoneal defect with resulting pneumoperitoneum. This did, however, occur in thirty-three cases (28%) in the study and in only six (5%) was conversion to another type of repair necessary. The other reasons for conversion were difficult lateral dissection (two cases), difficulty in defining the anatomy (one case) and major bleeding from epigastric vessels (one case). Other authors who have used the totally extra-peritoneal approach have also reported the difficulties created by causing a tear in the peritoneum.[238,240]

The COALA Trial reported a total of ten recurrences in the one hundred and seven patients who had reached the six-month review period.[258] This represented an actuarial recurrence rate of 10% at six months. In those patients who had re-operation the reasons for recurrence were reported as follows: poor positioning of the mesh (three cases), a missed indirect sac (three cases), failure to separate the cord from the sac adequately (two cases). It was therefore felt that most of the recurrences were due to surgical errors. In keeping with the observations of See et al.,[283] it was found that the greatest number of early recurrences had occurred with a surgeon who had received less support from an experienced colleague than the others had received.[258] A fall in recurrence rates with increasing experience of the laparoscopic hernia repair has also been reported by other studies. Toy and co-workers reported seventeen

recurrences (3.8%) following repair of 441 hernias using the ePTFE peritoneal onlay technique.[189] With the completion of twenty-five cases per surgeon the recurrence rate fell to 0.39%. In 1995, Fitzgibbons et al. published the results of a multi-centre study of laparoscopic inguinal hernia repair which included three different procedures: the TAPP repair, the TEP repair, and the intraperitoneal onlay technique.[191] With a median follow-up of twenty-one months the overall recurrence rate in the study was 4.5%. A learning curve effect was identified with the highest recurrence rate occurring in the surgeon's first ten cases. There was a subsequent downward trend in the incidence of recurrence over the next forty cases.

1.23 Mini hernia repair

Darzi and colleagues have argued that, with recurrence rates less than 1%, the Lichtenstein repair should provide the standard against which other repairs are measured.[298] They did, however, recognised that the laparoscopic repairs have been reported to offer short-term advantages such as less post-operative pain and an earlier return to normal activity. In an effort to combine the advantages of the two types of repair Darzi et al. proposed the 'mini' hernia repair.[298-300] This was essentially a Lichtenstein repair performed via a two-centimetre groin incision, using a fan retractor and laparoscopic equipment to place the mesh. The procedure may be performed under general or local anaesthesia. In 1997, Darzi and Nduka reported the results of eighty-five primary inguinal hernia repairs using this technique.[299] The mean operation time was forty-two minutes and mean hospital stay was 1.2 days. The mean time for return to normal activity was eight days and, with a maximum follow-up of twenty-two months, two recurrences (2.4%) had been identified.

Cuschieri's group have developed a tension-free repair via a percutaneous endoscopic external ring (PEER) approach.[301,302] This repair was also designed to reproduce the advantages of an open mesh hernioplasty while retaining the early outcome advantages of a laparoscopic repair. The repair has been performed for patients with primary inguinal hernias and can be done under local, regional or general anaesthesia. A specially designed retractor was used to perform a Lichtenstein or mesh plug repair via a 2.5cm incision. In the mesh plug technique the prosthesis was fixed with fibrin glue or interrupted sutures. For moderate to large direct defects an onlay patch was

added, but this was not fixed with sutures or staples. Ko et al. described sixty PEER repairs using a Lichtenstein technique and, with a mean follow-up of twelve months, they found one bilateral recurrence.[301] In a later report thirty-seven patients who had either the Lichtenstein repair or a mesh plug repair were described.[302] In this series there were two conversions to open repair and one recurrence, which presented in the immediate post-operative period after a mesh plug repair of a direct defect. The median duration of post-operative pain was six days and the median time for return to normal activity was fourteen days.

1.24 Complications associated with laparoscopic repair

The introduction of laparoscopic hernia repair has presented a number of complications that were uncommon with open repair, or are specific to the laparoscopic approach. These complications include visceral injury, small bowel obstruction, port site hernia and subcutaneous emphysema.

Injuries to bowel and bladder have been reported during TAPP and TEP groin hernia repair.[191,206,212,228,231,259,274,275] These complications may require conversion to laparotomy,[259] or may be repaired laparoscopically.[191,206,212,228] Small bowel and bladder injuries have also been reported during balloon dissection of the preperitoneal space for TEP repair.[248,259] Three of the four patients with these complications had a past history of lower abdominal surgery and so Heithold et al. suggested that previous lower abdominal surgery was a relative contraindication to the TEP repair.[248]

Small bowel obstruction has been reported in up to 1% of TAPP repairs,[209,214,216,224,226,231,267,274275] and can also occur, although less commonly, following TEP repair.[235,236] Small bowel obstruction following TAPP repair may be precipitated by an inadequate closure of the peritoneal defect over the repair. Where staples are used to close the defect a 'shower curtain' effect can occur when the edges of the peritoneum hang down between the clips. The bowel may then herniate between the staples and become adherent to the underlying mesh.[209,274,275] Adhesions can also form onto the staples with resulting obstruction due to formation of an internal hernia.[216,267] Trocar site hernias have been reported following TAPP repair,[204,210,216,220,224,225,230,259,275,276] and these may cause small bowel

obstruction.[210,230,274] Use of the TEP approach was expected to minimise small bowel complications, as the peritoneal cavity is not opened, but obstructive complications have also been reported following this approach.[235,236] It is thought that in TEP repair the bowel can still be exposed to the mesh if the peritoneal defect is not closed following transection of the cord,[236] or if any peritoneal tear created during the dissection is not repaired. In addition, Halverson et al. demonstrated that preperitoneal dissection in the murine model can result in adhesion formation.[234] It was postulated that adhesion formation was precipitated by devascularization of the peritoneal tissue.

Pneumoscrotum has been reported following laparoscopic repair and this settled rapidly without causing any significant problems.[303] Extensive surgical emphysema extending up to the neck and face during TEP repair has been described.[304] This resulted in a sudden large rise in the patient's end-tidal carbon dioxide level but no haemodynamic changes were observed. The carbon dioxide level was reduced to within the normal range by hyperventilation and the procedure completed. The subcutaneous emphysema persisted for a further twenty-four hours, but the patient did not suffer any adverse effects. The preperitoneal space had been insufflated to 14-18mmHg during this case and it was felt that this relatively high pressure might have contributed to the development of surgical emphysema. McKernan and Laws have recommended that the insufflation pressure for the TEP repair be kept below 12mmHg to reduce the risk of this complication.[240]

1.25 Mesh infection and mesh rejection

Gilbert and Felton reported that, following inguinal hernia repair, over 70% of wound infections occurred in patients greater than sixty years of age.[305] The incidence of wound infection remained about 1% whether or not prophylactic antibiotics were used. There was also no difference in the incidence of clinical signs and symptoms of infection when mesh was used for the repair. Foschi et al. stated that the incidence of mesh infection is lower following laparoscopic repair because the port sites are distant from the mesh.[306] Mesh infection has, however, been described following laparoscopic repair[191,225,228,272,307,308] and in one case was reported to have caused necrotising fasciitis.[272] Acute post-operative wound infection involving the mesh

layer has been found to settle rapidly with surgical drainage and antibiotic therapy as appropriate.[134,170,305] Removal of the mesh is therefore not normally required in this situation.[134,305] Glassow has reported that patients who developed a wound infection had a greater incidence of recurrence following Shouldice repair.[309] Gilbert and Felton have suggested that this may not be the case following acute infection of a mesh hernia repair.[305] They reported no recurrence after follow-up of between one and three years in twenty-one patients who had acute infection of a mesh repair.

Leber et al. reported a 5.9% incidence of chronic infection and sinus formation following mesh repair of incisional hernias.[310] The incidence of chronic complications was found to be related to the type of mesh used for the repair. Mersilene had a much higher incidence of complications than other types of mesh such as Prolene and Marlex. The incidence of chronic mesh infection has been reported to be less than 1% following open[125] or laparoscopic[191,228,307] inguinal hernia repair. In a review of chronic mesh infection following inguinal hernia repair Taylor and O'Dwyer reported that the majority of cases were initially managed with surgical drainage, as appropriate, and antibiotics.[311] In all of the cases reviewed the sepsis failed to settle and complete or partial excision of the mesh was required.[117,308,311]

Kaufman was the first to report the formation of an enterocutaneous fistula following placement of mesh in the peritoneal cavity.[312] Leber et al. subsequently reported a 3.5% incidence of this complication after prosthetic incisional hernia repair.[310] Weitzel at al. have reported a colocutaneous fistula caused by migration of a metallic mesh placed twenty years before for bilateral inguinal hernias.[105] In addition, the formation of a colovesical fistula following a TAPP inguinal hernia repair has been described by Gray et al.[313] In this report it was stated that the peritoneum had not been closed properly at the end of the repair and this had allowed the sigmoid colon to become adherent to the mesh. At cystoscopy the mesh was found to have eroded through the bladder wall.

The reported incidence of mesh rejection following inguinal hernia repair is very low.[125,134] Foschi et al. have reported a case that presented three years following TAPP repair of an inguinal hernia.[306] At laparotomy the mesh was remove along with the surrounding necrotic tissue. The late mesh rejection following laparoscopic groin

hernia repair was claimed to have created a specific clinical picture and Foschi et al. suggested that this be termed 'chronic meshoma'.[306]

1.26 Chronic pain following inguinal hernia repair

Chronic pain following inguinal hernia repair is of importance as it has both economic and lifestyle implications for the patient, and economic implications for society. A high intensity of post-operative pain has been associated with the development of chronic pain after procedures such as leg amputation and thoracotomy.[314] Callesen et al. reported that chronic pain following inguinal hernia repair was correlated with the cumulative pain scores recorded daily over the first week after operation and at four weeks after the procedure.[315] The incidence of chronic pain was also greater following recurrent hernia repair compared with that following primary inguinal hernia repair. The mechanism of chronic pain is not clear. It has been suggested that severe initial pain, which may be due to nerve injury at the time of operation, induces neuropathic changes within the central nervous system.[315]

In a review of patients who had undergone either Bassini, McVay or Shouldice repair Cunningham et al. reported an 11.9% incidence of moderate to severe pain at one year, and 10.6% incidence at two years.[316] The type of repair performed did not influence the incidence of chronic pain. In a report on long-term follow-up following modified Bassini repair, Shouldice repair and herniotomy with tightening of the deep ring Beets et al. reported chronic pain in 3.7%, 0% and 4.4% of patients respectively.[317] Millikan et al. found a 25.5% incidence of pain lasting an average of eight months in a group of patients having Bassini, Shouldice or Lichtenstein repair.[211] Callesen et al. reported a similar incidence of chronic wound pain following conventional sutured types of repair and primary mesh repair.[318] In a review of 5506 inguinal and femoral hernia repairs performed over a one year period in Scotland, Hair and co-workers reported a 3% incidence of severe/very severe pain at three months follow-up.[319]

Lichtenstein stated that the cause of chronic pain following inguinal hernia repair was ligation or crushing of sensory nerves.[320] He therefore advocated prosthetic tension-free repair as it was claimed to allow preservation of all of the sensory nerves in the

groin. However, several reports of outcome following open prosthetic repair have recorded the presence chronic groin pain.[129,134,148,321] Heise and Starling reported a series of twenty patients who had groin exploration for chronic pain following prosthetic inguinal hernia repair.[322] They concluded that the presence of mesh caused chronic groin pain, and that the condition was non-specific as to which nerve was trapped. Heise and Starling suggested that the incidence of chronic groin pain due to mesh could increase rapidly with the expansion in use of prosthetic inguinal hernia repair.[322]

It is not clear whether or nor elective division of the ilio-inguinal nerve influences the incidence of chronic pain following inguinal hernia repair. In a review of 100 patients from the Shouldice Clinic who developed chronic pain the operative protocols showed that the ilio-inguinal and ilio-hypogastric nerves had been carefully preserved in 90% of cases.[323] Wantz reported that chronic pain was not seen following division of the ilio-inguinal nerve in 546 cases, but was seen in patients in whom the nerve had been carefully preserved.[324] Pappalardo et al. reported that of 180 anterior prosthetic repairs with elective division of the ilio-hypogastric nerve none developed chronic pain.[325] After two years follow-up 1% of the patients still had an area of reduced sensation, but none of them considered it incapacitating. Neurectomy of the ilio-hypogastric nerve was therefore considered a useful step in preventing persistent post-operative pain. In contrast to these reports the Canadian Co-operative Hernia Study found that transection of the ilio-inguinal, ilio-hypogastric or genito-femoral nerves had no influence on the incidence of chronic pain.[316] In a small randomised study of nerve preservation or division in twenty patients having bilateral primary inguinal hernia repair Ravichandran et al. reported no significant difference in the incidence of chronic pain at six months follow-up.[326] In this study there was also a relatively low incidence (15%) of complaints of numbness over the area supplied by the divided nerve.

Injury to the ilio-inguinal, ilio-hypogastric and genital branch of the genito-femoral nerve are recognised to occur in 1-2% of open anterior inguinal hernia repairs.[320,327,328] As the nerves affected in open inguinal hernia repair lie in a plane superficial to the preperitoneal dissection, it was thought that the incidence of nerve injury would be less following laparoscopic repair.[176] However, although the

incidence of injury to the ilio-inguinal, ilio-hypogastric and genital branch of the genito-femoral nerve has decreased, a further group of nerves not usually injured in the anterior repair have been found to be at risk during the laparoscopic repair.[329,330] The femoral branch of the genito-femoral nerve, the lateral cutaneous nerve of the thigh and the femoral nerve lie in the infero-lateral area of the dissection during laparoscopic inguinal hernia repair. Kraus therefore stated that, in order to avoid nerve injury, the lower lateral part of the mesh should not be stapled routinely.[329] This point was reiterated by Seid and Amos who defined the area bounded by the iliopubic tract superiorly, the vas deferens medially and the anterior superior iliac spine laterally as being 'off limits' for staple placement.[330] It was also noted that, even if this area was avoided, excessive pressure with the stapler could result in entrapment of the ilio-inguinal, ilio-hypogastric and genital branch of the genito-femoral nerves that are normally protected in a more superficial plane. Lantis and Schwaitberg described a case of ilio-inguinal nerve entrapment by this mechanism.[331]

Nerve entrapment symptoms have been described in a large number of the early series of laparoscopic inguinal hernia repair.[190,205,206,209,212,217,221,224,227,231,242,249,259,264-267,328,329] Fitzgibbons et al. reported a higher incidence of neuralgia following the IPOM repair than after the other types of laparoscopic repair.[191] With the recognition that staples should not be placed below the ilio-pubic tract lateral to the deep ring, and the trend not to use staples at all for many TEP repairs, the reported incidence of nerve injury has reduced.[328,332] Other surgeons advocate the use of titanium spiral tacks rather than staples as they are thought to reduce the risk of nerve entrapment.[227]

The majority of cases of chronic post-operative pain will resolve with conservative measures over a period of months.[211,320,321,332] However, some patients fail to settle and may require further surgical intervention with division of the affected nerve,[320,324,333] or removal of the mesh.[134,148,322,334] Heise and Starling reported that of twenty patients in whom the mesh was removed, plus neurectomy if scarring involved the nerves, 60% reported a good or excellent result at an average follow-up of sixteen months.[322] Of the patients reported to have chronic pain in the early series of laparoscopic repair many were successfully treated by re-exploration and removal of staples.[205,206,221,242,259,266,267] However, Fielding has cautioned that laparoscopic

removal of staples may be difficult due to the fibrotic reaction that occurs around the mesh.[267]

Testicular pain has also been reported in a number of series of laparoscopic repair.[191,217,222,225,274,275,303] Tetik et al. postulated that extensive dissection around the cord could cause oedema and inflammation, with resulting congestion of the lymphatic and venous channels.[274] Alternatively, it was postulated that the pain could be secondary to trauma to the genital branch of the genito-femoral nerve or testicular plexus contained within the preperitoneal fascia.[274] These theories were supported by Diaco et al. who observed that testicular pain appeared to be related to dissection of the indirect sac and when the sac was transected at its neck, rather than dissected off the cord, there was no incidence of testicular pain.[335] LeBlanc et al examined the effects of polypropylene and PTFE mesh in a pig model thirty and ninety days after implantation in the preperitoneal space.[336] They reported that at ninety days some of the specimens from the polypropylene group demonstrated pronounced venous congestion of the testes. This effect was not seen in the PTFE group where the tissue response to the mesh was much less. It was therefore suggested that the likelihood of testicular complications might be related to the type of mesh used.

1.27 Open repair using local anaesthesia

Inguinal hernia repair using local anaesthesia has been strongly advocated by many surgeons on the grounds that it involves less physiological stress and therefore greater safety for the patient,[37,137,337] reduced theatre and recovery room time,[37,137] less tension in sutured repairs,[37] less post-operative pain,[127,338] and reduced costs.[37,137,339] However, the published evidence is not conclusive with regard to many of these issues.

Several studies have compared outcome following conventional sutured repair under general and local anaesthesia. Behnia et al. performed a non-randomised comparison of the haemodynamic changes that occurred in American Society of Anesthesiology (ASA) category I patients during inguinal hernia repair under general anaesthesia and regional field block.[340] No significant difference was found between the groups in cardiac output, mean arterial pressure, total peripheral resistance or heart rate during

the procedure. The authors did however comment that there might be differences in the responses of patients with pre-existing cardiac disease. Several studies have indicated that a large proportion of patients report feeling pain during local anaesthetic repair,[341-343] which may lead to intra-operative physiological stress. In a retrospective comparison Young found that there was no significant difference in operation time between general and local anaesthetic repair, but the total time that the patient spent in theatre and the recovery room was greater for the general anaesthetic group.[342]

Makuria et al. found that a greater proportion of general anaesthetic patients required post-operative parenteral medication following sutured repair, but there was little difference in the mean number of doses of parenteral or oral analgesia given to each group.[338] Peiper et al. reported greater pain scores at four and eight hours after Shouldice repair under general anaesthetic compared with the same procedure under local anaesthesia.[343] Analgesic use on the day of operation was also greater in the general anaesthetic group. However, by the first post-operative day there was no difference in pain scores or analgesic use between the two groups. Young has also reported that the local anaesthetic group required less parenteral analgesia, but found no significant difference in the use of oral analgesics.[342] Godfrey et al. found no significant difference between the groups in the use of post-operative analgesia.[344] In a randomised study Teasdale et al. reported no significant difference in post-operative pain scores or parenteral analgesia use between groups.[341] In addition, this study also showed a greater use of oral analgesics in the local anaesthetic group. In many of these studies the general anaesthesia group were not given local anaesthetic infiltration at the end of the operation. This procedure is now commonplace and may alter the early use of analgesics following repair under general anaesthesia.

No significant differences were found in the incidence of wound complications following local and general anaesthetic repairs.[338,341-344] General anaesthesia was, however, associated with an increased incidence of sore throat, nausea and vomiting, and headache.[341,342] Peiper reported a greater incidence of urinary retention in the general anaesthetic group,[343] but other studies have not found any significant difference between the groups.[341,342] No statistically significant differences were identified in the time to return to normal activities or work.[338,344] Peiper reported a

slightly faster return to work in the local anaesthetic group (15 days vs 19 days), but did not provide any statistical analysis to support this.[343] The hospital costs for general anaesthetic repair have been calculated to be greater than those for local anaesthetic repair.[340] Kingsnorth et al. demonstrated a learning curve effect with a higher incidence of recurrence after a surgeons first six repairs under local anaesthesia.[345] However, the results of several reported series suggest that, in experienced hands, local anaesthetic repair does not have a greater incidence of recurrence.[37,60,126,337]

Glassow stated that bilateral inguinal hernia repairs should be staged due to the risk of exceeding safe doses of local anaesthetic.[37] However, Lichtenstein has reported the safe repair of bilateral inguinal hernias under local anaesthetic using both sutured repairs[60] and prosthetic tension-free repair.[128] Local infiltration was preferred to regional field block as it required less time to perform and also required a lower total volume of local anaesthetic.[125,127] It was claimed that simultaneous repair reduced psychological stress for the patient, time off work and hospital costs.

The uptake of local anaesthetic inguinal hernia repair in Scotland has remained low. Hair et al. found that of 5506 inguinal and femoral hernia repairs performed between April 1998 and March 1999 only 6% were performed under local anaesthesia.[319]

1.28 Laparoscopic repair under regional or local anaesthesia

In their description of TEP repair, McKernan and Laws commented that the requirement for general anaesthesia was a potential drawback for laparoscopic hernia repair.[240] However, Pendurthi and colleagues subsequently published the first report of laparoscopic TAPP repair under local anaesthesia.[346] The patient, who had bilateral inguinal hernias, was sedated with small increments of intravenous propofol and midazolam while regional anaesthesia was achieved with bilateral inguinal field blocks. Pneumoperitoneum with carbon dioxide was known to cause significant discomfort and so nitrous oxide, which is more tolerable within the peritoneal cavity,[347,348] was used for insufflation. Using laparoscopic localisation further local anaesthetic was infiltrated at the proposed site of peritoneal incision, and this was

then performed using an ultrasonic scalpel. Electrocautery was not used due to the risk of explosion in the presence of nitrous oxide.

TAPP repair may also be performed under regional anaesthesia by using an abdominal wall lifting technique to replace the pneumoperitoneum. Tagaya et al. reported a series of twenty repairs in which this technique was compared with repair using carbon dioxide pneumoperitoneum under general anaesthesia.[349] Regional anaesthesia was achieved using epidural or spinal anaesthesia to the level of T_5. Abdominal wall retraction was then performed using two subcutaneously placed wires. In this small, non-randomised study no difference was found between the groups in operation time or hospital stay. No recurrences were identified in either group at a mean follow-up of fourteen months.

TEP repair has been described under regional,[350] and local anaesthesia.[248,351] In a retrospective comparison of sixty-seven patients having TEP repair under epidural anaesthesia and eighty-one patients having repair under general anaesthesia, Schuricht et al. reported a significant reduction in post-operative pain and nausea in the epidural group.[350] 6% of cases in this group required conversion due to inadequate sensory blockade. Heithold et al. reported that inadvertent tearing of the peritoneum resulted in painful carbon dioxide pneumoperitoneum necessitating conversion to general anaesthesia.[248] Liem et al. found a 28% incidence of peritoneal injury during the learning curve for TEP repair.[258] The incidence of peritoneal damage fell as the surgeon progressed along the learning curve and so there is a case for surgeons not to attempt repair under local anaesthesia until they are proficient with TEP repair under general anaesthesia. Ferzli et al. have also reported the successful completion of ten primary inguinal hernia repairs using the TEP technique under local anaesthesia, with carbon dioxide insufflation of the preperitoneal space.[351] Four of these patients required intravenous sedation in addition to the local anaesthetic. It was concluded that laparoscopic repair under local anaesthesia is an option for patients in whom general anaesthesia is contraindicated.

1.29 The physiological effects of CO_2 pneumoperitoneum

The most commonly used gas in laparoscopic surgery is carbon dioxide (CO_2). This agent has the advantages that it does not support combustion and it has a high blood solubility, which reduces the risk of gas embolus. CO_2 is a normal product of human metabolism and so at physiological levels is non-toxic. However, absorption of CO_2 from the insufflation space may cause hypercarbia. The factors influencing the rate of absorption of a gas from a cavity are the partial pressure gradient of the gas between the cavity and the blood, the diffusion coefficient of the gas, the surface area of the cavity, and the perfusion of the walls of the cavity.[352,353]

Hypercarbia exerts both direct and indirect effects on the cardiovascular system.[354-356] The direct effects result in myocardial depression and arteriolar dilatation. The indirect effects are caused by the release of catecholamines, which produce an inotropic and chronotropic response. These effects result in an overall increase in cardiac work and therefore increased myocardial oxygen requirements.[354] The creation of a CO_2 pneumoperitoneum is known to produce a number of haemodynamic changes including an increase in systemic arterial pressure and, less consistently, an increase in heartrate.[357-364] Cardiac work is therefore further increased. Similar haemodynamic changes have been reported using other insufflation agents, including nitrous oxide,[365] helium,[366,367] and argon.[368,369] However, other authors have described smaller haemodynamic disturbances with these alternative insufflation agents.[370-372] The pneumoperitoneum has also been shown to produce an increase in the central venous filling pressure (CVP),[364,373,374] but Ivankovich et al. argued that direct measurement of the CVP could not be used clinically as a measure of venous return because it includes a composite of pleural pressure and intra-abdominal insufflation pressure.[359] Diament et al. stated that cardiac transmural pressure, rather than directly measured central venous pressure, would be required to assess venous return to the heart.[375]

It has been reported that measurement of end-tidal CO_2 concentration will give a reasonable assessment of the arterial CO_2 tension in patients who do not have significantly compromised cardio-respiratory function.[376-381] In addition, the pattern of change of end-tidal CO_2 will reflect the changes in arterial CO_2. However, patients

with significant cardio-respiratory disease tend to have a greater dead-space disparity and so the accuracy of end-tidal CO_2 measurement is less. Invasive monitoring provides a more precise assessment in these patients.[366,382-385]

Insufflation of CO_2 during laparoscopic surgery produces an increase in arterial pCO_2 and a fall in arterial pH.[358,360,373,386] The time course of these blood gas changes has now been described by several investigators.[373,379,380,387] There is an initial rapid rise in the $PaCO_2$ over the first fifteen to twenty minutes, and then there is a subsequent prolonged second phase where only very gradual change occurs. The increase in arterial pCO_2 can be seen in healthy individuals breathing spontaneously, and occurs despite an increase in their minute ventilation.[373,388] In most healthy patients the change arterial pCO_2 does not cause any significant physiological stress, and in the ventilated patient it may be controlled with moderate hyperventilation.[376,389] These changes may still carry a risk, even in healthy patients, as Reed and Nourse have reported significant bradycardia during pneumoperitoneum in 0.5% of patients with no previous history of cardiac or respiratory disease.[390] In the majority of cases the bradycardia was rapidly reversed by release of the pneumoperitoneum. Ishizaki et al. have also demonstrated, in the dog model, that the haemodynamic consequences of carbon dioxide insufflation were much less marked at insufflation pressures of 8mmHg and 12mmHg compared with those seen at 16mmHg.[391] It was therefore recommended that the insufflation pressures should be kept below 16mmHg. McKernan and Laws have recommended that the insufflation pressure should be kept at or below 12mmHg during totally extraperitoneal hernia repair in order to reduce the risks of acidosis and surgical emphysema.[240]

A greater rise in arterial CO_2 levels has been observed in patients with pre-existing cardio-respiratory disease, and this may occur even in the presence of increased pulmonary ventilation.[366,383] Careful perioperative respiratory and cardiovascular monitoring is therefore recommended for patients with cardio-respiratory disease who are planned for laparoscopic procedures.[361,363,383,384,392] Greif and Farse have also examined the effects of CO_2 laparoscopy in a porcine model simulating sepsis.[393] The laparoscopic group of animals demonstrated significantly greater hypercarbia and acidosis than was seen in a control group undergoing laparotomy. These changes occurred despite an increase in ventilation and so it was concluded that the pulmonary

capacity to excrete CO_2 is further decreased during sepsis. The resulting haemodynamic compromise was similar to that seen during laparoscopy in patients with significant cardio-pulmonary disease. It has therefore also been recommended that laparoscopy be used with care in patients suffering from systemic sepsis.

1.30 Comparison of intra- and extraperitoneal CO_2 insufflation

Mullet and co-workers described the changes in end-tidal CO_2 level during pneumoperitoneum for laparoscopic cholecystectomy and extraperitoneal insufflation for pelviscopy in patients with no history of cardio-respiratory disease.[394] The insufflation pressure in these patients was limited to 13cmH_2O. In the pneumoperitoneum group there was a rapid rise in end-tidal CO_2 over the first twenty minutes followed by a plateau phase, which was consistent with previous descriptions of blood gas changes during CO_2 pneumoperitoneum.[373,379,380,387] In contrast, during extraperitoneal inflation there was a more rapid and greater total increase in end-tidal CO_2. It was also noted that the end-tidal CO_2 had not reached a plateau by 40 minutes in the extraperitoneal insufflation group. These results suggested that extraperitoneal insufflation poses a greater risk than pneumoperitoneum for patients with pre-existing cardio-respiratory disease. Liem et al. compared the haemodynamic and blood gas changes that occurred during laparoscopic cholecystectomy and totally extraperitoneal laparoscopic inguinal hernia repair.[395] The maximal inflation pressure in both groups was 15mmHg. This study demonstrated a rise in mean arterial blood pressure in both groups, but that in the pneumoperitoneum group was greater than in the extraperitoneal insufflation group. The mean maximum values of $PaCO_2$ were not significantly different between the groups. In the pneumoperitoneum group the $PaCO_2$ reached a plateau after fifteen to twenty minutes. In contrast the $PaCO_2$ in the extraperitoneal group rose more rapidly and had not reached a plateau by forty minutes. The total rise in the extraperitoneal insufflation group was therefore much greater. Sumpf and co-workers compared CO_2 absorption in ten patients having TAPP repair and ten patients having TEP repair.[396] In the TAPP group the CO_2 absorption increased for twenty minutes then reached a plateau while in the TEP group it continued to rise throughout the procedure. The total CO_2 absorption was therefore greater for the TEP group than that for the TAPP group. This study also reported a distinct relationship between the degree of surgical emphysema, which was

seen more frequently and to a greater degree in the TEP group, and the magnitude of the CO_2 absorption. Wolf et al. compared CO_2 insufflation to 15mmHg for pneumoperitoneum and for retroperitoneal insufflation.[397] This study showed that the retroperitoneal group had a smaller fall in pH and smaller rise in $PaCO_2$ than was observed in the pneumoperitoneum group. Chui et al. reported that retroperitoneal insufflation to 15mmHg produced less increase in systemic arterial blood pressure than was produced by a pneumoperitoneum inflated to the same pressure.[398] Bannenberg et al. compared intra- and extraperitoneal insufflation to 15mmHg for one hour in the porcine model.[399] End-tidal CO_2 rose more slowly during extraperitoneal than during intraperitoneal insufflation, but the overall rise was of similar magnitude. Arterial pCO_2 increased by a significantly greater degree during intraperitoneal insufflation. Baird et al. found no difference in the haemodynamic effects of intraperitoneal and retroperitoneal insufflation when performed sequentially in pigs.[400] There is therefore conflicting evidence in the literature on the relative effects of CO_2 pneumoperitoneum and extraperitoneal insufflation.

1.31 Mechanical retraction

Laparoscopic procedures may be performed without the use of gas insufflation using a mechanical retractor.[349,401] Chui et al. examined the haemodynamic changes that occurred during CO_2 pneumoperitoneum, CO_2 retroperitoneal insufflation and mechanical retraction in a porcine model.[398] It was demonstrated that abdominal wall retraction to a force equivalent to 15mmHg produced no haemodynamic changes. Rademaker et al.[402] and McDermott et al.[403] have also demonstrated that abdominal wall retraction does not cause any significant haemodynamic changes. It was therefore suggested that mechanical retraction may have advantages for patients with pre-existing cardio-respiratory disease, although factors such as adequacy of visual field would have to be assessed.[403] Koivusalo et al. reported a randomised trial of CO_2 pneumoperitoneum versus mechanical retraction for patients undergoing laparoscopic cholecystectomy.[404] This study showed significantly less haemodynamic and respiratory changes in the mechanical retraction group and the authors suggested that the use of mechanical retraction may reduce the risk of ischaemic cardiac episodes. The operative field was however less well visualised in the abdominal wall retraction group with a resultant increase in operation time.

1.32 The metabolic response to surgery

Infection, injury, malignant tumour and a variety of immunological disorders trigger a complex reaction known as the acute phase response.[405] This response is characterised by fever, leucocytosis, negative nitrogen balance, increased vascular permeability, alterations in plasma metal and steroid concentrations, and an increase in hepatic acute phase proteins. In humans, the acute phase protein response includes C-reactive protein (CRP), which increases by between ten- and one hundred-fold. The CRP level does not rise measurably until six to eight hours after surgery is commenced, and peak levels are reached twenty-four to forty-eight hours later.[406-409] Colley et al. found no relationship between the age of the patient and the magnitude of the CRP response.[406] The severity of the injury did not affect the time course of the response.[406] The hepatic synthesis of albumin is also inhibited during the acute phase response.[410] The mediators between the site of injury and the liver include the cytokine interleukin-6 (IL-6). IL-6 levels has been shown to rise within two to four hours of surgery and to peak between three and twenty-four hours after surgery.[407,409,411] IL-6 is therefore used as an early marker of activation of the acute phase response. A significant correlation has been found between the degree of surgical trauma and the magnitude of the IL-6 response.[407,409] In addition, the magnitude of the IL-6 response is proportional to the duration of the surgical procedure.[407,411] Cruikshank et al. demonstrated a role for IL-6 in the induction of CRP synthesis,[407] but the IL-6 response is thought to be more sensitive than the CRP response in demonstrating the degree of surgical trauma.[407,409,411] Amongst the metabolic changes induced by surgery there may be a rise in blood glucose levels. This response is influenced by the afferent somatic and autonomic neural input from the operative site.[412] Complete neural blockade - as may be achieved with surgery to the limbs, pelvis or eye – prevents the hyperglycaemic response but does not affect the acute phase protein response.

A non-randomised study to compare metabolic response to the Lichtenstein repair and conventional sutured repair under general anaesthesia was reported by Gurleyik and colleagues.[413] From the thirty-six patients studied no significant differences were identified in the IL-6 and CRP response. A randomised study to compare the same two types of repair under local anaesthesia was reported by Di Vita et al.[414] This

study found a significantly higher IL-6 and CRP response in the Lichtenstein repair group. By seven days after the procedure normal levels of inflammatory markers were found in both groups.

A number of studies have shown that the metabolic, endocrine and acute phase response to laparoscopic surgery is less than that produced by open cholecystectomy via a subcostal incision.[415-420] McMahon et al., however, showed no significant difference in metabolic response to laparoscopic and mini-laparotomy cholecystectomy.[421] Several non-randomised studies have compared the metabolic response to open and laparoscopic inguinal hernia repair. Takahara et al. reported a comparison of five patients having a Cooper's ligament repair under spinal anaesthesia and five patients having a 'standard extraperitoneal' repair performed under general anaesthesia.[422] Inflammatory and immunological markers were assayed pre-operatively and at one and five days after the procedure. The only significant difference found between the groups was a greater CRP level in the laparoscopic group on day one. Hill et al. reported a study in which thirty-four patients for primary, unilateral inguinal hernia repair under general anaesthesia were assigned to TAPP repair, Lichtenstein repair or open sutured repair.[423] No significant differences in IL-6 and CRP levels were found between groups at six and twenty-four hours after the procedure. Akhtar et al. reported a comparison of ten patients having a 'modified Shouldice' repair or a TAPP repair under general anaesthesia.[424] Assays were performed pre-operatively and at multiple time points between three hours and five days post-operatively. The open group demonstrated a significantly greater rise in CRP at forty-eight hours compared with the laparoscopic group. There were no significant differences between groups in the levels of cortisol, growth hormone, prolactin or IL-6. In a randomised comparison of the TAPP repair and the Shouldice repair Schrenk et al. found no significant differences in the acute phase reactant or cytokine responses.[425] To date there have been no randomised comparisons of the metabolic response to open mesh repair and laparoscopic repair.

A significant hormonal and glycaemic response has been demonstrated following diagnostic laparoscopy.[426] It is postulated that this response is stimulated by peritoneal distension. As TEP repair does not involve peritoneal insufflation it may

produce less response than has been reported by those studies which have use the TAPP repair in the laparoscopic group.

1.33 The respiratory effects of surgery

The effects of surgery on respiratory function can be broken down into mechanical factors, gas exchange factors and influences on respiratory control. The characteristic post-operative mechanical abnormality following abdominal surgery has a restrictive pattern. This is manifest by a reduction in inspiratory capacity, vital capacity and functional residual capacity.[427] The decreased inspiratory capacity reduces the patient's ability to cough effectively. The changes in vital capacity are less marked following surgery in the lower abdomen compared with those seen following upper abdominal surgery.[428,429] Nevertheless, Godfrey et al. have demonstrated a significant reduction in forced expired volume in the first second (FEV_1) and forced vital capacity (FVC) at four and twenty-four hours after inguinal hernia repair under local, epidural or general anaesthesia.[344] Furthermore, a significant correlation has been demonstrated between ventilatory depression and minor chest complications following open inguinal hernia repair.[430]

Gas exchange abnormalities in the post-operative period are split into two time periods. General anaesthesia results in arterial hypoxaemia, which occurs immediately following reversal and lasts between a few minutes and two hours.[427] Therefore, in the absence of pre-existing pulmonary abnormalities, gas exchange returns to normal within two hours of a minor procedure. Procedures that affect the patient's ability to inspire deeply are associated with on-going gas exchange abnormalities.[427] Impairment of the functional residual capacity, for example due to abdominal pain, results in narrowing or closure of small airways. As a consequence there is an alteration in the ventilation/perfusion ratio with resulting hypoxaemia.[427] In the post-operative period the use of narcotic analgesics may also produce respiratory depression. This occurs because narcotics depress alveolar ventilation, the response to hypoxia or hypercapnia, and the number of periodic sighs, which are important in maintaining lung inflation.[427,431]

Laparoscopic cholecystectomy has been shown to produce less post-operative pain and less reduction in post-operative pulmonary function compared with open cholecystectomy via a subcostal incision,[432-434] or a minilaparotomy incision.[434,435] Laparoscopic inguinal hernia repair has been shown to produce less post-operative pain than open repair in several randomised studies.[294,297,436-443] The influence on post-operative respiratory function has not been investigated.

1.34 Return to normal activity following hernia repair

The advice given to hernia repair patients about return to normal activity has been contentious for many years. Standard advice following sutured repair has been that the patients should avoid strenuous activity for four to six weeks, and then gradually increase the intensity of their activity. Several surgeons with an interest in inguinal hernia repair have challenged this advice. Iles, from the Shouldice Clinic, advocated that patients should be advised to immediately resume the activities that they could carry out in comfort.[444] Thus, by four weeks the patient should have resumed all normal activities without need for a further period of adjustment. This approach was supported by Lichtenstein and Shore's work on wound strength following surgery.[445] They showed that during the first eight weeks after a wound is sutured healing did not contribute to the strength of the repair. After eight weeks a healing wound has only reached 40% of the strength of normal tissue. In contrast the strength provided by a non-absorbable suture, which is present from the moment of the repair, is 70% of normal tissue strength.[445]

Semmence and Kynch have reported an analysis of the factors which contribute to the length of convalescence following inguinal hernia repair.[446] The period of absence from work was increased in association with incidence of complications, particularly respiratory complications, and the degree of physical activity involved in the patient's occupation. The period of convalescence was also inversely proportional to the social class of the patient and the level of invalidity payments. Patients were found to return to work more quickly when the surgeon gave an estimate of expected time of work pre-operatively.[446,447] Rider et al. have shown that time to return to work correlated well with the patient's pre-operative expectations of time to convalesce.[448] This

expectation was based on information derived from work colleagues, the general practitioner, and the surgeon. Salcedo-Wasicek and Thirlby have shown that the duration of perceived pain and time to return to work are significantly greater in patients receiving workers compensation compared with matched patients with commercial insurance.[449] These authors concluded that the pain perceived by the patient was influenced more by socio-economic factors than by the procedure or the anatomy involved. The motivation of the patient was considered a primary factor in determining the time taken to return to work. The importance of controlled trials in comparing outcomes following invasive procedures was therefore emphasised. Barkun et al. have also reported that return to normal activity was influenced by whether or not the patient was receiving disability compensation.[450]

The incidence of recurrence in relation to time off work has also been investigated. Ross found no evidence that a prolonged convalescent period reduced the recurrence rate following sutured inguinal hernia repair.[451] Bourke et al. compared the recurrence rates in 500 sutured inguinal hernia repair patients returning to work after different time periods.[452] The overall recorded incidence of recurrence at one year was 3.9%. There was no difference in recurrence between the group who returned to work 'early' (median 48 days), and a control group who returned to work 'later' (median 65 days). Taylor and Dewar reported a randomised comparison of return to normal activities in ninety-seven naval ratings and officers who had unilateral inguinal hernia repair.[447] At one-year follow-up no recurrences were identified in those patients who returned to normal duties at twenty-one days. In the group resuming light duties at twenty-one days, and normal duties after three months, there were two recurrences at one-year follow-up. It was concluded that there was no contraindication to resuming normal activities three weeks after uncomplicated unilateral inguinal hernia repair.

The introduction of prosthetic hernia repair has been reported to reduce post-operative pain,[47,441,453] and may therefore allow earlier return to normal activity.[441,454] This may be enhanced by the perception that a mesh repair will provide more security than a sutured repair in the early post-operative stages. Several studies have reported that laparoscopic hernia repairs cause less post-operative pain than open repair,[294,297,436-443,455] and have also been associated with an earlier return to normal activity in some randomised studies.[294,297,441,443,455-461]

A question that is commonly asked by patients following inguinal hernia repair is when they can return to driving. The amount of discomfort that the patient feels is an important factor in determining their ability to perform such tasks. Although patients may rapidly feel comfortable enough to perform the routine tasks of driving, they must be able to perform an emergency stop in order to drive safely. Welsh and Hopton have previously compared the ability to perform an emergency stop in patients who had plication repair of a right inguinal hernia and a group of healthy control subjects.[462] The response times were measured pre-operatively and on the third, seventh and tenth days post-operatively. The inguinal hernia repair group were found to have significantly prolonged response times on the third and seventh post-operative days when compared with the control group. By the tenth post-operative day there were no significant differences between the groups. Welsh and Hopton recommended that patients do not drive until ten days after inguinal hernia repair.[462]

It has been postulated that the impairment of emergency stop reaction times could be due to fear of pain or discomfort during the task.[462] Prosthetic inguinal hernia repair has been reported to produce less post-operative pain and allow a faster return to normal activities than is observed following sutured repair.[47,294,297,436-438,441,453,455] The possibility therefore arises that prosthetic repair may allow a faster return to driving. Wilson et al. reported an assessment of reaction time to perform an emergency stop following laparoscopic repair, Lichtenstein repair and conventional sutured repair.[463] By seven days after the repair 82% of the laparoscopic group, 64% of the Lichtenstein group and 33% of the sutured repair group had returned to pre-operative values. There was no difference in recovery time between those open repairs performed under general anaesthesia and those performed under local anaesthesia.

1.35 Economic aspects of hernia repair

Approximately 80,000 inguinal hernia repairs are performed each year in the United Kingdom. With ever tightening constraints on the resources of the NHS the costs of any new method of hernia repair are of great importance. The rapid development of laparoscopic techniques for procedures such as cholecystectomy has resulted in increased theatre costs, particularly when disposable instrument are used.[464-467] However, these costs may be offset against shorter hospital stay, thus reducing the

total hospital costs. In the case of hernia repair, where a large proportion of the patients may be suitable for day case surgery and in-patient stay is relatively short, this effect may be less apparent. The issue of cost is further compounded by the impact of the technique on societal factors such as the convalescence time, and in particular the time to return to work.[464,468] Heikkinen et al. stated that the total cost of sick leave to an employer and to community is approximately three times the patient's salary for that period.[469] This figure consisted of the patient's salary plus additions such as the salary for the worker's substitute, health insurance expenses, overtime work, production losses, quality impairment, delays and administrative expenses.

The concept of cost-effectiveness analysis was developed to compare interventions where both the cost and the outcome are to be assessed.[468,470] The ratio of cost and benefit may further be expressed as marginal cost-effectiveness. This analysis compares the cost of the intervention in question with the care that would be provided if that intervention were not available.[468] In the case of laparoscopic inguinal hernia repair the absolute cost is therefore less important than the difference in cost compared with accepted open methods of hernia repair. McIntosh et al. have emphasised the importance of opportunity cost as a method of economic assessment.[471] This method involves measuring how resources are utilised rather than their monetary value. For example, the increased time taken to perform a new procedure compared with an established treatment can be considered in terms of other procedures which must be forgone to facilitate the required theatre time, or in terms of increased waiting list times.

Some early studies compared the cost of open and laparoscopic repairs by analysing the hospital charges.[208,459] This technique is inaccurate and calculation of actual hospital expenditure to perform each type of procedure provides a better assessment of cost.[215] Several studies have reported the comparative costs of laparoscopic repair and either sutured or prosthetic open repair.[296,441,442,457,469,472,473] In all of these studies the theatre costs and total hospital costs were greater for the laparoscopic procedure than for the open technique used. The use of disposable instruments and staplers accounted for a major component of the theatre costs in the laparoscopic group.[442,472,473] Liem et al. concluded that the replacement of disposable instruments

with reusable instruments may be essential for the survival of laparoscopic hernia repair.[296] The majority of studies comparing costs have used the TAPP repair in the laparoscopic arm,[441,442,457,469,472,473] and all used a stapler for fixation of the mesh and closure of the peritoneum. In the TEP repair the mesh often does not require fixation and there is no requirement to close a peritoneal defect.[251,270] The cost of a stapler can therefore often be discounted when considering the TEP repair.

A smaller number of studies have considered the societal costs associated with time to return to work. Liem et al. showed that when this is considered the laparoscopic repair was still more expensive than the open repair, but the difference was only one quarter of that found when hospital costs alone are considered.[296] It was further calculated that if the recurrence rate at five years follow-up in the laparoscopic repair group was 6.9% less than that in the open group the costs would be even. In this study the open group had a sutured repair and this difference in recurrence appeared possible from the trial's early recurrence data. However, the recurrence rate for open mesh repair would appear to be much lower.[125,129,130,134,160] Heikkinen et al. calculated that the earlier return to work found in their laparoscopic group resulted in lower overall costs for the laparoscopic repair.[469] It has therefore been argued that the laparoscopic repair may have economic advantages for patients still in employment but not for those who have retired.[457,469]

1.36 Randomised trials in surgery

The strongest evidence in the assessment of a therapeutic technique is considered to come from randomised controlled trials and they are therefore considered to be the best method to determine treatment effectiveness.[474] If the benefits of a new procedure or treatment are so large that the value is self-evident then it may not be necessary to perform controlled trials before it's introduction.[474] In keeping with this stance Hellmen et al. argued that a medical practitioner should only enter patients in a randomised trial if they truly have no preference for either treatment.[475] These authors stated that to enter patients into a trial where the practitioner believes one arm has apparent benefit is inconsistent with fidelity to the patient. Commonly in modern medicine technological developments and surgical interventions will produce only small increments in survival or quality of life. It is therefore necessary to carefully

compare extraneous factors in these cases to ensure that any observed benefit is due to the treatment in question. In this situation randomised controlled trials are necessary to identify any potential advantage associated with a new procedure.

There are drawbacks associated with randomised controlled trials, including the fact that the time required to plan and implement a trial then follow-up the patients is often considerable.[476] In addition, the trials are expensive to perform and strict inclusion criteria may affect the ability to generalise the results to the entire patient population. In the situation where a disease or outcome is rare or only occurs after a long period of time a randomised controlled trial is not practicable. Finally, as alluded to above, the ethical implications of a randomised, controlled trial are controversial.

Randomised controlled trials in surgery have the additional problem that standardisation of a procedure is difficult because surgeons may vary in their experience with, and their ability to perform, the procedure. There may also be individual preferences in technique and modifications may occur as the procedure evolves. Furthermore, differences in the peri-operative and post-operative care may influence the outcome. In relation to the surgeons experience with a procedure the issue of timing of trials is complex. Chalmers argued that the first patient in whom a procedure is performed should be randomised.[477] This position was based on ethical rather than methodological concerns. Most surgeons would argue that a learning curve exists for any new procedure, both for the surgical community and for the individual surgeon, and so inclusion of these early cases in a study would bias the results against the new procedure.[478] On the other hand it may be difficult to initiate a trial when the procedure is widely accepted by both the patient population and surgical community. A trial in which all the surgeons involved are highly experienced with the procedure will test its efficacy. If many surgeons who do not have special expertise perform the trial the effectiveness of the procedure will be tested.[474]

Although the first randomised, controlled trial in surgery was reported by Golligher in 1964,[479] the use of this technique to compare outcome after inguinal hernia repair has been limited until recently. With the exception of Berliner's comparison of the two- and three-layered modifications of the Shouldice repair,[45] all of the reports of randomised trials of inguinal hernia repair have been published in the past decade.

1.37 Randomised trials comparing the Shouldice repair with other anterior sutured repairs (Appendix A.1)

In 1992, Tran et al. published a randomised, controlled trial to compare a modified Bassini repair with the Shouldice repair.[480] This study did not demonstrate any significant differences in outcome between the groups, but the authors did comment that the recurrence rate in the Shouldice group was much higher than anticipated. It was suggested that this might have been due to the surgeons relative lack of experience with the repair as only fifty-four Shouldice repairs had been performed by the total of thirteen surgeons before the trial was commenced. Panos et al.[481] and Kingsnorth et al.[482] have also reported no significant difference in outcome between the Shouldice repair and other types of sutured repair. In 1994 Kux et al. reported a trial which compared the traditional Shouldice repair, and a two-layer modification of the Shouldice repair, with the Bassini repair.[47] This study showed a significantly lower recurrence rate for the Shouldice repairs compared with the Bassini repair, but no significant difference between the two types of Shouldice repair (Table 1.1). Several other groups have also found a significantly lower incidence of recurrence following Shouldice repair when compared with other forms of sutured repair.[317,483,484]

Simons et al. reported a metanalysis of the trials published up to 1994 comparing the Shouldice repair with other sutured repairs.[485] This study showed a significantly lower recurrence rate in favour of the Shouldice repair. It was concluded that the Shouldice repair was probably the best conventional repair and that it should provide the standard against which the open and laparoscopic prosthetic repairs were compared.

1.38 Randomised trials comparing sutured repairs with open prosthetic repair (Appendix A.2)

Friis et al. reported a comparison of the Lichtenstein repair against a protocol in which indirect hernias were treated by herniotomy and hernias with evidence of a posterior wall defect were repaired using the McVay technique.[486] No significant difference was found in early outcome but the recurrence rate at two years follow-up

was significantly lower in the Lichtenstein group. Proir et al. compared early outcome following a 'modified' Bassini repair and the Lichtenstein repair.[453] The Lichtenstein group reported lower post-operative pain scores, but there was no difference found in hospital stay, total number of complications or time to return to work. Callesen et al. have reported a comparison of pain scores in eighty-four patients found to have indirect inguinal hernias with a deep ring greater than 1.5cm diameter.[318] These patients were randomly allocated to either herniotomy and tightening of the deep ring or Lichtenstein repair. No significant differences in pain scores were identified in the first week and at four weeks after the procedure. In a small randomised comparison of conventional sutured repair and the Lichtenstein repair Di Vita et al. reported lower pain scores and less analgesic requirements in the first forty-eight hours for the Lichtenstein group.[414]

Several trials have studied outcome following mesh repair and the Shouldice repair.[441,454,487,488,531] The mesh repair was reported by some to be simpler and quicker to perform,[487,531] but other groups found no significant difference in operation times.[441,454] Zieren et al. reported lower pain scores following plug and patch repair.[441] Other studies have found no significant difference in pain scores when the Lichtenstein repair was compared with the Shouldice repair.[454,487] Three studies reported no significant difference in hospital stay following Shouldice or Lichtenstein repair.[441,454,531] Kux et al. reported a higher incidence of post-operative complications following the Shouldice repair.[531] This difference was predominantly due to a higher incidence of urinary retention than was seen following the mesh repair. All of the other studies have reported a similar incidence of post-operative complications in the two groups.[441,454,487,488] Barth et al. reported that 50% of each group had returned to normal activities by nine days,[487] but other studies have found that the time to return to work was less after mesh repair.[441,454] Only one of the four studies that have reported recurrence data has shown a significant difference in recurrence rates.[441,454,488,531] This study had an unusually high recurrence rate in the Shouldice group at one year (10%).[454] Zieren et al. reported that the material costs for the Shouldice and plug and patch repairs were similar.[441]

The EU Hernia Trials Collaboration have reported a metanalysis of open mesh versus conventional sutured repairs for inguinal hernia.[489] Firm conclusions could not be

reached for many of the outcome measures due to variations in data reporting which precluded metanalysis. The overall conclusions of this assessment were that the incidence of post-operative complications was similar for both groups and that there was no evidence that the use of mesh increased the specific risks of deep infection or chronic pain. There was also a consistent pattern of fewer recurrences in the mesh repair group.

1.39 Randomised trial comparing different types of open mesh repair (Appendix A.3)

Kingsnorth et al. have reported the only trial to compare different types of open prosthetic repair.[149] This prospective, double-blind randomised trial compared the early outcome following the Lichtenstein repair and the 'plug and patch' repair. The 'plug and patch' repair was found to require a smaller incision and the mean operation time was 5.6 minutes shorter than the Lichtenstein repair, although the authors did indicate that this was probably negligible. The combined pain scores over the first fourteen post-operative days were significantly lower for the 'plug and patch' repair, but there was no significant difference in return to normal activity or work. The cost of the prosthesis for the 'plug and patch' repair was greater than that for the Lichtenstein repair. These authors however concluded that the Lichtenstein repair should remain the 'Gold Standard' for open prosthetic repair as surgeons were more familiar with it, the greater costs of the 'plug and patch' repair were not justified by the outcomes, and several authors have cautioned against use of the 'plug and patch' repair for direct inguinal hernias.

1.40 Randomised trials comparing laparoscopic and open sutured repair (excluding the Shouldice repair) (Appendix A.4)

Vogt et al. reported the only randomised trial to compare the IPOM technique alone with an open sutured repair.[192] Although no statistical analysis was provided, the laparoscopic repair was found to have a shorter operation time, less analgesic use and a faster return to normal activity. However, longer-term review of the same patients showed a 43% incidence of recurrence in the IPOM group at a mean follow-up of 41

months.[193] The authors concluded that the IPOM technique should not be used for inguinal hernia repair.

Several randomised trials have compared the TAPP repair with open sutured repair using techniques other than the Shouldice repair.[297,436-438,455,490-492] Several of these trials have excluded patients with either bilateral,[436,437,491,492] or recurrent[436,455,491,492] inguinal hernias. In the study from Maddern et al. there was a significantly greater proportion of patients with bilateral hernias in the laparoscopic group ($p < 0.001$, Chi-squared test).[490] These patients had repair of both hernias at one operation, whereas the patients in the open group had two operations separated by several weeks. In this study the laparoscopic group also had a much lower average age than the open group. In some studies the operation time was significantly longer for the TAPP procedure,[297,436,438,455,491] while others have not found any significant difference.[437,490,492] The majority of studies have recorded lower pain scores after TAPP repair,[297,436,437,438,455] but two studies found no significant difference between groups.[490,492] The open repair group were discharged earlier than the laparoscopic group in two of the three studies which performed the surgery on a day-case basis.[490,491] In the other day-case study Stoker et al. found no significant difference between the groups.[297] In those reports where the surgery was performed on an in-patient basis, there was no significant difference in the time to discharge.[438,455,492] Stoker et al. found a lower incidence of complications following the TAPP repair,[297] but the majority of studies have found no difference in the total number of complications for each group.[436-438,455,490,492] The two largest studies have shown a significantly earlier return to normal activities for the laparoscopic group.[297,455] Lawrence et al. reported a faster return to normal social function in the laparoscopic group,[436] but there was no significant difference in the time to return to work. The smaller studies have demonstrated a trend for an earlier return to normal activity in the laparoscopic group, but the differences did not reach statistical significance.[438,490,492] The only study to show a significant difference in the recurrence rate was that of Dirksen et al.[455] This study had a high incidence of recurrence in the open group after a mean follow-up of two years. However, these repairs had been performed using 'Bassini' technique with an absorbable suture. Kux et al. have also reported an excessively high recurrence rate following Bassini repair with an absorbable suture.[47] Hospital costs were found to be greater for the laparoscopic repair.[297,436,492]

Liem et al. reported a multicentre randomised comparison of the TEP repair with open sutured repair.[294] Patients in this study had unilateral primary or first recurrence inguinal hernias. In the open group a variety of sutured repairs were used for the majority of patients, but 3% were repaired with a prosthesis where it was considered impossible to achieve an adequate repair with a sutured method. Of the 487 TEP repairs performed, twenty-four were converted to TAPP repair or to open repair. There was a greater number of operative complications in the laparoscopic group, 50% of which were related to equipment failure. The laparoscopic group required a shorter hospital stay, had less post-operative pain and returned to normal activity and work more quickly.[294,295] The incidence of early recurrence was also significantly lower in the laparoscopic group. The greatest single cause of post-operative morbidity was chronic pain, which occurred in 14% of the open repairs and 2% of the laparoscopic repairs. It was also reported that while the hospital costs for the laparoscopic repair were significantly greater than for the open repair, 75% of this was offset when considering societal factors such as an earlier return to normal activity.[296]

1.41 Randomised trials comparing laparoscopic and the Shouldice repair (Appendix A.5)

The Shouldice repair has been advocated as the 'Gold Standard' for sutured repair,[484,485] and several randomised studies have been performed to compare it with the laparoscopic repairs. Of the trials to compare laparoscopic repair with the Shouldice repair the one from Bessell et al. is of questionable value.[493] The 'Shouldice repair' described did not include the basic tenet that the transversalis fascia be double breasted. Instead the fascia was approximated to the ilio-pubic tract and this was covered with a darn between the conjoint tendon and the inguinal ligament. Also, of the 104 patients randomised, fifty were allocated to the laparoscopic group. Eighteen patients in this group were initiated as, or converted to, open repair, but have been analysed with the open group rather than by intention to treat.

As with other trials of laparoscopic repair, many of the studies have excluded patients with bilateral,[439,441,456,458] or recurrent[332,441,456,458] inguinal hernias. In the majority of cases the operation time was significantly greater for the laparoscopic repair.[439-441,457,458,493] Pain scores and analgesic use were less for the laparoscopic group in the majority of studies.[439-441,456,458] In a comparison of inflammatory responses Schrenk et al. found no significant difference in the acute phase reactant and cytokine responses to TAPP and Shouldice repair.[425] The total number of complications in each group were also similar.[332,439-441,456-458,493] Bessell et al. reported a shorter day-case hospital stay for the open group,[493] but other studies have found no significant difference between groups for day-case,[457] or in-patient treatment.[439,441,458] Several of the studies reported an earlier return to normal activity and work following laparoscopic repair.[441,456-458] Other studies have, however, found no significant difference between groups.[332,439,493] Kald et al. reported a 3.4% recurrence rate at one year following Shouldice repair compared with no recurrences after laparoscopic repair ($p = 0.04$).[457] The other studies found no significant difference in recurrence rates between groups, although follow-up was relatively short in the majority of them.[332,439-441,456,458,494] The laparoscopic repair was reported to have greater costs in two studies,[441,457] but Lorenz et al. reported that, although hospital costs were greater for the laparoscopic repair, the overall societal costs were greater for the Shouldice repair.[332]

1.42 Randomised trials comparing laparoscopic and open mesh repair (Appendix A.6)

A number of studies have been reported which compare the laparoscopic repairs with open mesh repair, the use of which has grown exponentially in recent years.[442,443,459-461,469,473,494-497] The majority of these studies have compared the TAPP repair with the Lichtenstein repair, but some have compared the TEP repair with open preperitoneal repair[443,461] or with the plug and patch repair.[460]

Analysis of operation times has shown variable results as some studies found a greater time for the laparoscopic repair,[473,496,497] while others found no significant difference.[442,459,460,469] In the comparison of laparoscopic and open preperitoneal repair Champault et al. reported that the operation time for the laparoscopic repair was significantly longer.[443] Wellwood et al. calculated that, when adjustment was

made for co-variates, bilateral repair was quicker laparoscopically than with bilateral Lichtenstein repairs.[442] However, it could be argued that a preperitoneal repair may be a better option for these patients. While several studies have found no significant difference in post-operative pain scores,[461,469,473,495,496] other studies have reported lower pain scores in the laparoscopic group.[442,443,460] Picchio et al. are the only group to report higher pain scores following laparoscopic repair.[497] The majority of studies have recorded a similar total number of complications following open mesh and laparoscopic repair.[459,461,469,473,496,497] Champault et al.[443] and Khoury[460] have, however, found a significantly lower incidence of complications following laparoscopic repair. Two studies reported that hospital stay was greater for the laparoscopic repair in those patients managed as day-cases.[442,469] Champault et al. reported a shorter in-patient stay following laparoscopic repair compared with open preperitoneal repair.[443] Other comparisons of in-patient stay have reported no significant difference between the groups.[495,497]

Payne et al. used a series of exercises to assess the patient's ability to perform physical activities.[459] In the group of patients with physically demanding occupations the straight leg raising performance significantly favoured the laparoscopic group and correlated well with the return to work data. Wellwood et al. reported a 'Short Form 36' assessment of post-operative well-being which showed significant benefits in favour of the laparoscopic group after one month but not after three months.[442] Several studies reported a faster return to normal activity and work following laparoscopic repair,[442,443,459-461] but others have found no significant difference.[473,496] Picchio et al. are the only group to report a slower return to normal activity following laparoscopic repair.[497] None of the studies that have reported recurrence rates have identified a significant difference between groups.[459-461,469,473,494-496] The hospital costs for the laparoscopic repair were greater than those for open mesh repair.[442,459,461,469,473] Heikkinen et al. also considered the community costs and calculated that, as the laparoscopic repair allowed an earlier return to normal activity, the total costs were less for the laparoscopic repair.[469]

In a metanalysis of the laparoscopic versus open randomised controlled trials Chung and Rowland reported that, compared with sutured repair, the laparoscopic repairs took significantly longer to perform.[498] However, they did result in less post-operative

pain and an earlier return to normal activity. When compared to the open prosthetic repairs the laparoscopic repair had no advantages in terms of post-operative pain but there were marginal advantages in terms of the recovery period. Compared to open sutured and prosthetic repair the TAPP repair was found to have a similar incidence of early recurrence. The EU Hernia Trialists Collaboration have also published a metanalysis of randomised trials comparing laparoscopic and open methods of groin hernia repair.[499] They concluded that the laparoscopic repairs produced less post-operative pain and a faster return to normal activity but required a longer operation time and were associated with an increased risk of rare, but serious, complications.

1.43 Randomised trials comparing different laparoscopic repairs

Schrenk et al.[439] have published data on a series of patients with primary unilateral inguinal hernias randomised to Shouldice repair, TAPP repair or TEP repair (Appendix A.4). Due to the nature of the report direct statistical comparison of the two laparoscopic approaches is not provided for much of the data. Mean operation time and hospital stay were both longer for the TEP repair. The incidence of post-operative complications was similar for TAPP and TEP repair. Post-operative pain scores were significantly greater in the TEP group on the day of surgery and on the first post-operative day, but thereafter there was no difference in the pain scores. The time off work was similar for the two groups. There was one early recurrence in the TAPP group and none in the TEP group. Sarli et al. have reported a randomised comparison of the TAPP and IPOM techniques.[500] This study showed a much higher incidence of post-operative neuralgia and recurrence in the IPOM group. In keeping with other authors who have reported on the outcome following IPOM repair,[193] Sarli et al. concluded that the IPOM technique should be avoided.

CHAPTER TWO

THE TOTALLY EXTRAPERITONEAL LAPAROSCOPIC REPAIR

2.1 Preperitoneal inguinal anatomy

At laparoscopy a number of peritoneal folds may be identified on the anterior abdominal wall. In the midline the remains of the urachus form the median umbilical ligament, which runs from the apex of the bladder towards the umbilicus. On either side of the midline the medial umbilical ligaments can be identified. These fibrous cords represent the remains of the foetal umbilical arteries and have been advocated as a guide to the limit of medial dissection of the peritoneum to avoid bladder injury.[501] The inferior epigastric vessels may also produce a peritoneal fold called the lateral umbilical ligament.

On the upper and inner aspect of the superior pubic ramus the periosteum is supplemented by dense fibrous tissue to form Cooper's ligament. The iliopubic tract is a band of fibrous connective tissue running from the iliopectineal arch laterally to the pectineal line on the superior pubic ramus, and is in continuity superiorly with the transversus abdominus aponeurosis. The medial attachment of the tract lies just anterior to Cooper's ligament and fans out to form the medial border of the femoral ring. There has been debate as to the existence of the iliopubic tract as a discrete structure but Condon described the iliopubic tract as a separately identifiable structure in 98% of 135 male groin dissections,[502] and this has convinced other surgeons of its existence.[501,503] From the preperitoneal perspective, the inferior margin of the inguinal canal is formed by Cooper's ligament and the iliopubic tract. The superior margin of the canal is formed by the transversus abdominus arch, which is formed by the lower border of the transversus abdominus aponeurosis. The arch curves laterally from the rectus sheath and passes just above the deep inguinal ring. Medial to the deep ring the aponeurosis normally becomes muscular and these fibres insert into the ilium and iliacus fascia. Lying deep to the transversus abdominus aponeurosis is the transversalis fascia and this forms part of a connective tissue sheet lining the musculature of the abdominal cavity. It is this layer that forms the majority of the posterior wall of the inguinal canal.

The inferior epigastric vessels arise from the external iliac vessels just proximal to the inguinal ligament. They curve forward in the extraperitoneal tissue and ascend obliquely along the medial margin of the deep inguinal ring. Piercing the transversalis

fascia they pass in front of the arcuate line to enter the rectus sheath. A number of branches are distributed to the abdominal wall muscles and so, to avoid bleeding during preperitoneal dissection, it is important not to pull the vessels away from the muscle layer. The inferior epigastric vessels form the lateral margin of Hesselbach's triangle. The medial margin of the triangle is formed by the lateral border of the rectus abdominus muscle, and the inferior border is parallel to the inguinal ligament. Direct inguinal hernias pass through Hesselbach's triangle. The inferior epigastric vessels therefore provide a landmark during dissection to differentiate direct and indirect inguinal hernias. Aberrant obturator vessels have been recorded in 25% of patients, although some series have reported a much higher incidence.[504] These vessels may run medial to, lateral to, or directly across the femoral ring before crossing over Cooper's ligament to enter the obturator canal. Aberrant veins are more common than aberrant arteries and these represent a particular risk in laparoscopic surgery as they may not bleed significantly until the space is desufflated.[504] The retropubic space may also contain aberrant vessels arising from the urinary bladder.

In the male patient the vas deferens runs from the scrotum through the inguinal canal as part of the cord structures. On passing through the deep ring the vas leaves the other cord structures and curves around the lateral side of the inferior epigastric vessels. It then ascends for approximately two centimetres anterior to the external iliac artery before turning backward and downward to cross the external iliac vessels and enter the lesser pelvis. The gonadal vessels run downwards and laterally on the anterior surface of the psoas muscle then cross the iliac fossa to unite with the vas deferens at the level of the deep inguinal ring. On their approach to an apex at the deep ring the gonadal vessels form the lateral border of a triangle, and the vas deferens forms the medial border. Spaw described this region as the 'Triangle of Doom' because it contains the external iliac artery and vein, which are at risk of injury if the area is dissected or stapled.[505] In the female patient, the round ligament of the uterus traverses the deep ring. This narrow, flat band commences at the lateral angle of the uterus and passes between the layers of the broad ligament. After crossing the external iliac vessels the ligament passes through the deep ring to run within the inguinal canal.

The area lateral to the gonadal vessels and below the iliopubic tract has been named the 'Electrical Hazard Zone' because it contains nerves that are at risk if staples are placed in this area.[501] The femoral nerve is the largest branch of the lumbar plexus and descends through the fibres of the psoas muscle. It emerges at the lower part of the lateral psoas border and passes between it and the iliacus muscle, deep to the iliacus fascia. It then passes behind the inguinal ligament and divides into anterior and posterior divisions. Behind the inguinal ligament the nerve lies lateral to the femoral artery and is separated from it by part of the psoas major. The nerves most at risk of injury appear to be the lateral cutaneous nerve of the thigh and the femoral branch of the genitofemoral nerve.[506] The lateral cutaneous nerve of the thigh emerges from the lateral border of the psoas major and crosses the iliacus muscle, running towards the anterior superior iliac spine. It then passes either behind or through the inguinal ligament approximately two centimetres medial to the anterior superior iliac spine. The femoral branch of the genitofemoral nerve arises from division of the nerve on the psoas muscle and it continues downwards on the muscle surface, lying approximately one centimetre lateral to the iliac artery and passing behind or through the inguinal ligament. None of these three nerves may normally be seen during the dissection for laparoscopic inguinal hernia repair but they can be exposed by sweeping away the loose areolar tissue forming the iliacus fascia over the iliac and psoas muscles. The genital branch of the genitofemoral nerve crosses the 'Triangle of Doom' and passes through the deep ring to run alongside the cord in the inguinal canal. The Electrical Hazard Zone also contains the deep circumflex iliac vessels, which arises from the external iliac vessels.

2.2 The method of totally extraperitoneal laparoscopic repair

The totally extraperitoneal (TEP) laparoscopic hernia repair is the endoscopic equivalent of the open preperitoneal approach. In addition to the repair of primary, unilateral groin hernias this technique may therefore be used for bilateral and recurrent defects. Contraindications to the TEP repair include previous extensive lower abdominal surgery or the presence of an irreducible hernia. A large inguino-scrotal sac or a defect greater than five centimetres diameter are also relative contra-indications due to the technically difficult involved in reducing the sac and in placing the large piece of mesh required to cover the defect.[269] The use of antibiotics for

hernia repair is contentious, but the majority of surgeons do still use a single prophylactic dose when performing a prosthetic repair.[319] The use of deep venous thrombosis prophylaxis should be in line with current guidelines.[507] Before attempting the TEP repair it is important to ensure that the patient's bladder is empty. Although some surgeons may catheterise the patient for the duration of the operation this is not usually necessary if the patient is asked to micturate before entering the operating suite. Although TEP repair can be performed under local or regional anaesthesia,[346,350,351] most surgeons prefer a general anaesthetic with full muscle relaxation.

The patient should be placed on the operating table in a supine position, with a 15^0 Trendelenburg tilt. Both arms should be placed by the patient's side to allow the operator and assistant to stand on opposite sides of the table at the level of the patient's epigastrium. The operator stands on the contralateral side to the hernia. The monitor(s) is positioned at the foot of the table.

A 1.5cm vertical incision is made in the midline extending inferiorly from the lower margin of the umbilicus. The subcutaneous tissues are then separated with forceps and Langenbeck's retractors used to expose the anterior rectus sheath on the side of the hernia. A 1cm transverse incision is made in the sheath at this level. The edge of the rectus muscle is retracted laterally from the midline and forceps used to develop the space between the muscle and the posterior rectus sheath. A 10mm blunt-nosed (Hasson) trocar is inserted and moved medially, laterally and posteriorly to develop the preperitoneal space. If necessary, the skin around the cannula may be sealed with a stitch. Insufflation with carbon dioxide is commenced, with the maximum pressure set to 12mmHg.[240] Once insufflation is complete a 0-degree laparoscope is inserted and this can be gently used as a blunt dissector to further develop the preperitoneal space. During this dissection it is important to be aware of the position of the pubic symphysis, while staying in the midline behind the rectus muscle. Once the pubic arch is visible two further 5mm trocars are inserted in the midline. These trocars are 60mm in length and have a fixation thread to prevent their movement when changing instruments. The trocars are placed one third and one half of the way between the symphysis pubis and the umbilicus. It is not our practice to use a balloon to develop the extraperitoneal space.

Having developed the space Cooper's ligament is next exposed on the ipsilateral side to the hernia. Two dissectors that will grasp, but not tear, the peritoneum are required to continue the dissection. A pair of dissecting scissors may also be required. The external iliac vein will be visible laterally and the accessory obturator vessels, if present, will be seen crossing Cooper's ligament. The avascular plane between the perivascular and extraperitoneal fat is developed using blunt dissection. The CO_2 insufflation pressure usually aides this procedure. The retropubic space can now be further developed in the midline and then extended laterally towards the side of the hernia, above the level of the obturator nerve and vessels. The inferior epigastric vessels are identified and the space between them and the extraperitoneal fat developed. It is important to use one dissector to hold the epigastric vessels up against the rectus muscle while performing this dissection to avoid damaging small branches which run into the muscle. Lateral to the inferior epigastric vessels the lateral margin of the condensed transversalis fascia, which forms a U-sling around the cord structures, is encountered. To facilitate access to the space lateral to the deep ring the fascia is best divided with a combination of sharp and blunt dissection. The lateral dissection should extend to level of the anterior superior iliac spine.

If present, a direct inguinal hernia sac will be encountered during the dissection to develop the extraperitoneal space. The defect lies within Hesselbach's triangle lateral to the rectus muscle and medial to the inferior epigastric vessels. The direct sac and extraperitoneal fat are usually easily reduced with traction using forceps. When the hernia sac is reduced the characteristic appearance of a pseudosac, the attenuated transversalis fascia, can be seen. This should be allowed to fall back into the defect. Once reduced there is no requirement to open or ligate the sac. The cord must then be examined at the deep ring to exclude a synchronous indirect sac. Femoral hernias should be reduced in the same way as direct inguinal hernias.

Having developed the extraperitoneal space it should be possible to identify the sac of an indirect inguinal hernia. The hernia will be found to lie immediately lateral to the inferior epigastric vessels as it passes through the deep ring. The sac should be reduced by grasping it and breaking down the adhesions to the inguinal canal. Tension needs to be kept on the sac during this part of the dissection. This is achieved by using the forceps in a step-wise fashion, otherwise the sac will return to the

inguinal canal when it is released. It is important to clear all of the attachments of the sac as far back as the junction with the peritoneum. Once this has been achieved the sac can be lifted up and the vas deferens will be visible at the posterior border. The vas can be dissected free from the sac, along with the testicular vessels, such that it can be seen descending into the pelvis. It is important to avoid grasping the vas deferens as this may be a cause of chronic post-operative pain. In small to moderate sized hernias it is possible to reduce the entire sac out of the inguinal canal. If the sac is large and entering the scrotum it is preferable to transect it at an appropriate point as this will reduce the risk of injury to the cord structures. The open end of the distal sac is left in situ.

The final space developed should extend laterally to the anterior iliac spine and medially beyond the midline. For bilateral hernias the operator can then change to the other side and repeat the process to reduce the contralateral hernia. There is no requirement to reposition the port sites to do this. An open weave, monofilament polypropylene mesh is used to repair the hernia defect. The mesh should be at least 10x15cm in size with the corners rounded to facilitate placement within the preperitoneal space. The rolled mesh is introduced blindly via the subumbilical port and pushed down into the retropubic space with the laparoscope. The mesh is then unrolled using the forceps and placed to cover all the sites of potential defects. This is achieved by grasping the mesh with one forceps and using the other to push the mesh into the desired position. The mesh should overlap the edges of the hernia defect by at least three centimetres,[262] and inferiorly should cover the vas and testicular vessels by at least two centimetres. The edge of the mesh must sit clear of the peritoneal reflection. Medially the mesh should cover Cooper's ligament and also extend beyond the midline. Laterally it should extend to the level of the anterior superior iliac spine. There is no need to divide the mesh to fit around the cord. For indirect hernias and small direct hernias there is no requirement to staple the mesh. If there is a large posterior wall defect present the mesh should be stapled or sutured to Cooper's ligament. This prevents the lower border of the mesh slipping up into the defect. To staple the mesh one of the 5mm ports is removed and replaced with a 12mm port. Two or three staples are then used to fix the mesh to Cooper's ligament. Additional sutures into the rectus muscle medially and the transversalis fascia laterally do not add any further strength to the repair, and carry the risk of nerve

injury. It is possible to avoid changing the ports by using a 5mm 'spiral tacker' (Origin Medsystems Inc., Melno Park, California,USA) or a prolene suture to fix the mesh. On desufflation of the extraperitoneal space it is important to ensure that the lower edge of the mesh does not roll up with the peritoneum. After desufflation the ports are removed and the rectus sheath at the subumbilical wound is closed with a vicryl suture. The skin is then closed with absorbable subcuticular sutures.

2.3 Assessment of the learning curve for laparoscopic repair

2.3.1 Introduction

It has become clear that the learning period for many laparoscopic procedures is relatively long, even for surgeons who have had ample experience of the corresponding open procedure.[289,292,508] During this learning period the outcomes achieved may fall below the standards reported by surgeons with more experience of the technique, and also below those of the comparative open technique. In addition, to optimise outcome, surgeons should be able to deal with the technical difficulties and complications that may arise during the procedure and in the post-operative period. Rutkow has suggested that the technical difficulty involved in performing a particular technique should be considered when comparing different forms of inguinal hernia repair.[509] As the learning curve will reflect the degree of difficulty in performing the laparoscopic repair, it may therefore be of importance in determining the place of laparoscopic surgery in the hernia surgeons' practice.

2.3.2 Patients and methods

In order to assess the learning curve for the totally extraperitoneal inguinal hernia repair the initial experience of three surgeons was examined. The participants were already experienced in other laparoscopic procedures such as cholecystectomy. For each surgeon the early cases were supervised and instructed by a single consultant surgeon who was experienced in the technique of TEP repair. Supervision was continued until both the surgeon and trainer felt confident that the procedure could be completed satisfactorily. The three surgeons were not allowed to randomise patients

within the trial to compare laparoscopic and open hernia repairs until they had completed at least ten laparoscopic repairs.

All adult patients with inguinal or femoral hernias were eligible for this study unless they met one of the exclusion criteria for the main trial. These were that the patient was medically unfit for a general anaesthetic, had a previous lower midline or paramedian incision, had an incarcerated or inguino-scrotal hernia, had an uncorrected coagulation defect, or the patient was pregnant. Following discharge patients were reviewed at the out-patient clinic one week after the operation. If they had no problems at that time arrangements were made for clinical review one year later. Patients were provided with a contact telephone number to allow them to reach the research team if they became aware of any difficulties in the interim.

The first thirty cases for each of the three surgeons were included in the study. These were divided into groups of ten for the purposes of analysis ie. case 1-10, case 11-20 and case 21-30. Data were collected on total operation time (from first incision to placement of the final suture), incidence of conversion to another procedure and the reason for conversion, and the incidence of early recurrence. Comparison of operation times was performed using a one-way analysis of variance. Incidence of conversion and recurrence were analysed using the chi-squared test.

2.3.3 Results

Table 2.1 shows the median and range of operation times for each individual surgeon and the combined results for all three surgeons. For Surgeon 1 and Surgeon 3 there was an identifiable reduction in operation time with increasing experience of the procedure. This trend was not seen for Surgeon 2 where the median operation time increased following the first ten cases. Analysis of the change in operation times for the group as a whole showed a reduction in median operation time by fifteen minutes between cases 1-10 and cases 21-30 ($p = 0.04$). The trend for individual surgeons did not reach statistical significance. For all three surgeons there was a greater reduction in the maximum operation time than was found for the median operation time.

Table 2.1: Change in operation time with progression along the learning curve

Case Group	Surgeon 1	Surgeon 2	Surgeon 3	Cumulative Results*
Cases 1-10	77.5min (50-160)	74min (50-152)	70min (60-175)	75min (50-175)
Cases 11-20	72.5min (45-90)	81min (60-100)	66min (51-120)	75min (45-120)
Cases 21-30	60min (55-90)	81min (45-100)	60min (42-74)	60min (42-100)

Values given are median with range given in parenthesis.
*One-way analysis of variance, p=0.043

The incidence of conversion to another procedure is shown in Table 2.2. There were a total of thirteen cases converted from TEP repair to another procedure. Two of these cases were converted to a TAPP repair and the other eleven to an open procedure. The cumulative results for conversion show a reduction in incidence between the first twenty cases and cases 21-30. The differences for individual surgeons, and for the group as a whole, did not reach statistical significance. The most common reason for conversion to another procedure was the creation of a tear in the peritoneum (eight cases), with resulting pneumoperitoneum and loss of the preperitoneal operating space. In two cases the surgeon encountered difficulty in adequately reducing the hernia, and in a further two cases there was difficulty in defining the preperitoneal anatomy. One patient was converted due to technical difficulties with the laparoscopic equipment.

The incidence of early recurrence for individual surgeons and the cumulative results are shown in Table 2.2. The majority of early recurrences (four) occurred in the group of cases 1-10. There was a subsequent reduction to one in cases 11-20, and two in cases 21-30. The trend for individual surgeons and for the group as a whole did not reach statistical significance.

2.3.4 Discussion

The learning curve for the TEP inguinal hernia repair has been evaluated using the outcome of the first thirty patients from three separate surgeons. The results show a trend of reduction in operation time for the first thirty cases suggesting that the learning curve for laparoscopic hernia repair is at least this long. Surgeon 2 demonstrated an increase in operation time following the first ten cases. This corresponded with the withdrawal of supervision by the more experienced surgeon and it is therefore possible that supervision was withdrawn too early. There was also a trend for a reduction in the incidence of conversion to another procedure following the first twenty cases. The main reason for conversion to another procedure during the first thirty cases was the creation of a hole in the peritoneum during dissection. The incidence of recurrence was highest early in the series but early recurrences also occurred in cases 21-30. This again suggests that the learning curve for TEP inguinal hernia repair was of the order of at least thirty cases.

Table2.2: Incidence of conversion and recurrence with progression along the learning curve

Case Group	Surgeon 1		Surgeon 2		Surgeon 3		Cumulative Results	
	Con	Rec	Con	Rec	Con	Rec	Con	Rec
Cases 1-10	2	1	3	2	1	1	6	4
Cases 11-20	2	0	2	1	2	0	6	1
Cases 21-30	0	1	0	1	1	0	1	2

Con: conversions, Rec: recurrences at one year

The results from this study are similar to those reported for the COALA Trial, which is the only other formal report of the learning curve for laparoscopic inguinal hernia repair in the literature.[258] Both studies have shown a significant reduction in operation time over the first thirty cases. The numbers of intra-operative conversions to another type of repair and reasons for conversion are also similar between the two studies. In both groups the most common reason for conversion to another form of repair was the creation of a rent in the peritoneum with subsequent loss of the operating space. The COALA Trial reported ten recurrences in one hundred and seven patients who had reached six months follow-up since their hernia repair. It was felt that most of the recurrences were due to surgical errors. Within the current study there has been a similar incidence of early recurrences.

There are a number of technical points that will improve as a surgeon proceeds along the learning curve for laparoscopic inguinal hernia repair. A thorough understanding of the preperitoneal anatomy is a pre-requisite for effective extraperitoneal groin hernia repair as full exposure of the relevant anatomical structures and assessment of all of the potential hernial orifices is required. Failure to fully assess all of the potential sites of hernia may result in a missed hernia. This has been defined as "repair of an isolated hernia defect but with incomplete evaluation and failure to repair a co-existing hernia in the ipsilateral groin".[262] The pre-peritoneal plane of dissection is unfamiliar to many surgeons when they begin laparoscopic hernia repair and so they will acquire increasing understanding of the anatomical planes during their initial experience of the technique. In addition, as the results of this study and the COALA trial have highlighted, correct tissue handling is also of great importance. Until this skill is developed there is an increased risk of damaging the peritoneum during the TEP repair which may lead to an inability to complete the procedure.

Lateral dissection is the area most commonly performed inadequately during the early phase of the learning curve for laparoscopic preperitoneal hernia repair. The surgeon must also take care to adequately reduce the hernia to allow correct placement of the mesh inferiorly, where it should lie flat on the pelvic floor. Inadequate dissection may result in rolling of the mesh and this increases the risk of subsequent recurrence. The exposure must allow the fascial edges of the hernia defect to be clearly defined. Incomplete dissection leads to a number of secondary mechanisms of recurrence

including placement of too small a piece of mesh or incorrect positioning of the mesh. Placement of a small piece of mesh over an isolated defect may result in recurrence for a number of reasons. Firstly, a small piece of mesh may prolapse into the hernia space if there is inadequate overlap of the edges of the defect. It has been stated that the mesh overlap should be at least two centimetres if the mesh is stapled, and three centimetres if it is not fixed.[262,263] Secondly, subsequent migration or shrinkage of the mesh due to fibrous in-growth will predispose to recurrence if the initial overlap of mesh was too small. The mesh must also cover the entire inguinal and femoral area to protect against subsequent recurrence due to enlargement of the original defect, or formation of a secondary hernia at a related site due to a generalised weakness of the entire area. It is now apparent that a mesh size of at least 15cm x 10cm is required to minimise the risk of recurrence.[249,262,263,273] The change in the recommended size of mesh to be used reflects progression along the learning curve for the surgical community as a whole.

The use of videodocumentation has been recommended to allow surgeons to identify the probable causes of operative and post-operative problems. Scheyer and Zimmermann reported on the retrospective analysis of problems arising in a series of two hundred and forty-five hernia repairs using video tapes recorded at the time of operation.[510] They concluded that the three recurrences they had suffered were due to use of too small a piece of mesh. It was also claimed that videoanalysis had helped reduce the post-operative complication rate from 21% to 1.6%. Lowham et al.[262] have also used videotapes to analyse the cause of thirteen of the recurrences reported in the multicentre trial of Fitzgibbons and colleagues.[191] The primary causes of recurrence identified in this study in order of prevalence were; incomplete dissection (six cases), inadequate mesh overlap (four cases), inadequately sized mesh (two cases) and inadequate re-approximation after mesh splitting to allow it to be passed around the cord (one case).

2.3.5 Surgeons attitude towards the TEP repair

Rutkow has suggested that the technical difficulty in performing any particular form of hernia repair should be included in its evaluation.[509] In the period before commencement of this study one experienced surgeon was involved in teaching the

TEP repair to a total of twelve consultant surgeons who had expressed an interest in taking part in the trial. Of these surgeons only six went on to randomise patients within the trial. One further surgeon who had previous experience with the TAPP repair was also tutored in the TEP repair. He subsequently elected to continue with the TAPP technique as he felt it was less difficult to perform. There was therefore a relatively low uptake of the procedure amongst experienced surgeons even after tuition from a surgeon experienced in the technique. Post-trial only three surgeons continue to perform the TEP repair for selected cases. These observations may reflect the relative technical difficulty of the laparoscopic inguinal hernia repair.

CHAPTER THREE

A PROSPECTIVE RANDOMISED TRIAL TO ASSESS LAPAROSCOPIC HERNIA REPAIR

3.1 Introduction

Groin hernia repair is one of the most common elective procedures performed in general surgery and rates range from ten per 10,000 of the population in the United Kingdom to twenty-eight per 10,000 of the population in the USA.[511,512] Long-term follow-up indicates that, outwith specialist centres, 10-30% of all sutured inguinal hernia repairs may fail,[26,193,317,454,455,480,483,484,486] and 50-60% of these will cause symptoms.[42,317] Due to apparent low recurrence rates the techniques of tension-free prosthetic repair, via either an anterior[125] or preperitoneal approach,[160] have gained wide acceptance. The preperitoneal prosthetic repair has been advocated as the procedure of choice for recurrent and bilateral hernias.[160] In contrast, other investigators have argued that prosthetic material is not required for the repair of an indirect inguinal hernia with a normal posterior inguinal wall. It has therefore been recommended that the hernia repair used should be tailored to the patient and to the type of hernia present.[513] The use of laparoscopic methods for groin hernia repair remains controversial. Good short-term results have been reported in the hands of enthusiasts but concerns remain over factors such as long-term outcome and costs. This study was designed as a pragmatic multicentre, randomised controlled comparison of current open versus laparoscopic methods of groin hernia repair.

3.2 Patients and methods

This multicentre trial involved the participation of twenty-seven consultant surgeons from twenty-six hospitals throughout the United Kingdom and Ireland. Study approval was given by all of the relevant local research ethics committees. Before commencing randomisation each surgeon was required to have performed at least ten laparoscopic inguinal hernia repairs. During this learning period an experienced surgeon visited those participants who felt that they required further advice with regard to the laparoscopic technique. Additional training and supervision of cases was thus provided until the surgeon was comfortable with the procedure.

Patient recruitment was commenced in January 1994 and was continued through to March 1997. All adult patients with an inguinal or femoral hernia were eligible for the trial unless they met one of the exclusion criteria. These were that the patient: was

medically unfit to receive a general anaesthetic, had a previous lower abdominal midline or paramedian incision, had an incarcerated or inguino-scrotal hernia, had an uncorrected coagulation disorder, or the patient was pregnant. The first 227 randomised patients were assigned using a sealed envelope technique, with computer-generated random allocation stratified by surgeon. The remaining 701 randomised patients were allocated through a centralised telephone service based at the Health Services Research Unit in Aberdeen. This randomisation was stratified by consultant surgeon, with minimisation (randomisation balanced with respect to specific variables) on patients' age (within specific bands), sex, site and type of hernia, and whether or not the hernia was recurrent. Within the randomisation structure the choice of repair for each patient was determined by the surgeon involved. For patients randomised to the laparoscopic group the repairs performed used the transabdominal preperitoneal (TAPP) approach or the totally extraperitoneal (TEP) technique. For patients randomised to the open group the surgeon was free to use the repair that was felt to be most appropriate for the individual patient and hernia defect present. The patients were not blinded to the type of repair they received as this was felt to be impracticable. DVT prophylaxis was used in line with current recommendations,[507] and the use of antibiotic prophylaxis was left to the discretion of the individual surgeon. All of the laparoscopic repairs within the study were performed under general anaesthesia. As part of the process of individualisation of the repair to the patient and hernia type the choice of anaesthesia for open repair was left to the discretion of the surgeon.

The principal outcome measures to be considered by the trial were: the total number of complications, time to return to normal activity, hernia recurrence, incidence of chronic groin pain, and costs to the National Health Service. Other outcome measures also assessed included: total anaesthetic time (from patient entering anaesthetic room to leaving theatre), total operation time (from first incision to placement of last suture), and hospital stay. Data were collected prospectively on a standard form to record pre-operative, operative and post-operative indices (Appendix B). The surgeons were asked to discharge their patients when clinically appropriate and out-patient review was then performed one week post-operatively. In the main recruitment centres of Glasgow and Edinburgh the Research Fellow (myself) or one of two trained Research Nurses performed this review. In the other centres the

surgical team involved with the procedure performed the review. A questionnaire was sent to all participants three months after the operation. This contained questions about return to normal activity, a general health assessment instrument (Short Form 36),[514-516] hernia specific items, and some questions related to the use of resources (Appendix C). A linear analogue pain score was also included in the questionnaire. All participants in the trial were invited to attend for clinical review at yearly intervals. It is intended that each patient be followed post-operatively for a period of five years.

Within a multicentre trial inter-investigator differences may mask true differences between the groups being studied, or alternatively create differences which may not be valid. In addition the outcome data may be skewed by the results of the less experienced surgeons within the trial group due to a learning curve effect. Therefore, in addition to the main trial, a prospective analysis was made of 300 patients randomised by a single surgeon within the trial. This surgeon already had experience of over one hundred laparoscopic inguinal hernia repairs at the time of commencing the study. Within this sub-group all patients were given prophylactic subcutaneous heparin peri-operatively and intravenous antibiotics on induction of anaesthesia. In the open randomisation group patients with a Nyhus type I defect had herniotomy and tightening of the deep ring. Those with unilateral Nyhus type II or IIIa/b hernias had a Lichtenstein repair, and those with recurrent or bilateral hernias had an open preperitoneal mesh repair through a transverse lower abdominal incision (Table 3.6). The majority of patients in the endoscopic group had a TEP repair using a polypropylene mesh (15 x 10cm). In larger Nyhus type III and in type IV defects the mesh was fixed using staples, but this was not considered necessary for other defects. Laparoscopic bilateral hernia repairs were repaired using two separate pieces of mesh. All of the data recorded within the main trial were also recorded for this group of patients. In addition the patients also completed the follow-up questionnaire (Appendix C) at one week and one month after their operation.

Economic analysis

Certain elements of the cost analysis were determined from within the randomised, controlled trial. These factors include the length of operation and the length of hospital stay. The marginal cost for laparoscopic repair for these factors was then

calculated. Data on utilisation of resources was collected from observation of sixteen laparoscopic and ten open repairs performed in six of the main centres within the randomised trial (contributing 74% of the study population). Items of resource use were valued according to financial data from each centre, information from equipment suppliers and available literature sources (1997–98 prices). The cost of surgical staff was based on each theatre team and the grade of the surgeons operating. Overheads and capital charges were allocated on the basis of proportionate use of equipment and theatre space. Costs of reusable equipment were calculated on an annual basis, with a 6% discount rate, according to lifespan and use.

3.3 Statistical analysis

All data were analysed by intention to treat. For the main study between-group differences were expressed, where appropriate, with 95% confidence intervals (CI) for the primary outcome measures. Secondary outcome measures were expressed with 99% confidence intervals, which reflect the more exploratory nature of these analyses. Length of hospital stay was analysed using the Mann-Whitney U-test. Kaplan-Meier survival analysis and the log-rank test were used to measure return to normal activity.

In order to identify an absolute difference of 3% in the rates of recurrence with 80% power (two-tailed $p<0.05$), on the basis of an expected recurrence rate of 4% in the open repair group, it was calculated that 1000 patients would be required in each group. However, during the recruitment period the sample size was reduced from the originally estimated 2000 patients to 1000 patients. The reason for this was that the pooled estimate of the rate of recurrence was much lower than originally expected. In the period between setting up the trial and its commencement most surgeons had changed what they deemed to be their best open repair from a sutured repair to a prosthetic repair. The predicted recurrence rates were much lower for the prosthetic repair (1%), and this meant that the predicted absolute difference of 3% could be confidently identified with the smaller sample size.

3.4 Results

3.4.1 The multicentre trial

The multicentre study identified 1619 potentially eligible patients with a groin hernia, of which 928 patients were randomised. The main reasons for non-randomisation were: 159 (23%) patients who met exclusion criteria for the trial, 132 (19%) cases where the surgeon had not completed ten laparoscopic repairs, 121 (18%) cases where the patient refused to take part, 99 (14%) cases where randomisation envelopes were spoiled, and 92 (13%) cases where the surgeon did not wish to randomise the patient.

The demographic details for the two groups of randomised patients were similar at the time of recruitment into the trial (Table 3.1). Of the 468 patients randomised to the laparoscopic repair 419 (90%) had a laparoscopic repair initiated. 321 (77%) of these were TEP repairs and 98 (23%) were TAPP repairs. 31 (7.4%) of the laparoscopic repairs were converted to open repair. The reasons given for conversion were: a peritoneal tear (8 cases), an irreducible hernia (7 cases), presence of scars or adhesions (5 cases), equipment failure (5 cases), vascular or visceral injury (3 cases), and difficulty with placement of the mesh (1 case). In two cases no reason was given for conversion. The majority (94%) of repairs in the open group involved the use of mesh. Other open repairs used included the Shouldice repair, the Bassini repair, plication darn and herniotomy with tightening of the deep ring.

The mean operation time for the laparoscopic repair was fifteen minutes longer than that for the open repair (58min vs 43min; 99% CI: 12 to 18min). Operative complications (Table 3.2) occurred in 25 (5.3%) of the patients in the laparoscopic group and in 6 (1.3%) of the patients in the open repair group (difference 4%; 95% CI: 1.8% to 6.6%). Three major complications were identified in the laparoscopic group, all of which were associated with the TAPP repair. These were: injury to the lateral cutaneous nerve of thigh, a bladder injury, and a trocar injury to the left common iliac artery. In the open group a small bowel serosal tear was created during preperitoneal repair of a complex recurrent hernia. All of these complications were

identified at the time of operation and dealt with appropriately with no further complication.

The median post-operative stay was one day in each group, but a significantly greater proportion of patients in the open group required to stay for more than one day (32% vs 23%, p = 0.008). In some centres it was impractical to perform clinical review at one week. This was therefore performed for 361 (92%) of 394 possible patients in the laparoscopic group, and 356 (92%) of 388 possible patients in the open repair group (Table 3.3). At least one complication was reported in 107 (30%) of the laparoscopic repair patients, and in 155 (44%) of the open repair patients (difference -14%; 95% CI: –21% to –7%). One patient, who had a TAPP repair, developed a small bowel obstruction. At laparotomy a loop of small bowel was found to have become adherent to one of the clips used to close the peritoneum.

Table 3.4 shows the time taken to return to normal activities for the two groups. The time taken to return to normal social life, housework, hobbies and employment were all significantly shorter in the laparoscopic group. At three months after surgery there were no significant differences between the groups in any of the 'Short Form 36' general health domains.

Clinical review was performed at one year in 77% of the laparoscopic group and 74% of the open group (Table 3.5). Seven (1.9%) recurrences were identified in the laparoscopic group within the first year of follow-up and there were no recorded recurrences in the open group for the same period (difference 1.9%; 95% CI: 0.5% to 3.4%). There was no difference between groups in the incidence of testicular atrophy. Two patients in the laparoscopic group, both of whom had a TAPP repair, developed a port site hernia.

Table 3.1: Demographic details of patients randomised in multicentre trial

	Laparoscopic (n = 468)	Open (n = 460)	P
Mean (SD) Age (yrs)	55.3 (16.8)	55.7 (16.8)	n.s.
Sex :			
Male	441 (94.2%)	445 (96.7%)	
Female	27 (5.8%)	15 (3.3%)	n.s.
Type of hernia:*			
Inguinal	444 (98.0%)	442 (99.1%)	
Femoral	9 (2.0%)	4 (0.9%)	n.s.
Site of hernia:**			
Right	241 (52.4%)	233 (51.8%)	
Left	187 (40.4%)	180 (40.0%)	
Bilateral	33 (7.2%)	37 (8.2%)	n.s.
Recurrent hernia:***			
Yes	56 (12.2%)	42 (9.3%)	
No	404 (87.8%)	409 (90.7%)	n.s.

n.s. – not statistically significant at the 5% level
* data missing for fifteen of laparoscopic group and fourteen of open group
** data missing for seven of laparoscopic group and ten of open group
*** data missing for eight of laparoscopic group and nine of the open group

Table 3.2: Intraoperative complications in patients from multicentre trial

	Laparoscopic (n = 468)	Open (n = 460)	% Difference (99% CI)
Injury to vas or testicular vessels	5 (1.1%)	3 (0.7%)	0.4 (-1.2 to 2.0)
Nerve injury	1 (0.2%)	0	0.2 (not calculated)
Visceral injury	1 (0.2%)	1 (0.2%)	0 (-0.8 to 0.8)
Vascular injury	1 (0.2%)	0	0.2 (not calculated)
Injury to epigastric vessels	16 (3.4%)	1 (0.2%)	3.2 (1.0 to 5.5)
Diathermy burn	1 (0.2%)	1 (0.2%)	0 (-0.8 to 0.8)

Table 3.3: Clinical outcome at one week in patients from multicentre trial

	Laparoscopic (n = 361)	Open (n = 356)	% Difference (99% CI)
Wound Complications:			
Seroma	24 (6.6%)	38 (10.7%)	-4.0 (-9.4 to 1.5)
Haematoma	27 (7.5%)	56 (15.7%)	-8.2 (-14.3 to –2.0)
Infection	10 (2.8%)	11 (3.1%)	-0.3 (-3.6 to 3.0)
Scrotal Complications:			
Hydrocoele	5 (1.4%)	3 (0.8%)	0.6 (-1.5 to 2.8)
Haematoma	18 (5.0%)	19 (5.3%)	-0.3 (-4.7 to 4.4)
Genital oedema/ orchitis/epididymitis	27 (7.5%)	34 (9.6%)	-2.1 (-7.7 to 3.6)
General Complications:			
Urinary retention	10 (2.8%)	7 (2.0%)	0.8 (-2.1 to 3.7)
Urinary infection	2 (0.6%)	2 (0.6%)	0 (-1.4 to 1.4)
Small bowel obst.	1 (0.3%)	0	0.3 (not calculated)
Chest infection	5 (1.4%)	11 (3.1%)	-1.7 (-4.6 to 1.2)
DVT / PTE	0	1 (0.3%)	-0.3 (not calculated)

Table 3.4: Return to normal activity in patients from multicentre trial

	Laparoscopic	Open	P
Able to look after house	10 (6 – 21)	14 (7 – 27)	0.004
Able to enjoy usual social life	10 (7 – 21)	14 (7 – 28)	0.01
Able to enjoy usual interests or hobbies	14 (10 – 30)	21 (10 – 42)	0.049
Able to enjoy usual sex life	18 (10 – 34)	21 (14 – 40)	0.245
Able to return to paid employment	28 (14 – 24)	42 (21 – 61)	0.001

Values given are median (interquartile range) days

Table 3.5: Clinical outcome at one year in patients from multicentre trial

	Laparoscopic (n = 362)	Open (n = 349)	% Difference (99% CI)
Recurrence of hernia	7 (1.9%)	0	1.9 (0.5 to 3.4)*
New contralateral hernia	10 (2.8%)	12 (3.5%)	-0.7 (-4.1 to 2.7)
Testicular atrophy	2 (0.6%)	3 (0.9%)	-0.3 (-2.0 to 1.4)
Wound sinus	0	0	0 (not calculated)
Port site hernia	2 (0.6%)	0	0.6 (not calculated)

* 95% confidence interval

3.4.2 The single surgeon sub-group

Within the single surgeon sub-group studied a total of 379 groin hernia repairs were performed between January 1994 and March 1997. 300 of these patients were randomised within the protocol of the multicentre trial. The main reasons for non-randomisation were: 22 (28%) patients had an irreducible or inguino-scrotal hernia, 20 (25%) patients who refused randomisation, 11 (14%) cases where the surgeon preferred not to randomise the patient, 11 (14%) patients who had a previous lower abdominal incision, and 10 (13%) patients who were medically unfit for general anaesthesia. The demographic details of the two groups of randomised patients are shown in Table 3.6. There were no significant differences between the groups at the time of recruitment into the trial.

Table 3.6 also shows the types of repair performed in each group. The majority of laparoscopic repairs were performed using the TEP technique, and in the open group 91% of repairs involved the use of a polypropylene mesh. Staples were used in fifty-seven (38%) of the laparoscopic repairs. There were a total of eight conversions (5.4%) from the laparoscopic repair to a Stoppa repair. The most common reason for conversion to open repair was the creation of a peritoneal tear and subsequent pneumoperitoneum (four cases). In two cases it was not possible to reduce the hernia laparoscopically and one patient was converted to an open repair to allow accurate placement of the mesh. In a small number of cases a commercial balloon was used to develop the extraperitoneal space. In one of these cases the balloon ruptured necessitating conversion to an open repair. Two (1.3%) operative complications were identified in the laparoscopic group. One patient suffered an injury to the testicular artery and one patient developed surgical emphysema. In the open group there were three (2.0%) operative complications. These were a testicular artery injury, an inadvertent division of the ilio-inguinal nerve, and a serosal tear of the small bowel. The difference in incidence of intraoperative complications between groups was not statistically significant (difference 0.7%; 95% CI: –3.6% to 2.3%).

The mean total anaesthetic time was significantly greater for the laparoscopic repair (70min vs 54min; 99% CI: 11min to 21min). The mean operation time was also significantly greater for the laparoscopic repair (51min vs 39min; 99% CI: 8min to

17min). The median post-operative stay was one day in both groups. The proportion of patients requiring a longer stay was, however, greater in the open group (40% vs 15%, $p < 0.001$).

Clinical review at one week was performed in 146 (98%) of the laparoscopic repair group and 149 (99%) of the open repair group (Table 3.7). At least one complication was recorded in 31 (21%) of the laparoscopic group and 68 (46%) of the open group (difference -25%; 95% CI: –35% to –14%). The difference in the incidence of complications between groups was predominantly due to a greater incidence of wound haematoma and seroma in the open group. There was no significant difference in the incidence of wound infection between the groups. There was also no significant difference in the incidence of scrotal complications, urinary retention, neuropraxia or chest infection.

The completion rates for the post-operative questionnaires were 91% at one week, 82% at one month and 80% at three months. The pain score results from these questionnaires are shown in Table 3.8. The pain scores at one week showed no significant difference between groups at rest, but there was a significant difference in the scores on movement in favour of the laparoscopic repair ($p = 0.035$). There was no significant difference in the pain scores at rest or on movement at one month or three months. The results of the 'Short Form 36' health assessment for one week, one month and three months are shown in Table 3.9. These results are expressed as eight health concepts defined within the 'Short Form 36' protocol. All scales are scored from zero to one hundred such that a higher score correlates with a positive health state. At one week post-op the laparoscopic group scored significantly higher than the open group for all measures of functional status and also for 'pain'. There was no significant difference in the other measures of well-being or for general health perception. By one month the only significant difference between groups was in the score for physical function, and by three months there was no significant differences between the groups in any of the eight health concepts. The return to normal activity data are shown in Table 3.10. The laparoscopic group returned to normal activity significantly faster than the open group for all five of the parameters measured.

Table 3.11 shows the clinical outcome at one year follow-up. 134 (90%) of the laparoscopic group and 134 (89%) of the open group were reviewed at this time. In the laparoscopic group there were two patients who were recorded as having a 'failed repair'. In both these cases the hernia was noted to still be present within one day of the original operation. It was therefore felt that the hernia had not been repaired at the time of operation. Both patients have since had open repair of their hernia with no further problems. In the open group there was one patient who also had a failed repair. In this case a Lichtenstein repair was performed for an apparent direct inguinal hernia. At one week post-op the patient was found to still have a hernia and subsequent exploration showed the presence of a femoral defect. Within the first year there was one recurrence in the laparoscopic group and none in the open group. During the follow-up period twenty-seven (9.0%) of the patients died, none from causes directly related to the hernia repair. With a median follow-up of sixty months (range 40 - 80 months) there have been a total of three (2.0%) recurrences in the laparoscopic group and three (2.0%) recurrences in the open group (difference 0%; 95% CI: –3.6% to 3.6%). All three recurrences in the open group occurred after a Stoppa repair. During the follow-up period twenty-seven patients (10%) developed new contralateral hernias.

A greater proportion of patients who reported pain pre-operatively, compared with those who did not have pain before the operation, developed chronic pain post-operatively (14% vs 3.5%, p = 0.003). The incidence of chronic pain at one-year review was similar between the open and laparoscopic groups (Table 3.11). There was, however, a difference in the distribution of the pain. A significantly greater proportion of the open group complained of chronic wound pain at one-year follow-up. In contrast, the incidence of chronic testicular pain was greater in the laparoscopic group. There was no association between the use of staples and the incidence of chronic pain in the laparoscopic group. Of the nineteen patients with chronic wound pain at one year, fifteen (twelve open repairs and three laparoscopic repairs) were reviewed at two years. At this point seven of the open group and one of the laparoscopic group still complained of chronic pain. Of the eleven patients with chronic testicular pain at one year, nine (eight laparoscopic and one open) were reviewed at two years. At this time two patients in the laparoscopic group and none in the open group were still complaining of symptoms. Of the forty-eight patients who

had repair of a recurrent hernia forty-six (96%) were reviewed at one year. Five (10.9%) patients in this group reported chronic wound pain at one year. This was not significantly different from the overall incidence of chronic wound pain. Table 3.12 shows the incidence of chronic pain at one year for each type of repair performed. There was no significant difference in the incidence of this complication between the groups that had open and laparoscopic mesh repair. The results for laparoscopic repair of recurrent and bilateral hernias are also given for comparison with the incidence of chronic pain following Stoppa repair. The Stoppa repair has a higher incidence of chronic pain but the difference does not reach statistical significance. The pain scores at one week were compared for the cohort with chronic pain and the rest of the patient population. No significant differences were found between these two groups.

3.4.3 Economic analysis

The marginal costs for the laparoscopic repair are shown in table 3.13. The estimated hospital costs per patient was £278 greater for the laparoscopic repair compared with open repair. This difference was predominantly due to greater equipment costs for the laparoscopic repair. Sensitivity analysis showed a reduction to £93 on the assumption of a 100% re-usable instrument policy, and an increase to £567 on the assumption of a disposable only instrument policy.

Table 3.6: Demographic details and procedure performed for patients in single surgeon subgroup

	Laparoscopic (n = 149)	Open (n = 151)	P
Mean (SD) Age (yrs)	56.5 (16.2)	58.0 (16.7)	n.s.
Sex :			
Male	136 (91.3%)	141 (93.4%)	
Female	13 (8.7%)	10 (6.6%)	n.s.
Type of hernia:			
Inguinal	143 (96.0%)	148 (98.0%)	
Femoral	6 (4.0%)	3 (2.0%)	n.s.
Site of hernia:			
Right	83 (55.7%)	80 (53.0%)	
Left	50 (33.6%)	52 (34.4%)	
Bilateral	16 (10.7%)	19 (12.6%)	n.s.
Recurrent hernia:			
Yes	26 (17.4%)	22 (14.6%)	
No	123 (82.6%)	129 (85.4%)	n.s.
Procedure performed:			
	TEP – 147 (99%)	Lichtenstein - 105 (70%)	
	TAPP – 2 (1%)	Stoppa – 32 (21%)	
		Herniotomy – 6 (4%)	
		Plication Darn – 5 (3%)	
		Low Femoral – 3 (2%)	

n.s. – not statistically significant at the 5% level

Table 3.7: Clinical outcome at one week for patients in single surgeon subgroup

	Laparoscopic (n = 146)	Open (n = 149)	% Difference (99% CI)
Wound Complications:			
Seroma	1 (0.7%)	12 (8.1%)	-7.4 (-13.0 to –1.2)
Haematoma	9 (6.2%)	37 (24.8%)	-18.6 (-29.0 to –8.0)
Infection	5 (3.4%)	3 (2.0%)	1.4 (-3.5 to 6.3)
Scrotal Complications:			
Hydrocoele	3 (2.1%)	2 (1.3%)	0.8 (-3.2 to 4.6)
Haematoma	5 (3.4%)	8 (5.4%)	-2.0 (-8.2 to 4.3)
Genital oedema/ orchitis/epididymitis	9 (6.2%)	12 (8.1%)	-1.9 (-9.7 to 5.9)
General Complications:			
Urinary retention	2 (1.4%)	5 (3.4%)	-2.0 (-6.6 to 2.6)
Neuropraxia	1 (0.7%)	2 (1.3%)	-0.6 (-3.7 to 2.4)
Chest infection	1 (0.7%)	2 (1.3%)	-0.6 (-3.7 to 2.4)
DVT / PTE	0	0	0

Table 3.8: Pain scores from follow-up questionnaires for single surgeon subgroup

	Laparoscopic repair	Open repair	Difference (95% C.I.)
One Week:			
Rest	19.8 (28.9)	24.1 (28.4)	-4.3 (-11.8 to 3.1)
Moving	28.6 (28.3)	36.2 (28.9)	- 7.6 (-14.7 to –0.6)
One Month:			
Rest	14.7 (28.2)	19.3 (30.6)	-4.6 (-12.2 to 3.1)
Moving	20.4 (28.1)	25.3 (29.2)	-4.9 (-12.5 to 2.7)
Three Months:			
Rest	12.2 (24.2)	11.8 (23.5)	0.4 (-6.0 to 6.8)
Moving	19.1 (29.2)	17.7 (25.9)	1.4 (-6.0 to 8.8)

Values are mean (standard deviation)

Table 3.9: 'Short form 36' results for single surgeon subgroup

	One Week			One Month			Three Months		
	Laparoscopic	Open	P	Laparoscopic	Open	P	Laparoscopic	Open	P
Functional Status:									
Physical Function	75 (60-90)	65 (40-90)	0.005	85 (70-95)	80 (60-95)	0.02	95 (80-100)	90 (70-100)	n.s.
Social Function	78 (56-100)	67 (44-89)	0.002	100 (89-100)	100 (78-100)	n.s.	100 (89-100)	100 (78-100)	n.s.
Role Limitation -Physical	25 (0-75)	0 (0-25)	0.007	75 (0-100)	50 (0-100)	n.s.	100 (75-100)	100 (50-100)	n.s.
Role Limitation - Emotional	100 (33-100)	67 (0-100)	0.017	100 (67-100)	33 (33-100)	n.s.	100 (100-100)	100 (33-100)	n.s.
Well-Being									
Mental Health	88 (72-92)	80 (64-92)	n.s.	88 (72-92)	84 (68-92)	n.s.	88 (72-92)	88 (68-92)	n.s.
Energy / Fatigue	60 (45-95)	55 (40-70)	n.s.	70 (55-80)	70 (55-85)	n.s.	75 (55-85)	70 (50-85)	n.s.
Pain	67 (44-78)	44 (33-67)	<0.001	56 (44-56)	56 (44-56)	n.s.	100 (78-100)	89 (78-100)	n.s.
General Health Evaluation	80 (60-90)	75 (60-90)	n.s.	75 (65-90)	75 (50-90)	n.s.	80 (65-95)	75 (55-95)	n.s.

All scales are scored from zero to one hundred such that a high score is consistent with a positive health status.
Values given are median (interquartile range)

Table 3.10: Return to normal activity for patients in single surgeon subgroup

	Laparoscopic	Open	P
Able to look after house	10 (5 - 14)	14 (7 – 24)	0.005
Able to enjoy usual social life	10 (5 – 21)	14 (7 – 28)	0.015
Able to enjoy usual interests or hobbies	14 (7 - 26)	21 (10 – 30)	0.026
Able to enjoy usual sex life	14 (7 - 21)	21 (14 – 35)	0.012
Able to return to paid employment	21 (13 - 42)	42 (14 - 60)	0.028

Values given are median (interquartile range) days

Table 3.11: Clinical outcome at one year for patients in single surgeon subgroup

	Laparoscopic (n = 134)	Open (n = 134)	% Difference (99% CI)
Failed repair	2 (1.5%)	1 (0.7%)	0.8 (-2.5 to 4.0)
Recurrence of hernia	1 (0.7%)	0	0.7 (not calculated)
Chronic groin pain	5 (3.7%)	14 (10.4%)	-6.7 (-13.0 to –0.4)*
Chronic testicular pain	10 (7.5%)	1 (0.7%)	6.8 (0.6 to 13.0)
Testicular atrophy	0	0	0
Wound sinus	0	0	0

* 95% confidence interval

Table 3.12: Incidence of chronic pain within single surgeon subgroup

Type of repair	Number reviewed at one year	Number with chronic pain
All laparoscopic repairs	134	15 (11.2%)
Laparoscopic for recurrent and bilateral repairs	37	4 (10.8%)
Lichtenstein repair	97	9 (9.3%)
Stoppa repair	32	5 (15.6%)
Conventional sutured type repairs	5	1 (20.0%)

Table 3.13: Marginal hospital costs for the laparoscopic repair

Item	Cost
Fixed theatre costs (inc. staff)	£81.45
Equipment costs (inc. disposables)	£217.24
Sterilisation costs	£12.71
Consumables (dressings / sutures)	-£8.42
Peri-operative drugs	£3.14
'Hotel charges' (£95 per day)	- £28.50
TOTAL	£277.62

3.5 Discussion

This study was the first large trial to compare laparoscopic, predominantly totally extraperitoneal, inguinal hernia repair with open tension-free repair. Multicentre trials of surgical techniques have the advantage of rapid recruitment of large numbers of patients and, as a number of surgeons are involved, they are more likely to assess the general applicability of a procedure. The involvement of multiple surgeons can, however, produce interobserver variations that may mask true differences between the groups being studied or create apparent differences that are not real. For this reason the outcomes from both a multicentre trial and from a single surgeon contributing to the trial have been analysed independently. 57% of the patients identified with a groin hernia were randomised within the multicentre trial. Within the sub-group of patients from a single surgeon 79% of patients were randomised. The main reasons for the lower randomisation rate in the main trial were patients being recruited before the surgeon had completed ten laparoscopic repairs, and a group of patients in which the randomisation envelopes had been spoilt. The proportion of patients randomised does, however, compare favourably with the figures given by other studies where the number of patients excluded has been given.[332,436]

Until recently the only outcome measure commonly described in the assessment of inguinal hernia repair was the recurrence rate. It is now apparent that a number of factors should be considered when comparing outcome from different types of hernia repair.[509,517] These measures include: the technical difficulty of the operation, the overall complication rate and potential seriousness of these complications, the overall rehabilitation in terms of post-operative discomfort and return to normal activities, the recurrence rates, and socio-economic factors related to the procedures in question. The technical difficulty of a procedure is reflected in the length of its associated learning curve. As discussed in Chapter Two, the learning curve for totally extraperitoneal laparoscopic inguinal hernia repair appears to be at least thirty cases. Open tension-free inguinal hernia repair is generally thought to be technically easier to master and therefore to have a much shorter learning curve than the laparoscopic procedure. This is particularly true for the Lichtenstein repair as it is performed via the anterior approach, with which most surgeons are familiar for conventional sutured

inguinal hernia repair. Formal assessment of the learning curve for open inguinal hernia repair has not been reported in the literature.

There was no significant difference in the incidence of conversion from laparoscopic to open repair between the main trial group and the sub-group studied. The most common reason found for conversion was the creation of a tear in the peritoneum with a resulting pneumoperitoneum. This observation is in keeping with that of the COALA Trial[258,294] and other reported series of TEP repair.[231,259] The incidence of tears in the peritoneum is related to the tissue handling skills of the surgeon and is learning curve related.[258] Another reason for conversion was an inability to reduce the hernia. This may reflect the fact that large inguinal hernias, and in particular inguino-scrotal hernias, are difficult to reduce laparoscopically. This is especially true for the TEP repair and so a TAPP repair may be more appropriate for these types of hernia. One patient in the sub-study group was converted to open repair because of difficulty in positioning the mesh accurately during TEP repair. MacIntyre has commented that while large pieces of mesh are desirable to reduce the risk of the repair failing, not all groins will accommodate a large piece of mesh.[269] Accurate placement of mesh may therefore provide a technical challenge for the surgeon.

Within the multicentre trial there was a significantly greater incidence of intraoperative complications in the laparoscopic repair group compared with the open repair group. This difference between groups was due to a 3.4% incidence of injury to the inferior epigastric vessels during laparoscopic repair. None of these injuries resulted in significant post-operative problems for the patients involved. In the sub-study from a single surgeon there was no recorded injuries to the inferior epigastric vessels, and there was a similar incidence of intraoperative complications in the two groups. All three of the major intra-operative complications recorded in the main trial occurred in the laparoscopic group, and all were associated with the TAPP repair. All of these complications were identified at the time of operation and dealt with appropriately with uneventful post-operative recovery. The significance of the distribution of major complications within the laparoscopic group is debatable as the number of complications is small and the allocation of patients between TAPP and TEP repair was by surgeon preference rather than randomisation.

The incidence of post-operative complications recorded at one week was similar in the main trial and in the group from a single surgeon. In both cases there was a greater incidence of wound haematoma in the open group than was found in the laparoscopic group. Within the single surgeon sub-group the incidence of wound haematoma was 25%. Almost all of the patients within this subgroup were given low molecular weight (LMW) heparin for prophylaxis against deep venous thrombosis. Initially, the LMW heparin was administered subcutaneously into the abdominal wall on the morning of the operation. Previous studies have shown a greater incidence of wound haematoma when giving heparin into the abdominal wall compared with administration into the thigh or the upper arm (Dommering et al: 17% vs 5%;[518] De Lange: 30.5% vs 3%[519]). Administration at these different sites does not change the circulating levels of the heparin.[519] It has been demonstrated that heparin injected subcutaneously into the abdominal wall drains to the inguinal lymph nodes.[519] Undesirably high levels of heparin are therefore present locally within the inguinal region for up to four hours after the injection is administered. On recognising the high incidence of wound haematoma and seroma within the sub-study group the site of LMW heparin injection was changed to the patient's thigh or upper arm. We have subsequently demonstrated that the incidence of wound haematoma and seroma following open prosthetic inguinal hernia repair is reduced by 55% if the injection is administered at a site distant from the abdominal wall.[520]

There was no significant difference between the groups in the incidence of wound infections. Within the sub-group, the wound infections in the laparoscopic group all occurred at the umbilical port site and all settled rapidly with antibiotic treatment. In the open group the degree of infection ranged from erythema around the wound to the frank discharge of pus. All of these infections settled with antibiotic therapy and to date there has been no requirement to remove mesh from a patient for either mesh infection or mesh rejection. No significant differences were identified between groups in the incidence of scrotal complications or in the incidence of general complications such as chest infection and urinary retention.

Within the main trial the 'Short Form 36' results were only assessed at three months after the hernia repair. At this time point there were no significant differences between the groups in any of the health domains. Within the sub-group of patients

from a single surgeon the 'Short Form 36' questionnaires were also completed at one week and one month after the hernia repair. At one week after the operation there were significant differences in favour of the laparoscopic group in all four of the parameters assessing functional status. The assessment of well-being (Table 3.9) showed a significant difference in pain scoring but this was not reflected in the linear analogue pain scores at one week, where the difference between groups did not reach statistical significance (Table 3.8). No difference was found in the other measures in the assessment of well-being section nor in the patients overall evaluation of health. Overall, the findings suggest that at one week the laparoscopic repair patients suffered less discomfort and as a result reported a better functional status. By one month after the procedure the only significant difference between groups was in the assessment of physical function, again in favour of the laparoscopic group. As with the results of the main trial there were no significant differences between the groups by three months after the repair. Linear analogue pain scores were not significantly different at one month or three months. These results indicate that the patients who had a laparoscopic repair did perceive early benefits in terms of better functional status but the differences were marginal by one month after the procedure. All of the patients within the trial were advised to return to their normal activities whenever they felt comfortable to do so. The reported return to normal activity for the two groups was in keeping with the observed results on functional status. The main trial found a significantly faster return to normal activities in the laparoscopic group for all parameters except sexual activity. In the sub-study group the laparoscopic group reported a faster return to normal activities in all five of the parameters assessed. The earlier return to normal activity following laparoscopic repair accords with many of the other reported series comparing it with sutured and prosthetic open repair.[294,297,441-443,455-461] There have, however, also been several reports that found no significant difference in return to normal activity or work between open and laparoscopic repair.[436,438,439,473,490-493,495,496] It may be important that the sample sizes in the studies which have not found a significant difference between groups are significantly smaller (median 102 cases, range 79–128 cases) than in those studies which have reported a faster return to normal activity for the laparoscopic group (median 214 cases, range 100–994 cases; $p = 0.003$). The greater statistical power of the larger studies may have been important in demonstrating a significant difference. Picchio et al. have reported the only study which found a faster return to normal

activity following open compared with laparoscopic repair (6.1 weeks vs. 6.5 weeks, $p < 0.03$).[497]

Within the single surgeon sub-group three patients were identified who had a failed repair. In the open group there was one failed repair, in a patient who had a Lichtenstein repair for a direct inguinal defect. At the weekly clinical review the patient reported that the hernia was still present. Examination showed the presence of an ipsilateral femoral defect that was presumably missed at the original operation. This incident emphasises the point made by Nyhus that the femoral canal should always be inspected during repair of an inguinal hernia.[513] Within the laparoscopic group there were two patients who had a failed repair. In the first of these cases a large Nyhus type IIIb defect was repaired without the use of staples. Within twenty-four hours it became apparent that the hernia was still present and the patient was taken back to theatre on the first post-operative day. An open approach was used to remove the laparoscopically placed mesh and perform a Lichtenstein repair. In the second case bilateral large Nyhus type IIIa defects were repaired using staples. The unilateral failed repair was apparent on the day after surgery. Due to practical considerations the patient did not return to theatre until several weeks later when a Lichtenstein repair was performed. The laparoscopic failed repairs emphasise the importance of obtaining an adequate overlap of the margins of the defect when placing the mesh. The overlap should be at least three centimetres in order to reduce the risk of failed repair due to mesh migration or prolapse into the hernia defect.[262,263]

Within the main trial, 76% of the randomised patients attended for clinical review one year after operation. At this time point there were a significantly greater number of recurrences in the laparoscopic group. The relatively high incidence of early laparoscopic recurrences was not seen in the sub-group of patients where all of the repairs were performed by a single surgeon with extensive experience of laparoscopic repair. At the time of planning the trial it had been thought that a total of ten laparoscopic repairs was adequate to allow a surgeon to surmount the main part of the learning curve. Within this study and also the COALA Trial it has been demonstrated that the learning curve is at least thirty cases,[258] and other authors have stated that it may be longer than this.[228,521] The possibility that the early recurrences in the study were learning curve related was therefore further investigated. The analyses were

limited by the small number of events, but there were no detectable correlations between the recurrences and their position within the surgeons series of patients.

Initially surgeons thought that any recurrence following prosthetic repair would present within the first few months and would be related to technical errors. Examination of the incidence of recurrence in the sub-group of patients, who have been followed up for a median of sixty months, shows that most of the recurrences have occurred more than one year after the repair. In the laparoscopic group two of the three recurrences recorded have presented more than one year after the repair. Two of these recurrences were stapled repairs of direct defects and one was an unstapled repair of an indirect defect. It is thought that the recurrences may be secondary to shrinkage of the mesh caused by fibrous tissue ingrowth.[262,522] Within the open group there have been three recurrences and all of these patients had bilateral primary Nyhus type III defects at the initial operation. As all of the recurrences presented over one year following repair it is thought that mesh shrinkage may also be a contributing factor in their development. Lateral placement of the mesh is probably the weakest area of a Stoppa repair. Therefore inadequate placement of the mesh in this area may have contributed to these recurrences.

Twenty-seven (10.2%) of the single surgeon sub-group patients who had a unilateral hernia repair performed, and twenty-two (2.6%) of the multicentre group, were subsequently found to have developed a contralateral groin hernia within the follow-up period. Sayad et al. have shown that many of these hernias may have been present at the time of the original procedure.[523] They reported an 11.2% incidence of occult hernias during exploration of the contralateral side while performing TEP repair of clinically unilateral groin hernias. The median increase in operation time to perform the exploration was 2.8 minutes (range 2–5min). It was therefore argued that exploration of the contralateral side should be performed routinely as this would identify a significant number of coincidental hernias.

Chronic wound pain may significantly affect the patients occupation and social activities. The incidence of this complication is therefore of importance. In this study chronic post-operative pain occurred with equal frequency following open and laparoscopic repair, but the distribution of the pain differed between the groups.

There was a greater proportion of patients with chronic wound pain in the open group and a greater proportion of patients with testicular pain in the laparoscopic group. The pain in the open group is presumably associated with nerve injury,[320] or entrapment of nerves in the fibrotic tissue associated with the mesh.[322] In the laparoscopic group the pain may be related to nerve injury,[274] or to the congestion of lymphatic and venous channels in the testis.[274,336] The use of staples in the laparoscopic repair has also been associated with nerve injury and subsequent chronic pain.[328,329] The incidence of chronic pain following laparoscopic repair in the single surgeon sub-group in this study was no different for those patients in whom staples were used and for those where staples were not used. This may have been related to the surgeons awareness and avoidance of the potential areas of danger.[501,505]

Of the nineteen patients who complained of chronic groin pain at the one-year review, fifteen attended for review at two years. Seven of these patients reported that the pain had settled in the intervening period. Over half of the patients however continued to have chronic groin pain. It has been suggested that by this time the somatic pain has induced neuropathic changes within the spinal cord which perpetuate the pain.[315] Local measures therefore become less effective in control of the pain. The incidence of chronic testicular pain persisting for up to two years was much less. This may be due to resolution of lymphatic or venous congestion, which has been proposed as a mechanism of chronic testicular pain.[274,336] A greater incidence of chronic pain has been reported following repair of recurrent inguinal hernias compared with repair of primary hernias.[315] The current study however showed no evidence of increased incidence of chronic pain following open or laparoscopic repair of recurrent hernias. All of the recurrent hernias in this study were repaired via a preperitoneal approach. In the study reported by Calleson et al. the Lichtenstein repair was used for the repair of recurrent inguinal hernias.[315] This raises the possibility that the incidence of chronic pain may be greater following anterior repair of recurrent hernias compared with preperitoneal repair, whether it be open or laparoscopic. A greater proportion of the patients who complained of pain pre-operatively from the hernia site developed chronic post-operative pain, compared with those patients who did not complain of pain pre-operatively. This may be because the pre-operative pain had already induced neuropathic changes predisposing the patient to post-operative pain. Alternatively, the patients may have been suffering pain from another source such as hip pain or

prostatic pain, which was attributed to the hernia. This pain would therefore still be present following the hernia repair.

Analysis of marginal hospital costs showed the laparoscopic repair to be £278 more expensive than the average cost of the open repairs. The bulk of the difference in hospital costs is related to expenditure for equipment. The equipment costs calculated were based on the observed use of re-usable and disposable equipment. Sensitivity analysis was therefore performed which showed that a 're-usable only' policy would reduce the marginal cost for the laparoscopic repair to £93. If a 'disposable only' policy was used the marginal cost of the laparoscopic repair would be £567. The use of a disposable stapler contributes significantly to the costs of the laparoscopic repair. Reduction in the number of repairs requiring the use of staples will therefore reduce the average costs of the laparoscopic repair. It does, however, appear that some marginal costs for laparoscopic equipment will remain. Fixed theatre costs are also greater for the laparoscopic repair. This difference is predominantly due to the greater mean operation time for the laparoscopic repair, but this has been shown to fall with increasing experience of the technique in this study and in other reports.[258,297] In considering the operation times the opportunity cost is of greater importance than the absolute difference measured. It is unlikely on a mixed general surgical list that a difference in operation time of fifteen minutes for a hernia repair would influence the number of procedures that could be performed on the list. The majority of hernias within this study were repaired under general anaesthesia. There is a growing impetus to perform open inguinal hernia repair under local anaesthesia, particularly in the day-case setting. The use of local anaesthesia may further reduce the fixed theatre costs, particularly if the anaesthetist was replaced with an anaesthetic nurse to monitor the patient. However, the availability of an anaesthetist in case of difficulties would still have to be ensured.[524] The use of local anaesthesia should also be acceptable to the patient population. When questioned about their preferences, half of a cohort of fifty patients admitted to our unit for inguinal hernia repair expressed a preference for general anaesthesia. While laparoscopic repair under local anaesthesia has been described,[346,349,351] this remains a procedure for the enthusiast. Furthermore local anaesthetic repair using a lifting device,[349] rather than insufflation, would further increase the costs of the procedure.

Within this study surgeons were advised to discharge patients on the first post-operative day unless they felt that there was a specific reason for a longer hospital stay. A greater proportion of the laparoscopic group were discharged on the first post-operative day, which resulted in a lower marginal 'hotel charge' in this group. This study may be criticised for the in-patient management of inguinal hernia as there is a growing pressure to perform the procedure on a day-case basis. The Royal College of Surgeons of England 'Clinical Guidelines on the Management of Groin Hernias in Adults' (1993) states that at least 30% of elective inguinal hernias repairs should be performed on a day-case basis. Hair et al. recently reported that 22% of groin hernia repairs performed in Scotland between April 1998 and March 1999 were achieved as a day case.[319] A large proportion of the patients presenting with an inguinal hernia are elderly and have significant co-morbidity. They may also have social circumstances that are not suitable for day-case surgery. Therefore, there will remain a large group of patients who will not be suitable for this type of management. For those patients who are suitable for day-case surgery it may be argued that laparoscopic repair could also be performed. However, the use of local anaesthesia for an open repair will allow earlier mobilisation.

The societal costs of inguinal hernia repair are difficult to quantify. Estimates of the cost can be made on the basis of a patients salary.[469] However, this may not reflect the true costs as other workers at no extra cost may take up the patient's contribution in the workplace, or the patient's contribution may be foregone for the duration of their invalidity. Therefore, while the benefits of an earlier return to work may be apparent on an individual patient basis, this is not necessarily translated into equivalent savings in societal costs.

CHAPTER FOUR

SUB-STUDIES WITHIN THE RANDOMISED CONTROLLED TRIAL

4.1 Introduction

Prosthetic inguinal hernia repairs were introduced with conflicting reports as to whether or not they caused less post-operative pain than conventional sutured repair.[318,414,441,453,454,487] Laparoscopic repairs were then developed with similar conflicting claims with regard to post-operative pain.[294,297,436-443,455,456, 58,460,461,469, 473,490,492,495,496] Conventional inguinal hernia repair has been shown to cause a significant impairment in post-operative pulmonary function,[344] and this has been correlated with minor chest complications.[430] Laparoscopic cholecystectomy has previously been shown to produce less impairment of pulmonary function than the open procedure,[432-435] but an assessment of post-operative pulmonary function has not been performed for laparoscopic hernia repair. Several studies have also demonstrated a smaller metabolic response to laparoscopic cholecystectomy compared to that via a subcostal incision.[415-420] The metabolic response to open and laparoscopic inguinal hernia repair has been compared in several small, non-randomised studies with conflicting results.[422-424] In the only reported randomised comparison of laparoscopic (TAPP) and open (Shouldice) inguinal hernia repair Shrenk et al. found no significant difference in acute phase reactant or cytokine response.[425] The aim of this study was to compare the pain scores, respiratory function and metabolic response to open prosthetic inguinal hernia repair and the totally extraperitoneal laparoscopic repair.

Following inguinal hernia repair patients commonly ask when they can return to driving. It has previously been shown that emergency stop reaction times are impaired until the tenth post-operative day following plication types of inguinal hernia repair.[462] An important factor in determining the patients ability to perform such tasks is the amount of discomfort they are feeling following their operation. Furthermore, while patients may rapidly feel comfortable enough to perform the routine tasks of driving they must be able to perform an emergency stop in order to drive safely. A study was therefore designed with the objective of comparing the change in emergency stop reaction times following open prosthetic and totally extraperitoneal laparoscopic inguinal hernia repair.

4.2 Patients and methods

In this study all patients randomised to the laparoscopic group had a TEP repair. Patients randomised to the open group with a primary, unilateral inguinal hernia had a Lichtenstein repair, and those with recurrent or bilateral hernias underwent an open preperitoneal mesh repair. Pain scores and analgesic use were measured in sixty patients from each group. Pre-operatively the patients were introduced to the concept of a visual analogue pain score.[525] Two separate lines were used; one for discomfort at rest and one for discomfort on movement. The patients were asked to put a cross at the appropriate point on each line. Pain scores were recorded at six hours and twenty-four hours after the operation. In order to exclude inter-observer variation a single investigator recorded all measurements. Intramuscular and oral analgesic prescription was standardised and a record kept of analgesic consumption. Patients were also provided with standardised oral analgesia on discharge.

Pulmonary function tests were measured in the same sixty patients from each group. The measurements were made using a Respiradyne handheld spirometer (Cheseborough-Ponds Inc., Greenwich, Conn. USA).[526,527] Baseline measurements were made pre-operatively and then at six and twenty-four hours post-operatively. On each occasion the mean of three technically satisfactory results was recorded. All measurements were again made by one investigator to exclude inter-observer variation. In twenty patients from each group pulse oximetry was continuously recorded for the first eight hours following the operation using an Ohmeda Biox 3740 pulse oximeter (Ohmeda, Louisville, CO, USA). The oximeter contained an internal memory that recorded one data point every twelve seconds over the eight-hour period. This information was then downloaded into a personal computer, which was used to calculate the distribution of oxygen saturation over the time period recorded (Commander software, Ohmeda, Louisville, CO, USA). The anaesthetist, who anaesthetised all cases in this part of the study, determined the use of post-operative oxygen therapy based on clinical indications.

The inflammatory and metabolic response was compared in twenty patients from each group. Venous blood samples were taken pre-operatively and then at four, eight and twenty-four hours after the operation. The samples were immediately separated

by means of centrifugation and the serum was frozen at –20^{0}C. Levels of C-reactive protein, albumin and glucose were measured by means of nephelometry. The detection limit for CRP was 6mg/L. Interleukin-6 was measured by means of enzyme-linked immunosorbent assay (Quantikine Human IL-6 Immunoassay, R&D Systems, Minneapolis, Minn., USA).

Driver reaction times were assessed in sixty-four randomised patients. A system was designed and built to measure both hand and foot reaction times. The subject, sitting in a car seat looking at a video display unit, was instructed to respond to a change in the colour of the screen from black to red. Hand response times were taken from the time taken to move the hand from a switch at the rim of the steering wheel to a centrally situated horn. Foot reaction times were measured as the time taken to transfer the foot from the accelerator to the brake pedal, which were in the normal positions. The position of the car seat relative to the steering wheel and pedals was adjustable for the subject's height in the normal way. The brake pedal contained a 100-Newton spring to simulate the force required to depress the brake in performing an emergency stop.[528] Once started the system ran through a series of ten measurements in which the screen changed from black to red at random intervals, which was intended to prevent the subject anticipating the change. The response was measured as the time from the change of colour of the screen to full depression of the horn or brake pedal. On each occasion a series of measurements were made for the hand responses followed by a series for the foot responses. The average of the ten responses was recorded on each occasion. A pilot study showed that by one week after the operation the reaction times for open and laparoscopic patients were no longer than they had been pre-operatively. It was therefore decided to concentrate on the changes in the first week after surgery. The subjects performed the tests pre-operatively and then on days one, three and six following surgery. As with all patients in the sub-study these patients were provided with oral analgesia (coproxamol) post-operatively. On each occasion that the reflexes were tested the subject's analgesia use was recorded.

Statistical Analysis

All data were analysed by intention to treat. The standard deviation of the results for pain scores and pulmonary functions tests previously recorded for patients in a trial of

laparoscopic and mini-laparotomy cholecystectomy were used as an estimate of the standard deviations for the current study.[435] It was thus possible to calculate that a sample size of sixty patients in each group would provide an 80% power to detect a 10% difference between groups at the 5% level. Ordinal data comparison between groups was performed using the Mann-Whitney U-test. For metabolic response the area under the curve was calculated using the median value at each time point. The groups were then compared with the Mann-Whitney U-test.

For the driver reflex study estimation from the pilot study data showed that a sample size of thirty-one subjects in each group would provide an 80% power to detect a difference between groups of one standard deviation at the 5% level. A Chi-squared test was used to compare the distribution of hernia site and the proportion of subjects using analgesia on each post-operative day. The reaction times are expressed as the change from the pre-operative value recorded for each patient. These values are then expressed as the mean and standard deviation for the group, and comparisons between groups reported using 95% confidence intervals for the difference.

4.3 Results

4.3.1 Pain scores and analgesic use

There were no significant differences in the demographic details of the patients in the two groups used to compare pain scores, pulmonary function and metabolic response. The pain scores recorded at six and twenty-four hours post-op are shown in Table 4.1. Statistically significant differences in favour of the laparoscopic group were detected both at rest and on movement at both times. Patients in the open group also required a greater amount of analgesia in the first twenty-four hours after surgery. The median number of doses in the open group was 2.5 (IQR: 2 – 4 doses) compared with 2.0 (IQR: 1 – 3 doses) in the laparoscopic group (p=0.008).

4.3.2 Post-operative respiratory function

In both groups there was a significant reduction in forced vital capacity (FVC), forced expired volume in one second (FEV_1) and peak expiratory flow rate (PEFR) at six

and twenty-four hours post-op (Table 4.1). There was no significant difference between groups in the magnitude of the change that occurred at either time. There was also no significant difference in the post-operative oximetry levels recorded in the first eight hours following surgery.

4.3.3 Post-operative metabolic and inflammatory response

Table 4.2 shows the results of the metabolic and inflammatory response assays. In both groups there was a significant increase in the IL-6 levels by four hours after the operation (median rise in laparoscopic group: 56pg/ml, IQR: 30 – 108pg/ml; median rise in open group 46pg/ml, IQR: 28 – 70pg/ml), and IL-6 levels remained above pre-operative values at twenty-four hours in both groups. There was, however, no significant difference in IL-6 response between the groups. There were no significant changes in the glucose levels in either group. In both groups there was a significant decrease in the albumin level by four hours after the operation (laparoscopic: 45mg/dl to 40mg/dl, open: 43mg/dl to 40mg/dl), but no significant difference between groups. The CRP level did not rise measurably in either group until twenty-four hours after the operation. At this time point there was no difference between the groups in the magnitude of the response.

4.3.4 Driver reaction times

There were no significant differences in the demographic details of the patients involved in the driver reaction time study (Table 4.3). The proportion of patients still using oral analgesics on each post-operative test day was less in the laparoscopic group than in the open group (Table 4.3), but the difference on each day was not statistically significant. The mean pre-operative hand reaction times in the laparoscopic group (326msec +/-70msec SD) and the open group (321msec +/-68msec SD) were not significantly different (difference 5msec; 95% CI: –29msec to 40msec). Similarly, the mean pre-operative foot reaction time for the laparoscopic group (327msec +/- 63msec SD) and for the open group (330msec +/-61msec SD) were not significantly different (difference -3msec; 95% CI: –34msec to 28msec). The post-operative changes in mean reaction times are shown in Table 4.4. A positive value reflects an increase in reaction times and, conversely, a negative value

represents a reduction in the reaction time. The laparoscopic group showed a gradual improvement in hand reaction times over the study period. In the open group there was a slight prolongation of the reaction time on days one and three, but by day six the response was also faster than the pre-operative value. There was no statistically significant difference in hand reaction times between the groups on any of the days tested. In the endoscopic group the foot reaction times followed a similar pattern to that of the hand reaction times. The open group showed a slowing of the mean foot reaction times on days one and three. By day six the foot reaction times were also faster than pre-operative values in this group. The difference between groups in foot reaction times on days one and three were statistically significant ($p = 0.01$, and $p = 0.003$ respectively).

Table 4.1: Inflammatory and metabolic response to laparoscopic and open prosthetic repair

Assay	Laparoscopic repair (n = 20)	Open repair (n = 20)	P
*IL-6($pg.ml^{-1}.h$)	950 (534 – 2458)	1235 (1081 - 1839)	n.s.
*Glucose($mmol.l^{-1}.h$)	150 (140 – 165)	163 (143 - 179)	n.s.
*Albumin($g.l^{-1}.h$)	988 (936 – 1081)	957 (930 - 995)	n.s.
+CRP($mg.l^{-1}$)	30 (21 – 45)	34 (22 - 53)	n.s.

Values are median (interquartile range)

n.s. – not statistically significant at the 5% level

* Area under the curve at 24 hours.

+ Value recorded at 24 hours.

Table 4.2: Pain scores and pulmonary function following laparoscopic and open prosthetic repair

	Laparoscopic repair (n = 60)	Open repair (n = 60)	P
Pain scores (mm)			
6 hours :			
Rest	21.5 (9.8 – 32.5)	25.0 (14.8 - 52.5)	0.04
Moving	48.5 (22.7 – 61.5)	73.5 (43.8 - 84.2)	0.0002
24 hours :			
Rest	12.0 (6.8 – 20.0)	19.0 (7.5 - 37.0)	0.02
Moving	35.0 (17.5 – 62.0)	63.0 (23.2 - 81.0)	0.0039
Percentage reduction in pulmonary function			
6 hours:			
FVC (L)	18 (11 – 36)	23 (14 - 38)	n.s.
FEV_1 (L)	19 (4 – 37)	24 (11 - 40)	n.s.
PEFR (L/min)	24 (9 – 46)	28 (16 - 46)	n.s.
24 hours:			
FVC (L)	11 (2 – 23)	14 (6 - 29)	n.s.
FEV_1 (L)	13 (0 – 28)	17 (6 - 33)	n.s.
PEFR (L/min)	20 (7 – 39)	22 (6 - 38)	n.s.

Values are medians (interquartile range)

n.s. – not statistically significant at the 5% level

Table 4.3: Demographic details and analgesic use for patients in driver reaction time study

	Laparoscopic repair (n = 31)	Open repair (n = 33)	P
Mean (SD) Age (yrs)*	56 (15)	54 (17)	n.s.
Sex :			
Male	30 (97%)	33 (100%)	
Female	1 (3%)	0	n.s.
Site :			
Right	19 (61%)	16 (48%)	
Left	6 (19%)	11 (33%)	
Bilateral	6 (19%)	6 (18%)	n.s.
Recurrent :			
Yes	2 (6%)	4 (12%)	
No	29 (94%)	29 (88%)	n.s.
Post-op analgesia :			
Day 1	21 (68%)	28 (85%)	n.s.
Day 3	15 (48%)	23 (70%)	n.s.
Day 6	10 (32%)	17 (52%)	n.s.

n.s. – not statistically significant at the 5% level

Table 4.4: Change in driver reaction times following laparoscopic and open prosthetic repair

	Laparoscopic (n = 31)	Open (n = 33)	Difference (95% CI)
Hand Reaction (msec):			
Day 1	-0.1 (35.2)	6.9 (53.3)	-7.0 (-33.0 to 17.2)
Day 3	-12.6 (42.8)	5.9 (37.2)	-18.5 (-41.9 to 4.9)
Day 6	-26.3 (47.6)	-9.6 (32.0)	-16.7 (-38.1 to 4.8)
Foot Reaction (msec):			
Day 1	-4.2 (36.6)	30.6 (59.4)	-34.8 (-62.1 to –7.6)
Day 3	-10.4 (46.6)	32.5 (49.0)	-42.9 (-70.7 to –15.1)
Day 6	-16.9 (36.2)	-7.0 (31.9)	-9.9 (-28.1 to 8.1)

Values are mean change in reaction time (standard deviation)

4.4 Discussion

Several randomised trials have recorded pain scores following laparoscopic and open sutured inguinal hernia repair. The majority of these studies have reported that the laparoscopic repair caused significantly less pain[294,297,436-441,455] but some studies have found no significant difference between the groups.[332,461,490,492] It has been argued that open prosthetic repair, which does not produce tension in the tissues, should cause less pain than conventional sutured repair. This may be reflected in the observation that while one study has shown significantly lower pain scores for the TAPP repair compared with the Lichtenstein repair,[442] the majority of studies have found no significant difference in pain scores.[461,469,473,495,496] This study is the first to compare pain scores following open prosthetic repair and the TEP repair. The differences recorded in pain scores at rest between the groups at six and twenty-four hours were statistically significant. However the magnitude of the differences was relatively small and therefore may not have been of great clinical significance. This study has demonstrated lower pain scores on movement following the TEP repair at six hours and twenty-four hours and these differences, which are of greater magnitude, are more likely to be of clinical significance. These results correlate with the 'Short Form 36' scores for the first week following the operation where the laparoscopic repair group scored more highly for the assessments of functional status (Chapter 3, Table 3.9).

A comparison of the respiratory sequelae following TEP and open prosthetic inguinal hernia repair has not previously been reported in the published literature. In this study no significant differences were identified in the post-operative oximetry between the two groups during the first eight hours after the procedure. Significant reductions in pulmonary function were demonstrated in both groups at six and twenty-four hours after surgery, but there were no significant differences between the groups. The similarity in respiratory effects produced by the two types of repair is in keeping with the observation that the incidence of post-operative respiratory complications is not significantly different between the two groups (Chapter 3, Tables 3.3 and 3.7).

This is the first reported study to compare metabolic response to open prosthetic and TEP inguinal hernia repair, and is also the largest reported comparison of metabolic

response to open and laparoscopic inguinal hernia repair in the published literature.[422-425] Two of the other four reported studies have shown a greater CRP response in the open group, one at twenty-four hours and one at forty-eight hours. There were no other significant differences between groups in these studies suggesting that the metabolic responses to open and laparoscopic procedures are similar. In keeping with these reports this study has shown no significant differences between groups in the inflammatory or metabolic responses measured.

In the driver reflex study there was no significant difference between the groups in their pre-operative hand and foot reaction times, indicating that they were evenly matched. The observation that a greater proportion of patients in the open group were using oral analgesics on the days tested is in keeping with the study observations on larger groups of patients (Chapter 3). After surgery, there were differences between the groups in the pattern of both the hand and foot reactions. The endoscopic group showed a gradual reduction in the hand and foot reaction times over the period tested. This appears to be due to an underlying learning curve for the test procedure. In contrast, there is an increase in both the hand and foot reaction times on post-operation days one and three in the open group. The small increase in hand reaction times in the open group relative to the endoscopic group may be due to a greater proportion of these patients using coproxamol on the days tested. This would be in keeping with previous reports of opiate group analgesics impairing reaction time, muscle co-ordination and attention when used in the short term.[529,530]

Compared with the changes in hand reaction times, there is a much greater increase on days one and three for the foot reaction times in the open group. Here the difference between the open and endoscopic groups does reach statistical significance. Open tension-free hernia repair therefore significantly impairs emergency stop reaction times on post-operation days one and three. If the smaller increase in hand reaction times that is seen in the open group is due to a greater proportion of these patients using oral analgesics, this must also contribute partly to the increase in foot reaction times. However, the greater increase in foot reaction times indicates that an additional factor is also acting. This is thought to be the effect of discomfort from the groin wound impairing transfer of the foot from the accelerator to the brake switch. In contrast there is no evidence of any impairment of

reaction times following endoscopic repair. This observation is in keeping with the finding that patients in the endoscopic group initially have much lower pain scores on movement compared with the open group (Table 4.1). The foot reaction times for the open group are faster than pre-operative values by day six. It can therefore be concluded that following open tension-free repair patients can return to driving by one week after their operation. This is earlier than currently recommended on the basis of observations from patients who had undergone conventional types of repair.[462]

As the reaction time results were obtained in an experimental situation using a simulator the absolute values obtained for changes in reaction times may not be directly applicable to driving. However, the relative change in reaction time compared with pre-operative values will give an indication of the degree of impairment experienced by these subjects. The increase in reaction times at days one and three in the open group represent an increase of 9.4% and 9.7% respectively. The current legal limit for alcohol when driving (80mg/dl) reduces steering efficiency in a simulated driving test by 11%.[462] The impairment of function recorded in this study are therefore similar to this in magnitude.

This study has shown that laparoscopic TEP inguinal hernia repair causes less early post-operative discomfort and that this may be reflected in a faster return to normal activities such as driving. No significant difference in pulmonary function changes or metabolic response was identified between the laparoscopic and open prosthetic repairs.

CHAPTER FIVE

BLOOD GAS AND HAEMODYNAMIC CHANGES DURING CO_2 PNEUMOPERITONEUM AND EXTRAPERITONEAL INSUFFLATION

5.1 Introduction

Until recently most laparoscopic procedures were of short duration and were performed on relatively young, healthy patients. The advent of therapeutic laparoscopic techniques in general surgery has resulted in extended insufflation periods in patients who often have pre-existing cardio-respiratory disease. There has therefore been a renewed interest in the physiological changes that occur during the period of gas insufflation. The pattern of blood gas changes during CO_2 pneumoperitoneum has now been consistently described by several authors.[373,379,387,394-396] There is an initial rapid rise in the $PaCO_2$ over the first fifteen to twenty minutes, and then there is a prolonged second phase where only very gradual change occurs. These changes may occur even in the face of increased pulmonary ventilation where patients have pre-existing cardio-respiratory disease.[366,383] CO_2 pneumoperitoneum is also known to produce haemodynamic changes such as an increase in mean arterial pressure, with a resulting increase in cardiac work.[357-364] Several studies have compared the relative changes caused by CO_2 pneumoperitoneum and extraperitoneal insufflation with conflicting results. Some studies have shown a greater CO_2 absorption with extraperitoneal insufflation,[394-396] while others have demonstrated no significant difference between the groups,[400] or a greater rise in CO_2 during pneumoperitoneum.[397,399] Similar contrasts are seen in the reports of haemodynamic changes during gas insufflation.[395,398,400] This study was designed to compare the relative blood gas and haemodynamic changes during pneumoperitoneum and extraperitoneal insufflation for TEP inguinal hernia repair.

5.2 Patients and methods

Extraperitoneal CO_2 insufflation was examined in twenty-two patients undergoing totally extraperitoneal inguinal hernia repair. The effects of intraperitoneal CO_2 insufflation were measured in eleven patients undergoing laparoscopic cholecystectomy. The demographic details of the two patient populations are given in Table 5.1.

All patients were premedicated with temazepam (0.3mg/kg) and received a standardised general anaesthetic with thiopentone (3-5mg/kg), nitrous oxide in 50% oxygen, enflurane (1-2% inspiratory volume), atracurium (0.5mg/kg) and morphine. An Ohmeda 7750 ventilator (Ohmeda, Hatfield, UK) was used in a low flow circuit with carbon dioxide absorber. Ventilation was held constant throughout the operation by maintaining a tidal volume of 10ml/kg at ten breaths per minute. End-tidal CO_2 was measured using a continuous flow sampler and infra-red analyser (Datex Capnomac Ultima; Instrumentation Corporation, Helsinki, Finland). A 10-15 minute period was allowed for the end-tidal CO_2 to stabilise before pre-insufflation recordings were made and the insufflation was then commenced.

For extraperitoneal insufflation a Hasson trocar was inserted after open dissection and development of the preperitoneal space using a Foley catheter dissection technique.[256] In the pneumoperitoneum group a blunt trocar was introduced by an open technique and then insufflation commenced. In both groups the insufflation pressure was held constant at 10cmH_2O by automatic regulation of the CO_2 inflow (Surgical CO_2 Insufflator 9L, Olympus Keymed, Southend-on Sea, UK). The duration of insufflation in both groups was similar (Table 5.1). After stabilisation, and again just before the end of the insufflation period, arterial blood gas samples were taken. The blood gas samples were analysed immediately using a Ciba Corning 288 Blood Gas System (Ciba Corning Diagnostics Corporation, Medfield, MA, USA). In addition, the mean arterial blood pressure, the heart rate and the end-tidal CO_2 was noted after stabilisation and then at five minute intervals during the insufflation period.

Statistical Analysis

Analysis of paired data was performed using the Wilcoxon matched-pairs test, and non-paired data was analysed using the Mann-Whitney U test. Comparison of regression coefficients was used to assess the relative changes in end-tidal CO_2 levels in the two groups. The comparison of changes in blood pressure between the two groups was performed using area under the curve analysis.

Table 5.1: Patient characteristics and insufflation time

	Insufflation	
	Extraperitoneal	Intraperitoneal
Sex	21 male, 1 female	1 male, 10 female
Age (years)*	62 (55-70)	42 (35-63)
ASA	I - 15	I - 9
	II - 7	II - 2
Insufflation (min)*	40 (25-50)	35 (29-40)

* Values are median (interquartile range).
ASA: American Society of Anesthesiologists Physical Status Class

5.3 Results

The observed changes in blood gas levels during the insufflation period are shown for both groups in table 5.2. With both extraperitoneal and intraperitoneal carbon dioxide insufflation there was a significant rise in the arterial pCO_2 from the pre-insufflation level ($p<0.01$). However, no significant difference in the magnitude of the rise was demonstrated between the groups. A similar pattern was found in $[H^+]$ changes with a significant rise in both groups ($p<0.01$), but no significant difference found between the groups. A slight fall in arterial pO_2 occurred in both groups during the insufflation period. There was no change in bicarbonate level in either group.

Figure 5.1 shows the mean changes in end-tidal CO_2 levels recorded during the two types of insufflation. During intraperitoneal insufflation there was a rapid rise over the first fifteen minutes and then there was a second phase of much slower change. The gradient of the rise during the first phase is 0.063 kPa/min. In comparison the rise during extraperitoneal insufflation has a gradient of 0.024 kPa/min, which is significantly slower than that observed during pneumoperitoneum ($p<0.05$). During extraperitoneal insufflation the end-tidal CO_2 continues to rise for the duration of the operation. However, the magnitude of the total rise is not significantly different from that found with intraperitoneal insufflation. The peak airway pressure increased by a median of 4 cmH_2O (IQR: 3 to 5 cmH_2O) during extraperitoneal insufflation, while during pneumoperitoneum the median increase was 2 cmH_2O (IQR: -2 to 3 cmH_2O; $p= 0.004$).

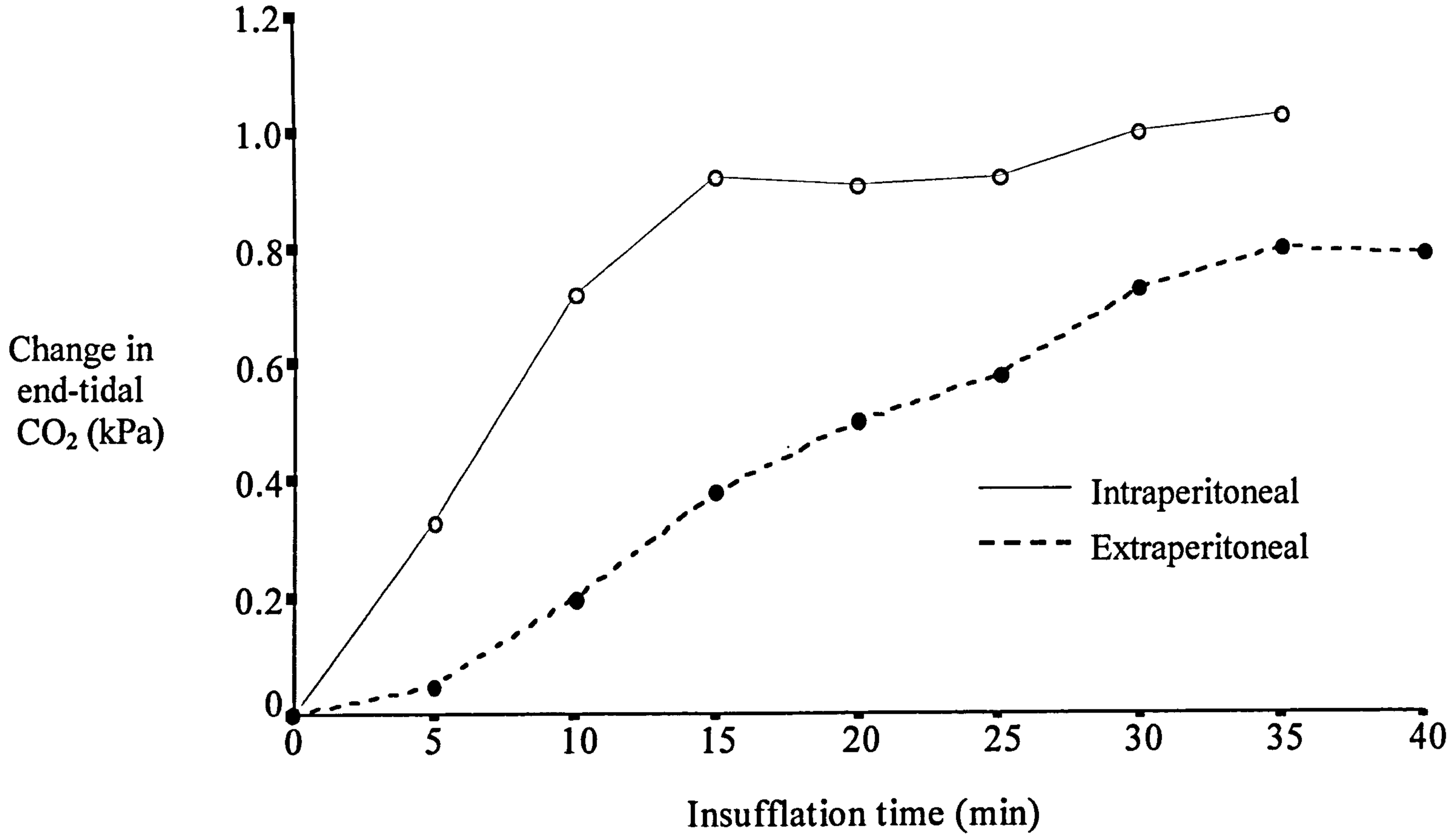
The effects of extra- and intraperitoneal insufflation on mean arterial blood pressure (MAP) are shown in figure 5.2. During extraperitoneal insufflation a rise in MAP was seen at five minutes, but by ten minutes the MAP had returned to the pre-insufflation level and then remained stable. In contrast, during intraperitoneal insufflation there was a rise in MAP over the first ten minutes and it then remained raised for the duration of the insufflation. Analysis of the area under the curve showed a significantly greater rise in the MAP for the intraperitoneal insufflation group ($p=0.046$). There was no statistically significant change in the heart rate demonstrated in either group.

Table 5.2: Change in blood gases during insufflation

	Insufflation		
	Extraperitoneal	Intraperitoneal	P
$PaCO_2$ (kPa)	0.83 (0.18 - 1.20)*	1.00 (0.70 - 1.00)*	n.s.
H^+ (mmol/l)	4.00 (1.73 - 8.00)*	6.00 (5.00 - 9.00)*	n.s.
PaO_2 (kPa)	-5.35 (-8.60 - 0.60)	-2.80 (-6.40 - 0.90)	n.s.
HCO_3^- (mmol/l)	0.00 (0.00 - 1.25)	0.00 (0.00 - 0.90)	n.s.

Values are median change (interquartile range).
* Significant rise from pre-operative value, $p<0.01$
n.s. - not statistically significant at the 5% level

Figure 3.1: Change in end-tidal CO_2 during extra- and intraperitoneal insufflation



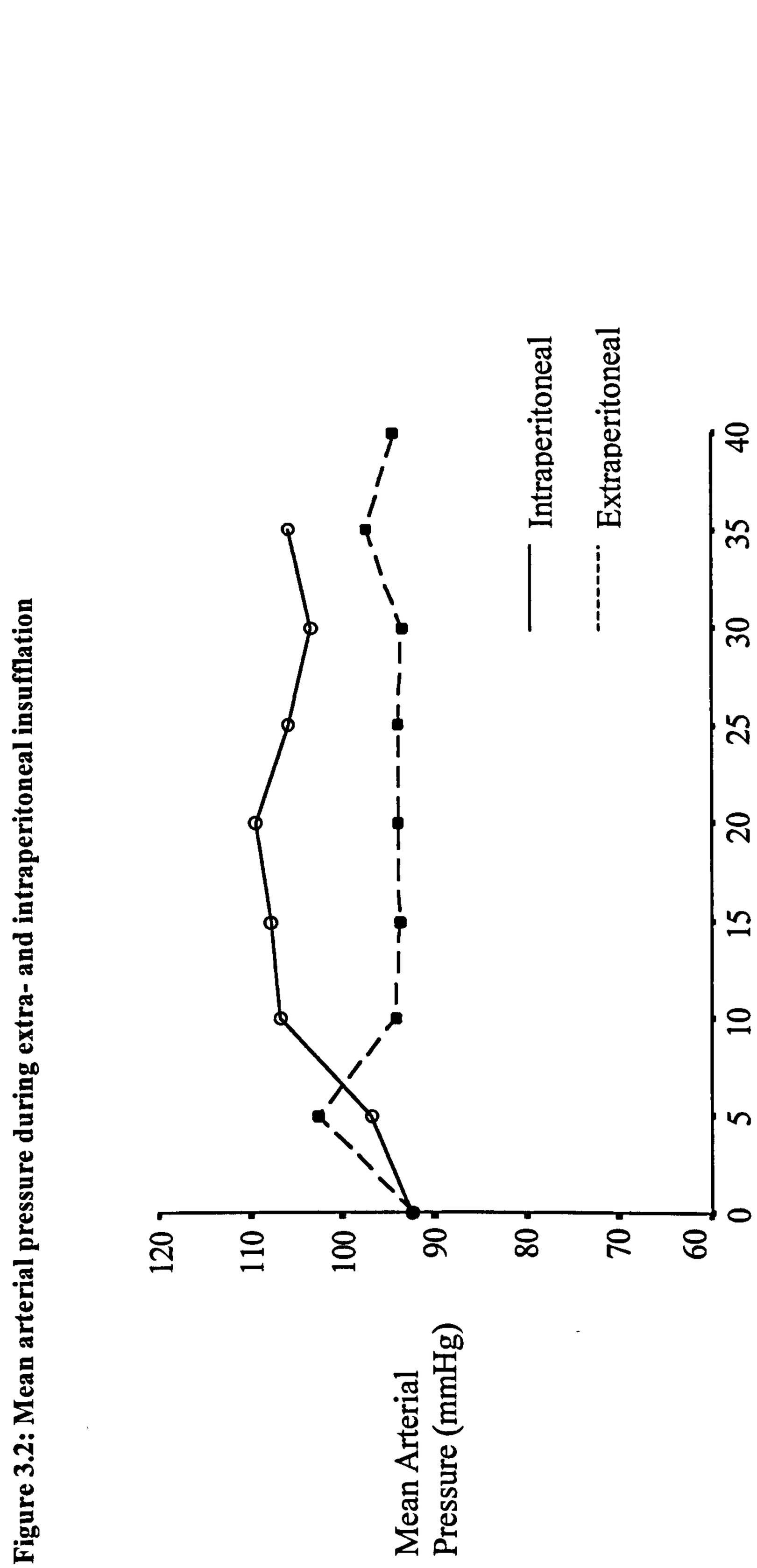


Figure 3.2: Mean arterial pressure during extra- and intraperitoneal insufflation

5.4 Discussion

This study has shown that the rises in arterial pCO_2 during extra- and intraperitoneal CO_2 insufflation are of similar magnitude after 35–40 minutes, but the rate of rise is significantly slower during extraperitoneal insufflation. There was a significant rise in the MAP during intraperitoneal insufflation and this persisted for the duration of the procedure. In contrast, there was a brief rise in MAP with extraperitoneal insufflation followed by a return to pre-insufflation levels.

Due to the differing nature of the operations being performed it was not possible to match the two groups of patients. However, as the pneumoperitoneum group was younger, any potential difference in cardio-respiratory function is likely to favour this group. This would tend to reduce, rather than enhance, the differences that have been found between the groups. The difference in the nature of the two procedures may also account for the small difference in the rise in peak airway pressure. Patients in the extraperitoneal insufflation group were placed in a slight head down position, therefore the pressure of abdominal contents on the diaphragm is likely to have caused of the increase in airway pressure in this group.

The observed effects of CO_2 pneumoperitoneum are in keeping with previous descriptions of blood gas and $ETCO_2$ changes during CO_2 insufflation.[373,387,394-396] As there have been conflicting reports on the effects of extraperitoneal insufflation, the findings for extraperitoneal insufflation in this study do contrast with some other studies.[394,395,396] In keeping with the effects described by Wolf et al.[397] and Bannenberg et al.[399] this study found that the rate of rise in end-tidal CO_2 was slower during extraperitoneal insufflation than that found during pneumoperitoneum. The reason why various studies have described contrasting results for CO_2 absorption is not clear. Work in the piglet model has shown that gas clearance across the peritoneal surface is more efficient than that from subcutaneous tissue.[352] Greater CO_2 absorption from a pneumoperitoneum than from extraperitoneal insufflation therefore fits logically with this observation. The insufflation pressure used in this study was $10cmH_2O$, while in the other reported series the pressure was greater. However, the relatively small differences in insufflation pressure seem unlikely to be the sole cause of the reported differences in CO_2 absorption. The other possible factor that could

account for the difference is the surface area for absorption. At a constant inflation pressure the rate of CO_2 absorption from a space is dependent upon the surface area of the space and the perfusion of the walls of the space. It is possible that the surface area for absorption during extraperitoneal insufflation varied in the different studies. For example, a commercial balloon device was used by Liem et al.[395] to develop the extraperitoneal dissection and this is likely to have created a larger space than that formed using the Foley catheter technique. The slower rate of CO_2 absorption that we have observed during extraperitoneal insufflation may therefore be due to a smaller surface area for absorption. This theory is supported by the observation that the rise in CO_2 levels is proportional to the extent of gas distribution in patients who develop surgical emphysema.[396]

The haemodynamic changes in this study are in keeping with some other studies,[395,398] although another group found no difference in haemodynamic changes during intra- and extraperitoneal CO_2 insufflation.[400] A number of laparoscopic operations may now be performed via a totally extraperitoneal or a transabdominal route depending on the preference of the surgeon. These procedures include repair of groin hernias, staging of prostatic and uterine tumours and ligation of varicocoeles. With the advent of these techniques an older patient population, with a higher incidence of co-existing cardiorespiratory disease, are exposed to the potential physiological stresses of laparoscopic surgery. In these patients a slower rate of CO_2 absorption, as we have described during extraperitoneal insufflation, may be safer. In both of the groups in this study the change in heart rate during insufflation was not significant, but there was a significant difference in the effects on MAP. Apart from a brief initial rise, there was no significant change in the MAP during extraperitoneal insufflation. During pneumoperitoneum the rise in MAP persisted throughout the period of insufflation. Therefore, this study suggests that extraperitoneal insufflation will cause less stress for the myocardium than occurs during pneumoperitoneum. The findings of this study therefore indicate that extraperitoneal insufflation may be safer than pneumoperitoneum for patients with pre-existing cardiorespiratory disease. There may therefore be potential advantages in using the totally extraperitoneal route rather than the transabdominal route for inguinal hernia repair, especially in those patients with pre-existing cardio-respiratory disease.

CONCLUSIONS

Repair of groin hernia is one of the most common operations performed in general surgery. Long-term follow-up after conventional herniorrhaphy demonstrates a high incidence of recurrence, at least 50% of which are symptomatic. Open tension-free prosthetic repair has recently increased in popularity due to the relative ease with which they are performed and reports of a much lower incidence of recurrence. Within the past decade the use of minimal access surgery has expanded to encompass a large proportion of general surgical procedures. Despite this, cholecystectomy remains the only procedure where a clear advantage for laparoscopic over open surgery has been generally accepted. The use of laparoscopic techniques in the repair of groin hernias is controversial.

It has been suggested that, when comparing different forms of inguinal hernia repair, the technical difficulty of a technique should be considered. The learning curve may therefore be of importance in determining the place of laparoscopic surgery in the hernia surgeons' practice. In this study, assessment of the first thirty cases for three surgeons learning the TEP repair demonstrated a reduction in operation time, conversion rates and incidence of early recurrence over this period. The learning curve for the TEP laparoscopic hernia repair therefore appears to be at least thirty cases, which corresponds with the observed learning curve for other types of laparoscopic procedure.

This pragmatic randomised comparison of laparoscopic, predominantly TEP, repair versus open repair has demonstrated early outcome advantages for the laparoscopic group. These include a lower incidence of bleeding related wound complications, but no significant difference in the incidence of wound infection or general complications. Pain scores were significantly lower for the laparoscopic group within the first twenty-four hours of the procedure and health assessment at one week using the 'Short Form 36' instrument showed significantly better functional scores for this group. There was, however, no significant difference in the other measures of well-being or for general health perception. The longer term outcome results demonstrated less marked advantage for the laparoscopic group as by one month the only significant difference between groups was in the score for physical function, and by three months there was no significant differences between the groups. The reported early advantage in functional status for the laparoscopic group was reflected in an

earlier return to normal activities such as housework, social life and hobbies. Return to work was also significantly earlier for the laparoscopic group. Assessment of the ability to perform an emergency stop whilst driving also demonstrated early advantages for the laparoscopic group. The results for the open repair group also indicate that, following tension-free repair, patients can return to driving earlier than previously advised for conventional herniorrhaphy.

Analysis of the respiratory effects of surgery showed significant reductions in function at six and twenty-four hours after the procedure for both groups, but no significant difference between the groups. This was reflected in a similar incidence of chest complications following laparoscopic and open hernia repair. Similarly, significant metabolic and inflammatory changes occurred in both groups but there were no significant differences between the groups.

The early outcome advantages for the laparoscopic repair are counter-balanced by the greater technical skills required to perform the procedure and greater hospital costs. A large proportion of the marginal cost of the laparoscopic repair is due to equipment costs and these vary according to the use of reusable or disposable instruments and the use of a stapler. Even with a totally reusable instrument policy the hospital costs are greater for the laparoscopic repair. Additional costs occur due to a greater theatre time, although the significance of this in terms of opportunity cost is questionable. Assessment of society costs following surgery is complex and there does not appear to be any reliable method to perform this. Therefore, the overall societal costs of the procedures cannot be compared.

Review at one year for the main trial showed a significantly greater recurrence rate for the laparoscopic group. This may have been related to a learning curve effect as no significant difference was seen in the sub-group of patients treated by a single surgeon who had performed more than one hundred laparoscopic repairs. After a median follow-up of five years in this sub-group, there was no significant difference in recurrence rates between the laparoscopic and open groups. Notably, there were no recurrences found following the Lichtenstein repair. With relatively low recurrence rates following prosthetic hernia repair other outcomes measures such as chronic pain may have greater significance when comparing different types of repair. This study

demonstrated a similar incidence of chronic pain following both open and laparoscopic inguinal hernia repair at one year follow-up, although the distribution of the pain varied between the types of repair.

The laparoscopic inguinal hernia repair therefore has advantages in early outcome measures, but this is counterbalanced by greater technical difficulty in performing the procedure and greater hospital costs. It appears that the long term recurrence rates following open or laparoscopic prosthetic repair will be low for the experienced surgeon. It is notable that no recurrences were identified following the Lichtenstein repair. It may therefore be argued that, despite some disadvantages in early outcome measures, the Lichtenstein repair is the procedure of choice for primary, unilateral inguinal hernias as it is relatively straight forward to perform and has good long-term outcome. There may, however, be an economic argument for the laparoscopic repair in those patients who are still part of the workforce to allow an earlier return to work. This argument requires adequate reinforcement for the patient and general practitioner that an earlier return to work is appropriate following laparoscopic repair. The preperitoneal approach has been advocated for the repair of recurrent and bilateral hernias. This being the case, there may be an argument for laparoscopic repair in these patients. This study did not have the statistical power to assess this particular sub-group of patients and there is little evidence in the current literature. A further randomised study may therefore be appropriate to answer this question.

Laparoscopic repair may be performed via a totally extraperitoneal approach or a transabdominal approach, which involves creation of a pneumoperitoneum. There is conflicting evidence in the literature with regards to the relative physiological effects of these two approaches. This study demonstrated a slower rate of accumulation of carbon dioxide and less increase in mean arterial blood pressure using the extraperitoneal approach, when compared with a pneumoperitoneum. The extraperitoneal approach may therefore be safer than the transabdominal approach, particularly in those patients with pre-existing cardio-respiratory disease.

APPENDIX A

RESULTS OF RANDOMISED TRIALS

Appendix A.1: Randomised trials comparing the Shouldice repair with other anterior sutured repairs

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
1.Tran et al. (1992)[480]	Adult primary inguinal hernia	Bassini (72) Shouldice (70)	2 years (96.9%)	Clinical exam by GP	Median op times: Bassini 45min, Shouldice 50min (ns) Mean post-op stay 10 days each (ns) Complications: Bassini 13, Shouldice13 Recurrence: Bassini 12.5%, Shouldice 10% (ns)
2. Panos et al. (1992)[481]	Adult primary direct inguinal hernia	McVay (136) Shouldice (136)	Mean 36m (87%)	Clinical exam	Recurrence: McVay 8.8%, Shouldice 6.6% (ns)
3. Kingsnorth et al. (1992)[482]	Adult primary inguinal hernia	Plication darn (171) Shouldice (151)	2 years (70%)	Clinical exam	Mean post-op stay: 2.9 days each group (ns) Complications: Plication 17, Shouldice 21 Recurrence: Plication 2.3%, Shouldice 4.6% (ns)
4. Kux et al. (1994)[47]	Adult primary and recurrent inguinal hernia	Bassini (200) Shouldice (200)	2 years (94.5%)	Clinical exam	Recurrence: Bassini 8.7%, Shouldice 3.6% ($p<0.05$)
5. Paul et al. (1994)[483]	Adult primary unilateral inguinal hernia	'Bassini' (135) Shouldice (130)	Mean 3.3yrs (92.1%)	Clinical exam	Mean op times: Bassini 47min, Shouldice 55min ($p<0.05$) Mean post-op stay: Bassini 5.6 days, Should. 6.3 days (ns) Complications: Bassini 35, Shouldice 35 Recurrence: Bassini 9.6%, Shouldice 1.7% ($p=0.006$)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.1 (cont): Randomised trials comparing the Shouldice repair with other anterior sutured repairs

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
6. Hay et al. (1996)[484]	Adult male primary inguinal hernia	'Bassini' (420) 'McVay' (407) Shouldice with prolene (419) Shouldice with steel (401)	Median 5.7 years (94.4%)	At 3 years: 88% clinical exam 12% questionnaire 3-8 years: 72% clinical exam 28% phone/letter	Med post-op stay: 'Bassini 7 days, 'McVay' 8 days Shouldice(pr) 7 days, Shouldice(st) 8 days (ns) Complications: 'Bassini' 62, 'McVay' 51 Shouldice(pr) 32, Shouldice(st) 40 No sig. difference between groups in return to work. Recurrence: 'Bassini' 8.6%, 'McVay' 11.2% Shouldice(prolene and steel) 6.1% ($p<0.001$ for Shouldice versus either Bassini or McVay repairs)
7. Beets et al. (1997)[317]	Adult male primary inguinal hernia	For Nyhus I/II: 'Bassini' (57) Herniotomy (45) For Nyhus III: 'Bassini' (160) Shouldice (103)	Mean 13.7 years (67.4%)	92% clinical exam 8% telephone	Complications: 'Bassini' 12, Herniotomy 8 Recurrence: 'Bassini' 33%, Herniotomy 34% (ns) Complications: 'Bassini' 36, Shouldice 23 Recurrence: 'Bassini' 32%, Shouldice 15% ($p=0.03$)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.2: Randomised trials comparing sutured repairs with open mesh repair

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
1. Kux et al. (1994)[531]	Patients >60yrs with primary Nyhus IIb/III defect	2-layer Shouldice (107) Lichtenstein (102)	Up to 2.5 yrs (100%)	Clinical exam	Post-op stay: Shouldice 7.2 days, Licht. 6.7 days (ns) Complications: Shouldice 45, Licht. 12 Recurrence: Shouldice 0%, Licht. 1% (ns)
2. Friis et al. (1996)[486]	All elective inguinal hernias	McVay / Herniotomy (106) Lichtenstein (102)	2 years (95.8%)	Clinical exam	Complications: McVay/Hernio. 6, Licht. 5 Return to work: McVay/Herniotomy 18.6 days, Lichtenstein 21.5 days (ns) Recurrence: McVay/Hernio. 15.1%, Licht. 5% (p=0.025)
3. Barth et al. (1998)[487]	Adult primary inguinal hernia	Shouldice (51) Lichtenstein (54)	4 weeks (100%)	Clinical exam	Median op time: Shouldice 95min, Licht. 80min (p=0.01) Complications: Shouldice 1, Lichtenstein 4 No sig. difference in reported pain or analgesic use. 50% return to normal activity by 9 days in both groups
4. Prior et al. (1998)[453]	Adult primary unilateral inguinal hernia	'Bassini' (38) Lichtenstein (42)	Mean 7 weeks (81.2%)	Clinical exam	Mean op time: 'Bassini' 27.5min, Licht. 26.8min (ns) Post-op stay: 'Bassini' 1.3 days, Licht. 1.1 days (ns) Complications: 'Bassini' 16, Lichtenstein 25 Mean pain scores: 'Bassini' 56.9, Licht. 41.7 (p=0.029) Return to work: 'Bassini' 3.1wks, Licht. 3.6wks (ns)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.2 (cont): Randomised trials comparing sutured repairs with open mesh repair

Authors	Hernia Type	Repair*	L.ength Of Follow-Up**	Method Of Follow-Up	Results
5. Zieren et al. (1998)[441]	Primary unilateral inguinal hernia	Shouldice (80) Plug & patch (80)	Mean 25 months (95%)	Clinical exam	Mean op time: Shouldice 47min, P&P 36min (ns) Mean post-op stay: Sh. 4 days, P&P 2 days (ns) Complications: Shouldice 13, P&P 12 Mean return to work: Sh. 26 days, P&P18 days ($p<0.05$) Pain scores sig. Greater in Shouldice group ($p<0.05$) Mean analgesic use: Sh. 10 days, P&P 3 days ($p<0.05$) Recurrence: Shouldice 0%, P&P 0%
6. McGillicuddy (1998)[488]	Adult male inguinal hernia	Shouldice (337) Lichtenstein (371)	Mean 5 years (64.5% at 4 years)	Clinical exam	Complications: Shouldice 69, Lichtenstein 65 Recurrence: Shouldice 2%, Lichtenstein 0.5% (ns)
7. Danielsson et al. (1999)[454]	Elective adult inguinal hernia	Shouldice (89) Lichtenstein (89)	1 year (95.5%)	Clinical exam	Mean op time: Should. 62min, Licht. 60min (ns) Mean post-op stay: Sh. 1.9 days, Licht. 2.0 days (ns) Complications: Shouldice 36, Lichtenstein 37 Return to work: Sh. 24 days, Licht. 18 days ($p=0.038$) No sig. difference in pain scores on days 1,2 or 3. Recurrence: Shouldice 10%, Lichtenstein 0% ($p=0.001$)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.2 (cont): Randomised trials comparing sutured repairs with open mesh repair

Authors	Hernia Type	Repair*	L.ength Of Follow-Up**	Method Of Follow-Up	Results
8. Hetzer et al. (1999)[532]	Adult, male primary inguinal hernia	Shouldice (171) Lichtenstein (239)	3 months	Clinical exam	Mean op. time: Sh. 88min, Licht. 80min (p=0.008) Mean post-op stay: Sh. 3.3days, Licht. 3.5days (ns) Complications: Shouldice 12, Lichtenstein 15 Mean time off work: Sh. 41d, Licht. 25d (p<0.001) Pain present at 3mths: Sh. 12%, Licht. 6% Recurrence: Shouldice 1, Lichtenstein 0

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.3: Randomised trial comparing different types of open mesh repair

Authors	Hernia Type	Repair*	L.ength Of Follow-Up**	Method Of Follow-Up	Results
1. Kingsnorth et al. (2000)[149]	Adult, primary unilateral inguinal hernia	Lichtenstein (68) Plug & Patch (73)	6 weeks	Clinical exam	Mean op time: Li. 37.6m, P&P 32.0m (p<0.001) Complications: Licht. 249, P&P 247 Ret. to normal activity: Li. 3.6d, P&P 2.8d (ns) Time off work: Li. 16.1d, P&P 14.3d (ns) VAS pain scores: Licht. > P&P (p=0.011) Analgesic use: Licht. 4.6d, P&P 4.0d (ns) Cost of prosthesis: Licht. $20, P&P $120

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.4: Randomised trials comparing laparoscopic and open sutured repair (excluding the Shouldice repair)

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
1. Stoker et al. (1994)[297]	All elective inguinal hernias	TAPP (83) Plication darn (84)	Mean 7 months	Clinical exam	Median op time: Unilateral - Lap 50min, Open 35min ($p<0.001$) Bilateral – Lap 92min, Open 60min (ns) Median post-op stay: 10hrs both groups (ns) Complications: Lap 6, Open 16 ($p<0.005$) Med. return to work: Lap 14d, Open 28d ($p<0.002$) Mean pain scores: Lap 1.8, Open 3.1 ($p<0.001$) No recurrences in either group.
2. Maddern et al. (1994)[490]	All elective inguinal hernias	TAPP (57) Plication darn (44)	Median 243 days	Clinical exam to 30 days then review by telephone	Median op time: Lap 35min, Open 30.5min (ns) Median post-op stay: Lap 225min, Open 134.5min ($p<0.05$) Complications: Lap 17, Open 21 Median return to work: Lap 17.5d, Open 30d (ns) No significant difference in post-op pain scores. Recurrence: Lap 3.5%, Open 0%
3. Rudkin et al. (1995)[491]	Primary unilateral inguinal hernia	TAPP (29) Plication darn (30)	Not given	Clinical exam	Mean op time: Lap 66.6min, Open 44.8min ($p<0.001$) Mean discharge time: Lap 224.2min, Open 139.1min ($p<0.002$) Mean return to work: Lap 26.0days, Open 31.8days

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.4 (cont): Randomised trials comparing laparoscopic and open sutured repair (excluding the Shouldice repair)

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
4. Lawrence et al. (1995)[436]	Primary unilateral inguinal hernia	TAPP (58) Moloney darn (66)	6-weekly review (99.2%)	Clinical exam at 6 weeks then questionnaire	Mean op time: Lap 72min, Open 32min (P<0.0001) Complications: Lap 6, Open 1 Return to work: Lap 22 days, Open 28 days (ns) Pain scores: No significant difference at rest. Lap significantly lower on movement. Recurrence: Lap 1.7%, Open 0% Mean cost: Lap £850, Open £268 (p<0.001)
5. Barkun et al. (1995)[492]	Primary unilateral inguinal hernia	TAPP/IPOM (43) Variety of open repairs (49)	Median 14 months	Clinical exam	Mean op times: Lap 86.7min, Open 79.8min (ns) Median post-op stay: Lap 1 day, Open 1 day (ns) Complications: Lap 22.5%, Open 11.9% Convalescense: Lap 9.6 days, Open 10.9 days (ns) Mean pain scores (day 1): Lap 18.2, Open 19.2 (ns) Recurrence: Lap 0%, Open 2.0% Mean cost: Lap $1718, Open $1224
6. Vogt et al. (1995)[192] Kingsley et al. (1998)[193]	All inguinal hernias	IPOM (30) Open repair of surgeons choice (28)	Mean 41 months (86%)	Clinical exam or telephone interview	Mean op time: Lap 63.2min, Open 80.9min Complications: Lap 5, Open 5 Mean return normal act: Lap 7.5 days, Open 18.5 days Mean oral analgesia: Lap 5 doses, Open 16 doses Late complications: Lap 5, Open 2 Recurrence: Lap 43%, Open 15% (p<0.05)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.4 (cont): Randomised trials comparing laparoscopic and open sutured repair (excluding the Shouldice repair)

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
7. Kozol et al. (1995)[437]	Primary and recurrent unilateral inguinal hernia	TAPP (30) Variety of mesh/ sutured repairs selected by hernia type (32)	48 hours (100%)	Pain questionnaires	Mean op time: Lap 128min, Open 126min (ns) Complications: Lap 6, Open 7 McGill score day 1: Lap 0.9, Open 2.3 (p=0.02) VAS score day 1: Lap 3.4, Open 4.9 (p=0.006) McGill score day 2: Lap 1.3, Open 1.8 (p=0.03) VAS score day 2: Lap 1.6, Open 3.8 (p=0.002)
8. Liem et al. (1996)[294]	Unilateral primary or or first recurrence inguinal hernia	TEP (487) Variety of open repairs selected by surgeon preference (507)	Median 607 days (97%)	Clinical exam	Median op time: Lap 45min, Open 40min (p<0.001) Median post-op stay: Lap 1d, Open 2d (p<0.001) Operative complications: Lap 20, Open 4 Post-op complications: Lap 54, Open 97 Median return to work: Lap 14 days, Open 21 days (p<0.001) Pain scores sig. less in lap. group (p<0.001) Recurrences: Lap 3.5%, Open 6.1% (p=0.05)
9. Tanphiphat et al. (1998)[438]	All elective inguinal hernias	TAPP (64) 'Bassini' / Lichtenstein (63)	Mean 32 months (95.8%)	Clinical exam (77.4) Telephone / postal (22.6%)	Mean op time: Lap 95min, Open 67min (p<0.001) Mean post-op stay: Lap 2.6d, Open 3.0d (ns) Complications: Lap 22, Open 28 (ns) Median return to work: Lap 14d, Open 15d (ns) Mean pain score: Lap 36.2, Open 49.3 (p=0.006) Recurrence: Lap 1.6%, Open 0% (ns)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.4 (cont): Randomised trials comparing laparoscopic and open sutured repair (excluding the Shouldice repair)

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
10. Dirksen et al. (1998)[455]	Primary inguinal hernia	TAPP (114) 'Bassini' (103)	Mean 2 years (98.8%)	Clinical exam in 96.5% and telephone in 3.5%	Mean op time: Unilateral – Lap 82min, Open 45min (p<0.005) Bilateral – Lap 109min, Open 48min (p<0.005) Operative complications: Lap 3, Open 1 Post-op stay <24hrs: Lap 91%, Open 97% (ns) Post-op complications: Lap 68, Open 43 Mean time disability: Lap 14d, Open 22d (p<0.001) Mean pain scores: Lap 2.0, Open 2.9 (p=0.002) Recurrence: Lap 6.1%, Open 21.3% (p=0.001) Chronic wound pain: Lap 17, Open 12

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.5: Randomised trials comparing laparoscopic and the Shouldice repair

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
1. Leibl et al. (1995)[533] Leibl et al. (2000)[456]	Adult, primary unilateral inguinal hernia	TAPP (54) Shouldice (48)	Median 70 months (90%)	Clinical exam	Median op times: Lap 65min, Open 47.5min (ns) Complications: Lap 4, Open 4 Oral analgesia at day 3: Lap 0%, Open 26.9% (p<0.05) Median return to work: Lap 21d, Open 38d (P<0.05) Recurrence: Lap 1 (2%), Open 2 (5%) (ns)
2. Schrenk et al. (1996)[425]	Elective unilateral inguinal hernia	TAPP (15) Shouldice (15)	5 days (100%)	Clinical exam	Mean op time: Lap 41.7min, Open 36.6min (p=0.03) Mean hospital stay 3.6 days in both groups. Mean pain scores: at rest – no significant difference. on movement – Lap 5.0, Open 7.5 (p=0.028) No significant difference in acute phase reactants or cytokine response in first 48 hours.
3. Schrenk et al. (1996)[439]	Elective unilateral inguinal hernia	TAPP (28) TEP (24) Shouldice (34)	3 months	Clinical exam	Mean op time: TAPP 46.0min, TEP 52.3min, Open 38.4min (Open sig. less, p=0.04) Hospital stay: TAPP 3.7d, TEP 4.4d, Open 3.7d (p=0.04) Complications: TAPP 7, TEP 6, Open 6 Return to work: TAPP 4.9wks, TEP 4.6wks, Open 4.8wks (ns) Pain scores on day of op: Open/TEP > TAPP (p=0.02) Recurrence: TAPP 3.6%, TEP 0%, Open 0%

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.5 (cont): Randomised trials comparing laparoscopic and the Shouldice repair

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
4. Bessell et al. (1996)[493]	All elective adult inguinal hernias	TEP (32) Shouldice (72)	Median 220 days	Not stated	Median op time: Lap 87.5min, Open 50min (p<0.001) Median stay: Lap 240min, Open 162.5min (p=0.003) Complications: Lap 4, Open 7 Median return to work: Lap 30.5d, Open 32d (ns) Recurrence: Lap 6.2%, Open 0%
5. Tschudi et al. (1996)[440]	All elective inguinal hernia >50 years age	TAPP (56) Shouldice (52)	Mean 201 days	Clinical exam	Mean op time: Unilateral – Lap 87min, Open 59min (p<0.001) Bilateral – Lap 124min, Open 79min (p<0.001) Complications: Lap 6, Open 9 Pain scores: Open > Lap (p=0.05) Recurrence: Lap 1.8%, Open 3.8%
6. Kald et al. (1997)[457]	All elective inguinal hernias	TAPP (122) Shouldice (89)	All reached 1 year (98%)	Clinical exam	Mean op time: Lap 72min, Open 62min (p<0.009) Mean hospital stay 12 hours in both groups. Complications: Lap 8, Open 9 Mean return to work: Heavy – Lap 14 days, Open 32 days (p=0.0007) Moderate – Lap 10 days, Open 19 days (p=0.009) Sedentary – Lap 6 days, Open 13 days (p=0.01) Recurrence: Lap 0%, Open 3.4% (p=0.04) Mean cost: Lap 13182 SEK, Open 9145 SEK

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.5 (cont): Randomised trials comparing laparoscopic and the Shouldice repair

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
7. Zieren et al. (1998)[441]	Primary unilateral inguinal hernia	TAPP (80) Shouldice (80)	Mean 25 months (95%)	Clinical exam	Mean op time: Lap 61min, Open 47min (p=0.05) Intra-op complications: Lap 2, Open 0 Mean hospital stay: Lap 3 days, Open 4 days (ns) Post-op complications: Lap 15, Open 13 Mean return to work: Lap 16d, Open 26d (p<0.05) Mean pain scores greater in open group (p<0.05) No recurrence in either group Mean cost: Lap $1211, Open $69 (p<0.01)
8. Champault et al. (1998)[494]	All inguinal hernia >40 years age	TEP (233) Shouldice (179) Stoppa (49)	Median 4 years Min 2yrs (92%)	Clinical exam (or telephone if necessary)	Recurrence: TEP 3.4%, Shouldice 4.5%, Stoppa 4.0% (ns)
9. Juul et al. (1999)[458]	Primary unilateral inguinal hernia	TAPP (138) Shouldice / Herniotomy (107 / 23)	Median 12 months (97.8%)	Clinical exam (92.9%) or questionnaire (7.1%)	Median op time: Lap 77min, Open 45min (p<0.001) Median hospital stay 1 day in both groups. Complications: Lap 13, Open 15 Median return to normal activity: Lap 13 days, Open 18 days (P<0.005) Median analgesic use: Lap 2.1d, Open 2.7d (p<0.02) Recurrence: Lap 2.9%, Open 2.3% (ns)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.5 (cont): Randomised trials comparing laparoscopic and the Shouldice repair

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
10. Lorenz et al. (2000)[332]	Adult primary unilateral or bilateral inguinal hernia	TAPP (86) Shouldice (90)	Median 14 months (92% lap. / 90% open)	Clinical exam	Median op. time (uni): Lap 60min, Open 60min (ns) Hospital stay: Lap. 4 days, Open 6 days ($p<0.001$) Post-op. complications: Lap. 9, Open 8 Return to work: Uni: Lap. 24 days, Open 34 days (ns) Bil: Lap. 38 days, Open 42 days (ns) Pain scores: Uni: No sig. diff. In first 4 days Bil: Lap. significantly lower. Recurrence: Lap. 2, Open 1 (ns) Costs: Hospital: Lap. 2145DM, Open 1863DM Non-hosp: Lap 2970DM, Open 3726DM Total: Lap 5198DM, Open 5589DM

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.6: Randomised trials comparing laparoscopic and open mesh repairs

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
1. Payne et al. (1994)[459]	Nyhus type III and IV inguinal hernia	TAPP (52) Lichtenstein (58)	Median 10 months (98%)	Clinical exam	Mean op time: Unilateral: Lap 68min, Open 56min (ns) Bilateral: Lap 93min, Open 87min (ns) No sig. difference in discharge times. Complications: Lap 6, Open 9 Mean return to work: Sedentary: Lap 7.4d, Open 15d ($p<0.005$) Manual: Lap 11.7d, Open 23d ($p<0.002$) No recurrence in either group. Mean cost: Lap $3093, Open $2494 ($p<0.001$)
2. Filipi et al. (1996)[495]	Adult male unilateral inguinal hernia	TAPP (24) Lichtenstein (29)	Mean 11 months (94.3%)	Questionnaire	Mean op time: Lap 109min, Open 87min Mean hospital stay: Lap 1.7d, Open 1.8d No significant difference in activity assessment. No significant difference in pain scores. Recurrence: Lap 0%, Open 6.9% Chronic pain: Lap 2, Open 3
3. Champault et al. (1997)[443]	Nyhus type IIIa/b and IV inguinal hernia in men >40yrs	TEP (51) Stoppa (49)	Mean 605 days	Clinical exam	Mean op time longer for rec/bil lap repair ($p=0.01$) Mean hospital stay: Lap 3.2d, Open 7.3d ($p=0.01$) Complications: Lap 2, Open 11 ($p=0.01$) Mean return work: Lap 17d, Open 35d ($p=0.01$) Pain scores less for laparoscopic repair ($p=0.001$) Recurrence: Lap 6%, Open 2% (ns)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.6 (cont): Randomised trials comparing laparoscopic and open mesh repairs

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
4. Sarli et al. (1997)[496]	All adult inguinal hernias	TAPP (64) Lichtenstein (66)	Median 36 months	Clinical exam	Operation times sig. greater in lap group ($p<0.05$) Complications: Lap 10, Open 9 No significant difference in return to work. No significant difference in pain scores. No recurrences in either group.
5. Heikkinen et al. (1998)[469]	Primary unilateral inguinal hernia	TAPP (20) Lichtenstein (20)	Median 17 months	Clinical exam at 1 week then questionnaire	Mean op time: Lap 62min, Open 65min (ns) Post-op stay: Lap 6.5hr, Open 3.5hr ($p<0.001$) Complications: Lap 5, Open 8 Median pain scores: Lap 2.0, Open 2.1 (ns) No recurrence in either group. Cost: Lap 5976FIM, Open 3915FIM ($p<0.001$)
6. Khoury (1998)[460]	All inguinal and femoral hernias	TEP (169) P&P (146)	Median 17 months (89%)	Clinical exam at one week then every four months	Median op time: Lap 31.5min, Open 30.5min (ns) 98% of each group discharged on day of operation. Intra-op complications: Lap 2, Open 0 Post-op complications: Lap 20, Open 33 ($p<0.01$) Median return to work: Lap 8d, Open 15d ($p<0.01$) Mean pain score: Lap 3, Open 7 ($p<0.01$) Recurrence: Lap 1.8%, Open 2.7% (ns)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.6 (cont): Randomised trials comparing laparoscopic and open mesh repairs

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
7. Wellwood et al. (1998)[442]	All elective inguinal hernia	TAPP (223) Lichtenstein (224)	3 months	Clinical exam	No sig. diff. in median op time for each procedure. Hospital stay longer in laparoscopic group (p<0.01) Complications: Lap 313, Open 446 Median return to work: Manual – Lap 21days, Open 26 days (ns) Sedentary–Lap 11 days, Open 18 days (p<0.05) Pain scores: Open sig. greater in weeks 1 and 2. No sig. difference in weeks 3 and 4. Mean cost£335 greater for laparoscopic repair.
8. Paganini et al. (1998)[473]	All elective inguinal hernia	TAPP (67) Lichtenstein (72)	Median 28 months (100%)	Clinical exam	Mean op time: Lap 67min, Open 48min (p=0.002) Operative complications: Lap 1, Open 0 Post-op complications: Lap 20, Open 18 Median return to work: Lap 15d, Open 14d (ns) No difference in pain scores in first week. Recurrence: Lap 3.0%, Open 0% Chronic pain: Lap 3, Open 6 Mean cost: Lap $1249.1, Open $306.4 (p<0.001)

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

Appendix A.6 (cont): Randomised trials comparing laparoscopic and open mesh repairs

Authors	Hernia Type	Repair*	Length Of Follow-Up**	Method Of Follow-Up	Results
9. Johansson et al. (1999)[461]	Elective primary unilateral / first recurrence in men 40-75 yrs of age	TAPP Open preper-itoneal mesh. Open sutured. (Total of 613 patients randomised)	One year (97.8%)	Clinical exam (98.3%) Telephone (1.7%)	Mean op time: Sut. 37min, Mesh 38min, TAPP 65min Post-op complications: Sut. 43, Mesh 45, TAPP 57 Return to normal activity: TAPP (18.4d) shorter than sutured (26.4d) or mesh (24.2d) ($p<0.001$) No sig. diff. between groups in pain scores at 7 days Recurrence: Sut. 4, Mesh 11, TAPP 4 Chronic pain: Sut. 0, Mesh 2, TAPP 5
10. Picchio et al. (1999)[497]	Primary inguinal hernia	TAPP (53) Lichtenstein (52)	Not stated	Clinical exam at 1wk & 4wk. Questionnaire on return to normal activity (99%)	Mean op time: Lap 50min, Open 34min ($p<0.001$) Mean stay: Lap 2.3 days, Open 2.2 days (ns) Complications: Lap 14, Open 13 (ns) Mean return to normal activity: Lap 6.5 wks, Open 6.1 wks ($P<0.03$) Mean pain scores: Day 1 – Lap 3.1, Open 2.7 (ns) Day 2 – Lap 2.3, Open 1.8 ($p<0.03$) No sig.diff. in IM analgesic requirement

* number of repairs given in brackets, ** percentage follow-up given in brackets, ns – not statistically significant at the 5% level

APPENDIX B

PERI-OPERATIVE DATA COLLECTION FORM FOR THE MULTICENTRE RANDOMISED TRIAL

SECTION A -TRIAL DATA

(This section to be completed by the Resident prior to the operation.)

1. **Hospital number** ☐☐☐☐☐☐☐☐☐☐

2. **Name** _____

3. **Address** _____

_____

4. **Telephone number** ☐☐☐☐☐☐☐☐☐☐

5. **Sex**

Male ☐ 1
Female ☐ 2

6. **Date of birth** ☐☐☐☐☐☐

7. **Date of admission** ☐☐☐☐☐☐

8. **Randomisation**

Conventional ☐ 1
Laparoscopic ☐ 2
Not randomised ☐ 3

If not randomisation, please give reason
(please tick one box)

The patient refuses randomisation ☐ 1
The surgeon has not completed 10 laparoscopic hernia repairs ☐ 2
The patient is medically unfit for general anaesthetic ☐ 3
The patient has a previous lower midline or paramedian incision ☐ 4
The patient has an incarcerated or inguinoscrotal hernia ☐ 5
The patient has an uncorrected coagulation disorder ☐ 6
The patient is pregnant ☐ 7
Other ☐ 8

Please specify _____

SECTION B - PATIENT DETAILS

(This section to be completed by the Resident prior to the operation)

1. Employment Status

Full-time	☐	1
Part-time	☐	2
Retired	☐	3
Unemployed	☐	4
Housewife	☐	5
Other	☐	6

Please specify _____

2. Occupation type (*please tick one box*)

Sedentary	☐	1
Moderate manual	☐	2
Heavy manual	☐	3
Not applicable	☐	4

3. Pre-operative height ☐☐☐ cm

4. Pre-operative weight ☐☐☐ kg

5. Please indicate the patient's physical status using the following ASA grading.

CLASS 1 - Normal

CLASS 2 - Mild to moderate systemic disease (e.g. controlled diabetes or HBP)

CLASS 3 - Severe systemic disease (e.g. uncontrolled diabetes or HBP)

CLASS 4 - Incapacitating systemic disease that is a threat to life (e.g. CCF, severe angina)

(please tick appropriate box)

Class 1	☐	1
Class 2	☐	2
Class 3	☐	3
Class 4	☐	4

6. Duration this hernia present ☐☐ **months**

7. Hernia related history (*please tick one box for each option)*

	Yes 1	No 2
Pain	☐	☐
Days off work	☐	☐
Has effected leisure activities	☐	☐
Nausea or vomiting	☐	☐
Has become irreducible	☐	☐
History of recent severe straining	☐	☐
Previous hernia	☐	☐

If yes, please specify type _____

	Yes 1	No 2
Family history of hernia	☐	☐

If yes , please specify type _____

8. Site of hernia (*please tick one box)*

Right	☐	1
Left	☐	2
Bilateral	☐	3

9. Type of hernia (*please tick one box)*

Indirect inguinal	☐	1
Direct inguinal	☐	2
Inguino scrotal	☐	3
Femoral	☐	4

10. Is the hernia recurrent?

Yes	☐	1
No	☐	2

If no, go to Section C

11. Please indicate the number of previous operations. *(please tick one box)*

One	☐	1
Two	☐	2
Three	☐	3
Four	☐	4
Five	☐	5
More than Five	☐	6

12. Please indicate the first operation type (if known) *(please tick one box)*

Laparoscopic: extraperitoneal	☐	1
Laparoscopic: transperitoneal	☐	2
Laparoscopic: closure of internal ring	☐	3
Bassini	☐	4
Shouldice	☐	5
Plication darn	☐	6
Moloney darn	☐	7
Lichtenstein	☐	8
Other	☐	9

Please specify _____

13. Please indicate the interval between the first operation and the most recent recurrence. ☐☐ **years**

14. Please indicate the grade of surgeon performing the first repair. *(please tick one box)*

SHO	☐	1
Registrar	☐	2
Senior Registrar	☐	3
Consultant	☐	4
Not Known	☐	5

15. Please indicate whether any of the following post-operative complications were present after the first repair.
(please tick one box for each complication)

	Yes	No
	1	2
Wound infection	☐	☐
Haematoma	☐	☐
Other	☐	☐

Please specify _____

SECTION C - OPERATIVE DETAILS

(This section is to be completed by the Surgeon at the time of the operation)

All the information in this section is crucial for the statistical analysis of this project.

1. Date of Operation ☐☐☐☐☐☐

2. Was the operation (*please tick one box*)

Elective ☐ 1
Urgent ☐ 2

3. Grade of operator (*please tick one box*)

SHO ☐ 1
Registrar ☐ 2
Senior Registrar ☐ 3
Consultant ☐ 4

4. Grade of assistant (*please tick one box*)

SHO ☐ 1
Registrar ☐ 2
Senior Registrar ☐ 3
Consultant ☐ 4

5. If laparoscopic, number of laparoscopic hernia operations:

Performed by operator ☐☐☐

Performed or assisted by assistant ☐☐☐

6. Type of anaesthesia (*please tick one box*)

General ☐ 1
Spinal ☐ 2
Epidural ☐ 3
Local ☐ 4

7. Duration of anaesthesia ☐☐☐ mins

8. Duration of operation ☐☐☐ mins

9. If hernia is bilateral, site operated on

Left	☐	1
Right	☐	2
Both	☐	3

If both, please indicate both in Question 10.

10. Type of hernia; Nyhus classification *(please tick all that apply)*

Type 1	Indirect inguinal hernia with normal internal ring	☐	1
Type 2	Indirect inguinal hernia with enlarged internal ring	☐	2
Type 3a	Direct inguinal hernia	☐	3
Type 3b	Indirect and direct inguinal hernia (Pantaloon hernia)	☐	4
Type 3c	Femoral hernia	☐	5
Type 4a	Direct recurrent hernia	☐	6
Type 4b	Indirect recurrent hernia	☐	7
Type 4c	Recurrent femoral hernia	☐	8
Type 4d	Combination of Type 4a and Type 4b	☐	9

11. Type of repair *(please tick one box)*

Laparoscopic: extraperitoneal	☐	1
Laparoscopic: transperitoneal	☐	2
Laparoscopic: closure of internal ring	☐	3
Bassini	☐	4
Shouldice	☐	5
Plication Darn	☐	6
Moloney darn	☐	7
Lichtenstein	☐	8
Other	☐	9

Please specify _____

12. Operative complications?
(please tick one box for each complication)

	Yes 1	No 2
Damage to vas or testicular vessels	☐	☐
Nerve Injury	☐	☐
Bladder Injury	☐	☐
Visceral Injury	☐	☐
Vascular Injury	☐	☐
Other	☐	☐

If yes to any of the above, please give details of injury _____

If conventional operation, please go to Section D

13. If laparoscopic

Was the repair converted to an open operation

Yes ☐ 1
No ☐ 2

If yes please specify reason _____

Was the prosthesis stapled or sutured?

Yes ☐ 1
No ☐ 2

(a) If extraperitoneal
Was the sac?

Reduced ☐ 1
Reduced and ligated ☐ 2
Transected ☐ 3
Transected and ligated ☐ 4

Was the peritoneal cavity entered?

Yes ☐ 1
No ☐ 2

Was a balloon used?

Yes ☐ 1
No ☐ 2

(b) If transperitoneal
Was the peritoneum closed?

Yes ☐ 1
No ☐ 2

If yes, was it

Stapled ☐ 1
Sutured ☐ 2

(c) If closure of internal ring,
Was the ring closed with:

Interrupted sutures ☐ 1
Pursed string sutures ☐ 2

SECTION D - POST - OPERATIVE DETAILS

(This section to be completed by the Resident on patient's discharge)

1. Was the Patient?

Day case ☐ 1
In - patient ☐ 2

2. Date of discharge ☐☐☐☐☐☐

3. Did the patient request a home-help or other resource during convalescence?

Yes ☐ 1
No ☐ 2

4. All analgesia prescribed

Name	**Total dose**

SECTION E - ONE WEEK OUT PATIENT REVIEW

(This section to be completed by the Clinician at the out patient review visit)

1. Date of out-patient review ☐☐/☐☐/☐☐

2. Is there evidence of any of the following complications?
(please tick one box for each complication)

Wound complications

	Yes 1	No 2
Bruising (including flare formation)	☐	☐
Seroma	☐	☐
Haematoma	☐	☐
Infection	☐	☐

Scrotal complications

	Yes 1	No 2
Hydrocele	☐	☐
Genital oedema	☐	☐
Haematoma	☐	☐

Special complications

	Yes 1	No 2
Retention of urine	☐	☐
Nerve injury	☐	☐
Visceral injury	☐	☐

General complications

	Yes 1	No 2
Chest infection	☐	☐
DVT or pulmonary embolism	☐	☐
Cardiovasular accident	☐	☐

Other complications, please specify _____

3. Has patient been re-admitted? Yes ☐ 1 No ☐ 2

If yes
Please specify reason _____

Number of days in hospital ☐☐ days

Post-discharge analgesics prescribed Yes ☐ 1 No ☐ 2

If NO, go to Question 5

A. Name _____

B. Dose _____

C. Analgesia being used at present Yes ☐ 1 No ☐ 2

How many days post-discharge were analgesics used? ☐☐ days

5. Date of 1 year out-patient review appointment ☐☐☐☐☐☐

Thank you. Your help in the completion of this questionnaire is very much appreciated.

Please give patients their 1 week questionnaire, with instructions to complete as soon as they get home

APPENDIX C

QUESTIONNAIRE FOR ONE-WEEK POST-OPERATIVE FOLLOW-UP

The following questions ask for your views about your health and how you feel about life in general since returning home after your operation. If you are unsure about how to answer any questions, try and think about your overall health and give the best answer you can. Do not spend too much time in answering as your immediate response is likely to be the most accurate.

1. In general, would you say your health is:

Excellent	☐	1
Very good	☐	2
Good	☐	3
Fair	☐	4
Poor	☐	5

2. How is your health now compared with before your operation?

Much better now than before operation	☐	1
Somewhat better now than before operation	☐	2
About the same	☐	3
Somewhat worse now than before operation	☐	4
Much worse now than before operation	☐	5

3. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
		1	2	3
i.	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
ii.	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
iii.	Lifting or carrying groceries	☐	☐	☐
iv.	Climbing several flights of stairs	☐	☐	☐
v.	Climbing one flight of stairs	☐	☐	☐
vi.	Bending, kneeling or stooping	☐	☐	☐
vii.	Walking more than a mile	☐	☐	☐
viii.	Walking half a mile	☐	☐	☐
ix.	Walking 100 yards	☐	☐	☐
x.	Bathing and dressing yourself	☐	☐	☐

4. **Since returning home, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

		Yes 1	No 2
i.	Cut down on the amount of time spent on work or other activities	☐	☐
ii.	Accomplished less than you would like	☐	☐
iii.	Were limited in the kind of work or other activities	☐	☐
iv.	Had difficulty performing the work or other activities (eg it took extra effort)	☐	☐

5. **Since returning home have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

		Yes 1	No 2
i.	Cut down on the amount of time you spent on work or other activities	☐	☐
ii.	Accomplished less than you would like	☐	☐
iii.	Didn't do the work or other activities as carefully as usual	☐	☐

6. **Since returning home, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?**

Not at all	☐ 1
Slightly	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

7. **How much bodily pain have you had since returning home?**

None	☐ 1
Very mild	☐ 2
Mild	☐ 3
Moderate	☐ 4
Severe	☐ 5
Very severe	☐ 6

8. **Since returning home, how much did pain interfere with your normal work (including work both outside the home and housework)?**

Not at all	☐ 1
A little bit	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

9. These questions are about how you feel and how things have been with you since returning home from your operation. (For each question, please indicate the one answer that comes closest to the way you have been feeling).

How much time since returning home:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5	6
i. Did you feel full of life?	☐	☐	☐	☐	☐	☐
ii. Have you felt particularly nervous?	☐	☐	☐	☐	☐	☐
iii. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
iv. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
v. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
vi. Have you felt downhearted and miserable?	☐	☐	☐	☐	☐	☐
vii. Did you feel worn out?	☐	☐	☐	☐	☐	☐
viii. Have you been happy?	☐	☐	☐	☐	☐	☐
ix. Did you feel tired?	☐	☐	☐	☐	☐	☐
x. Has your health limited your social activities (like visiting friends or close relatives)?	☐	☐	☐	☐	☐	☐

10. Please choose the answer that best describes how true or false each of the following statements is for you.

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
	1	2	3	4	5
i. I seem to get ill more often than other people	☐	☐	☐	☐	☐
ii. I am as healthy as anybody I know	☐	☐	☐	☐	☐
iii. I expect my health to get worse	☐	☐	☐	☐	☐
iv. My health is excellent	☐	☐	☐	☐	☐

The following questions are just about your hernia.

11. During the last week how much of the time have you had pain in your groin (the site of your hernia)?

All the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

12. How bad has pain in your groin (the site of your hernia) been in the last week?

No pain	1
Very mild	2
Mild	3
Severe	4
Very Severe	5

13. Have you experienced any numbness around your groin (the site of your hernia) in the last week?

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

14. Have you experienced any numbness down your thigh in the last week?

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

15. If male, have you experienced any pain in your testicles in the last week?

All the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

16. How satisfied are you with the appearance of your operation scar(s)?
(Please tick the box which best describes you)

Very satisfied	1
Satisfied	2
Neither satisfied nor dissatisfied	3
Dissatisfied	4
Very dissatisfied	5

17. **If you were prescribed pain-killers on leaving hospital, did you use:**

More than recommended ☐	1
As recommended ☐	2
Less than recommended ☐	3
None at all ☐	4
Pain killers were not prescribed ☐	5

18. **How has the operation changed your day-to-day life so far?**

(Please tick one box)

Much better ☐	1
Slightly better ☐	2
No change ☐	3
Slightly worse ☐	4
Much worse ☐	5

19. **Has your recovery from the operation been faster than you expected, slower than you expected or about as expected?**

Faster than expected ☐	1
About as expected ☐	2
Slower than expected ☐	3

20. **If someone else were to have the same hernia problem as you have had, would you recommend the operation you received?**

Yes ☐	1
No ☐	2

21. **Since your operation how many medical appointments have you been to?**

Number of appointments with:

GP _____

Hospital outpatient _____

Other _____

If other, please specify _____

22. **What would you estimate you have spent on total travelling costs to and from medical appointments for your hernia, since your operation?**

£_____

23. **How much time would you estimate you have spent going to medical appointments for your hernia since your operation?**

_____

The following questions ask about your daily life since your operation. If any of the questions do not apply to you, tick the "Not Applicable" box.

24. Have you returned to your job (paid employment)?

Yes ☐ 1
No ☐ 2
Not applicable ☐ 3

If YES, how long after your operation did you return to your job? ☐☐ days

25. Are you able to look after the house (cleaning, cooking, repairs, odd jobs around the home and so on)?

Yes ☐ 1
No ☐ 2
Not applicable ☐ 3

If YES, how long after your operation were you able to look after the house? ☐☐ days

26. Are you able to enjoy your usual social life (going out, seeing friends, going to the pub, etc)?

Yes ☐ 1
No ☐ 2
Not applicable ☐ 3

If YES, how long after your operation were you able to enjoy your usual social life? ☐☐ days

27. Are you able to enjoy your usual sex life?

Yes ☐ 1
No ☐ 2
Not applicable ☐ 3

If YES, how long after your operation were you able to enjoy your usual sex life? ☐☐ days

28. Are you able to enjoy your usual interests or hobbies (sports, DIY, arts, crafts, etc)?

Yes ☐ 1
No ☐ 2
Not applicable ☐ 3

If YES, how long after your operation were you able to return to your usual interests or hobbies? ☐☐ days

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