Incisional hernia prevention: Prevalence, Prediction and Prophylaxis

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Summary

Background and Aims

Incisional hernia is a common consequence of abdominal surgery that affects as many as 1 in 3 patients. The aims of this thesis are to quantify the impact of incisional hernia, identify modifiable risk factors for incisional hernia development and determine barriers to prophylactic mesh use in patients.

Materials and Methods

A series of studies were performed, including a cohort study using population level data, a retrospective analysis of randomised control trial data, external validation of a predictive model using an existing dataset. A mixed-methods cohort study was designed and conducted to determine the acceptability of mesh prophylaxis to patients.

Results

The incidence of incisional hernia in midline incisions has increased from 12.6% to 16.8%. Patients who develop incisional hernia have higher rates of post-operative complications with higher associated healthcare costs than those that don't. Grade of surgeon performing abdominal wall closure significantly impacts IH rate ($p<0.001$). The Penn hernia calculator shows moderate performance in predicting the development of IH in colorectal cancer patients (AUC 0.68). Finally, in spite of negative pre-conceptions of mesh driven by the media, patients would be willing to accept it as a prophylactic treatment option. Acceptability of mesh was dependent on the nature of the information provided and the setting in which it was provided.

Discussion

Incisional hernia has a significant impact on patients and healthcare services alike. Focus needs to be on prevention, through implementation of strategies to reduce risk at a local level and changing attitudes towards abdominal wall closure. Identification of the high-risk patient is possible, and surgeons should look at themselves as a barrier to mesh prophylaxis, not the patient.

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List of Publications

1. Smith L, Wilkes E, Rolfe C, Westlake P, Cornish J, Brooks P and Torkington J

Incidence, Healthcare Resource Use and Costs Associated with Incisional Hernia Repair.

J. Abdom. Wall Surg. 2024. 3:12452. doi: 10.3389/jaws.2024.12452

2. Smith L, Coxon-Meggy A, Shinkwin M, Cornish J, Watkins A, Fegan G, Torkington J; HART Trial Collaborators.

"Happy to close?" The relationship between surgical experience and incisional hernia rates following abdominal wall closure in colorectal surgery.

Colorectal Dis. 2023 Jun;25(6):1222-1227. doi: 10.1111/codi.16537. PMID: 36965056.

3. Amro C*, **Smith L***, Shulkin J, McGraw JR, Hill N, Broach RB, Torkington J, Fischer JP.

*Recognised as co-authors

The enigma of incisional hernia prediction unravelled: external validation of a prognostic model in colorectal cancer patients.

Hernia. 2024 Jan 16. doi: 10.1007/s10029-023-02947-0. PMID: 38227093.

4. Smith L, Meggy A, Watts T, Knight L, Torkington J, Cornish J,

Incisional hernia prevention: risk-benefit from a patient perspective (INVITE) - protocol for a single-centre, mixed-methods, cross-sectional study aiming to determine if using prophylactic mesh in incisional hernia prevention is acceptable to patients. BMJ Open 2022. doi: 10.1136/bmjopen-2022-069568

List of Oral Presentations

1. **A systematic review and meta-regression of factors influencing incisional hernia rates in midline incisions over a 10-year period**
   Winner of the British Hernia Society BJS abstract prize, British Hernia Society Conference, Oxford, October 2024

2. **“Happy to close?" The relationship between surgical experience and incisional hernia rates following abdominal wall closure in colorectal surgery.**
   Winner of the BJS Prize session, British Hernia Society conference, Oxford, November 2024

3. **Incidence, Healthcare Resource Use and Costs Associated with Incisional Hernia Repair.**
   Association of Coloproctologists of Great Britain and Ireland (ACPGBI) conference, Newport, July 2024

4. **The enigma of incisional hernia prediction unravelled: external validation of a prognostic model in colorectal cancer patients.**
   46th European Hernia Society (EHS) Congress, Prague, Czech Republic, May 2024

5. **“The three pillars of incisional hernia prevention”**
   Invited speaker at the Robotic Colorectal and Hernia Conference, Royal College of Physicians and Surgeons of Glasgow, Glasgow, April 2024.

6. **“Happy to close?" The relationship between surgical experience and incisional hernia rates following abdominal wall closure in colorectal surgery.**
   Association of Coloproctologists of Great Britain and Ireland (ACPGBI), Manchester, July 2023

7. **Incidence, Healthcare Resource Use and Costs Associated with Incisional Hernia Repair.**
   45th annual EHS Congress, Barcelona, Spain, May 2023

8. **‘"Happy to close?" The relationship between surgical experience and incisional hernia rates following abdominal wall closure in colorectal surgery.**
   Association of Surgeons of Great Britain and Ireland (ASGBI), Harrogate, United Kingdom, May 2023

9. **"Happy to close?" The relationship between surgical experience and incisional hernia rates following abdominal wall closure in colorectal surgery.**
   44th annual EHS congress, Manchester, United Kingdom, October 2022.

10. **"Happy to close?" The relationship between surgical experience and incisional hernia rates following abdominal wall closure in colorectal surgery.**
    17th annual European Society of Coloproctology congress, Dublin, Ireland, September 2022

Abbreviations

A&E: Accident and Emergency

AAA: Abdominal aortic aneurysm

AI: Artificial Intelligence

AIC: Akaike information criterion

ASA: American Association of Anaesthesiologists

ATP: Adenosine Triphosphate

AUC: Area under the curve

AWC: Abdominal Wall Closure

BIC: Bayesian information criterion

BMI: Body Mass Index

BRCA: Breast Cancer gene

C statistic: Concordance statistic

CDC: Centre for Disease Control and Prevention

CI: Confidence Interval

COPD: Chronic Obstructive Pulmonary Disease

CPET: Cardio-Pulmonary Exercise Testing

CT: Computerised Tomography

EA: Extracorporeal Anastomosis

EHS: European Hernia Society

ERAS: Enhanced Recovery after Surgery

FDA: Food and Drug Administration

HART: Hughes Abdominal Repair Trial

HES: Hospital Episode Statistics

HRG: Healthcare Resource Group

IA: Intracorporeal Anastomosis

ICD-10: International Statistical Classification of Diseases and Related Health Problems 10th Revision codes.

IH: Incisional Hernia

IQR: Interquartile range

MeSH: Medical Subject Headings

NELA: National Emergency Laparotomy Audit

NHS: National Health Service

NICE: National Institute for Care and Excellence

Non-RCT: Cohort studies, Case-control studies, experimental studies

NPV: Negative predictive value

OPCS: Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures Codes.

OR: Odds Ratio

PDS: Polydioxanone

PPI: Patient and Public Involvement in research

P-POSSUM: Portsmouth Physiological and Operative Severity Score for the enumeration of Mortality and morbidity

PPV: Positive predictive value

PR: Precision-recall

RCT: Randomised Control Trial

ROC: Receiver operator characteristic

SD: Standard Deviation

SD: Standard Deviation

SLWL ratio: Suture length to wound length ratio

SSI: Surgical Site Infections

STITCH: Small Bite Small Stitch Trial

WHO: World Health Organisation

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Chapter 1: Introduction

The scale of the problem

1.1 Incisional Hernia

This introductory chapter aims to put into context the existing body of literature on incisional hernia prevention. The chapter covers fifty years of research on incisional hernia development. It examines risk factors and wound healing studies from the 1970s to early 2000s, and recent interventional trials aimed at modifying these risk factors published in the last fifteen years.

Before discussing risk factors for incisional hernia development however, it is important to understand the development of incisional hernia and challenges of treating it.

a) Definition, Epidemiology and Aetiology

Incisional hernia is defined as "any abdominal wall gap, with or without a bulge, in the area of a postoperative scar, perceptible or palpable by clinical examination or imaging" (Korenkov et al. 2001). It is a common complication of abdominal surgery, with an incidence of between 10 and 30%. Incisional hernias can form through any incision made in the abdominal wall, but the highest prevalence is in midline abdominal incisions (Sanders and Kingsnorth 2012).

There are over 7 million surgical procedures performed in the United Kingdom every year (Abbott et al. 2017). Over 30,000 operations for colorectal cancer alone are performed annually in the United Kingdom (2018 NBOCA report 2018) alongside over 20,000 emergency laparotomies leading to a conservative estimate of 6,500 additional incisional hernias being formed each year from within just one surgical sub-specialty (Seventh Patient Report of the National Emergency Laparotomy Audit [2022]).

The pathophysiology of incisional hernia is multi-factorial and not completely understood. The primary cause is disruption and weakening of the abdominal wall by surgical incision, and the subsequent failure of the fascial layers of the abdomen to heal (Berrevoet 2018). Incisional hernias could be viewed as a failure of abdominal wall healing, and therefore an understanding of causes of impaired wound healing is vital to understanding the pathogenesis (Belokonev et al. 2000).

b) Wound healing

The physiology of wound healing is a dynamic process that can be categorised into four phases. Deficiencies or interruptions in each phase can lead to delayed wound healing. An understanding of normal wound healing is essential to understanding the risk factors for delayed wound healing and incisional hernia development.

The normal wound healing process can be categorised broadly into four groups seen alongside a phase summary in **Error! Reference source not found.**

The haemostatic phase begins immediately after the wound occurs. Nitric oxide is released from damaged cells causing vasoconstriction, aggregation of platelets and the creation of thrombus follows. Interleukin release causes inflammation, increased permeability of the vascular membrane and characterises the beginning of the inflammatory stage. During this stage, the thrombus and surrounding tissue release growth factors which aid the recruitment of neutrophils, macrophages and lymphocytes into the wound. These immune cells enable phagocytosis of cellular debris and bacteria, and recruit fibroblasts. This process typically lasts between 4-6 days and lays the framework for rebuilding of the wound.

The proliferation phase is not separate to this process and in reality often occurs alongside the inflammatory phase. Between 5 days and 3 weeks, fibroblasts begin to lay down type 3 collagen and the extra-cellular matrix is formed. Re-epithelisation of the wound begins to occur, alongside angiogenesis.

Table 1: *The phases of wound healing*

Phase	Phase Summary
Haemostasis	1. Vascular Constriction 2. Platelet Aggregation, clot formation
Inflammation	1. Recruitment of immune cells 2. Macrophage differentiation
Proliferation	1. Re-epithelialisation 2. Angiogenesis 3. Collagen synthesis
Remodelling	1. Collagen remodelling 2. Wound contraction

The maturation phase begins around week 3 but can take up to 12 months to complete. The extra-cellular matrix matures, and type 3 collagen is converted to the more stable type 1 collagen. Wounds contract and reach maximal tensile strength at around 12 weeks (Guo and DiPietro 2010).

There are many factors that affect normal wound healing. Healthy tissue requires a good blood supply to provide oxygen to healing tissues. Oxygen is not only crucial for aerobic respiration and production of Adenosine Triphosphate (ATP) but also to several stages of wound healing such as angiogenesis, cell migration and collagen synthesis. Due to the increased metabolic activity of cells, healing tissues have a degree of hypoxia which helps to promote growth factor production in the inflammatory stage. Ongoing hypoxia can lead to overproduction of growth factors and a prolonged inflammatory response (Bishop 2008). Any factor that impairs oxygen delivery to tissues, such as smoking, or increased tension across the wound can disrupt the microvascular blood supply and increase the risk of delayed wound healing.

An understanding of normal and abnormal wound healing helps clinicians to understand both the risk factors that contribute to incisional hernia formation and the science behind interventions that may reduce incisional hernia occurrence.

c) Challenges in treatment of incisional hernia

Surgical treatment of incisional hernia can be performed as open, laparoscopic or robotic operations and pose challenges to surgeons. Incisional hernia repairs have a recurrence rate of around 20% for the first operation (Köckerling 2019), and this rate increases with each subsequent repair (van Silfhout et al. 2021). Whilst the use of surgical mesh has reduced these numbers, the recurrence rates remain high (Silecchia et al. 2015). Patients undergoing incisional hernia repair suffer high rates of post-operative complications such as wound infection alongside high recurrence rates, which in turn have a higher cost-burden on healthcare services. (Fischer et al. 2015).

d) Patient Impact

As a result of surgical challenges and poor outcomes, it is estimated that only 5% of patients undergoing laparotomy will undergo subsequent repair of incisional hernia, compared to

the 10-30% of patients that will develop them (Gignoux et al. 2021). Incisional hernias increase in size over time and can be symptomatic with pain, episodes of bowel obstruction and strangulation requiring emergency surgery (Read 1989).

Asymptomatic incisional hernias can still have a significant impact on a patient's quality of life, with significantly lower quality of life and body image scores compared to patients without incisional hernia, suggesting a psychosocial impact which is often overlooked (van Ramshorst et al. 2012).

e) Cost to healthcare services.

The financial cost of incisional hernia repair should not be underestimated. One study published in the United States estimated cost of incisional hernia repair at one institution to be $17.5 million over an eight-year period (Fischer et al. 2015). A similar study by Gillion et al. (Gillion et al. 2016) looked at the cost of incisional hernia. They performed a multi-centric cost-analysis of 3239 incisional hernias over 51 hospital sites in France and estimated the cost to be 6451 euros per incisional hernia repair. Interestingly, they suggested that a 5% reduction in the incidence of incisional hernia could save on average 4 million euros per year. This study used incisional hernia repair as a surrogate for incisional hernia, which, as already discussed, would in fact represent an underestimate of the true cost of incisional hernia. In reality, this figure is likely to be far higher after taking into consideration non-operative costs such as outpatient and emergency department attendances. To date, there is little in the literature quantifying the true cost of either incisional hernia or incisional hernia repair when considering all healthcare resources.

f) Summary

Incisional hernia is common and may result in significant morbidity for patients. Surgical repair remains challenging, with high recurrence rates and costs to healthcare services.

In the case of incisional hernia, prevention is better than cure.

1.2 Risk factors for developing incisional hernia

Risk factors for developing incisional hernia are multi-factorial. They can be broadly categorised into three groups: Patient factors, surgical factors and post-operative factors.

This section aims to explore each of these three groups individually. Incisional hernia development and prevention has been extensively studies over the decades, and the papers presented below are testament to the evolution of our understanding of this condition. As mentioned earlier, there is considerable overlap between incisional hernia development and abnormal wound healing, and each section focusses on key papers that demonstrate this risk.

a) Patient factors

Patient risk factors can be defined as any pre-operative medical co-morbidities or patient lifestyle factors that increase the risk of incisional hernia.

Obesity

Obesity, defined as Body Mass Index (BMI) >30kg/m^2, is a risk factor for developing incisional hernia. With regard to the impact on wound healing, this prolongs the phases of wound healing, discussed earlier, leading to altered collagen deposition and remodelling and impaired wound strength, alongside increasing rates of surgical site infections (Höer et al. 2002). Obesity also increases tension across the surgical wound through raised intrabdominal pressure which decreases wound perfusion, thus increasing the risk of delayed wound healing and therefore incisional hernia.

Obesity is considered one of the most significant risk factors for incisional hernia development, due to both its role in hernia formation and in its prevalence within the general population (Veljkovic et al. 2010). In the United Kingdom, nearly two-thirds of adults (63%) are estimated to be overweight (BMI >25kg/m^2), a level above which risk of incisional hernia is significantly increased (Fryar CD et al. 2020). There is a linear relationship between increasing BMI and increased risk of incisional hernia development: A large retrospective cohort study of over 26,000 patients published by Lau et al. in 2012 found that patients who have a BMI >60kg/m^2 have 12 times the risk of developing a ventral hernia, of which

incisional hernia is a component, compared to patients with a BMI <25kg/m^2 (Lau et al. 2012).

Recent work has focussed on differences between types of obesity and rates of incisional hernia. Fat located around abdominal organs, so-called visceral obesity, has been shown to be associated with a significantly higher rate of incisional hernia when compared to fat located under the skin. The increased abdominal pressure produced by visceral obesity supports the theory of increased wound tension and impaired wound healing being the pathogenesis of incisional hernia formation (Aquina et al. 2015).

Previous abdominal surgery

Prior abdominal surgery in the form of previous laparotomy has been identified as an independent risk factor for incisional hernia by multiple studies (Lamont and Ellis 2005; Israelsson and Millbourn 2013; Bosanquet et al. 2015). The exact pathogenesis of this is unclear and is again likely to be multifactorial. De-vascularised scar tissue will impair wound healing, and incisions through previous scars are associated with increased risks of surgical site infections (Reeves et al. 2021). Incisions through previous laparotomy scars also increase the risk of complete abdominal wall dehiscence ("burst abdomen") which itself is a risk factor for incisional hernia formation (Walming et al. 2017).

Chronic Obstructive Pulmonary Disease and Smoking.

As discussed, the normal wound healing process can be interrupted, prolonged or delayed by numerous factors. Any chronic underlying health condition or chronic disease, alongside the treatments of these conditions, will alter the body's immune system and impair wound healing.

A history of underlying lung disease has been associated with increased incisional hernia rates in a number of studies (Sørensen 2005). Its pathogenesis is again likely to be multifactorial. Chronic Obstructive Pulmonary Disease (COPD) and chronic lung conditions increase intra-abdominal pressure through coughing. This increases wound tension and increases the risk of abdominal wall dehiscence and suture rupture (van Ramshorst et al. 2010). Patients with underlying COPD are more likely to have a history of corticosteroid use,

again, a risk factor for incisional hernia development (Pavlidis 2001), while patients with underlying lung disease are also more likely to be to be current smokers or have a history of smoking (Terzikhan et al. 2016).

Smoking itself is an independent risk factor for incisional hernia formation. A retrospective cohort study of 916 patients performed by Sørensen et al identified 5 risk factors for hernia development: re-laparotomy, smoking, postoperative wound complications, age and male sex. Whilst re-laparotomy was the strongest factor associated with hernia (OR 5.89), smokers had a 4-fold increased rate of incisional hernia when compared to non-smokers, independent of other risk-factors or confounders (Sørensen 2005).

Both a current or prior history of smoking impairs wound healing through many different factors. Smoking causes tissue hypoxia through micro-vascular damage and impaired oxygen-transport. It impairs the body's immune response, delaying the recruitment of immune cells to the wound, as well as impairing the synthesis of collagen(Jensen 1991; Allen 1997). These factors all impair wound healing and increase the risk of developing incisional hernia (Jorgensen et al. 1998).

Age and Gender

Both increasing age and male sex are associated with higher rates of incisional hernia (Bosanquet et al. 2015). Collagen formation and degree of normal inflammatory response decrease in these groups, which are factors that play a significant role in wound healing and strengthening. Interestingly, post-menopausal women have similar delays in collagen formation, however this returns with the use of hormonal therapy, suggesting a link between oestrogen and collagen formation (Brincat et al. 1987).

Connective tissue disease

Collagen has a significant role in wound healing. As previously discussed, during the proliferative phase of normal wound healing process, fibroblasts lay down type 3 collagen, which is subsequently re-modelled to type 1 collagen. As collagen is the main determinant of wound strength, any condition that impacts collagen formation such as smoking, obesity and gender will impact overall wound strength.

Through the same process, conditions that are associated with impaired collagen formation are also associated with an increase in incisional hernia development. Patients with genetic disorders of collagen formation such as Ehlers-Danlos syndrome are reported to have increased risk of incisional hernia, however this is anecdotal and not yet supported by high-quality data (Harrison et al. 2016).

Patients undergoing repair of aortic aneurysms, a disease linked to impaired collagen synthesis, are at increased risk of incisional hernia however. A systematic review by Antoniou et al aimed to identify a link between aneurysm surgery and incisional hernia development. The review found that patients undergoing repair of abdominal aortic aneurysms were 3 times more likely to develop incisional hernia when compared to patients undergoing surgery for occlusive iliac disease, an operation which requires the same approach and performed by the same surgeon, yet whose aetiology is cardiovascular plaque and thrombus formation. This perhaps offers the clearest link between impaired collagen synthesis and incisional hernia (Antoniou et al. 2011).

More recently, genetic profiling has identified common mutations between diverticular disease, connective tissue disorders and abdominal wall hernias. A population study published by Perez et al compared incisional hernia rates in colorectal patients and stratified them into those undergoing resection for cancer vs resection for diverticular disease. They reported a 2-fold increased risk of incisional hernia diagnosis, and a 2-fold increased risk of needing incisional hernia repair in those undergoing surgery for diverticular disease, again suggesting possible genetic links with increased risk of incisional hernia (Perez et al. 2021).

Summary

An understanding of patient risk-factors is crucial in identification of the high-risk patient, and in adequately consenting patients as to their risk of developing an incisional hernia before surgery. In Chapter 5, as well as later on in this chapter, we will discuss the development of risk-predictive tools which utilising many of these risk factors.

b) Surgical factors

Surgical risk factors for developing incisional hernia can be defined as any decision made by the surgeon that impacts incisional hernia development.

Abdominal wall closure technique

The primary area of focus in identifying surgical risk factors is abdominal wall closure. Technique, in particular, has been extensively researched and is an ever-evolving field. Despite this, there are surgical principles that are well-established that should be followed.

It is well recognised that a minimum 4:1 ratio of suture length to wound length should be observed to ensure that the optimal volume of suture material is used to bring the abdominal wall together. This was first reported by Jenkins in his seminal paper assessing burst abdomen (Jenkins 1976). In it, he proposed that the that the wound may lengthen by up to 30% in the post-operative period, therefore requiring an "adequate reserve of suture length" in order to accommodate for this. Through diagrams plotting suture technique as a series of triangles, he demonstrated that an increase in wound length is associated with a decrease in distance between the sutures and therefore an increase in wound tension. Jenkins proposed that a 4:1 suture length to wound length ratio was the most important factor in preventing wound dehiscence, and this has formed a cornerstone of abdominal wall closure technique since.

Regarding wound healing principles, an increased suture length to wound length ratio is rational when considering principles of wound healing. Increased volume of suture material in the wound ensures that tension is evenly distributed across the suture line, avoiding tissue and muscle ischaemia and subsequent impaired oxygen delivery to the healing wound (Kushner et al. 2022).

Suture material plays a role in reducing incisional hernia rates, with evidence suggesting that a slowly absorbable, or non-absorbable suture is superior to rapidly absorbable suture in terms of hernia rates (van't Riet et al. 2002), with no difference between hernia rates in non-absorbable vs slow-absorbable sutures. As for suture type, there is evidence to suggest that monofilament sutures have lower incidences of post-operative wound infection when

compared to multifilament, however there is no evidence that suture type (monofilament/multifilament) reduces incisional hernia rates (Bosanquet et al. 2015).

With respect to surgical technique, in elective surgery there is evidence that continuous suturing (**Figure 1**) is superior to interrupted suturing in reducing incisional hernia rates (Diener et al. 2010), and in 2015, European Hernia Society (EHS) Consensus guidelines (Muysoms et al. 2015) recommended using a continuous, slowly-absorbable suture based on available evidence. In practice, this is often used with a monofilament suture, such as Polydioxanone (PDS). There is, however, still controversy over suture material and type, with a 2018 systematic review and meta-analysis concluding that there is no difference in incisional hernia rates between suture material, types or technique (Henriksen et al. 2018). This likely highlights the multifactorial nature of incisional hernia formation, and the difficulty in conducting high-quality randomised control trials with reproducible outcomes.

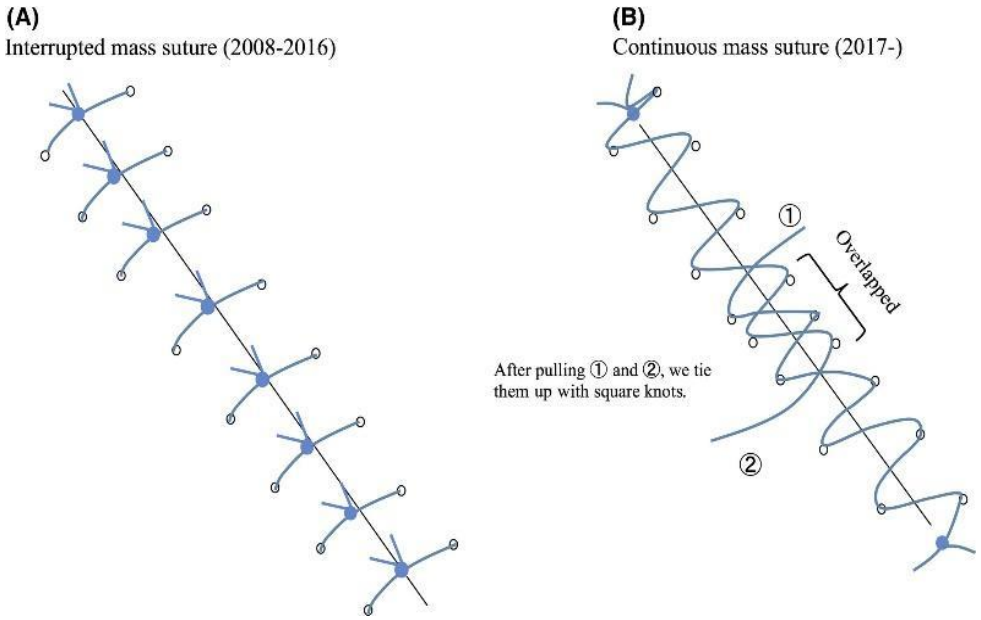

Figure 1: Interrupted vs continuous suturing technique (Chida et al. 2019) CC Non-Com 4.0 license

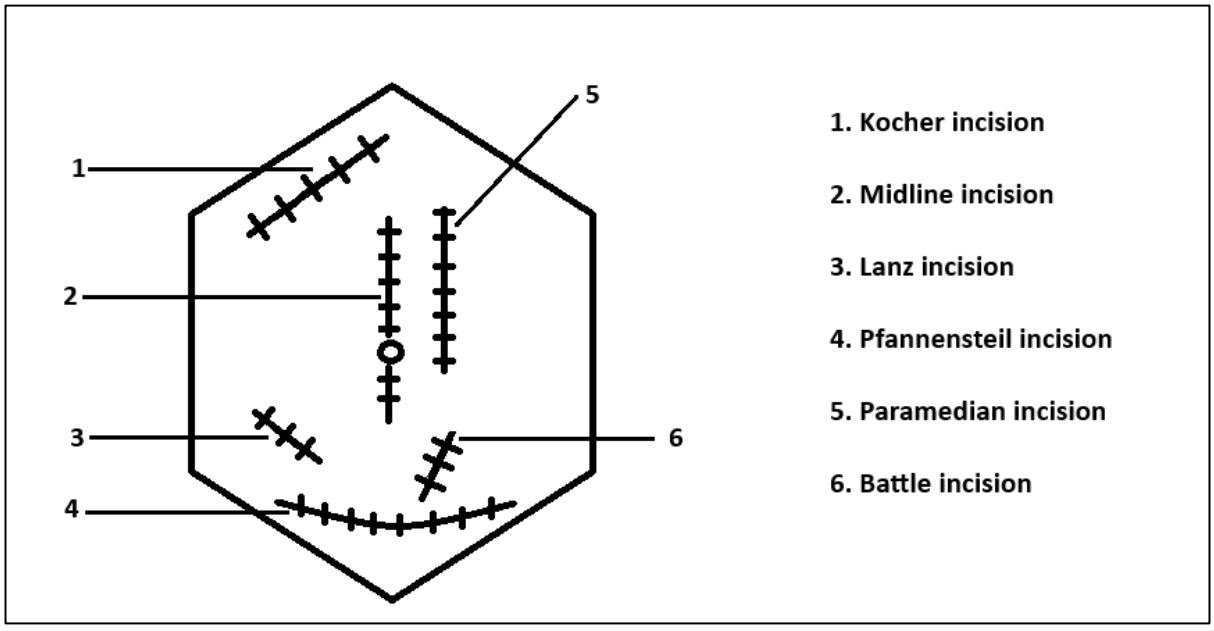

Figure 2: Location of surgical incisions. Figure created for this thesis

Location of incision

Abdominal incisions are placed by surgeons to maximise the efficiency and safety of the operation by optimising the view of the target organ. There are numerous eponymously named incisions, and some can be seen in **Figure 2** (above).

Traditionally, the midline laparotomy has been the incision of choice in both emergency and elective abdominal surgery, for its ease of access, safe views of almost all abdominal organs, and its ability to allow access to all areas of the abdomen. Midline incision, however, is a risk factor for incisional hernia when compared to off-midline approaches (Lee et al. 2017). A systematic review and meta-analysis published by Den Hartog et al. in 2022 identified an incisional hernia rate of 16% in midline wounds, compared to just 2.1% in Pfannenstiel wounds, with similar rates of surgical site infections (Den Hartog et al. 2022). In another study off-midline incisions were associated with decreased opioid use post-operatively, alongside improved respiratory function (Brown and Tiernan 2005).

In 2022, the EHS recommended in its abdominal all closure consensus guideline that non-midline approaches should be used “whenever possible” (Deerenberg et al. 2022).

Emergency surgery

Over 20,000 emergency laparotomies are performed in the United Kingdom alone every year for a wide range of emergency conditions (Seventh Patient Report of the National Emergency Laparotomy Audit 2022). Incisional hernia rates in this group are significantly higher, with one paper quantifying a 4-fold risk of incisional hernia in patients undergoing emergency surgery (Basta et al. 2019). The exact pathogenesis of this is unclear, and again is likely to be multifactorial.

Patients undergoing emergency laparotomy, by their very nature, are more likely to be co-morbid, or to have poorly controlled health conditions when compared to those undergoing elective surgery. A paper by Garg et al. in 2014 identified predictors of abdominal wound dehiscence, itself a risk factor for incisional hernia formation, including obesity, anaemia, low serum albumin, higher American Association of Anaesthesiologists (ASA) grade, and contaminated/dirty laparotomy wounds (Garg et al. 2014). All of these factors are more

likely to be found in patients undergoing emergency laparotomy compared to elective surgery.

As previously discussed, off-midline abdominal incisions should be used wherever possible to reduce risk of incisional hernia. However, this is rarely possible in the case of emergency abdominal surgery. Furthermore, the optimal abdominal wall closure techniques described earlier have been studied in elective settings, and there is no optimal closure technique or material in emergency patients due to a lack of high-quality trials being performed within this cohort (van 't Riet et al. 2002).

c) Post-operative factors

Post-operative factors can be defined as events that occur after an operation that increase the risk of incisional hernia to the patient.

Surgical site infection

Surgical site infections (SSIs) can be classified as either incisional or organ-space. Incisional SSIs are defined by the Centre for Disease Control (CDC) as infections occurring in the operative wound within 30 days of the operation. They can be further classified as superficial (involving only the skin or subcutaneous tissue), or deep (involving the muscle or fascial layers (Berríos-Torres et al. 2017)). Surgical site infections impair normal wound healing through prolonging the inflammatory phase of normal wound healing, leading to chronic or non-healing wounds. Whilst infection impairs normal wound healing, any factor that alters the normal immune response found in wound healing will increase the likelihood of developing a surgical site infection. As a result, SSIs share many of the same risk factors as incisional hernia.

Surgical site infections are a common complication of abdominal surgery, with rates as high as 20% in colorectal surgery (Reeves et al. 2021). SSIs are a source of considerable cost to the NHS, up to £10,500 per patient, and can impact patient's quality of life and return to function following surgery (Tanner et al. 2009). A retrospective review published in 2017 by Walming et al. demonstrated surgical site infection as being strongly associated with both incisional hernia and wound dehiscence with hazard ratios of 3.68 and 3.00 respectively

(Walming et al. 2017). Rates of SSI are increased in emergency surgery due to increased likelihood of contaminated operative fields, and this may well contribute to the increased incisional hernia rates experienced in those undergoing emergency laparotomy or elective colorectal surgery (Pinkney et al. 2011).

Return to strenuous activity

Return to activity following abdominal surgery is a common question posed to surgeons by patients. It impacts their return to work, return to driving and return to exercise. In the United Kingdom, there are no fixed guidelines for return to activity following abdominal surgery. However, anecdotally, a period of 6 weeks with "no heavy lifting" is often recommended.

Wound healing has been extensively studied in animal models. In 1965, Levenson et al. reported that the tensile strength of healing skin in rats reached 50% of its pre-operative strength at 6 weeks, peaking at 80% at 3 months (Levenson et al. 1965). This correlates with our understanding of wound healing and collagen deposition, which peaks at around the same time (Harrison et al. 2016). This work by Levenson is used by surgeons to this day and may well inform the anecdotal "6-week" rule. It is worth noting however that Levenson's work involved skin tensile strength in rat models. In abdominal wall healing, fascial strength, not skin strength should be the main focus with respect to incisional hernia formation.

A systematic review of literature published by Loor et al. in 2021 aimed to provide clarity on both the basic science of abdominal wall healing, and the clinical literature surrounding return to function. Of the seven studies that met the criteria for the basic science review, there was widespread variability in time to fascial healing and maximal tensile strength. When looking at the twenty-two studies considered for the clinical review, there was widespread heterogeneity in terms of study design and outcomes, leading to no clear conclusion, and the question of whether physical activity in the post-operative period increases or decreases the risk of incisional hernia remains unanswered. Further research in this area is needed before clear guidance can be set (Loor et al. 2021a).

Summary

Operative and post-operative risk factors have been extensively studied, as they are the most modifiable areas when looking to reduce incisional hernia rates. The next section will discuss different strategies for reducing risk of incisional hernia, and many of these will be referenced throughout this thesis.

1.3 Current strategies for modifying risk

a) Abdominal Wall Closure techniques

Closure of the midline abdominal incision has evolved over the years with an expanding evidence base attempting to answer questions regarding optimal closure technique. Here commonly performed techniques and their evidence base are discussed.

Mass Closure

Mass closure of the midline abdominal wound has been the accepted technique amongst surgeons for decades and is regularly taught to all junior surgeons as part of their Basic Surgical Skills training (The Royal College of Surgeons 2022)

It uses a continuous suture technique, with a large – typically 1.0 or 0 suture placed 1cm from the fascial edge at 1cm intervals (Jenkins 1976). This is typically performed using two slowly absorbable sutures like Polydioxanone (PDS), starting from each end of the incision and incorporating all layers of the abdominal wall.

Care must be taken not to put too much tension on the sutures, to avoid muscle ischaemia and subsequent loosening of the sutures, and to ensure adequate overlap of sutures in the middle of the wound.

Mass closure is used as the control in the majority of randomised trials studying the development of new abdominal wall closure techniques due to its common usage and ease of replicability. It is important to highlight that “Mass closure” is a generic term that comprises an amalgamation of closure principles over decades. It must be remembered that the technique itself has never been studied as an intervention.

The Hughes (Cardiff) repair

The Hughes repair (otherwise known as the Cardiff repair) was first described by Professor Les Hughes in 1986 (Hughes 1986). It comprises of a standard running mass closure, supported by interrupted double-mattress sutures, using a non-absorbable suture such as 1.0 nylon (**Figure 3**).

There is evidence for its use in incisional hernia repair and as a technique for closure following abdominal wound dehiscence and laparostomy (A-Malik and Scott 2002; R Godara et al. 2006).

The Hughes Abdominal Repair (HART) Trial, published in 2022 was a randomised control trial comparing the Hughes closure with surgeon's preference of closure technique, and aimed to assess the differences in incisional hernia rate (Torkington et al. 2022). 802 patients were recruited to the two arms, and the presence of incisional hernia was detected on clinical examination at 1 and 2 year follow ups. Whilst incisional hernia rates were lower in the Hughes closure arm at both 1 and 2 year follow up (14.8% vs 17.1 % and 28.7% vs 31.8%) the difference was not great enough to reach statistical significance (p=0.402 and 0.429 respectively). The HART trial is, to date, the largest randomised control trial assessing abdominal wall closure techniques. Its strengths include a pragmatic approach to trial design, with a broad inclusion criteria, making it applicable to real clinical practice. Two-year follow-up allows adequate time for incisional hernia development, in accordance with EHS guidance and further strengthens the findings of high incisional hernia rates. Its weaknesses are clinical rather than radiological assessment of hernia presence, and a lack of standardisation in training in the Hughes closure technique. Overall the HART trial was a well-designed, pragmatic study that showed the complexities of conducting research in incisional hernia prevention. Whilst the HART trial failed to demonstrate a significant difference between closure arms, its high rates of incisional hernia in both arms (28.7% and 31.8%) highlight the scale of the problem that incisional hernia presents in colorectal surgery.

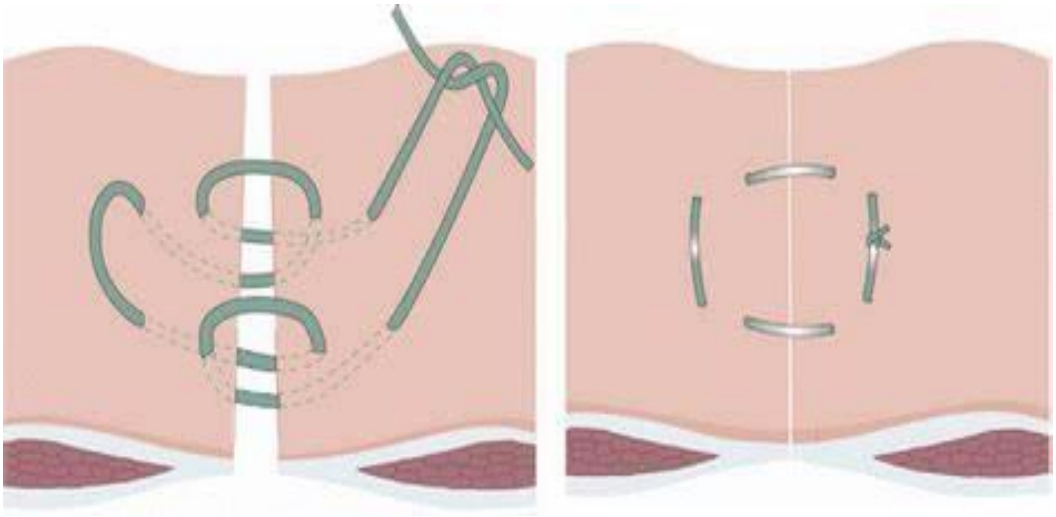

Figure 3: The double-mattress suture component of the Hughes technique (Cornish et al. 2016) CC Non-Com 4.0 license

Small Bites, Small Stitch technique (Small Stitch)

As previously explained, traditional abdominal wall closure technique has mandated large bites, with a large suture to provide adequate strength to the wound and prevent dehiscence. This has been challenged in recent years by the development of the Small bite, Small stitch "Small Bites" technique.

The principle is based around Jenkin's rule of a 4:1 suture length to wound length ratio which has been previously discussed. In 1996, this rule was confirmed by Israelsson et al. in a prospective cohort study which confirmed that a suture length to wound length ratio of <4 was an independent risk factor for incisional hernia (Israelsson et al. 1996).

In 2001 a research group, again led by Israelsson, demonstrated in an experimental study that wound strength was higher in wounds closed with fascial bites taken 3-6mm from the wound edge when compared to bites taken 10mm from the fascial edge (Cengiz 2001).

The technique relies on smaller bites taken closer together, increasing the volume of suture material in the wound and therefore increasing the suture length to wound length ratio to 4 or greater. The effect of small bites is to more evenly distribute the tension throughout the wound, thus mitigating for smaller bites of fascia.

This effect was demonstrated by a randomised control trial published in 2009 (Millbourn 2009). Millbourn et al. randomised 737 patients having midline incisions to closure with either small or large bites technique and were followed up by clinical examination at 1 year. Incisional hernia rates were higher in the large bites group vs small bites group (18% vs 5.6%, $p<0.01$), as were the rates of surgical site infection (10.2%vs 5.2%, $p=0.02$). On multivariate analysis, long stitch length and a suture length to wound length ratio of <4 were independent risk factors for incisional hernia development.

Small Bites vs Large Bites trial (STITCH)

The effect of the small bites technique was further assessed in a multi-centre double-blind randomised control trial conducted from the Netherlands and published in 2015 by Deerenberg et al. This RCT compared mass closure using large bites (as previously discussed) to a standardised closure using a continuous small suture (2.0 PDS), with bites taken every

5mm and placed 5mm from the fascial edge. This stitch was to incorporate only the aponeurosis of the fascia and use a suture length to wound length ratio of at least 4:1 (Deerenberg et al. 2015).

560 patients undergoing elective surgery were recruited and followed up at 1 year with both clinical examination and ultrasound assessment to identify incisional hernia. The trial demonstrated a significant reduction in incisional hernia in the small stitch group when compared to conventional large bite closure (21% vs 13%, p=0.02) with no difference in adverse events between the two arms.

Whilst the study was well powered and used a radiological assessment to define incisional hernia, it has to date only reported follow up at 1 year. Moreover, the findings may not be generalisable as the population studied only included elective midline incisions, with laparoscopic and emergency surgery excluded.

This trial is one of the first to demonstrate a significant reduction in incisional hernia rates in a new closure method and the result has subsequently been confirmed in a number of RCTs and in meta-analyses (Elsamani et al. 2022), leading to EHS guidance recommending small stitch closure as the technique of choice for closing elective incisions (Deerenberg et al. 2022).

b) Location of incisions

As previously discussed, there are numerous incisions that allow the surgeon access to the abdominal cavity. Broadly speaking, these can be defined as midline or transverse, and account for the majority of the incisions used in modern-day surgery. Choice of incision is dictated by the surgeon and must consider ease of access to the organ or area, speed of access (in case of emergency) and the experience and preference of the surgeon performing the procedure (Ellis 2008).

Midline access

Midline access, in the form of midline laparotomy, is quick, bloodless and has the ability to be extended, allowing the surgeon to access all parts of the abdomen (Ellis 2008). In theory, midline laparotomy allows minimal trauma to the abdominal wall, as entry through the

single fascial layer of the linea alba (**Figure 4**) does not disrupt the abdominal wall muscles, nerves or blood supply. In reality, however, studies have shown weakness in abdominal wall musculature after uncomplicated midline laparotomy, indicating that the linea alba plays a more important role in abdominal wall function than previously thought (Paiuk et al. 2013).

The anatomy of the linea alba itself may well play a role in the aetiology of midline incisional hernia. Firstly, as a continuation of the muscular aponeurosis that serves to join the paired rectus muscles, disruption leads to lateral retraction of the abdominal wall musculature, placing tension across the wound. Secondly, the avascular nature of the linea alba leads to prolonged wound healing as discussed earlier. Both of these factors together may explain why incisional hernia rates are higher in midline wounds when compared to transverse.

Off-midline access

There are numerous, often eponymously named, transverse incisions that allow surgeons access to the abdomen, as shown in **Figure 2**. Transverse incisions are often targeted to a specific organ, in the case of Kocher's incision (Liver/Biliary tree), or an area of the abdomen, as in a Pfannenstiel (Pelvis). Whilst this gives access to the organ or area in question, there is often little scope to extend the incision should the surgeon require, and these incisions often do not allow access to other areas of the abdomen. Moreover, dissection through the layers of the abdominal wall is time-consuming.

As discussed earlier, there is strong evidence that transverse incisions, however, are associated with a lower rate of incisional hernia, which again may be explained by the anatomy of the abdominal wall as shown in **Figure 4.** Closure of the individual layers decreases likelihood of wound dehiscence, and splitting, rather than cutting the muscle allows a tension-free closure with optimised ability to heal (Brown and Tiernan 2005; Bickenbach et al. 2013).

The evolving use of laparoscopic surgery, particularly in colorectal cancer surgery, has re-ignited the discussion regarding location of abdominal incisions. Laparoscopic surgery minimises the need for large abdominal incisions through the use of multiple incisions 10mm or less, however there is still need for a larger (approximately 5cm) wound to extract the specimen, which is typically placed in the midline (Jayne et al. 2007). Whilst laparoscopic

colorectal resection has been associated with reduced morbidity, shorter length of stay and increased quality of life (Lacy et al. 2002), rates of incisional hernia after laparoscopic colorectal resection remain high at between 10-30%, due to this midline extraction site (Lee et al. 2017).

c) Difficulties in conducting randomised control trials

Research into incisional hernia prevention has developed over the last 40 years, producing an increasing body of evidence, yet the burden of incisional hernia remains high. From Jenkin's rate of 13% published in 1976, to the literature rate of 13.6% in 2015, to the HART trial's 1-year rate of 14.8% in 2022, the rates of incisional hernia have remained static for 40 years.

One challenge of conducting research is the heterogeneity of the population studied. As discussed, the risk factors for incisional hernia development are multi-factorial, and factoring this into trial design and patient selection is difficult. Alongside the patient risk factors are the variables to be compared. Whilst trials tend to focus on one variable, for example either closure method or location of incision, the number of operative variables, such as suture choice, suture technique and post-operative factors, such as surgical site infection, make standardisation of a control difficult. The number of patient-associated variables and intra-operative variables makes developing a comprehensive, replicable RCT very challenging. This means that results are often not replicable, leading to conflicting outcomes and a wide-ranging body of evidence.

A further difficulty is heterogeneity in the length of follow up between trials. Incisional hernias can continue to develop until 3 years following surgery (Fink et al. 2013), whilst the majority of prospective studies end at one or two year follow up due to practicalities and cost of conducting research trials over that length of time. This has almost certainly led to an under-reporting of incisional hernia rates, and a variation in trial follow-up, again contributing to the wide range of incisional hernia rates in the literature.

A third challenge is posed in how incisional hernias are detected in trials. Whilst incisional hernia is a clearly defined pathology, there is heterogeneity in the method of detection. Physical examination provides an assessment of clinically relevant incisional hernia (i.e.

hernias that may cause symptoms or require further surgery). However, it is not as sensitive as imaging in detecting smaller hernias, leading to an under-reporting of true incisional hernia rates. Imaging such as Computerised Tomography (CT) is readily available and reproducible, however provides a radiation dose to the patient. Assessment with ultrasound is safer than CT scanning as there is no radiation exposure, however it is operator dependent and requires a specific technique to be used effectively (Beck et al. 2013).

It is widely accepted that some form of imaging modality must be included in the follow-up assessment for prospective studies investigating incisional hernia rates. However, there is no consensus on preferred modality (Muysoms et al. 2015). This again increases the heterogeneity of studies and weakens the overall body of evidence.

These factors pose a challenge for prospective trials, but also for surgeons attempting to follow best evidence. The heterogeneity of trials, and lack of high-quality RCTs is commented on in almost all systematic reviews, and the EHS guidance on abdominal wall closure recognises that there is limited high quality data, therefore many of its recommendations are based on weak evidence (Deerenberg et al. 2022). Recently, core outcome sets for trials have been developed by the COMET (Core Outcome Measures in Effectiveness in Trials) initiative. This has led to development of core outcome sets for trials involving colorectal cancer, and a set for abdominal wall hernias is currently underway. Development of a core outcome set for incisional hernia trials is critical in standardising the outcomes of future research.

1.4 High-risk patients and mesh prophylaxis

The previous section explored strategies to modify risk and discussed the evidence behind some of these yet as we have discussed, many patient risk factors are non-modifiable. This section discusses attempts to quantify patient risk pre-operatively to identify those patients at increased risk of incisional hernia development and target interventions at the time of primary abdominal wall closure that may reduce their hernia risk.

a) Identification of high-risk patients

Predictive modelling is an established principle within medicine. Risk-prediction tools are used to inform clinicians and patients on many things, from 5-year risk of suffering a stroke, to the likelihood of dying from emergency surgery (Gage et al. 2001; Thahir et al. 2021). The aim of the models is two-fold; to advise and educate patients, and to allow early and optimised intervention for clinicians, in order to reduce the likelihood or impact of the disease or condition. In hernia surgery, predictive tools have been used to identify patients at risk of recurrence following incisional hernia repair, allowing surgeons to identify and modify their approach, along with educating and optimising patients to modify risk factors such as smoking and obesity (Hodgkinson et al. 2021).

With regards to incisional hernia prevention, two risk-predictive tools have been developed that aim to categorise patients into low, medium and high-risk groups. In 2015, the HERNIAscore was developed by a group in the United States (Goodenough et al. 2015). 625 continuous patients undergoing abdominal surgery were followed up for a median of 41 months and assessed for incisional hernia using both clinical examination and imaging. From this group, four predictors of incisional hernia were identified: laparotomy, hand-assisted laparoscopy, COPD and BMI >25kg/m^2. By converting the associated hazard ratio to points, they were able to classify patients into three groups, which was validated internally with high predictive scores. The same group externally validated and modified the model in a retrospective analysis in 2017 (Cherla et al. 2017). Whilst the prospective design of this study adds weight to the identification of predictive variables, both cohorts used to validate the model had relatively low numbers (197 and 247 respectively), and whilst this may aid clinicians in categorising patients to low, medium or high risk, it does not provide an individualised score that considers surgical factors.

In 2019, Basta et al. published the development of their risk-predictive model, again in the United States (Basta et al. 2019). This large, retrospective review of nearly 30,000 patients identified pre-operative risk factors, along with intra-operative predictors, which when combined into a predictive score, allowed patient-specific risk tailored to the type of surgery being undertaken. This model has been developed into a free-to-access website and app for ease of use and provides the likelihood of developing incisional hernia and surgical site

infection as a percentage, along with comparing this to the average for the type of surgery, be that colorectal, gynaecology or urology.

This broad-based approach utilising multiple variables allows surgeons to tailor the score to the individual and recognises differing hernia rates throughout surgical specialties. This model has not been externally validated however, so we have no understanding of how it performs outside of the cohort. It is also worth noting that due to the size of the database, patients were defined as having incisional hernia if they had undergone subsequent repair of incisional hernia, rather than having a clinical or radiological diagnosis of incisional hernia, which will have led to an under-representation of the true incidence of incisional hernia in their population.

Both risk-predictive models described have the potential to identify patients at increased risk of incisional hernia before their operation. However, both have limitations in their methodology which reflect the broader issues with research in incisional hernia prevention which were discussed earlier. Prospective studies often lack the sample size with which to comprehensively identify variables and draw meaningful conclusions, whereas retrospective databases offer larger cohorts, however, often must compromise in areas such as outcome definition. Moreover, using studies to create a predictive tool installs bias into the model from the outset. Populations that are not represented within the study cohort will not be represented in the calculator, and this is the reason why external validation is crucial before models can be widely used.

In-spite of limitations, it appears that predictive-tools can help surgeons in identifying patients at increased risk of incisional hernia development. These tools may eventually allow patients and clinicians to implement prehabilitation programmes in an attempt to reduce risk, as well as raising patient awareness of their risk of developing incisional hernia as part of the consent process. Accurate identification of higher risk patients may allow surgeons to modify their operative strategy, such as using prophylactic mesh placement.

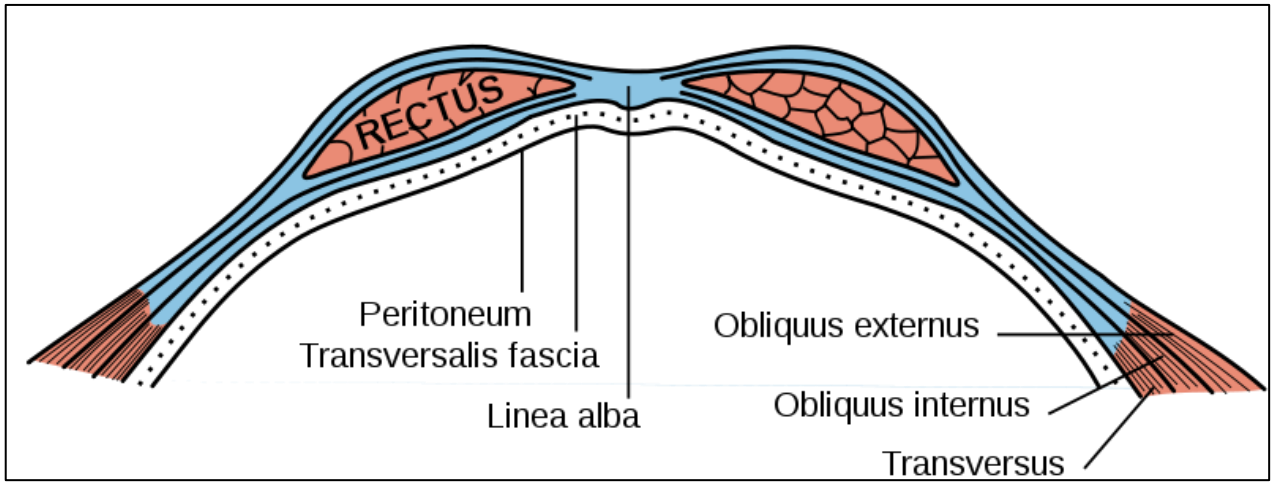

Figure 4: The layers of the abdominal wall (Gray 1918) License; Public domain

b) Mesh Prophylaxis

The principle of using mesh to strengthen the abdominal wall is well established in hernia surgery. Mesh is routinely used in inguinal hernia repairs and has been shown to reduce recurrence rates (Smith et al. 2021). Likewise, mesh is routinely used in repair of incisional hernia, again with evidence for both safety and efficacy (Burger et al. 2004). Prophylactic mesh placement for the prevention of incisional hernia follows the same principles, augmenting and strengthening the wound through the use of permanent (synthetic) or slowly-absorbable (biologic) mesh. This is placed into the wound at the end of the operation, at time of primary abdominal wound closure. Mesh can be placed in a number of locations in the abdominal wall (**Figure 4**Error! Reference source not found.).

The evidence for prophylactic mesh placement is rapidly increasing. A large, multicentre, RCT was published by Jairam et al. in 2017, aiming to assess incisional hernia rates between primary suture closure and mesh augmented closure, and identify the optimal mesh location (onlay vs sublay). 480 patients undergoing elective midline laparotomy and had either a history of aortic aneurysm or BMI >27kg/m^2 were randomised to receive primary suture closure, sublay mesh or onlay mesh and followed up for 2 years with clinical and radiological assessments. Both onlay and sublay mesh groups (18% and 13% respectively) had significantly lower rates of incisional hernia than the primary suture group (30%), with no increased rates of surgical site infections between the three arms (Jairam et al. 2017).

It is worth noting that this trial was conducted in patients at high risk of incisional hernia development and returned results very similar to those of non-mesh closure trials such as STITCH which used a much lower risk demographic of patients. Patients were followed up for an appropriate length of time with radiological assessment, however mass closure was used as the primary suture closure of choice, perhaps limiting the generalisability of the findings, and raising the question how mesh augmentation would compare to small bites closure.

The results of this study have been confirmed by a systematic review and meta-analysis of 1815 patients which demonstrated the superiority of mesh augmentation over primary sutured closure, without increasing rates of post-operative SSI (Jairam et al. 2020). A second systematic review and meta-analysis published in 2020 again confirmed lower incisional

hernia rates in those undergoing mesh-augmented closure in 20 RCTs (Tansawet et al. 2020). This analysis primarily looked at location of mesh placement and determined that both onlay and retro rectus mesh placement provided the most effective incisional hernia prevention. However, rates of post-operative seroma were higher in the onlay group, suggesting further work is needed to determine optimum mesh location.

Prophylactic mesh placement appears cost-effective when compared to sutured closure. A paper published in 2015 compared the cost and Quality Adjusted Life Years (QUALYs) of primary sutured closure vs primary mesh augmentation. They concluded that mesh augmented closure was more effective and less costly and overall, more cost-effective than primary sutured closure (Fischer et al. 2016). Another paper published in 2018 demonstrated that when mesh placement was used in conjunction with the HERNIAscore, higher risk patients, especially those with obesity, showed a significant reduction in total cost when receiving mesh augmented closure. Interestingly, lower-risk patients had a higher total cost when undergoing mesh augmented closure (Argudo et al. 2014).

In 2022, the EHS guidance advised that prophylactic mesh could be recommended in the high-risk patient (Deerenberg et al. 2022).

c) Barriers to implementation of mesh prophylaxis

Despite increasing evidence for efficacy, safety and cost-effectiveness, uptake of this new technique has been slow within the surgical community. A survey of 500 surgeons in North America in 2019 suggested that around 90% of surgeons were aware of the literature surrounding prophylactic mesh, however only 15% were using as part of their practice (Fischer et al. 2019a). The two most cited barriers to use were concern about mesh-related complications and not being convinced of the benefit of using mesh. Understanding and addressing hesitancy from surgeons is the next step in developing widespread use of mesh.

Whilst surgeons' views on mesh prophylaxis have been well documented, little is understood about the patient's perspective.

The use of mesh in surgery in the United Kingdom has come under scrutiny following media coverage and public concerns relating to the use of mesh in uro-gynaecological procedures,

culminating in the Cumberledge report in 2020, which highlighted issues with chronic pain, urinary and sexual dysfunction and mobility issues. (Cumberledge. 2020).

With the growing controversy and media coverage, public concerns about the use of mesh in hernia surgery have led many regulatory bodies, including the Royal College of Surgeons of England, to issue statements defending its use for hernia surgery (*RCS statement on hernia mesh complications* 2018). Currently, there is no evidence whether this controversy has any impact on patient perceptions of mesh. When considering barriers to implementation of mesh prophylaxis, this is an area that needs further work.

1.5 Summary

- Incisional hernia is a common complication of abdominal surgery.
- Its causes are multi-factorial but broadly speaking represent a failure of the abdominal wall to heal.
- Our understanding of incisional hernia risk has changed over the decades, through identification of patient risk factors, to modifying surgical risk factors.
- Whilst closure strategies can reduce the risk slightly, there is not one intervention that can eliminate the risk entirely.
- Current risk-prediction tools have not yet received external validation, and their role has not been well defined.
- Mesh prophylaxis remains controversial, with significant barriers to implementation that require addressing before its use can become more widespread.

1.6 Aims and Hypotheses

a) Aim of thesis

1. To quantify the incidence of incisional hernia in abdominal surgery, and the impact it has on patients.

2. To identify modifiable surgical risk factors for incisional hernia and discuss strategies for implementing them into current practice

3. To validate and modify a risk-predictive tool for accurately identifying the patient at high-risk for developing incisional hernia in a colorectal cancer population.

4. To determine barriers to implementation of mesh prophylaxis.

b) Hypotheses

1. Rates of incisional hernia in midline abdominal wounds have not decreased significantly over the past 10 years

2. We can accurately identify patients undergoing colorectal surgery who are at increased risk of incisional hernia.

3. Prophylactic mesh placement would be acceptable to many patients if given the correct information.

Chapter 2: The cost of incisional hernia

Incidence, healthcare resource use and costs associated with incisional hernia repair.

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I am very grateful to both Becton Dickinson and Open Health for their methodological and financial help in this project.

2.1 Introduction

The previous chapter has discussed risk factors for incisional hernia development and current strategies to reduce incisional hernia occurrence, however the impact of incisional hernia to both patients and healthcare services should not be overlooked.

Patients with incisional hernia report significantly lower quality of life and body image scores compared to patients without (van Ramshorst et al. 2012). Furthermore, operative repair of incisional hernia is challenging, with high recurrence rates and an overall mortality rate of 1% (Basta et al. 2019; Ortega-Deballon et al. 2023a). Patients undergoing repair of incisional hernia may enter a vicious cycle of recurrence and re-operation with increasingly poor outcomes with each attempt (Fischer et al. 2015). To date, no cost analysis of incisional hernia repair has been performed in the United Kingdom, yet the cost in other healthcare systems is significant, with hernia-related healthcare expenditure in the United States reaching $3.2 billion dollars annually (Fischer et al. 2016).

Prevention of incisional hernia is of the utmost importance in reducing both the associated morbidity and cost of incisional hernia. Recent techniques such as the small stitch technique and mesh prophylaxis have shown promising results, yet widespread uptake both remains low (Fischer et al. 2019b). Delays in changing practice in abdominal wall closure potentially reflect a lack of understanding about the burden of incisional hernia to patients and healthcare services.

This chapter aims to quantify the impact of incisional hernia to patients and healthcare services in England.

2.2 Methods

This was a retrospective cohort study performed using population level observational data taken from the Hospital Episode Statistics (HES) database. The primary objective was to describe the rate of incisional hernia repair following open abdominal surgery, and its subsequent impact on both the patient and healthcare services. Secondary objectives include the rate of incisional hernia repair according to surgical specialty, identifying risk

factors for subsequent incisional hernia repair and the Healthcare Resource Usage (HCRU) and cost associated with incisional hernia repair..

a) HES database

HES is a data warehouse containing records of all patients admitted to NHS hospitals in England, including private patients treated in NHS hospitals and patients who reside outside of England. Also included in HES is care delivered by treatment centres, including those in the independent sector, which are funded by the NHS (Thorn et al. 2016). The HES database contains data on hospital diagnoses, procedures, treatment, healthcare resource use (including inpatient admissions [elective and non-elective], outpatient visits, and Accident and Emergency [A&E] visits). Associated Healthcare Resource Group (HRG) codes are also recorded in HES to track the activity-based income hospitals in England get for given HCRU (Chapman et al. 2016).

International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) codes are used to define disease diagnoses, and Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures 4th Revision (OPCS-4) codes are used to classify interventions, procedures, and procurement for treatment.

Healthcare providers and researchers can apply for access to HES, which provides anonymised observational level data, ensuring patient confidentiality. Small numbers (events occurring < 7 times within the database) are suppressed to avoid identification of patients with rare or unusual conditions. Patient data is split into coding categories and needs to be requested separately before being combined. OPCS (operative) codes, ICD-10 (diagnosis) codes and Electronic Medical Record (EMR) data each contain different aspects of patient data and are provided independently based on a generic HES-assigned patient code.

b) Patient selection: Identification of index surgery and incisional hernia.

All adult patients (over the age of 16) with an OPCS-4 code recording an inpatient admission for intra-abdominal, urologic or gynaecologic surgery in HES between 1st April 2014 to 31st March 2017 were requested from HES and included. These OPCS codes (**Appendix 1**) were used to define our population undergoing surgery. Many patients, however, underwent

multiple operations throughout this time period, so the first major operation identified was termed the "index surgery". These patients were then followed up with OPCS codes for 2 years prior to their index surgery (June 2012) to allow identification of pre-existing surgery and previous incisional hernia repair, as well as for 5 years after index surgery (until June 2022) to assess for subsequent operations and incisional hernia repair.

Electronic medical records for patients undergoing index surgery were accessed from HES between 1st June 2012 to 30th June 2022. These were used to identify risk factors for incisional hernia development present at index surgery and comorbidities, as well as post-operative complications and post-operative HCRU. Patients were excluded if they had less than 12 months follow up as this would not allow enough time for incisional hernia to occur, had an incisional hernia repair prior to or during their index surgery, had multiple surgical specialties at the time of index surgery (for example undergoing a joint gynaecological and urological procedure), or who had a caesarean section recorded at any time. A flowchart of this search strategy can be seen in **Figure 5.**

Patients identified as undergoing index surgery were further categorised into two sub-cohorts: those with incisional hernia repair after index surgery (termed incisional hernia repair, and used as a surrogate for incisional hernia), and those who did not undergo repair. Incisional hernia repair was defined by the presence of both an ICD-10 code for abdominal hernia and an OPCS-4 procedure code for incisional hernia repair within the post-operative follow up period.

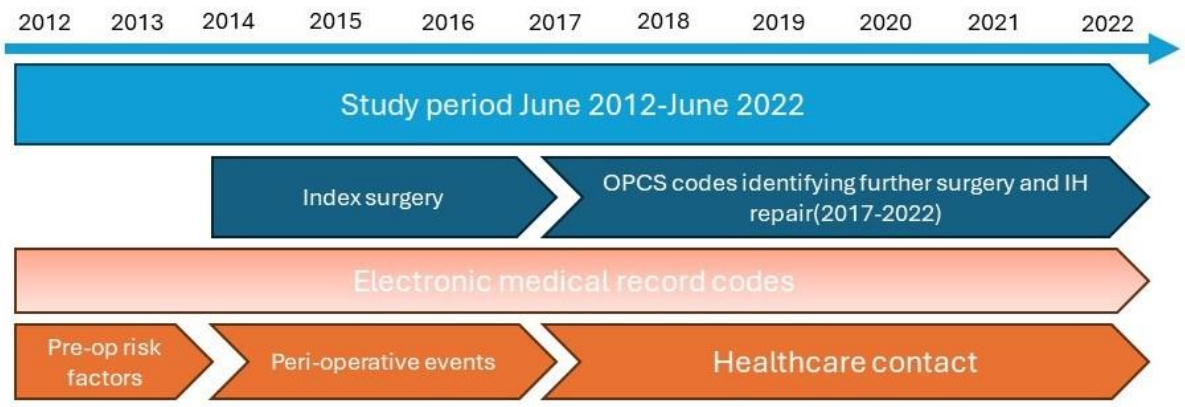

Figure 5: A flowchart showing search periods for different datasets within HES

c) Identification of pre- and post-index surgery variables

ICD-10 codes from the EMR were used to identify relevant pre-operative risk factors recorded in HES at the time of index surgery and post-operative complications. If an incisional hernia repair was recorded after index surgery, only post-operative complications recorded prior to the incisional hernia repair were recorded, and follow-up stopped after the incisional hernia repair. This was done to avoid including complications and costs following the incisional hernia repair and give an accurate reflection of the patient burden and costs associated with primary incisional hernia.

HES data was used to identify scheduled and unscheduled secondary care encounters including elective and non-elective inpatient admissions, outpatient visits and A&E attendance in the follow-up period. Length of stay (LOS) was calculated as the duration of each unique non-elective inpatient admission in days.

HCRU costs were derived by mapping HRG codes to Payment by Results (PbR) NHS National Tariff Workbooks of costs for the applicable financial year of resource use (NHS Digital 2009). All-cause HCRU costs were defined per patient as the cumulative cost of index surgery, all post-index inpatient admissions (elective and non-elective) and outpatient visits within the study period.

d) Statistical analysis

Statistical analysis was completed using R version 4.2.2 (R Core Team, 2022). Rates of incisional hernia repair were calculated as a percentage of patients undergoing a post-index incisional hernia repair over the total population of patients with an index surgery of interest recorded between 1st April 2014 to 31st March 2017.

In addition, separate univariate Cox proportional hazard (PH) models were used to determine the incidence risk of incisional hernia repair from index surgery for pre-operative risk factors of interest with hazard ratios (HRs) with 95% confidence intervals (95% CIs) and associated p-values presented. Person-years at risk was calculated from index surgery until earliest of first incisional hernia repair recorded, patient death, emigration from England or end of the study period (30th June 2022).

Descriptive statistics were used to describe post-index surgery complications and HCRU.

Small number suppression (i.e., events with <7 occurrences are replaced with a '*') was conducted in line with NHS digital guidance to prevent inadvertent patient identification (Herbert et al. 2017).

2.3 Results

A total of 297,134 patients were included in the study who had undergone abdominal surgery between 1st April 2014 to 31st March 2017, and were followed up for a median time of 6.5 years following that index surgery. Of those, 5.1% (n=15,138) underwent subsequent operative repair of incisional hernia. When analysed by index surgical specialty, colorectal surgery had the highest rates of incisional hernia repair at 10.0%, with gynaecological surgery having the lowest rates at 2.6%. A complete breakdown can be seen in **Table 2**Error! Reference source not found.. The median time from index surgery to incisional hernia repair was 24 months (Interquartile range [IQR] 13,42), patients most commonly underwent incisional hernia repair within the first 18 months following index surgery (**Figure 6**).

Table 2: *A breakdown rate of incisional hernia repair by surgical specialties*

Surgical Specialty	Number of patients undergoing index surgery	Number of patients undergoing Incisional hernia repair
Overall	297,134	15,138 (5.1%)
Bariatric & Gastrectomy surgery	18,344	635 (3.5%)
Colorectal surgery	68,127	6,778 (10.0%)
Gynaecologic surgery	83,268	2,142 (2.6%)
Hepatobiliary surgery	9,693	797 (8.2%)
Transplant surgery	11,548	781 (6.8%)
Urologic surgery	75,663	3,030 (4.0%)
Vascular surgery	30,491	975 (3.2%)

a) Risk factors for incisional hernia repair.

Patients undergoing incisional hernia repair had higher rates of diabetes (15.2% vs. 12.5%), smoking (23.5% vs 18.1%), Chronic Obstructive Pulmonary Disease (COPD) (8.6% vs. 5.1%) and obesity (18.7% vs. 14.7%) at the time of their index surgery when compared to patients who did not have incisional hernia repair. Univariate analysis of pre-operative risk factors revealed that patients older at index surgery (>50 years of age) (HR: 1.82, 95% CIs: 1.75-1.89, p<0.001), male (HR: 1.44, 95% CIs: 1.39 – 1.48, p<0.001) and with COPD (HR: 1.91, 95% CIs: 1.80-2.02, p<0.001) had the greatest risk of requiring subsequent incisional hernia repair (see **Table 3**).

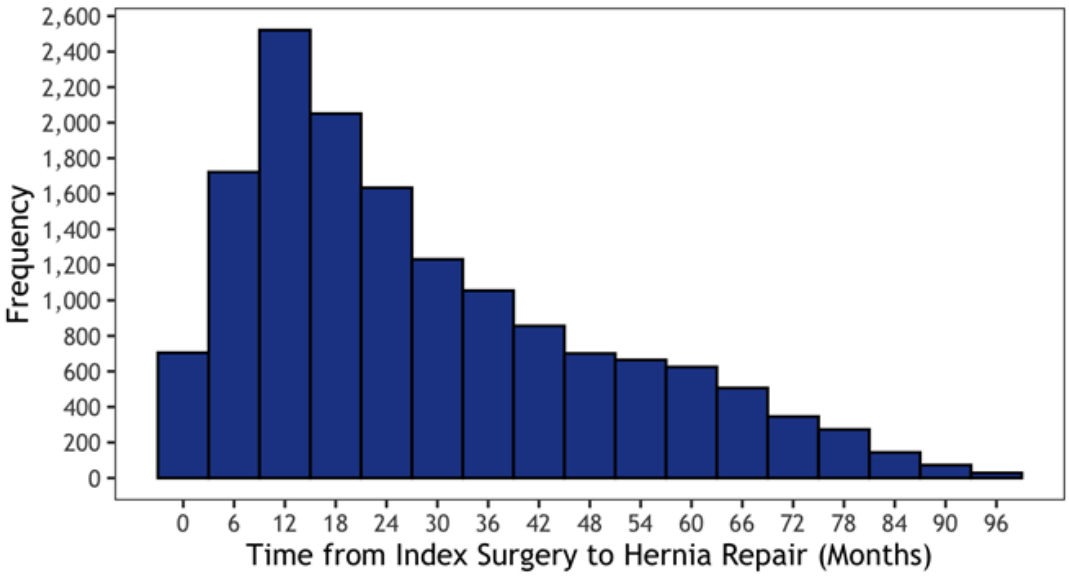

Figure 6: A histogram of time from index surgery to first incisional hernia repair for all incisional hernia repair patients

Table 3: *Univariate analysis of risk factors for incisional hernia repair*

	Hazard ratio	95% CIs	P-value
Gender			
Female	Reference	Reference	Reference
Male	1.44	1.39, 1.48	<0.001
Age at index operation			
18-50	Reference	Reference	Reference
51-70	1.82	1.75, 1.89	<0.001
71+	1.83	1.75, 1.92	<0.001
Ethnicity			
White (Caucasian)	Reference	Reference	Reference
Asian	0.74	0.67, 0.81	<0.001
Black or Black British	0.59	0.52, 0.66	<0.001
Other	0.75	0.66, 0.86	<0.001
Not known	0.57	0.53, 0.61	<0.001
Not Recorded	0.29	0.17, 0.49	<0.001
Charlson Comorbidity Index (CCI)			
0	Reference	Reference	Reference
1	0.65	0.41, 1.02	0.061

2+	1.74	1.69, 1.80	<0.001
Comorbidities			
Diabetes*	1.31	1.25, 1.37	<0.001
Smoking*	1.38	1.33, 1.44	<0.001
Chronic obstructive pulmonary disease [COPD]*	1.91	1.80, 2.02	<0.001
Obesity*	1.29	1.24, 1.35	<0.001
Immunosuppression*	1.26	1.14, 1.40	<0.001

*reference level = 'absence'

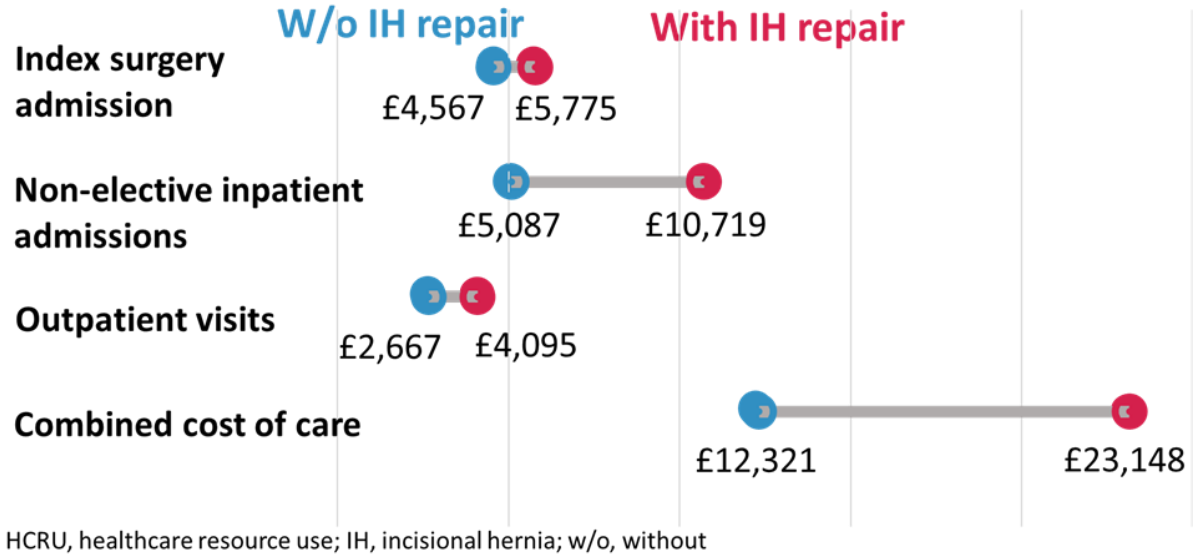

Figure 7: A breakdown of healthcare-associated costs

b) Post-operative complications

Of all patients undergoing abdominal surgery, 32.8% (97,371) experienced a postoperative complication, breakdowns of which can be seen in **Table 4**. Following index surgery, patients who went on to have incisional hernia repair had experienced higher rates of surgical site infection (23.6% vs 10.1%), wound dehiscence (7.2% vs 1.6%), bleeding (necessitating blood transfusion) (13.9% vs 6.8%), fistulation (2.8% vs 0.6%), and small bowel obstruction (10.2% vs 4.0%). This translated to a longer median length of stay (LOS) at index surgery (7 days [IQR: 4,13] vs 3 days [IQR: 2,7]) for patients who would have a future repair. Patients undergoing incisional hernia repair had higher rates of referral to mental health services (19.8% vs 11.5%), and chronic pain services (2.1% vs 1.0%) in the follow-up period compared to patients who did not have incisional hernia repair.

c) Healthcare Resource Usage and costs

Table 5 shows the differing healthcare-related attendances between those undergoing incisional hernia repair and those who did not, alongside associated costs. In the period following index surgery 62.5% of patients with an incisional hernia repair had ≥2 non-elective admissions to hospital, with the median number of non-elective admissions being 2 (IQR: 1,5) vs. 37.0% of patients without a post-index incisional hernia repair, with the median number of non-elective admissions being 1 (IQR: 0,3) in these patients. The median cumulative LOS per patient for non-elective inpatient admissions was 8 days (IQR: 1, 28) in patients with an incisional hernia repair and 1 day (IQR: 0, 10) in patients with no repair post index surgery.

Patients who underwent incisional hernia repair averaged total costs of £23,147 per person (pp) in the follow-up period between index surgery and incisional hernia repair, compared to £12,320pp in those who did not undergo incisional hernia repair, as shown in **Figure 7**, above. The average cost of an operative incisional hernia repair admission per patient was £2,155. The total cost of care in all patients undergoing incisional hernia repair within this study period was £350,414,424 compared to £186,515,298; a cost-difference of £163,899,126. A complete breakdown of healthcare usage and cost can be seen in **Table 5**.

Table 4: *Surgical complications following index surgery*

Surgical complications following index surgery	Total patients with index surgery	IH repair (n=15,138)	No incisional hernia repair (n=281,996)
All combined	97,371 (32.8%)	8,648 (57.1%)	88,723 (31.5%)
Superficial wound infection	32,125 (10.8%)	3,579 (23.6%)	28,546 (10.1%)
Wound dehiscence	5,714 (1.9%)	1,083 (7.2%)	4,631 (1.6%)
Wound haematoma	10,622 (3.6%)	1,525 (10.1%)	9,097 (3.2%)
Post-operative bleeding [1]	21,269 (7.2%)	2,108 (13.9%)	19,161 (6.8%)
Fistula	2,049 (0.7%)	431 (2.8%)	1,618 (0.6%)
Sepsis	28,898 (9.7%)	2,511 (16.6%)	26,387 (9.4%)
Small bowel obstruction	12,950 (4.4%)	1,539 (10.2%)	11,411 (4.0%)
Depression[2]	35,553 (12.0%)	2,998 (19.8%)	32,555 (11.5%)
Chronic pain[2]	3,175 (1.1%)	321 (2.1%)	2,854 (1.0%)

[1] Necessitating blood transfusion / use of blood products.

[2] New diagnosis or referral to secondary services post index surgery and prior to incisional hernia repair (if recorded).

Table 5: *Healthcare resource use and costs*

Healthcare Resource Use		
	IH repair	**No incisional hernia repair**
Index surgery length of stay (LOS) (Days)	7* (4, 13)	3* (2, 7)
Number of patients with at least 1 non-elective admission	12,296 (81.2%)	160,481 (56.9%)
Number of patients with ≥2 non-elective admissions	9,454 (62.5%)	104,227 (37.0%)
Number of non-elective inpatient admissions per patient	2* (1, 5)	1* (0, 3)
Number of elective inpatient admissions per patient	1* (0, 1)	0* (0, 0)
Total cumulative LOS for non-elective inpatient admissions per patient (Days)	8* (1, 28)	1* (0, 10)
Healthcare Resource Use Costs		
Total Costs, Mean per patient (standard deviation [SD])	**IH repair**	**No incisional hernia repair**
Admission for index surgery	£5,774.78	£4,567.13
Non-elective inpatient admissions	£10,718.94	£5,086.53
Outpatient visits	£4,095.12	£2,666.84
All-cause HCRU costs	£23,147.70	£12,320.55
Total cost of care for matched cohort size	£350,409,883	£186,508,486

*Median (IQR)

2.4 Discussion

This retrospective review of population-level data from England describes the post-operative journey that patients undergo following abdominal surgery in England. A recent publication from the French national database estimated the cost of incisional hernia repair to be €4153 per repair, in keeping with other publications (Ortega-Deballon et al. 2023b). This work is the first, however, to describe the morbidity and cost incurred to patients between their index surgery and repair.

Our results demonstrate that 5% of all patients undergoing abdominal surgery will undergo subsequent repair of incisional hernia. This figure is identical to data published from the French national database by Gignoux et al. who demonstrated a re-operation rate of 5% over a 5-year follow-up period, alongside data from a systematic review by Bosanquet et al which reported the risk of undergoing incisional hernia repair of 5.2% (Bosanquet et al. 2015; Gignoux et al. 2021). Surgical specialties with higher rates of incisional hernia included colorectal, hepatobiliary and transplant surgery, with lower rates identified in urologic, bariatric, vascular and gynaecologic surgery.

Higher rates of incisional hernia repair in colorectal and transplant patients are consistent with the findings of Basta et al. (2019), who reported rates of 7.7% and 4.8% respectively (Basta et al. 2019). Hernia repair has traditionally been the bastion of the general surgeon, and higher rates of hernia repair in the general surgical subspecialties may simply be due to increased awareness and early detection, without the delays of referral to another specialty. This is supported by lower-than-expected rates of repair in non-general surgical specialties such as gynaecology and urology.

In this study, the median time from index surgery to incisional hernia repair was 24 months, with 46% undergoing incisional hernia repair within 18 months of index surgery. As previously discussed, the risk of developing incisional hernia post-operatively peaks at 3 years, therefore a rate of repair of 50% at 24 months implies a selection bias towards a certain cohort of patient. A similar finding was reported in a 2015 paper assessing outcomes of incisional hernia repair. (Köckerling et al. 2015). In their cohort of patients, 55.7% of patients with recurrence after IH repair had undergone another repair within 2 years. The

authors postulated that this early recurrence was due to surgical or "technical" factors such as suture failure, whereas later recurrences were due to "hernia biology" such as tissue weakening, aging and patient-related factors. This has also been observed in inguinal hernia repair (Magnusson et al. 2010). This study noted that increased rates of post-operative complications was associated with early recurrence, something that was especially prevalent in our cohort of patients who underwent incisional hernia repair. It is possible therefore, that the high rate of early incisional hernia repair may well be due to "technical" failure of the abdominal wall to heal, with higher rates of post-operative complications in the hernia repair group compared to those who did not undergo repair.

Patients undergoing vascular surgery, specifically aortic surgery (Antoniou et al. 2011), are at increased risk of incisional hernia development, so it is perhaps surprising to see lower rates of incisional hernia repair than average in our cohort. The reasons for this are not immediately apparent but may reflect a more comorbid population group that are unfit for subsequent incisional hernia repair.

This study demonstrates that patients undergoing incisional hernia repair have increased rates of complications after their index surgery, such as surgical site infection (SSI), wound dehiscence and fistulation compared to patients that do not undergo repair. Incisional hernia occurs as a result of failure of the abdominal wall to heal. SSI, dehiscence and fistulation represent impaired wound healing and have been recognised in the literature as risk factors for IH development (Henriksen et al. 2013; Tubre et al. 2018; Hope and Tuma F 2023). In our cohort, 19.8% of patients undergoing incisional hernia repair were referred to mental health services in the time period between index surgery and incisional hernia repair. Van Ramshorst et al. in 2012 demonstrated lower quality of life and body image scores in patients with incisional hernia compared to those without, yet there was no difference in scores for the mental health component of the Short Form 36 questionnaire (SF-36) between the two groups (van Ramshorst et al. 2012). The link between incisional hernia and referral to mental health services in our results is not clear; the differing rates in our study may reflect the impact that post-operative complications have on the patient rather than being attributed to the hernia alone. Nonetheless, our data supports the importance of "getting it right first time" both in terms of reducing post-operative complications and subsequent impact on patient wellbeing.

Given that patients undergoing incisional hernia repair have higher rates of post-operative complications, it is perhaps not surprising that healthcare associated resource use is higher in this group of patients than in those with no repair. Increased post-operative length of stay and more unplanned hospital attendances translates to an average cost difference of £10,827 per patient between each group, and a matched cohort-size cost difference of over £163 million. Consistent with the findings reported above, a cost analysis of incisional hernia in a population of US patients published by Fischer et al. demonstrated higher average readmission costs in patients with incisional hernia, as well as higher combined costs of care ($41,053 vs $81,183, p<0.001) (Fischer et al. 2016). The costs described in these results exclude those of the incisional hernia repair along with subsequent care and suggest that the financial burden of incisional hernia is greater still.

a) Strengths and limitations

The strengths of this study lie chiefly in the sample size, with inclusion of nearly 300,000 patients. This allows us to have confidence in our conclusions and the narrative that this observational study describes. As discussed above, the results of this work fits with data published elsewhere in the literature suggesting the data to be both accurate and reliable. Moreover, this is the first study that aims to highlight the cost of incisional hernia within the United Kingdom.

There are limitations to this work, chiefly the use of incisional hernia repair as a surrogate for diagnosis of incisional hernia. As previously mentioned, rates of incisional hernia vary from 12.8-30% in the literature, therefore our rate of repair is an underestimate of the true rate of herniation in our cohort. As discussed earlier, patients who do not undergo early repair of incisional hernia may have developed them due to reasons such as poor tissue healing, increasing age, or co-morbidities, which in turn may make them unsuitable for surgical repair. This is also likely to contribute to the lower rates of repair in specialties with co-morbid populations such as vascular surgery. Further work is needed to identify and chart the morbidity, cost and decision making in patients diagnosed with incisional hernia who do not undergo operative repair, as it appears that it is the minority of patients who undergo incisional hernia repair. It is a sobering thought to consider that these calculations

are likely an underestimate of the true burden on incisional hernia to patients and healthcare services.

Another limitation is the inability to draw cause and effect between cost, attendances, and incisional hernia repair. Our data demonstrates that most of the cost difference is in non-elective admissions. Whether these admissions are related to the incisional hernia itself, or as a consequence of the increased rates of post-operative complications is not clear, and further work in this area is needed. Nonetheless, the risk of needing incisional hernia repair is increased in patients who suffer complications following their index surgery. Focus should be on prevention of not just incisional hernia at index surgery, but also on the post-operative complications, such as SSI and wound dehiscence that correlate with increased incisional hernia rates.

2.5 Conclusion

This data has shown that 5% of all patients undergoing abdominal surgery will undergo further surgery to repair an incisional hernia, and charts what happens to these patients before they undergo their repair. In order to reduce the risk of incisional hernia and the burden to both patients and healthcare services, the focus needs to be on prevention. Implementation of current European and American Hernia Society guidance (Deerenberg et al. 2022), alongside pre-operative risk assessment and targeted mesh-augmented abdominal wall closure will reduce the incidence of incisional hernia but need to be combined with broader national improvement programmes such as “Getting It Right First Time” (GIRFT) in order to reduce variation in all aspects of peri-operative surgical care, across surgical specialties(Abercrombie. 2022). Prevention of incisional hernia should not be the focus of one surgical specialty and further work is needed to raise awareness of both incisional hernia and prevention outside of the traditional specialties.

Patients undergoing abdominal surgery are at risk of developing incisional hernia, regardless of surgical specialty. Patients who undergo repair of incisional hernia are more likely to have increased rates of post-operative complications and have higher rates of healthcare usage and costs of care compared to patients who do not undergo surgery.

Chapter 3: How are we doing?

A systematic review and meta-regression of incisional hernia rates in midline incisions.

Acknowledgments

I am grateful to Mr David Bosanquet, the lead author of the original paper referenced in this chapter, for his help in replicating the methodology used. Mr Bosanquet provided verbal clarification about how certain steps were taken, as well as access to original databases used in the 2015 paper which ensured that the correct variables were collected.

I must also thank Mr Brenig Gwilym, who offered statistical support in performing the meta-regression, and to Mrs Harriet Coxon-Meggy, Mr Ife Osinkolu, Mr Alexander Lukaszewicz and Mr Matthew Mckenna who helped with data collection.

3.1 Introduction

As discussed in the previous chapter, incisional hernia is a prevalent condition that has a huge burden on patients and healthcare services alike. With a large body of evidence, discussed in Chapter 1, it is worth considering if implementation of international guidelines has impacted rates of incisional hernia within the literature.

In 2015, Bosanquet et al. published a systematic review of incisional hernia rates in 14,618 patients undergoing midline abdominal incisions between 1980 and 2013 (Bosanquet et al. 2015). Their widely cited paper reported an incisional hernia rate of 12.8%, alongside patient factors (increasing age, obesity surgery, surgery for AAA, upper midline incision), study factors (including patients with previous laparotomies and those with previous incisional hernia) and circumstantial variables (later year of publication and specifying an exact significance level) that correlated with increased incisional hernia rates.

Over the last 9 years however, the landscape has changed. EHS guidance published in 2015 set standards for abdominal wall closure, alongside standards for trials into prevention of incisional hernia, such as radiological reporting and minimum length of follow-up (Muysoms et al. 2015). Awareness of abdominal wall closure techniques such as small stitch has become widespread, although adoption is low, and attention has turned to mesh-augmented abdominal wall closure to reduce incisional hernia rates (Jairam et al. 2020).

In this systematic review, we aimed to identify the rates of incisional hernia in midline incisions since 2013, alongside factors identified through meta-regression that contribute to incisional hernia development. When compared and contrasted this to the original paper published by Bosanquet et al. (2015) in an attempt to establish both what has changed, and the reasons for this.

Aims:

1. To identify the rate of incisional hernia in midline incisions
2. To identify risk factors for incisional hernia development

3.2 Methods

A systematic review of literature was conducted according to PRISMA guidelines (Page et al. 2021) and registered on PROSPERO (CRD42022348857).

This study was designed to be an update of the 2015 publication by Bosanquet et al., which identified factors affecting incisional hernia rates in midline incisions from 1980 to March 2013 (Bosanquet et al. 2015). They identified a midline incisional hernia rate of 12.8% alongside predictors of incisional hernia development. In order to allow comparisons over time, study design was matched to the original paper with the support of the original study team.

a) Design of search strategy

A search strategy was designed to capture incisional hernias that form in the midline. MeSH terms were created around three domains: type of hernia, location of incision and hernia. The term "AND" was used to combine the three domains, which can be seen in **Table 6**.

Databases including Medline, Embase via OVID, Pubmed, Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews were searched from April 2013 to October 2022. All papers were included in this search and collated into a spreadsheet on Microsoft Excel®.

Table 6: *Design of search strategy*

Type of hernia	Location of incision	Hernia
Incisional OR Ventral OR Abdominal	Midline OR Laparotomy	Hernia OR Herniation
Final search terms		
(Incisional OR Ventral OR Abdominal) AND (midline OR laparotomy) AND (hernia or herniation)		

b) Paper selection

Two independent reviewers screened all titles and abstracts for relevant texts, with disagreements being settled by a senior author. At full-text review, papers were included if they were available in English, included a population of adult patients undergoing abdominal surgery through a primary midline incision, and had both rate of incisional hernia and length of follow-up specified. Papers were excluded if they reported incisional hernia repair, included non-midline incisions, or employed additional methods of abdominal wall closure such as mesh prophylaxis or deep tension sutures, alongside studies that did not report length of follow-up.

Papers comparing primary midline closure with another closure or incision such as mesh prophylaxis or non-midline wounds were eligible to be included, provided that the data from the midline closure group was able to be independently extracted. Randomised-control trials, cohort studies and case-control series were eligible to be included. We excluded population-based studies.

C) Data extraction

An existing database used by this group for previous systematic reviews was used as a template for data abstraction. This was tested on two papers, and, following feedback from

authors, adapted to capture large or small bite suture technique. Five reviewers assessed full text papers for eligibility according to inclusion/exclusion criteria detailed above and extracted data for included studies. A full list of variables extracted can be seen in **Appendix 2**. In papers that reported patients lost to follow-up, we included the number of patients at follow-up, rather than enrolment, as the denominator.

d) Quality assessment

The Downs and Black checklist were chosen to assess methodological quality of included studies as it allows comparable assessment of both randomised and non-randomised trials

e) Statistical analysis

Data was collated in Microsoft Excel®. Forest plots and weighted means were created in OpenMeta[Analyst]® (Accessed from: www.cebm.brown.com/openmeta) using random-effects modelling (Wallace et al. 2012). Continuous data was summarised using means or median (means if available). Means were weighted by number of patients to estimate incisional hernia rates. Confidence intervals were calculated by weighted t-tests or regression outputs.

Meta-regression was performed using the statistical programming environment 'R'® using the 'mice' package. Prior to regression analyses, missing data were analysed for the pattern of missingness which was 'missing completely at random', therefore, multiple imputation was used to handle missing data using the Markov chain Monte Carlo method (25 imputation sets). Regression analyses were conducted on imputed data using the weighted least squares method. Variables selected for univariate analyses were selected by author consensus. Variables with a p-value<0.2 in univariate analyses were included in multivariate analysis. Backward stepwise multivariate regression was conducted, with significance set to $p<0.05$.

3.3 Results

Initial searches identified 4579 papers, of which 85 were included for full text review (**Figure 8**). 63 papers (21 RCTs, 36 cohort studies and 6 case-control studies) were judged to have met the inclusion criteria and were included in this analysis (**Appendix 2.2**). Of these, 19 studies (11 RCTs, 6 Cohort studies and 2 Case-control series) had more than one independently extractable arm, allowing analysis of 82 individual groups comprising a total of 18,126 patients. The median Downs and Black score was 20 (Range 14-28, IQR 18-23). A forest plot of incisional hernia rates by included studies can be seen in **Appendix 2.3.**

The mean incisional hernia rate was 16.8% (95% C.I 14.6-18.3%) at a weighted mean follow-up of 31.3 months (**Appendix 2.3**). There was significant heterogeneity between included studies (I^2 94.4%, p<0.001). Duration of study follow-up did not affect incisional hernia rates (p=0.848). A funnel plot of incisional hernia rate by study size can be seen in (**Figure 10)**. The graph shows an uneven spread of patients around the mean, with smaller studies having a wider spread of incisional hernia rates, and larger studies trending towards lower-than-expected rates.

Year of publication was used as a surrogate for the date of surgery. shows no significant change in incisional hernia rates over the study period (**Figure 9**) (p=0.941). When combined with data from studies included in the 2015 paper however, an increase in both number of papers and incisional hernia rate can be seen over time (**Figure 11).**

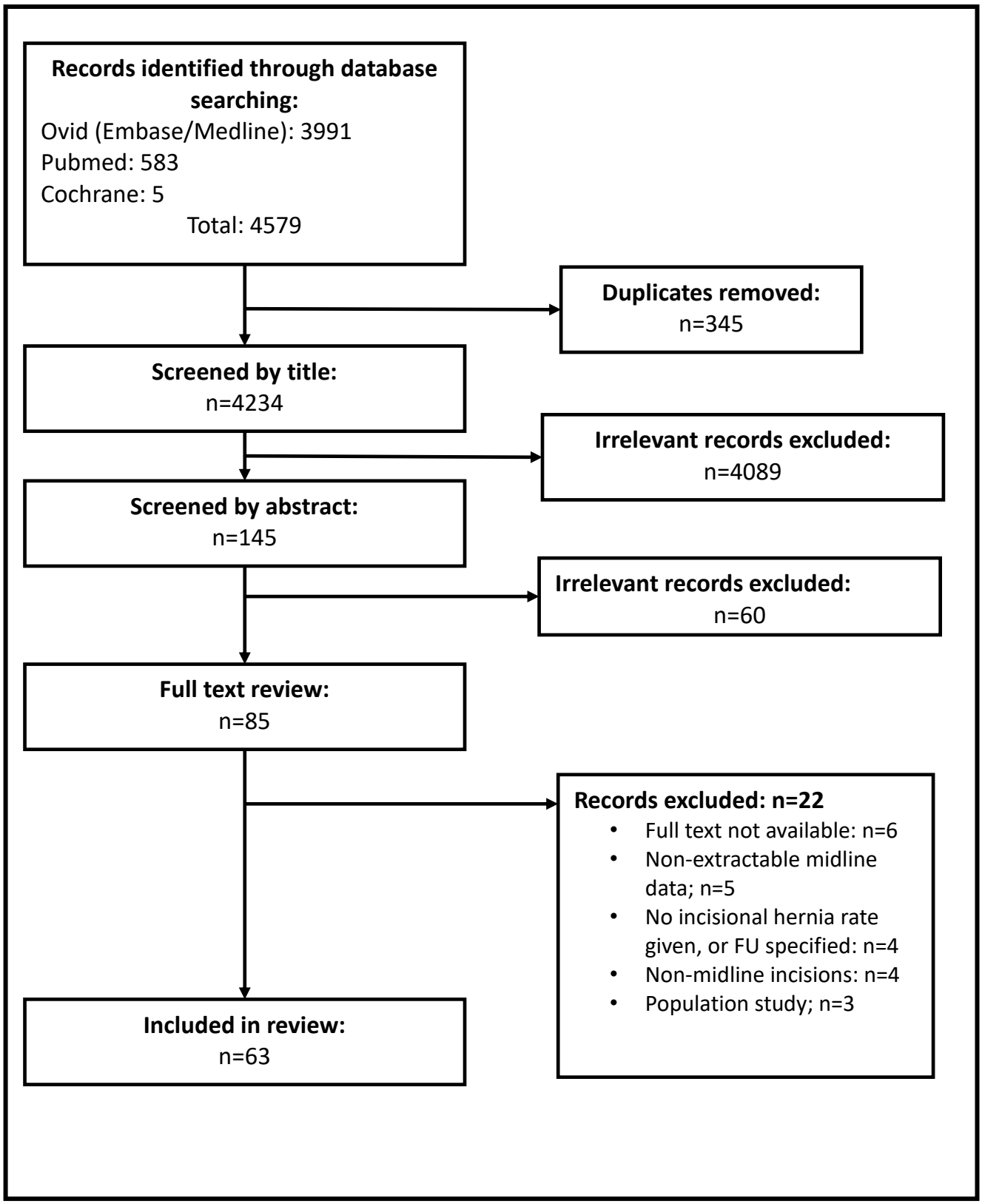

Figure 8: A PRISMA diagram of search strategy

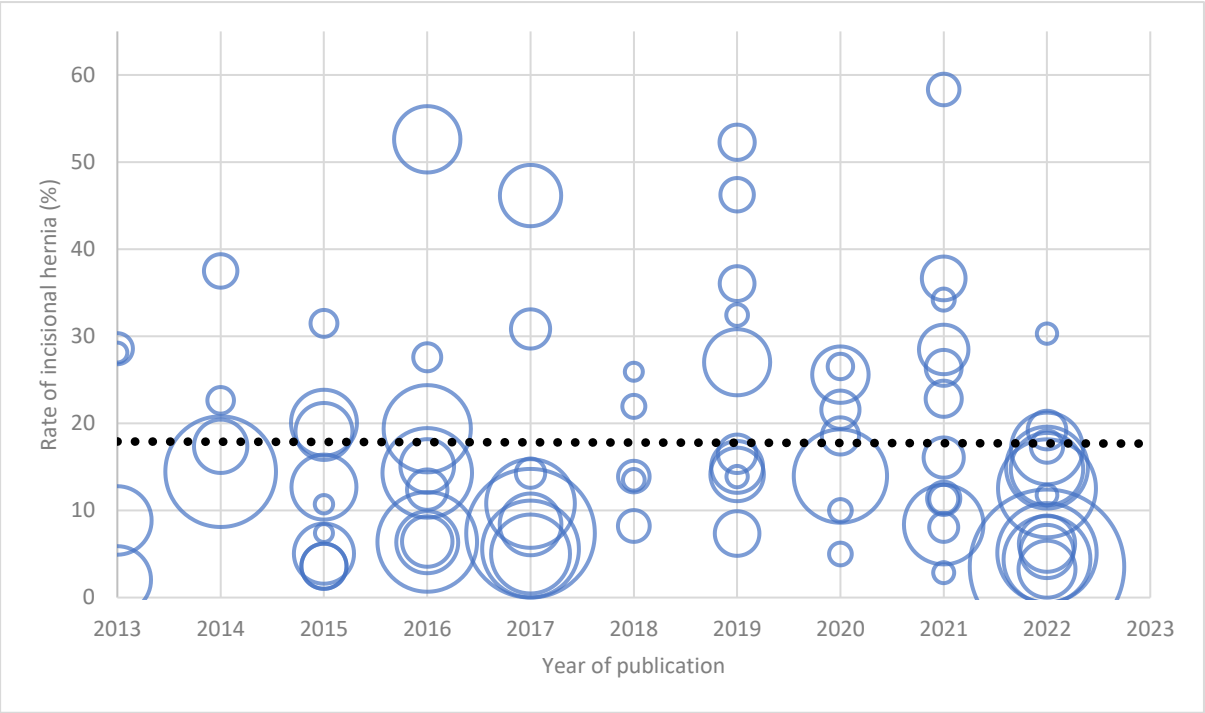

Figure 10: a bubble chart of incisional hernia rate by year of publication from 2013-2022 (Bubble size indicates size of study population)

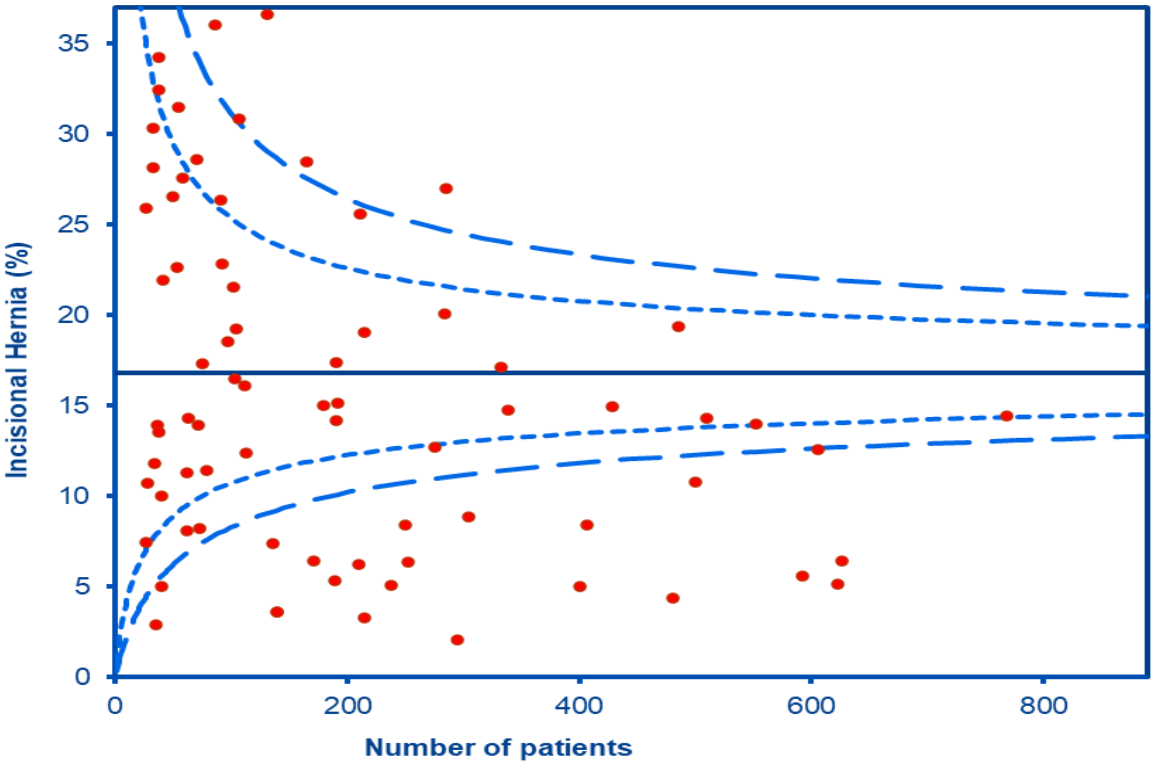

Figure 9: A funnel plot of incisional hernia rate (Y axis) and number of patients (X axis). Dashed lines indicate +- 3 standard deviations from the mean. Feint lines indicate +- 2 standard deviations

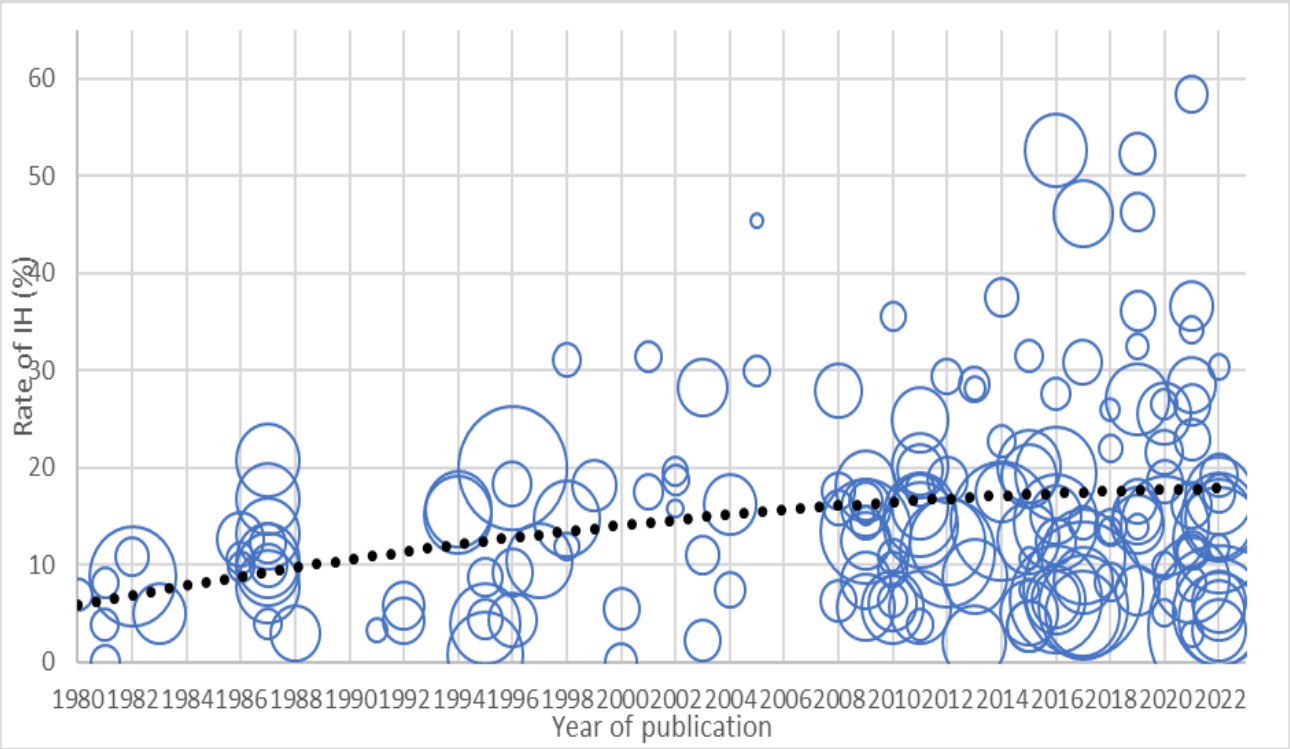

Figure 11: A bubble chart of incisional hernia rate by year of publication, from 1980 to 2022

a) Study characteristics

We observed comparable incisional hernia rates between studies that performed retrospective and prospective data analysis (17.47% vs 18.27%, 95% C.I -6.51-4.91, p=0.781), and studies that included patients on steroid therapy (19.71% vs 18.44%, 95% C.I -8.58-11.11, p=0.798).

There were higher, but not significant, rates of incisional hernia in randomised control trials compared to non-RCTs (19.51% vs 16.79, 95% C.I -3.04-8.47, p=0.350), studies that did not recruit consecutive patients (22.20% vs 16.82 %, 95% C.I -17.59-6.83, p=0.382), studies that included patients with previous incisional hernia (22.79% vs 17.40%, 95% C.I -2.36-13.15, p=0.169), and in studies that included immunosuppressed patients (19.03% vs 15.95%, 95% C.I -12.91-6.73, p=0.531).

Significantly higher rates of incisional hernia were noted in studies that included a radiological definition of incisional hernia (21.68% vs 13.88%, 95% C.I -13.79 to -1.80, p=0.012), studies that included patients with previous laparotomy (20.16% vs 14.25%, 95% C.I -11.67 to -0.15, p=0.044) and studies that included patients undergoing emergency surgery (20.35% vs 12.10%, 95% C.I -13.73 to -2.76, p=0.004).

b) Regression analysis

Study characteristics were abstracted, and binary variables were aggregated into categorical variables. Nine variables; two patient factors, four operative factors and three study level factors achieved a significance level of 20% and were included in the meta-regression analysis (**Table 7**).

Meta-regression identified two variables that correlate with increasing incisional hernia rates (use of radiology for diagnosis of incisional hernia and patients undergoing a contaminated procedure), along with one variable (small bites technique) that correlated with a decrease in incisional hernia rates (**Table 8**).

Table 7: *Variables with p ≤0.2 identified on univariate analysis*

Variable	Coefficient (SE)	95% confidence interval	p value
Small bite closure*	-0.09 (0.04)	-0.17 to -0.02	0.013
Inclusion of patients undergoing emergency surgery	6.27 (3.06)	0.12 to 12.42	0.046
Incisional hernia detected radiologically	6.84 (3.49)	-1.12 to 13.8	0.054
Contaminated surgical field*	0.19 (0.11)	-0.02 to 0.40	0.078
Inclusion of patients with previous laparotomy	4.65 (2.82)	-1.00 to 10.32	0.105
Large bite closure*	0.06 (0.03)	-0.01 to 0.13	0.105
Continuous closure method*	0.04 (0.03)	-0.02 to 0.10	0.172
Trials conducted at a single institution	8.80 (4.36)	-4.46 to 22.05	0.190
Congestive Cardiac Failure*	0.12 (0.09)	-0.07 to 0.31	0.200
*Denominates a continuous variable representing the proportion of the cohort that the variable applies to			

Table 8: *Variables achieving significance (p<0.05) on multivariate analysis*

Variable	Coefficient (SE)	95% confidence interval	Significance level
Presence of contaminated operating field	0.27 (0.08)	0.10 to 0.44	0.002
Small bite closure	-0.09 (0.03)	-0.16 to -0.001	0.003
Only clinical diagnosis of incisional hernia included	Reference	n/a	n/a
Radiological *or* clinical diagnosis of incisional hernia included	7.20 (3.09)	1.04 to 13.36	0.023
Only radiological diagnosis of incisional hernia included	10.91 (5.10)	0.73 to 21.08	0.036

3.4 Discussion:

In this systematic review of 18,126 patients undergoing midline incisions, we identified a weighted mean rate of incisional hernia of 16.8%, alongside three predictors; two which increase incisional hernia rates; presence of a contaminated field, and using radiological diagnosis of IH, and one which decreases; Small bites closure.

Rates of incisional hernia in midline incisions have increased over time, from a weighted mean of 12.8% between 1980 and 2013, to 16.8% between 2013 and 2022. The reasons for this are multi-factorial and likely represent an under-reporting of historical incisional hernia rates rather than a true increase. Standardisation of reporting measures for trials implemented in 2015 have almost certainly helped in this and this change in rates over time suggest that we are getting better at detecting incisional hernia (Muysoms et al. 2015).

Since 2013 however, rates have plateaued implying that surgical technique alone is not reducing incisional hernia rate in midline incisions. The rate of incisional hernia has remained static since 2013, suggesting that implementation of EHS 2015 guidance on the closure of midline incisions and standardisation of both suture choice and suture material may be the cause for plateauing rates (Muysoms et al. 2015). The results of our meta-regression imply that small bite closure technique is associated with a lower rate of incisional hernia, and it will be interesting to see if the implementation of this closure technique impacts hernia rates over the next decade.

The remaining 16% risk is likely to represent underlying, non-modifiable risk in the form of patient risk factors and the risk of midline incision itself. Risk factors for incisional hernia development are multi-factorial and dynamic; as life-expectancy continues to increase, surgeons are operating on aged populations with more co-morbidities that may not have been offered surgery previously. A greater understanding of non-modifiable risk is important in allowing quantification of risk to patients and in targeting higher-risk patients for prophylactic interventions such as mesh placement.

Evidence that EHS standardisation of trials is having an impact is strengthened by our finding that incorporating radiological detection of incisional hernia into study design is a significant predictor of incisional hernia rate - a recommendation made in 2015 (Muysoms et al. 2015).

Higher rates of incisional hernia in RCTs compared to non-RCTs suggests that standardisation of trial methodology is increasing detection of incisional hernia. High levels of heterogeneity amongst included studies, however, suggest more can be done to improve this, and future non-RCTs should look to implement these standards in their methodology. It is hoped that development of a core outcome set for incisional hernia will help to further standardise methodology and reporting outcomes for future trials (Harji et al. 2022).

As previously discussed, abdominal wall closure has been the focus of considerable research. Currently, there is consensus on the suture choice (monofilament), material (slowly absorbable) and technique (continuous) (Muysoms et al. 2015). Small bites closure technique has been shown to reduce incisional hernia rates compared to large bites closure in a recent systematic review of literature published in 2022 (Elsamani et al. 2022), and is recommended as the closure technique of choice for elective midline incisions by the European and American Hernia Societies (Deerenberg et al. 2022). Our study identified 7 papers (2 RCT's, 5 non-RCTs) that reported groups undergoing small bites closure. Of these, one RCT (Deerenberg et al. 2015), two cohort studies and one case series demonstrated a significant reduction in incisional hernia rates within the cohort closed by small bites (Thorup et al. 2019; Pereira Rodríguez et al. 2021; Pereira-Rodríguez et al. 2023). One RCT (Fortelny et al. 2022) demonstrated a non-significant reduction in rates, and the remaining studies (de Vries et al. 2020; Söderbäck et al. 2022) did not demonstrate a significant difference in rates of IH. It is worth noting that of the non-RCTs, three reported significant differences in follow-up times between small and large bite groups (Thorup et al. 2019; de Vries et al. 2020; Söderbäck et al. 2022), and one used patient survey as the definition for incisional hernia (Thorup et al. 2019). In the two RCT's, follow-up was only reported at 12 months. Nevertheless, results of our meta-regression support the use of small bites closure to reduce incisional hernia rates in midline incisions, although we eagerly await the results of long-term follow-up.

Bosanquet et al. reported several patient risk factors for incisional hernia development; increasing age, obesity surgery, aneurysm surgery, previous laparotomy and previous incisional hernia were all associated with increased risk of incisional hernia development (Bosanquet et al. 2015). In our paper, however, we identified just one; presence of contaminated operating field, defined as wounds recorded as classified as CDC class 3 and 4

(Berríos-Torres et al. 2017). These wounds are at increased risk of developing surgical site infections and are more prevalent in emergency surgery; both of which are risk factors for impaired wound healing and incisional hernia development (Garg 2014; Walming et al. 2017). Our results identified studies that included patients having emergency surgery as having significantly higher incisional hernia rates, confirming findings throughout the literature that suggest patients undergoing emergency surgery are at high risk for incisional hernia development (Basta et al. 2019; Pereira-Rodríguez et al. 2023).

Attention to reducing incisional hernia rates has focused on identification of the high-risk patient, with development of predictive models (Goodenough et al. 2015; Basta et al. 2019) and targeted use of mesh-prophylaxis in these patients appearing to reduce rates of incisional hernia development (Jairam et al. 2020). Our results identify three elements of patient risk that are significant; operations undertaken with a contaminated surgical field, studies that include emergency patients, and studies that include patients with previous abdominal surgery. To date, research into mesh prophylaxis has centred on elective surgery and in clean wounds, suggesting that mesh-augmented abdominal wall closure may not be suitable for this cohort of high-risk patients. Given that there is no consensus on optimal abdominal wall closure technique in emergency patients, and these patients are often excluded from randomised control trials, there is an urgent need for high-quality research in this high-risk group of patients (Deerenberg et al. 2022).

Finally, this systematic review focusses on incisional hernia rates in non-modified midline incisions. Evidence for mesh prophylaxis in midline incisions suggests that rates can be significantly lowered with the use of this technique (Jairam et al. 2020). As previously discussed, this is not yet a commonly practiced technique, and thus was not included in the scope of this review. There is also strong evidence that off-midline incisions significantly reduce rates of incisional hernia (den Hartog et al. 2023), and this systematic review strengthens the argument that the midline should be avoided wherever possible. A meaningful reduction in incisional hernia rates is likely to come with increasing evidence and implementation of techniques to increase uptake of mesh-mediated abdominal wall closure and off-midline incisions.

3.5 Conclusions

Incisional hernia rates have increased over time affecting 1 in 6 patients undergoing midline incisions. Given the plateau of rates since 2013, this is likely to represent the true rate of incisional hernia and represents non-modifiable risk to patients. Small bites closure technique is associated with significantly lower incisional hernia rates and should be the closure technique of choice in the closure of midline incisions. Urgent attention is needed to address the optimal closure strategy in high-risk patients in whom mesh-augmented abdominal wall closure may not be suitable, alongside implementation strategies to increase the use of non-midline incisions.

Chapter 4: The surgeon as the risk factor

Identification and implementation of modifiable risk factors

Acknowledgements

This is an unplanned retrospective review of a published, funded randomised control trial. The findings in this study have not been published elsewhere and were not included in the funding report, thus constituting original findings.

I am grateful to the HART collaborators and HART trial for their support in publishing these findings.

4.1 Introduction

As established in previous chapters, the incidence of incisional hernia has increased over time, and this is posing a significant burden to both patients and healthcare services. Identification of modifiable risk factors may help to begin reducing these rates.

a) Modifiable vs non-modifiable risk factors

Risk factors can be generalised into two categories: modifiable and non-modifiable.

Non-modifiable risk factors have an important role in risk-prediction and can be used to risk-stratify patients, but the benefit that they offer is limited: They can be considered, but they cannot be altered or adjusted. Non-modifiable risk-factors for incisional hernia development include presence of previous surgery (Bosanquet et al., 2015), type of surgery such as emergency or elective (Basta et al., 2019), smoking history (Sørensen, 2005) and certain co-morbidities such as hypertension or renal disease. When taken into context prior to the operation, these risk factors can help clinicians to better explain risk to patients, and prompt surgeons to consider adjuvant closure strategies such as mesh prophylaxis.

Modifiable risk factors, as the name suggests, are any factor that can be altered or changed by either the clinician or patient. Regarding patient risk factors for developing incisional hernia, obesity, current smoking status, diabetes and physical conditioning are all elements that can be regulated, or improved, given enough time before an operation. Surgical factors, however, are modifiable for every patient and therefore have been the focus of extensive research. Factors such as closure method, type of suture and location of incision, alongside reducing surgical site infections have been the attention of multiple interventional trials, with surgeons attempting to reduce the risk to the individual (Pinkney et al. 2011; Deerenberg et al. 2015; Torkington et al. 2022).

Regarding incisional hernia prevention, modifiable risk factors are likely to provide the greatest chance of reducing overall risk to patients, not through any one intervention, but through a cumulative effect. It is important, therefore, that focus is paid to identifying, and correcting, these factors.

b) Surgical education

Midline laparotomy is among the most common general surgical procedure performed worldwide. It is the starting point for almost all open (non-laparoscopic) operations, and "mini laparotomy" is used by many to extract the specimen following laparoscopic resection. Midline laparotomy allows good access to all quadrants of the abdomen and is a straightforward technique to learn.

The procedure involves making a vertical incision through the mid-line of the abdomen; a central line from the xyphoid process, through the umbilicus to the pubic tubercle. Once the skin has been divided, the anterior sheath is exposed, and care is taken to divide the rectus sheath and linea alba which holds the two rectus abdominus muscles together. Once the peritoneum has been entered, the incision can be extended under vision to expose the target organ. Upon completion of the operation, the linea alba is re-opposed using a continuous running suture to ensure approximation of the two rectus muscles and restoration of anatomy (Kirk and Winslet M 2007).

Opening and closing the abdomen has traditionally been one of the first operations a trainee surgeon learns to perform, and mass-closure techniques are taught on basic surgical skills courses to junior doctors and surgical trainees around the world (The Royal College of Surgeons 2022). These typically involve placing large sutures (1.0 or 0 "loop" Polydioxanone) through the fascia and muscle with bites spaced 10mm apart and 10mm from the edge of the fascia. Recent development of the "Small bite, Small stitch" technique has moved away from traditional closure technique and placed emphasis on meticulous surgical technique (Deerenberg et al. 2015). Small stitch requires the use of a smaller suture such as 2.0 PDS. Emphasis is placed on the preparation of the wound and clearing of the fascial edge to avoid taking bites of muscle which could cause the suture to loosen. The umbilicus is disconnected from the fascia to ensure adequate spacing of sutures, and attention is paid to the starting and finishing knot. Meticulous attention to detail is needed to ensure suture placement and observe a greater than 4:1 suture length to wound length ratio.

Abdominal closure, historically in many health care systems, has been left to the trainee to perform often with junior assistance and at the end of a long operation. Traditionally a trainee would work for one consultant and be expected to learn their technique. This

consultant would be responsible for their training and develop confidence in a trainee's ability through frequent and continued operating together. Current trainees may find themselves working for multiple consultants at a time, operating with different surgeons, each preferring different closure techniques. This inevitably leads to a decrease in time spent with one trainer, meaning that a trainee may be expected to master several different closure techniques at the same time.

c) Experience vs outcomes

To improve at something, you must practice. Whilst there are a number of factors that influence performance, such as natural ability, quality of training and training environment, it is widely accepted that the only way to achieve mastery of anything is through practice and time.

The relationship between surgeon experience and surgical outcomes has been well documented. A systematic review published in 2015 by Maruthappu et al. concluded, unsurprisingly, that increasing surgical volume and years of practice are associated with improved performance and clinical outcomes across surgical specialties (Maruthappu et al. 2015). More recently, the National Emergency Laparotomy Audit (NELA) has reduced the mortality associated with emergency laparotomy in part by mandating the presence of consultant surgeons and anaesthetists in the operating theatre for high-risk patients (NELA Project report 2023).

In inguinal hernia surgery, a link between surgeon experience, case volume and recurrence rate has been documented by several studies (Neumayer et al. 2005; Maneck et al. 2020; Lederhuber et al. 2021). In 2018, the EHS *"International Guidelines for Groin Hernia Management"* recognised both surgeon case volume and surgical inexperience as risk factors for groin hernia recurrence (HerniaSurge Group 2018). A 2005 paper by Langer et al. found that recurrence rates after incisional hernia repair significantly decreased with increasing surgical experience (Langer et al. 2005). However, there is little in the literature, aside from observations, regarding impact of surgical experience on primary abdominal wall closure in preventing incisional hernia.

d) Summary

There is mounting evidence to suggest that a surgeon's experience plays a role in surgical outcomes and focus is shifting towards risk-reduction in prevention of incisional hernia, but the impact of the grade of the surgeon closing the abdomen and rates of incisional hernia following abdominal surgery is unknown.

4.2 Methods

This is an un-planned, post hoc analysis of data from the Hughes Abdominal Repair Trial (HART) performed with the aim of assessing if grade of surgeon performing abdominal wall closure impacts incisional hernia rates.

a) Retrospective analyses of randomised control trials.

Retrospective, or unplanned analysis of RCTs offer some advantages, yet also have limitations that are worth discussing.

RCTs are designed to capture high-quality data. As in the case of the HART trial, study protocols and statistical analysis plans are often published and peer-reviewed, and funding applications allow another opportunity for methodological assessment and peer-review. The interventions, study schedule and assessments are standardised and transparent. This in theory produces a large volume of high-quality data, however this is usually only used to address the study aims. Moreover, RCTs are often funded by a public or charitable body and using these RCT databases in other ways can provide more return on these investments.

Unplanned analyses of RCTs do have limitations, however. The study design may not be applicable to the unplanned analysis. One example being that it may not capture the same population, leading to biases. Additionally, outcomes of retrospective analyses are not defined in the study protocol therefore data points may not have been captured, again leading to incomplete data and the risk of bias. For the most part therefore, these databases remain unused; akin to building a sports stadium and playing only one game in it.

The HART trial provided a huge dataset of over 800 patients, with high-quality data captured on all aspects of pre- and intra-operative risk factors for developing incisional hernia. A secondary analysis of the data had the potential to identify new risk factors which may enhance our understanding of incisional hernia development.

b) HART data

HART was a prospective, multi-centre randomised control trial of 802 patients, comparing the Hughes abdominal closure method with mass closure technique of the operating

surgeon's choice (Torkington et al. 2022). Patients undergoing surgery for colorectal cancer were recruited between 2014 and 2018. All patients underwent surgery for colorectal cancer and were included if they had a midline incision over 5cm long, regardless of whether their surgery was laparoscopic or open.

Patients were randomised into two methods of abdominal wall closure, and the patient and trial team were blinded to the closure method. The control arm was closed using the mass closure technique of the operating surgeon's choice, while the intervention arm was closed using the Hughes abdominal repair method (Hughes technique); a technique combining standard mass closure using two loop 1-PDS sutures with interrupted near-far horizontal and vertical mattress sutures using 1 Nylon (see **Figure 3**).

c) Study training

To assure standardisation of technique, all participating consultant surgeons received training on the Hughes repair and were assessed by the study team before the start of the trial, following the principles of "Cascade training" otherwise known as the "Train-the-Trainers" technique.

Formal teaching sessions on the principles of the technique were provided, and consultants were assessed using models, and signed off once they had demonstrated mastery of the technique. The study team did not provide formal training to trainees, instead relying on the consultant leads to train their juniors. Trainees were allowed to perform closure once the site lead had provided them with training. There was, however, no formal assessment or record of this required, other than the trainee joining the delegation log.

With regards to the HART technique, this essentially created a group of surgeons who received standardised training in a new technique, and a group that possibly did not receive the same standard of training.

d) Study follow-up and outcomes.

Study participants were followed-up with quality-of-life questionnaires at 6-month, 1 year and 2 years, alongside a clinical examination by a medical professional at 1 and 2 years to assess for the presence of midline incisional hernia.

The primary outcome of the HART study was presence of incisional hernia on clinical examination at 1 year. Both cohorts were matched in terms of co-morbidities, age, gender and BMI. The HART study demonstrated that incisional hernia rates were lower in the Hughes closure arm at 1 year (14.8% vs 17.1%, OR 0.84, 95%CI 0.55-1.24, p=0.402) and at 2 years (28.7 vs 31.8%, OR 0.86, 95%CI 0.59-1.25, p=0.429), but this failed to reach statistical significance.

e) Patient identification

We conducted an exploratory analysis of participants in the HART trial with the aim of establishing if the grade of surgeon performing abdominal wall closure impacted incisional hernia rates. This analysis was not planned in the HART protocol and was not reported in the published paper (Cornish et al. 2016).

Recognised confounders for incisional hernia including age, gender, BMI, previous abdominal surgery, type of colonic resection, smoking status, diabetes, type of surgery, duration of surgery and immunosuppression were collated. Grade of surgeon closing the abdominal wall was collected and categorised into “Trainees” (Training grade surgeons on a specialty training programme, equivalent to registrar/resident level) and “Consultants” (those who have a qualification of completion of clinical training (CCT), and who were holding a consultant/attending position at time of surgery).

f) Statistical analysis

Data was collected using Microsoft Excel® and analysed using SPSS® version 27.0. Continuous numerical variables, such as BMI and age were assessed using F-tests and unpaired sample t-tests. Categorical variables, such as grade of surgeon, previous abdominal surgery and gender were assessed using Pearson’s chi-square test and Fisher’s exact test, where necessary. The level for significance was set at the conventional p=<0.05. A stepwise binary logistic regression model was developed. Univariate analysis was performed to identify risk factors for developing incisional hernia. Factors that reached significance were included in multivariate analysis to develop odds ratios.

4.3 Results

663 patients were identified from the HART trial database and were included in this analysis. The mean age was 68 (27-95). 63% were male (n=421), and the mean BMI was 28.1 (range 12.1-49.6).

Abdominal closure was performed by trainees in 289 cases and by consultants in 374 cases, and patient characteristics can be seen in **Table 9**. Patients closed by consultants were more likely to be younger, have a longer duration of operation, and as might be expected for the intervention arm of a randomised control trial, were more likely to undergo Hughes closure. Patients undergoing rectal surgery were more likely to be closed by trainees than those undergoing other types of colonic resection.

Of the patients included in this analysis, 104 patients had incisional hernia on clinical examination at 1 year, and a breakdown of this can be seen in **Figure 12**. incisional hernias were present in 59/289 cases closed by trainees and 45/374 cases closed by consultants (20.4% vs 12%, p<0.001).

In patients closed using the Hughes technique, incisional hernia rates were significantly higher in the trainee group (20% vs 12%, p=0.032). In the mass closure arm, there was a difference in incisional hernia rates again between trainees and consultants, however it failed to reach statistical significance (21% vs 13%, p=0.058).

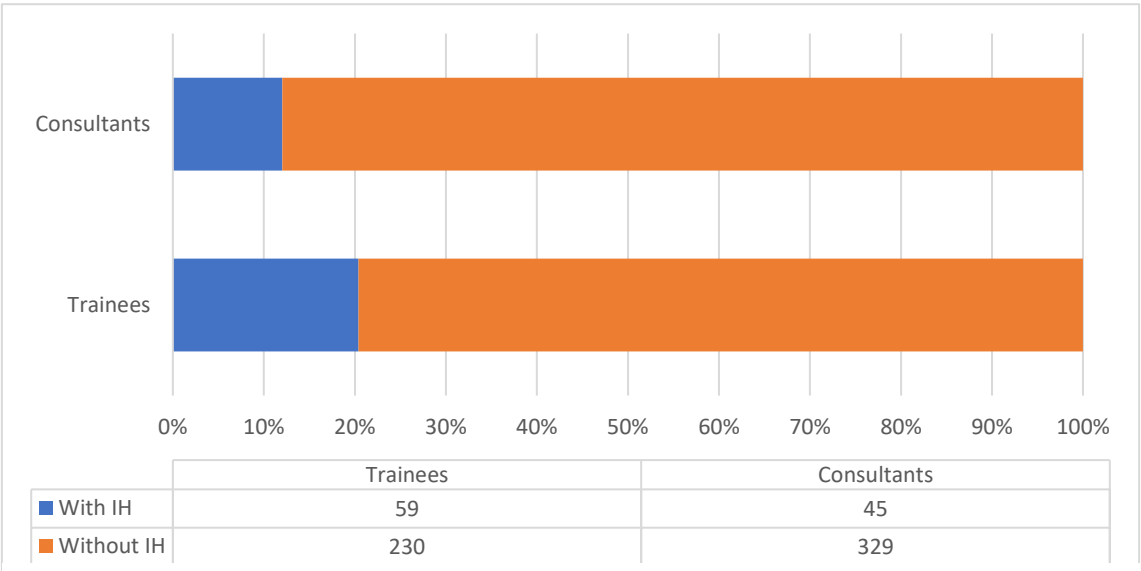

Figure 12: Incisional hernia rates between Trainee and Consultants

Table 9: *Patient characteristics*

	Trainees (n=289)	**Consultants (n=374)**	**P value**
Mean Age (SD)	70 (11.2)	67 (11.9)	<0.001
Mean BMI (SD)	27.7 (5.18)	28.3 (5.5)	0.083
Male sex	194 (67.1%)	227 (60.7%)	0.088
Previous Abdominal Surgery	117 (40.4%)	156 (41.7%)	0.348
Steroids	13 (4.5%)	11 (2.9%)	0.287
Pre-operative Chemotherapy	28 (9.7%)	33 (8.8%)	0.702
Pre-operative radiotherapy	28 (9.7%)	32 (8.6%)	0.614
Diabetes	45 (15.5%)	60 (16.0%)	0.869
COPD	45 (15.6%)	43 (11.5%)	0.125
Renal Failure	6 (2.1%)	2 (0.53%)	0.071
Smoking History	126 (43.6%)	167 (44.7%)	0.740
Length of operation (mins)	183 (SD:76.6)	205 (SD:88.7)	<0.001
Time of abdominal wall closure (mins)	17.8 (SD: 8.9)	17.6 (SD: 10.1)	0.749
Laparoscopic Surgery	125 (43.3%)	178 (47.6%)	0.266
Rectal Surgery	154 (53.2%)	158 (42.2%)	0.005
Hughes Closure	119 (41.1%)	217 (58.0%)	<0.001

a) Variate analysis

Univariate analysis of risk factors found in **Table 9** was performed, and the results can be seen in **Table 10**. This analysis revealed age, male sex, rectal surgery and trainee closure to be associated with increased risk of developing incisional hernia.

Multivariate analysis was performed using only factors with a p value <0.20 in univariate analysis and the variables that reached significance can be seen in **Table 11**. This demonstrated increasing age (p=0.036, OR 1.02, 95% CI 1.00-1.04), male sex (p=0.049, OR 1.61, 95% CI 1.00-2.59) and closure by a trainee (p=0.006, OR 1.85, 95% CI 1.20-2.85) to be independent risk factors for developing incisional hernia.

Table 10: *Univariate analysis of factors affecting incisional hernia rate*

Variable	Odds Ratio (95% confidence interval)	P value
Increased Age	1.02 (1.00-1.04)	0.070
High BMI	1.05 (1.00-1.09)	0.033
Male sex	1.71 (1.03-2.83)	0.037
Previous Abdominal Surgery	1.38 (0.88-2.17)	0.165
Steroids	1.04 (0.33-3.32	0.947
Pre-operative Chemotherapy	0.52 (0.14-1.86	0.312
Pre-operative radiotherapy	0.72 (0.20-2.69)	0.629
Diabetes	0.90 (0.49-1.64)	0.720
COPD	1.15 (0.62-2.14)	0.651
Renal Failure	1.15 (0.22-6.01	0.865
Smoking History	0.77 (0.50-1.21)	0.255
Length of operation	0.99 (0.99-1.00)	0.434
Laparoscopic Surgery	0.92 (0.58-1.44)	0.705
Rectal Surgery	1.47 (0.91-2.37)	0.116
Trainee closure	1.87 (1.20-2.92)	0.006

Table 11: *Multivariate analysis of factors affecting incisional hernia rate*

Variable	Odds Ratio (95% confidence interval)	P value
Age	1.02 (1.00-1.04)	0.036
Male sex	1.61 (1.00-2.59)	0.049
Rectal surgery	1.53 (0.97-2.40)	0.065
Trainee Closure	1.85 (1.20-2.85)	0.006

4.4 Discussion

This study identified three risk factors for incisional hernia development. Both male sex and age are recognised risk factors for incisional hernia development and have been commented on in several studies (Höer et al. 2002; Sørensen 2005; Bosanquet et al. 2015). Trainee-led abdominal wall closure, however, has not yet been recognised as a risk factor. This finding has been commented on historically - Jenkins observed a difference in abdominal closure technique between trainees and "experienced surgeons" in his 1976 paper describing his eponymous rule for AWC technique (Jenkins 1976). A similar observation was also made by Hughes in his paper first detailing the Hughes Abdominal Repair (Hughes 1986). These results, however, are the first to quantify this risk.

In our results, patients with rectal cancer were more likely to have abdominal wall closure performed by a trainee. Rectal surgery is potentially more challenging than other types of colonic resection due to the location of the rectum in the pelvis, therefore this finding may reflect abdominal wall closure being treated as an opportunity for the trainee to achieve some training following a technically difficult procedure or, possibly, simply due to fatigue of the surgeon. This latter suggestion is countered however, when considering that patients closed by consultants were more likely to have a longer duration of operation, suggesting that surgeon fatigue may not be the case. It is worth considering that whilst there was no significant difference in time taken to perform abdominal wall closure, the longer duration of operation may suggest a desire of the surgeon to perform a perceived quicker abdominal wall closure after a long operation.

There were significantly more abdominal closures using the HART technique in the consultant group, when compared to the trainee group, which is perhaps to be expected in an interventional arm of a randomised control trial. When comparing incisional hernia rates between the two closure methods, incisional hernia rates were higher in both Hughes closure and mass closure arms when performed by trainees, appearing to demonstrate that irrespective of technique used, closure by a trainee surgeon increases the risk of incisional hernia formation at 1 year; a finding confirmed on univariate and multivariate analysis.

The differences in performance in the Hughes closure between trainees and consultants is perhaps the most striking and carries relevance outside of this study. It implies that performance is better in those who undergo formal training in a technique compared to those who do not. This is relevant to implementation of other abdominal wall closure techniques, such as Small Stitch or mesh-augmented closure, as well as new techniques in other areas of surgery. It is worth considering that new techniques carry a learning curve, and surgeons looking to adopt them should seek formal training, either on courses or in the form of mentorship.

a) The current state of training

Mass closure is a commonly performed technique familiar to all grades of surgeon. It is taught to all prospective surgeons at part of the Intercollegiate Basic Surgical Skills course (The Royal College of Surgeons 2022). However, more recent AWC techniques, such as Small Stitch and the Hughes closure are not yet taught as part of the surgical curriculum in the UK. Training in these techniques is dependent on individual trainers at a local level. Currently, there is no requirement for trainees to achieve competence in AWC as part of their professional development in the UK (Brecknell J and Lintott P [2019]; Cook T and Lund [2019]). Consultants participating in the HART trial underwent standardised training in the Hughes technique, whereas trainees did not receive this same standard of training, and this may well explain the difference in outcomes within the Hughes closure arm when compared to mass closure. The difference in incisional hernia rates between trainees and consultants in both arms of the HART trial suggests that focused training in surgical technique is perhaps more important than case volume in abdominal wall closure. This highlights the importance of standardised training and providing evidence of competence in commonly performed AWC techniques.

The difference in incisional hernia rates between grade of surgeon should be overcome not by consigning the trainee to the role of the assistant, but by changing attitudes towards training and AWC. Implementation of standardised levels of competence and training in common closure techniques at a national level, alongside changing attitudes towards abdominal wall closure at an individual level may reduce the difference in incisional hernia rates between consultants and trainees.

b) Limitations

It is worth noting some limitations of this study. As previously discussed, this is an unplanned, retrospective analysis of a randomised control trial, therefore data on trainee supervision and grade of assistant were not captured and these are both likely to be important factors. Trainees supervised by a consultant would hopefully receive training in performing a technically sound closure, conversely more junior trainees performing AWC with junior or even no assistance may not have the guidance necessary to perform closure to the same standards.

The main limitation, however, is the discrepancy in training provided by the study team between trainees and consultants. Cascade training is a recognised system in mass training in a technique and follows the idea of a flow of information from one central source which increases speed and reach of the subject matter (Gask et al. 2019). Whilst this is an efficient means of disseminating information, it has its restraints, chiefly the dilution of information as it gets passed along. Alan Mackenzie summarises this nicely in his blog by categorising this into three areas: “Sponge”, whereby information is absorbed by the trainer but not passed on to the trainee, “Trickle-down”, where information is not passed on to the trainee to the same standard and “Flood” in which trainees feel overwhelmed by the amount of information passed to them by the trainer (Mackenzie 2010).

These challenges can be overcome, however it takes considerable planning and requires an understanding of attitudes of both individuals and the organisations that participate to facilitate adequate training. Given the attitudes towards abdominal wall closure discussed previously, it is perhaps reasonable to reflect that the trickle-down effect may have been observed, and the lack of robust feedback and evaluation of training in the study may have had a significant impact on its outcomes.

Whilst cascade training may well help to explain the difference in incisional hernia rates between trainees and consultants performing Hughes closure, it does not account for the difference in rates in the mass closure group; a technique that is widely performed by surgeons of all grades. This difference suggests a correlation between surgical experience and outcomes, comparable with studies in other areas of hernia surgery which link increased experience and case volume with improved outcomes. The results of this study

are therefore likely explained by a combination of two factors: inadequate training of one group in a new technique alongside relative inexperience in an established technique.

This study did not look at inter-hospital variability, which is important to consider in the context of national surgical training. There may well be variability in the training offered by smaller district general hospital compared to larger tertiary centres, or, for example between university teaching hospitals and their non-teaching counterparts. Given an absence of data on trainee-supervision, however, it would be difficult to comment on variation in training between hospitals, although this would be an interesting point to explore in future work in this area.

These limitations are important considerations for surgeons looking to adopt new surgical techniques, both in abdominal wall closure and on a broader scale. Standardised teaching programmes should be available for all new techniques, and, in the case of surgical education, these should be complemented with mandatory competencies and adequate supervision in order for trainees to show development and mastery of new techniques.

c) Conclusion

Rates of incisional hernia are higher when the abdominal wall is closed by a trainee surgeon compared to consultants, and trainee-led AWC is a risk factor for incisional hernia development. Abdominal wall closure should be seen as a procedure in its own right, with standardised training and mandatory competency assessments. Closure time should be treated as training time, not coffee time.

Chapter 5: Can we predict the future?

Validation of an external risk-predictive tool for personalising individual risk.

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I am grateful for the help and collaboration I have received from the above people in the process of producing this work.

5.1 Introduction

As discussed in previous chapters, there are a number of strategies for reducing risk of developing incisional hernia. As discussed in Chapter 1, Mesh-augmented abdominal wall closure (Mesh Prophylaxis) has a large body of evidence supporting its efficacy and safety. Current international guidelines recommend its use in "High-risk" patient groups, yet what constitutes "High-risk" is not entirely clear (Deerenberg 2022). One barrier to implementation of mesh prophylaxis may be the lack of ability to identify a "high risk" patient before their surgery and although risk predictive models have been developed, they lack external validation.

a) What is a predictive model?

For centuries, humans have been fascinated with predicting the future and since the time of Hippocrates clinicians have realised the importance of prognostication in disease management (Moons et al. 2009). In the last century, advancements in data collection and modern statistics have allowed predictive modelling to take a central role in clinicians' day-to-day lives.

Predictive modelling can take shape in many forms. Single predictors, such as genetic variants can predict the likelihood of developing certain types of cancer. Patients with a personal or family history of breast cancer for example can be screened for Breast Cancer Gene (BRCA)-1 and BRCA-2 mutations, which can increase the lifetime rates of breast and ovarian cancer in carriers by up to 70% (Kuchenbaecker et al. 2017). Identification of this mutation allows clinicians and their patients to discuss measures like prophylactic mastectomy or closer surveillance, in an attempt to prevent the disease from occurring.

For the majority of conditions, however, a single predictor is not enough to give an accurate prognosis, especially in conditions which are significantly impacted by more than one variable. Multivariable models allow clinicians to personalise risk to the individual based on a combination of factors unique to that individual.

The multivariable predictive models need to be accurate and simple to use. An inaccurate model may mean over or under treatment of patients, whereas a highly accurate model that

uses variables that are not widely available will struggle to find use in day-to-day clinical practice. Ultimately the outcome of the model should be used to alter or change the course of the disease, either through prophylactic intervention, such as medication or lifestyle changes, or through altering patient expectations or disease surveillance, such as in models that predict cancer recurrence (Lee et al. 2016).

b) Examples of existing models

National Emergency Laparotomy Audit (NELA) model

The NELA risk calculation tool is a commonly used model that predicts both 30-day mortality and morbidity after emergency laparotomy. The model is based on prospective data entered into the NELA database by all centres in the UK who perform the procedure and took over from the P-POSSUM score as the predictive model of choice in 2015 (Lai et al. 2021). Following a review of data in 2020, the model was updated to include newly identified variables, with plans to review the model's performance and re-calibrate going forward (Martin 2020). This method of risk prediction allows continuous development of the model through positive feedback, a unique approach that means the model does not become out-dated and allows for constant improvement in accuracy. Use of this model, incorporated alongside data entry into the NELA database has contributed to a fall in post-operative mortality from 11% in 2015 to 9% in 2022 (NELA Project Team 2023).

c) Development of predictive models.

Most multivariate models are developed using a large dataset of patients with and without the disease of interest. For the purposes of prevention, longitudinal cohort data is most useful when it comes to predicting the incidence of diseases. Ideally the dataset should be large enough to capture variability within the affected population and should be randomly divided into a development dataset (used to identify variables and allocate weight) and a validation dataset. Generally speaking, the more variables included, the less accurate and convenient the model may be to use; however this depends on the number of factors that contribute to the disease that is being studied. Univariate analysis can be used to identify significant predictors. These are combined with clinical relevance to determine which should be included in the model. The final model should undergo testing, through multivariate analysis to weed-out non-significant predictors. This also allows integer values to be added

to beta coefficients or odds ratios (for example 0.5, 0.6-0.8, 0.9 allocated a score of 1,2 or 3 respectively).

This model should then undergo internal validation against the remainder of the dataset to assess performance and accuracy. A number of statistical measures exist for evaluation of model performance and can be seen in **Table 12**.

Table 12: *Measures for assessing the performance of a predictive model*

Factor assessed	Test
Discrimination	AUC, *C* statistic
Predictive value	PPV/NPV
Likelihood	Positive/Negative Likelihood ratio
Accuracy	Brier Score, Youden index
Calibration	Homer-Lemeshow test
Model Determination	R^2 test
Statistical significance	*P* value
Magnitude of association	Beta coefficient, odds ratio
Model quality	AIC, BIC

The most commonly used statistic is area under the curve (AUC), or concordance (C)-statistic, which plots the probability of the event occurring on a graph and calculates the area under this curve. A c statistic value of 0.5 indicates a 50/50 chance of the event occurring. The higher the c statistic, the more readily the model is to discriminate between the event happening or not. A c statistic of 0.70-0.80 has an acceptable ability to discriminate, and a range of 0.80-0.90 is considered excellent.

Following internal validation, it is crucial to externally validate the model, either using an external dataset, or another dataset generated in a different way (for example using a prospective dataset to validate a model developed from a retrospective dataset). The use of external validation from another centre is vital to demonstrate generalisability and replicability. As a result, it is typical to see model performance dip when run through these external datasets due to differences in study populations (Lee et al. 2016).

When assessing the quality of predictive models, it is necessary to look at the raw data behind the model and the statistical methodology used to generate the tool. Models generated from small data sets expose to the potential for bias or who use variables not representative of the population as a whole, are unlikely to be accurate, nor reproducible.

d) Incisional hernia prediction

On the surface, incisional hernia appears to be a prime target for risk-predictive tools; it is a commonly occurring condition with a list of recognized preoperative risk-factors. Until recently however, no predictive tools existed. Whilst pre-operative quantification of risk may have helped the consent process, no methods or techniques existed to reduce risk in these patients. With the advent of mesh-reinforced abdominal wall closure, however, patients deemed “high-risk” can benefit from prophylactic mesh, and this has led to a renewed urgency for accurate and clinically relevant risk-predictive tools (Goodenough et al. 2015).

Existing hernia models:

In 2015, the HERNIAscore was developed by a group in the United States. Using a prospective cohort of 625 patients undergoing abdominal surgery, four predictors of

incisional hernia were identified: laparotomy, hand-assisted laparoscopy, COPD and BMI >25kg/m^2. By converting the associated hazard ratios to points, they were able to classify patients into three groups, which was validated internally with high predictive scores (Goodenough et al. 2015) . The same group externally validated and modified the model in a retrospective analysis in 2017 (Cherla et al. 2017). The HERNIAscore is straightforward to use and classifies patients into low, medium and high-risk categories, however, does not consider surgery-specific variables. Given the breadth of risk-factors for developing incisional hernia, the HERNIAscore seems too simple to be an accurate tool, perhaps explaining why in spite of excellent reported performance, it has failed to gain traction in the wider surgical community.

Another promising model has been developed by clinicians from the University of Pennsylvania and described in Chapter 1. Termed the "Penn Hernia calculator", this predictive model groups surgery-specific risk factors together through an easy-to-use app-based interface. To date, however, this model has not been externally validated.

e) Incisional hernia and colorectal cancer.

Colorectal cancer is the third most commonly occurring cancer worldwide, with higher incidences in high-income countries and increasing incidence in middle- and lower-income countries (Xi and Xu 2021). Despite advances in oncologic and endoscopic treatments, surgery remains the mainstay of treatment for both early and advanced disease (Shinji et al. 2022). Patients undergoing colorectal surgery, however, have the highest risk of developing incisional hernia amongst surgical specialties, with literature rates ranging between 7 -30%, and rates of incisional hernia repair of 17% (Gignoux et al. 2021; Torkington et al. 2022). With 5-year survival rates for stage 1 colorectal cancer at greater than 90%, and long-term survival of patients undergoing surgery for colorectal liver metastasis approaching 50%, attention must be given to reducing the morbidity of incisional hernia in this cohort of patients (Basta et al. 2019).

f) Summary:

Risk predictive tools have become commonplace throughout clinical medicine. Tools must be easy to apply, have clinically relevant endpoints and must allow clinicians to alter or

modify the disease state. Above all, they must be well designed and follow strict methodological standards.

Colorectal cancer patients have among the highest rates of incisional hernia of patients undergoing abdominal surgery, and with increasing survival rates, attention must focus on reducing the morbidity of incisional hernia. Accurate risk-prediction in this patient group may allow targeted mesh-prophylaxis, but as yet no externally validated model is available.

5.2 Methodology and development of existing models.

a) Development of the Penn Hernia calculator

The Penn Hernia calculator has been developed by clinicians at the University of Pennsylvania in Philadelphia. Published in 2015, it is a specialty-specific algorithm that tailors risk-factors to the type of surgery a patient is undergoing (Basta et al. 2019). The original dataset was compiled retrospectively from coding linked to electronic health records with 29,739 patients from three major hospitals included. Incisional hernia repair was used as a surrogate for incisional hernia, and risk factors were grouped together into broad categories (cardiovascular disease, pulmonary disease, liver disease). Operations were grouped together according to primary specialty, along with approach (open or laparoscopic) and nature of the operation (emergent or elective).

The cohort was randomly divided into derivation group (2/3rds of sample) and validation group (1/3rd). Following univariate analysis, variables with $p<0.05$ were included in a logistic regression analysis, and variables with $p<0.1$ were kept in the model (**Table 13**). Point values were assigned to the beta-coefficient and the model was applied to the validation cohort to assess performance (**Table 14**).

In order to allow quantification of risk, rather than broad risk categories, a Predicted Probability Equation was generated, allowing risk to be quantified as a percentage. The final calculator has been published as a web-based app to facilitate easy use by clinicians day to day.

Table 13: *Univariate analysis of factors included in the Penn Hernia calculator (Basta et al. 2019)*

Patient Factor	Subgroup	Prevalence, N (%)	Factor Absent, % IH	Factor Present, % IH	*P*
Sex	Male	10,894 (36.6)	3.1	5.0	<0.001
Race/ethnicity	Asian	697 (2.34)	3.9	0.6	<0.001
	African American	8,728 (29.3)	4.1	3.0	<0.001
	Caucasian	18,702 (62.8)	2.7	4.5	<0.001
	Hispanic	950 (3.25)	3.8	3.7	0.838
Age	Under 45 y	8,837 (29.7)	4.2	2.8	<0.001
	45–65 y	13,895 (46.7)	3.1	4.6	<0.001
	Over 65 y	7,007 (23.5)	3.9	3.5	0.19
Body mass index, kg/m^2	$<18\ kg/m^2$	1,103 (3.70)	3.9	1.8	<0.001
	$18–25\ kg/m^2$	8,021 (26.9)	4.1	2.9	<0.001
	$>30\ kg/m^2$	10,687 (35.9)	3.0	5.1	<0.001
Smoker		8,102 (27.2)	2.7	6.7	<0.001
Cardiovascular disease		7,678 (25.8)	3.0	6.0	<0.001
Pulmonary disease		8,632 (29.0)	2.8	6.3	<0.001
Hypertension		14,776 (49.6)	2.7	4.9	<0.001
Diabetes		5,720 (19.2)	3.3	5.7	<0.001
Recent weight loss		2,427 (8.16)	3.4	8.2	<0.001
Cancer		6,654 (22.3)	3.2	5.7	<0.001
History of chemotherapy/radiation		1,306 (4.39)	3.5	9.6	<0.001
History of drug/alcohol abuse		1,555 (5.22)	3.5	8.8	<0.001
Chronic anticoagulation		3,016 (10.1)	3.3	8.2	<0.001
2 or more Elixhauser comorbidities		18,711 (62.9)	1.6	5.1	<0.001
Surgical factor					
Open approach		11,628 (39.1)	2.2	6.3	<0.001
Laparoscopic approach		6,815 (22.9)	4.3	2.2	<0.001
Open hysterectomy		4,751 (15.9)	4.1	2.3	<0.001
Laparoscopic hysterectomy		2,446 (8.22)	4.1	0.8	<0.001
Emergent laparotomy		3,523 (11.8)	2.2	15.8	<0.001
Emergent vascular surgery		354 (1.19)	3.7	11.9	<0.001
Preoperative small bowel obstruction		3,561 (11.9)	2.8	10.7	<0.001
History of abdominal surgery		3,781 (12.7)	2.7	11.1	<0.001

IH indicates Incisional hernia.

Table 14: *Weighting of risk factors to develop the Penn Hernia calculator (Basta et al. 2019)*

Risk Factor	Derivation OR (95% CI) (N = 19,799)	*P*	Validation OR (95% CI) (N = 9,940)	*P*	Combined OR (95% CI) (N = 29,739)	*P*	Weighted Risk
Emergent laparotomy	4.65 (3.90–5.55)	<0.001	3.36 (2.60–4.33)	<0.001	4.17 (3.61–4.83)	<0.001	4
History of abdominal surgery	2.33 (1.95–2.79)	<0.001	3.04 (2.38–3.89)	<0.001	2.56 (2.22–2.96)	<0.001	2
Emergent vascular procedure	2.21 (1.39–3.50)	0.001	2.15 (1.14–4.08)	0.018	2.21 (1.52–3.21)	<0.001	2
Caucasian	1.95 (1.63–2.32)	<0.001	1.97 (1.53–2.55)	<0.001	1.95 (1.69–2.25)	<0.001	2
Indication: SBO	1.66 (1.38–2.00)	<0.001	1.86 (1.42–2.44)	<0.001	1.71 (1.47–2.00)	<0.001	1
Smoker	1.65 (1.40–1.94)	<0.001	1.60 (1.26–2.02)	<0.001	1.63 (1.42–1.86)	<0.001	1
2+ Elixhauser comorbidities	1.51 (1.18–1.91)	0.001	1.03 (0.75–1.41)	0.830	1.31 (1.08–1.59)	0.005	1
Open approach	1.42 (1.18–1.72)	<0.001	1.55 (1.19–2.02)	0.001	1.47 (1.26–1.71)	<0.001	1
WHO BMI >30 kg/m^2	1.42 (1.17–1.72)	<0.001	1.73 (1.30–2.30)	<0.001	1.51 (1.29–1.77)	<0.001	1
Chronic liver disease	1.36 (1.12–1.65)	0.001	1.52 (1.15–1.99)	0.002	1.41 (1.20–1.65)	<0.001	1
History of cancer	1.34 (1.11–1.60)	0.001	1.07 (0.81–1.40)	0.603	1.25 (1.07–1.45)	0.003	1
History of chemotherapy/XRT	1.33 (1.01–1.76)	0.042	1.21 (0.80–1.82)	0.348	1.29 (1.02–1.62)	0.030	1
Concurrent fistula/ostomy procedure	1.28 (1.02–1.59)	0.028	0.85 (0.60–1.19)	0.349	1.12 (0.93–1.34)	0.216	1
ASA/anticoagulant use	1.28 (1.04–1.56)	0.017	1.39 (1.04–1.85)	0.022	1.31 (1.11–1.55)	0.001	1
Chronic pulmonary disease	1.24 (1.05–1.46)	0.011	1.38 (1.08–1.75)	0.009	1.28 (1.12–1.47)	<0.001	1
Laparoscopic hysterectomy	0.56 (0.33–0.95)	0.033	0.20 (0.06–0.64)	0.007	0.44 (0.27–0.70)	0.001	−2
WHO BMI 18–25 kg/m^2	0.52 (0.42–0.64)	<0.001	0.75 (0.56–1.00)	0.052	0.59 (0.49–0.69)	<0.001	−2
WHO BMI <18 kg/m^2	0.20 (0.11–0.37)	<0.001	0.30 (0.13–0.68)	0.004	0.23 (0.14–0.37)	<0.001	−4

Derivation cohort *C*-statistic = 0.84, Validation Cohort *C*-statistic = 0.82, combined cohort *C*-statistic = 0.83.

ASA indicates aspirin; BMI, body mass index; CI, confidence interval; OR, odds ratio; SBO, small bowel obstruction; WHO, World Health Organization; XRT, radiation therapy.

b) The HART trial: Patient selection and database synthesis

The HART trial, as described in previous chapters, is a large, randomised control trial of patients undergoing colorectal cancer surgery. 802 patients were recruited, of which 673 had follow-up at one year and 532 at two years. Patients undergoing colorectal cancer surgery have greater than average risk of developing incisional hernia, as described in Chapter 2. Using data from a high-quality, pragmatic RCT to externally validate the colorectal component of this calculator has the potential to benefit a large cohort of patients. A collaboration between research groups in the University of Pennsylvania and Cardiff and Vale University Health Board was established to facilitate data transfer. This collaboration ensured that the methodology of both groups was understood and allowed for prompt identification and resolution of uncertainty. The Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD) checklist for prediction model validation was used to ensure transparent reporting of the process (Collins et al. 2015).

c) Database synthesis

Baseline variables collected at patient recruitment were matched to patient variables included in the Penn Hernia calculator and a breakdown of these can be seen in **Table 15**. Some variables were not independently recorded and were created through inference. Acute infection, for example, was determined through a combination of operation type, diagnosis and intraoperative contamination, using assessors' judgement where necessary. “Recent weight loss” was obtained from baseline quality of life questionnaires and was therefore a subjective, rather than objective assessment. Operation type was coded according to classification in the Penn Hernia calculator, with clinicians judgement being used in operations that included multiple procedures.

Table 15: *Variables collected from HART trial patients*

Demographics	
Age (1)	Gender
Ethnicity	BMI(1)
Pre-operative Comorbidities	
Diabetes	Hypertension
Smoking status (1)	Cardiovascular disease
Pulmonary disease	Renal Disease
Liver disease	History of Alcohol Excess
History of Drug abuse	Hyperlipidaemia
History of Wound complications	Presence of acute infection (1)
History of Inflammatory Bowel Disorder	Prior Herniorrhaphy
Recent weight loss (1)	Obesity (2)
History of Cancer	History of radiotherapy
History of Chemotherapy	Immunosuppression (1)
Coagulopathy (1)	Malnutrition
Anaemia	Previous abdominal surgery
Concurrent Ostomy (1)	Concurrent incisional hernia
Acute inflammatory process (1)	History of gynaecological malignancy
Intraoperative details	
Elective or emergency surgery	Operation type
Laparoscopic or open surgery	Stoma formation
Post-operative details	
Surgical Site infection	Incisional hernia on clinical examination
(1) At time of operation	(2) BMI > 30 kg/m^2

d) Definition of endpoint.

Initial data was provided for the 673 patients that underwent clinical examination at one year, however this was expanded to include patients who underwent examination at 2 years. This inclusion of year 2 patients added an additional 55 incisional hernias.

e) Statistical analysis

Data was collated and analysed centrally. Frequency of variables was reported as a percentage, with continuous data being summarised using mean, and categorical data using median as appropriate. Continuous data was compared using unpaired t-tests. Categorical data was compared using Chi-squared test for independence. Model performance was assessed using three metrics; Discrimination, using Area Under the Curve (AUC) receiver operator characteristic (ROC); Precision, using AUC Precision-recall (PR) and Accuracy, using the Brier score. All statistical analyses were performed using R programming language Version 4.2 (R Core Team, Vienna, Austria).

5.3 Results

Of the 802 patients recruited to HART, 674 underwent clinical examination to assess for presence of incisional hernia in the 2 years following surgery. 162 patients were diagnosed with incisional hernia (24.0%). At 1 year follow up, the incisional hernia rate was 15.9% (n=107), and this doubled to 30.3% (n=162) at 2 year follow up (**Figure 13**). Overall, the incisional hernia occurrence within 2 year follow up was 24% (

Table 16)

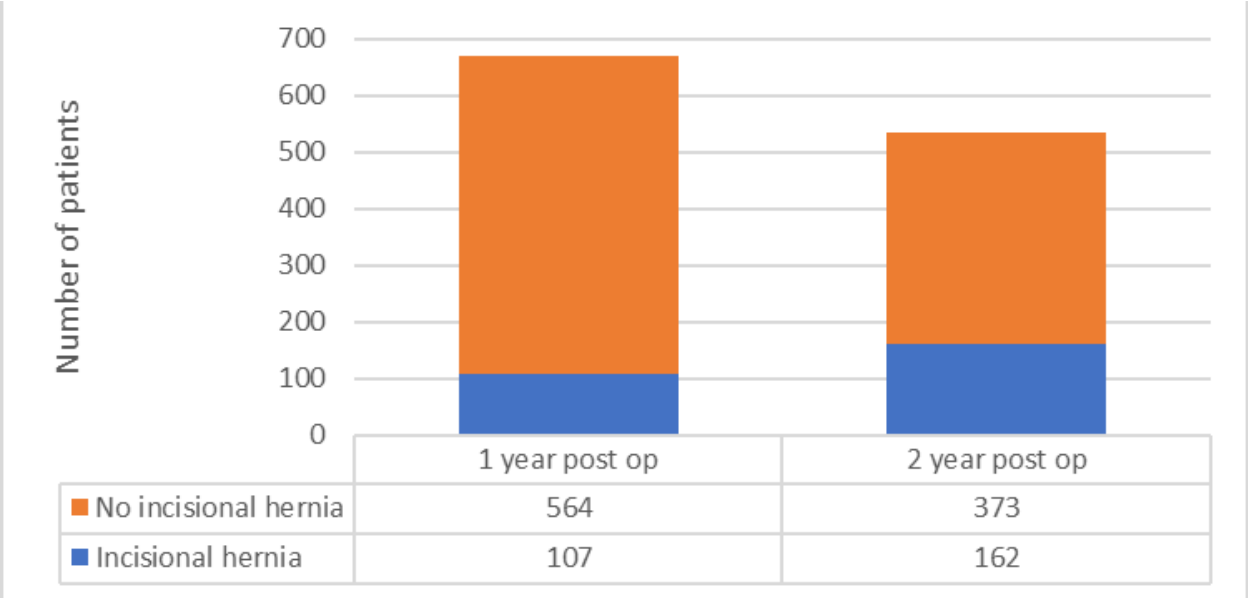

Figure 13: Incisional hernia rate on clinical examination at 1- and 2-years post operation

Table 16: *Incisional hernia and SSI occurrence in HART patients included in validation*

	Overall (N=674)
Hernia Occurrence within two year follow up	162 (24%)
Post-operative Surgical Site Infection	65 (9.6%)

a) Patient Characteristics

The mean patient age was 68 years old (SD 11.7, range 27-95) and the majority of patients (63.8%) were male. Almost all patients (96.4%) were Caucasian, and the mean BMI was 28.1 kg/m^2 (SD 5.32, range 12.1-49.6).

A comparison of Penn Hernia and HART characteristics can be seen in **Table 17**. There were statistically significant differences between variables in the Penn development group and the HART validation group across the board, with the exception of rates of diabetes. A complete breakdown of all variables, including percentages can be found in **Appendix 3.1**.

b) Operative characteristics:

The most performed surgical procedures were right hemicolectomy in 41.9% (n=283) of cases followed by anterior resection (35.3%, n=238). Open surgery was performed in 38% of cases (n=256) and laparoscopic in 33.1% (n=223), with 31.6% (n=213) of patients having a stoma formation at the time of their operation. A breakdown of operative variables can be seen in **Table 18.**

c) Model performance:

The AUC ROC score was 0.66 (**Figure 14**), with an AUC PR of 0.87 and a Brier score of 0.2. Adjustment or removal of variables did not significantly alter the performance of the model. The largest improvement in model performance came with the addition of 2-year data, revealing an additional 55 hernias.

.

Table 17: *Comparison of patient characteristics development and validation cohorts*

Characteristic	Number included in Penn model *n* = 3880 (%)	Number included in HART data n = 802 (%)	*p* value
Age (mean)	57	68.5	NA
BMI (mean)	27	27.8	NA
Male gender	1839 (47.40)	509 (63.47)	< 0.05
Race—White	2716 (70.0)	771 (96.13)	< 0.05
Race—Black	916 (23.61)	12 (1.50)	< 0.05
Smoking	1172 (30.20)	286 (35.66)	< 0.05
Hypertension	1886 (48.61)	124 (15.46)	< 0.05
Obesity	450 (11.59)	234 (29.17)	< 0.05
Diabetes	640 (16.49)	133 (16.58)	0.48
History of cancer	1459 (37.60)	801 (99.88)	< 0.05
Cardiovascular disease	481 (12.40)	107 (13.34)	< 0.05
Pulmonary disease	749 (19.30)	119 (14.84)	< 0.05
Liver disease	318 (8.20)	4 (0.50)	< 0.05
History of GI surgery	749 (19.30)	287 (42.6)	< 0.05
Total colectomy	334 (8.61)	18 (2.6)	< 0.05
Open colectomy	3026 (77.99)	451 (56.23)	< 0.05
Abdominoperineal resection	268 (6.91)	33 (4.11)	< 0.05
Follow up (mean)	56 months	24 months	NA

Table 18: *Operative characteristics of HART patients included in validation model*

Operation	Number (%)
Right Hemicolectomy	283 (41.9)
Anterior resection	238 (35.3)
Abdominoperineal resection	29 (4.3)
Hartmann's procedure	34 (5.0)
Left hemicolectomy	28 (4.2)
Pan proctocolectomy	5 (0.7)
Sigmoid colectomy	27 (4.0)
Subtotal colectomy	13 (1.9)
Other	17 (2.5)
Operation type	
Large bowel	665 (98.7)
Small bowel	2 (0.3)
Both	5 (0.7)
Neither/Other	2 (0.3)
Operation mode	
Open	256 (38.0)
Laparoscopic	223 (33.1)
Lap converted to open	111 (16.5)
Lap assisted	84 (12.5)

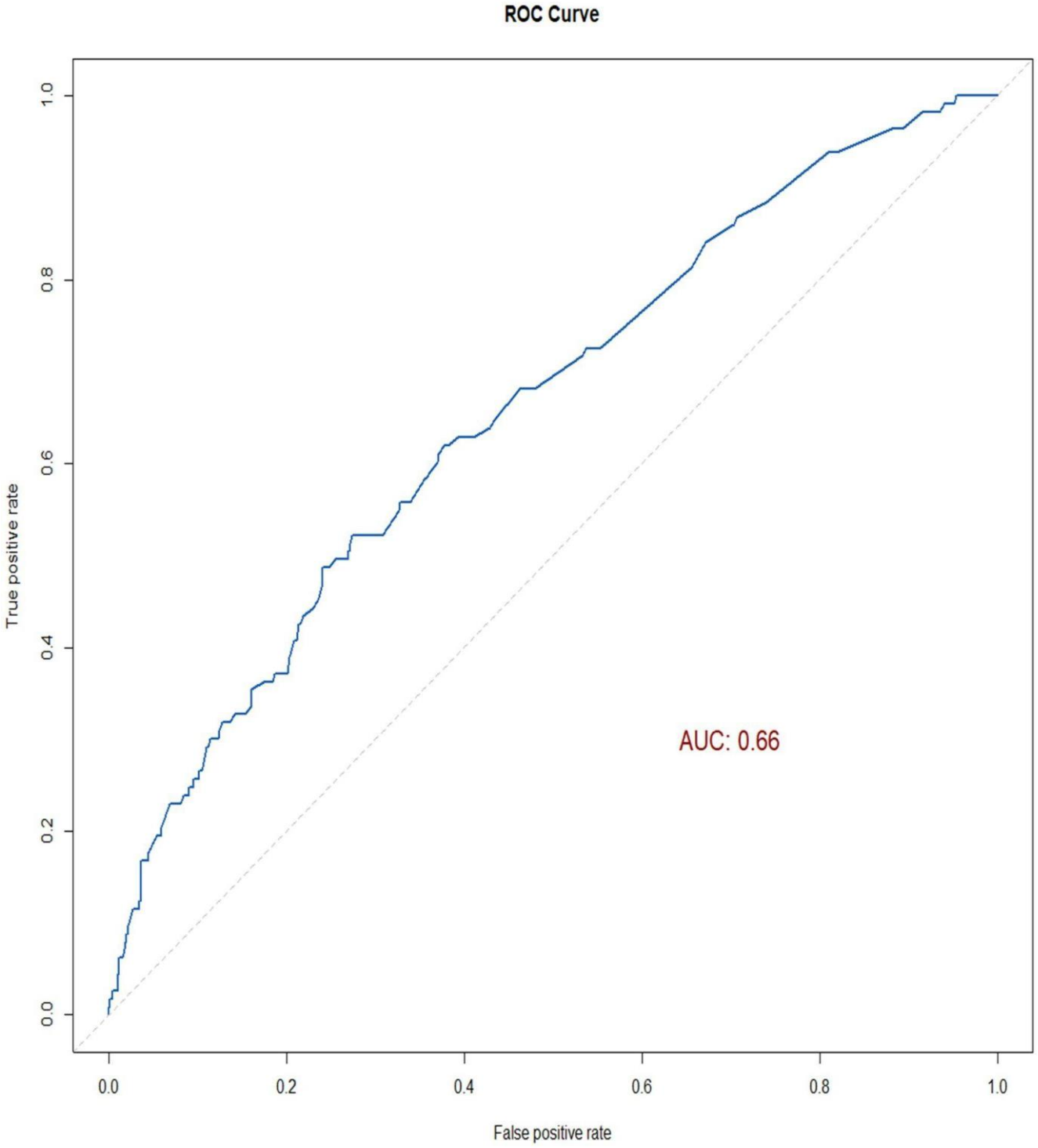

Figure 14: A graph showing the Receiver Operator Characteristic (ROC) curve of the Penn Hernia Calculator performance using data from the HART trial. The Area under the Curve (AUC is 0.66)

5.4 Discussion

Accurate prediction of incisional hernia occurrence is essential for guiding surgical decision-making and optimising patient outcomes, especially in the context of colorectal surgery. In this study, we aimed to validate a the "Penn Hernia" prediction model using an external dataset of patients who underwent colorectal surgery. Our findings demonstrate fair performance of the model in this external validation, indicating its potential for wider use in the context of colorectal surgery.

The Penn Hernia Calculator was developed based on certain patient characteristics, comorbidities, and surgical factors using a bioinformatics approach. Application of this model to an external international dataset from the HART trial allowed assessment of its performance in a distinct population of colorectal cancer patients, as patients undergoing colorectal surgery have among the highest risk of developing incisional hernia amongst surgical specialties (Moons et al. 2009; Gignoux et al. 2021; Torkington et al. 2022). The inclusion of diverse patient demographics, comorbidities, and surgical details from a pragmatic, well designed prospective randomized control trial strengthens the generalisability of the Penn Hernia Calculator to a broader population beyond that from which the model was developed.

The results showed that the external validation of the hernia prediction model yielded an AUC-ROC of 0.66, indicating fair discrimination ability. The AUC-PR was 0.87, reflecting excellent performance in terms of precision and recall. And lastly, the Brier score of 0.2 suggests good calibration of the model, indicating that the predicted probabilities were close to the observed probabilities of hernia occurrence.

External validation of a predictive model is crucial to establish a model's accuracy and applicability to populations outside of that from which the model was developed. It requires applying a previously developed model to new individuals whose data were not used to develop the model, allowing quantification of the model's predictive performance (Moons et al. 2009). When a model is applied to a new population, its performance is generally lower than the performance observed in development; thus, a decrease in performance or accuracy, such as experienced here, is to be expected.

a) Limitations

The complexity of predicting incisional hernia may have contributed to the moderate performance of the hernia prediction model in this external validation. As previously discussed, risk of incisional hernia is dynamic and involves interacting components such as patient-related factors (e.g., age, BMI, comorbidities), surgical techniques, and postoperative care. Although the existing model considers several key variables, the influence of intra-operative factors such as abdominal wall closure technique, and post-operative factors such as surgical site infections is not captured in this calculator. As discussed in Chapter 3, the relative impact of modifiable and non-modifiable risk factors to one another has not yet been quantified and remains unknown.

Another limitation is the variability in the two datasets, particularly in the endpoints used to define incisional hernia. The primary endpoint of the HART trial was clinically detected incisional hernia, whereas the Penn calculator used incisional hernia repair as its endpoint. Rates of incisional hernia range between 12-30% in the literature, whilst rates of incisional hernia repair, as discussed in chapter 2, sit at 5%, suggesting that the minority of patients with incisional hernia that undergo subsequent repair. The difference between the two primary endpoints may be the explanation for the considerable reduction in model performance. From a clinician's perspective, the Penn Hernia model is important in quantifying the risk of requiring further surgery to repair incisional hernia, rather than the true risk of developing incisional hernia. It would be interesting to see if external validation using this same endpoint would improve the AUC.

Despite these limitations, the reasonable performance in this external validation indicates that the Penn Hernia model holds promise in assisting clinicians in identifying high-risk patients and implementing preventive measures to reduce the incidence of incisional hernia. Incorporating the model into clinical practice may help optimize surgical decision-making, such as the selection of closure methods or the implementation of preventive strategies tailored to individual patient risk profiles (i.e. prophylactic mesh augmentation). Ultimately, more information allows for better decision-making with the end goal of reducing incisional hernia rates.

5.5 Conclusion

This study validates a hernia prediction model in an external dataset of colorectal cancer patients undergoing abdominal surgery, demonstrating moderate performance and potential for generalisability. The model's ability to predict hernia occurrence can assist clinicians in identifying high-risk patients and implementing preventive measures.

a) Future work:

Future work should involve applying the model to clinical practice and assessing the model's impact on both management and outcomes within the context of a prospective trial. Additionally, future research should also focus on refining and enhancing the hernia prediction model to further improve the model's performance, for example by exploring the potential of incorporating novel predictors such as genetic factors or biomarkers (Calaluce et al. 2013). Furthermore, to further establish the model's generalisability, it should be externally validated in other patient populations with different surgical approaches and techniques outside of colorectal surgery.

Chapter 6: What does the patient think?

The INVITE study: Incisional Hernia prevention: Risk-benefit from the patient's perspective.

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6.1 Introduction

Incisional hernia presents a significant burden of morbidity to patients, alongside significant costs to healthcare services. With incidence of incisional hernias in midline incisions on the rise, it is clear that changes to closure strategy must be made in order to alter these rates. As discussed in both Chapter 1 and Chapter 5, uptake of mesh augmented abdominal wall closure into everyday practice is slow, and the reasons for this are unclear. Chapter 5 has demonstrated that predictive models can accurately quantify "High-risk" patients pre-operatively. Potential barriers to mesh use remain, however, and this chapter aims to address the question of mesh hesitancy in our patient group.

a) Surgical mesh

Surgical mesh has been used to strengthen the abdominal wall during hernia repair since 1891 (Bilroth 1924). Over the past century, with advances in technology, mesh has evolved from hand-woven cotton and silk implants, through to carefully manufactured synthetic meshes which are chemically and physically inert in order to produce as little immunogenic reaction as possible (Baylón et al. 2017). Mesh usage in inguinal hernia surgery has increased since the 1990s and mesh-repair is now the most common type of inguinal hernia repair performed worldwide due to its ease of use and lower rates of recurrence when compared to sutured repair (EU Hernia Trials Collaboration 2002; Zendejas et al. 2012). Surgical mesh has been used in the repair of ventral and incisional hernias for decades and is recommended over primary suture repair for its lower recurrence rates (Liang et al. 2017).

b) Mesh prophylaxis

The use of mesh to prevent incisional hernia formation began in the 1990s, with the first randomised trial published in 1998 (Pans et al. 1998). There is increasing evidence for its efficacy in reducing incidence of incisional hernia; a summary of randomised control trials can be seen in **Table 19** on page 111. A systematic review published by Olavarria in 2023 of 12 randomised control trials found a lower incidence of incisional hernia after mesh placement compared with primary suture closure (11.1% vs 21.3%, RR = 0.32; 95% CI = 0.19-0.55, p< 0.001) (Olavarria et al. 2023). When adjusting for publication bias, the effect was still maintained, however with a more modest effect (RR = 0.52; 95% CI = 0.39-0.70). Mesh

also appears to be safe, with comparable levels of post-operative pain, and rates of surgical site infection, but mesh is associated with increased rates of post-operative seroma (14.2% vs 8.9%, RR = 1.57, 95% CI = 1.19-2.05; p< 0.001).

Combined European and American hernia Society guidance on abdominal wall closure published in 2022 currently recommends that mesh prophylaxis should be considered in elective midline laparotomy yet the quality of evidence behind this recommendation is low, and the strength of the recommendation was weak (Deerenberg et al. 2022). Further work is needed to address technical aspects such as mesh material, location of placement and use in contaminated fields. Moreover, research powered to detect long-term adverse events such as chronic pain, infection and need for further operations is needed.

Table 19: *A table of current randomised control trials looking at efficacy of prophylactic mesh*

Study	Year	Country (Lead author)	Study summary	Surgery type	Surgical specialty	Number of patients	Length of follow-up (mean)	Assessment of hernia	Results
(Pans et al. 1998)	1998	Belgium	Intraperitoneal synthetic mesh vs primary sutured closure (PSC)	Elective	Bariatric	288	29.8 months	Clinical + patient-reported	No difference in hernia rates (28.4% vs 22.9%)
(Gutierrez de la Pena et al. 2003)	2003	Spain	Synthetic onlay mesh vs PSC	Elective	Visceral	100	36 months	Clinical	Significantly lower rates in mesh group (11.2% vs 0%)
(Strzelczyk et al. 2006)	2006	Poland	Synthetic sublay mesh vs PSC	Elective	Bariatric	74	28 months	Clinical	Lower rates of hernia in PSC compared to mesh (21.1% vs 0%). Similar rates of surgical site occurrence (SSO)
(El-Khadrawy et al. 2009)	2009	Egypt	Synthetic sublay mesh vs PSC	Elective	Visceral	40	36 months	Clinical	Significant reduction in incisional hernia rates with mesh (10% vs 15%, p=0.01) Higher rates of seroma and pain in mesh group
(Bevis et al. 2010)	2011	UK	Synthetic sublay mesh vs PSC	Elective	Vascular	85	50 months	Clinical	Significantly lower rates of incisional hernia in mesh group (13.5% vs 37.2%, p=0.002)

(Abo-Ryia et al. 2013)	2013	Egypt	Synthetic sublay vs PSC	Elective	Bariatric	64	48 months	Clinical	Significantly lower rates of incisional hernia in mesh closure group (3.1% vs 28.1% p<0.01). Comparable rates of post-operative complications
(Caro-Tarrago et al. 2019)	2014	Spain	Synthetic onlay mesh vs PSC	Elective	Visceral	160	14 months	Radiological	Significant reduction in incisional hernia rate with mesh (2.5% vs 37.5%). Significantly higher SSOs in mesh arm
(Bali et al. 2015)	2015	Greece	Biologic (bovine pericardium) onlay mesh vs PSC	Elective	Vascular	40	36 months	Radiological and Clinical	Significant reduction in incisional hernia rates with mesh (0% vs 30% p=0.008). More seromas in mesh group but not significant
(García-Ureña et al. 2015)	2015	Spain	Synthetic onlay mesh vs PSC	Elective and Emergency	Colorectal	107	24 months	Radiological and Clinical	Higher rates of incisional hernia in PSC group compared to mesh (31.5% vs 11.3%, p=0.0011). No difference in SSOs
(Timmermans et al. 2015)	2015	Netherlands	Synthetic onlay mesh vs Synthetic sublay mesh vs PSC	Elective	All	480	1 month	Radiological	Higher rates of seroma in Onlay mesh group but no difference in rates of Surgical site infection (SSI)
(Muysoms et al. 2016)	2016	Belgium	Synthetic sublay mesh vs PSC	Elective	Vascular	120	24 months	Clinical	Significantly lower rates of incisional hernia in mesh

									group (0% vs 28%). No difference in SSO or SSIs
(Jairam et al. 2017b)	2017	Netherlands	Synthetic Onlay mesh vs Synthetic sublay mesh vs PSC	Elective	All	480	23 months	Radiological	Rates of incisional hernia lower in onlay group compared to sublay and PSC groups (13% vs 18% vs 30%) but higher rates of seroma. No difference in SSI rates
(Brosi et al. 2018)	2017	Switzerland	Composite intraperitoneal mesh vs PSC	Elective and Emergency	Not recorded	210	24 months	Clinical examination	Significantly lower rates of incisional hernia in mesh group (17% vs 39%, p<0.001).
(Pizza et al. 2020)	2020	Italy	Biosynthetic sublay mesh vs PSC	Elective and Emergency	Not recorded	92	24 months	Radiological and Clinical	Significant reduction in incisional hernia rates in mesh group (6% vs 22%, p<0.01).
(Lima et al. 2020)	2020	Brazil	Synthetic onlay mesh vs PSC	Emergency	Visceral	115	1 month	Radiological and Clinical	Significant reduction in fascial dehiscence in the mesh group (0% vs 13.5%, p=0.003).

c) Mesh and the media

The use of mesh in surgery in the United Kingdom has come under scrutiny following media coverage and public concerns relating to the use of mesh in uro-gynaecological procedures. Patients undergoing mesh repairs for pelvic organ prolapses and stress incontinence were experiencing complications such as debilitating pelvic pain, and pain on sexual intercourse attributed to mesh. In 2019, a group of women in Australia won a landmark court case against Johnson & Johnson, one of the largest mesh manufacturers in the world, arguing successfully that the products were not tested robustly and were aggressively marketed to doctors despite the company knowing the potential risks, alongside attempts by the company to prevent health regulators from publishing concerns (Knaus 2019).

In 2020, following an extensive public review, the Cumberledge report was published, offering a detailed assessment of surgical mesh use in stress incontinence and pelvic organ prolapse surgery, and its impact on affected women. It recommended a pause on the use of mesh in stress incontinence and pelvic organ prolapse surgery (Cumberledge 2020).

It is perhaps not surprising that concerns regarding mesh have also been raised in hernia surgery. Rates of chronic groin pain after inguinal hernia repair range between 10-12% and although a randomised control trial published in 2018 demonstrated no difference in rates of pain between mesh and non-mesh repairs (Öberg et al. 2018), concerns remain. In the United States, the U.S Food and Drug Administration (FDA) announced in 2019 that it was recalling its licence for uro-gynaecological meshes due to concern regarding safety. Shortly after it announced that it was monitoring the use of hernia mesh.

Concern surrounding mesh persists and has been perpetuated by social media. Fadee et al. demonstrated that public statements from the FDA regarding hernia mesh correlated with an increase in social media activity. On the social media platform Twitter™ (now known as “X”), tweets regarding hernia mesh were more likely to be negative than those for pelvic/vaginal mesh (36% vs 29%). On Facebook™, however, 95% of posts in mesh groups were negative. Interestingly, 3 of the top 5 most active tweeters about mesh were linked to major law firms involved in mesh-related lawsuits (Fadaee et al. 2020). Mesh-related lawsuits are a lucrative business in the United States, with vaginal mesh lawsuits pay-outs approaching nearly 8 billion dollars since 2010 (Cuniff M and Ramirez A 2023).

d) Barriers to mesh use

Uptake of mesh prophylaxis into everyday surgical practice has been slow and the reason for this is unclear. Despite a relatively large body of evidence demonstrating efficacy and safety in a targeted population, there is more hesitancy to implement this technique than there has been implementing small stitch suturing technique; one with far less evidence associated. Concern about the safety of mesh, alongside the negative media reporting in countries affected by mesh scandals such as the United Kingdom and United States has almost certainly affected implementation of mesh prophylaxis, compared to European countries that have not had such scandals. This is nicely demonstrated by Table 1; only one trial of mesh prophylaxis has been conducted in the United Kingdom or United States, by Bevis et al, published prior to the mesh controversy (Bevis et al. 2010).

Fischer et al. (2019a) attempted to quantify this hesitation in 2019 by surveying 497 members of both the American and European Hernia Societies. When asked about mesh prophylaxis, 15% of respondents stated they were using mesh prophylaxis, 45% stated they were aware of the literature and were interested in using mesh, and 25% stated they were aware of the literature and were not interested in using mesh. This is compared to 71.8% of respondents who said they currently use small bites suturing technique. This study highlights the hesitation in using mesh amongst members with an interest in hernia prevention; a finding which is likely to be more marked within the wider surgical community.

In summary it appears that surgeons are hesitant to use mesh prophylactically, and although the reasons are not entirely clear, recent mesh scandals and the concern in the public domain over mesh complications may well be factoring into this decision. To date, however, there is no research into patient views on mesh, and this study aims to address this knowledge gap.

Methods

a) Study aims and objectives

The primary aim of the study was to explore patient perceptions of prophylactic mesh, with secondary aims including:

1. Understanding patient's level of understanding of incisional hernia as a risk of abdominal surgery
2. Understanding factors that may change or influence the acceptability of prophylactic mesh.
3. Understanding patient attitudes towards patient-specific risk scores for incisional hernia

b) Study design

This was a mixed-methods, cross-sectional study exploring patient perceptions of the use of prophylactic mesh to prevent incisional hernia. The study comprised two components:

1. In the quantitative component, data was generated by means of a survey assessing patient knowledge and understanding of incisional hernia and the acceptability of management options including prophylactic mesh.
2. In the qualitative component, semi structured interviews were used to further explore patients' views on prophylactic mesh and to identify and understand factors affecting its acceptability.

3. Further detail of the research methods used can be found in the previously published protocol (Smith et al. 2022).

Mixed-methods research has been defined as the collection of both qualitative and quantitative data in response to a research question or hypothesis (Creswell et al. 2024). It incorporates rigorous collection, analysis, interpretation and integration of quantitative and qualitative data within a single study, using strengths of both approaches to provide a broader perspective on the matter in hand and uncovering information/ insights which may not have been possible through the use of one method alone.

This approach to research dates back to 1959 when Campbell and Fiske used multiple methods to study psychological traits (Campbell et al. 1959). It took off, however, in the 1980s and 1990s as a well-defined and widely recognised research method (Creswell et al. 2018).

For this study a convergent mixed-methods approach was selected, in which the quantitative and qualitative components were conducted and analysis of both were performed afterwards, as opposed to a sequential study design, whereby the analysis of one component influences the design and conduct of the other (Alele et al. 2023).

A convergent design was chosen for a number of reasons. Firstly, it was considered more efficient, as both arms of the study could be conducted at the same time, rather than waiting for one arm to end before the other could start. Secondly, it was felt that analysing both sets of data together would allow more flexibility in the data analysis which in turn would give richer, more holistic understanding of the research question. Finally, by analysing both streams together, it would reduce the risk of bias that one data stream could have on the other.

c) Quantitative component: Survey design and development

The primary purpose of the quantitative component of this mixed methods study was to assess patients' perceptions on mesh prophylaxis using a cross-sectional survey design. This design is well established in quantitative methodology. For this study it was considered to be the best method to address the study's aim and primary objective within the timescale. Surveys are advantageous as they are generalisable. When designed robustly and disseminated appropriately they may be accessible to the whole population. Surveys can also be economical and in facilitating rapid data collection, efficient.

Questionnaire development

Following a search of the literature, no pre-existing validated questionnaires relating to patients' views on mesh or relating to health behaviours and patient decision-making were found. Therefore a survey was developed using principles of study design outlined by Oppenheim (Oppenheim. 1992).

The research aims and hypotheses (see above) were scrutinised and used to create themes which were turned into variables to be measured. As the aims of the research were to explore patients' perceptions of mesh prophylaxis and factors that may affect acceptability, the Health Belief Model (Hochbaum et al., 1952), an internationally recognised framework for understanding health beliefs and identifying areas for change, was chosen as a framework for survey design.

Health Belief Model

The Health Belief Model was developed in the 1950s by psychologists who aimed to understand why some people do not use healthcare services (Becker 1974). The model is based on three pillars, supporting four drivers for change (**Figure 15,** below): Perception of illness (divided into perceived susceptibility and perceived severity), general health motivation and the assessment of behaviours to counter threat (divided into perceived benefit of intervention and perceived barriers to intervention).

The strengths of this model lie in its simplicity; it is easy to understand, which in turn makes it more relatable to individuals. It targets change on an individual level, taking into account personal beliefs regarding health risks and outcomes (Champion et al. 2008). Its versatility has been demonstrated in a wide-range of applications such as vaccine uptake and smoking cessation, and the model provides a framework for identifying barriers to change and then targeting interventions to combat these (Brewer et al. 2006).

The models limitations also lie in its simplicity, with critics arguing that it oversimplifies human behaviour. There is also concern that it fails to account for social and environmental influences, alongside the dynamic nature of how health beliefs change over time (Champion et al. 2008). It is important to consider these limitations in view of the research question, as social influences may be particularly pertinent in view of potential concern around mesh use.

Nevertheless, the effects of the health belief model have been assessed in several meta-analyses, with all four areas (susceptibility, severity, benefits and barriers) being shown to be significant in predicting direction, with "Percieved Barriers" being the most consistent predictor of behaviour and severity being the least consistent (Sutton 2001).

The health belief model was chosen as a framework for the development of the survey as it offers a simple and reproducible framework that tailors questioning to proven pillars of human decision making. The model offers a structure to assess patients perceptions and attitudes towards mesh prophylaxis, as well as their understanding of incisional hernia. By assessing patients' thoughts around the "threat of illness", we can understand how much patients know about incisional hernia as a risk, and what impact it might have on their lives (perceived susceptibility and severity) and start to understand how patients perceive mesh prophylaxis (benefits and barriers to intervention).

Survey items

A survey instrument comprised of three sections and with two spaces for free text comments was developed.

Section one focussed on collecting background information such as gender, smoking status and presence of incisional hernia.

Section two assessed participants prior knowledge of both incisional hernia and surgical mesh, as well as pre-existing attitudes towards mesh and the source of this information. These questions were developed using the "Perceived Susceptibility" and "Perceived Severity" sections of the Health Belief Model. This section aimed to help in understanding how attitudes to incisional hernia may influence subsequent decision-making regarding mesh prophylaxis, as well as how much information our patients retain and recall from the consent process before they undergo surgery.

Section three comprised of a series of questions around patient attitudes towards mesh. Survey items regarding prophylactic mesh use focused on "perceived barriers to use" as studies on the applicability of the Health Belief Model to real-life decision making has shown this section to be the most consistent source of predictive behaviour (Janz and Becker 1984). Participants were asked to read a statement and indicate their response on a 5-point Likert scale of "Strongly disagree" through to "Strongly agree".

Likert scales offer more varied response than a dichotomous "yes" or "no", without the fluid response of a hierarchical scale (Rattray et al. 2007). With respect towards the research

question, Likert scales offer categorical assessments of attitudes whilst respecting the "neutral" answer which is likely to be valuable in the case of attitudes towards mesh, as many participants may not have heard about surgical mesh or may not have a dichotomous response towards it. One disadvantage of using a Likert scale is that it assumes that the strength/intensity of responses is linear, which it is not likely to be the case. However it is a widely recognised and acceptable form of questionnaire design that fitted with the statements generated using the health belief model framework (Oppenheim. 1992).

Finally, free text boxes were used at the end of sections two and three to allow free hand comments from participants. These comments were screened and helped in purposive sampling of participants for the interview process described below.

The survey instrument was pilot tested on the first ten participants to assess usability: specifically language, clarity of wording and overall structure. This process is an essential part to survey development and allows researchers to ensure that their content and structure is relevant, easy to use and applicable to the population they are sampling (Oppenheim. 1992).

Following feedback, the questionnaire was reorganised with the third section being split into two questions: "Surgical mesh", which focused on participants' attitudes towards surgical mesh and drivers behind those attitudes and "Risk and Prevention" which focused on participants' thoughts regarding predictive tools and need for further information. Each section was prefixed by a short vignette drawing attention to the specific questions. The final questionnaire can be seen in **Appendix 4.3**.

It is worth noting that although the survey instrument was created using a recognised structure, there has been no opportunity to test either its validity or reliability. Threats to the validity of this instrument include the history of this cohort (a specific subset of patients who have undergone surgery) and the background demographic of this population.

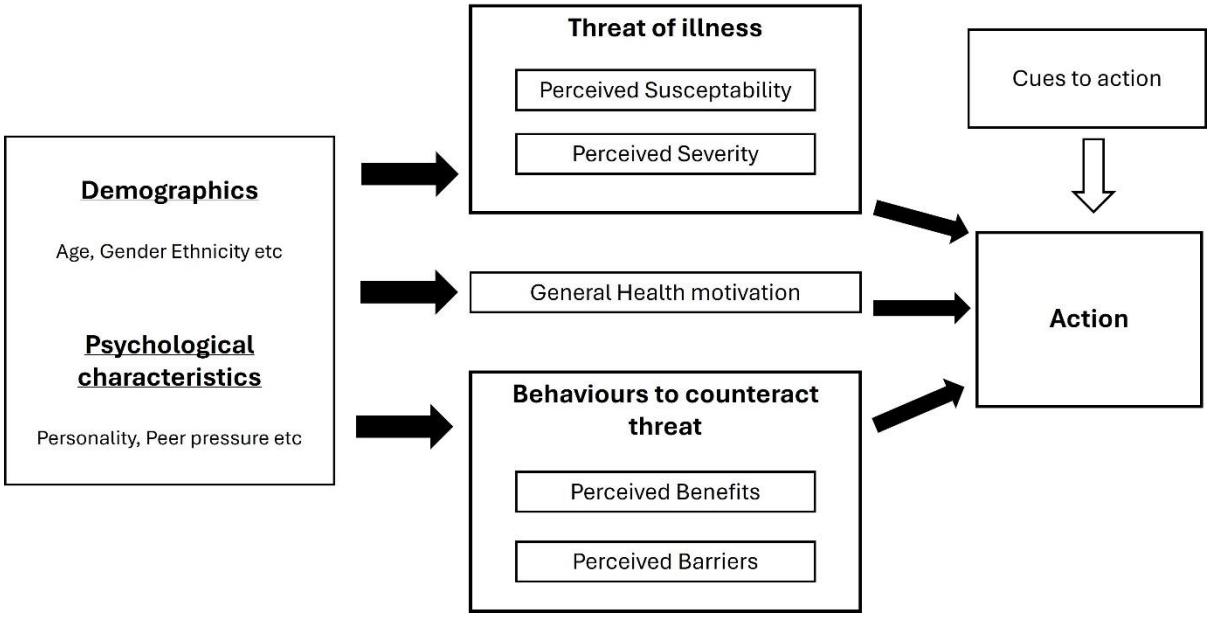

Figure 15: A diagrammatic representation of the Health Belief model created for this thesis

Table 20: Application of the Health Belief model to mesh prophylaxis

	Component of Health belief model			
	Susceptibility	Severity	Benefits	Barriers
Example questions	"How likely do you think you are to develop an incisional hernia after surgery?"	"If I develop an incisional hernia, it will be easy to treat"	"I am concerned about how much benefit I will get from mesh"	"I am worried about the mesh causing me pain" "I am worried about the safety of mesh"

d) Qualitative component: interview study

The aim of the qualitative component of this mixed methods study was to gain a better understanding of patients' perceptions of mesh prophylaxis and the factors that might influence acceptability. To achieve this, semi-structured interviews were conducted with a sample of participants who had indicated on their consent forms that they would be willing to participate in an interview.

Sampling

All participants who indicated they would like to participate in interviews were eligible to participate, and interviewing began once the first 50 surveys had been returned. In order to ensure a diverse range of opinions and views, and to incorporate all participants, the free text boxes of questionnaires were scrutinised to identify those with views or beliefs that might be of interest to answering the research question. Not all participants were approached in this way, and there was no set criteria defined by which to recruit interview participants, however expert judgement was used to ensure that respondents who highlighted potentially interesting viewpoints, both positive and negative, were prioritised to be approached for interview over those that did not.

Data collection

Data was generated for this component of the study using audio recorded, one to one semi-structured interviews between May 2023 and July 2023. Semi-structured interviews were chosen in place of other interviewing methods such as focus groups for a number of reasons. Firstly, it was felt single interviews would produce a greater volume of material from which to draw deeper insight than a focus group. Secondly, while a focus group might stimulate more varied discussion regarding views on mesh, it potentially offered more scope for individual and moderator bias. Thirdly, logistically interviews were the most straightforward option (Gill et al. 2018). Predominantly, interviews were conducted via secure videoconferencing platforms using either Microsoft Teams® or Zoom®. Two interviews were conducted in person as per participant preference. All interviews were conducted by a surgeon with no direct experience of mesh prophylaxis and with experience in qualitative interviews.

An interview guide (**Figure 16**) was developed aiming to build on questions asked in the survey. The interview guide included a series of open questions around the themes of mesh and patients' decision-making behaviour. When developing the questions, neutrality was of utmost importance as to avoid introducing implied bias to the participants. These questions were asked to each participant but were intended as a loose guide, allowing the interviewer to be fluid in asking questions around topics that came up during the interview.

Data collection continued until saturation was reached, i.e., until no new themes were identified as defined by the interviewing team. Saturation occurred after 10 interviews and was confirmed after 12 interviews had been completed. Interviews lasted between 10 and 30 minutes.

"What do you understand by the term surgical mesh?"

"What do you think about the term mesh/surgical mesh?"

"How much do you know about mesh in relation to hernias?"

"What do you think the risk of developing a hernia after surgery is on average?"

"How would you feel if you were offered mesh at the time of your operation?"

"What would you like to know about mesh before deciding if you wanted to have it?"

"Would you think more about the risks of mesh, or the benefit that you might gain from it?"

"At what level of risk for developing a hernia would you be prepared to consider mesh?"

"At what level of risk of complications would you not consider mesh?"

Figure 16: A list of semi-structured interview questions

e) Ethical approval and Patient and Public involvement

Following study set-up and registration (IRAS 310695, ClinicalTrials.gov: NCT05384600) the study received ethical approval from the Research and Ethics Committee for Wales, (Approval number 22/PR/0678) as well as approval from Cardiff and Vale Research and Development who were the site sponsor.

Given the study question, it was crucial that patients were consulted in the study design process, so as to create both appropriate and relevant questions in order to best answer the study question. Patient and Public Involvement (PPI) representatives were included in all aspects of study design, the development of patient information leaflets and in the design and testing of study questionnaires.

f) Patient identification and recruitment

Rationale and definition of the patient cohort

Given the broad nature of the research question, identifying a specific patient population presented challenges. Whilst random sampling of the general population might reflect the true attitudes towards mesh, this might not be representative of the population about to undergo surgery. Conversely, approaching patients who have had surgery might allow understanding of the patient's thought process and mind-set, but this would also be subject to recall bias and potentially influenced by subsequent operations and experiences with mesh.

To understand factors affecting acceptability, and how patients might process information, it was felt that patients who had undergone surgery would be best placed to comment and to apply the discussion regarding mesh to their lived experience of pre-operative consent. To assess if presence of incisional hernia influenced decision making regarding mesh prophylaxis, whilst also reducing the potential for bias, patients with and without a diagnosis of incisional hernia were included.

A population of patients undergoing emergency general surgery and elective colorectal cancer surgery was chosen as they reflect groups with a high incisional hernia rate as well as high percentages of midline incisions that would be suitable for mesh prophylaxis.

Inclusion Criteria

All patients who had undergone elective or emergency colonic resection within one University Health board in Wales were considered eligible for inclusion if they were:

- Over the age of 18 years old.
- Able and willing to provide valid informed consent.
- Undergone elective or emergency colonic resection >12 months ago.

Exclusion Criteria

Patients were excluded if they:

- Were unable or unwilling to give informed consent.
- Had a palliative diagnosis either at time of surgery, or since.
- Were unable to understand or complete study questionnaires due to intellectual or cognitive impairment or due to insufficient English-language skill

g) Patient identification, recruitment and consent

For the quantitative component, eligible patients were identified by a member of the study team through local databases of elective colorectal cancer resections and the national emergency laparotomy audit (NELA) database from a single institution over a three-year period (2017-2020). It was also considered that to choose a time prior to this could introduce excessive recall bias. Patients with incisional hernia identified through these databases were cross-referenced with primary care referrals for “Incisional hernia” across 2017-2020. Response rates from surveys vary, however acceptable rates vary from 30-40%. 331 eligible participants were identified through screening of the above databases, therefore a minimum target of 100 respondents (33.1%) was set.

Once identified, potential participants were approached by a member of the clinical team either face-to-face, if attending routine clinical appointments, or by post. All approached patients received a copy of the patient information sheet, a consent form and the questionnaire, with those approached by post also receiving a letter of invitation signed by

their treating clinician, along with a pre-paid return envelope. Potential participants were afforded as much time as required before deciding whether or not they wish to take part.

Participants were considered recruited following the return of the completed questionnaire and signed and dated consent form.

As part of the study design process, non-response bias (i.e. those that did not respond may have a reason connected to the study question) was considered particularly important in relation to the topic of mesh. People who did not respond were contacted by phone by a member of the study team to ask if they would like to participate. This phone call involved an explanation about the aims of the study in an attempt to encourage people with negative views in particular to participate. If they were uncontactable, refused or did not return the questionnaire or consent form no further attempt at contact was made.

Recruitment for the quantitative component was expected to take 6 months. Unfortunately recruitment was slower than anticipated and following a request for extension from the sponsor, the recruitment window was extended. Recruitment was completed by attending colorectal clinic and recruiting eligible patients directly, to avoid attrition by postal return. **Figure 17** shows the recruitment process over time.

Figure 17: A cumulative line chart showing study recruitment by month

	WIMD 2019 domain weight	WIMD 2014 domain weight
Income	22%	23.5%
Employment	22%	23.5%
Health	15%	14%
Education	14%	14%
Access to Services	10%	10%
Housing	7%	5%
Community Safety	5%	5%
Physical Environment	5%	5%

Figure 18: A breakdown of the Welsh Index of Multiple Deprivation grading with associated domain weights (Welsh Government 2019)

h) Demographics and background history

With their consent, each participants' electronic health record was accessed, and baseline demographics, namely, age, gender, operative history such as date of operation, nature of operation (benign/malignant, elective/emergency) and diagnosis of incisional hernia were recorded.

Given the controversy surrounding mesh in the media and the aims of this study, it was felt that socio-economic status of participants may influence their opinions on mesh. Moreover, level of education may be a factor in participant engagement in questionnaires, so a method of assessing both socio-economic status and level of education of participants was needed to understand the backgrounds of the population sampled and to assess for potential bias in those who participated.

The Welsh Index of Multiple Deprivation (WIMD) is the Welsh Government's official measure of relative deprivation (*Welsh Government.* 2019). WIMD is calculated through eight separate domains of deprivation (**Figure 18**) and ranks areas of approximately 1600 postcodes across Wales according to results of the most recent national census.

Whilst not a comprehensive assessment of education, WIMD offers insight into the background demographic of both the participants and those that did not participate. It does not offer data on the individual respondents, offering more a reflection of the socioeconomic state of the postcode as a whole, subjecting it to significant bias. Taking this into consideration however, it provides some insight into participants' education and socioeconomic status.

i) Data management and use

All collected data was entered into password protected Excel database and anonymised at this point, using an allocated study ID. Anonymised data was only accessible by investigators at the sponsor site. The Trial master file, containing essential documents and data logs were kept in a locked cabinet in a secure research office.

Data collected was kept confidentially and accessed only by members of the trial team. Participants personal details (name, address) were in sites under the guidelines of GDPR.

All interviews were recorded and transcribed. Post interview each transcript was checked against the corresponding recording for accuracy and to reflect on conscious or subconscious bias during the interview (reflexivity). Any potential identifiers noted during the transcription process, such as people or places, were removed and replaced with pseudonyms such as initials and generalised terms such as “the hospital” . Patients were coded by initials, linked to their unique study identifier.

j) Quantitative analysis plan

The data collected from the survey instrument was manually transcribed into a database stored in Microsoft Excel® before being analysed using SPSS® version 27(IBM® 2022). Data was assigned binary numbers (i.e. 1 for yes, 2 for no) to allow analysis. In the case of incomplete questionnaire response, pairwise deletion (deletion of just the missing data), as opposed to listwise deletion (deletion of the entire case) was performed. This allowed inclusion of other responses from participants that could prove valuable (Oppenheim. 1992)

Once the data had been prepared the process of statistical analysis commenced. Continuous data was summarised using means and standard deviation, with categorical data being summarised using percentages, median (IQR) and mode where appropriate. The WIMD data was categorised into deciles with 1 being the most deprived and 10 being the least. Data was analysed for completeness.

Chi-squared tests for independence was used to assess significance between categorical variables. Simple logistic regression was used for continuous variables.

Likert scales were reverse weighted where needed in order to produce homogenous scores. Scores were summarised using median and IQR. Stacked bar charts were generated using Microsoft Excel® to allow for visualisation of responses.

k) Qualitative analysis plan

Thematic analysis, as summarised by Naeem and Ozuem in 2023, was used to identify themes and topics within the qualitative data (Naeem et al. 2023). The principles of thematic analysis have been described in a number of sources but most notably by Braun and Clarke in 2006. It involves 6 key steps which can be seen in **Figure 19**.

Firstly, transcripts were read twice, one with the audio recording and once on their own to allow familiarisation with the data set and formulation of initial thought. Semantic coding was then used to systematically identify key words and phrases in the transcripts and was guided by the study aims. These codes were then grouped according to ideas or patterns, and this was supported by NVIVO® software (Lumivero® 2020 *NVivo* version 14®). These codes were then grouped into broader themes and checked against coded text. This process was conducted independently by two researchers who then came together to check coding, discuss their findings, with themes then further defined and named to create the narrative from the analysis.

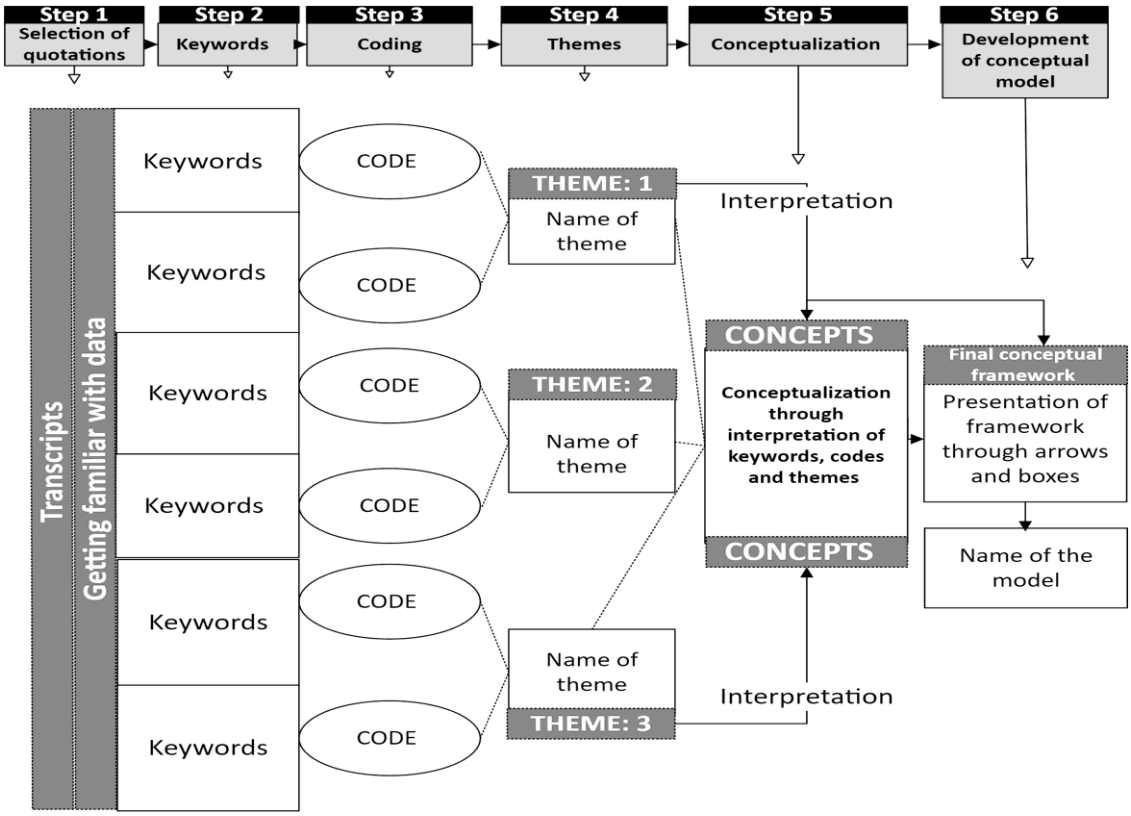

Figure 19: The six step systematic thematic analysis process (Naeem et al. 2023) Open Access, CC Non-Com 4.0 license

6.3 Results

a) Quantitative results

The survey instrument was shared with 331 patients. Of these 120 responded in the timescale, giving a response rate of 36.1%, which is higher than the anticipated 30%, however does offer the possibility of respondent bias. In theory, higher response rates should more accurately reflect the views of the population and lead to stronger conclusions, however in reality, a number of studies have shown that this is not the case, with studies including lower response rates having comparable or only marginally less accurate results than studies with higher rates (Morton et al 2012).

Participants' demographic profile

Most respondents were male (55% n=66), and the mean age of respondents was 65.98 years (SD 11.58, range 29-93). The median WIMD decile of respondents was 8, indicating low levels of social deprivation (IQR 4-10, mode 10). The median decile for all people approached however, was 7 (IQR 3-9, mode 10) suggesting that the sample who responded were representative of the population approached. Of the 120 respondents, 70 % (n=84) had elective surgery. For 75% (n=90) of respondents, surgery was for malignancy. Forty-five respondents (37.5%) had a diagnosis of incisional hernia. The mean time from operation to completing the survey was 40.7 months (SD 18.04, range 15.3-76.5). Sample demographics are presented in **Table 21**.

Table 21: Respondents' demographics

	Mean (SD)	**Range**
Age (Years)	66.0 (11.58)	29-93
Length of time from surgery to questionnaire (years)	3.39 (1.39)	1.28-6.38
BMI (kg/m^2)	28.09 (6.28)	16.23-54.57
WIMD score (Median)	7 (IQR 4-10)	2-10
Male Gender	66 (55%)	
Operation for malignancy	90 (75%)	
Elective operation	84 (70%)	
Incisional hernia diagnosis	45 (37.5%)	

Table 22: The correlation of variables with awareness of incisional hernia as a risk of an operation

Variable	**Number aware of IH as a risk of their operation(%)**	**X2 value**	**P value**
Subsequent diagnosis of Incisional hernia	84	3.15	0.076
Male sex	84	1.96	0.161
Elective surgery	84	2.44	0.118
Malignant disease	84	1.91	0.167
	b-coefficient	**95%CI**	**P value**
Age	0.927	-0.03 to 0.02	0.202

Prior knowledge and recall.

Only 26.7% (n=32) of respondents could recall being told that incisional hernia was a risk following their operation. This did not correlate with gender, elective surgery, subsequent diagnosis of incisional hernia or patients with malignant disease **(Table 22**).

Knowledge of surgical mesh

In terms of respondents' prior knowledge of mesh, 61.3% (n=73) had heard of doctors using mesh. Just over half (53.9%) felt that what they had heard was negative, compared to 15.7% which were positive (**Figure 20**). Of the negative responses, the majority (72%) reported hearing about mesh from news/media sources.

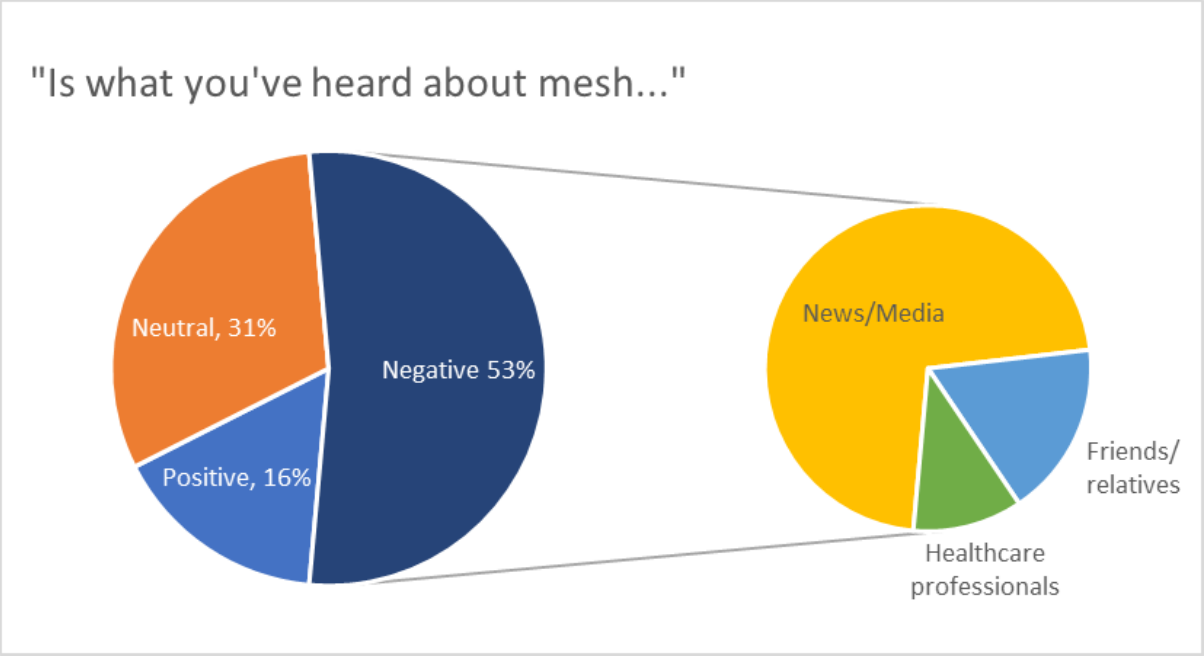

Figure 20: A bubble within a bubble graph of patient's prior knowledge of mesh and the source of their information

Concerns about mesh

Figure 21 shows responses to questions about mesh. Half of respondents (50%) had concerns about mesh, with 20% having no concerns at all. 40% of respondents were worried about the safety of mesh with similar numbers (42%) being concerned about the mesh causing them pain. Half of respondents surveyed (51%) were concerned the mesh would be difficult to remove should it not work, and 45% were worried about the benefit mesh might provide. Despite these concerns, however, only 9% of respondents felt that prophylactic mesh would not be acceptable to them, with the majority (55%) feeling it would be acceptable.

Risk-predictive tools and acceptability.

Most respondents (69%) felt they would have found predictive tools useful in understanding their risk of incisional hernia, with 50% feeling that predictive tools would have been useful in helping them decide about prophylactic mesh. Most respondents (78%) felt they would need more information about mesh before deciding about it (**Figure 22**).

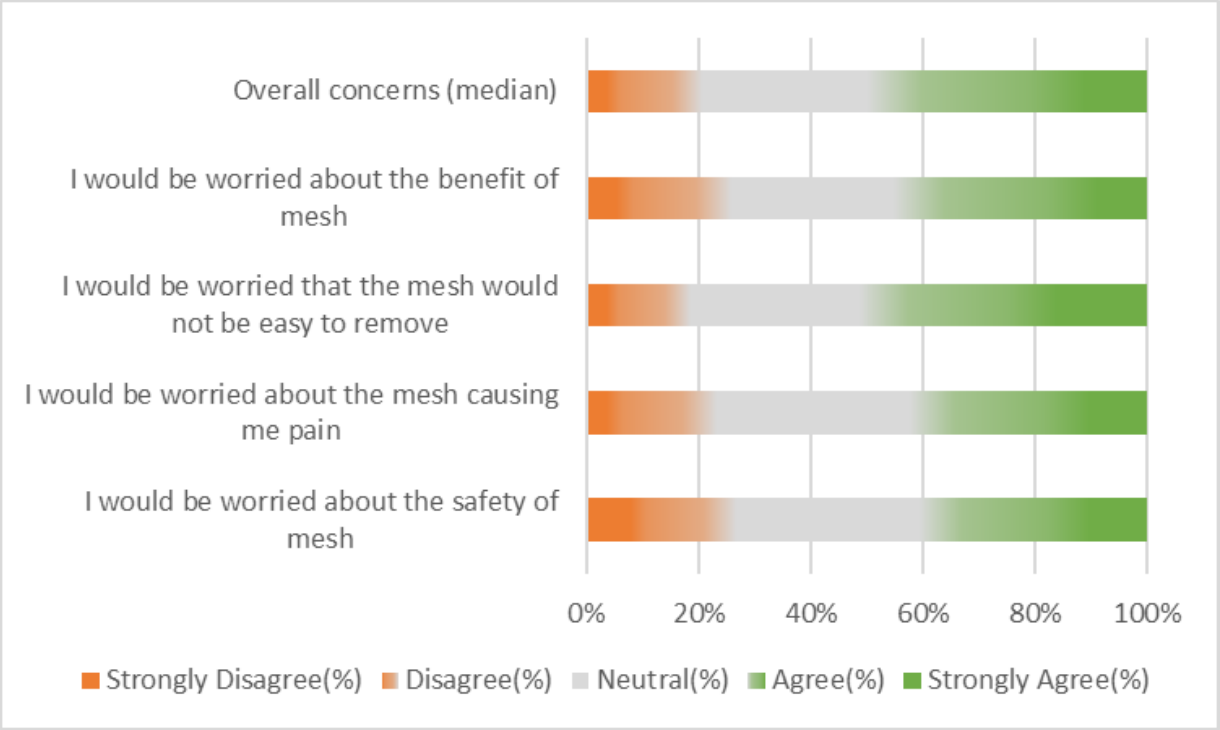

Figure 21: A 100% stacked bar chart showing breakdown of responses to questions about mesh

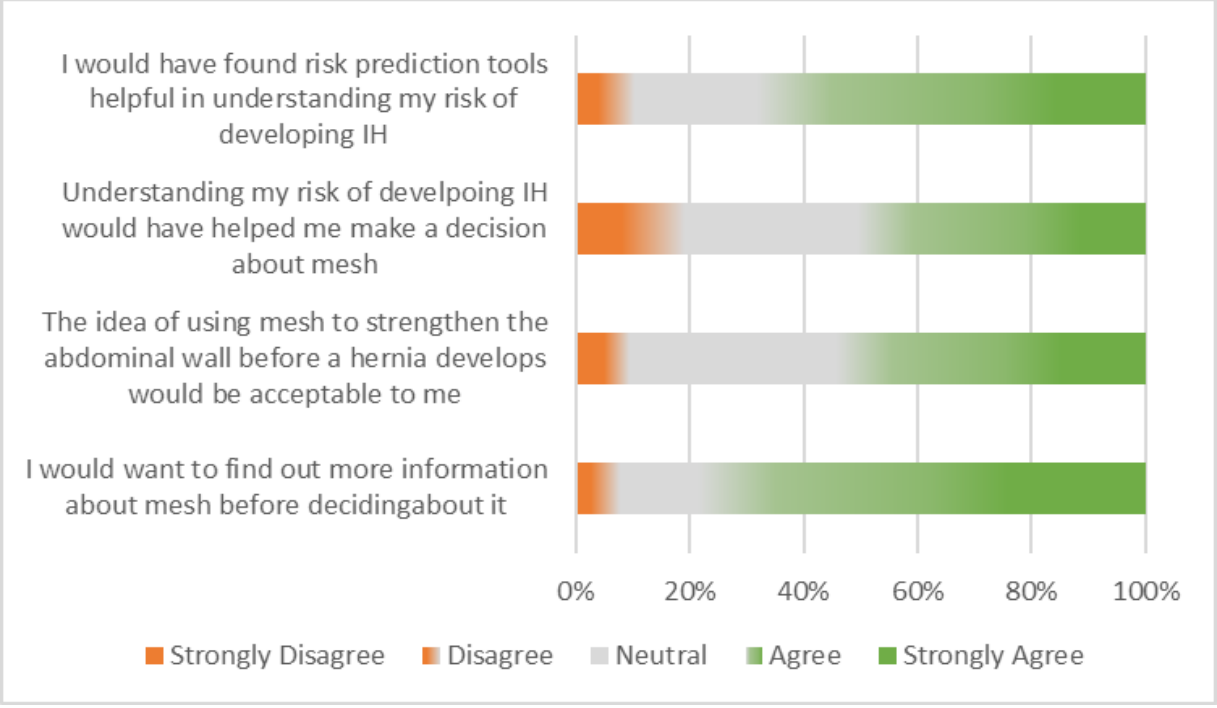

Figure 22: A 100% stacked bar chart showing patient responses to risk prediction and information about mesh

Table 23: Demographics of the interview participants

Patient ID	Age at time of response	Gender	Nature of surgery	Malignancy or benign	Post-operative Incisional hernia
01	73	Male	Elective	Malignancy	Yes
02	70	Male	Elective	Malignancy	Yes
03	79	Male	Elective	Malignancy	No
04	68	Female	Emergency	Malignancy	No
05	62	Male	Elective	Malignancy	Yes
06	58	Male	Elective	Malignancy	Yes
07	66	Male	Emergency	Malignancy	Yes
08	29	Female	Emergency	Malignancy	No
09	48	Female	Emergency	Benign	No
10	58	Female	Emergency	Benign	Yes
11	67	Male	Elective	Malignancy	No
12	73	Male	Elective	Malignancy	Yes

b) Qualitative results.

Twelve individuals participated in semi-structured interviews to discuss their thoughts on prophylactic mesh. Their demographics and clinical history can be seen in **Table 23** above. There was a wide range of ages (29-79) and a mix of gender and incisional hernia. Most participants had undergone elective surgery for malignancy, however there was a mix of benign and emergency cases. Following thematic analysis, three overarching themes were identified:

- Knowledge and understanding of mesh
- Acceptability of mesh
- Shared decision making

<u>Knowledge and understanding of mesh</u>

The participants' knowledge and understandings of "surgical mesh" were wide ranging. As seen in the quantitative data, participants were aware of mesh use in both hernia surgery and, as the following data extracts indicate, other types of surgery:

> *I think I've heard most about it* [mesh] *to do with bladder problems and it's more as I described it, almost like a sling that helps to support the pelvic muscles.* (**10**)

> *I know a bit about vaginal meshes. (….) it was like women had had lots of vaginal meshes put in after childbirth to help with prolapses.*(**08**)

Several participants indicated an awareness of the reasons for using surgical mesh:

> *To go under the abdominal cavity, under the wall in order to restrain the weaker points of the underlying core from breaking through from the intestines and causing a hernia.* (**07**)

> *It's* [mesh] *a very positive term for me, because the kind of thing that I imagine would strengthen the fault. (…).I think the concept is great. I think, the concept of putting in extra strength inside the stomach I think it's a great idea, sure.* (**02**)

Furthermore, across the data there was some understanding of the potential benefits, particularly in terms of reducing the risk of hernia:

> *There are benefits, the benefits being to maintain contain the hernia, or potential hernia.*(**03**)

Yet it was also clear that awareness of the composition of mesh among participants was variable:

> *I'm just gonna imagine a wire mesh put into your stomach where they're taking stuff out.* (**01**)

> *I just imagine it is like a piece of very fine gauze.*(**08**)

> *I'm guessing that what they had inserted was some kind of metal where I guess now is probably some kind of carbon fibre.* (**07**)

Furthermore, some participants indicated that they had never heard of mesh prior to participating in the study:

> *Not a term I have anything to do with. I don't know.* (**09**)

> *You're the first person that has mentioned it* [mesh]. (**02**)

Questions surrounding perceptions of mesh supported findings in the quantitative data. Of those participants who were familiar with mesh, data indicated that personal experience notwithstanding, sources of information were primarily the media, personal contacts and even work. Across the data however, negative perceptions of mesh, particularly in relation to gynaecological surgery, were evident and predominant:

> *They use it in ladies when they do repairs down below, and I've heard some horror stories about it. In fact, a colleague of mine, his wife had some mesh fitted and they've had to take it out because she's in severe pain and she's ended up paralysed from the waist down as a result of it.* (**06**)

> *I did listen to programs where women had mesh and ran into terrible difficulties, due to hysterectomies maybe*. (**05**)

However, one participant explained that despite negative media reporting about mesh, an acquaintance fitted with mesh had experienced no mesh related complications:

> *I have read articles in the news about mesh, and they've tended to be negative, having said that there's my other friend who had a hernia and he's not had any trouble since he's had the mesh fitted.* (**06**)

<u>Acceptability of mesh</u>

Despite the concerns about mesh expressed by many participants, in keeping with the findings of the quantitative data, most participants indicted that the idea of a prophylactic mesh to prevent hernias was acceptable. For some participants, acceptability of mesh was connected to their personal experience of having had mesh inserted and experiencing no mesh-related complications. Acceptability was also connected with surgeons' endorsement of mesh together with participants' trust in their surgeons to do the best for them:

> *I would have just left it to the surgeon. If he thinks it's good for me then carry on. Do it.* (**01**)

> *If they thought it was best for me, I would have probably agreed to it.* (**10**)

The acceptability of mesh was also connected with participants' understandings of incisional hernia as a risk, and what mesh would provide in terms of risk reduction:

> *If that had been put to me, you've got a one in four chance of developing hernia but if you have mesh one in 10 chance, I would have probably said I want to go with the mesh.* (**05**)

> *If the consultant said, 'we recommend that we use mesh. This will limit the possibility of help, limit the possibility of getting a hernia' yeah, I'm going to say, 'go ahead'.* (**11**)

Nonetheless, reservations about mesh remained. In particular, some participants voiced concerns about the mesh related complications, including the risk of infection and the potential for pain and feared something going wrong:

> *It's not natural and they've had problems with the mesh … and they seem to be in more pain after having the implant than they are without.* (**10**)

> *I would feel really nervous about having a mesh because it's a foreign thing put in my body, and I know about the whole vaginal mesh issue, and I would be worried that something would go wrong with it.* (**08**)

<u>Shared decision-making:</u>

The shared decision-making theme related to the clinician-patient relationship and how information was conveyed. This was split into three subthemes: content, provision and context. These broadly reflect the participants desire to have more information regarding mesh prophylaxis, which was also seen in the quantitative data.

The ‘content’ subtheme identified information that patients would like to receive about mesh that would influence their decision making around this, such as likelihood of success and possible complications.

> ***“****If I'd have the time and the opportunity. I’d have probably said, what are the drawbacks? Does anything go wrong with it?” (****07****)*
>
> *“You don’t tend to hear about the good side do you, so I don’t know if there’s something there that needs to be when people have the opportunity to have mesh fitted the positives are sold rather than just the negatives” (****06****)*
>
> ***“****I don't feel I know enough about it. And fine. It could be OK for the first year. Two years, five years. But what happens 10 years down the line or 15 or 20?” (****10****)*

The ‘provision’ subtheme focused on the delivery of information about mesh. Participants discussed possible use of a physical form of the information such as patient information leaflets or through previous patients’ experiences.

> “*Possibly a small pamphlet along with the chat with the Surgeon. I would think that would be for me the most helpful way of doing it*”. (**03**)
>
> *“I think I’d want to know the positives and the negatives first and foremost and I’d like perhaps to have some case studies from people like me that have a hernia and are living with a hernia……Or YouTube® videos or something”. (****06****)*

The ‘context’ subtheme focused on the co-existing factors that most of the patients had, which limited their ability to process information, for example having just been given a cancer diagnosis, needing a stoma, or undergoing an emergency procedure. They felt, therefore, that even if the mesh was explained to them prior to surgery, they wouldn’t have had the capacity to take in the extra information fully. This was not identified in the quantitative data and is important to consider as a factor that may negatively influence the acceptability of mesh to patients if not respected.

> *“It was a big op you know what I mean? You get told you’ve got cancer and things tend to go in one ear and out the other. You’re in a world of your own sometimes.” (****01****)*
>
> *“…..my concern is whether I would get the full operation, get the stoma, or get a reversible thing, you know….. It was how I would live without a bowel. The hernia business wasn’t any of my concern at all.”* (**02**)

*"I think that because my op was emergency … and there was a lot of overwhelming stuff going on and to know the hernia risk would have just been an extra thing for me to process." (**08**)*

*".....so you do need that period of time to process it, so right at the beginning when you know you're about to have surgery that's when you would need to hear about it to have time to read about it or do your research to make your decision, I think that's really important." (**06**)*

6.4 Discussion

This study aimed to assess perspectives on incisional hernia and mesh prophylaxis through the lens of the patient. The results demonstrate that pre-operative awareness of incisional hernia in our cohort of patients is low. Patients are aware of surgical mesh, but there is a predominance of negative views which appear to be driven by media influence. Despite these views, mesh prophylaxis is acceptable to patients, provided that patients are given enough time to process the information.

In this study, a cohort of patients who had undergone abdominal surgery were asked about their knowledge of incisional hernia and surgical mesh. When asked about the consent process, two thirds of patients had no knowledge of incisional hernia prior to their operation. Interestingly, quantitative and qualitative data demonstrate our study population is aware of surgical mesh, with 61.3% of patients saying they were aware of mesh being used in surgery. Qualitative data revealed that participants had heard of mesh use in relation to uro-gynaecological surgery as opposed to hernia surgery.

Given that the mean time from operation to completing the questionnaire was 3 years, this is perhaps not surprising, yet these results show no correlation between being diagnosed with incisional hernia and positive recall, nor in age, sex or nature of operation or if the patient had benign or malignant disease, suggesting that recall was similar between all patients participating. Considering that incisional hernia is the most frequently occurring complication of abdominal surgery, it is concerning that this may not be explained to patients in a manner that they can recall.

As previously discussed, there has been extensive negative media coverage regarding mesh, and our results indicate that this is impacting the view that our patients have, with 53% of

patients having a negative view of mesh, and the majority of this coming from media. The emergence of negative perceptions of mesh as a theme in the qualitative data enhances this finding, with participants referencing negative media sources.

Given the extent and reach of newer forms of media, such as social media, this influence is to be expected. In an analysis of posts regarding hernia mesh on two social media platforms, Fadaee et al. demonstrated that 39% of "Tweets" about hernia mesh on the platform "X®" (Previously known as Twitter) were negative, whereas on Facebook® this rose to 95% (Fadaee et al. 2020). Our results show that as a result, most participants had concerns about all domains of mesh (the domains being benefit, pain, safety and ease of removal), with only around 20% having no concerns at all. Despite these concerns, however, mesh prophylaxis was acceptable to 90% of respondents, and qualitative data supports the overall acceptability of mesh prophylaxis to patients. Our results suggest that in spite of negative preconceptions on mesh, if given time to discuss and the right information, patients would be willing to consider mesh prophylaxis.

a) High risk patients:

Explanation of risk to patients certainly appears to be a factor in determining acceptability of mesh, with 69% of our survey respondents indicating they would have found a risk predictor useful in understanding their risk of developing IH; a finding also backed up by qualitative data presented above.

Mesh prophylaxis is not acceptable to, nor suitable, for all patients and current EHS guidelines suggest that prophylaxis should be targeted to "High risk" patients (Deerenberg et al. 2022). As discussed in Chapter 5 this is a cohort that can be identified, yet how we define "high risk" has not yet been determined. Regarding complications, patients appetite for risk appears to be higher than surgeons. This finding is comparable to results from Neela et al., who asked patients and surgeons to complete three clinical scenarios with varying levels of risk of developing hernia and wound complications from mesh. For each of the three scenarios, patients were prepared to accept higher levels of risk than the surgeon, ranging from 11% in low-risk scenarios to 28% in high risk (Neela et al. 2023). This difference in attitudes likely reflects the difference between the static risk of the patient (a single roll

of a dice) compared to the longitudinal risk of the surgeon (multiple rolls of the dice), and surgeons should reflect on this when discussing risk to patients in the pre-operative setting.

b) Delivery of information:

Whilst the quantitative and qualitative data suggests a desire for patients to have more information about mesh, it was surprising to see the "context" subtheme emerge from the qualitative work. This suggests that a pre-operative discussion about mesh would have been too much information to process for some patients particularly at the time of cancer diagnosis or in an emergency setting.

Research into how patients process information has demonstrated that 40-80% of what a clinician explains is forgotten immediately after the consultation, and that this percentage increases in conjunction with the volume of information (Mcguire 1996; Kessels 2003). This percentage can be increased even more when associated with "attentional narrowing", whereby patients fixate on emotional or physical distress which further limits additional capacity to process information; seen in our study as those that reported only remembering being told they had cancer or that they might need a stoma (Schwabe et al. 2012).

With recent high court rulings such as "Montgomery vs Lanarkshire" (Chan et al. 2017) placing increased emphasis on informed consent, and with clinic time a precious commodity, awareness of how we deliver information to patients is of utmost importance. Moving forward, attention needs to focus on how we present information on risk-benefit to patients and allowing them the time and resource to think about it. The "content" and "provision" subthemes strengthen the survey results that show patients desire for more information and offer suggestions as to what this might involve and the medium in which it might be delivered. Further work should focus on development of patient-centred information, not only for mesh-prophylaxis but also for other peri-operative topics such as prehabilitation, stoma care and enhanced recovery programmes. The results of this study have the potential to influence information delivery across medical specialties and should not be seen as simply relating to incisional hernia prevention.

C) Strengths and Limitations:

The strength and weaknesses of this study lie in the study design and the patient population.

The convergent mixed-methods design was chosen to highlight the strengths of both quantitative and qualitative approaches and limit the weaknesses of both in answering the study question. One perceived limitation of this design is the unequal sample sizes between the quantitative and qualitative cohort giving less weight to the qualitative conclusions. With regard to these conclusions, it is worth noting that the triangulation between these qualitative and quantitative findings is excellent, strengthening and validating the qualitative results and helping to offset the difference in sample sizes. A second challenge with convergent mixed-methods studies is the potential discrepancy between findings in the qualitative and quantitative arms, something that was overcome in our study by using the same components in the design of both study arms and evidenced by the triangulation of findings between the two arms.

With regard to the selection of patients, there are a number of points to discuss. When considering time between surgery and participation, there will inevitably be recall bias in the accuracy of what patients can remember. As discussed in the methodology however, this patient group is best placed to comment on the pre-operative consent process. Whilst we may question the accuracy of information recall, our findings have allowed us to understand the mindset of our patients at the time of surgery, leading to findings that may well be important to other patient groups.

A limitation of mixed-methods studies is response bias and generalisability of results to the wider population. Response rates for postal surveys vary in the literature from 20-70% (Fincham 2008), and our response rate of 36.1% whilst acceptable, leaves potential for bias. Non-responder bias, in particular, has to be considered. Potential participants with strongly negative views towards mesh may have decided to ignore requests to participate and this may affect the generalisability of findings.

Level of participant education must also be considered. The national measure of deprivation used was low in our group, with a median decile of 8 and a mode of 10, implying a higher-

than-average level of education. Whilst this may affect the generalisability of our results, it is worth noting that the median WIMD decile of the population approached was 7, with a mode of 10, suggesting that our group of respondents does not differ significantly from the sampled population.

6.5 Conclusion

Mesh prophylaxis is acceptable to just under half of patients in spite of pre-existing concerns regarding mesh driven predominantly by negative media coverage, with some patients feeling that they had insufficient information to comment. Factors that influence acceptability are involvement of the patient in the decision-making process and the manner in which information is delivered to patients. It is important for clinicians to recognise the scenarios that might present information overload at the time of decision making for surgery in patients and to counter this by developing patient-centred resources to aid in information delivery.

a) Future work

Further work needs to focus on understanding how patients want to receive information and the development of patient information resources in conjunction with patient groups. These can be specific to mesh prophylaxis but are broadly applicable to patients undergoing any abdominal surgery.

Finally, the results presented here show that mesh prophylaxis may be acceptable to patients if given the right information around it. Further work is needed to understand the surgeon's viewpoint and identify barriers to mesh use from within the medical community in order to understand the issue of mesh hesitancy as a complete picture.

Chapter 7: Conclusions and future work

7.1 Review of Aims

This thesis aimed to discuss the incidence, impact and prevention of incisional hernia following abdominal surgery. The following aims, set at the beginning of this thesis were met.

1. To quantify the incidence of incisional hernia in abdominal surgery, and the impact it has on patients.

Chapter 2 describes the impact of incisional hernia on both patients and healthcare providers. By using routinely collected national level data it highlighted the incidence of incisional hernia repair by surgical specialty. Chapter 2 also charted the patient journey from index surgery to subsequent incisional hernia repair including the post-operative course and complications experienced by patients, alongside the costs incurred to healthcare services. This work is strengthened by Chapter 3, which updates the rates of incisional hernia in midline incisions and analyses changes in risk factors over time.

Incisional hernia rates have risen, likely through better recognition and detection. Patients undergoing midline abdominal incisions are at increased risk of developing incisional hernia, leading to reduction in quality of life and risk of needing further surgery, alongside significant cost to healthcare services. Both Chapter 2 and 3 work together to highlight the scale of the problem incisional hernia poses to surgeons, patients and healthcare services.

2. To identify modifiable surgical risk factors for incisional hernia and discuss strategies for implementing them into current practice.

Chapter 3 identified risk factors for developing incisional hernia through a systematic review and meta-regression. Much focus has been placed on abdominal wall closure technique, and this systematic review confirmed that small bites closure technique is associated with a significantly lower incisional hernia rate, targeting abdominal wall closure technique as a modifiable risk factor of interest.

In chapter 4 this was explored this further, discussing the surgeon as a risk factor for incisional hernia development and identifying surgical training in abdominal wall closure as a potential target for risk-modification. Although this work focuses on the Hughes technique

for abdominal wall closure, the principles of training and implementation of a new technique can be applied to both small bites closure and in training across medical specialties.

3. To modify and validate a risk-predictive tool for accurately identifying the patient at high-risk for developing incisional hernia in a colorectal cancer population.

Chapter 5 discussed attempts to quantify pre-operative, non-modifiable risk, further building on the results of chapter 3. Through collaboration and the re-purposing of RCT data, we have been able to show a moderate performance of the "Penn Hernia calculator" in predicting incisional hernia occurrence in colorectal cancer patients. Whilst the performance of the model in our cohort falls short of some predictive models, this is likely reflective of the multi-factorial nature of incisional hernia development, and the results allow clinicians to identify the "higher-risk" patients in order to target interventions such as off-midline closure or mesh-prevention.

4. To determine barriers to implementation of mesh prophylaxis.

Chapter 6 addresses the patient's perspective on mesh prophylaxis with an aim of understanding acceptability of mesh to patients. Broadly speaking, mesh prophylaxis was acceptable to patients, in spite of pre-held concerns regarding mesh safety. Patients were willing to accept medical advice when mesh was concerned, however patients wanted to be involved in the decision-making process and future implementation of mesh is likely to depend on the method and delivery of pre-operative information to patients.

7.2 Future work

This thesis has realised several areas for future research, practice and education. This relates both to incisional hernia prevention and areas of medical practice as a whole.

a) Implementation of change in abdominal wall closure:

This thesis has focused on identifying strategies for reducing the burden of incisional hernia to patients. Clear guidelines exist for abdominal wall closure techniques have been published (Deerenberg et al. 2022). However as previously discussed, implementation of

these on a local level remains slow. When considering barriers to implementation of techniques such as “Small Bites” closure, it helps to consider the “Health Belief Model” described in Chapter 6, and the drivers/barriers to making change which can be divided into the following categories:

1. Perceived susceptibility and severity:

As detailed in Chapters 2 and 3, there is a lack of data quantifying burden of incisional hernia to both patients and healthcare providers. Failure to recognise incisional hernia as both a frequent and significant complication of abdominal surgery, means that individuals do not consider acting as they do not perceive it as a problem. We hope that by publishing and presenting the work detailed in Chapters 2 and 3, we can begin to change attitudes towards abdominal wall closure.

2. Perceived Benefits and Barriers:

Part of this disconnect may be the disparity between findings of randomised control trials and the clinicians’ own practice. Results of RCT’s, such as the STITCH trial, with a selective inclusion criteria may not be seen as reflective of day-to-day practice. The nature of incisional hernia development and the risk factors that drive it make conducting a pragmatic randomised control trial difficult. This results in low quality evidence and a weak recommendation in the combined European and American Hernia Society guidelines (Deerenberg et al. 2022), thus providing uncertainty to the readers. When looking at this from a “Health Beliefs Model” framework, this manifests as a lack of perceived benefit, and the weak evidence may also act as a barrier to some individuals who are reluctant to change their practice.

The work presented in Chapter 5 and Chapter 6 is aimed at breaking down perceived barriers to mesh use. Risk-predictive tools can now be used with confidence in colorectal surgery to identify higher risk patients who would benefit from targeted mesh prophylaxis. Chapter 6 breaks down the barrier of the patient’s view on mesh and the manner in which we deliver information to our patients.

3. Cues to action

Finally, understanding and creating trigger points to enable a conversation about change is important. Many clinicians will have little idea of the scale of the problem within their practice.

b) "Cue to Action": a case study in abdominal wall closure implementation

Following the work presented in this thesis, it was decided to try to implement change within the Cardiff and Vale University Health Board colorectal surgery department using a targeted approach incorporating elements of implementation science described above.

1. Owning the problem

In order to present a "Cue to Action", an audit of incisional hernia rates within colorectal surgery was performed.

Patients undergoing colorectal surgery over a 1-year period were identified from retrospectively maintained databases. Emergency and elective patients were included and intraoperative data such as incision location and closure technique were recorded. Incisional hernia was assessed following review of year 2 CT scans, routinely performed in patients with colorectal cancer. 118 patients were included the final analysis, with an incisional hernia rate of 31.4% at a mean follow up time of 24.9 months. There was a significantly higher incisional hernia rate in patients undergoing midline extraction site compared to off-midline (40.7% vs 6.3%%, p=<0.001). When analysing closure techniques, there were lower, but non-significant incisional hernia rates in those closed with small bites technique compared to large bites (23.7% vs 35%.0%, p=0.216).

The aim of this work was to highlight the true rate of incisional hernia in colorectal cancer patients in our department. 1 in 3 patients undergoing colorectal cancer resections in our institution developed an incisional hernia, comparable to the 2-year results of the HART trial (Torkington et al. 2022).

2. Identifying and targeting barriers to change

This work was presented at the monthly general surgical audit meeting with the aim of stimulating discussion around small bites technique and off-midline extraction sites. The

discussion largely centred around concerns in the evidence for small bites technique, although other topics were identified, as seen in **Table 24**.

3. Targeted change

It was agreed that there should be a targeted, pragmatic guideline for abdominal wall closure for patients undergoing colorectal surgery based on the available evidence, which is currently under development. Following the agreement and implementation of these guidelines, a re-audit process is planned in order to assess the impact.

c) Summary

Implementation of new guidelines should follow a targeted approach, focussing on frameworks, such as the one demonstrated above, to target specific barriers to change on an individual level. National bodies should look at rolling out targeted implementation programmes to identify and then challenge barriers to implementation of abdominal wall closure guidelines.

Table 24: *Barriers and solutions to incisional hernia prevention*

Barriers identified	Example	Intervention
Lack of evidence for technique	"The issue here is weak recommendations in the guideline"	Explaining that there is no strong evidence for any abdominal wall closure technique, and small bites is the only technique with any evidence behind it.
Perceived lack of severity	"What proportion of these radiological hernias will go on to become clinically significant?"	Detailing the impact of incisional hernia to patients (Chapter 2)
Denial	"I never see any incisional hernias in my patients"	Highlighting follow-up methods in these patients combined with the data on incisional hernia repair (Chapter 3)
Lack of incentive	"It takes much longer" " I can't leave the trainee to close"	Education regarding benefits of small bite closure on a short-term basis (reduced burst abdomen rates etc)

7.3 The future of incisional hernia prevention:

Given the multi-factorial nature of incisional hernia development, it would be too simple to consider one intervention as definitive in reducing incisional hernia rates. Nor is it realistic to assume that incisional hernia can be eliminated entirely; there are no papers with incisional hernia rates of 0%, and papers reporting lower than expected incisional hernia rates should prompt closer analysis of the methodology. The future of incisional hernia is to be found in the combination of factors.

a) Marginal gains and care-bundles

The concept of marginal gains has been around since the 1920's (Durrand et al. 2014), however was popularised by Sir Dave Brailsford following the British Olympic cycling team's success at the 2008 and 2012 Olympic games (Slater 2012). The theory is nicely described by Brailsford himself: "*The whole principle came from the idea that if you broke down everything you could think of that goes into riding a bike and improved it by 1%, you will get a significant increase when you put them all back together"*. This principle has since been applied outside of professional sports, in business and engineering. In healthcare, examples of this can be found in care-pathways such as the Enhanced Recovery After Surgery (ERAS) care-pathway, developed to reduce mortality and morbidity in patients following abdominal surgery. The pathway breaks down components of the patient's journey into pre-operative, intra-operative and post-operative and looks at targeted improvement in components of these (**Table 25**).

This programme has been shown to reduce post-operative morbidity and reduce length of stay in patients, thus being cost effective, and as such is recommended by NICE for all patients undergoing elective abdominal surgery (NICE 2020).

There are multiple other examples of care-bundles throughout surgery, from the WHO checklist, aimed at reducing deaths from surgical error to bundles aimed at reducing surgical site infections (Public Health Wales NHS Trust 2018).

Table 25: *The Enhanced Recovery after Abdominal Surgery Pathway (ERAS)*

Pre-operative	
Optimising nutrition	Multidisciplinary team discussion
Prehabilitation	Cardio-pulmonary exercise testing
Patient education and counselling	Risk-stratification
Lifestyle modification (Smoking/Alcohol/Weight)	Pre-operative fasting and carbohydrate loading
Treatment of anaemia	
Intra-operative	
Surgical approach	Anaesthetic management
Prevention of hypothermia	Peri-operative fluid management
Post-operative	
Early mobilisation	Early drain removal
Early enteral feeding	Post-operative pain control

b) Incisional hernia prevention bundle:

In order to develop a bundle for incisional hernia prevention, it is important to break the process down into its core parts, in order to look for small improvements.

Pre-operative interventions

Much like the ERAS protocol, optimising the patient's condition before surgery is a key component to preventing incisional hernia, and all components of this should be incorporated.

Specific to incisional hernia prevention is the inclusion of pre-operative prediction and risk-stratification, and a summary of proposed interventions and their future development can be seen in **Table 26.** As we have demonstrated in Chapter 5, it is possible to quantify the risk of incisional hernia, and although these models need further external validation, they can aid clinicians and patients in decision making around abdominal wall closure and, as demonstrated in Chapter 6, are useful to patients in understanding their risk. These models are also likely to benefit from developments in understanding of risk using Artificial Intelligence (AI) to analyse large datasets or radiological images to identify new risk factors and aid in decision making (Elfanagely et al. 2021; McAuliffe et al. 2022).

Finally, as demonstrated in Chapter 6, patient awareness of incisional hernia as a complication of abdominal surgery is low, and patient's feel that they would like more information available to them. The work in Chapter 6 has highlighted that the method of information delivery is important to patients, and clinicians run the risk of information overload. Development of patient information resources is of utmost importance therefore, and future work should look at using qualitative analysis of patient focus groups and with the use of patient and public involvement in creation of resources. This work should be relevant to all aspects of abdominal surgery, as well as specifically to incisional hernia prevention and mesh prophylaxis.

Table 26: *A proposed pre-operative risk-reduction strategy to reduce incisional hernias*

Pre-operative risk-reduction	
Strategy	**Improvements required**
Prehabilitation (ERAS) *Weight-management, Anaemia, Smoking cessation, exercise programmes, CPET testing*	Implementation of pre-existing ERAS model
Risk-prediction	• Optimisation of predictive models • External validation • Quantification of the "high-risk" patient
MDT decision making *Incision location, closure technique, identification of patients for mesh-augmented closure*	Development of shared decision making on surgical method/patient identification.
Patient involvement *Education, Patient information resources*	Development of patient-centred resources regarding incisional hernia Development of mesh-specific information

Intra-operative interventions

Intra-operative prevention focuses on the implementation and strengthening of current strategies to reduce incisional hernia risk discussed in this thesis: closure technique, avoiding midline incisions and mesh prophylaxis. A summary or proposed changes can be seen in **Table 27**.

Of these three techniques, avoidance of midline incisions carries the lowest risk of incisional hernia by far. In trials comparing small stitch closure to mass closure technique, the lowest rate of incisional hernia was 13% (Deerenberg et al. 2015). In trials using prophylactic mesh, rates vary from 0%-23%, with a median rate of 11.9% (Olavarria et al. 2023). By comparison, incisional hernia rates in transverse incisions are 5.2% and as low as 2.1% in Pfannenstiel incisions (den Hartog et al. 2023); rates that simply are not consistently achieved by primary suture or mesh augmented closure. When combined with comparable surgical site outcomes between off-midline and midline incisions, and lower rates of pain, it seems that the most effective method of preventing incisional hernia may simply be avoiding the midline wherever possible.

Increasing use of off-midline extractions sites has been facilitated by this evolution of minimally invasive surgery. Traditionally, a midline extraction site would have to be created to extract the specimen and perform an extra-corporeal anastomosis (EA). The advancement of laparoscopic skills has resulted in the development of intra-corporeal anastomosis (IA), in which the anastomosis is created inside the abdomen. This allows smaller extraction sites, decreasing wound complications, and is associated with reduced short-term morbidity and decreased length of hospital stay when compared to EA (van Oostendorp et al. 2017).

Robotic-assisted surgery has facilitated the use of intra-corporeal anastomosis by offering improved visualisation and more precise dissection and handling of tissues, although the evidence base for robotic IA is lacking in high-quality evidence. A systematic review published in 2021 compared both robotic right hemicolectomy (RRC) and laparoscopic right hemicolectomy (LRC) in both IA and EA subgroups. A comparison of both RRC and LRC demonstrated that RRC was associated with shorter LOS, shorter time to first flatus and

lower overall complications compared to LRC. In the IA sub-group, RRC was associated with shorter length of stay than LRC, but longer operative times and increased cost (Genova et al. 2021).

There is a paucity of data on long-term outcomes of IA following right hemicolectomy, specifically with regard to incisional hernia. A retrospective, single-surgeon analysis performed by Widmar et al. in 2020 demonstrated a significantly lower rate of incisional hernia in patients undergoing RRC with IA compared with RRC and EA (12% vs 2%, p=0.007). The IA group was also associated with a decreased length of stay but increased operating time (Widmar et al. 2020). This echoed a small 2017 retrospective cohort study by Lujan et al. which showed fewer incisional hernias in patients undergoing robotic IA compared to laparoscopic EA (Lujan et al. 2018).

Whilst there is increasing evidence that intracorporeal anastomosis is comparable to extracorporeal anastomosis with regard to short-term outcomes, there are no randomised control trials exploring long-term advantages of IA as a technique. Robotic-assisted intra-corporeal anastomosis may be the best facilitator of off-midline extraction sites and further work is needed to strengthen the evidence base.

Quite what this work may look like, however, is unclear. Randomised control trials comparing IA and off-midline extraction with EA with midline extraction are unlikely to have equipoise between the groups, both with surgeons and indeed patients, given the strength of evidence for the benefit of off-midline incisions. An understanding of current day-to-day practice may be beneficial in aiding the design of future work and should incorporate current practice in other surgical specialties such as gynaecology and urology.

In some patients however, it is not possible to avoid midline incisions, therefore as highlighted in Chapter 3, it is important to strengthen evidence surrounding closure of midline incisions. This should take the form of strengthening evidence around optimal midline closure, and in the long-term outcomes of mesh prophylaxis.

Table 27: *A Proposed intra-operative strategy to reduce incisional hernia occurrence*

Intra-operative risk reduction	
Strategy	**Improvements required**
Increasing the use of off-midline incisions *Intra-corporeal anastomosis, Robotic surgery*	• Strengthening evidence base regarding minimally invasive surgery and techniques to facilitate off-midline incisions. • Snapshot study of current practice regarding the use of midline incisions. • Identification of optimal closure technique for off-midline incisions.
Identification and implementation of optimal closure technique	• Strengthening evidence base behind small stitch • Targeted implementation strategies on a local level.
Mesh-augmented abdominal wall closure *Mesh location, Mesh type, High-risk patient, Surgeon hesitancy*	• Trials into long-term impact of mesh (pain, abdominal wall function) • Mixed-methods research into surgeon's views into the acceptability of mesh
Surgical education *Standardisation of technique and training.*	• Inclusion of a standardised abdominal wall closure technique in teaching courses • Incorporation of abdominal wall closure techniques into pan-specialty national training curriculums

With regard to mesh prophylaxis, Chapter 6 has demonstrated that mesh prophylaxis is acceptable to patients, given the right context. In order to build on this, further work should focus on mixed- methods research assessing the acceptability of mesh to surgeons in order to build a complete picture of the barriers to mesh use.

Finally, as discussed in Chapter 4, further work is needed to standardise surgical teaching and changing the attitudes towards abdominal wall closure, and inclusion of abdominal wall closure on national surgical curriculums.

Post-operative interventions

Post-operative strategies to reduce incisional hernia occurrence should focus primarily on the reduction of surgical site infections. A summary of proposed interventions can be seen in **Table 28**.

As discussed in Chapter 1, SSI's have a strong correlation with incisional hernia development due to the impaired tissue healing that occurs (Bishop 2008). Both incisional hernia and surgical site infections share similar risk-factors (Walming et al. 2017), and therefore both stand to benefit from targeted intervention to reduce risk. Care bundles for surgical site infections in abdominal surgery exist, and meta-analysis of these has shown efficacy in reducing rates of infection, although no strong evidence for characteristics of effective care bundles was demonstrated (Wolfhagen et al. 2022). Perioperative interventions such as avoiding mechanical bowel preparation and pre-operative hair removal, using wound edge protectors and ensuring normothermia have been shown to be effective (Anthony 2011), alongside surgical closure techniques such as avoiding surgical staples, and changing gloves and drapes prior to skin closure (Kwaan et al. 2016). There remains, however, heterogeneity between studies, with multiple changes being compared and no consistency in diagnosis of SSI between studies, limiting the conclusions that can be drawn. Furthermore, RCTs into optimal wound closure technique are currently ongoing and may help to provide high quality evidence for one closure technique over others (Pinkney et al. 2011).

Table 28: *A Proposed post-operative risk-reduction strategy*

Post-operative risk-reduction	
Strategy	**Improvements required**
Reduction of surgical site infections	Implementation of surgical site infection bundles
Return to abdominal wall function *Impact of rehabilitation, return to strenuous activity*	Tissue studies assessing abdominal wall strength Research focussing on rehabilitation and timing of return to activity

To date, no evidence exists regarding return to function after abdominal surgery from the view of incisional hernia prevention. Advice to patients is dependent therefore on surgical opinion and not guided by hard evidence. A systematic review published in 2021 identified 7 studies that assessed abdominal wall tissue healing, however found significant heterogeneity in their methodology and findings, meaning no impactful conclusions could be drawn. The same systematic review identified 22 studies looking at return to function after abdominal surgery, but again was limited in its conclusions due to study heterogeneity (Loor et al. 2021b). The current EHS guidance on abdominal wall closure technique did not identify any prospective study assessing return to activity after abdominal surgery (Deerenberg et al. 2022). The impact of return to physical activity on abdominal wall healing is yet unknown and prospective studies into this are needed.

Finally, this thesis has demonstrated that both the manner in which we deliver information to patients, and the design of the information we provide is key to their understanding and engagement. Future work should focus on the creation of patient information resources surrounding the patient journey and providing information on all aspects of peri-operative care. This should be created using patient focus groups in order to understand the needs our patients and the manner in which they would like to receive information.

7.4 Original contribution to knowledge

The work contained in this thesis has contributed to furthering scientific knowledge in a number of key areas.

The work presented in Chapter 2 is the first to document the impact that incisional hernia has on patients and healthcare services. It provides a strong argument for incisional hernia prevention that it is hoped will help to convince surgeons of the day-to-day impact of incisional hernia and aid a change in practice.

The work presented in Chapter 5 is the first external validation of the Penn Hernia Calculator and as such, allows the promotion of this tool for colorectal surgeons around the world to use.

Finally, the work presented in Chapter 6 represents the first attempt at understanding external barriers to mesh prophylaxis. Understanding the patient's perspective is crucial, and the findings of attentional narrowing in patients is vital for any patient-facing healthcare professional to understand.

7.5 Conclusion

Incisional hernia is the most commonly occurring complication of abdominal surgery. For decades, surgeons have been under-reporting the prevalence of this iatrogenic condition, with little recognition of the consequences of its development on their patients. Whilst no single technique can eliminate risk of incisional hernia entirely, the risk can be modified, and this thesis adds weight to that body of evidence and strengthens the argument that further change is necessary.

This thesis has found that rates in midline incisions have increased, such as now 1 in 6 patients undergoing surgery through the midline will develop incisional hernia and has detailed the morbidity and cost of incisional hernia to both the patient and healthcare services.

As discussed in the introduction, incisional hernia rates in off-midline incisions are significantly lower (den Hartog et al. 2023). In spite of changes in recommended midline

closure techniques, rates in midline incisions fail to come close to those in off-midline, offering the strongest argument yet to avoiding the midline wherever possible. Targeted mesh-prophylaxis also needs to be explored further. As evidenced throughout this thesis, this is acceptable to patients if given the right information in the right manner and as demonstrated in chapter 5, can be targeted towards higher-risk patients using predictive calculators.

On a broader level, attitudes towards abdominal wall closure and incisional hernia prevention need to change. Current uptake of closure techniques such as small stitch and mesh prophylaxis is slow (Fischer et al. 2019a), and whilst the evidence base for both can certainly be strengthened, the value of more high-quality level 1 evidence needs to be considered. More importantly, perhaps, we should look to the surgeon as a barrier to mesh use and aim to identify factors that influence surgical decision making in an attempt to implement meaningful change.

Finally, incisional hernia rates quoted by randomised control trials with strict inclusion/exclusion criteria are unlikely to be reflective of day-to-day practice, so an understanding of local practice and national implementation strategies is likely to have more success at bringing the problem closer to home and promote ownership of the problem on an individual level.

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Appendices

Appendix 1: *The cost of incisional hernia*

1.1) A List of OPCS-4 codes used to identify patients in HES

Appendix 2: *How are we doing?*

1) Characteristics of included studies

2) A Funnel plot of included studies and calculation of incisional hernia rate

Appendix 3: *Can we predict the future?*

1) Characteristics of included patients from the HART study

Appendix 4: *What does the patient think?*

1) Patient consent form

2) Patient information sheet

3) Patient questionnaire

Appendix 1: *The cost of incisional hernia*

1) A list of OPCS-4 codes used to identify patients in HES

OPCS-4 or ICD-10 code	Code	Description
K43	ICD-10	Ventral hernia
T25	OPCS-4	Repair Hernia Incisional NEC
T26	OPCS-4	Repair Hernia Incisional Recurrent

Index Surgery Grouping	OPCS-4 code	Description
Colorectal surgery	H101	Sigmoid colectomy and end to end anastomosis of ileum to rectum
Colorectal surgery	H102	Sigmoid colectomy and anastomosis of colon to rectum
Colorectal surgery	H103	Sigmoid colectomy and anastomosis NEC
Colorectal surgery	H104	Sigmoid colectomy and ileostomy HFQ
Colorectal surgery	H105	Sigmoid colectomy and exteriorisation of bowel NEC
Colorectal surgery	H106	Sigmoid colectomy and end to side anastomosis
Colorectal surgery	H108	Other specified excision of sigmoid colon
Colorectal surgery	H109	Unspecified excision of sigmoid colon
Colorectal surgery	H111	Colectomy and end to end anastomosis of colon-to-colon NEC

Colorectal surgery	H112	Colectomy and side to side anastomosis of ileum to colon NEC
Colorectal surgery	H113	Colectomy and anastomosis NEC
Colorectal surgery	H114	Colectomy and ileostomy NEC
Colorectal surgery	H115	Colectomy and exteriorisation of bowel NEC
Colorectal surgery	H116	Colectomy and end to side anastomosis NEC
Colorectal surgery	H118	Other specified other excision of colon
Colorectal surgery	H119	Unspecified other excision of colon
Colorectal surgery	H121	Excision of diverticulum of colon
Colorectal surgery	H122	Excision of lesion of colon NEC
Colorectal surgery	H123	Destruction of lesion of colon NEC
Colorectal surgery	H128	Other specified extirpation of lesion of colon
Colorectal surgery	H129	Unspecified extirpation of lesion of colon
Colorectal surgery	H131	Bypass of colon by anastomosis of ileum to colon
Colorectal surgery	H132	Bypass of colon by anastomosis of caecum to sigmoid colon
Colorectal surgery	H133	Bypass of colon by anastomosis of transverse colon to sigmoid colon
Colorectal surgery	H135	Bypass of colon by anastomosis of colon to rectum NEC
Colorectal surgery	H138	Other specified bypass of colon
Colorectal surgery	H139	Unspecified bypass of colon
Colorectal surgery	H141	Tube caecostomy

Colorectal surgery	H142	Refashioning of caecostomy
Colorectal surgery	H143	Closure of caecostomy
Colorectal surgery	H144	Appendicocaecostomy
Colorectal surgery	H148	Other specified exteriorisation of caecum
Colorectal surgery	H149	Unspecified exteriorisation of caecum
Colorectal surgery	H151	Loop colostomy
Colorectal surgery	H152	End colostomy
Colorectal surgery	H153	Refashioning of colostomy
Colorectal surgery	H154	Closure of colostomy
Colorectal surgery	H155	Dilation of colostomy
Colorectal surgery	H156	Reduction of prolapse of colostomy
Colorectal surgery	H157	Percutaneous endoscopic sigmoid colostomy
Colorectal surgery	H158	Other specified other exteriorisation of colon
Colorectal surgery	H159	Unspecified other exteriorisation of colon
Colorectal surgery	H161	Drainage of colon
Colorectal surgery	H162	Caecotomy
Colorectal surgery	H163	Colotomy
Colorectal surgery	H168	Other specified incision of colon
Colorectal surgery	H169	Unspecified incision of colon
Colorectal surgery	H171	Open reduction of intussusception of colon

Colorectal surgery	H172	Open reduction of volvulus of caecum
Colorectal surgery	H173	Open reduction of volvulus of sigmoid colon
Colorectal surgery	H174	Open reduction of volvulus of colon NEC
Colorectal surgery	H175	Open relief of strangulation of colon
Colorectal surgery	H176	Open relief of obstruction of colon NEC
Colorectal surgery	H178	Other specified intra-abdominal manipulation of colon
Colorectal surgery	H179	Unspecified intra-abdominal manipulation of colon
Colorectal surgery	H181	Open colonoscopy
Colorectal surgery	H188	Other specified open endoscopic operations on colon
Colorectal surgery	H189	Unspecified open endoscopic operations on colon
Colorectal surgery	H191	Open biopsy of lesion of colon
Colorectal surgery	H192	Fixation of colon
Colorectal surgery	H193	Enterorrhaphy of colon
Colorectal surgery	H194	Open removal of foreign body from colon
Colorectal surgery	H198	Other specified other open operations on colon
Colorectal surgery	H199	Unspecified other open operations on colon
Colorectal surgery	H291	Subtotal excision of colon and rectum
Colorectal surgery	H292	Subtotal excision of colon and rectum
Colorectal surgery	H293	Subtotal excision of colon
Colorectal surgery	H294	Subtotal excision of colon and creation of colonic pouch NEC

Colorectal surgery	H298	Other specified subtotal excision of colon
Colorectal surgery	H299	Unspecified subtotal excision of colon
Colorectal surgery	H321	Resiting of colostomy
Colorectal surgery	H328	Other specified exteriorisation of colon
Colorectal surgery	H329	Unspecified exteriorisation of colon
Colorectal surgery	H331	Abdominoperineal excision of rectum and end colostomy
Colorectal surgery	H332	Proctectomy and anastomosis of colon to anus
Colorectal surgery	H333	Anterior resection of rectum and anastomosis of colon to rectum
Colorectal surgery	H334	Anterior resection of rectum and anastomosis NEC
Colorectal surgery	H335	Rectosigmoidectomy and closure of rectal stump
Colorectal surgery	H336	Anterior resection of rectum and exteriorisation of bowel
Colorectal surgery	H337	Perineal resection of rectum HFQ
Colorectal surgery	H338	Other specified excision of rectum
Colorectal surgery	H339	Unspecified excision of rectum
Colorectal surgery	H628	Other specified other operations on bowel
Colorectal surgery	H629	Unspecified other operations on bowel
Colorectal surgery	H661	Excision of ileoanal pouch
Colorectal surgery	H662	Revision of ileoanal pouch
Colorectal surgery	H668	Other specified therapeutic operations on ileoanal pouch
Colorectal surgery	H669	Unspecified therapeutic operations on ileoanal pouch

Bariatric and Gastrectomy	A272	Proximal gastric vagotomy
Bariatric and Gastrectomy	G301	Gastroplasty NEC
Bariatric and Gastrectomy	G302	Partitioning of stomach NEC
Bariatric and Gastrectomy	G303	Partitioning of stomach using band
Bariatric and Gastrectomy	G304	Partitioning of stomach using staples
Bariatric and Gastrectomy	G261	Allotransplantation of stomach
Bariatric and Gastrectomy	G269	Unspecified transplantation of stomach
Bariatric and Gastrectomy	G271	Total gastrectomy and excision of surrounding tissue
Bariatric and Gastrectomy	G272	Total gastrectomy and anastomosis of oesophagus to duodenum
Bariatric and Gastrectomy	G273	Total gastrectomy and interposition of jejunum
Bariatric and Gastrectomy	G274	Total gastrectomy and anastomosis of oesophagus
Bariatric and Gastrectomy	G275	Total gastrectomy and anastomosis of oesophagus to jejunum NEC

Bariatric and Gastrectomy	G278	Other specified total excision of stomach
Bariatric and Gastrectomy	G279	Unspecified total excision of stomach
Bariatric and Gastrectomy	G281	Partial gastrectomy and anastomosis of stomach to duodenum
Bariatric and Gastrectomy	G282	Partial gastrectomy and anastomosis of stomach to transposed
Bariatric and Gastrectomy	G283	Partial gastrectomy and anastomosis of stomach to jejunum NEC
Bariatric and Gastrectomy	G284	Sleeve gastrectomy and duodenal switch
Bariatric and Gastrectomy	G285	Sleeve gastrectomy NEC
Bariatric and Gastrectomy	G341	Creation of permanent gastrostomy
Bariatric and Gastrectomy	G342	Creation of temporary gastrostomy
Bariatric and Gastrectomy	G343	Reconstruction of gastrostomy
Hepatobiliary surgery	J021	Right hemihepatectomy NEC
Hepatobiliary surgery	J022	Left hemihepatectomy NEC
Hepatobiliary surgery	J023	Resection of segment of liver

Hepatobiliary surgery	J024	Wedge excision of liver
Hepatobiliary surgery	J025	Marsupialisation of lesion of liver
Hepatobiliary surgery	J026	Extended right hemihepatectomy
Hepatobiliary surgery	J027	Extended left hemihepatectomy
Hepatobiliary surgery	J028	Other specified partial excision of liver
Hepatobiliary surgery	J029	Unspecified partial excision of liver
Hepatobiliary surgery	J031	Excision of lesion of liver NEC
Hepatobiliary surgery	J032	Destruction of lesion of liver NEC
Hepatobiliary surgery	J033	Thermal ablation of single lesion of liver
Hepatobiliary surgery	J034	Thermal ablation of multiple lesions of liver
Hepatobiliary surgery	J035	Excision of multiple lesions of liver
Hepatobiliary surgery	J038	Other specified extirpation of lesion of liver
Hepatobiliary surgery	J039	Unspecified extirpation of lesion of liver
Hepatobiliary surgery	J041	Removal of lacerated fragment of liver
Hepatobiliary surgery	J042	Repair of laceration of liver
Hepatobiliary surgery	J691	Total excision of spleen and replantation of fragments of spleen
Hepatobiliary surgery	J692	Total splenectomy
Hepatobiliary surgery	J693	Excision of accessory spleen
Hepatobiliary surgery	J698	Other specified total excision of spleen
Hepatobiliary surgery	J699	Unspecified total excision of spleen

Hepatobiliary surgery	J701	Partial splenectomy
Hepatobiliary surgery	J702	Marsupialisation of lesion of spleen
Hepatobiliary surgery	J708	Other specified other excision of spleen
Hepatobiliary surgery	J709	Unspecified other excision of spleen
Hepatobiliary surgery	J724	Repair of spleen
Hepatobiliary surgery	J725	Banding of spleen
Transplant surgery	J011	Orthotopic transplantation of liver NEC
Transplant surgery	J012	Heterotopic transplantation of liver
Transplant surgery	J013	Replacement of previous liver transplant
Transplant surgery	J015	Orthotopic transplantation of whole liver
Transplant surgery	J018	Other specified transplantation of liver
Transplant surgery	J019	Unspecified transplantation of liver
Transplant surgery	J691	Total excision of spleen and replantation of fragments of spleen
Transplant surgery	J692	Total splenectomy
Transplant surgery	J693	Excision of accessory spleen
Transplant surgery	J698	Other specified total excision of spleen
Transplant surgery	J699	Unspecified total excision of spleen
Transplant surgery	J701	Partial splenectomy
Transplant surgery	J541	Transplantation of pancreas and duodenum
Transplant surgery	J542	Transplantation of whole pancreas

Transplant surgery	J543	Transplantation of tail of pancreas
Transplant surgery	J544	Transplantation of islet of langerhans
Transplant surgery	J549	Unspecified transplantation of pancreas
Transplant surgery	J551	Total pancreatectomy and excision of surrounding tissue
Transplant surgery	J552	Total pancreatectomy NEC
Transplant surgery	J553	Excision of transplanted pancreas
Transplant surgery	J558	Other specified total excision of pancreas
Transplant surgery	J559	Unspecified total excision of pancreas
Transplant surgery	J561	Pancreaticoduodenectomy and excision of surrounding tissue
Transplant surgery	J562	Pancreaticoduodenectomy and resection of antrum of stomach
Transplant surgery	J563	Pancreaticoduodenectomy NEC
Transplant surgery	M011	Autotransplantation of kidney
Transplant surgery	M012	Allotransplantation of kidney from live donor
Transplant surgery	M018	Other specified transplantation of kidney
Transplant surgery	M019	Unspecified transplantation of kidney
Gynaecologic surgery	Q071	Abdominal hysterocolpectomy and excision of periuterine tissue
Gynaecologic surgery	Q072	Abdominal hysterectomy and excision of periuterine tissue NEC
Gynaecologic surgery	Q073	Abdominal hysterocolpectomy NEC
Gynaecologic surgery	Q074	Total abdominal hysterectomy NEC
Gynaecologic surgery	Q075	Subtotal abdominal hysterectomy

Gynaecologic surgery	Q076	Excision of accessory uterus
Gynaecologic surgery	Q078	Other specified abdominal excision of uterus
Gynaecologic surgery	Q079	Unspecified abdominal excision of uterus
Vascular surgery	I713	Abdominal aortic aneurysm, ruptured
Vascular surgery	I714	Abdominal aortic aneurysm, without mention of rupture
Vascular surgery	I715	Thoracoabdominal aortic aneurysm, ruptured
Vascular surgery	I716	Thoracoabdominal aortic aneurysm, without mention of rupture
Vascular surgery	I718	Aortic aneurysm of unspecified site, ruptured
Vascular surgery	I719	Aortic aneurysm of unspecified site, without mention of rupture
Vascular surgery	I722	Aneurysm and dissection of renal artery
Vascular surgery	I723	Aneurysm and dissection of iliac artery
Urological Surgery	M01	Transplantation of kidney
Urological Surgery	M011	Autotransplantation of kidney
Urological Surgery	M012	Allotransplantation of kidney from live donor
Urological Surgery	M013	Allotransplantation of kidney from cadaver NEC
Urological Surgery	M014	Allotransplantation of kidney from cadaver heart beating
Urological Surgery	M015	Allotransplantation of kidney from cadaver heart non-beating
Urological Surgery	M018	Other specified transplantation of kidney
Urological Surgery	M019	Unspecified transplantation of kidney
Urological Surgery	M02	Total excision of kidney

Urological Surgery	M021	Nephrectomy and excision of perirenal tissue
Urological Surgery	M022	Nephroureterectomy NEC
Urological Surgery	M023	Bilateral nephrectomy
Urological Surgery	M024	Excision of half of horseshoe kidney
Urological Surgery	M025	Nephrectomy NEC
Urological Surgery	M026	Excision of rejected transplanted kidney
Urological Surgery	M027	Excision of transplanted kidney NEC
Urological Surgery	M028	Other specified total excision of kidney
Urological Surgery	M029	Unspecified total excision of kidney
Urological Surgery	M03	Partial excision of kidney
Urological Surgery	M031	Heminephrectomy of duplex kidney
Urological Surgery	M032	Division of isthmus of horseshoe kidney
Urological Surgery	M038	Other specified partial excision of kidney
Urological Surgery	M039	Unspecified partial excision of kidney
Urological Surgery	M04	Open extirpation of lesion of kidney
Urological Surgery	M041	Deroofing of cyst of kidney
Urological Surgery	M042	Open excision of lesion of kidney NEC
Urological Surgery	M043	Open destruction of lesion of kidney
Urological Surgery	M048	Other specified open extirpation of lesion of kidney
Urological Surgery	M049	Unspecified open extirpation of lesion of kidney

Urological Surgery	M05	Open repair of kidney
Urological Surgery	M051	Open pyeloplasty
Urological Surgery	M052	Open revision of pyeloplasty
Urological Surgery	M053	Nephropexy
Urological Surgery	M054	Plication of kidney
Urological Surgery	M055	Repair of laceration of kidney
Urological Surgery	M058	Other specified open repair of kidney
Urological Surgery	M059	Unspecified open repair of kidney
Urological Surgery	M06	Incision of kidney
Urological Surgery	M061	Open removal of calculus from kidney
Urological Surgery	M062	Drainage of kidney NEC
Urological Surgery	M063	Closure of nephrostomy
Urological Surgery	M064	Code retired - refer to introduction
Urological Surgery	M068	Other specified incision of kidney
Urological Surgery	M069	Unspecified incision of kidney
Urological Surgery	M08	Other open operations on kidney
Urological Surgery	M081	Open biopsy of lesion of kidney
Urological Surgery	M082	Open denervation of kidney
Urological Surgery	M083	Exploration of kidney
Urological Surgery	M084	Exploration of transplanted kidney

Urological Surgery	M088	Other specified other open operations on kidney
Urological Surgery	M089	Unspecified other open operations on kidney
Urological Surgery	M18	Excision of ureter
Urological Surgery	M181	Total ureterectomy
Urological Surgery	M182	Excision of segment of ureter
Urological Surgery	M183	Secondary ureterectomy
Urological Surgery	M184	Excision of duplex ureter
Urological Surgery	M188	Other specified excision of ureter
Urological Surgery	M189	Unspecified excision of ureter
Urological Surgery	M19	Urinary diversion
Urological Surgery	M191	Construction of ileal conduit
Urological Surgery	M192	Creation of urinary diversion to intestine NEC
Urological Surgery	M193	Revision of urinary diversion
Urological Surgery	M194	Cutaneous ureterostomy NEC
Urological Surgery	M195	Revision of ureterostomy stoma
Urological Surgery	M196	Percutaneous tunnelled kidney to bladder bypass using prosthesis
Urological Surgery	M198	Other specified urinary diversion
Urological Surgery	M199	Unspecified urinary diversion
Urological Surgery	M20	Replantation of ureter

Urological Surgery	M201	Bilateral replantation of ureter
Urological Surgery	M202	Unilateral replantation of ureter
Urological Surgery	M203	Replantation of ureter after urinary diversion
Urological Surgery	M208	Other specified replantation of ureter
Urological Surgery	M209	Unspecified replantation of ureter
Urological Surgery	M21	Other connection of ureter
Urological Surgery	M211	Direct anastomosis of ureter to bladder
Urological Surgery	M212	Anastomosis of ureter to bladder using flap of bladder
Urological Surgery	M213	Ileal replacement of ureter
Urological Surgery	M214	Colonic replacement of ureter
Urological Surgery	M215	Revision of anastomosis of ureter NEC
Urological Surgery	M216	Ureteroureterostomy
Urological Surgery	M218	Other specified other connection of ureter
Urological Surgery	M219	Unspecified other connection of ureter
Urological Surgery	M22	Repair of ureter
Urological Surgery	M221	Suture of ureter
Urological Surgery	M222	Removal of ligature from ureter
Urological Surgery	M223	Closure of ureteric fistula
Urological Surgery	M228	Other specified repair of ureter
Urological Surgery	M229	Unspecified repair of ureter

Urological Surgery	M23	Incision of ureter
Urological Surgery	M231	Open ureterolithotomy
Urological Surgery	M238	Other specified incision of ureter
Urological Surgery	M239	Unspecified incision of ureter
Urological Surgery	M25	Other open operations on ureter
Urological Surgery	M251	Excision of ureterocele
Urological Surgery	M252	Open excision of lesion of ureter NEC
Urological Surgery	M253	Ureterolysis
Urological Surgery	M254	Open biopsy of lesion of ureter
Urological Surgery	M255	Open exploration of ureter
Urological Surgery	M258	Other specified other open operations on ureter
Urological Surgery	M259	Unspecified other open operations on ureter
Urological Surgery	M34	Total excision of bladder
Urological Surgery	M341	Cystoprostatectomy
Urological Surgery	M342	Cystourethrectomy
Urological Surgery	M343	Cystectomy NEC
Urological Surgery	M344	Simple cystectomy
Urological Surgery	M348	Other specified total excision of bladder
Urological Surgery	M349	Unspecified total excision of bladder
Urological Surgery	M35	Partial excision of bladder

Urological Surgery	M351	Diverticulectomy of bladder
Urological Surgery	M358	Other specified partial excision of bladder
Urological Surgery	M359	Unspecified partial excision of bladder
Urological Surgery	M36	Enlargement of bladder
Urological Surgery	M361	Caecocystoplasty
Urological Surgery	M362	Ileocystoplasty
Urological Surgery	M363	Colocystoplasty
Urological Surgery	M368	Other specified enlargement of bladder
Urological Surgery	M369	Unspecified enlargement of bladder
Urological Surgery	M37	Other repair of bladder
Urological Surgery	M371	Cystourethroplasty
Urological Surgery	M372	Repair of vesicocolic fistula
Urological Surgery	M373	Repair of rupture of bladder
Urological Surgery	M61	Open excision of prostate
Urological Surgery	M611	Total excision of prostate and capsule of prostate
Urological Surgery	M612	Retropubic prostatectomy
Urological Surgery	M618	Other specified open excision of prostate
Urological Surgery	M619	Unspecified open excision of prostate
Urological Surgery	M62	Other open operations on prostate
Urological Surgery	M831	Drainage of paravesical abscess

Urological Surgery	M832	Exploration of retropubic space
Urological Surgery	M24	Other urinary diversion
Urological Surgery	M245	Creation of continent cystostomy NEC
Urological Surgery	M246	Creation of continent cystostomy using appendix
Urological Surgery	M247	Creation of continent cystostomy using ileum
Urological Surgery	M248	Other specified other urinary diversion

Appendix 2: *How are we doing?*

2.1) A list of study variables extracted

Study-Level variables	Patient-related variables[1]	Surgery-related variables[1]	Outcomes	Exclusion Criteria[2]
Year of publication	Age*	Emergency/Elective surgery	Incisional hernia	Previous Laparotomy
Type of study	BMI*	Cancer/Benign surgery	Follow up time (months)*	Previous IH
Number of patients	Sex	Colorectal surgery	Symptomatic incisional hernia [1]	Steroid use
Includes consecutive patients	Diabetes	Other GI surgery	IH undergoing repair [1]	Immunosuppression
Type of data analysis (retrospective/prospective)	Cardiac Failure	Vascular surgery	Burst abdomen [1]	Pregnancy
Definition of IH (Radiological/Clinical/Either/Both)	Renal disease	Urology surgery	Surgical site infection [1]	Emergency surgery
Number of surgeons/institutions	Abdominal Aortic Aneurysm	Gynaecological surgery	Patient reported outcomes	
Exclusion Criteria[2]	Hepatic disease	Other surgery	Measure of costs	
Previous Laparotomy	History of cancer	Open/Laparoscopic/Lap-assisted		
Previous IH	COPD	Location of midline incision		
Steroid use	Steroids or Immunosuppression	Closure technique (Continuous/Interrupted)		
Immunosuppression		Closure technique (Small bites/Large bites/Other)		
Pregnancy		Suture material		
Emergency surgery		SL:WL ratio		
		Wound contamination		

*Recorded as mean where possible

1 Recorded as number of cases reported.

2 Recorded as Yes/No

2.2) Characteristics of included studies

Study	Year	Type of study	Data analysis	Diagnosis of IH	Number of surgeons or institutions	Consecutive patients?	Group Number	Number of pts	Number of IHs (%)Click or tap here to enter text.	Follow-up (months): mean (default) or median	Downs & Black score[27]
Honig(Honig et al. 2022)	**2022**	**RCT**	**Prospective**	**Clinical *and* Radiological**	**Multiple Institutions**	**NR**	**1**	**34**	**4 (11.76)**	**24**	**25**
							2	**33**	**10 (30.30)**	**24**	
Wong (Wong et al. 2020)	**2020**	**Cohort**	**Retrospective**	**NR**	**Single Surgeon**	**Yes**	**1**	**552**	**77 (13.95)**	**33**	**14**
Yamada (Yamada et al. 2016)	**2016**	**Cohort**	**Retrospective**	**Radiological**	**Single Institution**	**Yes**	**1**	**626**	**40**	**54**	**18**
Heimann (Heimann et al. 2017)	**2017**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**500**	**54 (10.80)**	**80**	**20**
							2	**250**	**21 (8.40)**		

Baucom (Baucom et al. 2016)	**2016**	**Cohort**	**Retrospective**	**Radiological**	**Single Institution**	**Yes**	**1**	**287**	**151 (52.61)**	**13.2**	**20**
Tofigh (Mohammadi Tofigh and Jafarzadeh 2021)	**2021**	**RCT**	**Prospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**62**	**7 (11.29)**	**12**	**23**
							2	**62**	**5 (8.09)**		
Aicher (Aicher et al. 2021)	**2021**	**Cohort**	**Retrospective**	**Clinical**	**Single Institution**	**NR**	**1**	**38**	**13 (34.21)**	**24**	**18**
Seveso (Seveso et al. 2017)	**2017**	**Cohort**	**Retrospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**400**	**20 (5.00)**	**20.2**	**16**
Kuncewitch (Kuncewitch et al. 2019)	**2019**	**RCT**	**Retrospective**	**Clinical**	**Single Institution**	**No**	**1**	**37**	**12 (32.43)**	**11**	**19**
							2	**31**	**5 (13.89)**		
Fortelny (Fortelny et al. 2022)	**2022**	**RCT**	**Prospective**	**Radiological**	**Multiple Institutions**	**Yes**	**1**	**210**	**7 (3.26)**	**12**	**28**
							2	**204**	**13 (6.149)**		

Cherla (Cherla et al. 2017)	**2017**	**Cohort**	**Retrospective**	**Radiological**	**Single Institution**	**Yes**	**1**	**247**	**114 (46.15)**	**31.3**	**21**
Samia (Samia et al. 2013)	**2013**	**Cohort**	**Retrospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**305**	**27 (8.85)**	**42**	**17**
Cano-Valderrama (Cano-Valderrama et al. 2020)	**2019**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**86**	**31 (36.05)**	**28**	**18**
Greemland (Greemland et al. 2021)	**2021**	**Cohort**	**Retrospective**	**Radiological**	**Single Institution**	**Yes**	**1**	**72**	**42 (58.33)**	**15.3**	**20**
Benlice (Benlice et al. 2016)	**2016**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**510**	**73 (14.31)**	**73.1**	**17**
							2	**485**	**94 (19.38)**	**66.5**	
							3	**192**	**29 (15.10)**	**72.5**	
Kurmann (Kurmann et al. 2013)	**2013**	**Case-Control**	**Retrospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**70**	**29 (15.10)**	**17**	**15**
	2019	**Cohort**	**Retrospective**	**NR**		**Yes**	**1**	**136**	**10 (7.35)**	**31.3**	**15**

De Vries (de Vries et al. 2020)					**Single Institution**		**2**	**191**	**27 (14.14)**		
Pereira-Rodriguez (Pereira-Rodríguez et al. 2022)	**2022**	**Cohort**	**Prospective**	**Clinical *or* Radiological**	**Single Institution**	**NR**	**1**	**75**	**13 (17.33)**	**29.23**	**16**
Harr (Harr et al. 2016)	**2016**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**113**	**14 (12.39)**	**16.5**	**20**
Caro-Tarrago (Caro-Tarrago et al. 2019)	**2019**	**RCT**	**Prospective**	**Clinical *and* Radiological**	**Single Institution**	**Yes**	**1**	**80**	**37 (46.25)**	**60**	**24**
Choi (Choi et al. 2022)	**2022**	**Cohort**	**Retrospective**	**Clinical *and* Radiological**	**Single Institution**	**Yes**	**1**	**1472**	**52 (3.53)**	**41**	**20**
Kim (Kim et al. 2022)	**2022**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**429**	**64 (14.92)**	**3.3**	**23**
Caro-Tarrago (Caro-	**2014**	**RCT**	**Prospective**	**Clinical *or* Radiological**	**Single Institution**	**NR**	**1**	**80**	**30 (37.50)**	**12.5**	**27**

Tarrago et al. 2014)											
Lozada-Hernandez (Lozada-Hernández et al. 2022)	**2022**	**RCT**	**Prospective**	**Clinical *or* Radiological**	**Single Institution**	**NR**	**1**	**104**	**20 (19.23)**	**36**	**27**
Jairam (Jairam et al. 2017a)	**2017**	**RCT**	**Prospective**	**Clinical *or* Radiological**	**Multiple Institutions**	**Yes**	**1**	**107**	**33 (30.84)**	**24**	**25**
Muysoms (Muysoms et al. 2016)	**2016**	**RCT**	**Prospective**	**Clinical *or* Radiological**	**Multiple Institutions**	**Yes**	**1**	**58**	**16 (27.59)**	**19.2**	**28**
Glauser (Glauser et al. 2019)	**2019**	**RCT**	**Prospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**88**	**46 (52.27)**	**63.6**	**21**
Abo-Ryia(Abo-Ryia et al. 2013)	**2013**	**RCT**	**Prospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**32**	**9 (28.13)**	**49**	**18**

Khorgami (Khorgami et al. 2013)	**2013**	**RCT**	**Prospective**	**NR**	**Multiple Institutions**	**Yes**	**1**	**295**	**6 (2.03)**	**5**	**25**
Pizza (Pizza et al. 2021)	**2021**	**RCT**	**Prospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**92**	**21 (22.83)**	**24**	**26**
Argudo (Argudo et al. 2014)	**2014**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**190**	**33 (17.37)**	**16.7**	**22**
Schiavone (Schiavone et al. 2016)	**2016**	**Cohort**	**Retrospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**171**	**11 (6.43)**	**27**	**21**
Navaratnam (Navaratnam et al. 2015)	**2015**	**Cohort**	**Retrospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**139**	**5 (3.60)**	**24**	**20**
Ohira (Ohira et al. 2015)	**2015**	**RCT**	**Prospective**	**Radiological**	**NR**	**Yes**	**1**	**28**	**3 (10.71)**	**12**	**19**
							2	**27**	**2 (7.41)**		
Borie (Borie et al. 2014)	**2014**	**Case-Control**	**Retrospective**	**NR**	**NR**	**No**	**1**	**53**	**12 (22.64)**	**96**	**14**
	2018		**Retrospective**			**Yes**	**1**	**72**	**10 (13.89)**	**34.5**	**18**

Wiegering (Wiegering et al. 2018)		**Case-Control**		**Clinical *or* Radiological**	**Single Institution**		**2**	**27**	**7 (25.93)**	**35.7**	
Mishra (Mishra et al. 2014)	**2014**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**768**	**111 (14.45)**	**44**	**18**
Lee (Lee et al. 2018)	**2018**	**RCT**	**Prospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**73**	**6 (8.22)**	**12**	**22**
Guitarte (Guitarte et al. 2016)	**2016**	**Cohort**	**Retrospective**	**Clinical**	**Single Surgeon**	**NR**	**1**	**252**	**16 (6.35)**	**20.4**	**17**
Chen-Xu (Chen-Xu et al. 2019)	**2019**	**Cohort**	**Retrospective**	**Clinical *and* Radiological**	**Single Institution**	**NR**	**1**	**103**	**17 (16.50)**	**28**	**21**
Navaratnam (Navaratnam et al. 2015)	**2015**	**Cohort**	**Retrospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**139**	**5 (3.60)**	**24**	**23**
HART Collaborative	**2022**	**RCT**	**Prospective**	**Clinical**	**Multiple Institutions**	**NR**	**1**	**339**	**50 (14.75)**	**12**	**26**
							2	**333**	**37 (17.12)**		

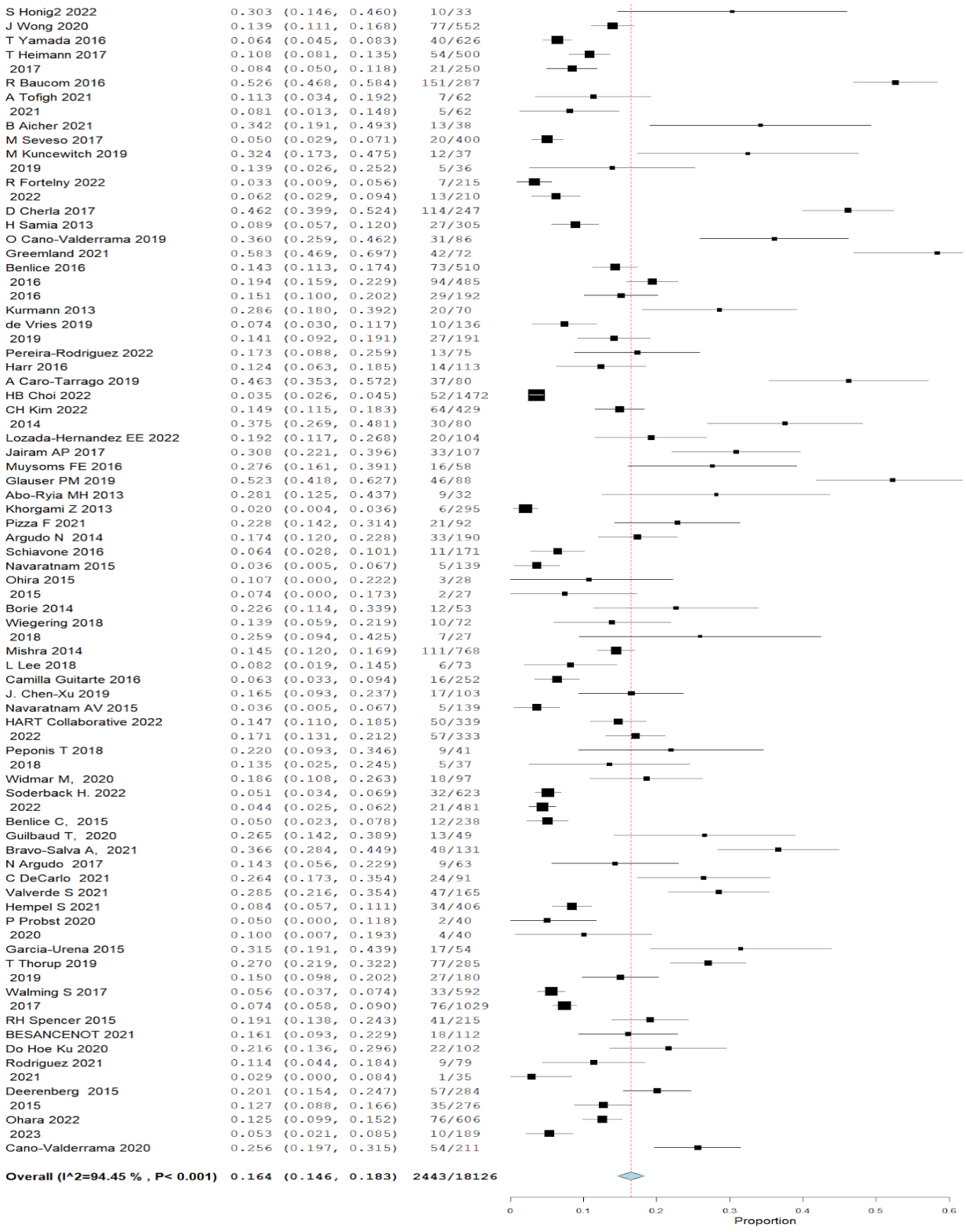
(Torkington et al. 2022)											
Peponis (Peponis et al. 2018)	**2018**	**RCT**	**Prospective**	**Clinical**	**Single Institution**	**NR**	**1**	**41**	**9 (21.95)**	**7.1**	**26**
							2	**37**	**5 (13.51)**	**7.7**	
Widmar (Widmar et al. 2020)	**2020**	**Cohort**	**Retrospective**	**Clinical *and* Radiological**	**Single Surgeon**	**Yes**	**1**	**97**	**18 (18.56)**	**14**	**21**
Soderback (Söderbäck et al. 2022)	**2022**	**Case-Control**	**Retrospective**	**Clinical *and* Radiological**	**Single Institution**	**Yes**	**1**	**623**	**32 (5.14)**	**32**	**18**
							2	**481**	**21 (4.37)**	**73**	
Benlice (Benlice et al. 2015)	**2015**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**238**	**12 (5.04)**	**116**	**20**
Guilbaud (Guilbaud et al. 2020)	**2020**	**Cohort**	**Retrospective**	**Clinical *and* Radiological**	**Single Institution**	**Yes**	**1**	**49**	**13 (26.53)**	**25**	**21**
Bravo-Salva (Bravo-Salva et al. 2021)	**2021**	**Case-Control**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**131**	**48 (36.64)**	**64.4**	**24**

Argudo (Argudo et al. 2017)	**2017**	**Cohort**	**Prospective**	**Clinical *or* Radiological**	**Single Institution**	**Yes**	**1**	**63**	**9 (14.29)**	**31.2**	**21**
DeCarlo (DeCarlo et al. 2021)	**2021**	**Cohort**	**Retrospective**	**NR**	**Single Institution**	**Yes**	**1**	**91**	**24 (26.37)**	**38.4**	**20**
Valverde (Valverde et al. 2022)	**2021**	**RCT**	**Prospective**	**Clinical *and* Radiological**	**Multiple Institutions**	**Yes**	**1**	**165**	**47 (28.48)**	**24**	**25**
Hempel (Hempel et al. 2021)	**2021**	**Cohort**	**Retrospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**406**	**34 (8.37)**	**1937**	**18**
Probst (Probst et al. 2020)	**2020**	**RCT**	**Prospective**	**Clinical**	**Single Institution**	**Yes**	**1**	**40**	**2 (5.00)**	**12**	**21**
							2	**40**	**4 (10.00)**		
Garcia-Urena (García-Ureña et al. 2015)	**2015**	**RCT**	**Prospective**	**Clinical *and* Radiological**	**Single Institution**	**Yes**	**1**	**54**	**17 (31.48)**	**24**	**21**
	2019		**Retrospective**	**Clinical**		**No**	**1**	**285**	**77 (27.02)**	**19**	**20**

Thorup (Thorup et al. 2019)		**Case-Control**			**Single Institution**		**2**	**180**	**27 (15.00)**	**52**	
Walming (Walming et al. 2017)	**2017**	**Cohort**	**Retrospective**	**NR**	**Multiple Institutions**	**Yes**	**1**	**592**	**33 (5.57)**	**41**	**21**
							2	**1029**	**76 (7.39)**		
Spencer (Spencer et al. 2015)	**2015**	**Cohort**	**Retrospective**	**Clinical *and* Radiological**	**Single Institution**	**NR**	**1**	**215**	**41 (19.07)**	**24**	**15**
Besancenot (Besancenot et al. 2022)	**2021**	**Cohort**	**Retrospective**	**Clinical**	**Multiple Institutions**	**Yes**	**1**	**112**	**18 (16.07)**	**50**	**16**
Do Hoe Ku (Ku et al. 2020)	**2020**	**Cohort**	**Retrospective**	**Radiological**	**Single Institution**	**NR**	**1**	**102**	**22 (21.57)**	**31**	**18**
Pereira-Rodriguez (Pereira Rodríguez et al. 2021)	**2021**	**Cohort**	**Prospective**	**Clinical *and* Radiological**	**Multiple Institutions**	**Yes**	**1**	**79**	**9 (11.39)**	**11.1**	**19**
							2	**36**	**1 (2.86)**		

Deerenberg (Deerenberg et al. 2015)	**2015**	**RCT**	**Prospective**	**Clinical *and* Radiological**	**Multiple Institutions**	**Yes**	**1**	**277**	**57 (20.07)**	**12**	**26**
							2	**268**	**35 (12.68)**		
Ohara (Ohara et al. 2022)	**2022**	**Cohort**	**Retrospective**	**Clinical *and* Radiological**	**Single Institution**	**Yes**	**1**	**606**	**76 (12.54)**	**55**	**17**
							2	**189**	**10 (5.29)**	**7**	
Cano-Valderrama (Cano-Valderrama et al. 2020)	**2020**	**Cohort**	**Retrospective**	**Clinical *or* Radiological**	**Single Institution**	**No**	**1**	**211**	**54 (25.59)**	**22**	**17**

2.3) A Funnel plot of included studies and calculation of incisional hernia rate



Appendix 3: *Can we predict the future?*

3.1) Variables extracted from the HART database

Variable	Overall (n=674)
Diabetes (n, %)	106 (15.7%)
HTN (n, %)	110 (16.3%)
Smoker (n, %)	246 (36.5%)
Cardiovascular Disease (n, %)	85 (12.6%)
Pulmonary Disease (n, %)	94 (13.9%)
Renal Disease (n, %)	8 (1.2%)
Hepatic Disease (n, %)	2 (0.3%)
Alcohol Use (n, %)	43 (6.4%)
Drug Abuse (n, %)	0 (0.0%)
Hyperlipidaemia (n, %)	14 (2.1%)
History of Wound Complications (n, %)	0 (0.0%)
Acute Infection (n, %)	59 (8.8%)
Prior Herniorrhaphy (n, %)	58 (8.6%)
Recent Weight Loss (n, %)	236 (35.0%)
Obesity (n, %)	206 (30.6%)
History of Cancer (n, %)	674 (100.0%)
History of Radiation (n, %)	63 (9.3%)
History of Chemotherapy (n, %)	65 (9.6%)
Immunosuppression (n, %)	24 (3.6%)
Coagulopathy (n, %)	1 (0.1%)
Malnutrition (n, %)	0 (0.0%)
Anaemia (n, %)	21 (3.1%)

Previous Abdominal Surgery (n, %)	287 (42.6%)
Concurrent Ostomy (n, %)	16 (2.4%)
Previous Hernia (n, %)	53 (7.9%)
Proctectomy (n, %)	41 (6.1%)
Inflammatory Process (n, %)	92 (13.6%)
Benign Gynaecological Mass (n, %)	6 (0.9%)
Stoma Formation (n, %)	213 (31.6%)

Appendix 4: *What does the patient think?*

4.1) Patient consent form

The INVITE Study

Incisional Hernia Prevention: Risk-Benefit From A Patient's Perspective

Version 1.0, 05/04/2022

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board

CONSENT FORM FOR PARTICIPANTS

Participant ID: _____

If you agree to participate, please write your initials in the relevant box for each statement and sign, name and date below before completing any of the study assessments. Thank you.

	STATEMENT	INITIALS
Section 1- Taking Part		
1.1	I confirm that I have read the Patient Information Sheet dated (version ..... dated .....) for the INVITE study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. I understand why the research is being done, what is involved and any foreseeable risks.	
1.2	I understand that my participation is voluntary and that I am free to decline participation, or withdraw at any time without giving any reason, without my medical care or legal rights being affected. If I withdraw, or am withdrawn, I agree that the information collected about me up until the point of my withdrawal may be kept and analysed in this study and future studies.	
1.3	I understand that I may be invited to take part in a one-to-one interview with the research team regarding hernia risk and use of surgical mesh. I understand that I am free to decline the interview, without affecting my contribution to the rest of the study, my medical treatment or legal rights.	
1.4	I agree to take part in the above study.	
Section 2- Data collection and usage		
2.1	I understand what information and data is being collected, why it is collected and how it will be stored. I understand that all staff involved in this study must comply with the requirements of the General Data Protection Regulation (GDPR) and Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information.	
2.2	I give permission for members of the research team to access and record information from my medical records, where it is relevant to this research. I understand that this may include the results of blood tests, surgery or other investigations done as part of my medical treatment and the information may be accessed and linked electronically.	

CONTINUES OVERLEAF.

2.3	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the sponsor (Cardiff and Vale Health Board), or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to access my records.	
2.4	I agree that the information collected about me will be kept and used to support other research in the future. I understand that my data may be shared anonymously with other researchers, including those outside the European Economic Area. I understand that this will not include my personal identifiable information, such as my name and address, so other researchers will not be able to identify my personally.	
2.5	I agree to be invited to take part in an interview, asking about my understanding and opinions on incisional hernia. I understand that this is optional and I am free to decline taking part in the interview without affecting my status in the rest of the study. I agree that this interview will be recorded and analysed as part of this research, which may involve the recording being shared securely with an NHS-approved external transcription service provider.	
Section 3- Future contact		
3.1	I know how to contact the research team if I need to.	
3.2	**Optional**: I agree to be contacted in the future about this or other research opportunities. I understand that any future participation is voluntary and I am free to decline and deciding not to take part will not affect my contribution to this study.	Yes/No
3.3	**Optional**: I would like to receive a newsletter with the results of the study	Yes/No

Participant name (PRINT)	Date	Signature
Name of person seeking consent (PRINT)	Date	Signature

I request study questionnaires to be sent to me via:

❑ Post

❑ Email (address: _____)

Filing arrangements: Original stored in the Investigator Site File; 1 copy provided to participant; 1 copy stored in medical notes

4.2) Patient information leaflet

Incisional Hernia Prevention: Risk-Benefit from a Patient's Perspective (INVITE)

Participant information Sheet
Version 1.0, 05/04/2022

We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why the research is being done, and what it would involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors.
- Please ask us if there is anything that is not clear, or if you would like more information

Important things that you need to know

- After having abdominal surgery there is a risk that some of the abdominal contents can push through a weakness left in the muscle at the site of the operation. This is called an incisional hernia.
- Recent research has developed risk scores to predict how likely it is that people will develop Incisional hernias.
- However, there is no understanding of what patients view as 'high risk'
- It has been suggested that 'high risk' patients may benefit from having surgical mesh put into their abdomen during their operation to avoid the hernia forming in the first place.
- However, there is no understanding of how acceptable this is for patients.
- In order to address these questions, we are inviting patients to give their opinions and thoughts.
- We are inviting patients who have, and haven't, developed incisional hernias after abdominal surgery to take part in this study.

Contents

Who are we?

We are a group of researchers based at Cardiff and Vale University Health Board, who are passionate about improving the treatment, care and outcomes of patients with a variety of Colorectal conditions. Our multi-disciplinary team has experience in all types of research, and we are pleased to invite you to help us with this study.

1. Why are we doing this research study?

Incisional hernia is a common side effect of abdominal surgery, that can lead to pain or discomfort and often require further operations to repair.
Recent research means that it's now possible to identify which patients are at 'high risk' of developing incisional hernias. It's been suggested that using surgical mesh could stop the hernia developing in the first place, avoiding the pain, discomfort and further surgery.
However, so far no one has asked patients themselves what they consider to be 'high risk' or how they feel about having surgical mesh inserted.

In this study, we aim to gain patients' views on both these issues and use the information to help to make future decisions on medical treatment.

2. Why am I being asked to take part?

We are asking two groups of people to take part:
• Adults (over 18) who have had abdominal surgery over 12 months ago and may have an incisional hernia.
• Adults (over 18) who have had abdominal surgery over 12 months ago but do not have an incisional hernia.
• Adults (over 18) who are about to undergo abdominal surgery
We are inviting you to take part as you fit into one of these three groups.

3. Do I have to take part?

No. You do not have to take part in the study. If you agree now but change your mind, that's okay. If you decide not to take part, or to withdraw at any stage, you do not have to give a reason. In this case the information you have provided up to this point will be kept and analysed and may be used in future research. Your current or future medical care will not be affected in any way.

It is estimated that a total of 15 minutes of your time will be needed to complete the questionnaire. If you indicate that you would like to, and are eligible, you may be invited to attend an interview to explore your thoughts further. This will be conducted virtually or face-to-face, depending on your preference. We estimate that this will take 1-2 hours of your time.

4. What would I need to do if I decided to take part?

If you decide to take part, we would ask you to provide us with information related to your health, surgery and understanding of incisional hernia. This would involve:

We will look at, and record, relevant sections of your medical notes. This will include your most recent blood tests. We will also collect some extra information about your surgery, such as the techniques used.

Answering a short questionnaire covering topics including your health, surgery and understanding. This will be done by post or online and will take approximately 15 minutes.

A small group (approximately 24 people) will be invited for a one-to-one interview in the coming months. The interview will ask about your opinion on hernia risk and the use of surgical mesh, and will be conducted face-to-face or virtually (for example, by Zoom or Microsoft Teams). The interview will be recorded and your responses will be analysed.
You may, or may not, be invited for an interview. If you are invited for an interview, you do not have to take part. Deciding not to take part will not affect your contribution to the rest of the study.

5. What about the risks and benefits of taking part?

There are no anticipated risks from the study. You will not receive any additional medication or surgery, or be required to have any more tests.
All questionnaires will be completed online or by post. You will be given pre-paid and addressed envelopes to return postal questionnaires. There will be no additional cost to you.
If you need to travel to take part in this research, for example if you are invited to complete an interview, we will cover any travel costs you incur.

Taking part in this research is unlikely to benefit you directly. However, we hope that the results of this research can be used to improve the treatment of patients in the future.

6. Will my information be confidential?

All of the information that you provide is confidential and is kept in accordance with the Data Protection Act 2018.
All participants will be given a unique study code rather than using names or NHS numbers. Any data that can identify you will be stored in a secure location and on NHS computer systems that are password protected.

It's possible that we'll need to transfer data to a bonafide service provider outside the NHS, for example when transcribing your interview from a recording to text. Where this happens, we will make sure that data is transferred using secure NHS systems and legal arrangements will be in place to protect your welfare, confidentiality, and rights. Any audio recordings will be typed up and then deleted when the study ends.

All data will be stored for 5 years, in line with Cardiff and Vale UHB's Research Archiving Standard Operating Procedure for clinical research.

7. How will my information be used?

Cardiff and Vale UHB is the organisation sponsoring this study and is based in the United Kingdom. The sponsor is responsible for the design and conduct of the study. We will need to use information from you and your medical records for this research project. This will include:

The sponsor will need to use information from your medical records for this research project, including results of blood tests, surgery or other investigations done as part of your medical treatment. The sponsor will keep all information about you safe and secure.
This information will include your initials, NHS number, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a study code number instead.

Your research data (including anonymised medical information and questionnaire responses) will be combined with other participants' data and analysed together in order to understand more about the effects of abdominal surgery.
We will also keep the anonymous research data for use in future projects. This might involve sharing your data with other researchers, including those outside the European Economic Area. This will not include any of your personal information, so they won't be able to identify you, contact you or trace the data back to you.

Once the study is finished, the sponsor will keep some of the data so they can check the results. They will write reports in a way that no-one can work out that you took part in the study.

8. What will happen to the results of the research?

We plan to share the results of the study to help researchers, the clinical team and patients in the future. This will be done through presentation at medical conferences and publication in medical journals.
We would also like to send you a summary at the end of the project by post or email. Let us know on the consent form if you would like to receive this.

9. What are my choices about how my information is used?

• You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
• We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
• If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

10. Where can I find out more about how my data is used?

You can find out more about how we use your information:
• www.hra.nhs.uk/information-about-patients/
•our leaflet is available on: www.hra.nhs.uk/patientdataandresearch
•by sending an email to the sponsor's data protection officer at: cav.ig.dept@wales.nhs.uk, or
•by asking one of the research team, using the contact details at the beginning (or end-depending on where you decide to put them) of this information sheet.

11. Who is organising and funding this research?

This research is being organised by Mrs Julie Cornish, Consultant Colorectal Surgeon at Cardiff and Vale University Health Board.
This study has not received any additional external funding.

12. Who has reviewed this study?

This study has been reviewed and approved by the Cardiff and Vale UHB Research & Development department as study sponsor, as well as Health and Care Research Wales and a national Research Ethics Committee (REC) [Insert REC Details].

13. What if I have a complaint?

If you have any concerns about the study, you should speak to the research team (led by Mrs Julie Cornish) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via the Patient Concerns Service (Wales):
Concerns Department, Cardiff and Vale University Health Board Headquarters, University Hospital of Wales, Heath Park, Cardiff CF14 7XB, **Telephone** 02920742202. **Email** concerns@wales.nhs.uk
In the unlikely event that something goes wrong, and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Thank you for taking the time to read this information

Contact details

If you have any questions or concerns about the study, please talk to a member of research team on 02921842934 or alternatively email ColorectalResearch.CAV@wales.nhs.uk

4.3) Example Questionnaire

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro University Health Board

INVITE

Incisional Hernia: Risk-benefit from a patient's perspective

Participant Questionnaire

Version 1.0, 11/05/2022

Please circle your choice of answer in each case.

Section 1: Background

We are trying to understand a bit more about you and the effects of your operation on your health.

What is your height? _____ cm / ft What is your weight? _____ Kg / Stone

Have you ever smoked on a daily basis?

Yes, currently a smoker Yes, but an ex-smoker Never Smoked

Do you currently feel pain at the site of the scar from your operation?

Yes No Sometimes

Do you ***feel*** a swelling or bulge at the site of your scar?

Yes No Sometimes

Do you ***see*** a swelling or bulge at the site of your scar?

Yes No Not sure

Section 2: Knowledge of Incisional Hernia

After having abdominal surgery, there is a risk that some of the abdominal contents can push through a weakness left in the muscle at the site of the operation. This is called an incisional hernia.

Did you know what an incisional hernia was before your first operation?

Yes No Don't know/Unsure

Were you told that Incisional Hernia was a risk for your operation?

Yes No Unsure/Don't know

How much information regarding incisional hernia was given to you before the operation?

None Not enough The right amount Too much

Have you heard of doctors using mesh as part of a hernia repair?

Yes No Don't know/Unsure

Is what you've heard about mesh...

Positive Negative Neutral Not Applicable

Do you know someone who has had a hernia repair?

Yes No

If yes, did it involve mesh?

Yes No Don't know/unsure

Was their outcome positive or negative?

Positive Negative Not sure Not applicable

If you have heard of mesh, where have you heard about it from?

Doctor/Healthcare professional News/Media Friend/relative

Other:_____ Not applicable

If you have any other comments about mesh, please feel free to record them below.

Section 3: Risk and prevention

What is a risk-prediction tool?

Risk-prediction tools are used by doctors to work out a person's risk of developing a medical condition, for example the risk of having a heart attack based on the risk factors that they have. This allows doctors to convey the risk to patients in the form of a number, for example 10% or 1-in-10.

Risk-prediction and Incisional Hernia

Risk-prediction tools are being developed with the aim of working out a person's risk of developing an incisional hernia **before** their operation. We hope that this will allow surgeons to give patients an idea of what their risk is before the operation. Patients can then understand if they are at high, medium or low risk, and what they might be able to do about it before the operation.

For patients that are predicted to be "high risk" for developing an incisional hernia, it may be possible to use a synthetic mesh, similar to those used to fix groin hernias. This would be placed in the wound at the end of the initial operation to strengthen the wound to try and reduce the chance of developing an incisional hernia.

Aims of the study

We want to know whether mesh placed to prevent hernias during the initial surgery would be acceptable to patients, and if patients would find a risk-prediction tool helpful when learning more about risk of incisional hernia before surgery.

Please read the questions below and circle the answer that best applies to you.

Q1. If you were told before your operation that you were "high risk" of developing an incisional hernia, and that using mesh might help to reduce that risk, to what extent would you agree or disagree with the following statements?

a. **"I would be worried about the safety of mesh"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

b. **"I would be worried about the mesh causing me pain"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

c. **"I would be worried that if the mesh was implanted, it would not be easy to remove at a later date if it didn't work"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

d. **"I would be worried about how much benefit I will get from mesh"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

e. **"I do not think I have enough information about mesh to make a decision about it"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Q2. Thinking back to your original operation, please read the questions below and circle the answer that best applies to you.

a. **"I would have found risk-scoring before an operation useful in helping me understand my risk of developing incisional hernia"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

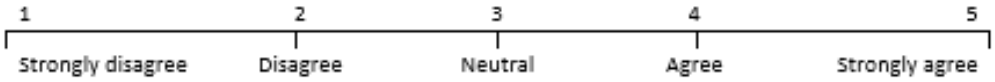
b. **"Understanding my risk of developing incisional hernia would have helped me to make decisions about different treatment options"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

c. **"The idea of using mesh to strengthen the wound before a hernia develops would be acceptable to me"**

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

d. "I would want to find out more information regarding mesh before deciding if it would be acceptable to me"



What additional information about mesh would you want to know in order to make a decision about it?

Please record your answer in the box below

Thank you for taking the time to complete this questionnaire.

If you have any further comments about any of the topics discussed, please feel free to contact the research team phone on 02921 842934 or email ColorectalResearch.CAV@wales.nhs.uk.