Abdominal Wall Hernias: Symptoms and Outcome

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Submitted in fulfilment of the requirements for the Degree of Doctor of Medicine

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May 2014

Abstract

Introduction and Aims

Pain is the most common symptom associated with hernias but there is little in the literature on its effects on an individual's physical activity or quality of life. Up to one-third of patients with an inguinal hernia have no symptoms from the hernia. Repair of a ventral hernia is a common operation and increasing in frequency. Many operations for hernia are on patients with minimal symptoms but data on outcomes are lacking.

The aims of the studies are to: assess the frequency of pain and its effects on physical activity and quality of life in patients with inguinal and ventral hernias; to determine the long term outcome of patients with a painless inguinal hernia randomised to observation or operation; to assess the long term outcomes of patients with an asymptomatic ventral hernia managed by a period of observation; and to examine the incidence of umbilical hernias in a general adult population and establish the long term outcome of patients with an umbilical hernia.

Patients and Methods

All patients undergoing operation for an elective inguinal or ventral hernia over a 16 month period were asked to complete a questionnaire recording data on baseline characteristics, a 4-point Verbal Rating Scale (VRS) and Visual Analogue Scale (VAS) of their pain. They also completed the short form Brief Pain Inventory (BPI) to assess pain severity and interference.

160 men aged 55 years or more with an asymptomatic inguinal hernia were randomised to observation or operation. Clinical follow up was undertaken at a median of 5 years and final follow up at a minimum of 6 years from randomisation. Ventral hernia patients presenting to a surgical clinic over a one year period were identified and those who were asymptomatic were followed up either by annual clinical examination or review of their electronic case records. All new patient referrals to a general surgical clinic over a year without a previous history of abdominal surgery were examined for clinical evidence of an

umbilical hernia. All general practitioner referrals with an umbilical hernia were assessed for symptoms and both groups were followed up by review of their electronic case records.

Results

124 patients (72 inguinal, 52 ventral), completed the pain questionnaire and 93 (75%) registered pain on the BPI. There was good correlation between VRS, VAS and BPI scores (Correlation Coefficient >0.8). Patients with a ventral hernia had more pain (P=0.037), interference with mood (P=0.027), sleep (P=0.004), relations with other people (P=0.019), and enjoyment of life (P=0.029) than their inguinal hernia counterparts.

At a median follow up of 7·5 (range 6·2–8·2) years in patients with an asymptomatic inguinal hernia randomised to observation or operation, 46 of the 80 in the observation group had converted to an operation. The estimated conversion rate for the observation group using the Kaplan–Meier method was 16% (95 % confidence interval 9 to 26%) at 1 year, and 72% (59 to 84%) at 7·5 years. The main reason for conversion was pain in 33 men, and two presented with an acute hernia. Over a one year period 112 patients were identified with 115 ventral hernias. 62 (55%) had an asymptomatic hernia, 14 of whom opted for operation. 48 patients with 50 asymptomatic hernias participated in the study. At a median follow up of 6.2 years (IQR 5.8-6.9 years) 3 (6%) patients converted to operation due to pain.

The incidence of umbilical hernia in the general population was 2.4% (15 or 622 patients) and all were asymptomatic with only 2 who were aware of their hernia. 36 patients were referred by their general practitioner for assessment of an umbilical hernia and 18 were asymptomatic. 28 of the 36 underwent operation of which 3 (Kaplan-Meier estimate 10% (95% CI 3% – 30%)) required re-operation for a recurrent hernia at a median follow-up of 6.1 years (IQR 5.8 – 6.2 years). Of the 15 patients with an incidental hernia, 2 (Kaplan-Meier estimate 15% (95% CI 3% – 44%)) required an operation for pain at a median follow-up of 6.1 years (IQR 5.9 – 6.4 years).

Conclusions

The BPI is an easy and effective way of assessing pain and its impact on physical activity and quality of life in patients with an inguinal or ventral hernia. Most patients with a painless inguinal hernia develop symptoms over time and will require an operation therefore surgical repair is recommended for medically fit patients with a painless inguinal hernia. In contrast, a policy of non-operation is a satisfactory alternative for patients with an asymptomatic ventral hernia although further studies in this area are required to confirm these outcomes. Umbilical hernias are common in the adult population and most cause no symptoms and are unlikely to become symptomatic. Clinical trials are necessary to assess the value of operation in patients with an asymptomatic umbilical hernia.

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Acknowledgement

I am grateful for all the help and support over the years from the Western Infirmary surgical team including the consultants, trainees, and nursing staff.

I would like to thank Professor Patrick O'Dwyer, my supervisor and mentor. Without his continuous support, encouragement, patience and vast knowledge in this field of surgery, my research and thesis would not have been possible.

I would like to thank Professor David George who was my co-supervisor. Professor John Norrie, who helped with the statistics in the study on the long term outcome of patients with an asymptomatic inguinal hernia. Felix (Phil) Duffy, research nurse deserves acknowledgement. He introduced and orientated me to the asymptomatic inguinal hernia trial. Without him, taking over the research would have been difficult.

A special thank you to Gwen Thomson, Professor O'Dwyer's secretary. She has been amazing at giving me support over many years. Without her I would not have been able to do my research. She has been generous with her time and has always been patient and willing to help.

I would also like to thank all my friends who have helped out during the time I was writing up my thesis. This included general IT advice and proof-reading the final document. Thank you, Yvonne Bramma, Emma Hamill, Niall MacDougall, and Lisa Seerathun. Finally, I would like to thank my family for their patience and support when I was neglecting them during the time I was writing up this manuscript.

Author's Declaration

I declare that, except where explicit reference is made to the contribution of others, that this thesis is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institution.

Definitions/Abbreviations

AAA	Abdominal Aortic Aneurysm
BMI	Body Mass Index
BPI	Brief Pain Inventory
CI	Confidence Interval
CCS	Carolina Comfort Scale
EHS	European Hernia Society
GP	General Practitioner
HES	Hospital Episode Statistics, England
IPQ	Inguinal Pain Questionnaire
IQR	Interquartile Range
ISD	Information Services Division, Scotland
MPQ	McGill Pain Questionnaire
MRC	Medical Research Council
NHP	Nottingham Health Profile
NRS	Numerical Rating Scale
PIS	Pain Interference Score, Brief Pain Inventory
PSS	Pain Severity Score, Brief Pain Inventory
QoL	Quality of Life
RCT	Randomised Clinical Trial
SD	Standard Deviation
SF-36	Short Form-36
SIP	Sickness Impact Profile
TAPP	Transabdominal Preperitoneal Repair in laparoscopic inguinal hernia repair
TEP	Totally Extraperitoneal Repair in laparoscopic inguinal hernia repair
TIPP	Transinguinal Preperitoneal Repair in open inguinal hernia repair
VAS	Visual Analogue Scale
VRS	Verbal Rating Scale

Presentations and Publications

Publications

Chung L and O'Dwyer PJ. Pain and Its Effects on Physical Activity and Quality of Life in Patients Before Operation Undergoing Elective Inguinal and Ventral Hernia Repair. *The American Journal of Surgery* 2014 In Press.

Chung L, Norrie J and O'Dwyer PJ. Long-term follow-up of patients with a painless inguinal hernia from a randomized clinical trial. *British Journal of Surgery* 2011; 98: 596-599.

Chung L and O'Dwyer PJ. Inguinal hernia recurrence and pain. In *Recurrent Hernia: Prevention and Treatment*, Schumpelick V and Fitzgibbons (Editors), Springer-Verlag Berlin Heidelberg 2007; 317-319.

Chung L and O'Dwyer PJ. Treatment of asymptomatic inguinal hernias. *Surgeon* 2007;**5**(2): 95-100.

O'Dwyer PJ and **Chung L**. Watchful Waiting was as safe as surgical repair for minimally symptomatic inguinal hernias (Commentary). *Evidence-Based Medicine* 2006; 11: 73.

Presented Abstracts

L Chung and P J O'Dwyer. Long Term Outcome of Patients with Asymptomatic Abdominal Wall Hernias – oral full paper presentation at the *Association of Surgeons of Great Britain and Ireland (ASGBI)* Conference 2013

L Chung, J Norrie, A Alani, and PJ O'Dwyer. Long Term Follow-up of Patients With a Painless Inguinal Hernia: A Randomised Clinical Trial – oral presentation at the *Association of Surgeons of Great Britain and Ireland (ASGBI)* Conference 2010

L Chung, E Leung, U Ihedioha, I Jenkins, and PJ O'Dwyer. The Prevalence of Incidental Asymptomatic Umbilical/Paraumbilical Hernias in the Outpatient General Surgical Population: A prospective Observational Study – poster presentation at the *Association of Surgeons of Great Britain and Ireland (ASGBI)* Conference 2008

L Chung and P J O'Dwyer. Comparison of Pain in Patients With Ventral and Inguinal Hernias. – poster presentation at the *Association of Surgeons of Great Britain and Ireland (ASGBI)* Conference 2008

L Chung and P J O'Dwyer. Patient Definition of Pain Levels Using the Verbal Rating Scale (VRS) and Visual Analogue Scale (VAS) – poster presentation at the *Association of Surgeons of Great Britain and Ireland (ASGBI)* Conference 2008

L Chung, J Norrie, A Alani, and PJ O'Dwyer. Long-Term Outcome of Patients With an Asymptomatic Inguinal Hernia Randomised to Observation or Operation – oral presentation at the *Association of Surgeons of Great Britain and Ireland (ASGBI)* Conference 2008

1 Introduction

A hernia is classically defined as an abnormal protrusion of an organ or tissue through a defect in its surrounding walls. The word hernia is derived from the Greek word 'hernios' meaning 'a bud'. It can be described as incarcerated or irreducible when its contents cannot be replaced back into its surrounding musculature. Incarceration can be used to describe both non-acute and acute hernias. A hernia is strangulated if the vascular supply to its contents are compromised resulting in ischaemia or infarction. Obstruction may occur when the incarcerated hernia contains bowel. Normally obstruction and/or strangulation can only occur in the presence of an incarcerated hernia.

Abdominal wall hernias are common with a reported prevalence of approximately 1.7% for all ages and almost 4% in the population aged 45 years and over. Data from the National Health Service Information Centre, Episode Statistics for England (HES) and Information Services Division (ISD) Scotland between 2011 to 2012 reported over 110,000 abdominal wall hernia repairs.[1, 2]

1.1 History of Hernia and Hernia Repair

1.1.1 Inguinal Hernia

The history of inguinal hernia and its repair has been well documented with early sculptures illustrating abdominal wall or groin hernias. An Egyptian text from around 1550 BC known as the Ebers papyrus described as 'swelling of the coverings of the abdomen' and referred to its appearance on coughing. In the second century AD the first herniotomy procedure was carried out by Galen who was a Roman physician. This method was employed by surgeons for centuries until the 10th century AD when the Arab physician Albulcasis described a herniotomy and cauterisation as a treatment for inguinal hernia. This was an early account recognising scarring as a useful treatment of hernias.

By the 19th century there was better anatomical understanding of the inguinal canal. There was also the introduction of anaesthesia, antisepsis and aseptic technique and this led to further development in the field of inguinal hernia surgery. Bassini described the technique for repair of a direct hernia whereby the margins of the transversus abdominus and internal oblique were anchored

onto the inguinal ligament. Marcy described the technique to repair an indirect hernia which involved narrowing the internal ring by suturing the lateral side of the transversus abdominus aponeurosis to the medial side. These techniques were later adapted into the Bassini repair as described in current literature to repair both direct and indirect defects.[3]

1.1.2 Ventral Hernia

There is less historical literature on ventral hernias which may be explained by the fact that they were less common and probably caused less symptoms and complications compared with inguinal hernia. The first documentation was made by Celsus in 100 AD who described it as 'an indecent prominence of the navel'. The first repair in the United States was performed by Stoser in 1894. Mayo described his repair technique in 1898 and in 1901 he described the now well-known 'vest-over-pants' technique.[4, 5] Epigastric hernias were first described in 1285 by Arnauls de Villeneuve. The first successful repair of an epigastric hernia was described in 1802. Historically there was a belief that epigastric hernias were associated with intra-abdominal pathology and operations on these hernias were carried out to treat symptoms from diseases such as peptic ulcer disease.

The abdominal wall closure was also first documented by Celsus in 100 AD. One century later Galen described the closure of the abdominal wall including his preference towards the paramedian incision. Incisional hernias were uncommon before the days of anaesthesia, asepsis and anti-sepsis as abdominal surgery was carried out infrequently. By the beginning of the twentieth century the incidence of incisional hernias increased and caused surgeons to consider this problem carefully. This brings us to the present day repair of incisional hernias.[6]

1.2 Relevant Anatomy of Abdominal Wall Hernias

1.2.1 Anatomy of the Anterolateral Abdominal Wall

Good knowledge of the abdominal wall anatomy is essential for understanding abdominal wall hernias and the principles of hernia repair. The boundaries of the anterolateral abdominal wall are the costal margins and xiphoid process cranially; the mid-axillary lines laterally; and the anterior part of the pelvic

skeleton and symphysis pubis caudally. The muscles consist of the rectus abdominis and the three flat muscles, namely the external oblique, internal oblique and transversus abdominis (**Error! Reference source not found.**).
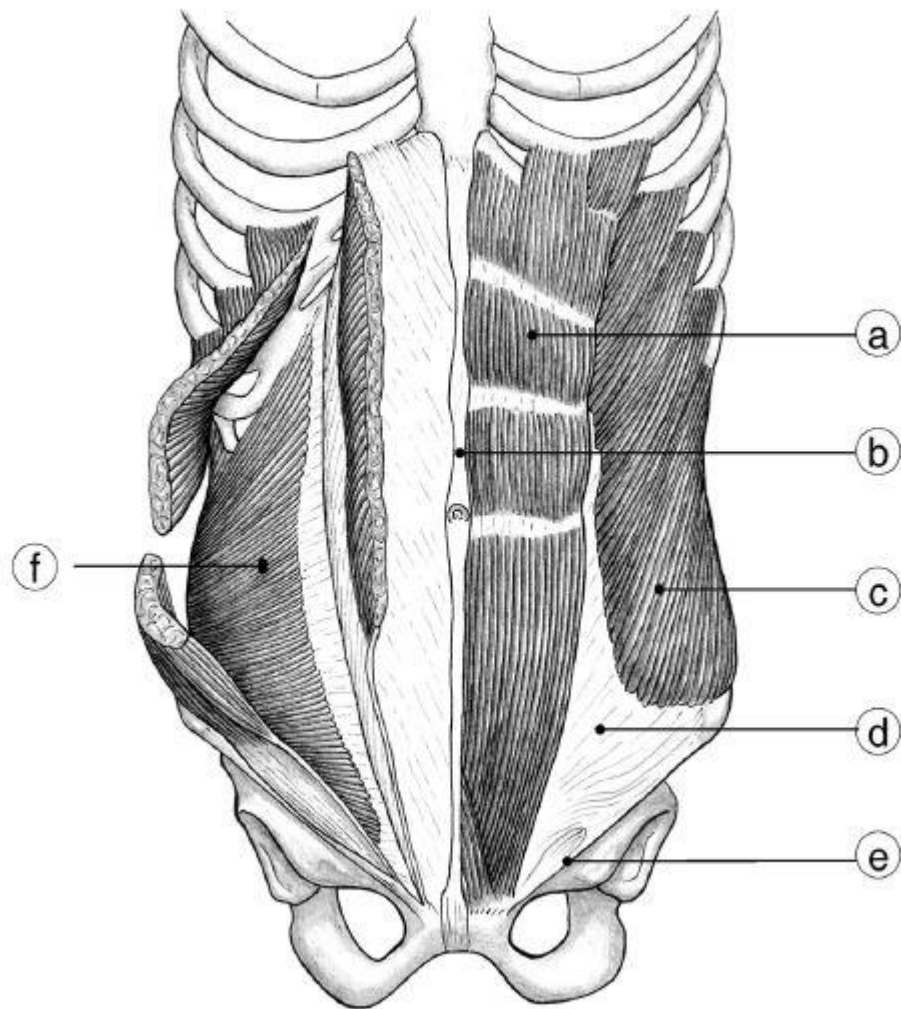
Figure 1.1: Anatomy of the Anterior Abdominal Wall
A – rectus abdominis, B – Linea Alba, C – External Oblique, D External Oblique
Aponeurosis, E - Inguinal Ligament, F – Internal Oblique. Reproduced with permission
from *Component Separation Technique to Repair Large Midline Hernias* by Bleichrodt RP et
al.[7]

The rectus abdominis run vertically on either side of the linea alba which is formed by the fusion of all the aponeurosis of the flat muscles into the midline to form a strong fibrous structure. The external oblique aponeurosis forms the

anterior layer of the rectus sheath and the muscle functions to lower the rib cage such as in expiration. The internal oblique lies deep to the external oblique and its unilateral contraction allows rotation and lowering of the ribs on the one side. The transversus abdominis is the main muscle responsible for retaining the abdominal viscera. Contraction of this muscle results in a pull along the midline and therefore contributes to the separation of a midline laparotomy wound. The transversalis fascia lies deep to the transversus abdominis which is structurally weak above the umbilicus but structurally more robust at the level of the inguinal canal.[8]

1.2.2 Anatomy of the Groin

Fruchaud stated that all groin hernias originate within a single weak area named the myopectineal orifice. Superficially it is divided into two levels by the inguinal ligament. Superiorly, or the inguinal level provides passage of the spermatic cord or round ligament, and inferiorly, the femoral level provides passage of the femoral vessels (**Error! Reference source not found.**).[9]
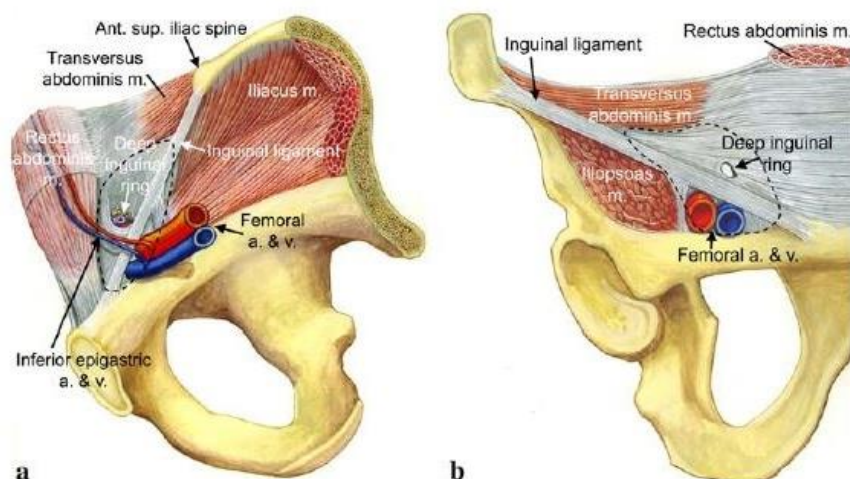
Figure 1.2: The Myopectineal Orifice
Schematic drawings of the anatomy of the of the lower abdominal wall as seen dorsomedially (a) and anteriorly (b) according to Frauchaud and Wantz. The dotted line outlines the myopectineal orifice. Reproduced with permission from *The Dimensions of the Myopectineal Orifice* by Wollowcheck and Konerding 2009 [9]

The inguinal canal runs obliquely and measures approximately 4 cm in length and sits 2 to 4 cm above the inguinal ligament between the deep and superficial rings. The anterior wall is formed by the external oblique aponeurosis and internal oblique laterally. The posterior wall is formed by the fusion of the transversus abdominis aponeurosis and transversalis fascia in 75% of individuals, whereas in the remaining 25% it is only formed by the transversalis fascia.

There are 3 main nerves which should be identified during an inguinal hernia repair to prevent chronic post-operative pain [10]:

The iliohypogastric nerve pierces the internal oblique above the anterior superior iliac spine and then the external oblique aponeurosis approximately 2.5 cm above the superficial inguinal ring supplying the suprapubic skin.

The ilioinguinal nerve runs parallel but inferior to the iliohypogastric nerve. It emerges between the external and internal oblique muscle near the anterior superior iliac spine which then enters the inguinal canal and exits from the superficial inguinal ring. It supplies the anterior one-third of the scrotum, the root of the penis and the upper and medial parts of the groin, or the equivalent anatomical part in a female.

The genital branch of the genitofemoral nerve enters the inguinal canal via the deep ring and provides motor innervation to the cremasteric muscle, and sensory innervation to the spermatic fascia, tunica vaginalis and the scrotal skin.

The femoral canal is conical in shape measuring between 1.25 and 2 cm in length. The femoral ring is inflexible and has a tranverse diameter of 8 to 27 mm and an anteroposterior diameter of 9 to 19 cm. It is bound laterally by the femoral vein and connective tissue, posteriorly by Cooper's ligament, anteriorly by the inguinal ligament, and medially by the transversalis fascia, aponeurosis of the transversus abdominis and lacunar ligament.[8]

1.2.3 The Anatomy of Aponeurotic Hernias

Askar published interesting work on aponeurotic hernias which is the term used to describe epigastric, umbilical, paraumbilical, and hypogastric hernias [11, 12].

Detailed structural knowledge imparted by Askar's studies of the anterior abdominal wall aponeurosis allows us to understand how aponeurotic hernias develop. He reported that 30% of individuals had 'single decussation' of their aponeurosis which is the crossing or decussation of the aponeurotic fibres from both sides of the abdominal wall at the midline (**Error! Reference source not ound.**). These individuals were considered to be at greater risk of midline hernias. In the other 70% there are 2 additional lines of decussation on either side of the midline described as 'triple decussation' (**Error! Reference source ot found.**). This structural difference is thought to reinforce the midline and hernias which develop in these individuals tend to lie on one side of the midline. He proposed that more hernia repair failures would be expected in the 'single decussation' group.

The biomechanics of the anterior abdominal is also important in the development of hernias. The abdominal wall can be divided into three zones: epigastric, umbilical and hypogastric zones.
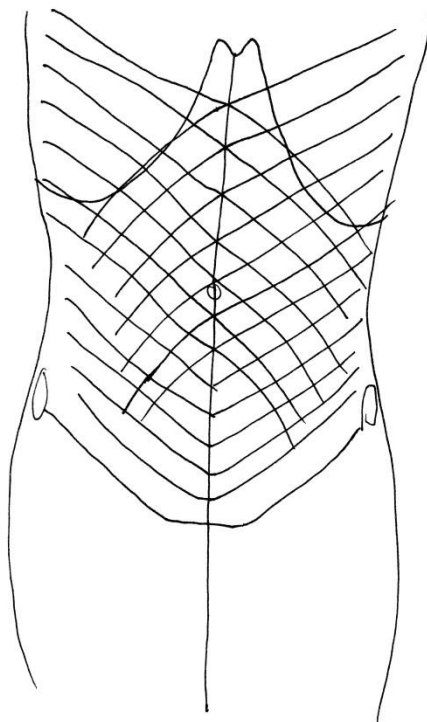
Figure 1.3: Single line of decussation of the aponeurosis as described by Askar[11]
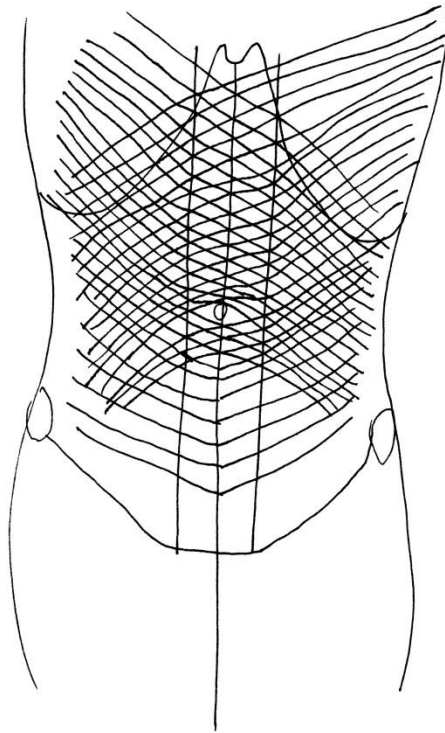
Figure 1.4: Triple line of decussation of the aponeurosis as described by Askar[11]

The epigastric zone is where an epigastric hernia is normally found mid-way between the xiphisternum and the umbilicus. This zone stretches longitudinally and this mid-point is the area which would sustain maximal force during coughing or straining. In addition, there is a tendinous intersection at this area which adds to the lateral force on this region. At the umbilical zone the linea alba widens and the aponeurotic fibres have an S-shaped course which allows for more stretch in this region. This area stretches transversely when force is applied. In the hypogastric zone, the linea alba tapers inferiorly and the aponeurosis also becomes an area of single decussation. There is some overlap of the medial edges of the recti in this region and it provides the main support for the abdominal wall. With this understanding it would be logical to ensure the recti are replaced back in the midline during the closure of the lower midline abdominal wound.

Askar's classification of the aponeurotic structure of the abdominal wall has been accepted in the surgical literature. However, Korenkov et al in 2001 carried out anatomical, histological and biomechanical studies on the linea alba

of 84 formalin-fixed cadavers to analyse Askar's theory. They could not confirm Askar's theory as they were unable to demonstrate the single and triple decussation of the aponeurosis. They developed their own classification on the morphological type of the linea alba: weak, which consists of thin and widely meshed fibres; intermediate, made up of closely and widely meshed fibres; and compact, which is the fascia with greatest tensile strength made up of closely knit thick fibres. [13]

In addition to Askar's theory on aponeurotic hernias, it is thought that epigastric hernias start as protrusions of preperitoneal fat and increased intra-abdominal pressure allow the preperitoneal fat to enter the fascial openings of the perforating neurovascular bundles. This may explain the pain associated with epigastric hernias when the neurovascular bundles are compressed by the hernia sac. [14]

1.3 Ventral Hernias

Ventral hernia, for the purposes of this thesis, is the term used to describe umbilical, epigastric and incisional hernias. Umbilical and paraumbilical hernia will be collectively referred to as umbilical hernia.

1.3.1 Umbilical Hernia

Umbilical hernias account for approximately 5% of all primary hernias. [15] The National Health Service Information Centre, Episode Statistics for England (HES) between 2011 and 2012 reported just over 17,000 umbilical hernia repairs. This accounted for around 16% of all abdominal wall hernia repairs with rates similar to the United States. [16] Umbilical hernias are reported to be up to five times more common in females than in males, however a recent published study from the UK has shown otherwise. They reported that men underwent more than double the number of umbilical hernia repairs than women. [17-19]

1.3.2 Risk Factors for Umbilical Hernia

Approximately 90% of adult umbilical hernias are acquired rather than due to the persistence of infantile umbilical hernias. Predisposing factors to umbilical hernia include any condition resulting in increased intra-abdominal pressure such

as obesity, multiparous women, ascites and intra-abdominal malignancy. [20] Biomechanically the umbilical zone is naturally weaker because it allows more transverse stretch.

The prevalence of umbilical hernia during and after pregnancy is not well documented in the literature although hernia texts will quote this as a risk factor for its development. [21] Approximately one-fifth of patients with liver cirrhosis and ascites will develop an umbilical hernia. This is multi-factorial from the ascites causing increased intra-abdominal pressure, weakening of abdominal wall fascia and muscles from poor nutrition, and also dilatation of the umbilical opening from umbilical varices. [22]

1.3.3 Surgical Management of Umbilical Hernia

Umbilical hernia repair can be open with or without mesh or laparoscopic with mesh. The Mayo repair which used an overlapping 'vest-over-pants' repair of the fascia with non-absorbable sutures was described in 1901. Another popular technique without mesh used interrupted transfascial sutures to close the umbilical hernia defect transversely. Mesh repair was later developed due to high recurrence rates associated with sutures repairs and this can be carried out open or laparoscopically.[23, 24] However, despite the known high recurrence rates associated with suture repair, this continues to be a preferred method of surgeons with 70% of repairs carried out this way in Denmark between 2005 and 2006. [25] These rates are probably representative of the current practice in the UK. [26]

1.3.4 Epigastric Hernia

The prevalence of epigastric hernia is around 3 to 5% of the population and is more common in men than women. It more frequently affects younger people between 20 and 50 years of age. [20] The National Health Service Information Centre, Episode Statistics for England (HES) between 2011 and 2012 reported almost 6000 other ventral hernia repairs excluding incisional hernia although the numbers for individual hernia types are not published.

The risk factors for epigastric hernia are similar to those for umbilical hernia and it is not uncommon for studies to group the two types of ventral hernia together.

The surgical management of epigastric hernia is the same as for umbilical hernia. Randomised clinical trials have not been carried out specifically on epigastric hernias because it constitutes a far smaller surgical workload. The Danish National Patient Registry has shown that suture repair is the most popular method used for 97% of operations. This is similar to the practice reported in a Scottish study published in 2003. [25, 26]

1.3.5 Incisional Hernia

Incisional hernia is a major late complication of abdominal surgery with a reported incidence of primary incisional hernia varying between 11 and 20%. A study by Mudge and Hughes reported that 50% of incisional hernias presented within the first post-operative year which increased to 79% within 3 years of surgery.[27] Interestingly, recurrent incisional hernias occur earlier with over 80% presenting in the first year. [28] The HES for the period from 2011 to 2012 reported over 8,400 incisional hernia repairs.

1.3.6 Risk Factors for Incisional Hernia

The risk factors for incisional hernia formation can be divided into patient-related and index operation-related factors. The patient and index operation related risk factors are listed on Table 1.1. [28, 29]

Risk Factors	
Patient-Related Factors	Index Operation Related Factors
- male gender - older age - obesity - abdominal aortic aneurysm disease - abdominal distension - chronic respiratory disease - jaundice	- type of incision - closure technique - suture material used - emergency surgery - wound failure including wound infection and dehiscence

Table 1.1: Risk Factors for Incisional Hernia

1.3.7 Association with Male Gender

Some studies have demonstrated that incisional hernia are more common in men and consider this to be an independent risk factor. Llaguna's study on incisional hernia after colorectal resection had an overall incisional hernia rate of 16% and of these 71% occurred in men. [29-31]

1.3.8 Association with Older Age

Krukowski et al studied closure of midline abdominal incisions and found the incidence of wound failure at 1 year is significantly greater in patients over 60 years of age at 12.2% compared with 5.8% in the younger population. [32] Mingoli et al conducted a retrospective study to determine the predisposing factors for incisional hernia after an emergency midline laparotomy and demonstrated elderly populations accounted for over two-thirds of all incisional hernias during the two years of follow-up. [33]

1.3.9 Association with Obesity

Morbid obesity is a significant risk factor for incisional hernia. Sugerman et al reported incisional hernia rates of 20% (198 of 968 patients) in the bariatric surgery group compared with 4% (7 of 171) in the ileal pouch-anal anastomosis (IPAA) group (p<0.001). [34] Puzziferri et al randomised 155 morbidly obese patients to laparoscopic or open gastric bypass surgery and reported incisional hernia rates of 39% at 3 years follow-up which is significantly higher than the rate reported by Mudge and Hughes in a general population. [27, 35]

A couple of studies have prospectively followed-up a cohort of patients who have undergone laparotomy and examined them for incisional hernia. Vejkovic et al reported incisional hernia rates of 7.8% in those with a Body Mass Index (BMI) of less than 24.4 kg/m^2 and 18.8% when the BMI was greater than or equal to 24.4 kg/m^2. Van Ramshorst et al had an incisional hernia rate of 20% at a median follow-up of 16 months and around two-thirds of the incisional hernias occurred in patients with a BMI of greater than 25 kg/m^2. [36, 37]

1.3.10   Association with Abdominal Aortic Aneurysm Disease

Patients with a history of abdominal aortic aneurysm disease are at a significantly higher risk of developing an incisional hernia. Holland et al found almost one-third of the patients after an abdominal aortic aneurysm (AAA) repair developed an incisional hernia compared with 19% of those who underwent operation for occlusive disease. These AAA repair patients were six times more likely to develop an incisional hernia than those operated on for occlusive disease even after accounting for all variables including age.[38]

This association led to the hypotheses that there are collagen metabolism or composition defects in individuals with an AAA and in those who develop an incisional hernia. Type I and III collagen is found in fascia and tendon. Type I gives strength and type III provides elastic recoil to tissues. Type II collagen is found in cartilage and IV in the basement membrane of cells. A study by Klinge et al analysed the ratio of collagen I/III and the expression of matrix metalloproteinase 1 and 13 (MMP-1, MMP-13) in patients undergoing a surgical procedure. Biopsies were taken from the healthy fascia of control patients and from the fascial scar of patients with and without incisional hernia. The ratio of collagen I/III were significantly lower in the fascia of incisional hernia patients as was the expression of MMP-1. Excessive accumulation of collagen in the hypertrophic scar was associated with an increased expression of MMP-1. Therefore, it was hypothesised that an accumulation of collagen III is associated with the reduced expression of MMP-1, hence suggesting an association with disordered collagen metabolism in these patients.[39-43]

1.3.11   Association with Other Patient-Related Factors

Lamont and Ellis studied over 1000 laparotomies over a 5 year period and identified jaundice and chest infections as risk factors for incisional hernia. Chronic respiratory disease has been indicated as a risk factor for incisional hernia. This is probably related to increased tension on the abdominal wound from coughing and the increased risk of developing a post-operative chest infection.[28, 29] Pulmonary disease has also been found to be a significant risk factor for wound dehiscence which in turn leads to incisional hernia formation.[44]

1.3.12   Association with Type of Incision and Closure Technique

Transverse incisions should theoretically have a lower risk of incisional hernia formation when considering the anatomical structure and biomechanical forces of the abdominal wall. A vertical incision through the linea alba would allow the abdominal wall to pull against the repair. The tension on the abdomen generated by contraction may also encourage the suture line to cut through the fascial closure. This may present with complete wound disruption as in full-thickness dehiscence or creation of button-hole defects.[45] A meta-analysis pooling the data from 6 randomised clinical trials demonstrated an incisional hernia rate of 8% in vertical incision laparotomy compared with 5.1% in the transverse group.[46] A further prospective study of a consecutive series over 4 years identified an incisional hernia rate of 16% from midline compared with zero out of the 139 Pfannenstiel incision extraction sites in hand-assisted laparoscopic surgery.[47]

The abdominal wall incision has no tensile strength during the first post-operative week. This is rapidly regained within 70 days and by 6 months the wound will have restored 70 to 80% of its final tensile strength.[48, 49] There are several studies on the suture technique and material used and its associated risk of abdominal wound dehiscence or incisional hernia. Before the mid-1980s the incidence of abdominal wound dehiscence was reported in up to 5.8% of laparotomies. Later studies reported a dehiscence rate of around 1.2% which was considered as no significant change.[50, 51] This complication is important because 94% of patients with an early fascial dehiscence will develop an incisional hernia and there is an associated high mortality rate of 9 to 44%.[44, 52] Franz et al examined for evidence of occult abdominal wall dehiscence following laparotomy. Occult dehiscence was defined as a fascial defect of greater than 12mm, and 17 of the 18 patients with occult dehiscence developed an incisional hernia.[52]

A 2011 systematic review compared wound closure using a slowly-absorbable suture such as Polydioxanone (PDS) with a non-absorbable suture such are nylon or polypropylene did not demonstrate any difference in abdominal wound dehiscence or incisional hernia rates.[51] Various abdominal wall closure techniques attempting to reduce wound failure have been described. Most

surgeons in current practice will use a continuous mass closure technique with at least a suture length to wound ratio of 4:1. A layered closure technique or the use of less suture length has been proven to be inferior.[53, 54] The large INLINE 2010 meta-analysis was able to confirm that continuous fascial closure is superior to interrupted sutures.[55] Attempts have been made to modify the continuous mass closure technique without success. An example was the continuous double-loop closure technique (CDLC) which is most easily described as a continuous mattress-type suture. Unfortunately, the randomised clinical trial found a significantly increased risk of pulmonary complications and mortality of more than double that for the standard continuous running suture.[56] A more recent technique described as a 'short stitch length' continuous suture involves taking smaller bites of tissue 5 to 8 mm from the wound edge and only incorporating the aponeurosis. The authors have demonstrated in a randomised controlled trial that surgical site infections were reduced in the 'short stitch' compared with the conventional 'long stitch' group. The incisional hernia rate at 12 months was also reduced in this study favouring the 'short stitch' group (5.6% vs 18%).[31] This may be one method to prevent incisional hernia as wound infection is a significant risk factor.[29] This has led to a multi-centre randomised clinical trial to look at the effects of small stitches on the incidence of incisional hernia. This study is expected to conclude in April 2013 with the results eagerly awaited.[57]

1.3.13   Association with Emergency Laparotomy and Re-opened Abdominal Incisions

Mingoli et al found that 18% of patients developed an incisional hernia less than 12 months following an emergency laparotomy.[33] Reopening a previous laparotomy scar is a risk factor for incisional hernia. This was shown in a study of over 860 laparotomies where the rate of incisional hernia was significantly higher at 12% compared with 6% in those with virgin abdomens at 5 years.[29]

1.3.14   Association with Surgical Site Infections

Surgical site infection is an independent risk factor for incisional hernia. Veljkovic et al reported an incisional hernia rate of 13.4% at a mean follow-up of 7 months. Deep surgical site and deep space infections are further confirmed significant risk factors for incisional hernia by van Ramshorst's (P<0.001).[36, 37]

1.3.15   Surgical Management of Incisional Hernia

Open incisional hernia repair can be suture only or with mesh. The position of mesh placement for incisional hernia repair has been a topic of discussion. Those include: inlay where mesh is sutured between the fascial gap; onlay where mesh is placed on top of the fascia; sublay or the Rives-Stoppa technique where mesh is place anterior to the posterior rectus sheath; or intra-peritoneal underlay which is the position adopted in laparoscopic repair. Some studies may use the term sublay and underlay interchangeably. A generous overlap of mesh by 4 to 5 cm over the hernia defect is recommended to reduce hernia recurrence therefore inlay techniques should not be used in current practice. [58, 59]

The majority of meshes used will either be non-absorbable or composite meshes. The composite meshes are partly non-absorbable mesh covered with a 'non-stick' absorbable layer to allow safe placement in the peritoneal cavity. In recent years biologic or collagen meshes have been available but are very expensive. The developers of these meshes are trying to find a role for its use in hernia repair in the elective and emergency setting especially in the presence of contaminated fields. [60]

Ramirez component separation technique may be considered for complex abdominal wall hernias with a significant loss of abdominal domain. This involves making a vertical incision down the length of the external oblique aponeurosis to mobilise it over the internal oblique allow closure of midline defects which may also be reinforced with onlay mesh which is illustrated on Figure 1.5. [7, 61]

The laparoscopic repair of incisional hernia was first described by Karl LeBlanc in 1991.[6] Composite mesh is usually used and secured with either transfascial sutures, tacks, or glue, or a combination of these methods. The fascial defect is normally left open unlike the open repair where attempts are made to close this defect if possible.
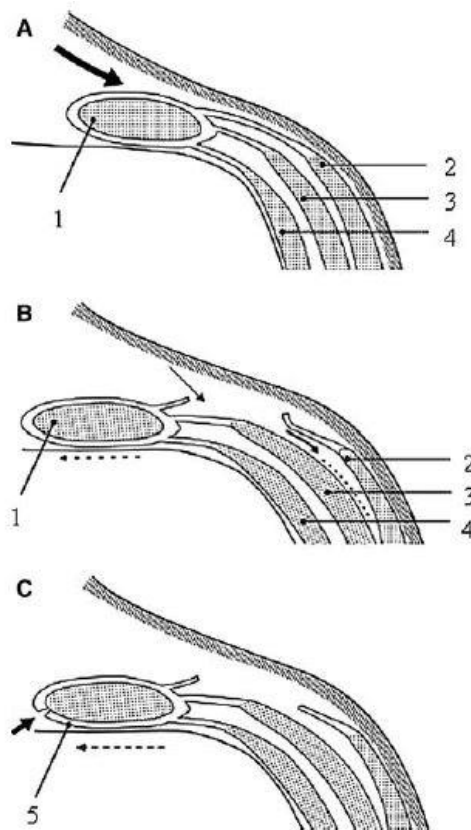
Figure 1.5: Component Separation Technique
1 – Rectus Abdominis, 2 – External Oblique, 3 – Internal Oblique, 4 – Transversus Abdominis, 5 – Posterior Rectus Sheath. A – Dissection of the skin and subcutaneous fat to expose the abdominal wall fascia. B – Incision 2cm lateral to the edge of the rectus sheath through the external oblique and separation from internal oblique. C – Mobilisation of the posterior rectus sheath is necessary to allow closure of the midline. Reproduced with permission from Repair of Giant Abdominal Wall Hernias: 'Components Separation Technique' versus Prosthetic Repair by de Vries Reilingh et al.[7, 62]

1.4 Inguinal Hernia

Inguinal hernias account for approximately 75% of all abdominal wall hernias with a lifetime risk of 27% in males and 3% in females.[63] Inguinal hernia repair is one of the most common operations in general surgery with rates of repair ranging from 10 per 10,000 of the population in the United Kingdom to 28 per

10,000 in the United States.[64] Based on the HES and ISD statistics data for England and Scotland, almost 80,000 inguinal hernia repairs carried out between 2011 and 2012.[1, 2] If calculations of cost for an inguinal hernia repair without the need for critical care services are based on the 2009/2010 Scottish Cross-boundary tariffs from ISD Scotland then inguinal hernia repair would cost the health service over £150 million each year. This illustrates the substantial financial burden to the health service.

1.4.1 Classification of Groin Hernia

The classification of groin hernia is useful for planning and conducting clinical trials. There are several classifications available for groin hernia. They can be classified simply as either 'direct' occurring medial, or 'indirect' occurring lateral to the inferior epigastric vessels. The Nyhus Classification published in 1993 is an example of a widely used detailed classification system based on the size of the fascial defect and the strength of the posterior wall of the inguinal canal. (Table 1.2)

Type	I	Indirect with normal internal ring
	II	Indirect with dilated ring, normal floor
	IIIA	Direct inguinal hernia
	IIIB	Large indirect inguinal hernia
	IIIC	Femoral hernia
	IV	Recurrent hernia

Table 1.2: The Nyhus Classification of Groin Hernia

More recently the European Hernia Society (EHS) have suggested the use of its own classification system which is similar to the Aachen classification and simple to use. The classification categorises the groin hernias into 'lateral' which is indirect, 'medial' which is direct, and 'femoral'. The size of the hernia orifice is measured by finger breadths with the assumption that the index finger measures approximately 1.5 to 2.0 cm (Table 1.3).[65]

EHS Groin Hernia Classification		Primary	Recurrent		
	0	1 (≤1 finger)	2 (1-2 fingers)	3 (≥3 fingers)	x
Lateral					
Medial					
Femoral					

Table 1.3: The European Hernia Society Groin Hernia Classification
P = Primary hernia; R = Recurrent hernia

1.4.2 Mechanism and Risk Factors for Inguinal Hernia Formation

The inguinal region is a naturally weak unprotected area of the abdominal wall in humans. However, there is a shutter mechanism in the inguinal canal which provides mechanical protection. This closes the deep ring during abdominal contraction such as during lifting and coughing. However, in certain conditions such as pregnancy or in the presence of ascites there is raised intra-abdominal pressure in the absence of abdominal muscle contraction which impairs this mechanism.

A patent processus vaginalis is present in approximately 20% of adult men and may contribute to inguinal hernia formation in a fraction of these individuals. Another possible contributory factor to inguinal hernia formation is a lipoma of the cord. This is a common intra-operative finding in around 20% of patients undergoing inguinal hernia repair.[66] There is little evidence to be certain that a lipoma of the cord may lead to dilatation of the deep ring and subsequent hernia formation. Factors affecting the integrity of the transversalis fascia may also predispose to inguinal hernia formation. Weakening of muscles associated with ageing or a lack of exercise has been implied as a contributory factor. Interestingly, weight loss is a risk factor for inguinal hernia development and obesity appears to have a protective effect.[67]

An epidemiological study by Ruhl et al examined the risk factors for inguinal hernia among American adults. This was based on data collected between 1971 and 1975 from the National Health and Nutrition Examination Survey (NHANES I)

and its follow-up study in subsequent years. They reported the cumulative incidence of inguinal hernia amongst men increased with the baseline age from 7.3% in the 24 - 39 years, 14.8% at 40 – 59 years, to almost 23% in the 60 – 74 years age groups. White men had a higher cumulative incidence of inguinal hernia over 20 years than black men (15.1% versus 8.4%). The diagnosis of a hiatus hernia was also a risk factor for inguinal hernia. Higher maximum lifetime weight and a body mass index (BMI) of greater than or equal to 30 significantly reduced the risk of inguinal hernia. This correlates well with a Swedish study which found that obesity in men reduced the risk of inguinal hernia by 43%.[68] In women risk factors associated with inguinal hernia include older age, taller stature, and the presence of an umbilical hernia.[67] The European Hernia Society (EHS) guidelines on the management of inguinal hernia provide a succinct list of risk factors (Table 1.4).[69]

Risk Factors	
• Smoker • Family history of hernia • Patent processus vaginalis • Collagen disease • Abdominal aortic aneurysm • Previous appendicectomy	• Previous prostatectomy • Ascites • Peritoneal dialysis • Chronic obstructive pulmonary disease (COPD) • Long term heavy work

Table 1.4: European Hernia Society Guideline Risk Factors for Inguinal Hernia[69]

1.4.3 Surgical Management of Inguinal Hernia

The operations for inguinal hernia can be open or laparoscopic repair. Open surgery can be tissue repairs or repairs with mesh. The well-known tissue repairs include the Bassini, darn, and Shouldice repairs. Repairs with mesh are regarded as tension-free repairs which include the Lichtenstein repair and its modifications, mesh-plug technique, and preperitoneal techniques such as the Rives and Stoppa operations. Currently, the most commonly performed open operation for inguinal hernia in the United Kingdom is the Lichtenstein repair and its modifications.

1.4.4 Open Tissue Repairs

The Bassini repair technique involves opening the external oblique aponeurosis which is then separated from the internal oblique aponeurosis. The spermatic cord with the cremasteric muscle is mobilised fully and the cremasteric muscle separated from the cord structures and divided and ligated. The transversalis fascia is divided from the level of the deep ring to the pubic tubercle. The indirect sac is opened and the contents of the sac returned to the peritoneal cavity. The neck of the sac is transfixed and the sac excised. The posterior wall of the inguinal hernia is repaired by the first suture placed through the transversalis fascia including the lateral edge of the rectus sheath, internal oblique, and transversus abdominis. The first suture also includes the pubic periosteum, iliopubic tract and inguinal ligament. The subsequent sutures include the iliopubic tract and inguinal ligament. The deep ring is reconstructed with the most lateral suture.[70]

The darn repair was one of the most popular hernia repair techniques in the 1980s and early 1990s. The darn repair is carried out with nylon sutures and involves several layers of sutures to form a mesh-like structure. The darn repair should not cause any significant tension in the tissues. Once the darn repair has been carried out the spermatic cord is replaced to its normal position and the external oblique aponeurosis closed. The technical aspects of this repair are beyond the scope of this literature review. The recurrence rates of between 4% for indirect and up to 20% for direct inguinal hernias were considered acceptable and reasonable at that time.[71, 72]

The Shouldice Hospital was established in 1945 and the current Shouldice repair for inguinal hernia was developed in 1952. The initial dissection for this repair is similar to the Bassini repair and the transversalis fascia is opened in a similar fashion. The repair is described using stainless steel suture material and involved 3 continuous layers of suturing to reconstruct the posterior inguinal wall. A new suture is used to place a fourth line of continuous sutures which is tied at the internal ring and finally the external oblique is closed. This continues to be one of the most popular tissue-only repairs.

1.4.5 Mesh Repairs

The current EHS guidelines on the treatment of adult inguinal hernia suggest the use of mesh in individuals over the age of 30 years with a symptomatic primary inguinal hernia. This can be carried out using the open Lichtenstein technique or laparoscopically. This use of mesh is recommended because of lower recurrence rates and there is some evidence to suggest that mesh repair reduces the risk of chronic groin pain.[69] However, the EHS have suggested that other open mesh techniques may be considered although the follow-up data available regarding recurrence is short term.

Lichtenstein introduced the concept of tension-free repair in 1986. He published a paper in 1987 based on his experiences with hernia repair on over 6300 cases of which around 94% were inguinal hernia repairs.[73, 74] 45% of the hernias were repaired without mesh, 42% with a mesh patch and 13% with a mesh plug or other mesh technique. He reported an overall recurrence rate of 0.7% although he did not specify the recurrence rates in those repaired with the mesh patch technique.[73] Lichtenstein came to the conclusion at this time that the recurrences were due to excessive tension on the suture line. Following this, the technique was adjusted to remove tension. The operation is similar to other anterior approaches to the inguinal canal whereby the external oblique aponeurosis is cut along its fibres to open the inguinal canal. The hernia sac is inverted without excision, suture or ligature unless it is very large then inversion with a single suture is permitted. A piece of polypropylene mesh measuring approximately 5 by 10 cm is then sutured using a continuous non-absorbable stitch medially onto the lacunar ligament and along the inguinal ligament. A slit is made in the lateral edge of the mesh to reconstruct the internal ring and the superior edge of the mesh is secured loosely with a continuous suture to the rectus sheath, conjoint muscle and tendon. The importance of a 2cm medial overlap with mesh is emphasised to reduce the risk of medial recurrence. When Lichtenstein described the technique the cases were done under local anaesthesia.[69, 75] This Lichtenstein repair and its inevitable modifications has become the most frequently performed open inguinal hernia repair technique in the US, UK and possibly the world.[76]

Lichtenstein reported on the use of mesh plug in the repair of femoral and recurrent inguinal hernia. Gilbert developed on the plug technique and used a preperitoneal mesh placed through the internal ring. This was then modified and commercialised into a three-dimensional polypropylene mesh patch (Prolene Hernia System) in which the pre-formed mesh consists of a preperitoneal patch and an onlay patch with an interconnecting cylinder of mesh.[76, 77] Rutkow described a mesh plug technique which uses either a pre-formed plug mesh or one made from a rolled up a piece of flat mesh. This is then used to 'plug' an indirect or direct defect. A further onlay 'patch' is used on the floor of the inguinal canal to reinforce this area. This is sometimes referred to as a 'plug and patch' repair and the authors reported recurrence rates of less than 1%.[78]

There are posterior or the preperitoneal approaches to open inguinal hernia repair, namely the Stoppa and the Rives operations. The posterior approach was first described by Goss and Mahorner in 1962 and Stoppa popularised the preperitoneal technique in 1980 which uses an abdominal incision to gain access to the myopectineal orifice to insert a large sheet of mesh to overlap all orifices. This was recommended for bilateral hernias and also for recurrent hernias. Since 1991, the Stoppa technique has been applied for the laparoscopic groin hernia repair. The Rives technique differs in that the preperitoneal mesh is placed via an inguinal incision.

1.4.6 Laparoscopic Repair

The first laparoscopic inguinal hernia repair was described by Ralph Ger in 1982 and over recent years it has gained popularity.[79] There are two approaches to the laparoscopic inguinal hernia repair: the transabdominal preperitoneal (TAPP) and the totally extraperitoneal (TEP). The aim of both methods is to place mesh into the preperitoneal space covering all hernia orifices as in the Stoppa open repair.

The TAP repair involves entering the peritoneal cavity and an incision is made in the peritoneum approximately 3 cm above the superior margin of the hernia defect. The preperitoneal space is developed for the mesh which is then normally secured with staples or tacks. The peritoneal incision is then closed over the mesh with a continuous absorbable suture to ensure that no mesh is

exposed to the abdominal viscera. The advantages of this technique are the familiar anatomy as the peritoneal cavity is entered and it allows inspection of the abdominal contents.[69, 80]

The TEP repair enters the preperitoneal space without entering the peritoneal cavity. The preperitoneal space is developed and the mesh placed in this space to cover the hernia orifices. The mesh is secured to the pectineal ligament and abdominal wall with tacks or staples. The gas in the preperitoneal space is released and the incision in the rectus sheath repaired. This is technically a more challenging operation compared with the TAPP technique with higher conversion rates.[81] Laparoscopic repair takes around 15 minutes longer to perform and is more expensive than open techniques.[69] Another argument for laparoscopic repair of inguinal hernia would be its use in women as they generally have higher recurrence rates after open repair compared with men. In approximately 40% the recurrences are femoral hernias therefore females with inguinal hernias may be better repaired laparoscopically to cover both hernia orifices.[69]

1.5 Pain Measurement Tools

As this manuscript relates to symptoms from abdominal wall hernias it is important to understand the definitions of pain and be aware of the pain measurement tools available. Pain has been defined in a number of ways [82]:

'An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.'

'Pain is what the experiencing person says it is, existing whenever (s)he says it does.'

Pain is a subjective sensation which can be described in several dimensions including its site, quality, frequency, and intensity and also its psychosocial impact to name a few. In clinical outcome studies, especially in surgical treatment outcomes, pain intensity is one of the most relevant and commonly measured factors.

The ideal pain measurement tool should be easy to administer and score. It should have a low scale failure rate and patients should be willing and able to use it. However, most pain measurement tools require satisfactory cognitive function to be valid. There are several commonly used subjective pain measurement tools. The uni-dimensional pain measurement tools which examine pain intensity include the popular Visual Analogue Scale (VAS), Numerical Rating Scale (NRS) and the Verbal Rating Scale (VRS). The multi-dimensional pain measurement tools include the McGill Pain Questionnaire (MPQ) and the Brief Pain Inventory (BPI). They include information on pain intensity and also the history, location, quality of the pain, and its interference with daily activities.

1.5.1 The Uni-Dimensional Pain Scales

1.5.2 The Visual Analogue Scale (VAS)

The VAS is usually a 100 mm horizontal or vertical line with each end of the scale representing the extremes of pain. 'No pain' is represented at 0 mm and 'most severe pain imaginable' at 100 mm. The line on the VAS should not contain any hatches or marks to represent the centimetres of pain as it will encourage individuals to score on the lines giving biased results (Figure 1.6). [83] The VAS is a validated pain measurement tool and is possibly considered to be an ideal scale as it is more independent from language compared with verbal rating scales.
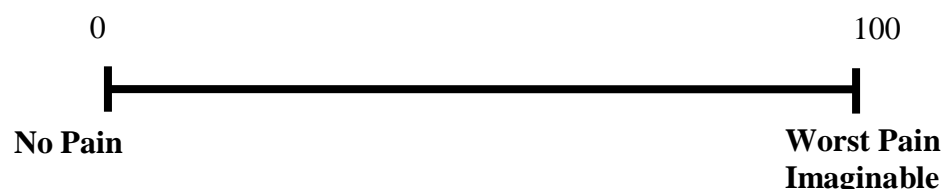
Figure 1.6: The Horizontal 100mm Visual Analogue Scale

There are two steps involved in the scoring the VAS. The subject is asked to draw a line through the scale to represent their level of pain followed by the researcher measuring the score. The two stage process has the risk of opening up opportunities for error. Increasing age is associated with higher rates of incorrect scoring, but this is probably related to the fact that older patients are more likely to have impaired cognitive and motor function than the younger patients.[84]

1.5.3 The Numerical Rating Scale (NRS)

The NSR used include the 11-point and sometimes the 101-point scales which can be presented as a Box Scale format (Figure 1.7). [85] Zero is usually taken to indicate no pain whereas the other extreme of the scale represent the worst pain imaginable. The Brief Pain Inventory uses an 11-point NRS. This scale is simple to administer and avoids the 2 step process involved in the VAS. The accuracy of measurement should not be degraded by motor or visual impairment of the patient. Cancer pain intensity studies have compared the NRS with the VAS. The NRS was found to give adequate discriminatory power in the measurement of pain and has comparable efficacy to the 100mm VAS.[86, 87] A reduction in 2 points on the NRS represented a clinically significant difference in the reduction of pain. [88] The NRS is reported as the most popular pain intensity measurement scale amongst patients. [84]

No pain	0	1	2	3	4	5	6	7	8	9	10	Pain as bad as you can imagine
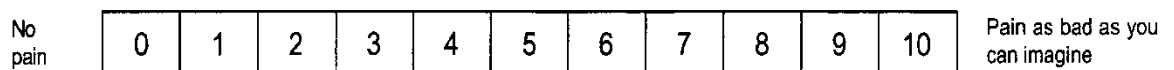
Figure 1.7: The 11-Point Numerical Rating Scale

1.5.4 Verbal Rating Scale (VRS)

The verbal rating scale consists of a list of adjectives describing different levels of pain intensity or pain effect which is usually placed in increasing order of severity on an ordinal scale. This is commonly a 4 or 5-point VRS as shown on Figure 1.8. This pain scale has the advantage of easy administration either in the written or verbal form allowing better compliance. The VRS has less response categories than the VAS or NRS therefore would only allow crude measurements of the pain intensity and will not allow the finer grading of pain. The other problem with the VRS is the assumption that the intervals between each ordinal pain intensity descriptor will represent equal intervals. [89, 90]

NO PAIN   **MILD**   **MODERATE**   **SEVERE**

Figure 1.8: The 4-Point Verbal Rating Scale

1.5.5 The Multi-Dimensional Pain Scales

1.5.6 The Brief Pain Inventory

The development of the Wisconsin Brief Pain Questionnaire was first reported in 1983 because the authors felt that there was a lack of consistency in the assessment of the severity, frequency and disruptiveness of cancer pain. Their aim was to produce a reliable and valid test. The authors wished to produce a pain questionnaire which would be superior to the McGill Pain Questionnaire by aiming to make it easier to self-administer and also assess the history of pain and pain interference with activities. [91] The long form of the Brief Pain Inventory (BPI) was then developed by Cleeland in 1989. This included the

measurement of 'least pain' and also the categorical rating scale associated with pain interference was changed to an 11-point NRS. This long format was later redeveloped into an easy and quick to administer 2-page BPI-Short Form (Appendix 1) which has been validated in many languages over the years. [86, 92]

Before an individual completes the BPI-short form there is a screening question inquiring whether they have been experiencing pain out with the normal daily expected 'everyday pains'. However, this is not a compulsory question. The second question consists of a diagram of the body and the individuals indicate where they feel the pain. There are 4 questions on pain severity; at its least, worst, average, and 'right now'. The last 7 questions measure pain interference with activities including: general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. These are in essence quality of life measures similar to those found in 'Quality of Life' questionnaires. The 7 questions on pain interference can be divided into 2 components, those affecting physical activity and those affecting emotions or affect. All the questions are measured on an 11-point NRS. There are also two questions which cover analgesia taken and the measure of pain relief associated with the analgesia. Although they are included in the BPI, Cleeland has not found them useful in studies. [92]

The BPI Pain Severity Score (PSS) can be calculated by adding the 4 scores assessing pain severity and dividing by 4 to calculating the mean. The BPI Pain Interference Score (PIS) can be calculated by adding all 7 pain interference measures and dividing by 7. Both will give a mean score out of a maximum of 10.

The BPI has been validated for use in cancer pain. It is one of the pain measurement tools recommended by the Expert Working Group of the European Association of Palliative Care for measuring pain severity and for 'pain syndrome characterisation'. The group have also recommended its use in long term follow-up studies. [86] There are studies published in the literature assessing its use in non-cancer pain. The BPI-short form has been validated in non-malignant chronic pain, arthritis, and low back pain studies. [93-95] Modified versions of the BPI-short form have also been used in post-operative analgesic trials supporting its valid use in non-cancer pain patients. [96]

1.5.7 The McGill Pain Questionnaire

The McGill Pain Questionnaire (MOQ) was developed by Professor Melzack of McGill University, Canada, in 1975. The questionnaire aimed to evaluate the three dimensions of pain: sensory, affective, and evaluative. There is a checklist of 87 descriptive words (78 sensory and emotional, 9 pain pattern descriptors) on the sensory qualities of an individual's pain and emotional effects associated with the pain (Figure 1.9). [97, 98] Due to its detailed descriptive qualities, the MPQ is one of the pain measurement tools recommended by the Expert Working Group of the European Association of Palliative Care for the assessment of 'pain syndrome characterisation'. [86]

There are a few problems with using this pain measurement tool. The questionnaire is complicated and time consuming which can take up to 10 minutes to complete. Melzack recognised this and developed the short-form MPQ. This consists of 15 descriptors of pain and each descriptor has its intensity measured on a 4-point verbal rating scale. There are also two other questions on present pain severity measured on a VAS and a 6-point VRS. [99] The MPQ requires patients to have a good range of vocabulary and good cognitive function to understand the descriptors of pain on the questionnaire. This would limit its use in the general study population. The MPQ and its short form measures multidimensional qualities of pain well but does not assess history of pain or interference with activities. [90]

The McGill Pain Questionnaire has been translated into around 26 different languages but sometimes there different versions of the MPQ in the one language. A 2009 systematic review of the cross-cultural adaptations of the MPQ suggested that there have been insufficient studies in different languages and cultures to assess the validity and reliability of the questionnaire. The conclusion was that results from non-English versions of the MPQ should be interpreted with caution. [100] This probably does not come as a surprise due to the wide range of descriptors requiring translation.
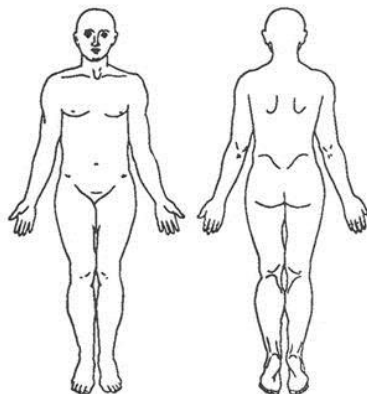
McGILL PAIN QUESTIONNAIRE

RONALD MELZACK

Patient's Name _____ Date _____ Time _____ am/pm

PRI: S _____ A _____ E _____ M _____ PRI(T) _____ PPI _____
    (1–10)   (11–15)   (16)   (17–20)   (1–20)

1 FLICKERING
  QUIVERING
  PULSING
  THROBBING
  BEATING
  POUNDING
	11 TIRING
	    EXHAUSTING

2 JUMPING
  FLASHING
  SHOOTING
	12 SICKENING
	    SUFFOCATING

3 PRICKING
  BORING
  DRILLING
  STABBING
  LANCINATING
	13 FEARFUL
	    FRIGHTFUL
	    TERRIFYING

BRIEF / MOMENTARY / TRANSIENT   RHYTHMIC / PERIODIC / INTERMITTENT   CONTINUOUS / STEADY / CONSTANT

1 FLICKERING QUIVERING PULSING THROBBING BEATING POUNDING

2 JUMPING FLASHING SHOOTING

3 PRICKING BORING DRILLING STABBING LANCINATING

4 SHARP CUTTING LACERATING

5 PINCHING PRESSING GNAWING CRAMPING CRUSHING

6 TUGGING PULLING WRENCHING

7 HOT BURNING SCALDING SEARING

8 TINGLING ITCHY SMARTING STINGING

9 DULL SORE HURTING ACHING HEAVY

10 TENDER TAUT RASPING SPLITTING

11 TIRING EXHAUSTING

12 SICKENING SUFFOCATING

13 FEARFUL FRIGHTFUL TERRIFYING

14 PUNISHING GRUELLING CRUEL VICIOUS KILLING

15 WRETCHED BLINDING

16 ANNOYING TROUBLESOME MISERABLE INTENSE UNBEARABLE

17 SPREADING RADIATING PENETRATING PIERCING

18 TIGHT NUMB DRAWING SQUEEZING TEARING

19 COOL COLD FREEZING

20 NAGGING NAUSEATING AGONIZING DREADFUL TORTURING

PPI
0 NO PAIN
1 MILD
2 DISCOMFORTING
3 DISTRESSING
4 HORRIBLE
5 EXCRUCIATING

E = EXTERNAL
I = INTERNAL

COMMENTS:

© R. MELZACK, 1975

Figure 1.9: The McGill Pain Questionnaire
Reproduced with permission from The McGill Pain Questionnaire: From Description to Measurement by Melzack [98]

1.6 Quality of Life Assessment Tools

In the assessment of disease, it is important to understand its impact on an individual's quality of life. Quality of life assessment tools are designed to quantify perceived health status and overall physical and emotional well-being. This allows measurement of the benefits from an intervention and allows resources to be targeted appropriately.   The majority of health questionnaires available are not specific to a disease. The most popular and widely validated generic quality of life measure is the Short Form-36 (SF-36). Other well published questionnaires include the Short Form-12 (SF-12), Nottingham Health Profile (NHP), and Sickness Impact Profile (SIP). In recent years disease-specific questionnaires have been developed for hernia patients: the Inguinal Pain Questionnaire (IPQ) from Sweden; the Carolina Comfort Scale (CCS) from the United States; and the EuraHS- Quality of Life scale developed by a working group of the European Registry for Abdominal Wall Hernias.

1.6.1 Generic Quality of Life Questionnaires

1.6.2 Short Form-36 and Short Form-12 Health Survey Questionnaire (SF-36, SF-12)

The SF-36 was developed from a more comprehensive 108 item questionnaire used for a health insurance study.[101, 102] It measures eight dimensions of health which covers the areas of functional status, well-being, and an individual's overall evaluation of health (Table 1.5, Appendix 2). The SF-36 has been validated against the older Nottingham Health Profile in the UK. It is sensitive at detecting small changes in health compared with the NHP and the SIP making it useful in studies involving conditions which cause less severe disability. The SF-36 is easy to administer and can be completed in 5 minutes with high compliance rates. This makes it a practical tool for use in both research and clinical practice.[103, 104]

However the process of interpreting data is more complex. Two summary scores are calculated: the Physical Component Summary (PCS) Score and the Mental Component Summary (MCS) Score.[103] These are calculated from factor-weighted scores which can also be country-specific. Scores are transformed to give a range from 0 to 100 with a higher score indicating better health. Due to the

complex process of computation and analysis of data, an experienced statistician would be required.

Area	Dimension	No of questions
Functional status	Physical functioning	10
	Social functioning	2
	Role limitations (physical problems)	4
	Role limitations (emotional problems)	3
Wellbeing	Mental health	5
	Vitality	4
	Pain	2
Overall evaluation of health	General health perception	5
	Health change*	1
Total		36

*This item is not included in the eight dimensions nor is it scored.

Table 1.5: Short Form-36 Eight Dimensions of Health
Reproduced with permission from *Validating the SF-36 health survey questionnaire: new outcome measure for primary care* by Brazier et al 1992.[101]

The SF-12 is an abbreviated form of the SF-36 with the aim for rapid assessment covering physical and mental dimensions of health. The summary results produced by the SF-12 have very good correlation with the SF-36.

1.6.3 Nottingham Health Profile (NHP)

The NHP was developed by the Department of Community Health at Nottingham University and was first published in 1980. This questionnaire was developed for use in the community but extended into measuring outcomes in clinical trials. It measures subjective feelings of health status including perceived physical, social, and emotional health issues. The NHP is divided into 2 parts. Part 1 measures the health status which includes questions on physical abilities, pain, sleep, social isolation, emotional reaction, and energy levels. Part 2 focuses on the impact of ill health on the activities of daily living including effects on

occupation, work in the home, personal relationships, social life, sex life, holidays, and hobbies. For each statement, 'Yes' or 'No' responses are recorded. The responses in part 1 are weighted which can make calculation difficult. The NHP has the advantage that it is easy to administer and reports good compliance rates. However, it has been shown that patients with minor disease can still have perfect scores therefore it is not sensitive in those with minor levels of disability. This level of sensitivity can be better assessed using the SF-36.[103-105]

1.6.4 Sickness Impact Profile (SIP)

The SIP measures health related functional status and studies the change in the patient's behaviour and daily activities due to illness. Its development was intended for use in measuring outcomes of care, health surveys, health care planning and policies, and monitoring progress. The areas covered by this quality of life questionnaire are shown on Table 1.6. The comprehensive 235-item SIP was finally refined to a 136-item questionnaire which is reported to take 20 to 30 minutes to complete making it too time consuming for widespread use. In 1994 a short version with 68 items known as SIP68 was developed. The SIP is able to assess for more severe levels of disability like the NHP, therefore its use will be limited in conditions which have smaller effects on function.

Questionnaire Categories	
• Social interaction	• Movement of the body
• Ambulation or locomotion activity	• Communication activity
• Sleep and rest activity	• Leisure pastimes and recreation
• Taking nutrition	• Intellectual functioning
• Usual daily work	• Interaction with family members
• Household management	• Emotions, feelings and sensations
• Mobility and confinement	• Personal hygiene

Table 1.6: Sickness Impact Profile Questionnaire Categories

1.7 Hernia-Specific Quality of Life Questionnaires

1.7.1 Inguinal Pain Questionnaire (IPQ)

The IPQ was developed to provide a standardised and validated tool for the assessment of post-operative groin pain following groin hernia repair. It follows a similar format to the BPI. There are questions pertaining to pain severity and pain interference with daily activities (Table 1.7). However, the IPQ uses a 7 step fixed point rating scale to pain behaviour rather than measurement on an 11-point NRS as in the BPI. An example of this 7 point rating scale is shown on (Table 1.8). There are 18 items and takes approximately 10 minutes to complete. The IPQ and BPI demonstrate statistically significant correlation.[106] Unfortunately, this questionnaire is not readily available for consultation and use outside Sweden despite being one of the few hernia specific quality of life questionnaires.

Pain Severity	Pain Interference
- Pain right now - Worst pain in the past week - How often have you felt pain? - How long have pain episodes lasted?	- Difficulties getting up from chair - Difficulties sitting down - Difficulties standing up - Difficulties climbing stairs - Difficulties driving a car - Difficulties with exercise - Use of painkillers - Testicular pain

Table 1.7: Inguinal Pain Questionnaire (IPQ) Pain Severity and Pain Interference Questions

7-Point Scale for Pain Severity
- No pain   - Pain present, easily ignored   - Pain present, cannot be ignored but does not interfere with activities   - Pain present, cannot be ignored and interfere with concentration and activities   - Pain present, interferes with most activities   - Pain present, necessitates bed rest   - Pain present, prompt medical advice sought

Table 1.8: Example of 7-Point Scale Used in the Inguinal Pain Questionnaire

1.7.2 Carolina Comfort Scale (CCS)

The CCS was developed and patented by the team at the Carolina Hernia Centre. The questionnaire was designed and validated against the SF-36 for the assessment of patients undergoing hernia repair with mesh. It is a 23-item questionnaire assessing the physical limitations from the mesh repair over eight categories which are shown on Table 1.9. This questionnaire also covers the psychological well-being of a patient. Scores are totalled with a range from 0 to 115 where a higher score indicates a worse outcome. Heniford et al correlated the CCS with the SF-36 which is considered the 'gold standard' quality of life measure. At best most of the measured variables only showed moderate agreement with the SF-36 (Kappa coefficient 0.41 – 0.60) except for pain where the correlation was good. However, statistically the correlation between the CCS and SF-36 is still significant.

Interference Categories	
• Laying down • Bending over • Sitting • Activities of Daily Living (ADL)	• Coughing or deep breathing • Walking • Stairs • Exercise

Table 1.9: Carolina Comfort Scale Categories Measuring Severity of Pain, Sensations, and Movement Limitations

The CCS has advantages of measuring physical restrictions which are likely to be secondary to a hernia repair and has shown increased popularity with patients when compared with the SF-36. It was considered easier to understand and more relevant to their condition after hernia repair. The drawback of this questionnaire is the patent which would incur costs with its use. [107]

1.7.3 EuraHS- Quality of Life Scale (EuraHS-QoL)

This questionnaire was developed by the working group of the European Registry for Abdominal Wall Hernias (Appendix 3). This group has been aiming to provide

an online platform for European surgeons to register and measure outcomes of operation for ventral abdominal wall hernias. This would allow the development of evidence-based practice in ventral hernia surgery. The EuraHS-QoL scale measures pain severity and pain interference similar to the BPI on an 11-point NRS. In addition, it contains 2 questions on 'cosmetic discomfort' which is unique to this questionnaire and important to measure in ventral hernia patients. It has the advantages of being free to use and widely available. The working group of the Eura-HS are actively promoting its use with interests in hernia research and improving patient care.[108] This questionnaire was introduced in 2012 and remains to be validated.

2 Literature Review: Symptoms

There is limited literature published on the symptoms associated with an abdominal wall hernia prior to surgery. Approximately 5% to 8% of all abdominal wall hernias present acutely with 63% having a mechanical bowel obstruction.[109, 110]

2.1 Ventral Hernia

Research on abdominal wall hernia has a tendency to combine umbilical, incisional and epigastric hernias under the heading of ventral hernia. This is due to the relatively small number of operations on each individual type of ventral hernia compared with inguinal hernia repair.

2.1.1 Acute Presentation of a Ventral Hernia

Around 10% of ventral hernias present acutely with incarceration or strangulation. Incarceration as a presenting complaint affects 16% of umbilical and 8% of incisional hernias. [26, 110] If ventral hernias are subdivided into different hernia types, 6% of umbilical and 2% of incisional hernias can present with strangulation.[26, 111] McEntee et al reported that 6 out of 57 intestinal obstructions secondary to strangulated hernia were from incisional hernias. [112] As epigastric hernias are less common, they account for around 10% of acutely incarcerated ventral hernias.[109]

2.1.2 Pain Associated with a Ventral Hernia

Mudge and Hughes recorded symptoms associated with incisional hernia such as difficulty in bending, discomfort from the size of the hernia, persistent abdominal pain and episodes of subacute obstruction requiring hospital admission. In their group of 62 patients, 23 had a symptomatic incisional hernia and 3 had reported episodes of subacute obstruction.[27] Another study found that just over a half of patients with an incisional hernia had discomfort from their hernia with the remainder being asymptomatic.[113] In questionnaire studies looking at trends in incisional hernia repair, just under one-quarter were asymptomatic and almost one-half were described as oligosymptomatic.[113, 114]

Pain as the presenting complaint occurred in 80% who were listed for an incisional hernia repair in a small study.[26]

There are no large studies with the primary objective of measuring symptoms from ventral hernias prior to surgery using uni-dimensional pain scales, but there are some studies comparing pre- and post-operative pain scores. This allows the extrapolation of data to quantify the level of pain in this group of patients. One study identified preoperative visual analogue scale (VAS) scores of around 21 to 26 mm in ventral hernia patients. Lauscher et al used the numerical analogue scale (NAS), which is an 11-point numerical rating scale, to measure pain from an incisional hernia. 52% scored 4 or more, which is their definition of a symptomatic hernia. Itani et al recorded mean preoperative pain scores of 25 – 31 mm at rest; 39 – 42 mm during normal activity; and 53 – 66 mm during exercise.[115-117] One large study of 512 patients with ventral and incisional hernias undergoing repair measured pre-operative and post-operative pain scores and effects on quality of life using the Carolina Comfort Scale (CCS). The CCS was developed by their unit and symptomatic patients were defined as those who scored great than or equal to 2 out of 5 on this scale. Pre-operatively 69% of patients had at least mild pain during some activities and around 28% experienced severe pain at times.[107, 118]

2.1.3 Other Symptoms Associated with a Ventral Hernia

Other complications associated with an incisional hernia include potential respiratory dysfunction in patients with large hernias due to impaired abdominal wall function. This topic has not been studied in detail. A large incisional hernia may also cause skin problems due to its pressure effects which may result in atrophy of the skin, capillary thrombosis and ulceration. The incidence of this is unknown. Another potential rare complication is spontaneous or traumatic rupture of the incisional hernia and this is also a recognised complication of an umbilical hernia in those with tense ascites. [119]

2.1.4 Effects on Quality of Life Associated with a Ventral Hernia

A small number of studies look at the impact which an incisional hernia has on an individual's quality of life. A study of 35 patients found that pre-operative

Short Form-36 scores for bodily pain and physical functioning were significantly lower that the Danish reference values (p<0.005).[120, 121] Uranues et al measured pre-operative quality of life scores in those with a symptomatic recurrent incisional hernia with a defect greater than 5 cm using the Gastrointestinal Quality of Life Index (GIQLI). The GIQLI was developed in 1995 which evaluates 5 domains including symptoms (19 items), physical (7 items), social (4 items), and emotional (5 items) functions. The patients with a symptomatic recurrent incisional hernia scored 98 out of the maximum 144 points. These scores were significantly improved following repair of their hernias.[122, 123] Van Ramshorst et al followed up a cohort of open abdominal surgery patients at 1 year and examined for a clinically detectable incisional hernia. All patients completed the Short Form-36 (SF-36) quality of life and Body Image questionnaires and those with an incisional hernia scored significantly worse in the components of the SF-36 measuring physical functioning, role physical, and the physical component score. They also scored lower on body image scores and cosmetic scores. All these results were adjusted for age, sex, and co-morbidity, therefore confirming that having an incisional hernia does impair a patient's quality of life.[36]

2.2 Inguinal hernia

Symptoms associated with inguinal hernias have been studied in more detail compared with ventral hernias. The European Hernia Society guidelines have defined the symptoms associated with inguinal hernia which are displayed on Table 2.1 with permission from the authors.[124]

Definitions	
Asymptomatic inguinal hernia	Inguinal hernia without pain or discomfort for the patient
Minimally symptomatic hernia	Inguinal hernia with complaints that do not interfere with daily normal activities
Symptomatic inguinal hernia	Inguinal hernia which causes symptoms
Non-reducible inguinal hernia	Inguinal hernia in which the contents of the sac cannot be reduced into the abdominal cavity; this can be in chronic cases (accreta) or acute cases (incarceration)
Strangulated inguinal hernia	Inguinal hernia which is non-reducible (incarcerated) and shows symptoms of strangulation (vascular disorders of the hernia content) and/or ileus

Table 2.1: European Hernia Society 2009 Definitions for Inguinal Hernia[124]

2.2.1 Acute Presentation of an Inguinal Hernia

Primatesta et al recorded the emergency inguinal hernia repair rate of around 9% which gradually reduced over the time period from 1976 to 1986. [63] More recent results indicate that around 3 and 5% of inguinal hernia repairs were carried out as an emergency. [110, 125] The reduction in numbers of acute hernia repairs over time may be reflected by the increased rates of elective repair. Women contribute to 12% of all emergency inguinal hernia admissions.[125]

The incidence of obstruction is around 40 per 100,000 of the population per year including all ages of which 25% are due to hernias. These results are based on a one year prospective study of approximately 600,000 people in the UK. Inguinal hernias contribute to around 58% of the hernia obstructions or 11.6% of all

intestinal obstruction. [112] Gallegos et al found that 5% of inguinal hernias presented as an emergency with the working diagnosis of strangulation. Intra-operatively, 64% of these patients had evidence of compromised tissue. They calculated the cumulative probability of strangulation from an inguinal hernia from first appearance at 3 months to be 2.8%, 24 months 4.5% and at 60 months 8.6%. The authors concluded that the rate of strangulation is highest during the first 3 months after recognition of a hernia. Other studies found that between 11 and 24% of inguinal hernias first present with strangulation. [126] Fitzgibbon et al estimated the lifetime risk of strangulation from an inguinal hernia for an 18 year old man to be 0.272% or 1 in 368, and for a 72 year old was 0.034% or 1 in 2941. [127]

2.2.2 Pain Associated with an Inguinal Hernia

There are a number of studies and randomised clinical trials which compare pre-operative and post-operative pain scores but not all studies have published pre-operative measurements for analysis. Most inguinal hernias cause mild to moderate discomfort which increases with activity. A prospective study of 699 patients found that one-third of the patients with an inguinal hernia scheduled for surgery had no symptoms and the other two-thirds complained of pain. The authors projected approximately 90% of patients with an inguinal hernia will present with pain within 10 years of developing their hernia. The irreducible hernias were more likely to be painful and the probability of a hernia becoming irreducible increased with time.[128] Similarly, another study from the Netherlands documented that almost 50% of their patients having a laparoscopic repair had pain pre-operatively.[129]

One of the first studies to measure pain from an inguinal hernia was published in 2002 in over 300 patients undergoing an inguinal hernia repair. The scores at rest and on movement were measured on a 100 mm visual analogue scale (VAS) and divided into 4 groups of no pain (0 mm), mild (<10 mm), moderate (10 – 50 mm) and severe (>50 mm) pain. Approximately one-quarter of patient reported no pain and 54% had mild pain at rest. Only 1.5% and 10.2% of the patients reported severe pain at rest and on movement, respectively in this study, therefore severe pain does not appear to be common in patients with an inguinal hernia.[130] Overall, the pre-operative pain scores in this cohort of patients were

10.1 cm at rest and 17.1 cm on movement.[131] A randomised clinical trial by Jorgensen et al comparing two types of mesh for a Lichtenstein hernia repair measured pre-operative symptoms. 68% of their patients undergoing repair had moderate to severe symptoms from their hernia. The symptoms they included were those of persistent pain, numbness or groin discomfort measuring greater than 30 mm on the visual analogue scale. 16% of this group scored 0 mm on the visual analogue scale for pain.[132] Pre-operative pain from an inguinal hernia occurred in 30 to 60% of patients undergoing an inguinal hernia repair in a few smaller studies.[133, 134]

A couple of studies focused on pain during sexual activity associated with an inguinal hernia which occurred in 15 to 32% of patients. Schouten found that 21% scored greater than or equal to 4 out of 10 on the visual analogue scale.[135, 136]

2.2.3 Effects on Quality of Life Associated with an Inguinal Hernia

There are several randomised clinical trials which measure a change in the quality of life scores in patients who undergo inguinal hernia surgery.[137-141] The Short Form-36 is the most commonly used tool. I could not identify studies which measured and compared quality of life scores between patients with an inguinal hernia and control patients. This makes it difficult to draw conclusions regarding how much an inguinal hernia impairs a patient's quality of life. Jones et al published pre-operative Short Form-36 scores for 98 patients who went for an inguinal hernia repair and compared them to the published Short Form-36 reference values for males within the 45 to 54 years age group. They specified that a difference of 10 points would be statistically significant. Based on this the only health domain scoring significantly poorer was the role-physical but generally the scores were high and comparable to the 'normal' population.[138] Bitzer et al used a combination of the Short Form-36 and their hernia symptom checklist (HSCL) which comprises of nine items for symptoms and restriction in activities due to a hernia. They found that moderate to severe impairment affect 57% when carrying out strenuous or sporting activities and 34% in work or household tasks.[137]

A couple of other studies identified 16 to 23% of patients with an inguinal hernia complain of problems with sexual dysfunction or impairment secondary to their hernia.[135, 142] This is an important yet probably commonly overlooked problem at a clinic consultation.

3 Literature Review: Outcomes of Hernia Repair

3.1 Ventral Hernia

Literature on the outcomes of ventral hernia repair frequently combines incisional with primary ventral hernia. Epigastric hernia is usually reported with umbilical hernia due to the much smaller numbers repaired.

3.1.1 Post-Operative Complications

A large Danish database study of over 3400 umbilical and epigastric hernia repairs found major complications occurred in 0.7% and minor complications in 3.3% of all repairs with no significant difference between laparoscopic or open operations.[25] Wound infections are common after an open umbilical hernia repair. The Veterans Administration group's retrospective study identified 29% of open mesh repairs and around 12% of suture repairs had post-operative infections which was statistically significant. However, another randomised clinical trial failed to show this difference.[23, 24]

Incisional hernia repairs are associated with high overall complication rates of up to 32% in laparoscopic to 48% in open repair.[115, 117, 143-146] Problems with wound complications can affect between 4 to 49% when onlay mesh is used and up to 2.5% of those require removal of the prosthesis.[147, 148] A randomised trial comparing laparoscopic with open surgery for incisional hernia follow a trend towards less wound complications in the laparoscopic group (6.6% vs 36%).[149] Ramirez component separation technique may be considered for complex abdominal wall hernias with a significant loss of abdominal domain. Wound complication rates related to the component separation technique are reported between 12 and 67% which is significantly higher than with conventional mesh repair.[7, 61] One would have to bear in mind these higher figures associated with component separation are likely related to the complexity of the hernias.

Wound infection rates for incisional hernia repair are variable but a meta-analysis found an overall rate of 1.5% in laparoscopic repair versus 10.1% in open repair.[150] Mesh removal rates were 0.7% and 3.5% of those with wound infection

in the laparoscopic and open groups, respectively. A few randomised trials have shown rates which are higher than the ones reported by the meta-analysis with up to 10.5% in laparoscopic and up to 28% in open repair having this complication.[115, 144, 151] However, a large retrospective study of 1242 patients described excellent wound infection rates of 0.64% and mesh infection rates of 0.16%.[152] These results should be interpreted with caution as the data was collected retrospectively.

Seroma can occur in up to one-third of all ventral hernia repairs and be as high as 49% for incisional hernias.[148, 153] A Cochrane Systematic Review published in 2011 have suggested generally high seroma rates but the high heterogeneity of the studies it did not allow meaningful comparisons between the laparoscopic and open techniques.[153] Results so far may favour either laparoscopic or open repair in terms of seroma formation. One study of 314 patients found open repair resulted in almost three times the seroma rates of laparoscopic repair.[115] However, a smaller study found seroma occurred more frequently in the laparoscopic group.[154] As seromas are a very frequent finding then identifying those which are symptomatic or require intervention would be of more clinical significance. Symptomatic or prolonged seroma occurred in 2.6% of laparoscopic ventral hernia repairs in an 850 patient study.[155]

3.1.2 Recurrence

Three-quarters of all hernia recurrences occur within the first 3 years of repair therefore studies need to have more than 3 years follow-up before the results can be meaningfully interpreted.[144]

Suture repair of umbilical hernias have consistently demonstrated high recurrence rate of up to 40%. The Mayo technique or 'vest-over-pants' overlapping suture repair is associated with high recurrence rates of up to 28%. Interrupted suture repair may be associated with a slightly lower recurrence rate of around 11%.[19, 20, 23, 24] The use of mesh in open repair of umbilical hernias can reduce recurrence rates to around 1%.[23, 24]

Recurrence rates following suture repair of incisional hernias are similarly high around 46% at 3 years and 63% at 10 years. Whereas, mesh repair have lower

but still significant recurrence rates of about 23% and 32% at 3 and 10 years, respectively. If an incisional hernia is small (≤10 cm^2) then the recurrence rate at 10 years is better at 17%.[111, 147, 156]   A Cochrane review of 7 randomised clinical trials on open incisional hernia repair confirms that mesh repair is superior in preventing hernia recurrence at the expense of an increased risk of wound infection.[157]

Laparoscopic repair of ventral hernias have been compared with open repair and recurrence can occur in up to 18% of patients with no significant difference between the two techniques.[153, 158-160]   However, the higher recurrence rate of 18% was identified by the use of radiological imaging when there was doubt clinically whether there was a hernia.[158]

The position of mesh placement for incisional hernia repair has been a topic of discussion. Methods of onlay and sublay mesh placement have been compared in incisional hernia repair. Sublay mesh gave better 12 month recurrence rates of around 2% compared with 10.5% with onlay repairs and this figure almost reached statistical significance.[148] A retrospective cohort study of Veteran Affairs hospitals also suggested that sublay was superior to onlay/inlay but the updated 2011 Cochrane review did not show this difference. The Veterans Affair study probably showed superiority of sublay mesh because they included the results of inlay and onlay mesh together which would skew the results as inlay mesh has similar recurrence rates to suture repair.[58, 59, 161]

The choice of mesh will also influence recurrence rates. The majority of meshes used will either be non-absorbable or composite meshes. In recent years biologic or collagen meshes have been available. Manufacturers are trying to find a role for these meshes in elective and emergency hernia repair especially in the presence of contaminated fields. Many of these studies have been retrospective case series and have demonstrated high hernia recurrence rates of around 21%.[60] The LAPSIS trial was the only multi-centre randomised clinical trial comparing Surgisis Gold collagen mesh with conventional mesh repair of an incisional hernia and also laparoscopic with open. Unfortunately, the trial closed early due to poor patient recruitment and the significantly higher recurrence rates in the Surgisis Gold mesh group.[162]

3.1.3 Chronic Pain

Chronic pain is generally accepted as pain which persists beyond 3 months. A number of studies also focus on the category of moderate to severe pain or 'clinically relevant pain' probably because mild pain is fairly common after an incisional or ventral hernia repair. Some studies extend this definition to identify 'clinically relevant pain' as those who are scoring 3 or more on an 11-point numerical rating scale.[160, 163]

Around one-third complain of clinically relevant pain 6 months after an open incisional hernia repair. At 18 months this reduces to 7.5% in those with a pre-operative minimally symptomatic hernia and 14% in those who were symptomatic. Lauscher et al reported that within the first 6 post-operative months only the symptomatic incisional hernia patients experienced any symptomatic benefit from their repair.[160] When researchers measure all levels of pain, around 28% still have pain scores of greater than zero at one year.[164] Generally, the most frequently quoted incidence of chronic pain after ventral or incisional hernia repair is less than 5% but can be as high as 26% after repair of an incisional hernia. [154, 155, 159, 161, 165, 166] However, a questionnaire study of 132 patients with a median follow-up of 36 months following a small umbilical or epigastric hernia repair (median 1 cm, range 0.2 – 8.0 cm) demonstrated higher than expects rates of moderate or severe chronic pain in 12%.[167] These higher rates may be that patients who elected to have surgery had pre-operative pain. This was well demonstrated by Tsirline et al where one-third of those with severe pre-operative pain scores continue to experience severe post-operative pain at 2 years.[118]

Snyder published results for a survey of 854 patients of which 371 responded at a minimum follow-up of 3 months (median 5 years).   Median pain scores at rest were around 4 mm; normal activity 9 mm; and exercise 19 mm for patients after an incisional hernia repair without evidence of a recurrence. 36.4% had pain of greater than 5 mm at rest after an incisional hernia repair without an active recurrence. The presence of pain was over 50% in those who have developed a recurrent hernia at the time of the survey.[168] Mean pain scores are recorded between 5 and 15 mm following both laparoscopic and open incisional hernia repairs at 1 to 2 years in couple of studies.[117, 160, 169] These results confirm that

the majority have very mild levels of pain although this may still be recorded as chronic post-operative pain. There is insufficient data in the literature to support either open or laparoscopic repair to reduce the risk of chronic post-operative pain.[153]

Attempts have been made to identify predictors for chronic pain. Pre-operative pain has been identified as a significant predictor. Although those with severe pre-operative pain were more likely to have chronic post-operative pain, they experienced less pain than before operation. Tsirline et al also found new onset chronic pain after a ventral hernia repair only occurred in less than 2% of cases.[118] Other predictors of persistent pain after ventral hernia repair include younger age, females, chronic cough, repair for recurrence and open repair of large hernias (>100 cm2).[118, 163, 168, 170]

3.1.4 Other Symptoms Associated with Hernia Repair

Chronic post-operative pain is by far the most commonly investigated symptom. Lauscher et al also reported clinically relevant dysaethesia which occurred in around 17% of open incisional hernia repair.[160]

3.1.5 Hernia Repair and Return to Daily Activities and Effects on Quality of Life

A randomised clinical trial of 171 incisional hernia repairs reported an average length of stay of 2.7 days after laparoscopic repair compared with 9.9 days in the open group.[146] Incisional hernia repair can significantly impair the ability to carry out daily activities in the short term. In the longer term improvement from baseline was observed for heavy lifting, tying laces, coughing and sneezing following incisional hernia repair in one study although the actual figures were not published.[165] Venclauskas measured return to full activity using a set of exercises and measurements and patients were consider as back to normal activity when follow-up scores matched pre-operative values. At 3 months approximately 90% of mesh repair patients have returned to full daily activities whereas this was only possible in 54% of suture repairs.[148] However, this does not translate into actual time to return to work as an Italian study found open repair patients returned to work after 25 days and laparoscopic repair after 13 days.[146]

Change in quality of life is an important aspect to measure because it quantifies the success of an operation. A small number of studies have published pre- and post-operative quality of life measures. Most of these compared different techniques for incisional hernia repair and used a variety of quality of life scales including the Short Form-36 (SF-36), Gastrointestinal Quality of Life Index (GIQLI), and the Carolina Comfort Scale (CCS). Patients with a ventral hernia were found to score below the national reference range on the SF-36 physical functioning and bodily pain scores and these returned to the reference range by the sixth post-operative month.[120, 121] Improvement from baseline values on the SF-36 occurred for both open and laparoscopic incisional hernia repair.[165] Favourable results were also found in recurrent incisional hernia repairs when measured with the GIQLI in the items related to an abdominal wall hernia such as abdominal pain, bloating, fullness and problems with eating. There was also significant improvement in general well-being and physical strength at a median follow-up of 25 months.[122]

Comparisons have been made between laparoscopic and open ventral hernia repairs. Laparoscopic ventral hernia repair patients may score worse than open repair in the short term but not in the long term. A large prospective American study of 710 patients found that there were significantly higher levels of pain and movement limitation at one month in the laparoscopic group.[171] A smaller quality of life study compared laparoscopic with open repair of symptomatic ventral hernias and their results at 6 months demonstrated better quality of life scores on the SF-36 and Carolina Comfort Scale (CCS) in the laparoscopic group.[172]

3.1.6 Patient Satisfaction

Approximately 50% of patients were satisfied with the cosmetic outcome after an incisional hernia repair with no significant difference between suture and mesh repair groups. However, overall satisfaction of the surgery was higher at 64% and 77% in the suture and mesh repair groups.[156] At a median follow-up of 5 years a questionnaire study found that 81% of patients without an incisional hernia recurrence following an incisional hernia repair were satisfied with their operation.[168] Another study of over 120 patients measured the overall satisfaction with the surgical procedure and the open repair group had a mean

score of 7 compared with 8.2 in the laparoscopic group which was statistically significant. However, their results do not indicate the proportion who are happy with the result but 82% of their laparoscopic patients would choose the operation again.[169]

3.1.7 Mortality

The mortality associated with acute ventral hernias depends on the timing of presentation. Kulah et al found admissions within 24 hours of onset of incarceration were associated with a mortality of 1.4% compared with the significantly increased rates of 10 to 21% in those admitted between 24 and 48 hours.[109, 173] Mortality rates following elective ventral hernia repair are generally low but still measureable. This figure is around 0.4% for incisional hernia, but has been reported as high as 5.3%, and 0.1% for umbilical and epigastric hernias.[25, 119, 169, 174]

3.2 Inguinal hernia

There is a vast volume of published literature on the outcomes of inguinal hernia repair.

3.2.1 Post-Operative Complications

Minor post-operative complications are common following an inguinal hernia repair. Approximately 4% of open and 8% of laparoscopic inguinal hernia repairs result in a seroma. A number of studies have concluded that laparoscopic repair is associated with an increased risk of seroma formation.[175-177] Seromas are common but the actual clinical significance is more difficult to determine. It is difficult to extrapolate from the available literature the proportion with a seroma go on to develop a surgical site infection. Haematoma is also a common finding and occur in 4 to 13% of laparoscopic and 6 to 16% of open inguinal hernia repairs. The general consensus is that TEPP repair is associated with significantly lower haematoma rates compared with open repair.[175, 178-180]

Wound infections are relatively common with a number of studies and meta-analyses identifying overall rates of 3 to 4.5% for open inguinal hernia repair but may be as high as 11%.[139, 177-179, 181-183] Mesh infections are rare affecting 0.08%

of laparoscopic and 0.13% of open repairs, although the difference is significant.[175, 184]

A much less common but important complication which can sometimes be missed at consent for surgery is ischaemic orchitis or testicular atrophy. A rate of 0.1% was found in a large series of open inguinal hernia repairs but other smaller studies have identified rates of testicular atrophy to be as high as 1% following a Lichtenstein repair.[139, 179, 183]

A few reported serious vascular and visceral injuries have occurred during laparoscopic inguinal hernia repair leading to the conclusion that it is associated with a higher risk of rare serious complications compared with the open procedure. [175] TAPP repair appears to have a higher risk of port-site hernias and of visceral injuries but firm conclusions cannot be drawn from the meta-analysis. The conversion rate to open repair is higher when a TEP approach is used. [69]

3.2.2 Recurrence

There are more techniques available for inguinal hernia repair compared with ventral hernia. The recurrence rates are dependent on the technique and of course the expertise of the surgeon. For tissue repairs such as the Shouldice repair recurrence rates are as low as 0.4% seen at the Shouldice clinic. This cannot be replicated in low volume centres but one unit in the UK achieved a recurrence rate of 0.8% at 6 years if stainless steel wire was used compared with 8.1% within 2 years when they used a polyester suture.[185] On the other hand, another centre reported a recurrence rate as high as 15%.[186] The 2012 Cochrane review stated that the Shouldice repair had the lowest recurrence rates compared with other tissue repairs (4.4% versus 6.9%).

Mesh repairs are popular and generally have the lowest recurrence rates of around 0.8% compared with non-mesh repairs.[179, 187] The Lichtenstein tension-free repair is probably the most popular of the methods with recurrence rates of 0% in 1000 cases at 1 to 6 years by Lichtenstein's team.[75, 76, 124] One large Danish database study of young males undergoing hernia repair found recurrence rates of 1.6% with the Lichtenstein repair at 5 years.[187] The Prolene Hernia System has similar results to the Lichtenstein repair with recurrence rates of around

1%.[188] Open pre-peritoneal mesh repairs are less commonly performed but are associated with comparable recurrence rates of 1 to 4%.[189]

The results of laparoscopic inguinal hernia repairs are more variable with the most frequently reported recurrence rates of 2 to 3% but vary between 0.6% and 10% with no discernible difference between TAPP or TEPP repairs. [175, 177, 180, 190-194] The large variation probably reflects the steep learning curve required to achieve good outcomes from laparoscopic repair.

3.2.3 Chronic Groin Pain

Chronic post-operative groin pain has been extensively studied and is defined as pain persisting or occurring after normal tissue healing has taken place. This can reasonably be defined as pain persisting for more than 3 months after a groin hernia repair. The rate of chronic groin pain in the literature following an inguinal hernia repair is variable from 2% to as high as 63%.[181, 195-209] The results of mesh repairs appear to be associated with more favourable results in which around 11% complained of chronic pain in a systematic review of 29 clinical trials.[210] When looking at trials comparing mesh with non-mesh repairs then the frequency of chronic groin pain is just under 6% and up to 18%, respectively.[181, 198-200] A meta-analysis of randomised clinical trials comparing laparoscopic with open inguinal hernia repair found that laparoscopic repair was associated with a significantly lower risk of chronic groin pain (13.8%) compared with the open procedure (19.1%). One of the larger randomised clinical trials actually found chronic groin pain occurred in as many as 28.7% of laparoscopic repairs and 36.7% of open cases one year after surgery.[193] A more recent meta-analysis of 13 randomised clinical trials including over 5400 patients still found a trend towards less chronic pain in the TEPP compared with Lichtenstein group but the figure did not reach statistical significance.[194] When the Lichtenstein repair is compared with the open preperitoneal technique (TIPP) the same trend is not seen.[211]

Chronic groin pain is common and it is probably more important to identify patients with clinically significant pain as this is more likely to affect quality of life. Some studies will identify the patients who suffer from moderate to severe chronic groin pain. Most identify around 3% in this category with one study

reporting a much higher rate of 9%.[131, 181, 195, 200, 206, 207, 210, 212-215] Some measure interference with daily activities caused by the chronic groin pain which occurs between 0.7 to 8.3%.[201, 213, 216, 217] One large study of over 8500 patients from the UK found 0.71% of open and less than 3% of laparoscopic inguinal hernia repair patients required attendance at a chronic pain clinic for severe chronic groin pain. Interestingly, after 1 year of non-operative treatment 69% were discharged pain-free.[218]

Due to the frequency of chronic groin pain, trials of other operative techniques or different types of mesh are used to reduce chronic post-operative pain. As mentioned earlier laparoscopic repair may reduce its incidence and the use of glue rather than tacks may reduce this further.[219] A meta-analysis of several randomised trials comparing lightweight with heavyweight mesh found lightweight mesh to be associated with reduced chronic pain (13.8% vs 22.5%) and without any significant increased risk of recurrence.[220] Randomised clinical trials have also attempted to explore sutureless mesh fixation with glue in the Lichtenstein repair which may reduce chronic pain although the results of the small studies cannot lead to definite conclusions.[221, 222] A small number of randomised trials comparing self-gripping mesh with sutured mesh in a Lichtenstein repair have not made a significant impact in reducing chronic groin pain.[223, 224]

Many authors have tried to identify risk factors or predictors for chronic post-operative pain. Topics of interest include the identification and preservation or division of the three nerves during inguinal hernia surgery. A number of papers have studied the effects of ilioinguinal nerve excision or division but not all have come to the same conclusion. A couple of studies have found that ilioinguinal nerve excision significantly reduced neuralgia at one year from around 20 -25% to 3 – 6%.[225, 226] Whereas a large randomised clinical trial of over 800 patients did not show any difference between the two groups for chronic pain.[227] Some authors have suggested that the reduction in chronic groin pain is achieved by the identification and preservation of the nerves. If 2 or 3 nerves are divided or not identified at the time of inguinal hernia repair then there is a significantly increased risk of chronic groin pain.[10, 228] A consistent predictor for chronic post-operative groin pain is severe pre-operative groin pain. In one study 26% of their study subjects with pre-operative groin pain developed chronic pain compared

with 5% of those with no pain prior to surgery.[229, 230] This would explain the short term findings of O'Dwyer's randomised clinical trial of asymptomatic inguinal hernias where operating on an asymptomatic inguinal hernia did not appear to cause chronic groin pain.[231] Other predictors include younger age, post-operative complication, intensity of acute post-operative pain and the presence of other chronic pain syndromes.[195, 229, 232, 233]

3.2.4 Other Symptoms Associated with Hernia Repair

Groin numbness is a common symptom following an inguinal hernia repair. The proportion of patients developing groin numbness varies significantly between trials. The best results are from a randomised clinical trial of over 1000 patients who had either a TAPP or Shouldice repair and at 3 months 0.1% and 3.1% had groin numbness, respectively.[176] However, another study reported much higher rates at 1 year following an open mesh repair. 34% of the patients complained of groin numbness and 13.5% of thigh numbness, but only 4.5% found this interfered with their quality of life.[234] Laparoscopic repair or open preperitoneal repair causes less groin numbness occurring in less than 13%.[235-238] There is a suggestion that the sensory deficit may reduce with time because in a 5 year follow-up study one-quarter of open mesh repair patients still complained of groin numbness.[235] Groin numbness may also be associated with chronic groin pain as 9% of chronic groin pain patients were found to have this sensory impairment.[210]

3.2.5 Hernia Repair and Return to Daily Activities and Effects on Quality of Life

Return to work following an inguinal hernia repair is variable depending on whether the job is manual or physical or whether patients are able to take sick leave due to social circumstances. An American study of open tissue repairs report return to work at a median of 7 days which seems earlier than would be expected.[138] Other studies have reported a longer period off work of around 3 weeks. When comparing return to normal activities between laparoscopic and open hernias, the laparoscopic patients recovered around 7 days earlier than open patients.[175, 213, 239] One large study of almost 2000 patients only showed a modest improvement in the laparoscopic group who returned one day earlier to work.[190]

Restriction of daily activities and effects on quality of life are closely related to chronic groin pain therefore those with severe pain are more likely to have severe functional impairment.[201, 207] A systematic review of 7 clinical trials found 32% with chronic post-operative pain experienced limitations in their leisure activities and employment.[210] When trials compare pre-operative and post-operative limitations in daily activities secondary to chronic groin pain, inguinal hernia repair significantly reduced this impairment which reflects the expected reduction of groin pain.[217] Sexual function may also be impaired in around one in six patients following an inguinal hernia repair. This can be related to the chronic groin pain or numbness. The majority of patients with sexual dysfunction after repair will notice an improvement in their function within 12 months.[136, 142, 201]

A number of studies have measured quality of life associated with an inguinal hernia repair. Most have found that the Short Form-36 scores are significantly better than baseline values in those with symptomatic hernias.[137, 141, 240] There is evidence to suggest that laparoscopic repair is associated with significantly better SF-36 scores compared with open repair in the immediate one month after surgery but there is no difference in results between the two groups after 3 months.[183, 241, 242]

3.2.6 Patient Satisfaction

Up to 99% of patients are satisfied with a mesh repair of their inguinal hernia repair.[243] Patients are generally highly satisfied with both the open and laparoscopic operations. Laparoscopic inguinal hernia repair patients may be more satisfied with the appearance of their scars compared with the open group but in the long term both are as likely to recommend their operation.[235] A patient satisfaction score of 9.6 out of 10 on the visual analogue scale was recorded following laparoscopic repair in one study.[244] Another study suggests that both groups are equally satisfied.[245]

3.2.7 Mortality

Operating on a patient presenting with an acute inguinal hernia is associated with a 10-fold increase in post-operative mortality.[246-248] An earlier UK study

recorded mortality rates of 33.8 per 1000 operations in the emergency repair group compared with 14.4 per 1000 in the elective group over the first 12 post-operative months. The deaths in the elective group were not clustered around the post-operative period therefore are unlikely to be related to the surgery whereas the deaths in the emergency group mainly occurred in the first post-operative month.[63] A large study of the Swedish Hernia Database identified an overall 30-day mortality rate of 0.28% for inguinal and femoral hernias but it was not possible to extrapolate from the paper the mortality rates of elective and emergency groups.[249] This group also published on the same cohort of patients in 2007 and indicated that 6277 (6%) were repaired as an emergency and from this information the mortality rate after groin hernia repair can be calculated at 2.4%. The mortality rate can be expected to be 20 times greater than the general population when bowel resection is required during the emergency operation.[250]

3.2.8 Clinical Trials on Asymptomatic Inguinal hernias

Two randomised clinical trials to compare the outcome of observing patients with an asymptomatic or minimally symptomatic inguinal hernia with operative management was developed to answer the question of how one should manage these hernias. One is from the United States by Fitzgibbons et al and the other by O'Dwyer et al from the United Kingdom.[127, 231, 251]

Fitzgibbons et al randomised 724 men aged 18 years and older with an asymptomatic or minimally symptomatic inguinal hernia. This was defined as the absence of hernia-related pain or discomfort limiting usual activities or difficulty in reducing the hernia within 6 weeks of screening. Approximately 40% of patients randomised to each group had hernias which were identified on cough impulse only. This left only 60% with a visible hernia. The patients were randomised to either 'watchful waiting' or for a standard Lichtenstein open tension-free mesh repair and were followed up for between 2 and 4.5 years. The primary outcomes of this study were pain and discomfort interfering with usual activities 2 years after enrolment, and change from baseline to 2 years in the physical component score of the Short Form-36, version 2. 23% of patients in the observation group crossed-over to surgery secondary to pain. This study only recorded an acute hernia rate of 0.3% at 2 years. The authors concluded

that watchful waiting is a safe and acceptable strategy in the management of patients with an asymptomatic or minimally symptomatic inguinal hernia.[127, 251]

The clinical trial by O'Dwyer et al randomised 160 men aged 55 years and older with an asymptomatic inguinal hernia to observation or to a standard open tension-free mesh repair. All patients had a visible hernia and were confirmed to be asymptomatic by the use of the 100mm visual analogue pain scale (VAS) and direct questions on pain severity at baseline assessment. The subjects were followed up at 6 months and at one year with the plan for annual follow-up thereafter. The primary outcome measure was pain measured using the 100mm VAS at rest and on movement at 6 and 12 months. The Short Form-36 questionnaire was also used to assess the change in quality of life at 6 and 12 months from the baseline. There was one acute hernia episode presenting as an incarceration. 19% of the observation patients crossed-over to surgery after 12 months. The short-term follow-up of this clinical trial concluded that asymptomatic inguinal hernia repair does not lead to chronic pain and may reduce serious morbidity and subjectively improve general health.[231]

The recent guidelines published by the European Hernia Society have recommended that watchful waiting is an acceptable option for men with minimally symptomatic or asymptomatic inguinal hernias. However, they recognise that the results from both clinical trials published in 2006 were not conclusive.[69] The most recent systematic review has not identified any further randomised clinical trials in this area. [252]

4 Aims

4.1 Definition of Pain Severity on the Visual Analogue Scale (VAS) and Validation of the Brief Pain Inventory (BPI) Against the 100mm VAS and Verbal Rating Scales

1. To define no pain, mild, moderate, and severe pain on the 100mm VAS.

2. To validate the BPI against the 100mm VAS and 4-point VRS.

3. To design a questionnaire to assess pain and effects on physical activity and quality of life in patients with an abdominal wall hernia.

4.2 Assessment of Pain and Its Effects on Physical Activity and Quality of Life in Patients Undergoing Elective Inguinal and Ventral Hernia Repair

Results from various studies have identified that between 12% and 83% of patients with an incisional hernia and two-thirds with an inguinal hernia experience pain.[36, 113, 253] The aims of this study are:

4. To assess pain severity from an inguinal or ventral hernia using the 4-point Verbal Rating Scale (VRS), 100 mm Visual Analogue Scale (VAS), and Brief Pain Inventory (BPI).

5. To assess the impact which an inguinal or ventral hernia has on physical activity and quality of life using the BPI.

4.3 Long Term Outcome of Patients with an Asymptomatic Inguinal Hernia Randomised to Observation or Operation?

Short term follow-up of asymptomatic or minimally symptomatic inguinal hernias have shown crossover rates of around 20% and a low risk of acute hernia presentations.[231] The aims of this study are:

1. To examine the long term outcome of patients with an asymptomatic inguinal hernia randomised to observation or operation

2. To identify the crossover rates to operation.

3. To measure recurrence rates, new inguinal hernias, and groin symptoms in observation and operation groups.

4. To determine the long term acute hernia rates in patients under observation.

4.4 Incidence and Outcome of Patients with a Ventral Hernia

Ventral hernia repair contribute to a significant proportion of the general surgical workload but there is little available evidence on the long term outcomes of patients with an asymptomatic ventral hernia. The rate of umbilical hernia repair is increasing and is the second most common hernia operation after inguinal hernia repair. The aims of this study are:

1. To establish the incidence of incidental umbilical hernias in the general population.

2. To record the prevalence of symptoms in patients referred by the general practitioner with an umbilical hernia.

3. To establish the long term outcomes of patients with an incidental umbilical hernia and those who undergo umbilical hernia repair.

4. To observe the long term outcome of patients with an asymptomatic ventral hernia managed by a period of observation.

5 Materials and Methods

5.1 Introduction

This chapter gives information on the overall methodology on the research carried out within this thesis. Each of the clinical studies comprised of separate groups of patients therefore any methodology not generalisable to all the studies will be detailed in the individual chapters to avoid confusion.

5.2 Patient Recruitment and Clinical Assessment

All the patients who participated in the studies with the exception of the asymptomatic inguinal hernia randomised clinical trial were recruited from the inpatients and outpatients attending a single surgical unit at the Western Infirmary, Glasgow. Outpatients attending the same surgeon were also recruited at Gartnavel General Hospital, Glasgow. The patients who participated in the asymptomatic inguinal hernia randomised clinical trial, which was a multi-centre study, were mainly from the Western Infirmary and Gartnavel General Hospital catchment area and also included those from the Glasgow Royal Infirmary and Southern General Hospitals.

I recruited all the patients in the study titled 'Pain and Its Effects on Physical Activity and Quality of Life in Patients Undergoing Elective Inguinal and Ventral Hernia Repair'. I examined all the patients and ensured the questionnaires were distributed to the appropriate participants. I collected the data and maintained the database prospectively.

The study titled 'Long term Outcome of Patients with an Asymptomatic Inguinal Hernia' was based on the same group of patients recruited in 2001 and 2002 for the randomised clinical trial of observation or operation in patients with an asymptomatic inguinal hernia. The short term results were published in the Annals of Surgery in 2006 by O'Dwyer et al.[231] I recalled patients for clinical follow-up and designed the follow-up proforma and examined all the patients at the research clinic. I set up a new database to accommodate the long term follow-up data. I gathered, designed, and maintained the information on a Microsoft Excel spreadsheet prospectively during the two phases of the follow-up.

For the combined studies on 'Long Term Outcome of Patients with and Asymptomatic Ventral Hernia' and the 'Incidence and Long Term Outcome of Patients with an Umbilical Hernia', patients were recruited from the outpatient departments of the Western Infirmary and Gartnavel General Hospitals. The patients were examined and the data gathered by the surgical trainees and consultant attending the surgical clinics. All trainees involved in the recruitment process were at a level of senior house officer III or above. I was present at the majority of the follow-up clinics examining patients. I was responsible for gathering the patient data from the doctors at the end of every clinic and I designed and maintained the database prospectively on Microsoft Excel spreadsheets.

5.3 Ethical Approval

The Ethics Committee were consulted for advice and approval in all the studies. No special arrangements were required as the randomised clinical trial on asymptomatic inguinal hernias had been granted ethical approval previously for continued follow-up. All follow-up studies were considered part of good clinical practice therefore the ethics committee did not require formal application for special permissions.

5.4 Statistical Analysis

The statistical analysis will be detailed in each of the study chapters. All analyses were carried out using SPSS® version 19.0 (SPSS, Chicago, Illinois, USA). I carried out all the statistical analyses of my results except for the Kaplan-Meier estimates in the 'Long term Outcome of Patients with an Asymptomatic Inguinal Hernia' study which was analysed by Professor Norrie from the Robertson Centre for Biostatistics, University of Glasgow. Professor O'Dwyer also advised on the appropriate statistical analyses required for the studies.

6 Development of the Pain Questionnaire to Assess Pain and Effects on Physical Activity and Quality of Life in Hernia Patients

6.1.1 Introduction

The simplest and most commonly used uni-dimensional pain measurement tools are the verbal rating scales and the 100mm visual analogue scales. The 4-point VRS provides a simple descriptive term of no pain, mild, moderate, and severe pain. However, neither scoring systems assess the impact of pain on daily activities and the patient's quality of life. The Brief Pain Inventory (BPI) was first designed to assess the effect of cancer pain on activity and quality of life, and was later validated for chronic pain for benign conditions. It is the most well recognised tool for assessing these issues.[86, 92] The BPI uses an 11-point numerical rating scale (NRS). There are 4 questions which measure severity of pain: rating pain at its worst and least in the last 24 hours; pain on average; and pain at the time of completing the questionnaire. The BPI Pain Severity Score (PSS) is calculated by adding the 4 scores and calculating the mean. The BPI Pain Interference Score (PIS) is calculated similarly using the 7 pain interference measures. Both give a mean score out of a maximum of 10.

This chapter details the development of the pain questionnaire used to define the severity of pain on the 100mm Verbal Rating Scale (VAS) and also for the validation of the Brief Pain Inventory against the 4-point Verbal Rating Scales (VRS) and the 100mm VAS.

6.1.2 Methods

The questionnaire was developed to serve three purposes. Firstly, it allowed assessment of pain severity and its impact on activities of daily living and quality of life in a group of hernia patients who are admitted for elective hernia surgery which will be detailed in the next chapter. Secondly, it allows the definition of pain severity as a measurement on the VAS. Finally, the BPI could be validated against the VRS and VAS. To achieve this all three pain measurement tools were incorporated into the one questionnaire (Appendix 4).

A group of consecutive patients admitted for elective hernia repair over a 16 month period to a single surgical unit were given the questionnaire to complete. Those with complex abdominal wall hernias, such as incisional hernia defects greater than 10cm in diameter, recurrent hernias, stomas, fistulas, and infected mesh, were excluded from this study. All patients with a good understanding of English without visual, significant cognitive or motor impairment were given the questionnaire the day before their operation. Patients were not supervised during the completion of questionnaire to avoid any external influence on the scores.

Patient demographics including age, sex, hernia type, time from first diagnosis were collected. All patients completed the VRS and VAS pain scales for both at rest and on movement to double the number of datasets for analysis. The BPI was completed once by each patient. I measured all the 100 mm VAS pain scores using the same ruler and technique for every case. A database was created on Microsoft Excel spreadsheet and once completed this was transferred to SPSS® version 19.0 (SPSS, Chicago, Illinois, USA).

6.1.1 Statistical Considerations

Metric data with a skewed distribution were calculated as a median with an interquartile range (IQR). Continuous data were given as a mean with 90% Confidence Intervals (CI) and compared using a t-test. A 90% CI was selected because the sample sizes were small and ensured outliers were excluded from analysis. It was also to ensure that too many datasets were not excluded in the severe category where there were few patients who scored their pain as such. The Pearson's correlation coefficient was used to determine association between two metric continuous variables and the Spearman's rank correlation coefficient was used for ordinal variables. For nominal data the Cohen's Kappa statistic was used to calculate the level of agreement. The statistical analyses were performed using SPSS® version 19.0 (SPSS, Chicago, Illinois, USA).

6.1.2 Results

124 patients (97 male and 27 female) with a median age of 57 years (range 19 to 84 years) admitted for an elective hernia repair were given the questionnaire to

complete. There were 72 inguinal hernia and 52 ventral hernia repairs, consisting of 18 incisional, 27 umbilical, and 7 epigastric hernias. There was excellent compliance with completion of the questionnaire with completion rates of 100% for the VRS, 99% (123 patients) for the VAS, and 98% (121) for the BPI.

6.1.1 Definition of No Pain, Mild, Moderate, and Severe Pain

The results of the VAS score against each category of the 4-point VRS are detailed on Figure 6.1. A VAS score of 4 mm or less defined 'no pain' on the VRS. Patients with mild pain score a mean of 19 mm, moderate 45 mm, and severe 69 mm. From the data available those who complain of moderate to severe pain score more than 40 mm on the VAS.
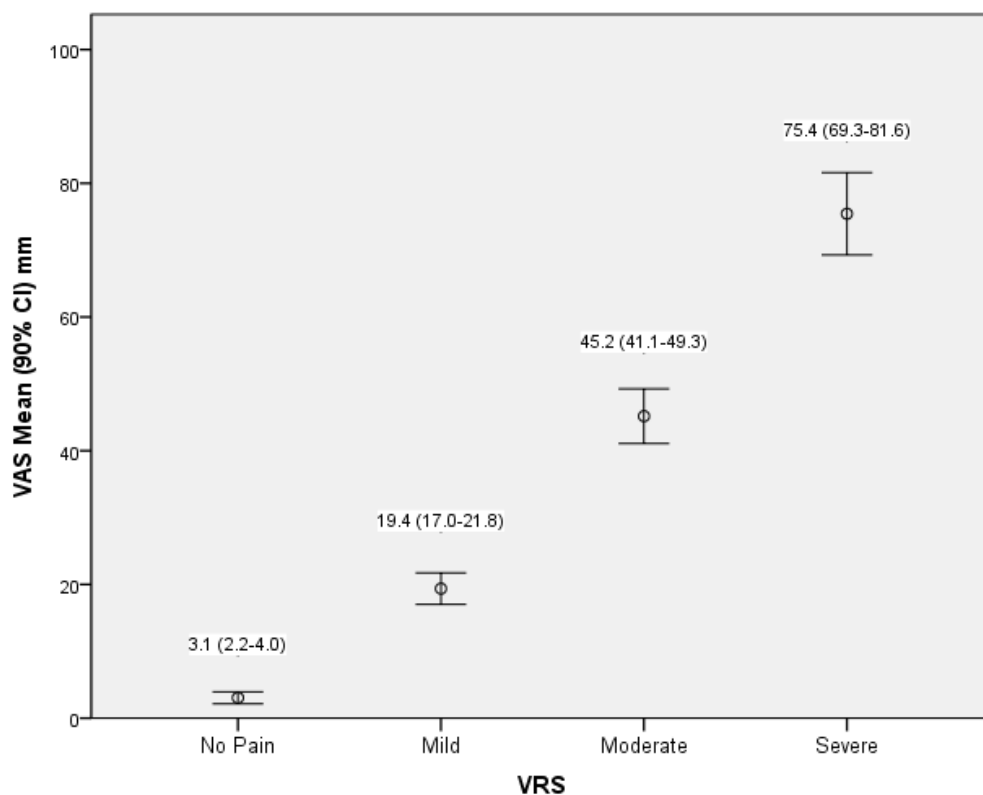
Figure 6.1: Mean VAS Scores and 90% Confidence Intervals for Each Point on the VRS

6.1.2 Validation of the BPI against the VRS

91 (73%) of the 124 patients reported pain on movement on the VRS and there was a positive correlation between the VRS on movement and the BPI PSS and also the BPI PIS (Spearman's rank correlation coefficient of 0.825 (P=0.01) and 0.760 (P=0.01) respectively).(Table 6.1) 91 (73%) of the 124 patients reported pain on movement on the VRS and there was a positive correlation between the VRS on movement and the BPI PSS and also the BPI PIS (Spearman's rank correlation coefficient of 0.825 (P=0.01) and 0.760 (P=0.01) respectively).(Table 6.1)

VRS On Movement	BPI Pain Severity Score Median (IQR)	BPI Pain Interference Score Median (IQR)
No Pain (N=33)	0 (0 – 0.13)	0 (0 – 0.39)
Mild (N=38)	1.25 (0.69 – 2.0)	0.64 (0.29 – 1.57)
Moderate (N=36)	3.0 (2.06 – 4.50)	3.0 (1.86 – 4.86)
Severe (N=17)	4.25 (2.63 – 5.50)	5.57 (3.79 – 6.71)

Table 6.1: VRS on Movement and the Corresponding BPI Pain Severity and Interference Scores

6.1.3 Validation of the BPI against the VAS

On analysis of VAS scores on movement there were 92 patients who scored greater than 4 mm. In those recording pain on the VAS the median VAS score was 37.0 mm (IQR 24.0 to 61.75 mm) and the corresponding median BPI PSS 2.25 (IQR 1.06 to 4.25). In those who scored 4 mm or less this was 0 mm (IQR 0 to 2.0 mm) and 0 (IQR 0 to 0.21) on the VAS on movement and BPI PSS, respectively (Table 6.2). A Cohen's Kappa coefficient determined a very good level of agreement between the VAS and BPI PSS results when divided into these two categories (Kappa coefficient = 0.81).

The average VAS score was calculated using the scores at rest and on movement. None of the patients who scored zero on 'pain on average' registered a score greater than zero on the pain interference questions indicating good internal

validity of the test. There was a strong positive linear correlation between the average pain score on the VAS and the BPI PSS (Pearson Correlation Coefficient R=0.869, P=0.01) (

Figure 6.2). This was slightly better than using the VAS score on movement alone (Pearson Correlation Coefficient R=0.823). The correlation between the average VAS and BPI PIS also demonstrated a good positive correlation (R=0.760).

BPI Question (11-point NRS)	Patients With Pain (N=93) Median (IQR)	Patients Without Pain (N=31) Median (IQR)
Pain Severity Questions		
Pain from hernia at its WORST in last 24 hours	4.0 (2.0 – 6.0)	0 (0)
Pain from hernia at its LEAST in last 24 hours	1.0 (0 – 2.0)	0 (0)
Pain from hernia on AVERAGE	3.0 (2.0 – 5.0)	0 (0)
Pain from hernia NOW	1.0 (0 – 3.0)	0 (0)
Pain Severity Score (PSS)	**2.3 (1.13 – 4.25)**	**0 (0)**
Pain Interference Questions		
General activity	2.5 (1.0 – 5.0)	0 (0)
Mood	2.0 (0 – 4.0)	0 (0)
Walking ability	2.0 (0 – 5.0)	0 (0)
Normal work	3.0 (1.0 – 6.0)	0 (0)
Relations with other people	0 (0 – 4.0)	0 (0)
Sleep	1.0 (0 – 3.0)	0 (0)
Enjoyment of life	2.0 (1 – 5.0)	0 (0)
Pain Interference Score (PIS)	**2.1 (0.71 – 4.54)**	**0 (0 – 0.29)**

Table 6.2: Brief Pain Inventory Pain Severity and Interference Questions Scores in Patients With Pain and Without Pain
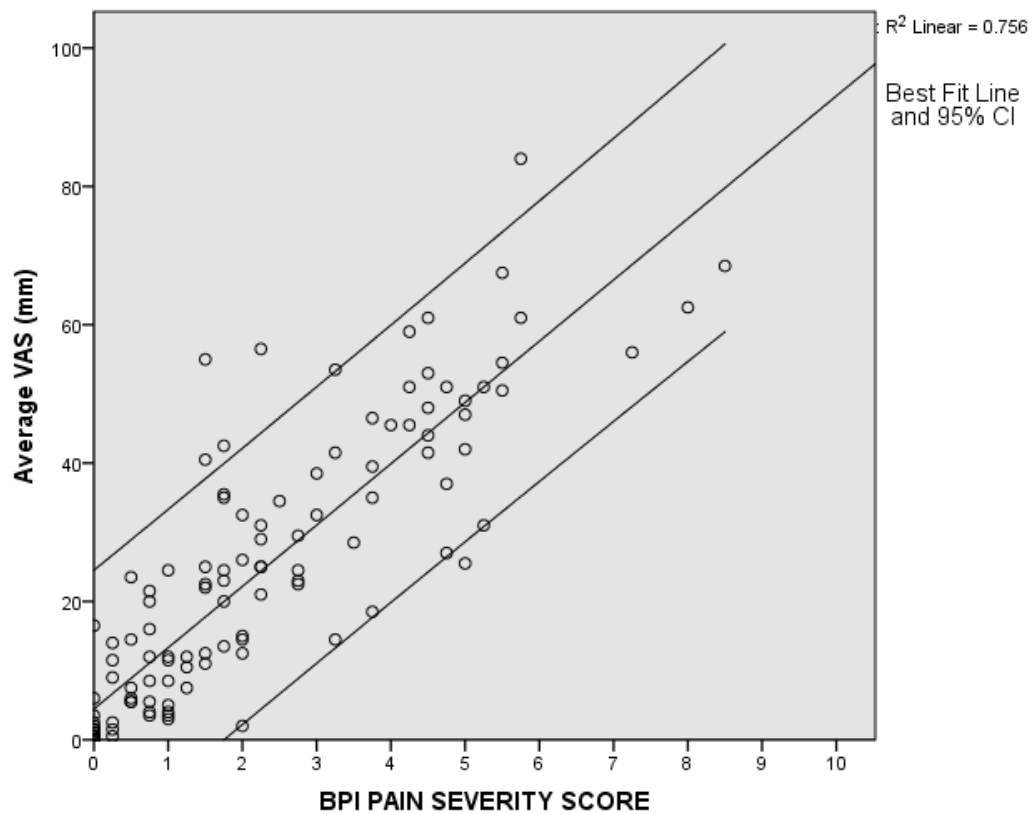
Figure 6.2: Scatterplot of Average VAS Scores and BPI Pain Severity Scores

6.1.4 Discussion

From this study it is clear that 'no pain' is not always equal to 0 on the 100 mm VAS and it would appear that these patients can score up to 4mm. This is important to highlight and also demonstrates the potential for error when using the VAS, especially in those with visual or motor impairment. This should be taken into consideration when interpreting results for other studies published in the literature and may explain why there is wide variation in the reported frequency of chronic post-operative groin pain. It is probably more important to identify 'clinically relevant' pain as in some studies. When using these results to define moderate and severe pain, patients should have scores of 40 mm or greater on the VAS.

The main limitation of this study is the relatively small number of patients scoring in the severe pain category limiting the interpretation of the definition of severe pain. As this study is based on elective hernia repair patients, severe pain is not very common. To increase numbers significantly then one would need to recruit consecutive patients over another year or more which would be difficult given the time constraints to carry out this research.

The BPI is succinct and easy for the patients to complete as indicated by the high compliance rates in this study. The Short Form-36 (SF-36) health survey questionnaire is a popular and validated alternative tool to assess quality of life. In a previous study from our unit, the SF-36 and its modification were used to assess the effects of an inguinal hernia on work and quality of life (Appendix 2).[101, 231] However, analysing SF-36 results is complex and requires the input of an experienced statistician. In addition, when used in observational studies other factors may interfere with results which may not be hernia related. To overcome this problem, other authors have designed questionnaires specific to hernias. An example is the patented Carolina Comfort Scale (CCS) which uses 6-point scales for their scoring system to measure quality of life variables. This has been correlated with the considered 'gold standard' SF-36.[107] At best, most of the measured variables only show moderate agreement with the SF-36 (Kappa coefficient 0.41 – 0.60), except for pain where the correlation was good. From this validation of the BPI the correlation is very good against the VRS and VAS and therefore would be a cost-effective and simple tool to use in the out-patient setting.

7 Pain and Its Effects on Physical Activity and Quality of Life in Patients Undergoing Elective Inguinal and Ventral Hernia Repair

7.1 Introduction

Data from the National Health Service England between 2011 to 2012 indicate that there were over 70,000 inguinal, 17,000 umbilical, 8000 incisional, and 6000 other ventral hernia repairs carried out.[1] In the United States the frequency of inguinal and ventral hernia repair were reported at 500,000 and 250,000 cases per year, respectively.[216, 254] Pain is the most common symptom associated with a hernia.[26, 119] In most patients, pain will be mild at rest and mild to moderate during activity. However, little is known about what impact this will have on the patient's daily activities and their quality of life.

The aim of this study was to assess pain and its effects on physical activity and quality of life using the BPI in patients undergoing elective inguinal or ventral hernia repair.

7.2 Methods

Research and ethics approval was granted for this prospective questionnaire based study analysing pain severity and pain interference in patients with an uncomplicated inguinal or ventral hernia. A questionnaire was created with four sections as detailed in chapter 6 (Appendix 4).

All patients admitted over a 16 month period to a single surgical unit for elective hernia repair were included in this study. Those with complex abdominal wall hernias, such as incisional hernia defects greater than 10cm in diameter, recurrent hernias, stomas, fistulas, and infected mesh, were excluded from this study. All patients with a good understanding of English without significant visual, cognitive, or motor impairment were given the questionnaire the day before their operation. Patients were not supervised during the completion of questionnaire to avoid any external influence on the scores.

7.2.1 Statistical Considerations

The baseline data was tabulated by hernia type (inguinal or ventral). Categorical data were compared between 2 groups by the Chi-square test or in the case of small sample size the Fisher's Exact test. Metric data with a skewed distribution were calculated as a median with an interquartile range (IQR). To compare the medians, the data was analysed using the Mann-Whitney U test. Continuous data were given as a mean with 90% Confidence Intervals (CI) and compared using a t-test. A 90% CI was selected because the sample sizes were small and ensured outliers were excluded from analysis. The statistical analyses were performed using SPSS® version 19.0 (SPSS, Chicago, Illinois, USA).

7.3 Results

124 patients (97 male and 27 female) with a median age of 57 years (range 19 to 84 years) admitted for an elective hernia repair were included in this study. There were 72 inguinal hernia and 52 ventral hernia repairs, consisting of 18 incisional, 27 umbilical, and 7 epigastric hernias. The completion rates were 100% for the VRS, 99% (123 patients) for the VAS, and 98% (121) for the BPI. The patient demographics for the inguinal and ventral hernias are displayed on Table 7.1. Those electing to have a repair had their hernias for a median of 12 months (IQR 6 to 36 months). Patients with an inguinal hernia presented significantly earlier for repair compared to those with a ventral hernia (Table 7.1).

	Inguinal (N=72)	Ventral (N=52)	
Age Mean (SD) years	57.7 (16.7)	52.7 (13.1)	Mean difference 4.97 (95% CI -0.59 – 10.52)
Gender Male Female	66 6	32 20	P<0.001
Duration of Hernia Months (IQR)	9.0 (4.5 – 30.0)	18.0 (6.3 – 45.0)	P=0.045

Table 7.1: Patient Demographics

7.3.1 Pain Severity and Pain Interference Scores

The BPI results for all patients who were admitted for elective abdominal wall hernia repair are shown on Table 7.2. Overall the median Pain Severity Score was 1.5 (IQR 0.31 to 3.44) and the Pain Interference Score 1.3 (IQR 0.14 to 3.89). 93 (75%) of the 124 patients had pain from their hernia on the basis of the BPI 'pain on average' question. For this group, the overall PSS was 2.3 (IQR 1.13 to 4.25) and the PIS was 2.1 (IQR 0.71 to 4.54). None of the patients who scored zero on 'pain on average' registered a score greater than zero on the pain interference questions indicating good internal validity of the test.

BPI Question (11-point NRS)	All Patients (N=124) Median (IQR)
Pain Severity Questions	
Pain from hernia at its WORST in last 24 hours	2.0 (0 – 5.0)
Pain from hernia at its LEAST in last 24 hours	0 (0 – 2.0)
Pain from hernia on AVERAGE	2.0 (0.25 – 5.0)
Pain from hernia NOW	1.0 (0 – 2.0)
Pain Severity Score (PSS)	1.5 (0.31 – 3.44)
Pain Interference Questions	
General activity	1.5 (0 – 4.25)
Mood	0 (0 – 3.0)
Walking ability	1.0 (0 – 4.0)
Normal work	2.0 (0 – 5.25)
Relations with other people	0 (0 – 2.0)
Sleep	0 (0 – 2.0)
Enjoyment of life	2.0 (0 – 4.0)
Pain Interference Score (PIS)	1.3 (0.14 – 3.89)

Table 7.2: BPI Scores for All Patients

7.3.2 Comparison of All Inguinal and Ventral Hernias

35 (48.6%) and 16 (22.2%) of the 72 inguinal hernia patients registered 'no pain' on the VRS at rest and on movement, respectively. Of the 52 ventral hernia patients, 26 (50%) and 17 (32.7%) recorded 'no pain' at rest and on movement. The differences between inguinal and ventral hernia groups were not statistically significant (P=0.879 at rest, P=0.273 on movement). Figure 7.1

shows the proportions of patients with an inguinal and ventral hernia scoring on each level of the 4-point VRS. The median VAS scores for the inguinal hernia group were 7.0 mm (IQR 1.0 to 17.0 mm) at rest and 27.0 mm (IQR 6.0 to 49.2 mm) on movement, compared with 10.0 mm (IQR 2.0 to 32.0 mm) at rest and 30 mm (IQR 4.0 to 60.0 mm) on movement in the ventral hernia patients. The difference in VAS pain scores between the two groups did not reach statistical significance (P=0.063 at rest, P=0.622 on movement).

7.3.3 Comparison of Inguinal and Ventral Hernia Patients With Pain

55 inguinal and 38 ventral hernia patients recorded pain on the BPI 'pain on average' question. The results of the BPI scores for these patients are displayed on Table 7.3. The patients with a ventral hernia scored significantly higher in the PSS than those in the inguinal hernia group (P=0.037). There was no significant difference in the PIS (P=0.055). However, in the pain interference questions ventral hernia patients scored significantly worse for interference with mood, relations with people, sleep, and enjoyment of life (Table 7.3).
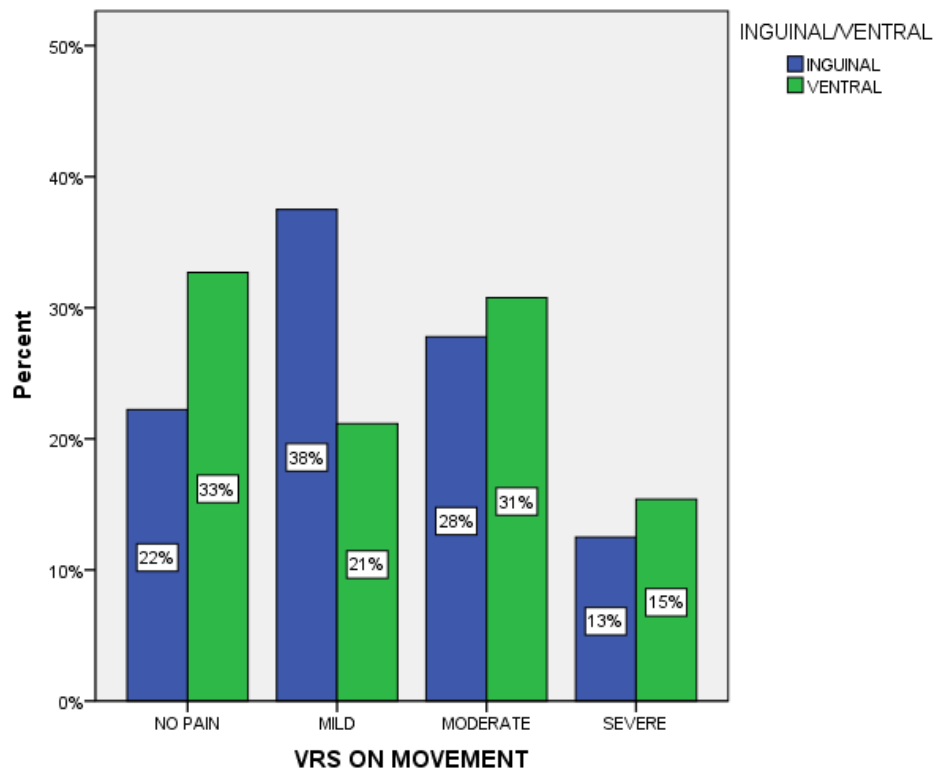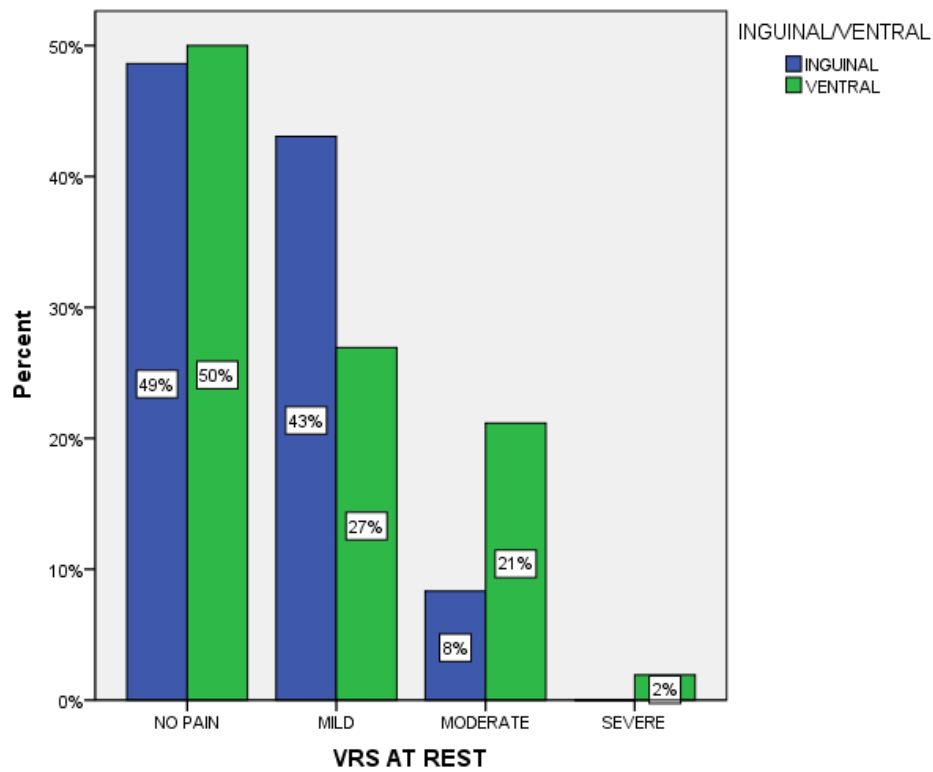
Figure 7.1: VRS Results for Inguinal and Ventral Hernias At Rest and On Movement (N=124)

BPI Question (11-point NRS)	INGUINAL (N=55) Median (IQR)	VENTRAL (N=38) Median (IQR)	P-Value
Pain Severity Questions			
Pain from hernia at its WORST in last 24 hours	3.0 (2.0 – 6.0)	4.0 (1.75 – 7.0)	0.189
Pain from hernia at its LEAST in last 24 hours	1.0 (0 – 1.0)	2.0 (0 – 3.0)	0.005
Pain from hernia on AVERAGE	3.0 (2.0 – 5.0)	4.0 (2.0 – 5.0)	0.235
Pain from hernia NOW	1.0 (0 – 2.0)	2.5 (0 – 5.0)	0.005
Pain Severity Score (PSS)	**2.0 (1.0 – 3.25)**	**3.25 (1.44 – 4.81)**	**0.037**
Pain Interference Questions			
General activity	2.0 (0 – 5.0)	2.0 (0 – 5.0)	0.230
Mood	1.0 (0 – 3.0)	2.0 (0 – 4.0)	0.027
Walking ability	2.0 (0 – 5.0)	1.0 (0 – 4.0)	0.482
Normal work	2.5 (1.0 – 6.0)	3.0 (0 – 6.0)	0.234
Relations with other people	0 (0 – 2.5)	1.0 (0 – 4.0)	0.019
Sleep	0 (0 – 2.0)	1.0 (0 – 4.0)	0.004
Enjoyment of life	2.0 (0 – 5.0)	2.0 (0 – 6.0)	0.029
Pain Interference Score (PIS)	**1.64 (0.54 – 4.07)**	**2.0 (0.3 – 4.7)**	**0.055**

Table 7.3: BPI Pain Severity and Pain Interference Question Scores for Inguinal and Ventral Hernia

7.3.4 Comparison of Pain Severity and Interference of Ventral Hernia Types

The number of epigastric hernias in this study was small (N=7) therefore excluded from this subgroup analysis. The pathophysiology of incisional and umbilical hernias is different therefore it would be appropriate to compare the two groups. Overall, individuals with an incisional hernia scored a median of 16.0 mm (IQR 1.8 to 41.0 mm) at rest and 35.7 mm (IQR 2.5 to 62.5 mm) on movement, whereas the umbilical group scored 7.5 mm (IQR 3.5 to 25.3 mm) and 21.0 mm (IQR 4.8 to 55.3 mm) respectively. Although median pain scores were consistently worse in the incisional hernia group, the differences did not reach statistical significance (P=0.565 at rest, P=0.315 on movement). There were 13 incisional and 20 umbilical hernia patients who recorded pain on the BPI 'pain on average' question. The results of the BPI scores are on Table 7.4. Pain interference with 'enjoyment of life' was the only question which resulted in a significant result where the incisional hernia patients scored worse (P=0.043).

BPI Question (11-point NRS)	INCISIONAL (N=13) Median (IQR)	UMBILICAL (N=20) Median (IQR)	P-Value
Pain Severity Questions			
Pain from hernia at its WORST in last 24 hours	6.0 (3.0 – 7.0)	3.0 (1 – 6.0)	0.114
Pain from hernia at its LEAST in last 24 hours	2.0 (0 – 3.0)	1.5 (0 – 3.5)	0.864
Pain from hernia on AVERAGE	5.0 (2.5 – 5.0)	3.0 (2.0 – 4.75)	0.145
Pain from hernia NOW	3.0 (0 – 5.0)	1.0 (0 – 4.0)	0.388
Pain Severity Score (PSS)	**3.75 (1.88 – 5.0)**	**1.75 (1.0 – 3.94)**	**0.161**
Pain Interference Questions			
General activity	5.0 (2.5 – 6.5)	1.0 (0 – 4.0)	0.084
Mood	3.0 (2.0 – 5.0)	0 (0 – 2.0)	0.177
Walking ability	3.0 (1.0 – 7.0)	0 (0 – 2.0)	0.154
Normal work	4.0 (4.0 – 7.0)	1.0 (1.0 – 6.0)	0.107
Relations with other people	3.0 (0 – 6.0)	0 (0 – 2.0)	0.161
Sleep	2.0 (0 – 7.0)	1.0 (0 – 3.0)	0.777
Enjoyment of life	4.0 (2.5 – 7.5)	1.0 (0 – 4.0)	0.043
Pain Interference Score (PIS)	**3.28 (2.21 – 6.07)**	**1.0 (0 – 4.0)**	**0.051**

Table 7.4: BPI Pain Severity and Interference Question Scores for Incisional and Umbilical Hernia

7.3.5 Impact of Patient Variables on Pain

A univariate analysis was carried out to identify the predictors for pain in those electing to undergo abdominal wall hernia repair. Female gender was the only variable associated with increased pain. Age and duration of hernia had no impact on pain intensity (Table 7.5).

VARIABLE	VAS On Movement (mm) P-value Median (IQR)	BPI PSS P-value Median (IQR)	BPI PIS P-value Median (IQR)
Age Group <40 Years 40 – 65 Years >65 Years	P=0.149 34.0 (12.5 – 66.0) 30.0 (4.0 – 59.0) 17.0 (4.0 – 37.5)	P=0.301 2.25 (0.50 – 4.13) 1.50 (0.25 – 3.75) 1.12 (0.44 – 2.06)	P=0.055 2.57 (0.79 – 5.29) 1.29 (0 – 3.57) 0.57 (0 – 2.61)
Sex Male Female	P=0.024 24.0 (4.0 – 45.0) 52.5 (25.0 – 62.5)	P=0.025 1.5 (0.25 – 2.75) 3.25 (0.75 – 4.75)	P=0.004 1.0 (0 – 2.86) 3.0 (1.0 – 5.71)
Hernia Type Inguinal (N=72) Ventral (N=52)	P=0.622 28.0 (6.0 – 50.0) 30.0 (3.25 – 59.75)	P=0.390 1.5 (0.5 – 2.75) 1.75 (0 – 4.5)	P=0.105 0.93 (0.11 – 3.5) 1.86 (0.29 – 4.68)
Duration ≤12 Months >12 Months	P=0.797 29.0 (6.5 – 56.5) 31.0 (2.0 – 54.0)	P=0.562 1.75 (0.5 – 3.38) 1.38 (0.25 – 3.13)	P=0.998 1.38 (0.25 – 3.13) 1.29 (0.29 – 3.0)

Table 7.5: Impact of Patient and Hernia Variables on Pain

7.4 Discussion

This study shows that most patients (75%) with an inguinal or ventral hernia admitted for elective operation experienced mild to moderate pain from their hernia. These interfered with general activity, walking, and work in both groups. The ventral hernia group had significantly more interference with their mood, sleep, relations with other people, and enjoyment of life than those with an inguinal hernia. This finding is in keeping with a study by van Ramshorst et al where incisional hernia patients had much lower mean cosmetic and body image scores.[36] Van Ramshorst suggested incisional hernias have a significant psychological impact on patients which correlates well with the results seen in our pain interference scores.

The BPI is simple to use and analyse compared with the SF-36. The disadvantage of the BPI is the absence of an assessment on the effects of cosmetic appearance on work or quality of life. This is addressed by the EuraHS-Quality of Life scale developed by a working group of the European Registry for Abdominal Wall Hernias (Appendix 3).[108] However, patients in this study who scored zero for

pain on the BPI, most of whom requested operation for cosmetic reasons also scored zero on interference with work and quality of life. This would suggest that although some patients may dislike the appearance of their hernia, overall their condition has a minimal effect on their work and quality of life.

Patients with an incisional hernia appeared to have more pain interference than their umbilical counterparts although the numbers were too small in this study to report this finding with confidence. To recruit larger numbers of patients who fit the inclusion and exclusion criteria for this study would require another year or more which is difficult given the time constraints for this research. Patients with an incisional hernia and abdominal pain can be difficult to assess as potentially there could be multiple sources for their pain. The pain or discomfort experienced may be secondary to adhesions as it is expected that around 9% of patients will develop adhesion related complications at 1 year and 35% at 10 years post-surgery.[255] Pain may also be secondary to functional gastrointestinal disorder (FGID) such as irritable bowel syndrome (IBS) or functional dyspepsia and may help explain the higher pain scores observed with females in this study. A further complicating factor in assessing these patients is obesity which is a known risk factor for incisional hernia.[36] In obese patients and those whose symptoms are not consistent with clinical findings, further assessment with a detailed history of bowel related symptoms and radiological imaging such as computed tomography (CT) may help determine whether repairing their hernia is likely to alleviate the abdominal pain.

Few studies have assessed pain from a hernia before repair and the effects which repair has on pain. This was discussed in more detail in the literature review chapters on symptoms and outcomes. A number of studies have shown improvements in quality of life following incisional hernia repair.[168, 171, 256] Follow-up in most have been relatively short and given the high recurrence rates associated with repair for this group of patients these effects may not be sustained.

7.5 Conclusions

Patients with ventral hernias complain of more interference with their quality of life than those with an inguinal hernia. This is found in the emotional aspects of

the BPI. The BPI is an easy and effective way of assessing pain and its impact on physical activity and quality of life in patients with an inguinal or ventral hernia. Use of the BPI in conjunction with clinical assessment should help identify those patients who are likely to benefit from a hernia repair. This is particularly relevant to those with an incisional hernia where long term outcomes are less satisfactory.

8 Long term Outcome of Patients with an Asymptomatic Inguinal Hernia

8.1 Introduction

Previous studies have demonstrated that up to one-third of patients presenting with an inguinal hernia have minimal symptoms or pain.[128] However, clinicians and surgeons are concerned that operation on these patients may result in the development of chronic postoperative groin pain. In the current literature, as discussed earlier, this can be debilitating in 3-6% of the patients which can affect their work and leisure activities.[131, 195, 257, 258]

Two recent randomised trials have addressed the issue of chronic postoperative pain in patients with no pain or minimal symptoms from a primary inguinal hernia.[127, 231, 251] There was no increased risk of chronic groin pain in patients who underwent an operation compared with those who were managed with a watchful waiting strategy. At 2 years Fitzgibbons et al reported 23% in the watchful waiting group crossed over to surgery and an acute hernia rate of 0.3%.[251] 28% in our current patient group crossed over to an operation at a median follow-up of just over 1.5 years.[231]

The questions which remain to be answered are: will the majority of patients with asymptomatic inguinal hernias managed on a watchful waiting strategy eventually become symptomatic and crossover to operation? Are clinicians merely delaying rather than avoiding hernia repair? The primary aim of this study is to examine the long term outcome of conversion to operation in patients with a minimally symptomatic inguinal hernia randomised to observation or operation. Secondary aims include comparing the measurement of pain and other hernia and hernia repair related symptoms between the two groups. The aims are displayed on Table 8.1.

Primary Aims
• Crossover rates from observation to operation

Secondary Aims
• Groin pain • Groin symptoms • Development of contralateral hernias • Recurrence rate in surgery group • Acute hernia rate

Table 8.1: Primary and Secondary Aims of Clinical Trial

8.2 Methods

Ethics approval was granted in 2001 to proceed with this clinical trial to randomise male patients aged 55 years or older to repair or watchful waiting for an asymptomatic or minimally symptomatic inguinal hernia between 2001 and 2003. For entry into the trial all patients had to record that they have had no pain from their hernia. Those who were unfit for a local anaesthetic repair or had an irreducible inguinal hernia were excluded from the trial. Patients randomised to operation had a tension-free mesh repair under local or general anaesthesia. Informed consent was obtained from all the patients who met the inclusion and exclusion criteria (Table 8.2).

Inclusion Criteria	Exclusion Criteria
• Male • Aged 55 years or over • Patients with inguinal hernia who register no pain at rest or on movement • Reducible inguinal hernia on lying down or with minimal pressure • Fit for local anaesthetic repair	• Those declining randomisation • Unable to consent • Unable to mentally or physically complete questionnaire • Symptomatic inguinal hernia • Irreducible inguinal hernia

Table 8.2: Inclusion and Exclusion Criteria

Patients in both groups were examined at 6 and 12 months post randomisation. The primary outcomes at 12 months from this trial have been published in the Annals of Surgery [231] and also reported in the University of Glasgow thesis titled 'Management of Asymptomatic Inguinal Hernias' [259]. The participants were given the research assistant's details to contact in the event that their hernia became symptomatic or if there were any related concerns. This randomised clinical trial had ethics approval for continued follow-up of the study groups.

The long term follow-up was over two stages. Clinical follow-up was carried out to allow a median follow-up of 5 years from randomisation. The hospital database was first investigated to identify any deaths since the last review to minimise family distress prior to sending out invitations for clinical follow-up. All patients known to be alive received a written invitation to attend the research clinic for a clinical review. Patients who could not attend were telephoned and sent questionnaires based on the research clinic review proforma (Appendix 5 and 6). Those patients who were not contactable by telephone on two separate occasions were sent a further invitation for follow-up in the second round. Patients who were unable to be contacted after two written and two telephone calls were considered lost to follow-up. I carried out all of the clinical reviews of the patients who attended for this interim follow-up. 15 minute appointments were allocated for each patient at the research clinic.

Patient demographics were updated and the review was based on a set proforma which included a history, clinical examination, and the completion of a questionnaire. The questionnaire collected information on pain severity which was measured on the 100mm Visual Analogue Scale (VAS). The four symptoms of groin pain, testicular pain, groin numbness, and thigh numbness from the inguinal hernia or hernia repair were recorded on 5-point Verbal Rating Scales (VRS). Data were also collected on evidence of hernia recurrence and contralateral inguinal hernias. The full review proforma can be found in Appendix 5.

The final follow-up was obtained at the end of 2009 to achieve at least 6 years of follow-up for all patients since the initial randomisation process. Information

was updated on patient deaths, clinic attendances and admissions for inguinal hernia repair.

Analyses were carried out to compare the long term outcomes between the groups randomised to observation and operation. The rates of conversion, recurrence and death were compared. Further subgroup analyses were carried out to identify symptoms in the two treatment groups: all those who had underwent hernia repair including the operation and cross-over groups and those who had not. This allowed comparison of symptoms related to inguinal hernia repair with those who were managed conservatively.

8.2.1 Statistical Considerations

The original study was powered to address the primary endpoint of pain at 1 year [231, 259] The baseline data was tabulated by treatment group. Categorical data was compared using the Chi-square tests. Continuous data were given as a mean (standard deviation) and compared using a t-test or analysis of variance. In those randomised to observation, a Kaplan-Meier time to crossover from observation to surgery curve was plotted. Survival curves for both groups were also plotted and compared using a log rank test. A P-value of <0.050 was considered statistically significant. The statistical analyses were performed using SPSS® version 19.0 (SPSS, Chicago, Illinois, USA).

8.3 Results

There were 232 eligible patients with an asymptomatic inguinal hernia during the initial recruitment process and 160 agreed to randomisation. The patient demographics and baseline characteristics are displayed on Table 8.3 with permission from the author.[231] There were no significant differences between the observation and operation groups. Figure 8.1 illustrates the study profile and a summary of the follow-up obtained.

At a median of 5.2 years (range 4.1 to 6.1 years) a total of 104 patients were followed-up with 54 from the observation and 50 from the operation arm of the trial. 91 patients, 46 from the observation and 45 from the operation groups, attended for clinical review. 13 responded to the questionnaire only and

declined attendance at the research clinic at this stage. At this interim review there were 15 deaths in each group.

Characteristic	Measure	Observation (n=80)	Operation (n=80)
Age (Yrs)	Mean (SD)	71.9 (7.5)	70.9 (8.6)
Hernia Type	Primary n (%) Recurrent n (%) Bilateral n (%)	79 (99%) 1 (1%) 8 (10%)	77 (96%) 3 (4%) 5 (6%)
Hernia Size (cm)	Mean (SD)	3.23 (1.22)	3.39 (1.31)
Duration of Hernia (Yrs)	Mean (SD)	3.04 (2.58)	3.46 (2.5)
Baseline Visual Analogue Scale (VAS) Pain Scores At Rest On Movement	100mm VAS (mm) Mean (SD)	2.0 (3.0) 2.3 (3.0)	2.0 (2.9) 2.4 (3.1)

Table 8.3: Patient Demographics and Baseline Characteristics at Randomisation

Extended follow-up at a median of 7.4 years (range 6.25 to 8.25 years) was obtained by tracking new deaths, out-patient attendances, and admissions for hernia repair. This allowed data to be collected at a minimum of 6 years after randomisation. There were 42 recorded deaths with 19 in the observation and 23 in the operation groups. The median age of death for the 42 patients was 82 years (range 61 to 90 years). The causes of death were predominantly secondary to cardiovascular disease and cancer. There was one post-operative death from myocardial infarction following an elective hernia repair from the observation arm of the study. The cause of death for 9 patients could not be confirmed as there was no documentation in the notes. There were no deaths associated with an acute hernia (Table 8.4). No differences in the survival curves were demonstrated for the two randomised groups (log rank test P=0.46, Figure 8.2).
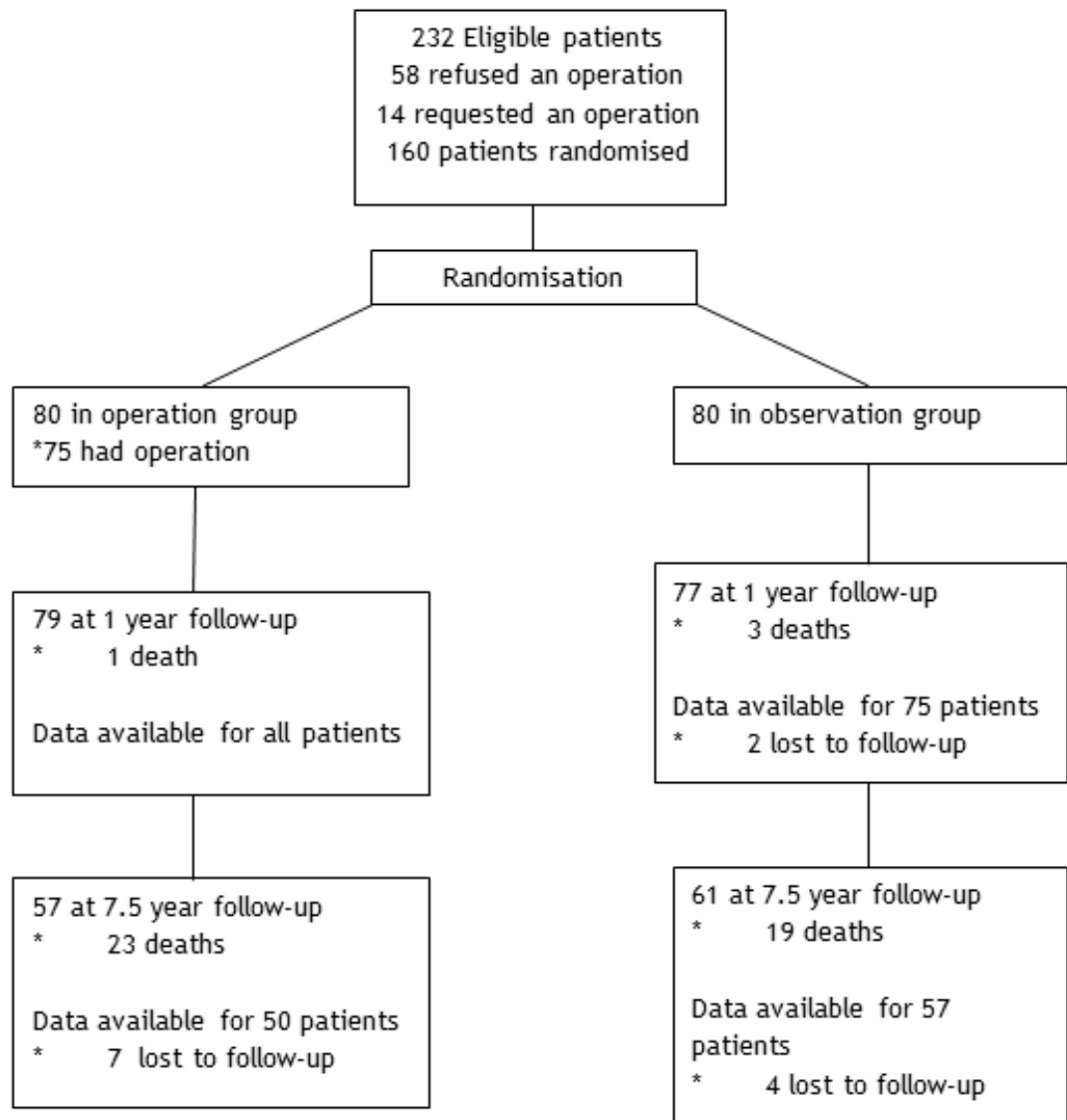
*1 died while awaiting operation, 1 was cancelled because of a myocardial infarct, while 3 refused operation.

Figure 8.1: Study Profile

Cause of Death	Number of Patients (N=42)
Respiratory	6
Cardiac	6
Intracranial/ Intracerebral Haemorrhage	5
Advanced Malignancy	11
Medical Conditions • GI bleed • Other	 1 3
Cause of Death Unavailable	9

Table 8.4: Causes of Death

Proportion alive by days since randomisation
Deaths: n=23 operation, n=19 observation
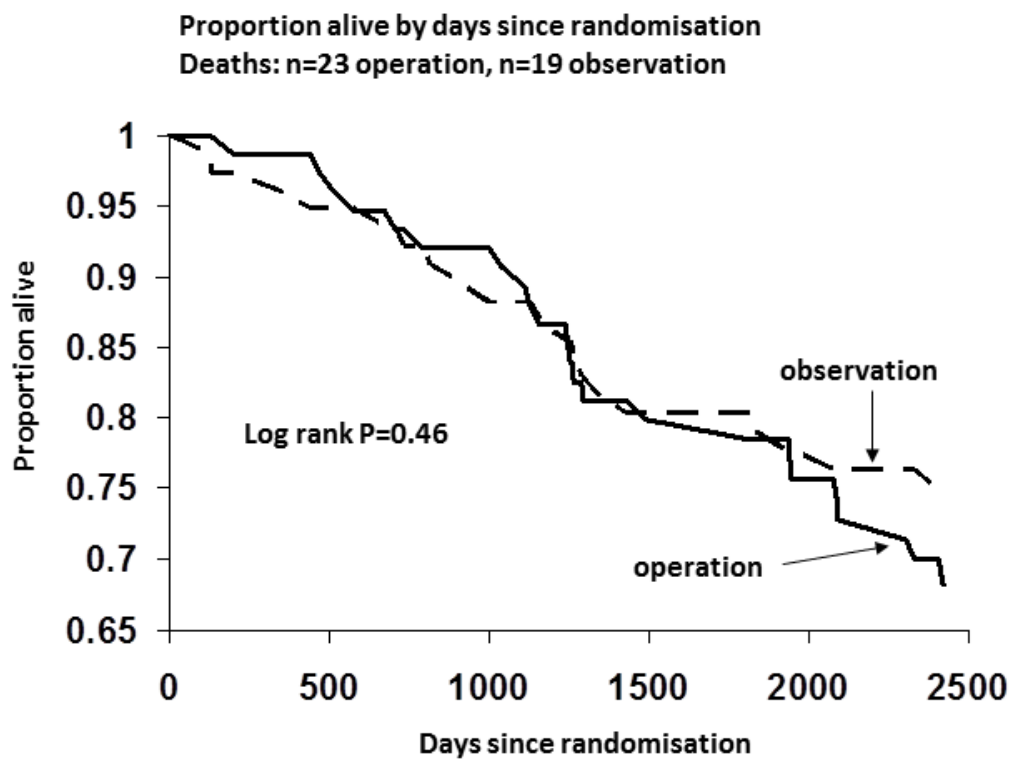
Time since Randomisation in Years	0	1	3	5	7
No. alive					
Observation Group	80	77	71	64	61
Operation Group	80	79	73	64	57

Figure 8.2: Kaplan-Meier Plot of Time to Death Compared Between the Two Randomised Groups (Observation and Operation)

8.3.1 Crossovers From Observation to Operation

At the interim period of 5.2 years after randomisation 42 of the 80 patients in the observation group crossed over to surgery. 4 more patients in the observation group went on to have surgery by the final follow-up period. If all the patients were still alive throughout the follow-up period then the estimated conversion rates for the observation group would be 16% (95% CI 9 to 26%) at 1 year, 32% (95% CI 23 to 44%) at 2 years, 54% (95% CI 42% to 66%) at 5 years, and 72% (95% CI 59 to 84%) at 7.5 years (Figure 8.3).

**Proportion converting to operation by days since randomisation
For those randomised to observation (n=80, n=46 converted)**

Time since Randomisation in Years	0	1	3	5	7
No. converted to operation	0	15	26	36	45
No. at risk	80	62	47	31	22

Figure 8.3: Kaplan-Meier Plot of Time to From Randomisation to Operation in the Observation Group

The reasons for conversion are shown on Table 8.5. 22 patients had noted an increase in size of their hernia over the follow-up period. In some, this occurred quite rapidly and was the only reason for conversion in 5 patients. 6 patients requested conversion as they felt their hernia, although painless, was affect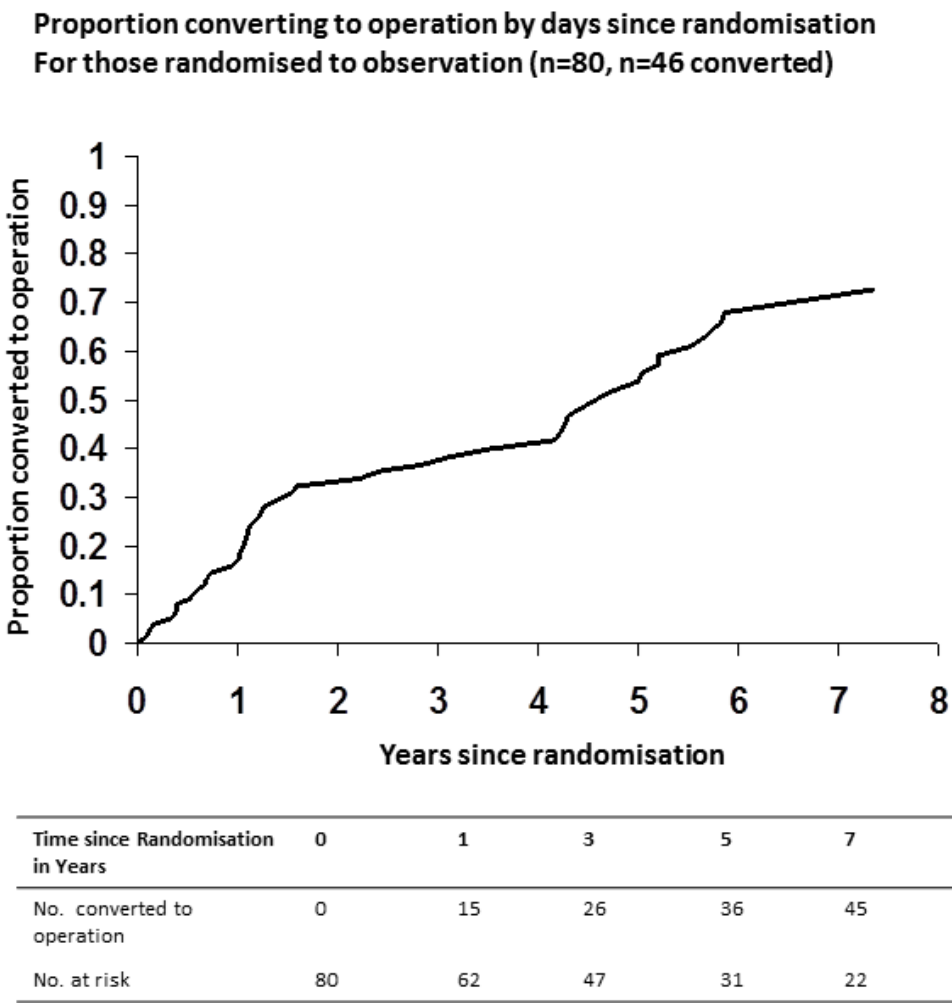ing their quality of life. The estimated median time from randomisation to conversion, which is the point at which 50% of the observation group had converted, was 4.6 years (95% CI 3.5 to 5.6 years). The first conversion took place at 34 days, and the longest time to conversion is currently 2648 days (7.3 years). 2 patients had presented acutely with their hernia and neither of these patients required a bowel resection.

Reason for Conversion	Number of Patients
Pain	33
Increase in hernia size	5
Impact on quality of life	6
Acute presentation	2

Table 8.5: Primary Reasons for Conversion to Operation

8.3.2 Pain

100mm VAS pain scores were available for 102 of the 104 patients. The 2 patients were unable to complete the VAS scores due to psychomotor impairment. The patients were divided into two groups to compare the intensity of pain related to an inguinal hernia repair: those who have had a repair and those who have not. At a median follow-up of 4.5 years (IQR 3.9 to 4.9 years) from date of surgery to interim review, 76 patients had undergone an inguinal hernia repair. 28 remained under observation at a median of 4.8 years (IQR 4.3 to 5.4 years) from the date of randomisation.

Comparison of the VAS scores at rest and on movement between the two intervention groups are shown on Table 8.6. There was no significant difference in the pain scores between the two groups.

VAS	N	Median (IQR) mm	P-value
At Rest			
Repair	75	2.0 (0 – 4.0)	P=0.489
No Repair	27	2.0 (0 – 8.0)	
On Movement			
Repair	75	1.0 (0 – 3.0)	P=0.247
No Repair	27	2.0 (0 -12.0)	

Table 8.6: VAS Pain Scores for Repair Versus No Repair

65 of the 75 patients (85%) in the operation group and 20 of 27 (71%) in the no operation group did not experience pain in their groin over the last week. The difference was not statistically significant (Chi-Square test P=0.228). When the patients were asked whether they have 'ever had pain in the groin' related to their hernia or hernia repair, 18 of 76 (24%) in the repair group and 14 of the 28 (50%) who have not had a repair said 'yes' which was a significant difference (Chi-Square test p=0.010).

8.3.3 Other Groin Symptoms

The other relevant groin symptoms measured on a 5-point VRS were testicular pain, groin numbness, and thigh numbness on the side of the hernia or hernia repair. The results for testicular pain, groin and thigh numbness are displayed on Table 8.7. In the repair group, 5 of the 6 who complained of testicular pain had it 'a little of the time' and one 'some of the time'. One complained of 'moderate' and one 'quite a bit' of groin numbness in the operation group with the remaining having only 'slight' numbness.

Symptom		Repair	No Repair	P-Value
Testicular Pain	Yes	6	1	P=0.672
	No	69	26	
Groin Numbness	Yes	12	1	P=0.176
	No	63	26	
Thigh Numbness	Yes	3	1	P=1.000
	No	72	26	

Table 8.7: Presence of Groin Symptoms in Repair and No Repair Groups

8.3.4 Clinical Examination Findings

91 of the 104 patients (46 observation and 45 operation groups) with a median age of 72 years (IQR 68 to 77 years) had a clinical examination at the interim period. Of the 20 patients who have not had surgery, 17 were in the initial observation group and 3 from the operation groups did not get their hernia repair. At randomisation these 20 patients had 10 right, 9 left and 1 bilateral inguinal hernia. One had a reducible asymptomatic inguinoscrotal hernia. On clinical examination there were 8 right, 5 left and 4 bilateral inguinal hernias and 3 patients no longer had visible or palpable hernias on standing. These 3 patients had small hernias with a protrusion measurement of approximately 3 cm at the time of randomisation. There were 2 inguinoscrotal hernias and all the hernias were reducible on examination. One patient had a tender hernia on examination who scored 46 mm and 62 mm at rest and on movement, respectively on the VAS. However, he only recorded his pain as mild on the 5-point VRS and declined repair.

8.3.5 Development of a Contralateral Inguinal Hernia

15 patients, 6 in observation and 9 in the operation groups, developed new primary contralateral inguinal hernia all of which were asymptomatic. 4 of the 6 in the observation group decided to have their contralateral hernia repaired. 3 of these patients had bilateral hernia repair. 8 from the operation group opted to have their contralateral hernia repaired.

8.3.6 Recurrent Inguinal Hernia

There have been 3 (2.3%) recurrent hernias out of 143 inguinal hernia repairs, 2 in the operation and 1 in the observation group, and all elected to have a further repair. The 3 patients had their recurrent hernia diagnosed at 4 years from their primary operation and one was asymptomatic.

8.4 Discussion

This study confirms the previous findings by Hair et al that most patients with minimal symptoms from an inguinal hernia will develop pain over time.[128]   Pain was the most common reason for the patient to request a hernia repair followed by pain accompanied by an increase in the size of the hernia. The Kaplan Meier calculation estimated a conversion rate of 72% (95% confidence interval 59% to 84%) at 7.5 years which is very similar to the rate of 90% at 10 years reported from a previous study [128].

It is interesting that 2 of the 80 patients presented acutely. This may indicate that the lifetime risk of an acute presentation is higher than previously reported in the literature. Fitzgibbon et al estimated that the lifetime risk of strangulation for a 72 year old was 1 in 2941 [127]. Our patients' average age was 72 years at presentation and they have been followed up for 938 patient years. This study provides important information because population-based studies indicate that there is a 10-fold increase in postoperative mortality associated with an acute presentation. [246-248]

If a health service were to adopt a watchful waiting strategy in the management of minimally symptomatic inguinal hernias for patients over 55 years of age, then based on these results this would reduce the number of operations by less than 10% over the long term. The cost savings achieved by this would have to be balanced against a small increase in mortality for those presenting with an acute hernia requiring emergency repair. There is the real risk that delaying an elective operation until the patient is older would significantly increase the risk of perioperative mortality as reported in other studies [246]. This would be difficult to justify for a benign condition with low recurrence rates and good outcomes after a successful operation.

One well reported concern regarding inguinal hernia repair is the risk of chronic groin pain. This has been reported in the literature to be as high as over 50%. A study has shown that repair of symptomatic inguinal hernias reduce groin pain overall. However, in those without pain the study raised concerns whether these patients develop groin pain as a result of the repair [130]. There has not been any significant difference demonstrated in VAS pain scores between those of have had an operation with those still under observation.

Testicular pain, groin and thigh numbness was also measured during the clinical follow-up. There was no significant difference between the operation and remaining observation patients. However, there was a slight but not statistically significant increased frequency of groin numbness in the operation group with the majority complaining of mild symptoms. A weakness of this study was that I have not attempted to measure the effects of post-operative symptoms such as groin numbness has on quality of life. Measuring this could clarify whether the slight trend towards groin numbness in the operation group actually has any impact on the patient. However, the numbers left were small and repeating the SF-36 may not have given any solid conclusions. The measurement of patient satisfaction may also have been useful in providing more evidence in the argument for early repair rather than watchful waiting.

The recent guidelines published by the European Hernia Society recommend that watchful waiting is an acceptable option for men with minimally symptomatic or asymptomatic inguinal hernias [69]. However, they recognise that the results from both clinical trials published in 2006 were not conclusive and that both authors had come to different conclusions.[231, 251] One suggested that watchful waiting was a safe and acceptable strategy, while the other indicated that repairing such hernias did not cause chronic pain, improved general health and may reduce serious postoperative morbidity. Our long-term follow-up of the patients with a painless inguinal hernia for a minimum of 6 years should help clarify some of the uncertainties. There seems little to be gained in a watchful waiting strategy when the majority of patients will require an operation at some point in the foreseeable future.

Another drawback of this study is that the results may not be generalisable to other regions. Many patients with an inguinal hernia in the UK will be aware

that they have a hernia for a number of years before attending their doctor. At the initial randomisation the patients have already had their hernia for an average of 3 years before attending a surgical clinic. Also rates of operation for inguinal hernia vary widely across the developed world [64]. This is unlikely to be related to differences in the prevalence of this condition and probably reflects patients and clinicians attitudes to intervention for such conditions. Operation on an inguinal hernia that is palpable on cough impulse without a visible or palpable lump on standing would be uncommon practice in the UK. In the US study this accounted for 40% of patients included in their trial [251]. The natural history of such hernias is unknown, in particular what percentage will progress to a visible symptomatic inguinal hernia.

Importantly, during a consultation with a patient presenting with an asymptomatic inguinal hernia one should discuss the potential outcomes of either conservative or operative management of their condition. This would allow them to make an informed decision regarding their treatment.

8.5 Conclusion

From the results of this long term follow-up study in patients with a painless inguinal hernia, most will develop symptoms over time requiring an operation. As repair does not increase the risk of chronic pain, operation should be recommended to patients who are medically fit.

9 Incidence and Outcome of Patients with an Ventral Hernia

9.1 Introduction

Repair of an abdominal wall hernia is a common operation with an estimated 20 million repairs annually worldwide.[216]   Repair of an umbilical hernia is a common operation with around 20 000 repairs in the UK annually.[1, 2] The frequency of repair is increasing and is now second to inguinal as the most common type of hernia repair. This means it imparts a significant cost to the health service but its repair has variable outcomes as discussed earlier such as recurrence rates for suture repair of between 10% and 40%, and for mesh repair between 0% and 5%.[19, 20, 23, 24] The reason for the increase in umbilical hernia repair is unclear but factors such as an increasingly obese and ageing population in developed countries may be important. There may also be a trend for recommending repair of small asymptomatic hernias in patients referred by the general practitioner for a surgical opinion. This may further be influenced by patient expectations. Ventral hernia repair, especially in the case of incisional hernia repair, is not uncommonly associated with significant morbidity, mortality and unacceptably high recurrence rates.

It is uncertain whether patients with a ventral or specifically an umbilical hernia benefit from an operation. The study is divided into two sections. The first focuses on umbilical hernias with the aims to establish the incidence of umbilical hernia in the general adult population; the prevalence of general practitioner referrals with symptoms; and the long term outcomes of these patients. Secondly, ventral hernias are studied as a group to assess the long term outcome of patients with an asymptomatic ventral hernia managed by a period of observation only.

9.2 Patients and Methods

The patients recruited for the two parts of the study had some overlap of the patients but were not identical patient groups as a proportion of patients were excluded from the incidental umbilical hernia group due to previous operations involving the midline or if there was evidence of a ventral hernia. The review of

electronic case records were necessary to follow up the prospectively collected two cohorts of patients. The electronic case records are on a system known as the Clinical Portal which provides a comprehensive record of all referrals, out-patient and in-patient attendances, results of all laboratory tests and radiological investigations covering all hospitals within the region.[260, 261]

9.2.1 Incidence and Outcome of Umbilical Hernia

All new patient referrals to a general surgical clinic between January 2006 and February 2007 were examined for clinical evidence of an umbilical hernia. Those with a previous history of abdominal surgery with any incision involving the umbilicus and those with a ventral hernia were excluded from this study. All were examined by a consultant or an experienced surgical trainee. Patient demographics including age, sex, symptoms related to their hernia and whether they were aware of its presence were documented. Simultaneously, data on all general practitioner referrals with an umbilical hernia were recorded in a similar way. All those who wished to have a repair were placed on the surgical waiting list. Operation notes were reviewed to determine the operating surgeon, surgical supervision, size of defect, type of operation, and whether a mesh or suture repair was carried out.

At approximately six years following diagnosis, electronic case records and paper records if required were investigated to determine the patient's current status. Our aims were to identify those have developed symptoms when previously asymptomatic and to establish the rate of re-operation for those who had a primary repair. Other abdominal operations and causes of death were recorded over the follow-up period.

9.2.2 Observational Study of Asymptomatic Ventral Hernia

All patients with a ventral (umbilical, epigastric and incisional) hernia presenting to the clinic of one surgeon over a one year period were recorded and followed up prospectively. One group of patients with ventral hernias were identified from general practitioner referrals to the surgical clinic and another group were those found to have an incisional hernia during routine clinic review following

laparotomy for a benign or neoplastic condition at least one year previously. The inclusion criteria for this observational study cohort are shown on Table 9.1.

The patient demographics including age, sex, co-morbidities, location and size of the defect if incisional were recorded on a database. The defect size was not measured in patients with an epigastric and umbilical hernia as all of these were small (1 to 2cm) making accurate measurement impossible. Patients were also asked if they have been aware of the presence of a hernia. This cohort was followed-up by either annual clinical examination at the surgical clinic or by review of their electronic case records and hard copies of their clinical notes when necessary. Patients were informed of the risks of an acute admission with their hernia and asked to make a return appointment if they experience any warning symptoms such as pain or if they notice a sudden increase in the size of their hernia. This reflected the normal practice in this unit for minimally symptomatic ventral hernias.

Inclusion Criteria
- Presence of a clinically detectable hernia.   - No pain/discomfort at rest/on movement from their hernia.   - The hernia had no effect on daily activities.   - The hernia was cosmetically acceptable to the patient.   - No evidence of skin atrophy, breakdown or ulceration over the hernia site.   - Patient did not want a repair at the time of review.

Table 9.1: Inclusion Criteria for Observational Study of Patients with an Asymptomatic Ventral Hernia

9.2.3 Statistical Considerations

Categorical data were compared between groups using the Chi-square test. Continuous data were given as a mean with a Standard Deviation (SD) and compared using a t-test. Data not demonstrating a normal distribution were given as a median with an interquartile range (IQR) and compared using the

Mann-Whitney U test. Differences were expressed as a mean difference with a 95% confidence interval (CI). A Kaplan-Meier estimate was used to calculate the prevalence of patients crossing over to an operation. All analyses were carried out using SPSS® version 19.0 (SPSS, Chicago, Illinois, USA) and a P-value of less than 0.050 was considered statistically significant.

9.3 Results

9.3.1 Incidence of Umbilical Hernia

Over a one year period, there were 622 new patients referred to the general surgical clinic who met the inclusion criteria. As part of the routine clinic consultation all patients had an abdominal examination and clinical evidence of an umbilical hernia was documented. The average age of individuals attending the surgical clinic was 52 (SD 18) years, 49% were male while 51% were female. The most common reasons for referral to the clinic were benign colorectal (39%), hernia (17%), abdominal pain (12.5%), benign upper gastrointestinal (9%), soft tissue lesions and a variety of minor conditions (17%). 5.5% were urgent referrals to exclude neoplastic disease.

15 (2.4%) of the 622 patients had clinical evidence of an umbilical hernia. Only 2 were aware of their hernia before the clinic review and none complained of any symptoms from their hernia. During this same period, 36 new patients were referred by their family practitioner with an umbilical hernia to discuss management options. 18 complained of pain as their primary symptom and the remaining 18 were asymptomatic. Patients were informed of the pros and cons of repair to allow them to make an informed decision on their management. 32 of the 36 patients, of which 14 were asymptomatic, opted for repair and were placed on the waiting list. The group with incidental umbilical hernias were significantly older than those referred for a surgical opinion (Table 9.2).

	GP Referrals (N=36)	Incidental (N=15)	P-Value
Age Mean (SD)	49 (11)	60 (13)	0.004
Male Female	26 10	10 5	0.649
Symptomatic Asymptomatic	18 18	0 15	0.002

Table 9.2: Characteristics of Patients with an Umbilical Hernia

9.3.2 Asymptomatic Ventral Hernia

During the study period 112 patients were identified with 115 ventral hernias. 96 patients were referred through their general practitioner and the other 16 were identified on follow-up after a laparotomy for a benign or neoplastic condition. The study profile is shown on Figure 9.1. 64 (56%) hernias in 62 patients caused no symptoms and fulfilled the inclusion criteria for a conservative approach.

The patients with an asymptomatic hernia were significantly older with a mean difference of 9.2 years (95% CI 3.7 to 14.6 years) and were more likely to have been operated upon for a cancer at their index operation (Table 9.3). 22 patients (20%) were not aware of their hernia (Table 9.4) and the incisional hernias in this group were significantly smaller with a mean difference of 3.4 cm (95% CI 0.24 to 6.57 cm).
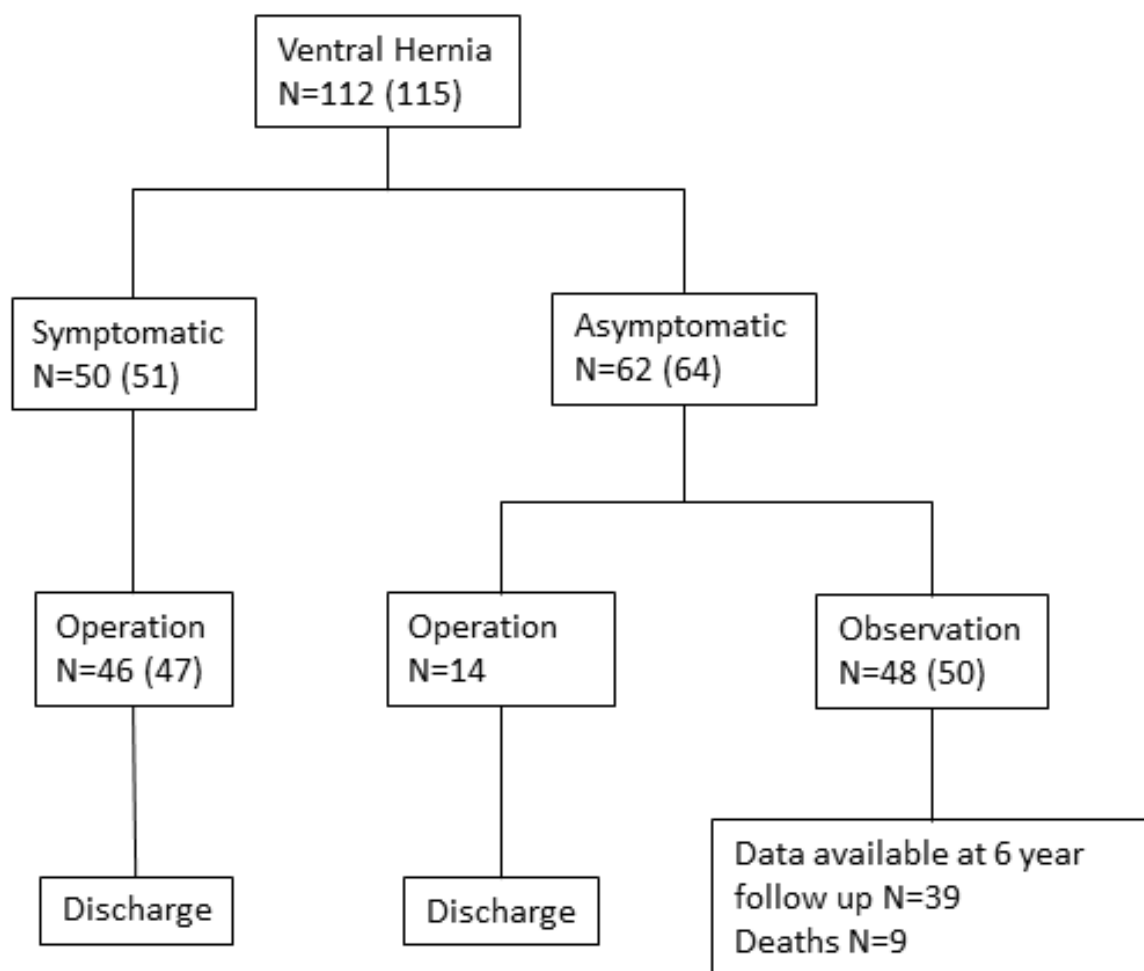
Figure 9.1: Study Profile of Patients With a Ventral Hernia
N = Number of patients (Number of hernias in parentheses)

VARIABLE	SYMPTOMATIC (N=50)	ASYMPTOMATIC (N=62)	
Age Mean (SD) years	53.0 (14.73)	62.2 (14.15)	P=0.001
Male Female	24 26	36 26	P=0.527
Hernia Type Incisional Umbilical Epigastric Epigastric and Umbilical	 28 19 4 -	 28 32 2 1	P=0.290
Incisional Hernias	N=28	N=28	
Defect Size Mean (SD) (N=26) Length Width	N=18 13.2 (6.91) 10.8 (4.89)	N=8 11.56 (6.31) 8.44 (3.18)	Mean Difference (95% CI) 1.637 (95% CI -3.806 – 7.081) 0.600 (95% CI -1.117 – 5.242)
Incision Type Midline Transverse Lateral/Kochers	 19 4 5	 25 2 1	P=0.125
Reason for Operation Benign Disease Cancer Unknown	 19 5 4	 10 16 2	P=0.010

Table 9.3: Demographics of Patients with Symptomatic and Asymptomatic Ventral Hernias

Hernia Type	Patient No.	Aware (%)	Not Aware (%)
Incisional	54	46 (85)	8 (15)
Umbilical	51	38 (74.5)	13 (25.5)
Epigastric	6	6 (100)	0 (0)
Epigastric and Umbilical	1	0 (0)	1 (100)
Total	112	90 (80)	22 (20)

Table 9.4: Patient Awareness in Relation to Hernia Type

9.3.3 Outcome of Umbilical Hernia Patients

The patients were followed up for a median of 6.1 years (IQR 5.9 to 6.3 years).

2 of the 15 patients with an incidental umbilical hernia required conversion to

operation at 242 and 1810 days because of pain. One other patient had their defect repaired during a laparoscopic cholecystectomy at 1302 days. There were 2 deaths which occurred at 332 and 1334 days with the causes of death being alcohol-induced severe pancreatitis and lung cancer (Figure 9.2). The Kaplan-Meier estimate for conversion at 6 years is 15% (95% CI 3 – 44%). 28 (78%) of the 36 patients referred by their family practitioner underwent repair for their hernia. There were 4 other patients placed on the waiting list but 3 did not attend for their surgery and therefore not reappointed and one was cancelled by the anaesthetist because of severe chronic respiratory disease. The type of repair and defect size is shown on Table 9.5.
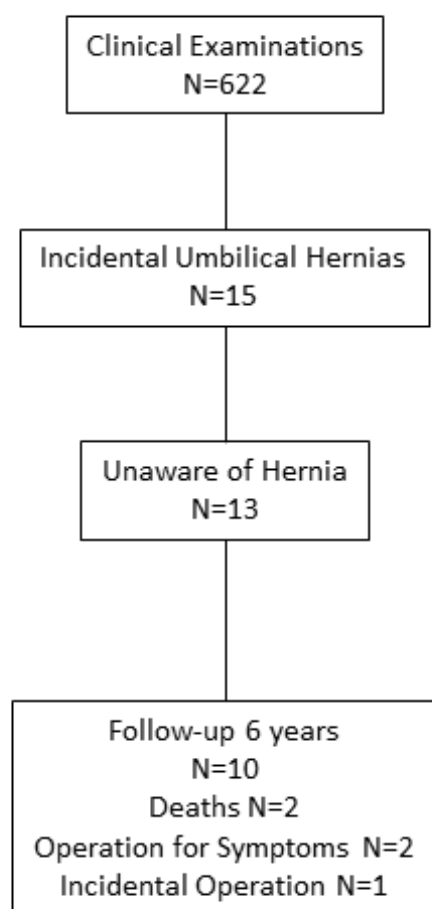
Figure 9.2: Incidental Umbilical Hernia Study Profile

	YES	NO
Pain	18	14
Operation*	28	4
Senior Supervision	19	9
Mesh Repair	10	18
Defect Size Median (IQR) #	3 (2.25 – 3.0) cm	1.5 (1.0 – 2.0) cm

Table 9.5: Details of Patients Referred with Umbilical Hernia Listed for Repair

#Defect size available for 15 patients. The difference in defect size between the mesh and suture repair groups was statistically significant (P=0.008).

At a median follow-up of 6 years 3 patients underwent further repair for a recurrent umbilical hernia. All 3 primary operations were carried out with senior supervision and 2 had a mesh repair (Table 9.6). Senior supervision is defined as a senior registrar or consultant either performing or supervising the operation. There were no deaths in this group who were referred with an umbilical hernia. The KM estimate for recurrence is 10% (95% CI 3 – 30%) at 6 years. There were no acute presentations from an umbilical hernia in either group.

| Variable	Recurrence (N)	P-value
Senior Supervision	3	P=0.530
No Senior Supervision	0	
Mesh Repair	2	P=0.284
Suture Repair	1	

Table 9.6: Details of Primary Operation in Recurrent Hernia Patients

9.3.4 Outcome of Asymptomatic Ventral Hernia Patients

The patients in this study were followed up for a median of 6.2 years (IQR 5.8 to 6.9 years). 14 of the 62 patients with an asymptomatic ventral hernia decided to opt for an operation leaving 48 for observation in this study. The median age of those who opted for surgery was significantly younger at 54.5 years (IQR 39.75 to 61.0 years) compared with 63.0 years (IQR 55.0 to 78.8 years) (P=0.006). There were 9 deaths in the observation group during this period of conservative management with the causes of death being cancer (6), cardiovascular disease (2), and sepsis secondary to alcohol-induced pancreatitis (1). There were 5 incisional, 3 epigastric and 1 umbilical hernia in those who died. The median time to death was 2.9 years (IQR 1.2 to 5.5 years) from time of inclusion in this study. There were 2 patients who remained asymptomatic but had their hernia repaired when they underwent an operation for a different condition. This occurred at 595 and 1302 days from diagnosis of their hernia. One with an umbilical hernia had a laparoscopic cholecystectomy and the other with an epigastric hernia had a gastrectomy for cancer.

Only 3 (6%) of the patients, 2 with an umbilical hernia and 1 with an epigastric hernia, converted to an operation. The reason for conversion was pain in all 3 cases and the times to conversion were 171, 242, and 1810 days. Two of the 3 patients had not been aware of their hernia at the initial clinical visit. Figure 9.3 is the Kaplan-Meier graph illustrating the proportion at risk of conversion during each time point. There was one acute presentation 5 years following diagnosis of an incisional hernia but the admission was secondary to pain from concomitant bilateral inguinal hernias. This settled on conservative treatment and the patient declined elective repair and remains well at a follow-up of 6.1 years. The Kaplan-Meier estimate for conversion to operation at 1 year was 4.2% (95% CI 0.7 - 15.4%) and at 6 years 6.7% (95% CI 1.9 - 18.8%).
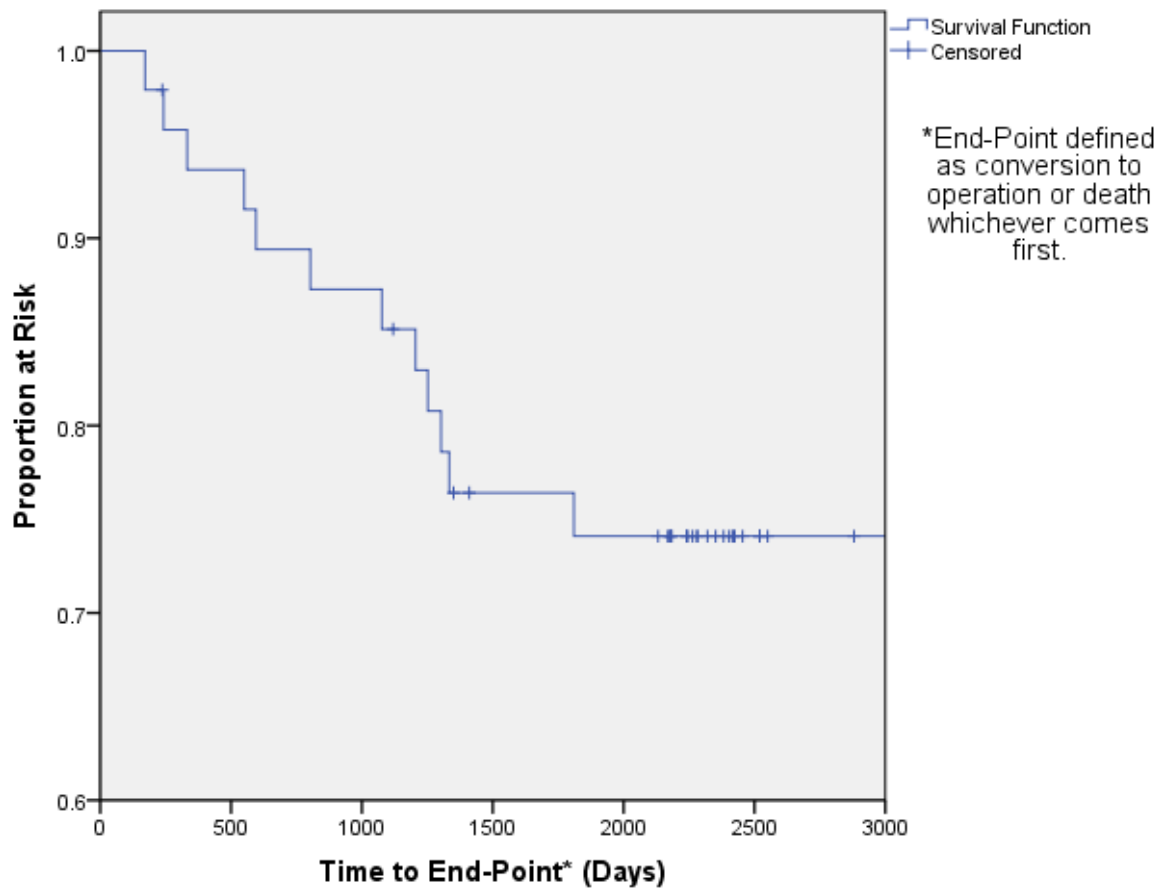
Time from Diagnosis of Hernia (Years)	0	1	2	3	4	5
Numbers at Risk	48	45	43	41	38	37

Figure 9.3: Kaplan-Meier Graph of Time to End-Point

9.4 Discussion

9.4.1 Umbilical Hernia

This study shows that about 1 in 40 of the adult population will have an umbilical hernia and most of these people are not aware of its presence and complain of no symptoms. This rate is probably reflective of the general adult population because the Scottish Census data indicates that 43% of adults are between the ages of 40 and 64 years and of those 51.5% are female.[262] In this

study the average age of new patient referrals was 52 years with 51% being female.

It is known that the rates of repair are increasing for umbilical hernias and this has been attributed to increasing obesity and an ageing population. Reports from the 1961 Scottish Census recorded 10.6% of the population were aged 65 years and over and this has increased to 17% in 2011.[262] Interestingly, a recent study has shown that umbilical hernias are more common in men than in women and is also confirmed by this study. However, it is likely that there are regional variations as reports from other regions still have a female preponderance.[17-19]

Around 50% of GP referrals in this study had no symptoms from their hernia yet most opted for a surgical repair. This is likely to be a factor in the increasing rate of repair which currently stands at 30 per 100 000 of the population.[2] We used the figures of re-operation as a surrogate marker for recurrence therefore actual recurrence rates are likely to have been significantly underestimated. This was demonstrated by Helgstrand et al who found a 4 to 5 fold underestimation of ventral hernia recurrence rates when only based on re-operation as a marker.[263] The re-operation rates for recurrence remain high and not dissimilar to rates of operation for those adopting a watch-and-wait policy. This should drive one to question whether an operation is appropriate in asymptomatic patients. There may be a need for a clinical trial in this area but before embarking on this it is necessary to establish the best operative technique for these patients. As with inguinal hernia, results from surgeons with a specialist interest in hernia surgery appear better. Kurzer et al reported no recurrence in a series of patients treated using a tension-free mesh repair of umbilical hernia under local anaesthesia.[264] However, 26% of the patients were excluded from the study because of obesity or a recurrent hernia.

There has been one randomised trial comparing sutured with mesh repair for umbilical hernia and this demonstrated a reduced recurrence rate from 11% to 1% in favour of the mesh repair at a mean follow-up of 64 months.[23] Mesh repair was used infrequently (36%) in this study and 2 of the 3 recurrences had a mesh implanted at their primary operation. Overall, there was no difference in recurrence rates compared with those who had a suture repair. This is probably related to the fact that larger defects were repaired using mesh or could

indicate that technical factors in undertaking the mesh repair may also be important. In all the mesh repairs in this study a flat mesh was placed in the preperitoneal space and the fascial defect was closed over the mesh with a continuous polypropylene suture. However, a weakness of this study is the small number of patients because of time constraints in recruiting patients and achieving long-term follow-up results for this thesis.

9.4.2 Asymptomatic Ventral Hernia

This study demonstrates that a small number of patients with an asymptomatic ventral hernia develop symptoms and require a hernia repair. At over 6 years of follow up, the percentage of patients converting to an operation because of pain was 6%. This rate of operation is comparable to the expected recurrence rates if these patients had opted for a repair rather than conservative management.[23, 156, 216, 265] It remains difficult to justify recommending an operation for these asymptomatic patients when there is evidence to support low conversion and high recurrence rates in addition to the significant associated post-operative morbidity and mortality. This is especially the case in those with an incisional hernia as discussed earlier in the literature review on outcomes.

Currently, there are a number of studies exploring a 'watchful waiting' strategy for incisional and ventral hernias.[266, 267] One randomised clinical trial started recruiting in 2011 and is aiming to randomise 600 patients with minimal symptoms from an incisional hernia to operation or observation.[267] The outcomes from these trials are important as there is no consensus regarding the best management of asymptomatic or minimally symptomatic ventral hernias. A recent review suggested that a common sense approach would be to offer surgical repair to everyone who is medically fit.[268] This approach is attempting to follow that recommended for minimally symptomatic inguinal hernia. However, given the mediocre outcomes associated with incisional hernia repair, it may not be the most appropriate management for these patients. It may be reasonable to consider this for epigastric and paraumbilical hernias. There are increasing numbers of operations carried out for these hernias in the UK therefore clinical trials are necessary to establish any health benefits associated with repair for these patients.

Some recent published literature suggests that symptoms from incisional hernia are common. In one study, 63 of 75 patients with an incisional hernia reported symptoms which included pain or discomfort in 45 and cosmetic complaints in 8 of the 75 patients. [36] The incisional hernia group reported lower scores for physical functioning and body image compared with controls who did not have a hernia. However, patients with a hernia were significantly older and more obese and these symptoms may possibly be related to this rather than their hernia. [36] These findings differ from studies by Pollock, Evans and Hesselink et al who reported 12% and 53% of patients respectively reported symptoms. [113, 253] This is in keeping with the present study where only 42% of patients had hernia related symptoms.

Up to 20% of patients in this study were not aware of having a hernia. This was equally distributed between those with umbilical and incisional hernias. This finding has been previously reported before for inguinal but not for ventral hernias. [110] These hernias were often quite large in the incisional group and had not concerned the patient who were significantly older and usually under follow up for a neoplastic condition. The umbilical hernias were small and not noted to be an issue for the patient at their first consultation.

We have observed a significant difference in rates of conversion to operation secondary to pain and other symptoms between the asymptomatic inguinal and ventral hernia patients. In our study on inguinal hernia, over 20% of patients had converted to operation at 1 year while 70% had converted at 7 years. [269] The observed differences may be accounted for by the location of the hernia defect and the size may also be important, especially during physical activity and with increases in intra-abdominal pressure.

This study has a few drawbacks. Firstly, this study lacks of an intervention arm as it was purely an observational study. The numbers of patients were also relatively small and the group includes all ventral hernias rather than analysing incisional hernias separately. To achieve meaningful results for each hernia type would require a much longer study period which cannot be carried out in the research time available for this completing this thesis.

For future research a randomised clinical trial may be necessary for surgeons who believe in adopting a policy of operating on all medically fit patients with a ventral hernia. This may be difficult to undertake for patients with an asymptomatic incisional hernia because of the potential for serious complications and poor outcomes in this group of patients.[156, 265] Alternatively, further large observational studies with close patient follow up may be more feasible.

9.5 Conclusion

To the best of my knowledge this is the first study which has attempted to address the incidence of umbilical hernia in the adult population and the findings indicate that they occur frequently and are predominantly asymptomatic. As the rates of umbilical hernia repair are increasing and many have minimal symptoms from their hernia, clinical trials are necessary to assess if there are any health benefits of hernia repair for these patients.

This study has also demonstrated that a policy of observation or 'watchful waiting' is a satisfactory alternative for patients with an asymptomatic ventral hernia. However, further studies in this area are required to confirm these outcomes.

10 Summary and Potential for Further Research

10.1 Pain and Quality of Life

The majority of patients admitted for elective uncomplicated abdominal wall hernia surgery complain of mild to moderate pain which interfere with their quality of life. Those who are most likely to experience symptoms of pain and pain interference are females. Younger age is likely to be a risk factor for poorer quality of life scores as shown by the trend in the study in chapter 7, although the figures did not reach statistical significance (P=0.055).

From my study, the Brief Pain Inventory provides an excellent tool for assessing pain severity and effects on quality of life. This measure is not only simple to administer, it also correlates highly with other popular uni-dimensional pain measurement scales such as the verbal rating scale (VRS) and visual analogue scale (VAS). From the results, it appears that a hernia normally has to cause pain to impact on an individual's quality of life. The SF-36 is considered a 'gold standard' but the BPI is probably a better alternative because it is widely available and much simpler to administer and analyse. It could be used routinely in patients with an abdominal wall hernia attending for a surgical opinion as part of the overall assessment process.

10.2 Inguinal Hernia Repair in Asymptomatic Patients

The study in chapter 8 has provided much needed evidence on the long term outcome of patients with an asymptomatic inguinal hernia. This is the first study of its type and has been published in a peer reviewed journal in 2011.[269] We have shown that over 50% will develop symptoms and convert to surgery at 5 years, increasing to just over 70% at around 7 years. The long term results from Fitzgibbons et al have been published and demonstrate similar findings. There was a conversion rate to operation of almost 80% in patients under 65 years at a median follow up of up to 11.5 years in their study.[270] With this strong supporting evidence from two randomised clinical trials we can conclude that most patients with an asymptomatic inguinal hernia will eventually develop symptoms and require an operation. However, acute hernia rates are low therefore watchful waiting is not an unsafe strategy. When a patient attends for

a surgical opinion it is important to inform them of the probable long term outcome. This should include the risk of conversion to surgery on a watchful waiting strategy and also the other risks and complications associated with surgery as described in the discussion earlier in chapter 8. This will allow patients to make an informed decision on their treatment. It seems sensible in younger patients to offer surgery whereas in the elderly, one may have to assess their risk of developing symptoms during their lifetime. The Association of Surgeons of Great Britain and Ireland have published the Groin Hernia Guidelines in May 2013.[271] They concluded that in the case of asymptomatic inguinal hernia, watchful waiting is safe but it is likely that a patient will require surgery in the future.

Chronic groin pain secondary to inguinal hernia repair is well reported although our study found that operating on an asymptomatic inguinal hernia does not cause chronic pain. Recently, there have been a few studies exploring techniques to reduce chronic groin pain following inguinal hernia repair. Mesh placement in the preperitoneal space may be associated with less chronic pain as shown by some studies of laparoscopic repair.[175, 178] The technique of open transinguinal preperitoneal (TIPP) mesh repair was developed to approach a hernia through the inguinal canal while placing the mesh in the preperitoneal space.[272-275] It can allow all groin hernia orifices to be covered by the preperitoneal mesh similar to the laparoscopic repair but should be easier to learn and with possibly fewer serious complications. Results from a randomised clinical trial published at the end of 2012 showed promising results with significantly less chronic groin pain at one year in the TIPP group compared with the standard Lichtenstein repair (3.5% vs 12.9%, P=0.004).[236] Manufacturers have developed meshes specifically for TIPP repairs and one case series reported chronic pain in 4 of 694 hernia repairs at 6 months using the ONSTEP technique with the Polysoft™ mesh patch.[276] Currently, the Onli Trial is randomising patients to the ONSTEP or Lichtenstein repair with the completion date expected in June 2015.[277] Long term results would be required to confirm the safety of this type of mesh as it has a stiff memory ring and one would have to be wary of the potential for mesh erosion to intra-abdominal structures similar to those rare cases reported with the Prolene Hernia System.[278]

Another theoretical mechanism for causing chronic groin pain is nerve injury from the placement of sutures for mesh fixation. There has been recent interest in this area in the aim to reduce chronic pain. The Parietene Progrip® mesh was developed as a self-gripping mesh with absorbable fixation hooks for inguinal hernia repair using the same approach as the Lichtenstein repair but without suture fixation. One randomised clinical trial of 334 patients did not demonstrate any difference in chronic pain at one year.[132] Comparable results from a similar randomised clinical trial by Sanders et al were also presented through personal communications. Currently, there is a double-blind randomised clinical trial comparing the Progrip mesh with a standard Lichtenstein repair.[279] The fixation hooks on the Progrip mesh may explain why chronic pain was not reduced in these studies. A potential area for research would be to carry out a randomised clinical trial using conventional flat mesh and compare fixation with no fixation in patients with small to moderate sized inguinal hernias.

10.3 Symptoms and Outcome for Incisional and Umbilical Hernia Repair

Incisional hernia repair is associated with high complication and recurrence rates as discussed earlier in the literature review. Patients with minimally symptomatic or asymptomatic incisional hernia pose a management dilemma for surgeons because of the unsatisfactory outcomes and uncertainty whether operation incurs a health benefit. A German group is currently randomising patients with oligosymptomatic incisional hernia to watchful waiting or operation which is due to conclude in 2017. The primary outcome measure at 2 years is of pain and secondary measures of cost and patient satisfaction.[267]

As with all RCTs it will take many years before we will know the long term outcome for this German trial which is why the work in this thesis is able to provide some information and guidance in the interim. From my study conversion rates due to pain from a ventral hernia was around 6% at a median of 6 years and none of the patients who converted had an incisional hernia repair. This highlights the problem that recurrence rates are higher than expected conversion rates for the asymptomatic patients therefore it is unlikely that operation for this group is beneficial. However, there are weaknesses to my

study due to the small numbers of individual ventral hernia types in a heterogeneous group of patients. This is an observational study but is still prospectively collected and although the results have to be interpreted cautiously, they should add some meaningful information to our current knowledge.

Umbilical hernias are neglected in surgical research even though it is the second most common type of abdominal wall hernia to be repaired. Many studies include umbilical hernias under ventral hernias therefore the results have to be interpreted carefully. We know mesh repair is associated with lower recurrence rates.[23, 24] My study has shown that umbilical hernias are present in around 2.5% of the population and around one half of general practitioner referrals for a surgical opinion are asymptomatic. Crossover rates from conservative management to operation due to symptoms are low in this group. This highlights the issue of whether operating on this type of asymptomatic hernia actually improves the quality of life and is cost effective. A randomised clinical trial to compare watchful waiting with operation is required in patients with asymptomatic umbilical hernia to answer these questions. As part of the recruitment process, researchers should encourage general practitioners to refer all patients seen in the community with an umbilical hernia. This would allow the results to be representative of the general population with an asymptomatic hernia and would avoid excluding a large cohort of patients who would not normally be referred for a surgical opinion. One major obstacle is that randomised clinical trials are expensive, difficult to set up, and would take several years for results to become available. My study provides some data to assist in surgeons in the discussion with patients prior to considering surgery and larger observational studies may be useful in the interim.

10.4 Other Considerations

Overall, the biomechanics of the abdominal wall and hernia formation are not sufficiently understood. Askar produced important theories on the structure and biomechanics of the abdominal wall. This includes those regarding the single and triple decussation of the abdominal wall fibres to explain the reason certain individuals are at higher risk of incisional hernia formation. Other researchers have not been able to prove this theory. Collagen metabolism defects and its

association with hernia formation has been a relatively new discovery. Further resources should be directed at understanding the structure and biomechanics of the abdominal wall. From cadaveric studies the abdominal wall linea alba can withstand a maximum transverse force of between 41.6 to 52.2 N/cm and less for vertical load.[280] However, most of the meshes can withstand a higher force in the longitudinal directions as shown on Table 10.1.[281] With this in mind the orientation of the mesh may be important during incisional hernia repair. This may be of more relevance when bridging a defect as with laparoscopic repair. Further studies into mesh degradation over time and response of abdominal wall tension are required as prosthetic material is being used more frequently and also in younger patients.

	PARIETENE	PROLENE	SURGIPRO	ULTRAPRO	VICRYL
Maximum Force on Transverse Extension Testing (N/cm)	26.6 ± 4.2	41.6 ± 5.4	46.5 ± 4.1	6.0 ± 8.2	45.5 ±13.5
Maximum Force on Longitudinal Extension Testing (N/cm)	38.9 ± 5.2	84.8 ± 15.0	38.6 ± 12.3	100.9 ± 9.4	78.2 ± 10.5

Table 10.1: Mechanical Properties Different Meshes in Transverse and Longitudinal extension testing

Table adapted with permission from *Mechanical Properties of Mesh* by Pott et al.[281]

10.5 Conclusion

The majority of individuals with asymptomatic inguinal hernias are likely to develop symptoms over time therefore it is sensible to offer repair to those who are medically fit following discussion of the potential risks of surgery.

Asymptomatic ventral hernias have a much lower conversion rate and the risk of developing an acute hernia is small. As operation is associated with significant morbidity and high recurrence rates, a watchful waiting strategy should be a safe and logical option until the results of RCTs become available over the next few years.

Appendices

Appendix 1: Brief Pain Inventory Short Form

Appendix 2: Short Form-36

Appendix 3: EuraHS Quality of Life Scale

Appendix 4: Study 1 Hernia Pain and Symptoms Questionnaire

Appendix 5: Study 2 Asymptomatic Inguinal Hernia Trial Clinical Review Proforma

Appendix 6: Study 2 Asymptomatic Inguinal Hernia Trial Questionnaire

Appendix 1: Brief Pain Inventory Short Form

Office Use Only
Date of Analysis: _____
MRN: _____
Pain Severity: _____
Pain Interference: _____

Hunter Integrated Pain Service
Brief Pain Inventory
Dec 2006
Reproduced with acknowledgement of the Pain Research Group
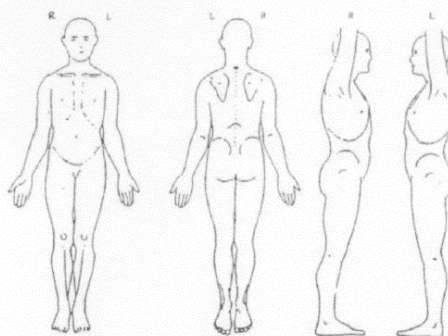The University of Texas MD Anderson Cancer Center, USA

Date: _____

Name: _____

1.   On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts most.

2.   Please rate your pain by circling the one number that best describes your pain at its worst in the last week.

   0   1   2   3   4   5   6   7   8   9   10
   No pain   Pain as bad as you can imagine

3.   Please rate your pain by circling the one number that best describes your pain at its least in the last week.

   0   1   2   3   4   5   6   7   8   9   10
   No pain   Pain as bad as you can imagine

4.   Please rate your pain by circling the one number that best describes your pain on average.

   0   1   2   3   4   5   6   7   8   9   10
   No pain   Pain as bad as you can imagine

5.   Please rate your pain by circling the one number that tells how much pain you have right now.
   0   1   2   3   4   5   6   7   8   9   10
   No pain   Pain as bad as you can imagine

6.   What treatments or medications are you receiving for your pain?
   _____

   _____

Page 1 of 2

7. In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that best shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No relief										Complete relief

8. Circle the one number that describes how, during the past week, pain has interfered with your:

a. General activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

b. Mood

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

c. Walking ability

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

d. Normal work (includes both outside the home and housework)

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

e. Relations with other people

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

f. Sleep

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

g. Enjoyment of life

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Does not interfere   Completely interferes

Brief Pain Inventory Scoring Instructions

1. Pain Severity Score
This is calculated by adding the scores for questions 2, 3, 4 and 5 and then dividing by 4. This gives a severity score out of 10.

2. Pain Interference Score
This is calculated by adding the scores for questions 8a, b, c, d, e, f and g and then dividing by 7. This gives an interference score out of 10.

Appendix 2: Short Form-36

SF-36 Page 1

Thank you for completing this booklet. Please follow the instructions.

Confidentiality: Your name and address do not appear anywhere on this booklet. The information that you give will not be used in any way that could identify you personally.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

GENERAL HEALTH

*For questions 1 and 2, please **circle the number** that best describes **your health**.*

	Excellent	Very good	Good	Fair	Poor
1. In general, would you say your health is:	1	2	3	4	5

	Much better	Somewhat better	About the same	Somewhat worse	Much worse
2. **Compared to one year ago**, how would you rate your health in general **now**?	1	2	3	4	5

HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities you might do in a typical day. Does **your health** limit you in these activities? If so, how much? ***Please circle one number on each line.***

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) **Vigorous activites**, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	1	2	3
c) Lifting or carrying groceries.	1	2	3
d) Climbing **several** flights of stairs	1	2	3
e) Climbing **one** flight of stairs.	1	2	3
f) Bending, kneeling or stooping.	1	2	3
g) Walking **more than a mile**.	1	2	3
h) Walking **half a mile**.	1	2	3
i) Walking **100 yards**.	1	2	3
j) Bathing or dressing yourself.	1	2	3

4. During the **past 4 weeks**, have you had any of the following problems with your work or other daily activities **as a result of your physical health**?

*Please **circle 1** for **Yes** or **2** for **No** on each line.*

	Yes	No
a) Cut down on the **amount of time** you spend on work or other activities	1	2
b) **Accomplished less** than you would have liked.	1	2
c) Were limited in the **kind** of work or other activities.	1	2
d) Had difficulty performing the work or other activities (for example, it took extra effort).	1	2

SF-36 Page 2

5. During the **past 4 weeks**, 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)?

Please **circle 1** *for* **Yes** *or* **2** *for* **No** *on each line.*

	Yes	No
a) Cut down on the **amount of time** you spend on work or other activities	1	2
b) **Accomplished less** than you would have liked.	1	2
c) Did not do work or other activities as **carefully** as usual.	1	2

For questions 6,7 & 8, please **circle the number** *that* **best** *describes* **you** *and* **your health.**

	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or other groups?	1	2	3	4	5

	None	Very Mild	Mild	Moderate	Severe	Very Severe
7. How much bodily pain have you had over the **past 4 weeks**?	1	2	3	4	5	6

	Not at all	A little bit	Moderately	Quite a bit	Extremely
8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?	1	2	3	4	5

YOUR FEELINGS

9. The following questions are about how you feel and how things have been with you **during the last month**. For each question, please **circle the number** that **best** describes the way you have been feeling.

Make sure that you circle one number on each line.

How much time during **the past month**:	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
a) Did you feel full of life?	1	2	3	4	5	6
b) Have you been a very nervous person?	1	2	3	4	5	6
c) Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d) Have you felt calm and peaceful?	1	2	3	4	5	6
e) Did you have a lot of energy?	1	2	3	4	5	6
f) Have you felt downhearted and low?	1	2	3	4	5	6
g) Did you feel worn out?	1	2	3	4	5	6
h) Have you been a happy person?	1	2	3	4	5	6
i) Did you feel tired?	1	2	3	4	5	6
j) Has your health limited your social activities (like visiting friends or close relatives)?	1	2	3	4	5	6

SF-36 Page 3

HEALTH GENERAL

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

*Please **circle one number** on **each** line.*

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
a) I seem to get ill more easily than other people.	1	2	3	4	5
b) I am as healthy as anyone I know.	1	2	3	4	5
c) I expect my health to get worse.	1	2	3	4	5
d) My health is excellent.	1	2	3	4	5

Appendix 3: EuraHS Quality of Life Scale

EuraHS

EuraHS QoL

version: english
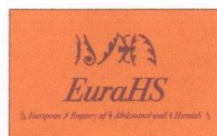
name of study	
study number	

EuraHS Quality Of Life scale

The EuraHS-QoL scale is a method to measure the quality of life for patients before (pre-operative) and after (postoperativ) an operation of an abdominal wall hernia with or without an implantation of a mesh to repair the defect.
It is a questionnaire developed by the Working Group of the European Registry for Abdominal Wall Hernias (EuraHS).

Please answer all of the 9 following questions in the 3 main fields of:

1. **Pain of the side of the hernia**
2. **Restrictions of activities because of pain or discomfort**
3. **Cosmetic discomfort**

Therefore, please mark a number corresponding to your current state.

Respectively, you will give a 0 (no pain, no restriction and cosmetically beautiful) **for the best conditions and a 10 for the worst state** (worst pain, completely restricted and cosmetically ugly). **If you do not perform one of these asked activities, please mark the X in the last column.**

Personal data:

name	
date of birth	
date of today	
date of operation	

EuraHS QoL

version: english

EuraHS Quality Of Life scale

Preoperative

1. Pain at the site of the hernia												
	0 = no pain						10 = worst pain imaginable					
Pain in rest (lying down)	0	1	2	3	4	5	6	7	8	9	10	
Pain during activities (walking, biking, sports)	0	1	2	3	4	5	6	7	8	9	10	
Pain felt during the last week	0	1	2	3	4	5	6	7	8	9	10	

2. Restrictions of activities because of pain or discomfort at the site of the hernia												
	0 = no restriction					10 = completely restricted						
Restriction from daily activities (inside the house)	0	1	2	3	4	5	6	7	8	9	10	X
Restriction outside the house (walking, biking, driving)	0	1	2	3	4	5	6	7	8	9	10	X
Restriction during sports	0	1	2	3	4	5	6	7	8	9	10	X
Restriction during heavy labour	0	1	2	3	4	5	6	7	8	9	10	X
	X = If you do not perform this activity											

3. Esthetical discomfort												
	0 = very beautiful					10 = extremely ugly						
Shape of your abdomen	0	1	2	3	4	5	6	7	8	9	10	
Site of the hernia	0	1	2	3	4	5	6	7	8	9	10	

EuraHS QoL

version: english
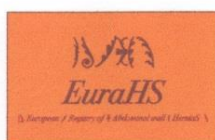
EuraHS Quality Of Life scale   Postoperative _____ w/m

1. Pain at the site of the hernia												
	0 = no pain					10 = worst pain imaginable						
Pain in rest (lying down)	0	1	2	3	4	5	6	7	8	9	10	
Pain during activities (walking, biking, sports)	0	1	2	3	4	5	6	7	8	9	10	
Pain felt during the last week	0	1	2	3	4	5	6	7	8	9	10	

2. Restrictions of activities because of pain or discomfort at the site of the hernia												
	0 = no restriction					10 = completely restricted						
Restriction from daily activities (inside the house)	0	1	2	3	4	5	6	7	8	9	10	X
Restriction outside the house (walking, biking, driving)	0	1	2	3	4	5	6	7	8	9	10	X
Restriction during sports	0	1	2	3	4	5	6	7	8	9	10	X
Restriction during heavy labour	0	1	2	3	4	5	6	7	8	9	10	X
	X = If you do not perform this activity											

3. Esthetical discomfort												
	0 = very beautiful					10 = extremely ugly						
Shape of your abdomen	0	1	2	3	4	5	6	7	8	9	10	
Site of the hernia and the scar	0	1	2	3	4	5	6	7	8	9	10	

Appendix 4: Study 1 Hernia Pain and Symptoms Questionnaire

Page 1

☐☐☐

Date: _____

Type of Hernia _____

Duration of Hernia _____

Pre-operative Questionnaire on Hernia Pain

Thank you for taking a few minutes to complete this questionnaire. This helps us to understand the amount of symptoms experienced by our patients who are about to have an operation to fix their hernia.

Page 2

<u>Section 1: Verbal Rating Scale</u>

Please rate your pain by circling the description that best describes the pain **from your hernia at rest.**

NO PAIN   **MILD**   **MODERATE**   **SEVERE**

Please rate your pain by circling the description that best describes the pain **from your hernia on movement.**

NO PAIN   **MILD**   **MODERATE**   **SEVERE**

Page 3

<u>Section 2: Visual Analogue Scale (0-100mm)</u>

Please put a line (ie. /) through the scale below to best describe the

pain **from your hernia at rest.**

<div align="center">

0   100

|———————————————————————|

No Pain   **Worst Pain**
Imaginable

</div>

Please put a line (ie. /) through the scale below to best describe the

pain **from your hernia on movement.**

<div align="center">

0   100

|———————————————————————|

No Pain   **Worst Pain**
Imaginable

</div>

Page 4
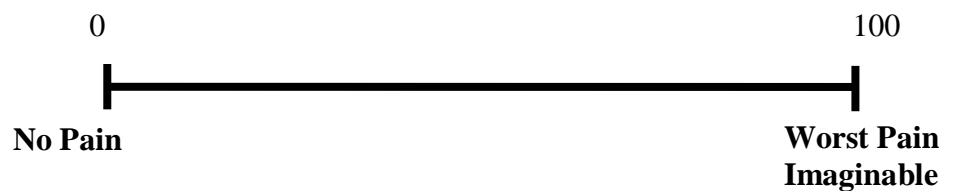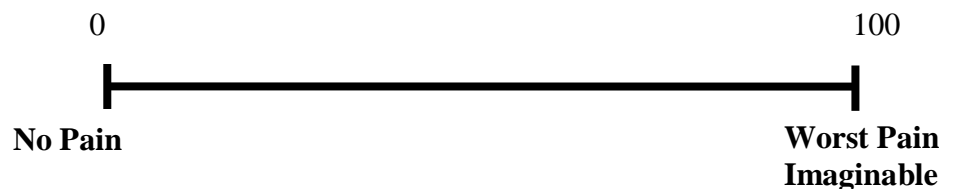
<u>Section 3:Short-form Brief Pain Inventory</u>

1. Please rate your pain by circling the one number that best describes the **pain from your hernia** at its **worst** in the last 24 hours.

No pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Pain as bad as you can imagine

2. Please rate your pain by circling the one number that best describes the pain **from your hernia** at its **least** in the last 24 hours.

No pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Pain as bad as you can imagine

3. Please rate your pain by circling the number that best describes the pain **from your hernia** on the **average**
.

No pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Pain as bad as you can imagine

4   Please rate your pain by circling the number that best describes the pain **from your hernia right now**.

No pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Pain as bad as you can imagine

5. What treatment are you receiving for your pain?

_____

_____

_____

Page 5

6.   In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

No relief | 0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100% | Complete relief

7.   Circle the one number that describes how, during the past 24 hours, **pain from your hernia has interfered** with your:

A.   General activity

Does not interfere | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Completely interferes

B.   Mood

Does not interfere | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Completely interferes

C.   Walking ability

Does not interfere | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Completely interferes

D.   Normal work (includes both work outside the home and housework)

Does not interfere | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Completely interferes

E.   Relations with other people

Does not interfere | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Completely interferes

F.   Sleep

Does not interfere | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Completely interferes

G.   Enjoyment of life

Does not interfere | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Completely interferes

Appendix 5: Study 2 Asymptomatic Inguinal Hernia Trial Clinical Review Proforma

FOLLOW-UP OF ASYMPTOMATIC INGUINAL HERNIA TRIAL

DATE: _____

DATE ENTERED TRIAL _____

ARM OF STUDY   OBSERVATION   OPERATION   DATE _____

SIDE OF HERNIA   RIGHT   LEFT   BILATERAL

OBSERVATION PATIENTS

CONVERSION   YES   NO

DATE OF CONVERSION _____

PLACE OF OPERATION _____

REASON FOR CONVERSION

INCREASE IN HERNIA SIZE	
PAIN	
INTERFERENCE WITH DAILY ACTIVITIES	
ACUTE HERNIA	

OTHER (STATE REASON) _____

SINCE ENTERING TRIAL HAS PATIENT DEVELOPED

A NEW HERNIA ON THE OTHER SIDE ⬚ FURTHER OP   YES   NO

     If further op (place, date)   _____   _____

RECURRENT HERNIA ON SAME SIDE ⬚ FURTHER OP   YES   NO

     If further op (place, date)   _____   _____

CLINICAL EXAMINATION FINDINGS

RIH

	INGUINO-SCROTAL	YES	NO
	REDUCIBLE	YES	NO
	TENDER	YES	NO
	RECURRENCE	YES	NO

LIH

	INGUINO-SCROTAL	YES	NO
	REDUCIBLE	YES	NO
	TENDER	YES	NO
	RECURRENCE	YES	NO

OTHER FINDINGS

Appendix 6: Study 2 Asymptomatic Inguinal Hernia Trial Questionnaire

INGUINAL HERNIA QUESTIONNAIRE

The following questions are about your hernia/ hernia repair now.

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

All of the time	
Most of the time	
Some of the time	
A little of the time	
None of the time	

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

No pain	
Very mild	
Mild	
Severe	
Very severe	

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

Not at all	
Slightly	
Moderately	
Quite a bit	
Extremely	

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

Not at all	
Slightly	
Moderately	
Quite a bit	
Extremely	

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

All of the time	
Most of the time	
Some of the time	
A little of the time	
None of the time	

If you have not had an operation for your hernia, please ignore questions 6, 7, 8 and go straight to question 9.

6.   Since your hernia operation, have you had to attend a hospital pain clinic for pain related to your hernia repair?

YES   NO   N/A

7.   Since your hernia operation, have you noticed any return of your hernia (a lump in your groin)?

YES   NO

8.   If YES, have you had to go back into the hospital to have this hernia fixed (another operation)?

YES   NO

If yes: where? _____   when? _____

What was the problem? _____

_____

9.   Have you had to attend your GP for any problems related to your hernia/ hernia repair?

YES   NO

If yes: why? _____

10.   Have you had to go into the hospital for any problems related to your hernia/ hernia repair?

YES   NO

1. Please put a line (ie. ╱) through the scale below to best describe the pain

   today from your hernia/ hernia repair side **at rest.**

   0   100

   ├──┤

   No Pain   **Worst Pain**
   Imaginable
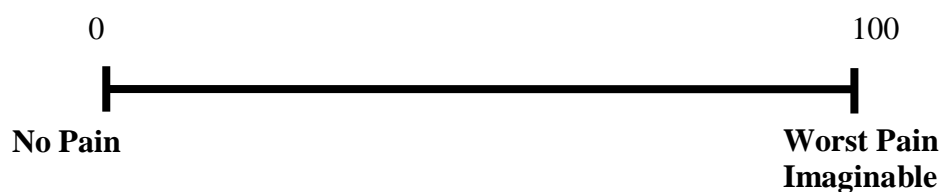
2. Please put a line (ie. ╱) through the scale below to best describe the pain

   today from your hernia/ hernia repair side **on movement.**

   0   100

   ├──┤

   No Pain   **Worst Pain**
   Imaginable
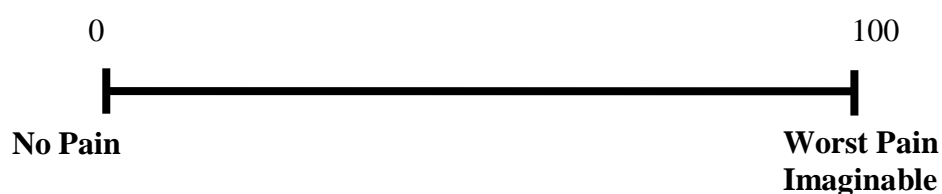
3. Are you taking any medication for pain relief?   **YES**
           NO
   If yes, please specify name of painkiller and dose:

   _____

   _____

4. Has your hernia/ hernia repair ever given you pain?   **YES**
           NO

Thank you for completing this questionnaire.

The information you have provided will be of great value in our study into how hernias can be best treated.

Please return the completed questionnaire in the pre-paid envelope provided.

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