Systematic review of the clinical effectiveness and cost-effectiveness of laparoscopic surgery for inguinal hernia repair.

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Conflicts of interest

Adrian Grant was principal investigator and Kirsty McCormack and Luke Vale were members of the secretariat for the EU Hernia Trialists Collaboration. The Advisory Group (Peter Go, Andrew Kingsnorth and Paddy O'Dywer) were also members of the Steering Committee for the Collaboration. Two of the referees (James Wellwood and Mark Sculpher) also contributed data or were members of the Collaboration. The EU Hernia Trialists Collaboration was funded by a grant from the EU Biomed II Workprogramme.

Paddy O'Dwyer was the principal investigator on the MRC laparoscopic groin hernia trial. Adrian Grant was a grantholder.

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Summary

Description of proposed service

Laparoscopic inguinal hernia repair is a minimal access surgical procedure. This approach avoids the need to open the abdominal wall. Instead, small incisions are made for the operating instruments and for a laparoscope. A piece of mesh is generally used to close the hernia defect and prevent the recurrence of the abdominal cavity content protruding through the abdominal wall. The main variations in laparoscopic approaches depend on whether or not the instruments enter the peritoneal cavity.

Epidemiology and background

About 70,000 surgical repairs of inguinal hernia are performed each year in England, constituting approximately 0.14% of the population each year and accounting for over 100,000 NHS bed-days. Inguinal hernia can occur unilaterally or bilaterally, and can recur after surgery necessitating re-operation. The most effective method of repair of inguinal hernia is by means of a tension-free technique involving the use of prosthetic mesh to reinforce the abdominal wall in the region of the groin. This can be accomplished by open or laparoscopic techniques. The most common open method in use in the UK is the flat mesh technique. However, about four percent of primary inguinal hernia operations, are currently carried out laparoscopically. The laparoscopic repair is usually undertaken by means of the trans-abdominal pre-peritoneal (TAPP) or total extra-peritoneal (TEP) repair.

This review assesses the effectiveness and cost-effectiveness of TAPP and TEP repair of inguinal hernia in comparison with open mesh repair and with each other. The primary outcomes considered were hernia recurrence and persisting pain. Other long–term outcomes assessed were persisting numbness and quality of life. Short-term outcomes included: complications, convalescence and descriptions of the operation e.g. duration of operation. Where data allowed, the patient population was split by whether or not the hernia was recurrent or bilateral and whether or not the patient received general anaesthesia.

Number and quality of studies, and direction of evidence

Thirty-seven randomised and quasi-randomised controlled trials (RCTs) met the inclusion criteria on effectiveness. Thirteen of these were newly identified for this update. The RCTs were of varying, generally moderate quality, with sample sizes ranging from 18 to 928 randomised patients and with a mean or median follow-up from one week to five years.

Summary of benefits

Laparoscopic repair is associated with a faster return to usual activities and less persisting pain and numbness. There also appear to be fewer cases of wound/superficial infection and haematoma. However, operation times are longer and there appears to be a higher rate of serious complications in respect of visceral (especially bladder) injuries. Mesh infection is very uncommon and similar between the surgical approaches. There is no apparent difference in the rate of hernia recurrence.

Costs

Laparoscopic repair is more costly to the health service than open repair with an estimated extra cost from studies conducted in the UK of about £300 to £350 per patient. The point estimates of cost provided by the economic model also suggest that the laparoscopic techniques are more costly (approximately £100 to £200 more per patient after five years).

Cost-effectiveness

The estimation of cost-effectiveness focused on the comparison of laparoscopic repair with open flat mesh. Estimates for open plug and mesh and open preperitoneal mesh techniques are based on very limited data and are likely to be unreliable. A Markov model incorporating the data from the systematic review was used to estimate cost-effectiveness for a time horizon up to 25 years.

For the management of unilateral hernias the base case analyses and most of the sensitivity analyses suggest that open flat mesh is the least costly option but provides less quality adjusted life years (QALYs) than TEP or TAPP. TEP is likely to dominate TAPP (on average TEP is estimated to be less costly and more effective). The results of the base case analysis

and much of the sensitivity analysis suggest that the mean incremental cost per QALY for TEP compared to open mesh is less than £10,000 and that there is approximately an 80% chance that TEP is the most cost-effective intervention should society's maximum willingness to pay for an additional QALY be £20,000.

For recurrent hernias and treatment choice guided by gender and age the data were sparse and results may be unreliable. In this circumstance extrapolation from the base case analysis for primary repair may provide the best available evidence. It is likely that for management of symptomatic bilateral hernias laparoscopic repair would be more cost-effective as differences in operation time (a key cost driver) may be reduced and differences is convalescence time more marked (hence QALYs will increase) for laparoscopic compared to open mesh repair. When possible repair of contralateral occult hernias is taken into account, TEP repair is most likely to be considered cost-effective at thresholds values for the cost per additional QALY above £20,000. Nonetheless, the results are sensitive to changes in estimates of prevalence and risk of progression of occult hernias, for both of which data are limited.

Sensitivity analyses

The results of the base case analysis were most sensitive to assumptions about the disutility associated with persisting pain and numbness. When persisting pain and numbness were excluded from the analysis then the results obtained are similar to those that formed the basis of the 2001 assessment and it is unlikely that laparoscopic repair would be associated with an incremental cost per QALY of less than £50,000. Use of patient utility data derived from a discrete choice experiment, which put weight on avoiding rare intraoperative complications, indicated that both TAPP and TEP were unlikely to be associated with net benefits compared with open flat mesh.

Limitations of the calculations (assumptions made)

The meta-analyses were conducted using a fixed effects model although subsequent re-analysis using a random effect model did not greatly alter effect estimates. The main limitations related to the quantity and quality of the data available. For example, little data

pertaining to greater than five year follow up were available and only one small randomised trial was identified comparing TAPP with TEP repair.

The nature of the data available also had an impact on the economic evaluation which extrapolated outcomes for up to 25 years. Assumptions were made by extrapolation about how baseline rates would change over time and about how long relative effects would persist. As far as possible these assumptions were in accordance with available data, and the results were insensitive to changes in the assumed duration of effects.

TAPP and TEP were indirectly compared. In reality, the difference in cost and outcomes between the two procedures may be much smaller than those suggested using data derived from indirect comparisons. For example, the TEP data may relate to more experienced surgeons than the data available for TAPP.

Other important issues regarding implications

The increased adoption of laparoscopic techniques may allow patients to return to usual activities faster. This may, for some people, reduce any loss of income.

For the NHS, increase use of laparoscopic repair would lead to an increased requirement for training which may be costly. During the training period laparoscopic repair is likely to have higher costs (and hence be less cost-effective). Furthermore, the risk of serious complications may be higher, although adequate supervision and training might minimise these risks.

Notes on the generalisability of the findings

The 37 trials considered in the clinical effectiveness review were mounted in a wide range of settings. Nonetheless, very limited data were available about rare complications and for the sub-group analyses of recurrent and bilateral hernias; although data are presented, these have questionable reliability and hence limited generalisability.

Need for further research

A liberal definition of 'persisting pain' was used in the meta-analyses with the consequence of widely varying prevalence rates across trials. Ideally, the issue of chronic pain should now be addressed prospectively using standard definitions and allowing assessment of the degree of pain. Furthermore, more evidence is required on the loss of utility caused by persisting pain and numbness.

Rare, serious complications are an important consideration in the context of minor surgery. Prospective population-based registries of new surgical procedures may be the best way to address this, as a compliment to randomised trials assessing effectiveness.

Questions remain about the relative merits and risks of TAPP and TEP. Ideally there should be more data from methodologically sound randomised controlled trials.

Further research relating to whether the balance of advantages and disadvantages changes when hernias are recurrent or bilateral is also required as current data is limited.

Laparoscopic groin hernia repair is technically challenging and performance is likely to improve with experience. This issue is important in its evaluation and further methodological research related to this is warranted in the context of both trials and meta-analyses of trial data.

List of abbreviations

CI	Confidence interval
EU	European Union
HES	Hospital Episode Statistics
HR	Hazard Ratio
IPD	Individual Patient Data
IQR*	Inter Quartile Range
MRC	Medical Research Council
NA	Not Applicable
ND*	No Data
NHS	National Health Service
NR*	Not Reported
OFM*	Open Flat Mesh
OPM*	Open Plug and Mesh
OPPM*	Open Preperitoneal Mesh
OR	Odds Ratio
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trial
RR	Relative Risk
SCUR	Scandinavian Clinics United Research
SD	Standard Deviation
SEM	Standard Error of the Means
TAPP	Transabdominal Preperitoneal Repair
TEP	Totally Extraperitoneal Repair
UK	United Kingdom
VAS*	Visual Analogue Score
WMD	Weighted Mean Difference

* Occurs only in tables

1 Aim of the review

The aim of this review is to determine: 1) whether laparoscopic methods are more effective and cost-effective than open mesh methods of inguinal hernia repair; and 2) whether laparoscopic transabdominal preperitoneal (TAPP) repair is more effective and cost-effective than laparoscopic totally extraperitoneal (TEP) repair of inguinal hernia. Where data allow, the patient population has been split by whether or not the hernia is recurrent or bilateral and whether or not the patient receives general anaesthesia.

2 Background

2.1 Description of underlying health problem

2.1.1 Introduction

An inguinal hernia is a protrusion of the intestine through a weakness in the abdominal wall. It usually presents as a lump, with or without discomfort, which may limit daily activities and the ability to work. Inguinal hernias can occasionally be life-threatening if the bowel strangulates or becomes obstructed and in these cases emergency surgery is indicated. Groin hernia repair is a common surgical procedure but a variety of methods of repair exist.

2.1.2 Epidemiology

In 2001/2, 62,696 primary inguinal hernia repairs were carried out in England. In addition to this 4939 repairs of recurrent inguinal hernias were also carried out. There were 2924 (4.7%) primary hernia repairs classed as emergency surgery while 427 (8.6%) of the recurrent hernia repairs were emergencies. Mean length of stay in hospital was 2.3 days for primary repair of inguinal hernia and 2.6 days for recurrent hernia repair. 26,527 (42.3%) of primary hernia repairs were carried out as day cases while the figure for recurrent hernia repair was 1045 (21.2%). For both primary and recurrent hernia repairs, the vast majority of patients were male: 92.4% and 96.4% respectively. The mean age of patients undergoing primary hernia repair was 57 years, while the figure for recurrent hernia repair was 63 years. A significant number of patients were aged 60 or over: 49.4% for primary hernia repair and 66.6% for recurrent hernia repair. The figures have remained relatively stable over the past four years and Tables 2.1 and 2.2 and Figure 2.1 provide further details.

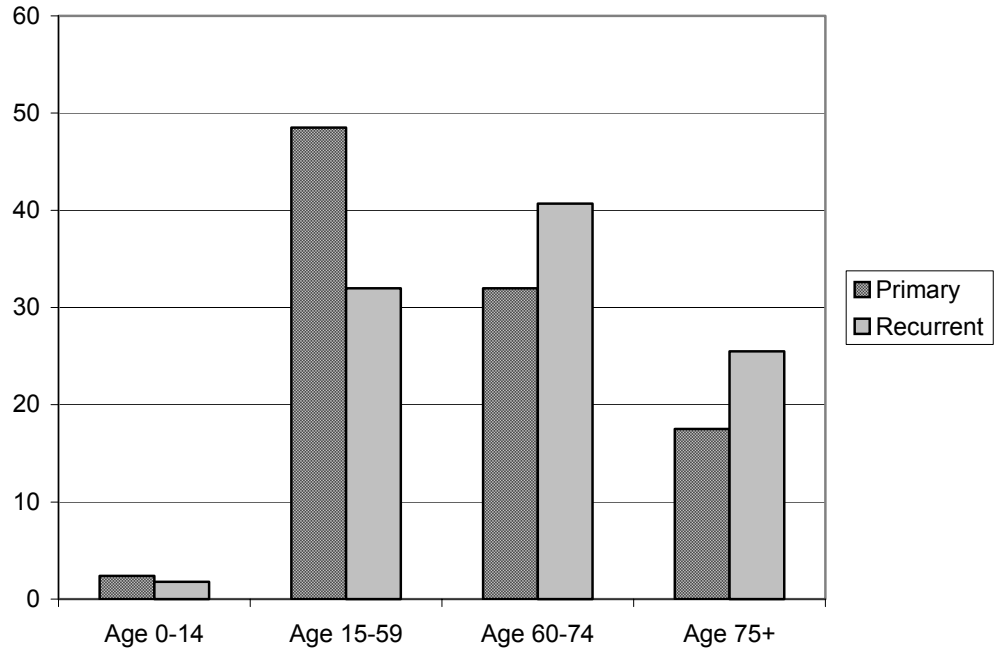
Table 2.1 Details of primary inguinal hernia repairs, England 1998-2001.

	Number of repairs	% emergency	% male	% day case	Average age	% over 60	Mean stay (days)
2001/2	62696	4.7	92.4	42.3	57	49.4	2.3
2000/1	64745	4.7	92.3	41.2	56	49.2	2.3
1999/0	63527	5.0	92.5	38.5	56	49.6	2.3
1998/9	66346	4.9	92.4	36.1	56	50.0	2.4

Table 2.2 Details of recurrent inguinal hernia repairs, England 1998-2001.

	Number of repairs	% emergency	% male	% day case	Average age	% over 60	Mean stay (days)
2001/2	4939	8.6	96.4	21.2	63	68.4	2.6
2000/1	5147	9.3	96.4	20.8	63	65.3	2.7
1999/0	5287	8.3	96.4	19.3	63	66.4	2.7
1998/9	5478	7.9	97.0	18.0	63	66.2	2.6

Figure 2.1 Age distributions for primary and recurrent hernia repair, England 1998-2001



Data taken from HES (Hospital Episode Statistics) database for England, Department of Health.[1]

2.1.3 Significance in terms of ill-health

Since inguinal hernia repair is such a frequently performed surgical procedure relatively small differences in health or quality of life are potentially important. The primary purpose of the procedure is to prevent the hernia recurring; recurrence is likely to lead to further surgery, which may be technically more difficult the second time. The significance of discomfort due to pain or numbness depends on whether it is short-term or persistent; severe chronic pain can occur after hernia repair.[2-4] There are also rare intra-operative risks of the surgical procedure themselves.[5]

2.2 Current service provision and variation in service

Surgical treatment is recommended in the majority of patients to prevent the bowel from becoming strangulated or obstructed or to alleviate symptoms. Most herniorrhaphies are

therefore performed as elective procedures. However, emergency repair of inguinal hernia is necessary if the hernia presents as a serious complication. In such circumstances there is a greater risk of post-operative morbidity and mortality.

Inguinal hernia can be repaired using traditional open methods or using newer laparoscopic techniques. The traditional method of open repair of groin hernias using suturing changed little in the one hundred years following the introduction of Bassini's method in the late nineteenth century. The use of open tension-free methods of inguinal hernia repair using prosthetic mesh has only recently become widely adopted.[6] The most common open technique in use in the UK is that popularised by Irving Lichtenstein. This involves the suturing of a mesh deep to the external oblique muscle thus reinforcing the posterior wall of the inguinal canal and deep internal ring.[7] Open mesh repairs can be further classified as flat mesh (including for example the Lichtenstein method of repair), open preperitoneal mesh (including the Stoppa and Nyhus methods of repair), and the plug and mesh (including the Rutkow and Robbins repair).

In 2001–2002 62696 primary operations were performed in England using 81730 bed-days.[1] The majority of these were prosthetic mesh repairs (84.5%). Within the four time periods surveyed, there was a relative increase in the proportion of primary prosthetic mesh repairs (rising from 77.8% to 80.2% to 82.4% to 84.5% of the total operations) and a fall in the proportion of non-mesh repairs (9% to 8.1% to 6.5% to 5.6%) over the same period. As the data suggest, this was mostly due to an increase in the number of mesh repairs performed at the expense of non-mesh repairs. A similar pattern of operation frequency was seen for repair of recurrent inguinal hernia.

The proportion of patients undergoing daycase procedures in England increased slowly over the same time periods (Primary prosthetic mesh repair: rising from 36% to 39% to 41% to 42%; Recurrent prosthetic mesh repair: rising from 18% to 19% to 20% to 21%).
Exact figures on the types of repair used in current surgical practice are not easy to obtain. Data taken from Health Episode Statistics (HES) for England report the number of primary and recurrent inguinal hernia repairs grouped within broad ranges of main operations. It

was not possible to obtain secondary procedure codes for laparoscopic surgery within the project timeframe. However, a study published in 2003, describing patterns of surgical repair using HES for England from April 1998 to December 2001, was able to provide this information.[8] The study found that 8960 (4.1% of the total operations) inguinal hernia repairs were carried out using laparoscopic surgery within the period surveyed. The rate of laparoscopic repairs as a proportion of all repairs was found to be increasing slowly and non-significantly by 0.014% (95% confidence interval 0.02% to 0.25%) per year.

In 2000, an audit of the NHS in Scotland between 1 April 1998 and 31 March 1999 found that 229 (4%) of inguinal hernia repairs were carried out using laparoscopic surgery, 4612 (84%) were open mesh surgery, 65 (1%) open preperitoneal surgery, and 600 (11%) were open non-mesh surgery.[9] Most repairs were performed using general anaesthetic on an inpatient basis and there was a significant trend to perform a laparoscopic repair or an open preperitoneal repair for patients with bilateral and recurrent hernias.

2.2.1 Current service costs

Assuming that 4.1% of all mesh repairs are carried out using laparoscopic techniques and taking the cost different types of repair of as £1,078, £987 and £942 for laparoscopic, open mesh repair and non mesh repair respectively, then the cost to the health service in England in 2001/2 pounds is £55.81 millions (Table 2.3).

Table 2.3 Cost of current and recent service provision: Use of NHS resources on operations for primary repair of inguinal hernia in England

Name of operation	Finished episodes		Cost per episode	Cost to the NHS
	No	%		
2001-2002				
Laparoscopic	2172†	4.1%	£ 1,078Ψ	£2,341,594
Open flat mesh	50805†	95.9%	£ 987ϒ	£50,141,003
Open non-mesh repair	3534	100%	£ 942Ω	£3,328,311
TOTAL				**£55,810, 908** **(95 CI £30,609,000 - £98,764,000)***

† Based on the assumption that 4.1% of the 52977 mesh repairs are laparoscopic repair and the remainder are open flat mesh

* 2.5 and 97.5 percentiles of the Monte Carlo Simulation

Ψ Unit cost procedure for TEP; ϒ Unit cost procedure for open flat mesh Ω Unit cost procedure for open non-mesh

2.3 Description of new interventions

2.3.1 Intervention

Laparoscopic techniques

The first report of a hernia repair using laparoscopy was made in 1982 using laparoscopic closure of the neck of the sac.[10] The first reported use of prosthetic mesh for laparoscopic inguinal hernia repair was in 1991.[11,12] Laparoscopic approaches allow hernia repair without the need to open the abdominal wall. Instead, small incisions are made for the operating instruments and for a laparoscope. As with open mesh techniques (see below), a piece of mesh is generally used to close the hernia hole and prevent the intestine again protruding through the abdominal wall. The main variations in laparoscopic approaches depend on whether or not the instruments enter the peritoneal cavity.

Transabdominal Preperitoneal repair

Transabdominal preperitoneal (TAPP) repair requires access to the peritoneal cavity with placement of mesh through a peritoneal incision.[13] A large piece of mesh is placed in the preperitoneal space covering all potential hernia sites in the inguinal region. The

peritoneum is then closed above the mesh leaving it between the preperitoneal tissues and the abdominal wall where it becomes incorporated by fibrous tissue.

Totally extraperitoneal repair

The totally extraperitoneal (TEP) approach is the newer laparoscopic technique and was first reported in 1992.[14] In this method, the peritoneal cavity is not entered and mesh is used to seal the hernia from outside the peritoneum. The TEP approach is considered to be technically more difficult than the TAPP approach but it may lessen the risks of damage to the intra-abdominal organs and of adhesion formation leading to intestinal obstruction, which has been linked to the TAPP technique.

2.3.2 Identification of subgroups of patients

Factors that might distinguish subgroups of patients for whom a particular type of repair is more (or less) appropriate include age, sex, whether the hernia is unilateral or bilateral, or primary or recurrent, and the fitness of a patient for anaesthesia.

Although inguinal hernias occur relatively frequently in children, particularly in the first few years of life they are managed differently from adults; paediatric hernias have not therefore been considered in this report. Although both men and women can develop inguinal hernias, the vast majority of hernia repairs are carried out on male patients, reflecting anatomical differences that affect the risk of a hernia developing.

When examined at operation, 10-25% of patients are found to have an occult hernia on the contralateral side.[15-19] Both laparscopic approaches allow assessment and treatment of the contralateral side at the same operation without the need for further surgical incisions (although TEP does require further dissection). Potential advantages of laparoscopic repair are the ability to repair bilateral hernias at the same time, and the ability to rule out the possibility of an undetected contralateral hernia during unilateral repair.

A proportion of the hernia repairs carried out in the UK are for recurrent hernia.[1] Although repair of recurrent hernia is generally considered as less straightforward, the same surgical options as for primary hernias are available.

Inguinal hernia may be repaired under general, local or regional anaesthesia. Laparoscopic repair is usually carried out under general anaesthesia while the option of surgery under local anaesthetic is more suitable for open mesh repairs. However, some patients express a strong preference for the type of anaesthesia used and for some patients general anaesthesia may be considered too risky clinically.

2.3.3 Criteria for treatment

An inguinal hernia is not in itself dangerous but it can lead to serious complications due to strangulation or bowel obstruction. However, not all inguinal hernias are brought to the attention of health care professionals, some may remain undetected until complications develop. Although the majority of hernia repairs are elective operations, a proportion of repairs, often involving strangulated hernias, are emergencies requiring immediate surgery. Surgical repair is the only method of repairing an irreducible hernia. In the case of reducible hernias, particularly in frail elderly patients, a decision may be taken not to operate, on the basis that repair may do more harm than managing the hernia non-surgically.

2.3.4 Personnel involved

The number of staff employed in laparoscopic operations is usually similar to the number involved in open repairs. The operating time for laparoscopic repair is believed to be longer. Laparoscopic repair is also technically more difficult and so takes longer to learn and tends to be performed by more experienced surgeons. It is therefore associated with a learning curve.[20]

2.3.5 Setting

Laparoscopic surgery is usually followed by at least one night's stay in hospital, although it can be carried out as a day case. There is a wide variation in the length of post-operative

stay for hernia repair, reflecting differences in surgeon and hospital policies, rather than differences in surgical techniques.

2.3.6 Equipment required

The main extra material costs of laparoscopic repair are associated with the endoscopy system, video unit, monitor, endoscope and CO_2 insufflator. Laparoscopic equipment costs are strongly influenced by whether disposable or reusable equipment is used. Disposable equipment can include all of the main surgical items required or it may be limited to specific items like trocars, staplers, diathermy scissors or ports.

2.3.7 Anticipated costs

The anticipated costs of adopting laparoscopic surgery are based on the degree of diffusion of this technique (Table 2.4). The total direct costs to the NHS are based on the cost in 2001/2 prices of £1,078, £987 and £942 for laparoscopic, open mesh and open non-mesh repair respectively (the methods used to derive these estimates are described in Chapter 5). In Table 2.4 it has been assumed that laparoscopic repair would displace open mesh repair rather than non-mesh repair.

If the actual percentage of repairs carried out by laparoscopically increased to 20% from the current service use of 4.1% the total cost to the NHS in England would increase by approximately one million pounds.

Table 2.4 Costs of hernia repair to the NHS (Based on 2001-2002 number of patients)

Percentage of total mesh repairs that are Laparoscopic	NHS mesh repair costs	NHS total costs (mesh and non mesh repairs)
5%	£525260,423	£55,854,353
10%	£52,767,411	£56,095,722
15%	£53,008,779	£56,337,090
20%	£53,250,148	£56,578,458

The data presented in Table 2.4 have assumed a fixed operation cost and have not considered whether the unit cost of laparoscopic surgery would change as diffusion of laparoscopic increases. Such changes might arise as a result of purchases of new equipment (diseconomies of scale) or equipment costs being spread over a greater number of hernia repair procedures (economies of scale) or the use of laparoscopic equipment for other surgical interventions (economies of scope). A further factor that has not been considered in these figures is the cost of training surgeons to perform laparoscopic repairs. The net impact of these factors on total NHS costs is uncertain.

3 Effectiveness

The original Technology Assessment Report submitted to NICE summarised the evidence on the effectiveness of laparoscopic compared with open non-mesh as well as open mesh procedures for the repair of inguinal hernia. [21] There was clear evidence that open mesh repair is more clinically and cost effective that open non-mesh techniques, and open mesh techniques became the standard. Open non-mesh repair is therefore not considered in this report. For this reason, not all the trials included in the original report are eligible for inclusion in this update. Evidence for assessing the clinical effectiveness thus comprises the eligible trials from the original report as well as additional randomised controlled trials or quasi-randomised controlled trials identified from literature searching specific to this review. Any new data to the original review, including individual patient data (IPD) obtained through the EU Hernia Trialists Collaboration, were added to the original data in a meta-analysis, where possible.

3.1 Methods for reviewing effectiveness

3.1.1 Search strategy

Electronic searches were conducted to identify reports of trials of laparoscopic inguinal hernia repair, including TAPP and TEP procedures. Systematic reviews and other evidence-based reports were also identified. The original Technology Assessment Report had searched MEDLINE and EMBASE up to 2000, therefore these databases were searched only from 2000 onwards using a revised strategy to reflect the scope of the new review. Since the original strategies used had not specifically searched for studies comparing TAPP with TEP procedures, supplementary searching of these databases for all years, was also undertaken. The following databases were searched, and full details of the strategies used are documented in Appendix 1.

MEDLINE (2000- Week 1 June 2003) Additional TAPP vs TEP search (1966 to Week 1 June 2003)

MEDLINE Extra (13th June 2003)

EMBASE (2000 to Week 23 2003) Additional TAPP vs TEP search (1980 to Week 23 2003)

CINAHL (1985 to Week 1 June 2003)

BIOSIS (1985 to 18th June 2003)

Science Citation Index (1981 to 21st June 2003)

Web of Science Proceedings (1990 to 21st June 2003)

Cochrane Controlled Trials Register (Cochrane Library Issue 2 2003)

Cochrane Database of Systematic Reviews (Cochrane Library Issue 2 2003)

Database of Abstracts of Reviews of Effectiveness (June 2003)

HTA Database (June 2003)

Journals@Ovid Full Text (July 16th 2003)

SpringerLink (July 16th 2003)

National Research Register (Issue 2 2003)

Clinical Trials (June 2003)

Current Controlled Trials (June 2003)

Research Findings Register (June 2003)

In addition, selected conference proceedings were hand-searched and websites consulted, details of which can also be found in Appendix 1. Reference lists of all included papers were scanned and experts contacted for other potentially eligible reports.

3.1.2 Inclusion and exclusion criteria

All titles and, where possible, abstracts identified by the search strategies were assessed to identify potentially relevant reports. A total of 1421 citations were identified from electronic searching and a further 23 abstracts from hand-searching. 213 reports (180 papers; 33 abstracts) were assessed as potentially relevant for which full text papers were then obtained where available. These were formally assessed independently by two researchers to check whether they met the inclusion criteria, using a study eligibility form developed for this purpose (Appendix 2). Any disagreements that could not be resolved through discussion were referred to an arbiter. The following inclusion criteria were applied:

Types of studies

All published and unpublished randomised controlled trials and quasi-randomised controlled trials were eligible for inclusion if they compared: 1) laparoscopic inguinal hernia repair with open mesh inguinal hernia repair; or 2) laparoscopic TAPP with laparoscopic TEP methods of inguinal hernia repair. Trials were included irrespective of the language in which they were reported.

Types of participants

The trials included all patients with a clinical diagnosis of inguinal hernia for whom surgical management was judged appropriate. Where possible, analyses based on individual patient data from randomised patients were included in the meta-analysis, including data obtained for any patients excluded from the original published analyses. Where data allowed, the patient population was split by whether or not the hernia was recurrent or bilateral and whether or not the patient was fit enough for general anaesthesia. Data from children aged 12 years and older were included where these patients were included in a trial of adults; however, trials specifically relating to children were not included.

Types of interventions

Methods of surgical repair of inguinal hernia:

a) Laparoscopic inguinal hernia repair (TAPP and TEP).
b) Open mesh inguinal hernia repair (including open flat mesh, open pre-peritoneal mesh and open plug and mesh).

Types of outcome measures

The following data items were sought for all trials:

Primary outcomes:

Hernia recurrence

Persisting pain

Secondary outcomes:

Duration of operation

Opposite method initiated

Conversion

Post-operative pain

Haematoma

Seroma

Wound/Superficial Infection

Mesh/Deep Infection

Port site hernia

Vascular injury

Visceral injury

Length of hospital stay

Time to return to usual activities

Persisting numbness

Quality of Life

3.1.3 Data extraction strategy

The titles and abstracts of all papers identified by the search strategy were screened. Full text copies of all potentially relevant studies were obtained and two reviewers independently assessed them for inclusion. Reviewers were not blinded to the names of studies' authors, institutions or publications. Any disagreements were resolved by consensus or arbitration.

A data extraction form was developed to record details of trial methods, participants, interventions, patient characteristics and outcomes (Appendix 3). Two reviewers extracted data independently. Any differences that could not be resolved through discussion were referred to an arbiter.

3.1.4 Quality assessment strategy

Two reviewers working independently assessed all studies that met the selection criteria for methodological quality. Any disagreements were resolved by consensus or arbitration. The system for classifying methodological quality of controlled trials was based on an assessment of four principal potential sources of bias. These were: selection bias from inadequate concealment of allocation of treatments; attrition bias from losses to follow-up without appropriate intention-to-treat analysis, particularly if related to one or other surgical approaches; detection bias from biased ascertainment of outcome where knowledge of the allocation might have influenced the measurement of outcome; and selection bias in analysis (Appendix 3).

3.1.5 Data synthesis

For each outcome the results were derived from the best available source: if IPD reanalysis was not available, information from aggregate data provided by the trialist or data from the trial publications were used. Dichotomous outcome data were combined using the relative risk (RR) method and continuous outcomes were combined using the Mantel-Haenszel weighted mean difference (WMD) method. Time to return to usual activities was described using hazard ratios (HR) derived from IPD reanalysis. The hazard ratio is defined as the ratio of the instantaneous adverse event rates of the groups, i.e. the ratio of the adverse event rate of the treatment group to that of the control group. Unlike the odds ratio, the HR can allow for the fact that some patients were not followed up for the full time period (censored). Even when the instantaneous adverse event rates of the groups both change with time the ratio of the two is always assumed to be constant (i.e. the HR assumes the survival curves are proportional and do not cross over). A HR of one indicates no difference between comparison groups. For undesirable outcomes a HR that is less than one indicates that the intervention was effective in reducing the risk of that outcome. In the context of meta-analysis Peto's formula gives an estimate of the odd ratio and this is also usually a close approximation to the HR. The results are all reported using a fixed effects model. Chi-squared tests were used to explore statistical heterogeneity across studies and where a significant result was found, possible reasons were explored using sensitivity analyses.

The review was conducted using the standard Cochrane software 'RevMan 4.1'. Appendix 7(1) considers TAPP versus open mesh repair. Within this analysis, the trials were ordered by the method of open mesh repair (open flat mesh, open pre-peritoneal mesh and open plug and mesh). Appendix 7(2) considers TEP versus open mesh repair and the trials were similarly ordered by the method of open repair (open flat mesh, open pre-peritoneal mesh and open plug and mesh). Appendix 7(3)-7(4), and 7(5)-7(6) repeat this but only include patients with recurrent and bilateral hernias respectively.

Duration of operation was defined as time from first incision to last suture or, where this was not available, time in theatre. "Opposite" method initiated was defined as a laparoscopic repair initiated when an open repair was allocated, or vice versa. A conversion was defined as a procedure initiated as a laparoscopic but converted to an open repair, or vice versa. 'Postoperative pain' could include data collected on the second or third day, if no data were reported for the first post-operative day. Haematoma included wound or scrotal haematoma or ecchymosis but not bruising. Seroma included hydrocele. Wound/superficial infection was defined as wound related infections only and included pus from wound, fistula and sinus formation. Length of postoperative stay was defined as time from admission to discharge. Time to return to usual activities was defined as number of days to resumption of normal social activities or work where this was not available. Persisting pain was defined as groin pain of any severity (including testicular) persisting at one year after the operation, or at the closest timepoint to one year providing this was at least three months after surgery. Persisting numbness included paresthesia, dysesthesia and discomfort persisting at one year after the operation, or at the closest timepoint to one year providing this was at least three months after surgery. Hernia recurrence data were based on the methods of ascertainment used in individual trials.

3.2 Results

3.2.1 Quantity and quality of research available

A total of 213 reports (180 papers; 33 abstracts) were identified as potentially relevant to the review. The full text of seven of these reports were unobtainable because no copies could be traced in the UK.

Number and type of studies included

Twenty four trials from the original review compared laparoscopic with open mesh procedures and were included in this updated review. In addition, from the searching conducted for this update, 37 new reports of trials met the criteria for inclusion. These comprised 20 reports relating to the originally included trials and 17 reports relating to 13 new trials. Thus, in total 37 eligible trials were identified. A list of these studies with their associated references is given in Appendix 4.

Number and type of studies excluded, with reasons for specific exclusions

168 articles (142 full text papers and 27 abstracts) were obtained but were excluded because they failed to meet one or more of the specified inclusion criteria in terms of study design, participants, interventions, or outcomes. Of the 168 articles excluded, 140 were not RCTs. Of the remaining 28 reports, 25were comparisons of laparoscopic versus open non-mesh[22-46], one compared two versions of TEP i.e. had no comparison to an open technique[47], one report had no usable results and one final article[49] had no results publishable until 2004.[48]

Tabulation of quality of studies, characteristics of studies and evidence rating

Appendix 5 contains the detailed quality assessment score for each of the included primary studies. The method of randomisation used was stated explicitly for 29 of 37 trials: central randomisation service in four, sealed envelopes in 18, computer generated random numbers in three, by birthdate in one, by alternation in two, and random selection by cards in one. In eight trials, the allocation was said to be 'randomised' but the method was not specified. The trials ranged in size from 18 to 928 randomised patients. The mean or median duration of follow-up ranged from one week to five years, 22 trials confirmed hernia diagnosis by

clinical examination and in 18 trials the operation was reported to have been performed by either an 'experienced' surgeon or by one who had performed at least ten laparoscopic hernia repairs.

Characteristics of included studies

Appendix 6 provides details of the characteristics of the included studies. There were 39 relevant comparisons in the 37 eligible trials (5560 randomised participants), because two trials had three-arms. Of the 37 trials included, 31 were reported in full papers and six as abstracts only. IPD reanalysis was available for 15 trials (2907 participants) two of which had a published abstract only, and additional aggregated data for a further four (506 participants). Published data only was available for the other 18 (2147 participants). 19 trials included recurrent as well as primary hernias, 13 were limited to primary hernias only, one included recurrent hernias only, and these details were not reported for four. The comparisons in the 37 trials were: TAPP versus open flat mesh (13 trials, 1408 participants);[50-66] TAPP versus open preperitoneal mesh (four trials, 937 participants);[67-71] TAPP versus plug and mesh (one trial, 160 participants);[72-75] TEP versus open flat mesh (seven trials, 664 participants);[76-83] TEP versus open preperitoneal mesh (five trials, 424 participants);[84-92] TEP versus plug and mesh (one trial, 293 participants);[93] TEP versus open flat mesh versus open preperitoneal mesh (one trial, 65 participants);[94] TEP versus open flat mesh versus plug and mesh (one trial, 299 participants);[95] mixed laparoscopic versus mixed open (two trials, 1058 participants);[96-107] mixed laparoscopic versus open flat mesh (one trial, 200 participants);[108] and TAPP versus TEP (one trial, 52 participants).[109,110] Across the trials, where reported, all but two patients allocated to laparoscopic repairs received a general anaesthetic (both had a regional anaesthetic). Patients in the open groups received general, regional or local anaesthesia, determined by the trial protocol or surgeon's choice.

Tabulation of results

The results of the meta-analyses are given in Appendix 7.

3.2.2 Assessment of effectiveness

Laparoscopic versus open mesh

Duration of operation

The average length of operation was longer in the laparoscopic groups in all but three trials with data (Comparison 01:01 and 02:01)(Appendix 7(1) and 7(2)). Overall, the weighted mean difference (WMD) was 13.33 minutes (95% CI 12.08 to 14.57; p<0.0001) for TAPP versus open mesh and 7.89 minutes (95% CI 6.22 to 9.57 p<0.0001) for TEP versus open mesh. There was evidence of statistical heterogeneity, but generally there was consistency in direction of effect in the sub-categories, although size of effect estimates varied (Table 3.1).

Table 3.1 Overall WMD for duration of operation (mins) when comparing TAPP versus open, and TEP versus open with sub-categories open flat mesh, open preperitoneal mesh, open plug and mesh, and open mixed mesh

Comparison Sub-category	WMD	95% CI	p-value
TAPP v Open mesh (16 RCTs)	**13.33**	**12.08, 14.57**	**<0.00001**
TAPP v Flat Mesh (10 RCTs)	10.93	9.38, 12.48	<0.00001
TAPP v Preperitoneal mesh (4 RCTs)	15.62	12.89, 18.36	<0.00001
TAPP v Plug and mesh (1 RCT)	25.00	20.96, 29.04	<0.00001
TAPP v Mixed mesh (1 RCT)	12.68	7.34, 18.02	<0.00001
TEP v Open mesh (8 RCTs)	**7.89**	**6.22, 9.57**	**<0.00001**
TEP v Flat Mesh (4 RCTs)	4.33	1.31, 7.34	0.005
TEP v Preperitoneal mesh (2 RCTs)	16.31	9.30, 23.31	0.00001
TEP v Plug and mesh (1 RCT)	1.30	-1.74, 4.34	0.4
TEP v Mixed mesh (1 RCT)	15.91	12.98, 18.84	<0.00001

"Opposite" method initiated

The 'opposite' method was initiated in 15/440 (3.4%) allocated TAPP repairs versus 1/437 (0.2%) allocated open mesh repairs (Comparison 01:02) and in 26/614 (4.2%) allocated TEP

repairs versus 9/590 (1.5%) allocated open mesh repairs (Comparison 02:02). The direction of effect was similar in all sub-categories where data were available.

Conversions

In total, 17 (1.4%) TAPP operations were stated to have been converted to an open procedure amongst 1249 allocated TAPP repairs and zero open mesh procedures were converted to a laparoscopic repair amongst 1226 allocated open mesh repairs (Comparison 01:03: RR 5.91, 95% CI 1.91 to 18.27; p=0.002). For TEP operations, 39 (3.6%) were converted to an open procedure amongst 1074 allocated TEP repairs compared with one (0.1%) open mesh procedure amongst 1113 allocated open mesh repairs (Comparison 02:03: RR 10.77, 95% CI 3.91 to 29.68; p<0.0001). Higher rates observed in TEP trials reflected one study in particular.[96-103]

Post-operative pain

Data were not presented in a form sufficiently similar to allow quantitative synthesis; in these cases a qualitative review looking for consistency between studies was performed, principally in the direction of apparent effect using the Sign test.[111] The conservative approach was taken of comparing the number of trials favouring laparoscopic management compared with all others, which included those where no differences in either direction were detected.

Twenty relevant comparisons in 19 trials reports included a measure of post-operative pain (one trial had three arms). Sixteen favoured the laparoscopic group, one trial favoured the open group, and in 3 trials there were no differences (Sign test, $p < 0.001$), (Table 3.2).

Table 3.2 Post-operative pain

Reference	Lap	Open	Comments
TAPP versus Flat Mesh			
Filipi 1996[50]	NR	NR	VAS (favours TAPP)
Gontarz 1998[51]	NR	NR	NR
Heikkinen 1997[53]	3.9	5.5	Median (estimated from graph)
Heikkinen 1998[52]	NR	NR	NR
Jess 2000[54]	NR	NR	NR
Köninger 1998[55]	NR	NR	NR
Mahon 2001[56]	2.4*	4.8*	VAS
Paganini 1998[58]	2(2-3)	2(1-3)	VAS (0-10) Median (IQR)
Payne 1994[59]	NR	NR	NR
Picchio 1999[61]	3.1(0.2)(1-7)	2.7(0.2)(1-5)	VAS (0-10) Mean (SEM) (range)
Sarli 1997[62]	2.3	2.5	VAS Mean
Sarli 2001[63]	1(1-3)	4(2-6)	VAS (1-10) Median (IQR)
Wellwood 1998[64]	NR	NR	Categorical data (favours TAPP)
TAPP versus Preperitoneal Mesh			
Aitola 1998[67]	NR	NR	Pain on coughing, movement (favours TAPP)
Beets 1999[68]	NR	NR	NR
Johansson 1999[70]	NR	NR	NR
Laporte 1997[69]	NR	NR	NR
TAPP versus Plug and Mesh			
Zieren 1998[72]	3.9	4.1	Mean (estimated from graph)
TEP versus Flat Mesh			
Andersson 2003[76]	NR	NR	NR
Bringman 2003[95]	1(0-3)	2(0-6)	VAS (0-10) Median (range)
Colak 2003[77]	2.73(1.69)	4.61(1.77)	VAS (0-10) Mean (SD)
Gholghesaei 2003[78]	NR	NR	NR
Heikkinen 1998[80]	NR	NR	NR
Lal 2003[81]	1.76(1.4)*	2.74(1.5)*	VAS (favours TEP)
Merello 1997[82]	NR	NR	NR
Payne 1996[83]	NR	NR	NR
Vatansev 2002[94]	NR	NR	NR

Table 3.2 Post-operative pain (cont)

Reference	Lap	Open	Comments
TEP versus Preperitoneal Mesh			
Bostanci 1998[84]	NR	NR	NR
Champault 1997[85]	NR	NR	Ratios given (favours TEP)
Ramon 1998[88]	NR	***NR***	NR
Simmermacher 2000[89]	NR	NR	NR
Suter 2002[90]	3.3(0-9)	3.36(0-8)	VAS Maximum (range)
Vatansev 2002[94]	NR	NR	NR
TEP versus Plug and Mesh			
Bringman 2003[95]	1(0-3)	2(0-7)	VAS (0-10) Median (range)
Khoury 1998[93]	3	7	VAS (0-10) 'Average'
Mixed Laparoscopic versus Mixed Open			
Barkun 1995[104]	NR	NR	McGill pain score (favours TEP)
MRC Trial Group[96]	NR	NR	NR
Mixed Laparoscpic versus Flat Mesh			
Snyder 1998[108]	4.7*	5.8*	VAS (0-10)

NR = Not Reported ; VAS = Visual Analogue Score; IQR = Interquartile range; SEM = Standard error of the mean
* Values unclear

NOTE: 3-armed trials entered twice in appropriate comparisons

Haematoma

Overall, there appeared to be fewer haematomas in the TAPP groups (Comparison 01:04: 117/841 vs 152/836: RR 0.76, 95% CI 0.62 to 0.94; p=0.009). However, these results were particularly influenced by the Wellwood 1998 trial[64-66] and the difference was not significant when this trial was removed. When TEP trials were considered there appeared to be a clear difference with fewer haematomas in the TEP groups (Comparison 02:04: RR 0.44, 95% CI 0.33 to 0.58; p<0.0001). The estimated effect was similar in all sub-categories.

Seroma

Overall, there were more seromas in the TAPP groups (Comparison 01:05: 49/836 vs 23/836: RR 1.91, 95% CI 1.27 to 3.07; p=0.003). Although the estimated effect was statistically significant when comparing TAPP with open flat mesh there were too few data

to judge whether or not there was a consistent finding across all the other sub-categories. There was no apparent difference when considering the TEP groups (Comparison 02:05: 28/810 vs 39/804: RR 0.73, 95% CI 0.46 to 1.14; p=0.17). Although these results were particularly influenced by the MRC laparoscopic groin hernia trial[96-103] the difference remained non-significant when this trial was removed.

Wound/superficial infection

Where reported, wound/superficial infection appeared less frequent in the TAPP groups (Comparison 01:06: RR 0.41, 95% CI 0.26 to 0.64; p=0.0001). However, these results were again influenced by the Wellwood 1998 trial[64-66] and the difference was not significant when this trial was removed. There were also fewer wound/superficial infections when comparing TEP with open mesh (Comparison 02:06: RR 0.62, 95% CI 0.33 to 1.16; p=0.14) but none of these differences were statistically significant.

Mesh/deep infection

There were only two reported cases of mesh/deep infection in all included studies: one case of deep infection in a open preperitoneal mesh group;[89] and one case of mesh infection in an open flat mesh group[51] (Comparison 01:07 and 02:07).

Vascular or visceral injuries

Overall, there were 1/764 (0.13%) potentially serious vascular and 5/764 (0.79%) potentially serious visceral injuries in the TAPP groups, zero potentially serious vascular and 1/644 (0.16%) potentially serious visceral injuries in the TEP group compared with zero potentially serious vascular and 2/1388 (0.14%) potentially serious visceral injuries in the open groups (Table 3.3: Comparison 01:08, 01:09, 02:09, 02:09). It should be noted that these data are difficult to interpret as it is unclear whether definitions have been used consistently.

Table 3.3 Potentially serious complications

Complication	TAPP	TEP	Open*
Intra-operative:			
Vascular:			
Trocar injury to left common iliac artery[96]	1/764	0/744	0/1475
Visceral:			
Bladder injury[67,70,96]	4/764	0/644	0/1388
Small bowel injury[76,96]	0/764	0/644	2/1388
Post-operative:			
Visceral:			
Small bowel obstruction[76,96]	1/764	1/644	0/1388

* Data combined for open groups from the RCT, comparing TAPP with Open and TEP with Open

Port-site hernia

There were only three cases of port site hernia reported.[64,96] All occurred within the TAPP groups (Comparison 01:10 and 02:10).

Length of stay (days)

There was marked heterogeneity in length of hospital stay, with greater differences in mean stay between different hospitals than there were between laparoscopic and open repairs in the same hospital (Comparison 01:11and 02:11). In respect of between trial group differences, the trials tended to show either no difference or a clear difference, sometimes in exact days.[73] This suggests that the overall findings reflect different health care systems rather than a true effect of the repair.

Time to return to usual activity (days)

In all trials with data, the time to return to usual activity was shorter in both the TAPP groups (Comparison 01:12: HR 0.66, 95% CI 0.58 to 0.75; p<0.0001) and the TEP groups (Comparison 02:12: HR 0.49, 95% CI 0.42 to 0.56; p<0.0001) (Table 3.4). It is difficult to

interpret the hazard ratios as absolute differences but a simple crude aggregation of return to usual activity data from the IPD reanalysis showed that this was about three days and four days shorter respectively when compared to open flat mesh. There is no obvious reason why the other open mesh procedures would perform very much differently. These data are consistent in terms of direction of effect with the findings of the hazard ratios (HR). The estimated effect was similar in all sub-categories. However, there was evidence of statistical heterogeneity when considering the TEP groups and this is likely to be due to differences between trials in: post-operative advice; definition of usual activity (e.g work, walking, sport); existing co-morbidity; and local 'cultures'.

Table 3.4 Overall HR for time to return to usual activities when comparing TAPP versus open, and TEP versus open with sub-categories open flat mesh, open preperitoneal mesh, open plug and mesh, and open mixed mesh

Comparison Sub-category	HR	95% CI	p-value
TAPP v Open mesh (7 RCTs)	**0.66**	**0.58, 0.75**	**<0.00001**
TAPP v Flat Mesh (4 RCTs)	0.59	0.50, 0.70	<0.00001
TAPP v Preperitoneal mesh (3 RCTs)	0.70	0.56, 0.87	0.001
TAPP v Plug and mesh (0 RCTs)	ND	ND	ND
TAPP v Mixed mesh (1 RCT)	0.86	0.62, 1.19	0.4
TEP v Open mesh (5 RCTs)	**0.49**	**0.42, 0.56**	**<0.00001**
TEP v Flat Mesh (3 RCTs)	0.35	0.25, 0.50	<0.00001
TEP v Preperitoneal mesh (0 RCTs)	ND	ND	ND
TEP v Plug and mesh (1 RCT)	0.22	0.16, 0.29	<0.00001
TEP v Mixed mesh (1 RCT)	0.80	0.66, 0.97	0.02

ND = No data

Persisting numbness

Overall, there were fewer cases of persisting numbness at one year after the operation in both the TAPP groups (Comparison 01:13: overall 23/750 versus 82/733; RR 0.26, 95% CI

0.17 to 0.40; p<0.0001) and the TEP groups (Comparison 01:13: overall 76/468 versus 110/438; RR 0.67, 95% CI 0.53 to 0.86; p=0.002) (Table 3.5). The estimated effect size was broadly consistent in all sub-categories.

Table 3.5 Overall RR for persisting numbness when comparing TAPP versus open, and TEP versus open with sub-categories open flat mesh, open preperitoneal mesh, open plug and mesh, and open mixed mesh

Comparison Sub-category	RR	95% CI	p-value
TAPP v Open mesh (8 RCTs)	**0.26**	**0.17, 0.40**	**<0.00001**
TAPP v Flat Mesh (4 RCTs)	0.10	0.03, 0.32	0.0001
TAPP v Preperitoneal mesh (2 RCTs)	0.07	0.00, 1.31	0.08
TAPP v Plug and mesh (1 RCT)	1.00	0.06, 15.71	1.00
TAPP v Mixed mesh (1 RCT)	0.38	0.24, 0.59	0.00003
TEP v Open mesh (4 RCTs)	**0.67**	**0.53, 0.86**	**0.002**
TEP v Flat Mesh (2 RCTs)	0.17	0.03, 1.16	0.07
TEP v Preperitoneal mesh (0 RCTs)	ND	ND	ND
TEP v Plug and mesh (1 RCT)	2.57	0.11, 62.38	0.6
TEP v Mixed mesh (1 RCT)	0.69	0.54, 0.89	0.004

ND = No data

Persisting pain

Overall, there were fewer cases of persisting pain at one year after the operation in both the TAPP groups (Comparison 01:14: overall 116/787 versus 154/763; RR 0.72, 95% CI 0.58 to 0.88; p=0.001) and the TEP groups (Comparison 02:14: overall 127/517 versus 159/474; RR 0.77, 95% CI 0.64 to 0.92; p=0.004) (Table 3.6). The direction of effect was similar in all sub-categories other than TAPP versus plug and mesh. Only one trial was available in this comparison, having only three cases of persisting pain and the confidence intervals are therefore very wide and statistically compatible with the overall results.

Table 3.6 Overall RR for persisting pain when comparing TAPP versus open, and TEP versus open with sub-categories open flat mesh, open preperitoneal mesh, open plug and mesh, and open mixed mesh

Comparison Sub-category	RR	95% CI	p-value
TAPP v Open mesh (8 RCTs)	**0.72**	**0.58, 0.88**	**0.001**
TAPP v Flat Mesh (4 RCTs)	0.68	0.52, 0.89	0.005
TAPP v Preperitoneal mesh (2 RCTs)	0.46	0.16, 1.32	0.15
TAPP v Plug and mesh (1 RCT)	2.00	0.19, 21.62	0.6
TAPP v Mixed mesh (1 RCT)	0.83	0.60, 1.14	0.2
TEP v Open mesh (4 RCTs)	**0.77**	**0.64, 0.92**	**0.004**
TEP v Flat Mesh (2 RCTs)	0.10	0.01, 0.66	0.02
TEP v Preperitoneal mesh (0 RCTs)	ND	ND	ND
TEP v Plug and mesh (1 RCT)	0.16	0.04, 0.69	0.01
TEP v Mixed mesh (1 RCT)	0.86	0.72, 1.04	0.11

ND = No data

Figure 3.1 TAPP versus Open Mesh: persisting pain

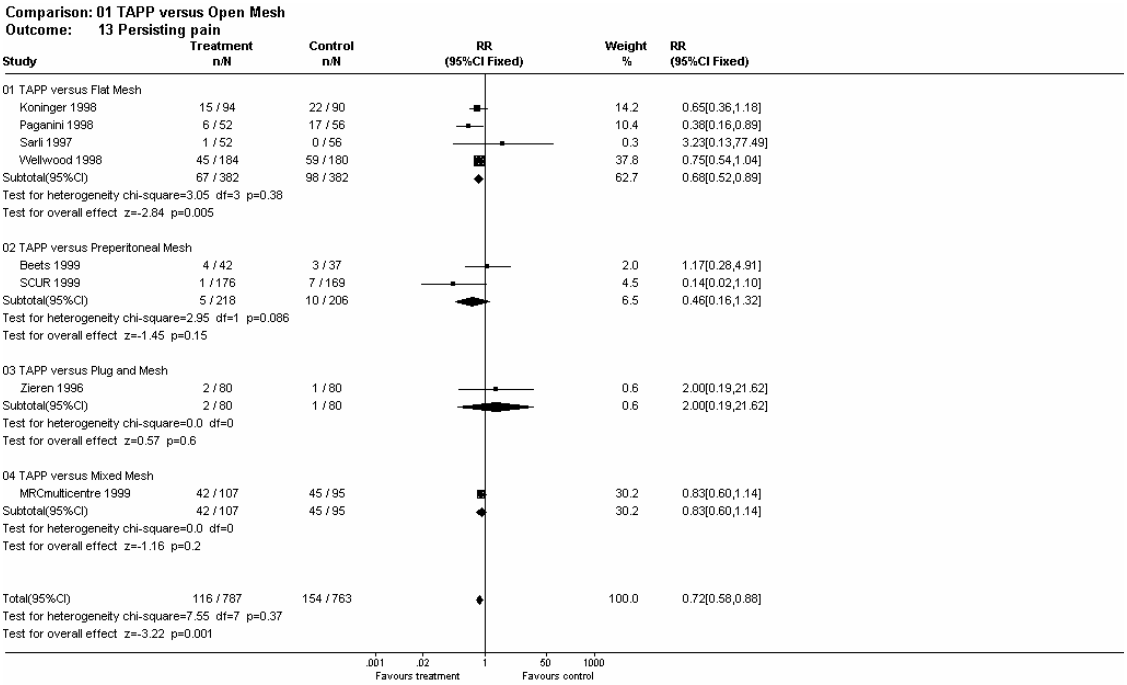
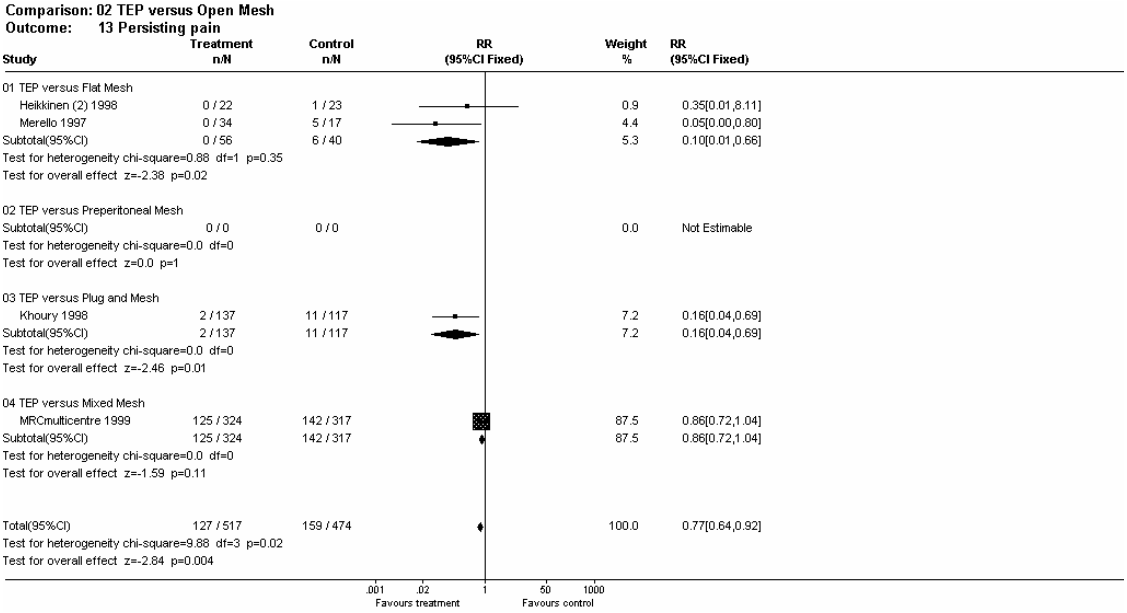


Figure 3.2 TEP versus Open Mesh: persisting pain



Hernia recurrence

The rates of recurrence were similar in the trial groups. A total of 26 recurrences were reported amongst 1052 allocated TAPP repairs versus 22 amongst 1062 allocated open mesh repairs (Comparison 01:15: RR 1.18, 95% CI 0.69 to 2.02; p = 0.5) and 23 recurrences amongst 1007 allocated TEP repairs versus 13 amongst 1002 allocated open mesh repairs (Comparison 02:15: RR 1.61, 95% CI 0.87 to 2.98; p = 0.13) (Table 3.7) [i]. The estimated effect size was broadly consistent in all sub-categories. It should be noted, however, that confidence intervals are all wide, even for the overall comparisons, and so clinically important differences may exist.

Table 3.7 Overall RR for hernia recurrence when comparing TAPP versus open, and TEP versus open with sub-categories open flat mesh, open preperitoneal mesh, open plug and mesh, and open mixed mesh

Comparison Sub-category	RR	95% CI	p-value
TAPP v Open mesh (15 RCTs)	**1.18**	**0.69, 2.02**	**0.5**
TAPP v Flat Mesh (10 RCTs)	1.68	00.73, 3.88	0.69
TAPP v Preperitoneal mesh (3 RCTs)	0.90	0.44,1.85	0.0049
TAPP v Plug and mesh (1 RCT)	Not estimable	Not estimable	Not estimable
TAPP v Mixed mesh (1 RCT)	Not estimable	Not estimable	Not estimable
TEP v Open mesh (13 RCTs)	**1.61**	**0.87, 2.98**	**0.13**
TEP v Flat Mesh (7 RCTs)	1.61	0.57, 4.60	0.4
TEP v Preperitoneal mesh (3 RCTs)	2.97	0.48, 18.28	0.2
TEP v Plug and mesh (2 RCT)	0.58	0.20, 1.73	0.3
TEP v Mixed mesh (1 RCT)	14.27	0.82, 248.59	0.07

[i] The higher rate of recurrence after TEP reflects the MRC multicentre trial. Questions have been raised as to whether this reflects inexperience with TEP and longer term follow-up in a sub-group of surgeons in this trial showed no difference at five years.[20,103]

Figure 3.3 TAPP versus Open Mesh: hernia recurrence

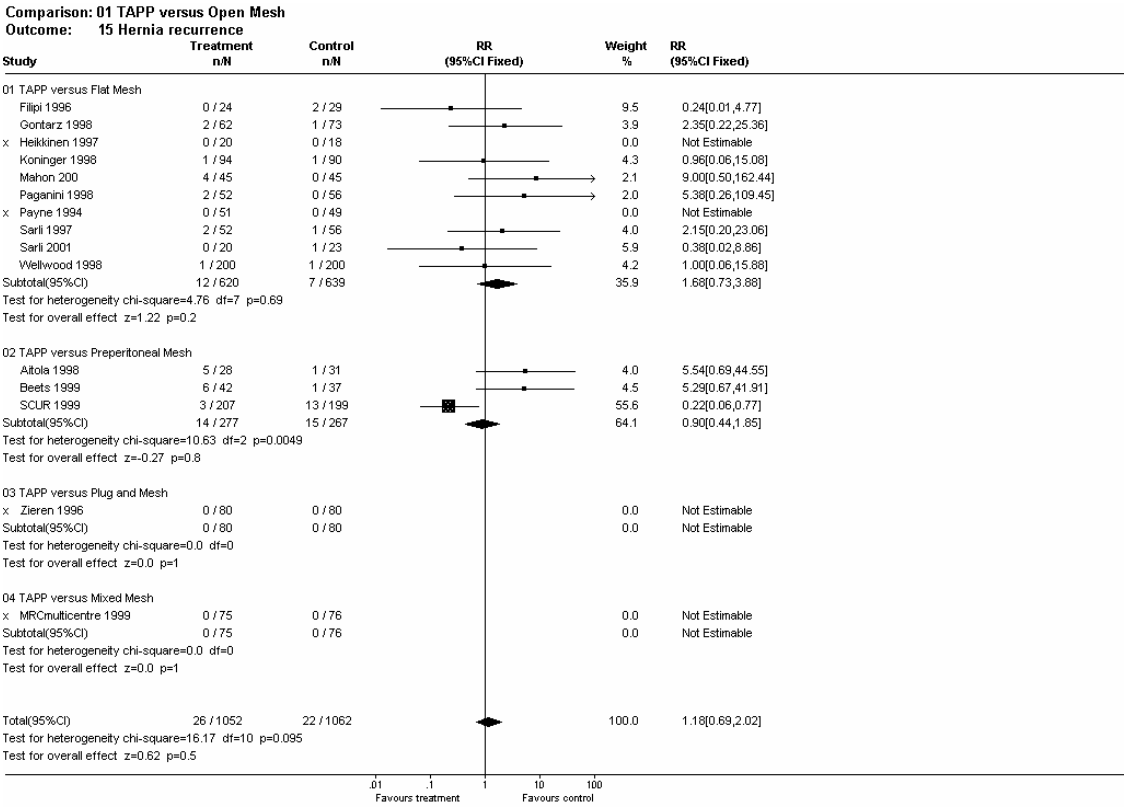
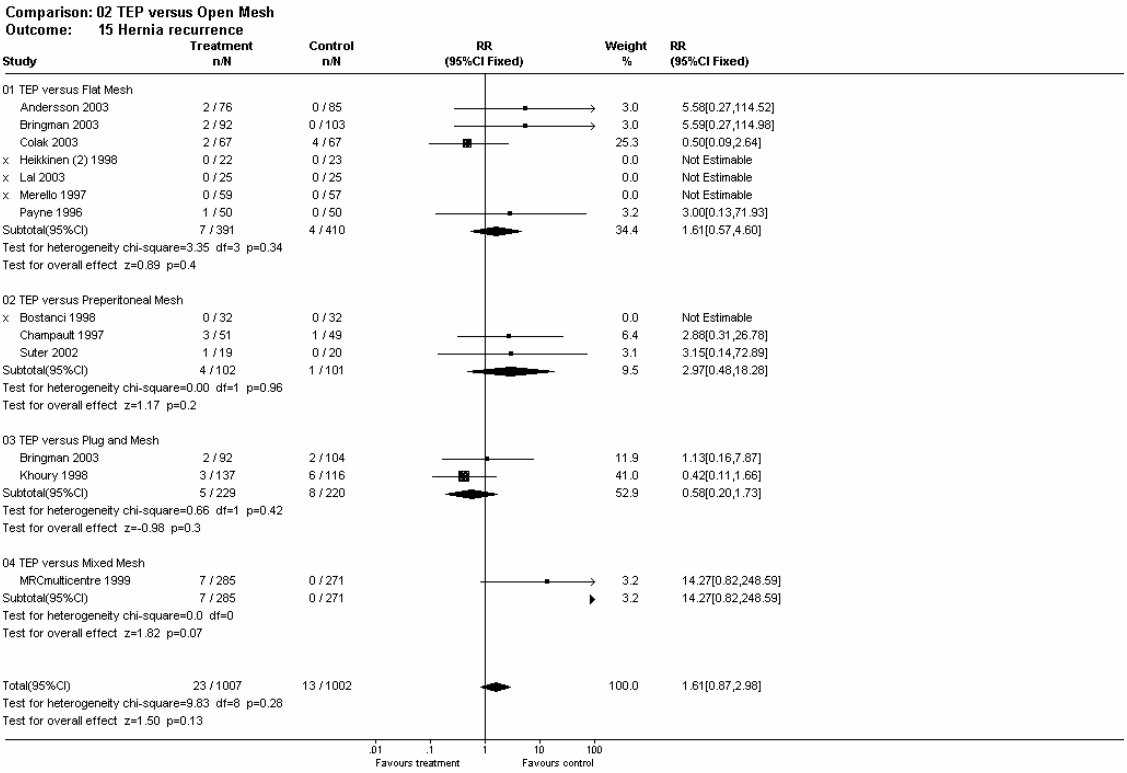


Figure 3.4 TEP versus open mesh: hernia recurrence



Five year follow-up

Only one report,[66] an update of Wellwood and colleagues,[64] presented results with five year follow-up comparing laparoscopic TAPP with open flat mesh repair. The main long-term objective of this trial was to compare the complication rates of these procedures. The results are tabulated in Table 3.8.

Table 3.8 Long-term complications in patients at least five years after undergoing inguinal hernia repair[ii]

Complication	TAPP (n=122) n(%)	Open flat mesh (n=120) n(%)
Mesh infection	0	1(1)
Groin pain	2(2)	12(10)*
Numbness	3(3)	27(23)*
Hernia recurrence	2(2)	3(3)

* Statistically significant

The follow-up included 65% of those still alive. No data were provided for assessing whether any differential loss to follow-up introduced selection bias. The much lower numbers of people reporting pain in the report by Douek and colleagues[66] when compared to the IPD provided by Wellwood and colleagues[64] (Comparison 01:14) is probably due to differing definitions of pain.

TAPP versus TEP

Only one randomised controlled trial[109] was available and reported outcomes on operation time, intra-operative and postoperative complications, length of hospital stay, time to return to work, time to return to usual activities and hernia recurrence. These results are tabulated in Table 3.9 (Appendix 7(3)).

[ii] IPD provided by Wellwood and colleagues[64] contributed to the meta-analyses (Appendix 7) and not the five year data for this trial.

Table 3.9 Results from study comparing effectiveness of TAPP with TEPP[109]

Outcomes	TAPP n=28	TEP n=24
Operation time (mean/SD)	46.0 (9.2)	52.3 (13.9)
Intraoperative complications	None	None
Haematoma	1/28	0/24
Time to return to usual activities (days) (mean/SEM):		
Walking	8.6 (1.4)	8.5 (1.3)
Driving a car	10.1 (1.4)	12.4 (1.7)
Sexual Intercourse	17.7 (2.7)	18.9 (2.6)
Sports	35.5 (4.9)	35.2 (4.6)
Time to return to work (weeks) (mean/SEM)	4.9 (0.7)	4.6 (0.6)
Length of hospital stay (mean/SD)	3.7 (1.4)	4.4 (0.9) *
Recurrence at 3 months	1/28	0/24

* Statistically significant result; SEM = Standard error of the mean; SD = Standard deviation

Duration of operation

The operating time was slightly longer in TEP than TAPP, however the difference was not statistically significant (Comparison 03:01: WMD –6.30, 95% CI -12.82 to 0.22; p= 0.06).

Haematoma

There was only one haematoma recorded in the study and this was in the TAPP group (Comparison 03:04: RR 2.59, 95% CI 0.11 to 60.69; p=0.6).

Length of stay (days)

Length of stay was shorter in the TEP group (Comparison 03:11: WMD -0.70, 95% CI –1.33 to -0.07; p=0.03).

Time to return to usual activity (days)

An overall figure for time to return to usual activities was not given in the paper, however several separate activities were listed. Of all of those listed there were no statistically significant differences between the TAPP and TEP.

Hernia recurrence

Hernia recurrence was only assessed up to three months. Within this time there was one recurrence in the TAPP group (Comparison 03:15: RR 2.59, 95% CI 0.11 to 60.69; p=0.6).

Complications/adverse events from non-randomised studies and observational studies

There were no reported complications or adverse events in the trial. For this reason studies using other designs were identified in order to provide further comparative evidence of complications and adverse events. This was not formally part of the protocol for the review. Attention was focussed on vascular injuries, visceral injuries, deep/mesh infections, port site hernia, and conversions as these were deemed to be the more serious complications. In order to achieve this, any studies which met the following inclusion criteria were used.

- Any study with TAPP and TEP as concurrent comparators where results of complications were given separately.
- Any non-concurrent comparative study of TAPP and TEP with greater than 1000 hernia repairs where results of complications were given separately.
- Any TAPP or TEP case series with greater than 1000 hernia repairs with results for complications.

On application of these criteria, nine studies were identified[112-120]: five studies with concurrent comparators were included[113-115,117,119]; one with a non-concurrent comparator[120]; and three studies[112,116,118] were case series (TEP[118], 5203 hernia repairs and TAPP[112,116], 2500[112] and 5203[116] hernia repairs respectively). Details of these studies can be found in Appendix 8 and results of potentially serious complications are detailed in Table 3.10.

Table 3.10 Results of potentially serious adverse events from non-randomised studies of TAPP and TEP

Study ID	Vascular injury		Visceral injury		Deep/mesh infection		Port site hernia		Conversions	
	TAPP % (n/N)	**TEP** % (n/N)	**TAPP** % (n/N)	**TEP** % (n/N)	**TAPP** % (n/N)	**TEP** % (n/N)	**TAPP** % (n/N)	**TEP** % (n/N)	**TAPP** % (n/N)	**TEP** % (n/N)
Comparative studies:										
Cohen 1998[113]	NR	NR	0.9% (1/108)	0% (0/100)	NR	NR	3.7% (4/108)	0% (0/100)	0% (0/108)	4% (4/100)
Felix 1995[114]	0% (0/733)	0% (0/382)	0.4% (3/733)	0% (0/382)	0% (0/733)	0% (0/382)	0.8% (6/733)	0% (0/733)	0% (0/382)	1.8% (7/382)
Khoury 1995[115]	0% (0/60)	3% (2/60)	0% (0/60)	0% (0/60)	0% (0/60)	0% (0/60)	1.7% (1/60)	0% (0/60)	0% (0/60)	0%
Lepere 2000[117]	0% (0/1290)	0% (0/682)	NR	NR	NR	NR	NR	NR	NR	NR
Van Hee 1998[119]	0% (0/33)	0% (0/58)	0% (0/33)	0% 0/58)	0% (0/33)	0% (0/58)	0% (0/33)	0% (0/58)	5% (2/33)	7% (4/58)
Weiser 2000[120]	NR	NR	NR	NR	0.2% (2/1216)	0% (0/1547)	0.3% (4/1216)	0.1% (2/1547)	NR	NR
Case series:										
Baca 2000[112]	0% (0/2500)	NA	0.64% (16/2500)	NA	0% (0/2500)	NA	0.24% (6/2500)	NA	0.24% (6/2500)	NA
Leibl 2000[116]	0.5% (29/5707)	NA	0.6% (34/5707)	NA	0.1% (6/5707)	NA	0.35% (20/5707)	NA	NR	NA
Tamme 2003[118]	NA	0.47% (24/5203)	NA	0.23% (12/5203)	NA	0.02% (1/5203)	NA	0% (0/5203)	NA	0.23% (12/5203)

NA = Not Applicable

NR = Not reported

Vascular injury

Seven studies reported vascular injuries[112,114-119] including three large case series.[112,116,118] In the comparative studies, three reported no vascular injuries[114,117,119] whilst one reported a higher rate (3% versus 0%) in TEP, however this was only a small study of 120 patients. [115] In the three case series, one reported no vascular injuries in TAPP[112] while the rates from the other two case series showed similar rates for TAPP (0.5%, based on 5707 cases)[116] and TEP (0.47% based on 5203 cases).[118]

Visceral injury

Seven studies reported visceral injuries[112-116,118,119] including the three large case series.[112,116,118] In the comparative studies, two reported no visceral injuries[115,119] whilst two reported a higher rate (0.9% versus 0% and 0.4% versus 0%) in TAPP than in TEP. [113,114] The combined number of cases in these studies was 1323. In the three case series, the two TAPP series[112,116] reported similar rates of 0.64% and 0.6% with a combined case number of 8207 [112,116] whilst the one TEP series reported a lower rate of 0.23% based on 5203 cases. [118]

Deep infection

Deep infections, primarily mesh infections are potentially more serious than superficial infections and can result in removal of the mesh. These were reported in seven studies.[112,114-116,118-120] In the comparative studies, three reported no deep infections[114,115,119] whilst one reported rates of 0.2% and 0% for TAPP and TEP respectively. [120] Rates for TAPP were low in the two case series[112,116] i.e. 0% and 0.1%. The rate in TEP was again low, 0.02%,[118] and did not indicate a difference between TAPP and TEP.

Port-site hernia

Eight of the nine studies reported port-site hernia. [112-116,118-120] The comparative studies showed rates of 0% to 3.7%.[113-115,119,120] In all four studies where cases of port-site hernia were reported, TAPP was associated with a higher rate than TEP. [113-115,120] In three studies there were no cases of port site hernia reported in the TEP groups compared to 3.7%,[113] 0.8%[114] and 1.7%[115] in the TAPP groups. This trend was also confirmed in the case series where there were no reported cases of port-site hernia amongst 5203 TEP repairs.[118] compared to 0.24%[112] and 0.35%[116] amongst 8207 TAPP repairs.

Conversions

The conversion rate was reported in six of the studies. [112-115,118,119] In three of the four comparative studies the rate was higher in the TEP group, with rates of 0% versus 4%,[113] 0% versus 1.8%[114] and 5% versus 7%.[119] The fourth comparative study was small with only 120 procedures and had no conversions.[115] However in the large case series the conversion rates between TAPP and TEP were very similar at 0.24%[112] and 0.23%[118] respectively.

3.2.3 Important sub-group differences for laparoscopic versus open techniques

Laparoscopic repair might be most useful in specified sub-groups of patients, such as those with recurrent or bilateral hernias. Subgroup analyses were performed for these groups of patients from the data provided in the included RCTs. Data were available from six trials for recurrent hernias when considering TAPP versus open mesh and five trials when considering TEP versus open mesh (Appendices 7(4)-7(5)). When considering bilateral hernias, data were available for seven RCTs comparing TAPP were open mesh trials and six comparing TEP with open mesh trials (Appendices 7(6)-7(7)). All subgroup analyses were not clearly different from those in less selected populations but these estimates were based on small numbers and so should be interpreted cautiously.

Recurrent hernias: TAPP versus open mesh

Duration of operation was reported for recurrent hernias separately in six trials.[59,67,68,70,70,96] Overall there was a statistically significant difference between TAPP and open mesh repair in favour of open mesh repair (Comparison 04:01: WMD 13.3, 95% CI 8.14 to 18.46; p<0.00001). For opposite method initiated four trials[59,67,68,96] reported results with no apparent difference between the groups (Comparison 04:02: RR 3.92, 95% CI 0.49 to 31.68; p=0.2). Five trials provided data about conversions. [59,64,67,70,96] Overall, 2/65 (3.1%) allocated TAPP repairs were converted compared with 0/56 (0%) allocated open mesh repairs (Comparison: 04:03 RR 2.28, 95% CI 0.25 to 20.47; p=0.5). The incidence of haematomas and seromas appeared to be similar between the groups (Comparison 04:04: RR 1.07, 95% CI 0.51 to 2.21; p=0.9, Comparison 04:05[64,67,68,96]: RR 1.45 95% CI 0.75 to 2.82; p=0.3). Results for wound/superficial infection were available for five trials with no apparent difference between the groups (Comparison 04:06 RR 0.6, 95% CI 0.24 to 1.54;

p=0.3). [64,67,68,70,96] Although some trials had collected data for mesh/deep infection, vascular injury and port site hernia, no cases were reported and therefore the relative risks could not be estimated. Overall, there was 1/59(2%)[67] potentially serious visceral injury in the TAPP group compared with 0/54 in the open mesh group (Comparison 04:09:[64,67,96] RR 2.18, 95% 0.1 to 46.92; p=0.6). Length of stay was compared in six trials with an overall WMD of 0.02, 95% CI -0.13 to 0.17 (p=0.8)(Comparison 04:11). [59,64,67,68,70,96] In all trials except one reporting this outcome, the time to return to usual activities was shorter in the TAPP groups (Comparison 04:12:[59,64,67,68,96] HR 0.6, 95% CI 0.41 to 0.87; p=0.008). There appeared to be fewer cases of persisting numbness in the TAPP groups, although this was not statistically significant (Comparison 04:13:[59,64,68,96] RR 0.33, 95% 0.1 to1.14; p=0.08). When considering persisting pain and hernia recurrence, there appeared to be no difference between the groups (Comparison 04:14:[64,68,96] RR 1.0, 95% 0.54 to 1.85; p=1, Comparison 04:15[59,64,67,68,96]:RR 1.32, 95% 0.53 to 3.31; p=0.5).

Recurrent hernias: TEP versus open mesh

Duration of operation was reported for recurrent hernias separately in five trials.[77,83,85,93,96] The overall WMD was 6.31, 95% CI 1.58, 11.05 (p=0.009) and favoured open mesh repair (Comparison 05:01). For opposite method initiated three trials reported results with no apparent differences between the groups, [83,93,96] the RR was only estimable for one trial (Comparison 05:02: RR 1.16, 95% CI 0.2 to 6.62; p=0.9). [96] Three trials provided data about conversions. [83,93,96] Overall, 8/63(12.7%) allocated to TEP repairs were converted compared with 1/62(1.6%) allocated to open mesh repairs (Comparison 05:03: RR 6.61, 95% CI 0.86 to 50.52; p=0.07). There appeared to be fewer haematomas in the TEP groups (Comparison 05:04:[93] RR 0.29, 95% CI 0.13 to 0.66; p=0.003). Similar rates of seromas were reported between the groups (Comparison 05:05: RR was only estimable in one,[96] 0.6, 95% CI 0.14 to 2.51; p=0.5). Relative risks were not estimable for wound/superficial and mesh/deep infection, visceral and vascular injury and port-site hernia due to no events being recorded. Length of hospital stay was compared in one trial with a WMD of 0.24, 95% CI -0.45 to 0.93 (p=0.5)(Comparison 05:11). [96] The time to return to usual activities appeared to be shorter in the TEP groups (Comparison 05:12[83,93]: HR 0.55, 95% CI 0.35, 0.89; p=0.01). There appeared to be no difference in the reported number of cases of persisting numbness,

persisting pain and hernia recurrence (Comparison05:13:[93] RR 1.22, 95% CI 0.63 to 2.35; p=0.6, Comparison 05:14:[93] RR of 0.9, 95% CI 0.59 to 1.38; p=0.6, Comparison 05:15[93]: RR of 1.08, 95% CI 0.57 to 2.05; p=0.8).

Bilateral hernias: TAPP versus open mesh

Duration of operation was reported for bilateral hernias separately in seven trials.[53,59,63,64,67,68,96] Overall there was no difference between TAPP and open mesh repair (Comparison 06:01: WMD –0.28, 95% CI –5.67 to 5.12; p=0.9). For opposite method initiated five trials reported results with no apparent differences between the groups (Comparison 06:02: RR 1.98, 95% CI 0.23 to 16.83; p=0.74). [53,59,67,68,96] One trial provided data about conversions. [96] Overall, there was only one (1.6%) conversion reported amongst 63 allocated to TAPP repair compared with zero in the open mesh group (Comparison 06:03: RR 3.5, 95% CI 0.17 to 70.95; p=0.4). The incidence of haematomas were similar between the two groups (Comparison 06:04[53,59,63,64,67]: RR 0.76, 95% CI 0.35 to 1.65; p=0.5). There appeared to be fewer cases of seromas in the open mesh groups, although this was not statistically significant (Comparison 06:05:[53,63,64,67,68] RR 2.62, 95% CI 0.92 to 7.48; p=0.07). Data about wound/superficial infection were provided for six trials.[96] This suggested fewer cases following TAPP repair (Comparison 06:06: RR 0.26, 95% CI 0.09 to 0.72; p=0.009). Relative risks were not estimable for mesh/deep infection, visceral and vascular injury and port site hernia, due to no events being recorded. The was no difference between the groups for the length of hospital stay (Comparison 06:11:[53,59,64,67,68] WMD –0.18, 95% CI -0.38 to 0.02; p=0.07). The time to return to usual activities was shorter in the TAPP groups (Comparison 06:12:[53,59,64,67,68] HR 0.51, 95% CI 0.32 to 0.81; p=0.005). There appeared to be fewer cases of persisting numbness in the TAPP groups (Comparison 06:13[59,64,68]: RR 0.23, 95% CI 0.06 to 0.94; p=0.04). However, there appeared to be no difference between the groups when comparing persisting pain and hernia recurrence (Comparison 06:14:[64,68] RR 0.8, 95% CI 0.45 to 1.45; p=0.5, Comparison 06:15: RR 2.02, 95% CI 0.52 to 7.83; p=0.3)

Bilateral hernias: TEP versus open mesh

The duration of operation was reported for bilateral hernias separately in five trials.[77,83,85,93,96] The overall WMD was 6.16, 95% CI 0.35 to 11.97 (p=0.04) favouring open mesh repair (Comparison 07:01). For opposite method initiated three trials reported results with no apparent difference between the groups (Comparison 07:02: estimable for one trial (3): RR 3.10, 95% CI 0.13 to 73.13; p=0.5). [83,93,96] Two trials provided data about conversions. [93,96] Overall, there were three (5.8%) conversion reported amongst 51 allocated TAPP repairs compared with zero in the open mesh group (Comparison 07:03: RR 2.48, 95% CI 0.35 to 17.44; p=0.4). The incidence of haematomas, seromas and wound/superficial infection were similar between the groups (Comparison 07:04[93]: RR 2.17, 95% CI 0.57 to 8.24; p=0.3, Comparison 07:05:[93] RR 0.58, 95% CI 0.12 to 2.91; p=0.5, Comparison 07:06:[93] RR 0.39, 95% CI 0.02 to 9.07; p=0.6). Relative risks were not estimable for mesh/deep infection, visceral and vascular injury and port site hernia, due to no events being recorded. Length of hospital stay was compared in one trial (Comparison 07:11: WMD –0.15, 95% CI -0.62 to 0.32; p=0.5).[96] The time to return to usual activities was shorter in the TEP groups, although this was not statistically significant (Comparison 07:12:[83,93] HR 0.79, 95% CI 0.49 to 2.22; p=0.4). There appeared to be no difference in the reported number of cases of persisting numbness, persisting pain and hernia recurrence (Comparison 07:13:[93] RR 1.05, 95% CI 0.49 to 2.22; p=0.9, Comparison 07:14:[93] RR 0.97, 95% CI 0.62 to 1.52; p=0.9, Comparison 07:15:[92,93] RR 4.44, 95% CI 0.52 to 38.01; p=0.17).

No separate data were available from the included trials to compare symptomatic and occult hernias although it is accepted that there may be an important implication of detecting occult bilateral hernias and therefore preventing further surgery.

Older versus younger patients

No separate data were provided in the included trials to compare older and younger patients.

Men versus women

No separate data were provided in the included trials to compare male and female patients.

Fitness for anaesthesia

No separate data were provided in the included trials to compare results in groups for different levels of fitness for anaesthesia. However, for those patients for whom general anaesthesia is not appropriate open repair would be preferable and for those patients who would choose not to undergo surgery under local anaesthesia, either approach could be used.

3.2.4 Learning effects

Limited data were available in the included trials describing the effects of learning of laparoscopic techniques on the relevant outcomes, although it is widely accepted that a learning effect exists for laparoscopic repair and particularly for the more complex TEP repair. It was concluded that this was an important consideration and therefore a separate search was carried out on MEDLINE, EMBASE and Science Citation Index databases to identify any papers reporting learning curves for TAPP and TEP. (See Appendix 1 (C) for full details.)

Searches identified an additional 175 reports, 37 of which were considered potentially relevant. Full text papers were obtained, where available, and formally assessed independently by two researchers to check whether they met the inclusion criteria, using a study eligibility form developed for this purpose (Appendix 9). Any disagreements that could not be resolved through discussion were referred to an arbiter. The following inclusion criteria were applied:

- Data reported for an individual operator rather than an institution
- Data reported for at least three points on the learning curve
- Consecutive procedures
- Data reported for at least one of the relevant learning outcomes

The relevant outcomes were: duration of operation; complications; length of stay; return to usual activities; hernia recurrence; persisting pain; and persisting numbness. Seven studies

were included, [20,121-126] although two provided the same data[123,126] and so results from the study with most detail are shown in the tables.[126]

Data were abstracted using a pre-designed and piloted data extraction form (Appendix 10). Two reviewers extracted data independently. Any differences that could not be resolved through discussion were referred to an arbiter. Appendix 11 provides details of the characteristics of the included studies. Two studies were prospective audits,[121,125] two were retrospective analyses,[122,127] one was a report of two RCTs,[126] and one was a systematic review.[124] Two studies[122,125] considered the TAPP repair, three studies considered the TEP repair[121,126,127] and one considered a combination of both.[126] The number of laparoscopic procedures performed prior to the study varied, however for the majority of surgeons TAPP and/or TEP were relatively new techniques. The characteristics of patients, where given, did not vary significantly between the studies. Studies ranged in size from 120 repairs for one surgeon to 1605 repairs for 29 surgeons.

Although data were collected for several outcomes, it was considered inappropriate (due to study heterogeneity and scarcity of data) to report on any outcome other than duration of operation. This data indicates that it takes between 30 and 100 procedures to become 'expert' in performing laparoscopic hernia repair, however in the majority of the studies the figure was more likely to be closer to 50 or more procedures. However this could be misleading since surgeons performing TEP may already be experienced in TAPP. Crude interpretation of these data provide estimates for duration of operation for inexperienced operators (up to 20 procedures) to be 70 minutes for TAPP and 95 minutes for TEP. For experienced operators (between 30 and 100 procedures) the estimated duration of operation are 40 minutes for TAPP and 55 minutes for TEP.

Results of operation time from the studies can be seen in Table 3.11.

Table 3.11 Operation time (mins) over the learning curve of TAPP and TEP

	Details	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5	Interval 6	Interval 7
Aeberhard 1999[121]	TEP 29 Operators Mean (SD)	**Series(cases): <16** Unilateral 105(38) Bilateral 147(55)	**Series (cases): 16-50** Unilateral 102(41) Bilateral 144(46)	**Series(cases): 51-100** Unilateral 85(28) Bilateral 128(36)	**Series(cases): >100** Unilateral 53(26) Bilateral 78(32)	None	None	None
Lau 2002[20]	TEP 1 Operator Mean	**Series(cases): 1-20** 92	**Series(cases): 21-40** 76	**Series(cases): 41-60** 74	**Series(cases): 61-80** 70	**Series(cases): 81-100** 58	**Series(cases): 101-120** 56	None
Leibl 2000[122]	TAPP 1 Operator Mean	**Series(cases): 1-5** Learner 72 Expert 55	**Series(cases): 16-20** Learner 62 Expert 62	**Series(cases): 31-35** Learner 58 Expert 50	**Series(cases): 46-50** Learner 50 Expert 45	**Series(cases): 61-65** Learner 54 Expert 40	**Series(cases): 76-80** Learner 50 Expert 50	**Series(cases): 91-95** Learner 52 Expert 52
Ramsay 2001[124]	TAPP and TEP 27 Operators Mean	**Series(case): 1** 70.5	**Series (case): 25** 56.6	**Series (case): 50** 54	**Series (case): 100** 51.5	**Series (case): 200** 49.1	None	None
Voitk 1998[125]	TAPP 1 Operator Mean	**Series(cases): 1-25** Unilateral 59 Bilateral 67	**Series(cases): 26-50** Unilateral 45 Bilateral 67	**Series(cases): 51-75** Unilateral 38 Bilateral 58	**Series(cases): 76-100** Unilateral 37 Bilateral 52	None	None	None
Wright 1998[126]	TEP 7 Operators Mean (range)	**Series(cases): 1-10** COALA 75 (32-155) MRC 75 (50-175)	**Series(cases): 11-20** COALA 68 (38-140) MRC 75 (45-120)	**Series(cases): 21-30** COALA 55 (25-120) MRC 60 (42-100)	None	None	None	None

SD = Standard deviation

3.3 Summary and conclusions of the evidence for and against the intervention

Since the last assessment of laparoscopic inguinal hernia repair for NICE, the results of the IPD meta-analyses conducted by the EU Hernia Trialists Collaboration have been published. IPD enabled the generation of necessary statistics not provided in the trial publications. This enhanced the information available for all outcomes and was particularly important for the analyses of persisting pain where usable data were only available in a small minority of published reports. The availability of IPD also helped to increase the data quality through detailed data checking, avoiding the need to estimate numerators and denominators (as was necessary for some published reports) and ensured randomisation integrity. The framework of this collaboration also meant that it is unlikely that important trials were missed, although two large trials with long-term follow-up are known to be currently unreported. However, IPD were not available for all trials considered by the Collaboration; for four, trialists checked aggregated data and supplied additional information when available; published data only were available for five trials (two of these trials were identified too late to approach the authors for individual patient data); and a further 13 trials have been identified for this update.

This update considered data for over 5000 randomised participants. These data indicate that after a laparoscopic repair return to usual activity is faster and persisting pain and numbness is less than with open repair. There appears to be fewer cases of wound/superficial infection and haematomas occur less frequently (TEP repair has lower incidence than the TAPP repair). However, operation times are longer and there appears to be a higher rate of serious complications in respect of visceral (especially bladder) injuries especially after TAPP. Seroma is more common, again mainly after TAPP repair. Mesh infection is very uncommon and not different between the groups. Our findings relating to hernia recurrence are consistent with those in the original Technology Assessment Report that there is no evidence of a difference in the rate of hernia recurrence when comparing laparoscopic methods (which use mesh) with open mesh methods of hernia repair. There appeared to be no differences in analyses stratified by whether the open mesh method used was flat mesh, preperitoneal or plug and mesh.

When considering the comparison of TAPP with TEP, only one small randomised trial[109] met the inclusion criteria. There appeared to be no differences between TAPP and TEP in terms of length of operation, haematomas, time to return to usual activities and hernia recurrence, but confidence intervals were all wide.

The data about complications from the additional non-RCT studies[112-120] of TAPP and TEP indicate that an increased number of port-site hernias and visceral injuries are associated with TAPP rather than TEP whilst there appear to be more conversions with TEP. These results appear to be broadly consistent regardless of the evidence source. Vascular injuries and deep/mesh infections were very rare and there was no obvious difference between the groups, the numbers being too small to draw any conclusions.

The results for many of the outcomes in this review displayed significant heterogeneity. However, there was generally consistency in direction of effect, even when size estimates varied. Much of the variation was explained by differences in the methods of open mesh repair (flat mesh, preperitoneal mesh or plug and mesh). Other likely sources of heterogeneity, however, are differences in the way the outcomes were defined or measured; in operator experience; in the types of people studied; and in length of follow-up.

Laparoscopic repair is, therefore, associated with short-term benefits in terms of more rapid recovery and long-term benefits in terms of less persisting pain and numbness. However, the findings relating to persisting pain should be interpreted cautiously. This is based largely on the work of the EU Hernia Trialists Collaboration. It adopted a broad definition and included any pain in the groin region (including testicular pain), regardless of severity or impact, reported around one year after the operation. As a consequence prevalence rates differed widely. There are currently few published data and most of those reported here came from IPD analysis. Laparoscopic repair is also associated with an estimated 4.6 serious adverse events per 1000 procedures and recurrence rates appear to be similar to open mesh repair.

A key issue for laparoscopic inguinal hernia repair is learning effects; studies show that it takes approximately 50 or more procedures to become experienced in the technique. There did not seem to be any differences between TAPP and TEP in this respect although this is clouded by the fact that some surgeons performing TEP were likely to be experienced in performing TAPP already.

3.3.1 Important sub-group differences

Only small amounts of data were available for all outcomes when comparing TAPP and TEP with open mesh for recurrent hernias and therefore true differences (if they exist) were unlikely to be detected. However, there was statistically significant evidence that the length of operation is longer in both TAPP and TEP when compared with open mesh repair and that the return to usual activities is shorter.

When comparing TAPP and TEP with open mesh for bilateral hernias, there was again a scarcity of data. When considering the TEP groups, the duration of operation is again longer than the open mesh groups ($p=0.04$). However, when considering the TAPP method of repair for bilateral hernias, the duration of operation appears to be similar to that of the open mesh groups ($p=0.9$). There is also statistically significant evidence to suggest that following a TAPP repair there are fewer cases of wound/superficial infection and persisting numbness and that time to return to usual activities is shorter.

3.3.2 Clinical effect size

A summary of the clinical effect size for all outcomes where data were available are given in Table 3.12.

Table 3.12 A summary of the clinical effect size

Outcome	TAPP vs open mesh	TEP vs open Mesh	TAPP vs TEP
Duration of Operation (WMD)	13.33 (12.08, 14.57)	7.89 (6.22, 9.57)	-6.30 (-12.82, 0.22)
Opposite method initiated (RR)	6.46 (1.74, 24.02)	2.87 (1.37, 6.04)	ND
Conversion (RR)	5.91 (1.91, 18.27)	10.77 (3.91,29.68)	Not estimable
Haematoma (RR)	0.76 (0.62, 0.94)	0.44 (0.33, 0.58)	2.59 (0.11, 60.69)
Seroma (RR)	1.97 (1.27, 3.07)	0.73 (0.46, 1.14)	ND
Wound/superficial infection (RR)	0.41 (0.26, 0.94)	0.62 (0.33, 1.16)	ND
Mesh/deep infection (RR)	0.39 (0.02, 9.44)	0.34 (0.01, 8.26)	ND
Vascular injury (RR)	2.83 (0.12, 68.58)	1.05 (0.27, 4.12)	ND
Visceral injury (RR)	4.26 (0.73, 25.02)	0.62 (0.08, 4.62)	ND
Port site hernia (RR)	4.03 (0.45, 35.70)	Not estimable	ND
Length of hospital stay (WMD)	0.15 (0.09, 0.21)	-0.12 (-0.18, -0.06)	-0.70 (-1.33, -0.07)
Return to usual activities (HR)	0.66 (0.58, 0.75)	0.49 (0.42, 0.56)	ND
Persisting numbness (RR)	0.26 (0.17, 0.40)	0.67 (0.53, 0.86)	ND
Persisting pain (RR)	0.72 (0.58, 0.88)	0.77 (0.64, 0.92)	ND
Hernia recurrence (RR)	1.18 (0.69, 2.02)	1.61 (0.87, 2.98)	2.59 (0.11, 60.69)

Values in parentheses are 95% confidence interval

ND = No data; WMD =-Weight Mean Difference; RR = Relative Risk; HR = Hazard Ratio

4 Systematic review of economic evidence

This section is an update of the HTA report considered by NICE in 2001.[21] The aim of this part of the review was to identify, summarise, and quality assess economic evaluations reported since the searches for the original HTA report were conducted. In order to set these studies in context the findings of the original report have also been briefly summarized.

4.1 Methods for the review of economic evidence

4.1.1 Search strategy

The literature searching for this review updated what had been undertaken for the original HTA report. Consequently, MEDLINE and EMBASE were searched only from 2000 onwards. Additional databases were also searched to identify relevant economic evaluations. Furthermore, all reports related to the RCTs included in the review of effectiveness and the submissions from Industry were also considered for inclusion. Listed below are the databases searched:

MEDLINE (2000 - Week 2 July 2003)
MEDLINE Extra (July 17th 2003)
EMBASE (2000 - Week 28 2003)
NHS EED Database (July 2003)
HMIC - Health Management Information Consortium (July 2003)
Journals @ Ovid Full Text (July 17th 2003)

Full details of the search strategies used are documented in Appendix 1.

4.1.2 Inclusion and exclusion criteria

To be included, studies had to involve the comparison of alternative methods of hernia repair in terms of their costs and effectiveness. Studies were not excluded on the basis of language. It should be noted that in the original HTA report studies published prior to 1990 were not included.

The abstracts of all reports identified by the supplementary searching for economic evaluations were assessed by an economist. All additional RCTs included in the update

of the systematic review of effectiveness were also assessed for inclusion. The full published papers were obtained for those studies that appeared potentially relevant and were formally assessed for relevance.

4.1.3 Data extraction

The following data were extracted for each included study:

1. The study characteristics

The research question

The study design

The comparison

The setting

The basis of costing

2. Characteristics of the study population

Numbers receiving or randomised to each intervention

Other systematic differences in clinical management (e.g. type of anaesthesia used, use of day case or inpatient care)

Inclusion/exclusion criteria

Dates to which data on effectiveness and costs related

3. Duration of follow-up for both effectiveness and costs

4. Results

Summary of effectiveness and costs (point estimate and if reported range or standard deviation (sd))

Summary of cost-effectiveness/utility (point estimate and if reported range or standard deviation (sd))

Sensitivity analysis[iii]

5. Conclusions as reported by the authors of the study

4.1.4 Quality assessment

Included studies were assessed against the 35-point BMJ checklist for referees of economic analyses.[128] Where possible, costs and cost-effectiveness were assessed from the perspective of the NHS and personal social services.

[iii] Including changes to single variable (univariant), two or more variables (multivariate), and stochastic (e.g. bootstrapping). In the first two cases this also includes when one or more variables are altered in order to identify when costs or benefits are equivalent (threshold analysis).

4.1.5 Data synthesis

No attempt was made to synthesise quantitatively the studies that were identified. Data from the included studies were summarised in order to identify common results and variations between studies. These data were then interpreted alongside the results of the systematic review of effectiveness to aid assessment of the relative efficiency of laparoscopic compared with open inguinal hernia repair.

The data reported in the studies conducted alongside RCTs were extracted and used to assess two outcomes: recurrences and time taken to return to usual activities/work. Recurrence was chosen because it has been reported that it is the single most important outcome to patients.[129] Time taken to usual activities has been chosen as a proxy for short-term benefits that may be provided by laparoscopic repair in comparison to open repair. Several studies considered the effect of earlier return to work on productivity costs. The inclusion and measurement of productivity costs (indirect costs) in economic evaluations is a contentious issue.[130] However, the implied value of earlier return to work or to usual activities was considered by determining what direct costs are incurred in order to provide an additional day at work or of usual activity. This recognised that a judgement still has to be made about whether the benefits from an additional day at work or usual activity and in any other outcomes are worth this sum.

4.2 Systematic review of published economic evaluation - Results

4.2.1 Quality and quantity of data available

Two hundred and eighty six potentially relevant reports were selected for full text assessment: 31 related to the RCTs included in the review of effectiveness and 255 reports of other studies were identified from the searches. From these, a total of seven new studies met the inclusion criteria (Appendix 12). In addition, seven studies had been identified as part of the previous Health Technology Assessment and are summarised later in this Chapter. One of the seven newly identified included studies (Ethicon Endo-Surgery Industry Submission, 2003) was based on a reanalysis of the MRC Laparoscopic Groin Hernia Trial economic evaluation which is also summarised later.[131] Three were based on models (two of which were based on systematic reviews) and four primary studies (one based on a RCT, three on non-randomised comparisons). Two of the modelling exercises used the same body of RCT evidence to estimate effects. In neither study was it immediately obvious how the parameter estimates were derived.

In one it was based on the application of relative effect differences to baseline effect data for one of the comparators (Vale and colleagues, University of Aberdeen, 2003). In the other it was unclear although it was likely to be similar to Vale and colleagues.[132] Costs in one study were based on Medicare charges[132] while the other used data from bottom-up costing exercises from three economic evaluations conducted alongside RCTs (two from the UK and one from the Netherlands). One study was a cost-utility analysis with utility estimates based on Quality of Wellbeing Index[132] and the other presented the results in terms of a cost-consequence analysis (balance sheet) and incremental costs per recurrence avoided and per additional day at usual activities. Both studies discounted where appropriate and both reported sensitivity analysis although only one attempted to formally incorporate parameter uncertainty (Vale and colleagues, University of Aberdeen, 2003). In this latter case the choice of distribution form was not clearly explained.

Bard as part of their submission conducted a further model (BARD Industry Submission, 2003). The model compared Bard's 'Perfix Plug' for open mesh repair with laparoscopic repair. The Recurrence rate for a 'Perfix Plug' is based on a crude aggregation of available data rather than consideration of the relative risk when compared with laparoscopic repair. It was assumed that the cost of the laparoscopic repair would be the same as the Perfix Plug apart from the cost of the materials required. This assumption is likely to be conservative as the national reference costs used are probably more appropriate to open mesh procedures. Therefore, they would tend to underestimate the cost of laparoscopic repair. Oneway sensitivity analysis was conducted to investigate the effects of differences in recurrence rates and the proportion of patients managed as inpatients.

One of the primary studies was a reanalysis of the published results of the MRC Laparoscopic Groin Hernia Trial[131] by Ethicon Endo-Surgery as part of their industry submission. The data used came from the MRC Laparoscopic Groin Hernia Trial which was, in general, well conducted and reported economic evaluation which took the perspective of the UK NHS. The main limitations of the trial data were the shortness of follow-up (three months) and the limited handling of the statistical uncertainty surrounding the results. The industry submission expanded on the results of this evaluation to explore how the cost-effectiveness of laparoscopic repair would change if

allowance was made for the management of occult bilateral hernias. No sensitivity analysis was reported and the validity of the estimate of 30% for the rate of occult bilateral hernias which laparoscopic repair could identify and treat was unclear.

Apart from the study by Papachristou[133] the costing component was poor. None of the other three primary studies were conducted in the UK. Follow-up was short (maximum of 17 months) and all relied on observational data with little or no attempts made to control for potential biases. In no study were the major outcomes of effectiveness aggregated into a single measure of effectiveness or utility. In each of the studies some or all of the following outcome measures were available: pain and analgesic use; return to work/usual activities; recurrences and complications. None of the studies reported any sensitivity analysis.

4.2.2 Comparison of Laparoscopic and open mesh repair

Modelling exercises

Comparators

Table 4.1 details the comparators considered in the three included studies.

Table 4.1 List of comparators used

Vale (unpublished)	Stylopoulos 2003[132]	Bard Industry Submission
TAPP	Laparoscopic	Laparoscopic
TEP	Open Mesh	Perfix Patch
Open flat mesh	Open non mesh	
Open non-mesh	Expectant management	

Summary of results

Two studies reported that over the time horizons considered (5 years and lifetime) open non-mesh was the most costly and least effective of the open procedures.[132](Vale and colleagues, University of Aberdeen, 2003) Vale and colleagues reported that over five years, open flat mesh was less costly (vs TEP Mean saving £101; 95% CI £63 to £177[iv]; vs

[iv] CI's are the 2.5 and 97.5 percentile points from the range of values produced by the Monte Carlo simulation

TAPP Mean saving £161; 95% CI £138 to £203); a similar rate of recurrence (TEP: two fewer recurrences per 1000 patients over five years (95% CI – 49.5 to 109.0), TAPP: one additional recurrences per 1000 patients over five years (95% CI -30.8 to 56.4)). However, laparoscopic repair was associated with more time spent at usual activities (TEP: 4.3 (95% CI 0.4 to 8.2) more days; TAPP: 3.2 (95% CI 1.8 to 4.5) more days) and fewer people with long-term pain (TEP: 67 (95% CI 41 to 107) fewer people per 1000; TAPP: 32 (95% CI 12 to 57) fewer people per 1000). The incremental cost per additional day at usual activities was also estimated with a probability of over 90% that the incremental cost per additional day at usual activities was less than £63 for TEP vs open flat mesh (data for TAPP not presented).

Stylopoulos and colleagues reported that laparoscopic repair was the dominant option.[132] The mean cost (in 2002 dollars) for laparoscopic was $4,086, and $4290 for open mesh. The lower cost of laparoscopic repair is explained by the inclusion of a patient opportunity cost of between $26 and $113 per day. Laparoscopic repair was also associated with more QALYs than open mesh (9.04 vs 8.975).

The default analysis provided by Bard concluded that the Perfix plug would be less costly and more effective than laparoscopic repair (BARD Industry Submission, 2003). In the analysis it was assumed that almost all patients receiving the Perfix plug approach could be managed as day cases whereas for laparoscopic repair only two thirds would be managed as day cases. The hypothesised cost-saving disappear should the proportions of patients managed as day cases be equal for both laparoscopic and open repair. The data from the RCTs and also the submission from the Association of Endoscopic Surgeons of Great Britain and Ireland suggest that the proportions could be equal. The lower recurrence rates reported for Perfix Plug approach is of questionable validity and potentially biased (rates of recurrence depend on the method of follow-up, the method of diagnosis and the length of follow-up and these differed between the studies on which the estimates were based).

Patient level analysis

One of the four patient level analyses focused on occult bilateral repairs and this study is considered separately below (Ethicon Endo-Surgery Industry Submission, 2003). The

remaining three studies compared laparoscopic with open repair and are summarised and critiqued next.

Comparisons made

TAPP and TEP were compared to the open mesh procedure in one of the studies.[133] TAPP was compared to open mesh in the second study.[134] The third study[135] did not report separately TAPP and TEP and it was unclear what type of open procedure was performed.

Results

As already indicated, none of the studies were conducted in the UK and it is unclear how applicable the data are to the UK. Furthermore, their observational nature makes their effectiveness results prone to bias and hence unreliable. For these reasons, only a brief description of the most salient results is presented here.

All of the studies reported that direct costs were, on average, higher for patients who received laparoscopic compared with open repair. The extra cost of laparoscopic ranged from 18% to 140% more. The data on effectiveness were more mixed. In terms of time before usual activities/work were resumed the data were broadly consistent with the results reported in the review of effectiveness (Section 3.2). None of the studies attempted to incorporate productivity gains (indirect costs) into their analysis but they suggested that these would compensate for the increased hospital costs. The data on recurrences and complications tended to favour open repair, in all but one of the studies.[135] However, the reliability of the effectiveness data is questionable due to the non-randomised nature of the studies.

Summary of findings from the original HTA report

In the earlier HTA review seven studies performed alongside RCTs comparing laparoscopic to open mesh techniques were identified.[53,58,59,64,68,83,131] At least four of these were of reasonable quality.[53,64,68,131]

In all but one of these studies[68] the direct costs of laparoscopic repair were greater than those for open repair. In those based on UK RCTs the additional cost per operation was 41%[131] and 122%[64] greater, although the absolute cost differences were very similar

(around £300). In the studies conducted alongside non-UK trials the additional cost varied between –2%(but probably equal to open mesh) and 65%. The study by Beets and colleagues was unusual in that only patients with recurrent hernias were included.[68]

The higher costs of laparoscopic repair principally reflected two factors. The first is the extra cost of the equipment. This is influenced by whether disposable or reusable equipment is used. If a policy of only using reusable equipment is followed, the extra cost per laparoscopic operation was reduced to about £100-£150. The second factor is extra theatre costs due to the longer operation time for laparoscopic repair (typically about an extra 15 minutes per procedure).

In terms of incremental cost per recurrence avoided open mesh repair was judged dominant as it was less costly and equally or more effective (except for Beets and colleagues where open mesh was as costly but more effective). It should be noted that while the cost differences may exist the systematic review of effectiveness found no evidence of a difference in recurrence rates.

Some of the studies reviewed included productivity costs and where this was done it tended to significantly reduce or eliminate the cost differential between laparoscopic and open repair.

Repair of bilateral hernias

Although none of the identified economic evaluations considered the use of laparoscopic techniques to repair bilateral hernias it can be argued that an advantage of laparoscopic techniques is that bilateral hernias can be repaired within a single incision whereas two separate open incisions would be required for an open bilateral hernia repair. Thus, laparoscopic repair could in principle, prevent significant morbidity and cost. Tentative extrapolation of this within the MRC Laparoscopic Groin Hernia Trial suggested that TAPP repair might be more efficient than open repair in these circumstances.[131]

The role of laparoscopic techniques to repair occult hernia

The only economic evaluation that explicitly addressed the issue of repair of occult hernia was the submission by Ethicon Endo-surgery. This submission presented a revised version of the economic evaluation performed alongside an RCT.[131] The

submission also presents a budget impact assessment considering the implications for the NHS of expanding the use of laparoscopic repair.

Summary of results and critique

The MRC Laparoscopic Groin Hernia Trial reported an Incremental cost per QALY of £55,549 for a time horizon of three months.[131] However, by assuming that 30% of all individuals would develop a contralateral hernia that would require further surgery which could be detected at the time of the initial operation it was estimated that the adoption of laparoscopic repair would reduce costs and improve the cost-effectiveness of laparscopic repair to £15,000 per QALY even without taking into account any health gains associated with avoiding an additional open operation.

This analysis does not make any allowance for occult hernias that would not go on to develop into a clinically significant hernia. A RCT reported that 29% (six out of 21 patients), only three of whom developed clinically overt hernias and were referred back by the GP, of those found to have incidental defects on the contralateral side progress to clinically apparent hernias in 12 months. None of those randomised to have their incidental defects repaired at the time of the initial operation subsequently developed a hernia (n = 16).[19] Therefore, although the evidence is limited it appears between ten percent and 25% of all patients have incidental finding on the contralateral side but within a twelve month period only a proportion will go on to develop a clinically demonstrable hernia.

4.2.3 Comparison of TAPP with TEP

Only one evaluation explicitly considered the relative cost-effectiveness of TAPP and TEP although the data were derived using indirect comparisons.(Vale and colleagues, University of Aberdeen, 2003) There was a trend favouring TEP in terms of time to return to usual activities, pain and cost but none of these were definite. Probabilistic sensitivity analysis suggests that in terms of cost per recurrence avoided there is nearly 40% chance that TEP was dominant or is associated with an incremental cost per recurrence avoided of less than €1000. In contrast, the probability that TAPP is dominant or is associated with a cost per recurrence avoided of under €1000 is less than 0.1%.

TEP repair appeared less costly because the evidence available for this study suggests that TEP repair takes less time but this indirect comparison might be biased despite patients groups appearing to be comparable (9-11). This is not certain and it is possible that the surgeons involved in the trials comparing TEP with open mesh were more experienced, and therefore quicker, than those involved in the trials of TAPP with open mesh. For surgeons with the same experience the operation time and hence cost of TAPP and TEP may be similar.

4.3 Summary and implications of studies reporting costs and outcomes

Estimates of laparoscopic costs were greater than those for open mesh in four of the five studies following the trend of the previous review.[21] In terms of cost per recurrence avoided almost all studies indicated that open mesh was the dominant option. However, it is possible that other health effects may make laparoscopic repair cost-effective.

Results from the previous review reported a cost per additional day at work between £86 and £130 based on UK studies[21]; unpublished data from Vale and colleagues were similar. Where productivity costs were included they eliminated the cost differential between laparoscopic and open mesh (regardless of whether productivity costs were assessed using a human capital or friction cost approach).

Overall, many of the studies considered were only partial analyses with incomplete descriptions of costs and effects. Several, including the two industry submissions, presented very simple analyses. Due to the simplicity of the analyses and the choice of data used the results are of limited validity. In all but two of the studies[132](Vale and colleagues, University of Aberdeen, 2003) the time horizon over which costs and benefits were considered was short. Even in these two studies costs and/or outcomes used are of limited use to priority setting within the UK NHS. Furthermore, their handling of uncertainty was also limited.

5 Economic Analysis

5.1 Introduction

As described in Chapter 4, existing attempts to investigate the relative efficiency of laparoscopic compared to open mesh methods of inguinal hernia repair are of limited value to decision-makers within the UK. Firstly, the identified studies are, in all but two cases, based on the results of a single study and their results may be imprecise and of limited transferability. Secondly, in all but two studies the time horizon considered was relatively short and the long-term implications for measures of clinical effectiveness and cost would not have been measured. Thirdly, only one study (with only a three month time horizon) reported QALYs based on a preference-based measure and using UK population valuations. A final limitation is that none of the available economic evaluations compare all the relevant alternatives. As a result of these limitations it was necessary to develop an economic model to compare the cost-effectiveness of the different surgical interventions.

5.2 Methods

A Markov model was used to assess the cost-effectiveness of the various laparoscopic and open mesh procedures for the surgical repair of inguinal hernias. The model was designed to estimate costs, from the perspective of the UK NHS, and outcomes, principally in terms of QALYs, for up to 25 years for the different management strategies (Figure 5.1). The model attempts to incorporate uncertainty in probabilities, costs and utilities by incorporating the input parameters of the model as probability distributions. These distributions were used in a Monte-Carlo simulation so that the uncertainty in the results of the model could be presented. The model was developed in Microscoft Excel using Crystal Ball to conduct the Monte Carlo simulation. Data from the model is presented for two time horizons: five years; and 25 years. The first time horizon was chosen as the reliable data from the RCTs and case series relate to no more than this time horizon. The second time horizon investigates the impact of extrapolating the available data over a longer period. All costs are presented in 2001/02 UK pounds and costs and benefits are discounted at 6% and 1.5% respectively.

5.2.1 Description of the model

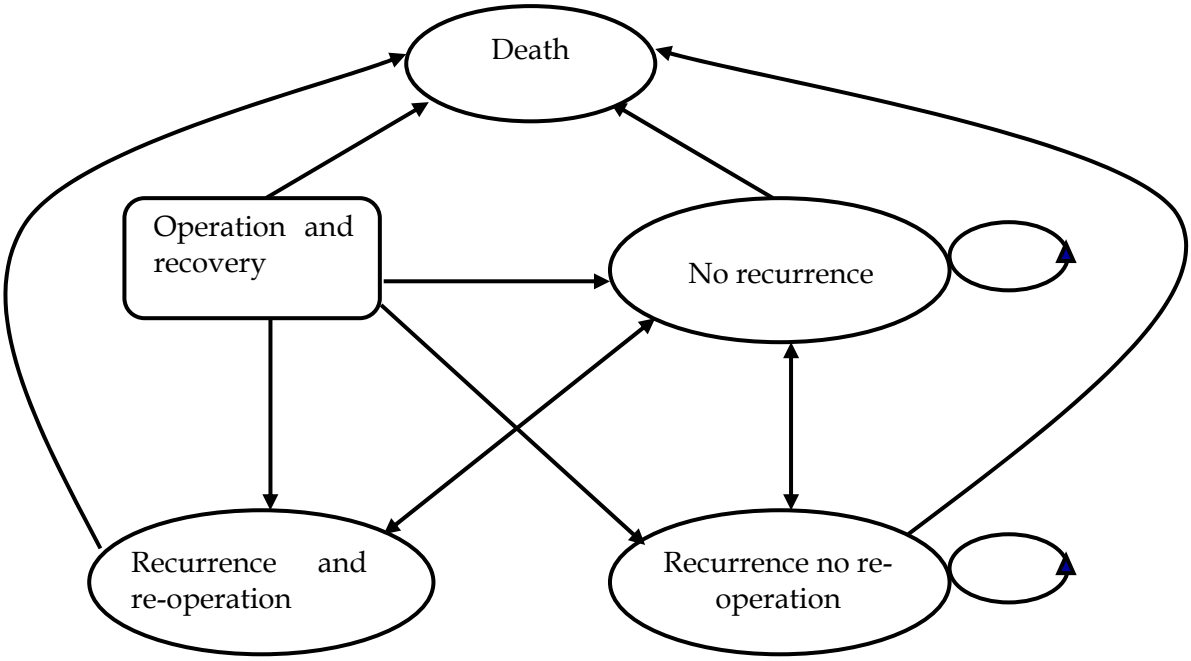
The model was composed of a series of defined health states between which a patient could move over specified periods. On entry into the model all patients had an inguinal hernia that was surgically treated with either a laparoscopic or an open mesh procedure. Providing the patient survived the operative procedure, they would then enter a period of convalescence followed by return to full health. Patients could at this stage move into one of the following states:

- No recurrence but potentially with persisting long-term pain or numbness;
- Recurrent hernia and proceeding straight to a re-operation;
- Recurrent hernia and choosing not to seek a re-operation. Whilst in this state patients face the risk of undergoing an emergency operation for complications associated with the recurrent hernia;
- Death (included as all cause mortality and also the operative mortality following both elective and emergency procedures).

Figure 5.1 provides a simplified summary of the model. Operative complications are assumed to be reflected in terms of longer operating times and length of stay. The rationale behind this assumption is that the weighted mean differences in operation length and length of stay which are reported in Chapter 3, were derived using data from those who suffered complications as well as those who did not.

The time spent in any of the states before a transition could be made to another state was one year (i.e. the cycle length was one year). In the years following the initial surgery a patient would either remain without a recurrence (no recurrence) or eventually move to a state of recurrence. Should they suffer a recurrence then they either received a re-operation or remained with an inguinal hernia. Thus, transitions between states are governed by four parameters: annual risk of recurrence; proportion of patients who experience a recurrence but do not get a re-operation; risk of emergency surgery for those with an untreated recurrent hernia; and mortality.

Figure 5.1 Markov model for the comparison of alternative methods of hernia repair



The model described in Figure 5.1 was used to compare five alternative surgical treatments for inguinal hernia:

1. Initial surgery: TAPP, surgery for recurrence: TAPP
2. Initial surgery: TEP, surgery for recurrence: TEP
3. Initial surgery: open flat mesh, surgery for recurrence: open flat mesh
4. Initial surgery: open plug and mesh, surgery for recurrence: open plug and mesh
5. Initial surgery: open preperitoneal mesh, surgery for recurrence: open preperitoneal mesh

The assumption that recurrent hernias would be repaired using the same procedure is uncertain. Therefore, as part of the sensitivity analysis a second set of interventions were considered which assumed that the recurrent hernias would be repaired using the open flat mesh procedure. The model did not allow anyone to receive more than a total of three surgical treatments (the initial surgery and two subsequent treatments). Provided the patient survived the third treatment it was assumed that a further recurrence would not occur.

The parameters required for the model included: the recurrence rates following the different procedures; probabilities of re-operation; probabilities of specific events used to estimate the cost of the health states; rates of long-term pain, numbness, time away from usual activities (used for the presentation of additional days at usual activities); and health status utilities.

5.2.2 Estimation of model parameters

Baseline parameters

The outputs of the systematic reviews derived in Chapter 3 were primarily presented in terms of relative effect sizes (relative risks and weighted mean differences). In order to incorporate these data within the model they needed to be combined with estimates of baseline rates for one of the interventions. Furthermore, while it might be argued that such relative effect sizes are transferable between settings it is important to ensure that that they are applied to baseline rates that are applicable to the UK, so that the resultant absolute differences between interventions are also more likely to be applicable. One of the problems faced in this study was that baseline rates were not always available for the same intervention. Therefore, the best available data has been used. Computationally this does not cause problems as the appropriate relative effect sizes can still be used to estimate the required absolute rates for the other interventions under consideration. As outlined below, open flat mesh repair has been used for all baseline effect sizes except for recurrence where superior data were available for TAPP. A further problem is that only very limited data are available for recurrent hernias. Therefore, except where otherwise stated, the values used for recurrent hernias are the same as those used for primary hernias.

Where possible, data on clinical outcomes (recurrences, operative mortality, long-term persisting pain and numbness) were sought from large case series and from recent pragmatic randomised controlled trials conducted within the UK. Both the Swedish and Danish Hernia Registries were contacted. Additional data were obtained from the Swedish Registry. Further data were also obtained from the MRC Laparoscopic Groin Hernia Trial Group.

Baseline event rates for the risk of recurrence came from the Swedish Registry with cumulative rates for both TAPP and TEP for up to 10 years (Personal communication:

Erik Nilsson, Swedish Registry). For the purposes of this study the data for TAPP (n = 2805) were chosen as the baseline event rates. From the available data annual rates were estimated for a five year follow-up as few patients had been followed up for a longer period. Data are therefore likely to be unreliable. On the basis of the available data it was assumed that the recurrence rates for the baseline comparator were constant after five years.

Data on operative mortality were also sought from the Swedish Registry. Rates of 0.2% (55 out of 27386 patients) and 0.1% (2 out of 2805 patients) for open and laparascopic procedures were reported respectively. Unfortunately these data aggregated mortality rates for relatively low risk elective and high risk emergency procedures. Emergency procedures were more likely to be performed as an open procedure i.e. 6% (N=74,741) of all open procedures performed as emergencies versus only 0.8% (N = 7849) laparoscopic procedures. Therefore, data reported in a UK surgical training website which reported mortality rates for both elective and emergency surgery separately were used in preference (www.surgical-tutor.org.uk/syste/abdomen/hernia.htm). It was assumed in the baseline analysis that the mortality rates for both laparoscopic and open procedures were the same.

Data on the risk of long-term pain and numbness applicable to the UK were obtained from a recent pragmatic multicentre RCT, the MRC Laparoscopic Groin Hernia Trial. Unpublished data from this trial are available for both persisting long-term pain and numbness. Both the outcomes were measured on a five point scale. For this analysis the proportion of patients with the two most severe categories of persisting long-term pain and numbness were obtained for the open mesh arm of the trial. (Personal communication: Neil Scott, University of Aberdeen) These data were collected at 12, 24, 36 and 60 months and are based on between 362 (12 months) and 269 (60 months) trial participants for persisting pain and 362 (12 months) and 271 (60 months) for numbness.

Baseline estimates of operation length, length of hospital stay for day case procedures and time before return to usual activities were based on the aggregation of data from the open flat mesh arms of the trials included in the systematic review reported in Chapter 3. The length of stay for inpatients was based on data reported in Hospital Episode Statistics for inguinal hernia repair procedures of primary (T20) and recurrent (T21)

hernias (http://www.doh.gov.uk/hes/free_data/index.html). These data do not make a distinction between open and laparoscopic procedures. Nonetheless, as reported in Chapter 2 the proportion of laparoscopic procedures performed in the UK is low and it has been assumed that these data are applicable to the open flat mesh procedure.

The baseline point estimates used in the model are detailed in Table 5.1. Also included in this table are notes summarising the method used to characterise the uncertainty in these estimates. Where beta distributions have been used to characterise uncertainty around the occurrence of an event the α parameter is the number of patients who experienced the event of interest and the β parameter is the total number of patients.

Table 5.1 Baseline parameter values used in the model

Parameter	Value	Baseline Intervention	Distribution	Values used to define the distribution
Operation length (primary)	54 mins	Open flat mesh	Normal	sd 16.4
Operation length (subsequent)	56 mins	Open flat mesh	Normal	sd 16.4
Length of stay (inpatient) (primary)	2.3 days	Open flat mesh	Lognormal	Median 2 days
Length of stay (day case) (primary & subsequent)	4.2 hours	Open flat mesh	Lognormal	sd 6.4
Length of stay (inpatient) (subsequent)	2.6 days	Open flat mesh	Lognormal	Median 2 days
Operative mortality (elective)	0.1%	All		
Operative mortality (emergency)	10%	All		
Return to usual activities (primary & subsequent)	11 days	Open flat mesh	Normal	sd 0.45
Annual risk of recurrence (primary & subsequent)	1.6% to 0.3%	TAPP		
Annual risk of pain (primary & subsequent)	2.2% to 1.5%	Open flat mesh	Beta	α 8 to 4; β 362 to 269
Annual risk of numbness (primary & subsequent)	5.5% to 2.2%	Open flat mesh	Beta	α 20 to 6; β 362 to 269

Relative effect sizes

Chapter 3 reports the relative effects from a series of meta-analyses comparing TAPP with open mesh, TEP with Open Mesh and TAPP versus TEP. For some of the comparisons only very limited data were available. Furthermore, relative effect sizes were not available for all relevant comparisons. Therefore, choices were made about which relative effect sizes were to be used in the model. These choices were based on the quantity of data available.

In order to reflect differences in the costs and outcomes between primary and subsequent procedures, data on relative effect sizes were sought for both the primary and subsequent procedures. Unfortunately, as detailed in Chapter 3, only very limited data were available on secondary procedures and such data are likely to be unreliable. Therefore, except where otherwise detailed the same relative effect sizes estimated for the primary procedure have been used for both primary and subsequent procedures. It has also been assumed that the relative risks of recurrence, long-term pain and numbness do not change over time. The relative effect size for time to return to usual activities was reported in terms of a hazard ratio. Such data are not readily interpretable in terms of differences in days at usual activities without information on the hazard rate for return to usual activities. Unfortunately such data were not available. As a compromise information was requested from the EU Trialists Collaboration on the mean (and sd) of the number of days before return to usual activities for each of the interventions based on a crude aggregation of data from the different arms of the trials included in the reviews conducted by this collaboration.(Personal communication: Neil Scott on behalf of the EU Trialists Collaboration) These data were consistent with the direction of effect indicated by hazard ratios although may not accurately reflect the true difference between interventions.

Table 5.2 details the point estimate of the relative effect sizes used in the model. Also included in the table are the 95% confidence intervals surrounding the point estimates and estimates for the time to return to usual activities for each intervention. This uncertainty was characterised by log normal distributions for relative risks and time to return to usual activities. Normal distributions were used for weighted mean differences.

Table 5.2 Relative effect sizes used in the model

Parameter	Point estimate	Limits of 95%confidence interval		Distribution
		Low	High	
Relative risk for long-term pain (primary and subsequent)				
TAPP vs OFM	0.68	0.52	0.89	Lognormal
TEP vs OFM	0.10	0.01	0.66	Lognormal
TAPP vs OPM	2.00	0.19	21.62	Lognormal
TAPP vs OPPM	0.46	0.16	1.32	Lognormal
Relative risk for numbness (primary and subsequent)				
TAPP vs OFM	0.10	0.03	0.32	Lognormal
TEP vs OFM	0.17	0.33	1.16	Lognormal
TAPP vs OPM	1.00	0.06	15.71	Lognormal
TAPP vs OPPM	0.07	0.00	1.31	Lognormal
Relative risk for recurrences (primary)				
TAPP vs OFM	1.68	0.73	3.88	Lognormal
TEP vs OFM	1.61	0.57	4.6	Lognormal
TEP vs OPM	0.58	0.2	1.73	Lognormal
TAPP vs OPPM	0.90	0.44	1.85	Lognormal
Relative risk for recurrences (subsequent)				
TAPP vs OFM	0.41	0.02	9.61	Lognormal
TEP vs mixed mesh	1.22	0.63	2.35	Lognormal
TEP vs OPM	0.31	0.02	5.95	Lognormal
TAPP vs OPPM	0.13	0.01	2.25	Lognormal
Weighted mean difference for operation time (primary) (minutes)				
TAPP vs OFM	10.9	9.4	12.5	Normal
TEP vs OFM	4.3	1.3	7.3	Normal
TAPP vs OPM	25.0	21.0	29.0	Normal
TAPP vs OPPM	15.6	12.9	18.6	Normal
Weighted mean difference for operation time (subsequent) (minutes)				
TAPP vs OFM	0.40	-8.5	9.3	Normal
TEP vs OFM	-26.0	-36.6	-15.4	Normal
TAPP vs OPM	25.0	21.0	29.0	Normal
TAPP vs OPPM	20.4	13.0	27.8	Normal
Weighted mean difference for length of stay (inpatients) (primary)(days)				
TAPP vs OFM	0.10	0.04	0.17	Normal
TEP vs OFM	-0.04	-0.11	0.02	Normal
TAPP vs OPM	1.00	0.51	1.49	Normal
TAPP vs OPPM	0.27	0.14	0.39	Normal
Weighted mean difference for length of stay (inpatients) (secondary)(days)				
TAPP vs OFM	0.07	-0.13	0.27	Normal
TEP vs OFM	0.24	-0.45	0.93	Normal
TAPP vs OPM	1.00	0.51	1.49	Normal
TAPP vs OPPM	-0.05	-0.3	0.19	Normal

OFM = Open flat mesh; OPM = Open plug and mesh; OPPM = Open preperitoneal mesh

Absolute parameter values for each intervention were derived by applying the relative rates obtained from the meta-analyses to estimates of the absolute rate for a baseline comparator. On testing the model it was found that for, open plug and mesh and open

preperitoneal mesh, estimates of length of stay were implausible for some simulations. Therefore, a decision was made to impose a lower bound on length of stay of 0.4 days as a plausible extreme minimum value. The choice of 0.4 days as a minimum value was informed by consideration of the total period of hospital stay that might be experienced by a day case patient.

Resource use and costs

The main cost components of the model were the costs of the operative period (i.e. initial operation and hospitalisation) and the costs of any subsequent re-operation. It was assumed that if a recurrence occurred then it would be repaired using an open flat mesh technique. This assumption was made as there was no evidence to suggest which method of repair would be used in routine practice to repair recurrent hernias. The impact of relaxing this assumption and assuming recurrent hernias were all repaired with the open flat mesh procedure was assessed as part of the sensitivity analysis. Costs of operative and post-operative complications were not explicitly modelled in the base case analysis, as their effect would principally be captured through longer operating times and hospitalisation. Nonetheless, the extreme assumption that all serious complications resulted in immediate death was assessed as part of the sensitivity analysis. The costs of management in the community were also excluded as a recent systematic review of economic evaluations and cost analyses has shown that these are typically a small proportion of total costs in this context.[21]

Data on costs and resources used were obtained from the costing exercises conducted as part of recently conducted pragmatic RCTs conducted in the UK.[64,131] Information on resource use and cost was requested from the investigators involved in these RCTs. Very similar costing methodology was used in the two studies but, as would be expected, the actual resources used to provide the different interventions did vary. From these studies estimates of resource use were derived under three headings:

- Cost per minute for operation staff and theatre time;
- Cost per day in hospital;
- Reusable and disposable equipment/consumables costs.

The cost of either a primary or subsequent procedure was estimated by:

1. Multiplying the cost per minute of operation staff and theatre time by the estimated operation length. The estimated operation length was in turn based on the baseline operation length and weighted mean differences between procedures.
2. Multiplying the cost per day by the estimated length of stay. The estimated length of stay was calculated in the same way as described above.

To the summation of (1) and (2) the cost of reusable and disposable equipment/consumables was added to provide an estimate of the cost of the surgical procedure. For the baseline analysis, data from the MRC Laparoscopic Groin Hernia Trial Group were used, although the use of alternative cost estimates was explored in the sensitivity analysis. Capital costs were obtained by annuitising unit costs over the lifetime of the capital at a 6% discount rate and dividing this figure by expected annual throughput. Appendix 13 provides details of the resource use and unit costs that form the basis of the procedure costs. The cost parameters used for each intervention are detailed in Table 5.3.

Table 5.3 Cost parameters used for each intervention[131]

Cost element	Value	Unit
Operation staff + theatre costs		
TAPP	£ 6.40	Cost per min
TEP	£ 6.40	Cost per min
Open flat mesh	£ 6.34	Cost per min
Open plug and mesh	£ 6.34	Cost per min
Open pre-peritoneal mesh	£ 6.34	Cost per min
Open non mesh	£ 6.34	Cost per min
Operation equipment costs - general anaesthetic, reusables		
TAPP	£ 166.58	Cost per procedure
TEP	£ 166.58	Cost per procedure
Open flat mesh	£ 97.60	Cost per procedure
Open plug and mesh	£ 97.60	Cost per procedure
Open pre-peritoneal mesh	£ 97.60	Cost per procedure
Open non mesh	£ 71.70	Cost per procedure
Operation equipment costs - general anaesthetic, disposables		
TAPP	£ 788.02	Cost per procedure
TEP	£ 788.02	Cost per procedure
Hospitalisation		
Cost per hospital day	£ 236.57	Cost per day

Estimation of QALYs

Data used to estimate utilities were available from two studies.[131,132] As outlined in Chapter 4, the data reported by Stylopoulos and colleagues (2003) was based on the Quality of Wellbeing index and potentially not relevant to the UK. Utilities in the MRC Laparoscopic Groin Hernia Trial Group were based upon responses to the EQ-5D questionnaire and valued using UK population Tariffs. Furthermore, the individual patient data from this trial were available. Therefore, this data has been used as the basis of utility estimates.

The utility weight for the operation state (cycle length one year) was based on the utility for the three month convalescence period following the initial operation plus the utility for the remaining nine months. During the remaining nine months an individual might

have reduced utility because of the risk of long-term pain and numbness. In order to reflect this, data from the MRC Laparoscopic Groin Hernia Trial were reanalysed to provide utility estimates for: (i) persisting long-term pain; (ii) persisting long-term numbness; (iii) persisting long-term pain and numbness and (iv) neither persisting long-term pain or numbness (Table 5.5). The proportions of patients that would fall into these four categories were estimated using data from the MRC Laparoscopic Groin Hernia Trial. These data showed that for open procedures 53% (76 out of 143) of patients who experienced numbness also experienced long-term pain. For laparoscopic procedures the corresponding figure was 62% (27 out of 71). Beta distributions were used to reflect the uncertainty surrounding these estimates using the methods outlined earlier.

Table 5.4 Utilities used in the estimation of QALYs for the three month operative period[131]

Type of repair	**1 week (sd)**	**1 month (sd)**	**3 months (sd)**
Laparoscopic	0.74 (0.24)	0.82 (0.23)	0.85 (0.22)
	(n = 308)	(n =249)	(n = 261)
Open mesh	0.68 (0.24)	0.79 (0.22)	0.86 (0.2)
	(n = 302)	(n = 246)	(n = 236)
Average		**0.805**	**0.855**

Table 5.5 Utility values used to estimate utility weights for each Markov State

Health state	Value	Distribution	Source	N	Sd
Healthy	0.952	Normal	MRC 3mth data	215	0.011
Persisting long-term pain	0.836	Normal	MRC 3mth data	77	0.021
Persisting long-term numbness	0.919	Normal	MRC 3mth data	14	0.023
Persisting pain & numbness	0.739	Normal	MRC 3mth data	88	0.021
Recurrence	0.836	Normal	Assumed equal to score for long-term pain		
Cumulative QALYs score at 3 month post op					
Operation	**QALYs (3mth)**		**Source**	**Notes**	
TAPP	0.212		MRC 3mth data	Based on Table 5.4	
TEP	0.213		MRC 3mth data	Based on Table 5.4	
Open flat mesh	0.209		MRC 3mth data	Based on Table 5.4	
Open plug and mesh	0.208		MRC 3mth data	Based on Table 5.4	
Open pre-peritoneal mesh	0.209		MRC 3mth data	Based on Table 5.4	

The utility weight for the 'No recurrence' state also reflected the risk that a patient might suffer long-term pain and/or numbness. The methods used to estimate this utility weight were the same as those outlined for the estimation of the utility weight for the operation state.

For patients in the state of recurrence and re-operation the utility weight depended on the proportion of the year spent: (i) with a recurrence; (ii) in convalescence following a re-operation; and (iii) no recurrence but possibly with persisting long-term pain or numbness. The proportion of time spent with a recurrence was based on the waiting time for the repair of a recurrent hernia (mean 0.47 years, median 0.31 years). The time spent in convalescence was assumed to be 0.25 years and the time spent with no recurrence (but potentially with persisting long-term pain or numbness) was the remainder of the year. In order to reflect the uncertainty surrounding the period in recurrence, a triangular distribution with a minimum value of 0.22 years (an assumed lower limit), a likeliest value of 0.31 years (equal to the median waiting time) and a

maximum of 0.75 (as the period in convalescence is 0.25 years and the total duration of the state is one year). The utility scores for the period spent in convalescence and time spent with no recurrence (but potentially with persisting long-term pain or numbness) were estimated using the same methods as described above. No data were available for the utility weight associated with an untreated recurrence. Stylopoulos and colleagues assumed that a person with an untreated recurrence would have the same utility as a patient who was otherwise healthy.[132] In this analysis it has been assumed that the presence of a hernia reduces utility to the level equal to that of long-term pain.

Table 5.6 details the utility weights attached to each state of the model. The utility values for these states were estimated using the methods outlined above and the data reported in Tables 5.4 and 5.5.

Table 5.6 Utility values attached to each state of the model

Procedure	Initial operation	No recurrence	Reoperation	Recurrence, no reoperation	Death
TAPP	0.924	0.950	0.871	0.837	0.000
TEP	0.926	0.951	0.872	0.836	0.000
Open flat mesh	0.918	0.946	0.867	0.836	0.000
Open preperitoneal mesh	0.916	0.943	0.866	0.836	0.000
Open plug and mesh	0.922	0.950	0.868	0.836	0.000

5.2.3 Assessment of cost-effectiveness

The results of the base case analysis are based on the costs and outcomes faced by a cohort of 57 year old males (the mean age of patients receiving a primary repair of inguinal hernia in England and Wales). The central outcomes of the analysis and the systematic review are first presented in terms of a balance sheet. In the balance sheet the incremental differences between the alternative interventions are presented in their natural units, e.g. days away from usual activities, recurrences avoided. The purpose of the balance sheet is to illustrate the trade-offs that would exist when choosing between interventions. Within the economic model the different outcomes are combined into a single measure of relative efficiency measured in terms of the incremental cost per QALY. Data on the incremental cost per QALY are presented in two ways. First mean costs and QALYs for the alternative interventions are presented and incremental cost per QALYs calculated where appropriate. These data are presented for two time horizons:

five years; and 25 years. The second way in which the cost-effectiveness of the alternative interventions is presented is in terms of cost-effectiveness acceptability curves (CEAC). CEACs have been used to illustrate the uncertainty caused by the combined statistical variability in the model's parameter estimates. These curves illustrate the likelihood that a strategy is cost-effective at various threshold values for society's willingness to pay for an additional QALY.

5.2.4 Sensitivity analysis and sub-group analysis

Sensitivity analysis

Sensitivity analysis focused on varying assumptions or parameters in the base case model. These sensitivity analyses are split into changes to the relative effect sizes, costs, structure of the model, and utilities. Justification and details are provided below.

Relative effect sizes

- Changes to the length of stay and operation length

The results of the baseline analysis are influenced by the scarcity of data available. In particular, the rates of operation time and length of stay for both open plug and mesh and TEP are suspect. For open plug and mesh estimates for both operation length and length of stay are very much less than for open flat mesh. A further issue is that for TEP the data on length of stay and operation length are based on indirect comparisons and suggest that length of stay and operation length are shorter for TEP than TAPP, whereas data from direct comparisons suggest that length of stay and operation length are the same or indeed longer for TEP. In the sensitivity analysis the analysis was repeated for the comparison of all five procedures assuming that open flat mesh and open plug and mesh had the same operation times and lengths of stay. A second sensitivity analysis was performed for the comparison of TAPP, TEP and open flat mesh that assumed that TAPP and TEP had the same operation length.

- Adoption of day case procedure

It has been reported that the open mesh procedures can be performed as day case procedures whereas the laparoscopic procedures are performed on an inpatient basis. However, It can be seen from the consideration of the trials included in Chapter 3, that discharge policies differ widely between settings and that although differences may exist between procedures, it is clear that it is hospital policy which determines length of stay

for many cases rather than need. Therefore, a sensitivity analysis has been conducted that assumes the same length of stay for all procedures.

- Effect of learning on cost-effectiveness of TAPP and TEP

As Chapter 3 reported both TAPP and TEP are associated with a degree of learning. Unfortunately, limited data describing learning were only available on operation length. Crude interpretation of these data provides estimates of operation time for inexperienced operators (up to 20 procedures) of 70 minutes for TAPP and 95 minutes for TEP. For experienced operators (between 30 and 100 procedures) the operation times are 40 minutes for TAPP and 55 minutes for TEP. These data were substituted into the model comparing TAPP, TEP and open flat mesh.

- Extrapolation of the relative effect sizes to a 25 year time horizon.

In the baseline model it has been assumed that between five and twenty five years there is a constant annual risk of recurrences, numbness and long-term pain. The limited data available from the review and from the MRC Laparoscopic Groin Hernia Trial Group suggest that this might not be unrealistic for recurrences and numbness respectively. However, data from the MRC Laparoscopic Groin Hernia Trial Group suggest that rates of pain for all interventions may not differ after five years. Therefore, in one sensitivity analysis it has been assumed that rates of pain after five years are the same for all interventions and in another it has been assumed that the relative effects for recurrences, persisting long-term numbness and persisting long-term pain do not persist beyond five years.

Source of unit cost data

Data for costs of procedures are available from different sources. In this sensitivity analysis the impact of different cost estimates on cost-effectiveness are explored. In the first sensitivity analysis the costs for disposable laparoscopic equipment reported in Tables 5.3 have been used. In the second sensitivity analysis alternative unit cost data derived from the original costing work performed by the MRC Laparoscopic Groin Hernia Trial Group and Wellwood and colleagues.[64,131] The data used in these sensitivity analyses are reported in Table 5.7.

Table 5.7 Unit costs used in cost sensitivity analysis

Cost element	Value		Source	
	(1)	(2)	(1)	(2)†
Operation staff + theatre costs				
TAPP	2.22	6.67	Wellwood	Stonehouse MRC
TEP	2.22	6.67	Wellwood	Stonehouse MRC
Open flat mesh	2.22	6.93	Wellwood	Stonehouse MRC
Open plug and mesh	2.22	6.93	Wellwood	Stonehouse MRC
Open pre-peritoneal mesh	2.22	6.93	Wellwood	Stonehouse MRC
Operation equipment costs - general anaesthetic, reusables				
TAPP	377.66	164.44	Wellwood	Stonehouse MRC*
TEP	377.66	164.44	Wellwood	Stonehouse MRC*
Open flat mesh	377.66	86.09	Wellwood	Stonehouse MRC**
Open plug and mesh	377.66	86.09	Wellwood	Stonehouse MRC**
Open pre-peritoneal mesh	377.66	86.09	Wellwood	Stonehouse MRC**
Hospitalisation				
Cost per hospital day	226.20	476.44	Wellwood	Stonehouse MRC

*consumables Edinburgh West

**local anaesthetics, prophylactic antibiotics, medium basic tray and self retaining extractors

† Within the MRC trial six centres contributed data towards costs. One centre formed the basis of the analysis for reuseable equipment and another formed the basis of the sensitivity analysis on disposable equipment.

Structural changes to the economic model

- Type of secondary repair

One area of structural uncertainty in the model is which of the available methods of surgical repair would be adopted for a recurrence. In the base case analysis it has been assumed that all recurrences will be repaired using the same procedure as the initial procedure. In this sensitivity analysis an alternative assumption has been adopted in which all recurrent hernias are repaired using an open flat mesh repair.

- Effect of serious complications

The base case of the model has assumed that the serious complications would be principally captured in terms of longer operation time and length of stay. The extreme assumption that all serious complications result in immediate death was used to test the extent to which this sufficiently captures the effect on outcomes. Using the data reported in Table 3.4 the risk of visceral and vascular complications are 0.79% (6/764) for TAPP, 0.16% (1/644) for TEP, and 0.14% (2/1388) for open mesh.

Utilities

- Uncertainty surrounding utility estimates

No data were available to determine the utility associated with time spent with a recurrence. In the base case analysis it has been assumed that the utility associated with a recurrence is the same as that associated with long-term pain. However, the analysis by Stylopoulos and colleagues[132] assumed that the utility associated with a recurrence was the same as that for cured. Within this sensitivity analysis the same assumption has been made.

- Utility estimates used for long-term pain and numbness

As has been stated previously the utility estimates used within the model come from one trial.[131] The data from this trial have been reanalysed to provide utility estimates for long-term persisting pain and numbness. These data are likely to be key determinants of QALYs but they may not be more generally applicable. In order to explore the importance of utility values for those with long-term persisting pain and numbness a series of sensitivity analyses have been conducted. In these sensitivity analyses it has been assumed that there is no disutility associated with long-term pain, numbness either alone or in combination.

- Alternative source of utilities

The base case analysis has adopted the perspective of the NHS for costs and the general population for utilities. The utility data used were based on patient responses to the EQ 5D questionnaire weighted using UK population tariffs. The extent to which these valuations match those based on preferences of patients is unclear. The results of a recent discrete choice experiment [136] were, therefore, integrated into the economic model in order to provide estimates of the net benefit of the different procedures.

Owing to the complex nature of this work a description of the methodology used by the discrete choice experiment is provided in Appendix 14. Table 5.8 reports the coefficients and welfare results of the ordered probit model for the strength of preference format used in the discrete choice experiment.

Table 5.8 Random effects ordered probit model – all responders

Variable	Attribute Unit	Coefficients (95% CIs)	SE	P	WTP (£) per unit (95% CI's)
Type of anaesthetic (0=General, 1=Local)	Categorical	-0.1660 (-0.12541, (-0.1801)	0.02345	0.000	£327.65 (£247.52, £355.44)
Risk of serious Complications (%)	0.01%	-0.3386 (-0.3786, -0.2232)	0.04825	0.000	£668.33 (£440.52, £747.26)
Days in pain following surgery (days)	1 day	-0.0609 (-0.0652, -0.05124)	0.00342	0.000	£120.20 (£101.13, £128.66)
Cost (£)	£	-0.0005 (-0.00057, -0.00044)	0.000032	0.000	N/A
Chance of long-term pain up to 1 year (%)	1%	-0.0432 (-0.043247, -0.0645)	0.00502	0.000	£85.35 (78.87, £127.37)
Chance of recurrence (%)	%	-0.0516 (-0.05877, -0.04653)	0.00221	0.000	£101.88 (£91.84, £116.00)
Constant		1.62143 (1.546, 1.711)	0.08834	0.000	N/A
Number of observations: 3,104 Unbalanced panel: 246 individuals Log-likelihood function: -3369.97 Restricted log-likelihood: -3714.41 Chi squared: 599 Significance level: 0.000 McFadden's R^2:0.09 % Correct Predictions: 40%					

SE = Structured error; P = p-value

The data reported in Table 5.8 were combined with estimates of recurrence at four years, pain at one year and cost derived from the economic model as well as estimates of risk of serious complications derived from the systematic review of effectiveness reported in Chapter 3. The number of days following surgery were based on data from the MRC Laparoscopic Groin Hernia Trial. These data were consistent with the data reported in Chapter 3 on short-term pain.

Incorporating the data on outcomes for each intervention into the regression equation allows the net benefits for each intervention to be estimated. Table 5.9 details the additional parameters values and distributions used in this analysis. The risk of serious complication is assigned with a beta distribution using the same methods outlined previously. Number of days in long-term pain was assigned a log normal distribution and all coefficients were assigned normal distributions, as this is the assumption underpinning random effects probit models.

Table 5.9 Additional parameters used in the assessment of net benefits using the discrete choice experiment

Parameters in DCE	Parameter Value		Source	Attribute Unit	Coefficients	SE of coefficient	Monetary valuation	Distribution of coefficient
Type of anaesthetic (1 = local, 0 = general)								
TAPP	0		Ass	1	-0.166	0.02345	£ 332.00	Normal
TEP	0		Ass	1	-0.166	0.02345	£ 332.00	Normal
OFM	0		Ass	1	-0.166	0.02345	£ 332.00	Normal
Risk of serious complications								
		Events	Sample					
TAPP	0.79%	6	764	Review	0.1%	-0.3386	0.04825	£ 677.20	Normal
TEP	0.16%	1	644	Review	0.1%	-0.3386	0.04825	£ 677.20	Normal
OFM	0.14%	2	1388	Review	0.1%	-0.3386	0.04825	£ 677.20	Normal
Days in pain following surgery								
		SE						
TAPP	3.56	0.241		MRC	1	-0.0609	0.00342	£ 121.80	Normal
TEP	3.56	0.241		MRC	1	-0.0609	0.00342	£ 121.80	Normal
OFM	4.2	0.256		MRC	1	-0.0609	0.00342	£ 121.80	Normal
Cost at 4 years								
TAPP	£ 1,272			Model		-0.0005	0.000032	£ 1.00	Normal
TEP	£ 1,303			Model		-0.0005	0.000032	£ 1.00	Normal
OFM	£ 1,020			Model		-0.0005	0.000032	£ 1.00	Normal

SE = Standard Error; Ass = Assumption

Table 5.9 Additional parameters used in the assessment of net benefits using the discrete choice experiment (cont)

Parameters in DCE	Parameter Value	Source	Attribute Unit	Coefficients	SE of coefficient	Monetary valuation	Distribution of coefficient
Chance of long-term pain at 1 year							
TAPP	1.59%	Model	1%	-0.0432	0.00502	£ 86.40	Normal
TEP	1.70%	Model	1%	-0.0432	0.00502	£ 86.40	Normal
OFM	2.21%	Model	1%	-0.0432	0.00502	£ 86.40	Normal
Chance of recurrence at 4 years							
TAPP	3.70%	Model	1%	-0.0516	0.00221	£ 103.20	Normal
TEP	4.41%	Model	1%	-0.0516	0.00221	£ 103.20	Normal
OFM	3.13%	Model	1%	-0.0516	0.00221	£ 103.20	Normal

OFM = open flat mesh

Sub-group analysis

The model parameters were adjusted in order to estimate relative cost-effectiveness for a number of pre-specified sub-groups. The first subgroup of interest was the surgical management of recurrent hernias. In this analysis the initial operation was given the same parameter values as subsequent procedures. In most cases due to the limited evidence available this did not result in a change in parameter value.

A final sub-group of interest was the management of bilateral hernias. Two specific scenarios can be defined for this subgroup; the first relates to the management of symptomatic bilateral hernias and the second relates to the management of occult second hernias. For the former scenario, reasonably clear evidence is provided from the existing economic evaluations on relative cost-effectiveness. Therefore, the focus of the sub-group analysis is on the management of occult bilateral hernias. The available evidence suggests that the laparoscopic techniques can both be used to detect occult hernias but only a proportion of these will develop into symptomatic hernias. These data have been incorporated into the model by increasing the risk of recurrence for open mesh procedure by the risk that there is an occult hernia that goes on to develop into a symptomatic hernia. The risk of recurrence following laparoscopic repair was also increased to reflect the probability

that a repaired occult hernia would recur. However, it was assumed that only repaired occult hernias that might otherwise have progressed, could recur. To reflect the extra procedure cost of repairing a contralateral hernia the operation time for both TAPP and TEP was based on that reported for the repair of a bilateral hernia. These data were based on the times reported in the systematic review of effectiveness. Details of the additional parameter values used and their distributions are reported in Table 5.10.

Table 5.10 Details of the parameters used to assess the cost-effectiveness of laparoscopic compared to open repair for the surgical treatment of occult hernias

Parameter	Value	Distribution
Risk of occult hernia	10 or 25%	
Risk of progression	29%	Beta; α 6; β 21.[19]
Duration of effect	NA	1 year*
Relative risk of recurrences	NA	Subsequent procedures the same as primary
Operation time TAPP	76.1 mins	
Operation time TEP	94.2 mins	
Operation time Open mesh	NA	Same as base case analysis

* Available data relates to rate of progression at one year. This assumes that if an occult hernia develops into symptomatic hernia it will do so in one year.

The risk of progression has been reduced to 14% (3 out of 21 patients presented to their GP with a recurrent hernia)[19] and 5% (one out of 21 patients with progression) to explore the impact of progression on cost-effectiveness.

Further sub-groups of interest are gender and age. Little information is available split by gender and for this reason it has been assumed that the results are equally applicable to females as males. In terms of age, few age dependent data are available, however, the lower

and higher ages have been modelled to illustrate the impact that changes in mortality rates have on cumulative risk of recurrence, long-term pain, numbness and hence QALYs.

5.3 Results

5.3.1 Management of primary inguinal hernias

Tables 5.11 and 5.12 presents the balance sheet for the comparison of both TAPP and TEP with open flat mesh for five year and 25 year time horizons. Laparoscopic repair is associated with more time at usual activities and fewer people with long-term pain but this is achieved at higher cost and an increased risk of rare but serious complications. The costs presented in Tables 5.11 and 5.12 are based on reusable laparoscopic equipment.

Table 5.11 Balance sheet for the comparison of laparoscopic repair to open flat mesh for a five year time horizon

Favours TAPP and TEP	**Favours Open Flat Mesh**
More time at usual activities after five years TAPP: 2.88 (95% CI 1.65 to 4.16) more days TEP: 3.91 (95% CI 2.78 to 4.90) more days	*Lower costs over five years* TAPP: mean saving £181; 95% CI £150 to £208) TEP: mean saving £105; 95% CI £67 to £234)
Fewer people with numbness TAPP: 20.1 fewer patients per 1000. 95% CI 6.2 to 36.7) TEP: 18.5 fewer patients per 1000. 95% CI –2.9 to 34.1)	*Potentially more serious complications* TAPP: 7.9 more serious complications per 1000 patients TEP: 0.2 more serious complications per 1000 patients
Fewer people have long-term pain TAPP: 4.8 (95%CI 1.0 to 11.2) fewer people per 1000 TEP: 13.4 (95%CI 2.3 to 29.7) fewer people per 1000	
Similar risk of recurrence for TAPP and TEP compared to OFM over five years TAPP: 2 more recurrences per 100 patients. 95% CI -2 to 3) TEP: 1 more recurrence per 100 patients. 95% CI -1 to 9)	

Ranges are the 2.5 and 97.5 percentile points from the range of values produced by the Monte Carlo simulations.

Table 5.12 Balance sheet for the comparison of laparoscopic repair to open flat mesh for a 25 year time horizon

Favours TAPP and TEP	Favours Open Flat Mesh
More time at usual activities TAPP: 2.87 (95% CI 1.57 to 4.37) more days TEP: 3.92 (95% CI 2.69 to 5.03) more days	*Potentially lower costs* TAPP: mean saving £188; 95% CI 137 to £226) TEP: mean saving £133; 95% CI £64 to £308)
Fewer people with numbness TAPP 20.1 fewer patients per 1000. 95% CI 6.2 to 36.7) TEP 18.5 fewer patients per 1000. 95% CI –2.9 to 34.1)	*Potentially more serious complications* TAPP: 7.9 more serious complications per 1000 patients TEP: 0.2 more serious complications per 1000 patients
Fewer people have long-term pain TAPP: 4.8 (95%CI 1.0 to 11.2) fewer people per 1000 TEP: 13.4 (95%CI 2.3 to 29.7) fewer people per 1000	
Similar risk of recurrence for TAPP and TEP compared to OFM over 25 years (TAPP 3 more recurrences per 100 patients over 25 years. 95% CI -4 to 6) (TEP 3 more recurrences per 100 patients over 25 years. 95% CI -2 to 19)	

Ranges are the 2.5 and 97.5 percentile points from the range of values produced by the Monte Carlo simulations

The data presented in Tables 5.11 and 5.12 allow implicit valuations about how the alternative outcomes can be traded off. These implicit valuations, which inform decisions about whether the use of laparoscopic repair should be increased, depend upon whether the benefits of laparoscopic repair (reduced persisting long-term pain and numbness and earlier return to usual activities) are worth the extra cost, the increased risk of serious complication, and the uncertainty of differences in rates of recurrence.

The different outcomes reported in Tables 5.11 and 5.12 are explicitly combined within the estimates of incremental cost per QALY. Nonetheless, the data from these tables are still useful as they allow discrepancies between implicit and explicit valuations to be identified

and explored. The results of a deterministic analysis of incremental cost per QALY are reported in Tables 5.13 which compares all five surgical interventions.

Table 5.13 Results of the deterministic model for a five year and a twenty five year time horizon

Time horizon		Cost	QALYs	Incremental cost	Incremental QALYs	Incremental cost per QALY
5 years	TAPP	£1190	4.44			Dominated
	TEP	£1113	4.45	£384 vs OPM	0.01 vs OPM	£46,443 vs OPM
	OFM	£1009	4.42			Dominated
	OPPM	£926	4.41			Dominated
	OPM	£730	4.44			
25 years	TAPP	£1211	16.23	£75		Dominated
	TEP	£1135	16.24	£373	0.02	£20,014 vs OPM
	OFM	£1022	16.19			Dominated
	OPPM	£944	16.16			Dominated
	OPM	£763	16.23			

OFM = Open flat mesh; OPM = Open plug and mesh; OPPM = Open preperitoneal mesh

TAPP repair is dominated by TEP over the time horizons considered. Furthermore, open preperitoneal mesh and open flat mesh are dominated by open plug and mesh. The point estimates of incremental cost-effectiveness provided in Tables 5.13 do not provide any indication of the uncertainty that exists. The uncertainty surrounding the precision of many of the parameter estimates is reflected in the likelihood that the interventions are cost-effective at different threshold values for societies willingness to pay for a QALY (Table 5.14).

Table 5.14 Comparison of the five interventions together with incremental analysis

Sensitivity analysis	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£ 10000	£20,000	£30,000	£50,000
Baseline model for a 5 year time horizon	TAPP	£1190	4.44	Dominated	1.1%	4.0%	5.2%	7.4%
	TEP	£1113	4.45	£46,443 vs OPM	6.6%	21.2%	34.8%	54.2%
	OFM	£1009	4.42	Dominated	2.2%	0.9%	0.0%	0.0%
	OPPM	£926	4.41	Dominated	5.1%	5.1%	4.9%	4.2%
	OPM	£730	4.44		85.0%	69.7%	55.1%	34.2%
Baseline model for a 25 year time horizon	TAPP	£1211	16.23	Dominated	6.4%	8.8%	9.9%	11.3%
	TEP	£1135	16.24	£20,014 vs OPM	28.5%	49.4%	57.9%	66.0%
	OFM	£1022	16.19	Dominated	0.1%	0.0%	0.0%	0.0%
	OPPM	£944	16.16	Dominated	3.8%	3.4%	3.2%	3.0%
	OPM	£763	16.23		61.2%	38.4%	29.0%	19.7%
Open flat mesh and open plug and mesh have the same operation length and length of stay (25 year time horizon)	TAPP	£1211	16.23	Dominated	10.3%	11.7%	12.5%	12.6%
	TEP	£1135	16.24	£2094 (£2093 vs OPM)	66.8%	72.1%	73.6%	74.8%
	OPM	£1096	16.23	ED (£2095 vs OFM)	18.7%	12.9%	10.8%	9.5%
	OPPM	£1037	16.16	Dominated	4.0%	3.3%	3.1%	3.1%
	OFM	£1022	16.19		0.2%	0.0%	0.0%	0.0%

OFM = Open flat mesh; OPM = Open plug and mesh; OPPM = Open preperitoneal mesh. ED = Extended dominance

The data presented in Table 5.14 indicate that the likelihood that the laparoscopic procedures will be considered as cost-effective increases as the maximum amount that society is willing to pay for an additional QALY and the time horizon increases. The data also illustrates some of the limitations of the data available for the model. In particular the results for open plug and mesh and open preperitoneal mesh are based on the results of only one or two relatively small trials. Therefore, some of the estimates derived from these trials are very imprecise as well being potentially unreliable. For example, the relatively low cost of the open plug and mesh procedure is driven by the estimates of length of stay and operation time used in the model. These estimates are based on the available data but it is quite possible that in reality there is no meaningful difference between open flat mesh and open plug and mesh in these outcomes. As Table 5.14 shows should the length of stay and operation length for open plug and mesh be the same then open flat mesh becomes the least costly option. It should be noted that the same reservations that can be raised about the cumulative costs of open plug and mesh and open preperitoneal mesh could also be raised for estimates of QALYs.

Due to the unreliability of data for open plug and mesh and open preperitoneal mesh the remainder of the analysis has been presented for the comparison of TAPP and TEP with open flat mesh. This makes the realistic assumption that open plug and mesh and open preperitoneal mesh have the same effectiveness as open flat mesh (Figure 5.2 and 5.3). As these figures show TEP is more likely to be considered cost-effective than TAPP at all threshold values for society's willingness to pay for an additional QALY. Furthermore, it appears that once society is willing to pay more than £10,000 per QALY the likelihood that open flat mesh is cost-effective is very low.

Figure 5.2 **Cost-effectiveness acceptability curves for the comparison of TAPP, TEP and open flat mesh for a five year time horizon**

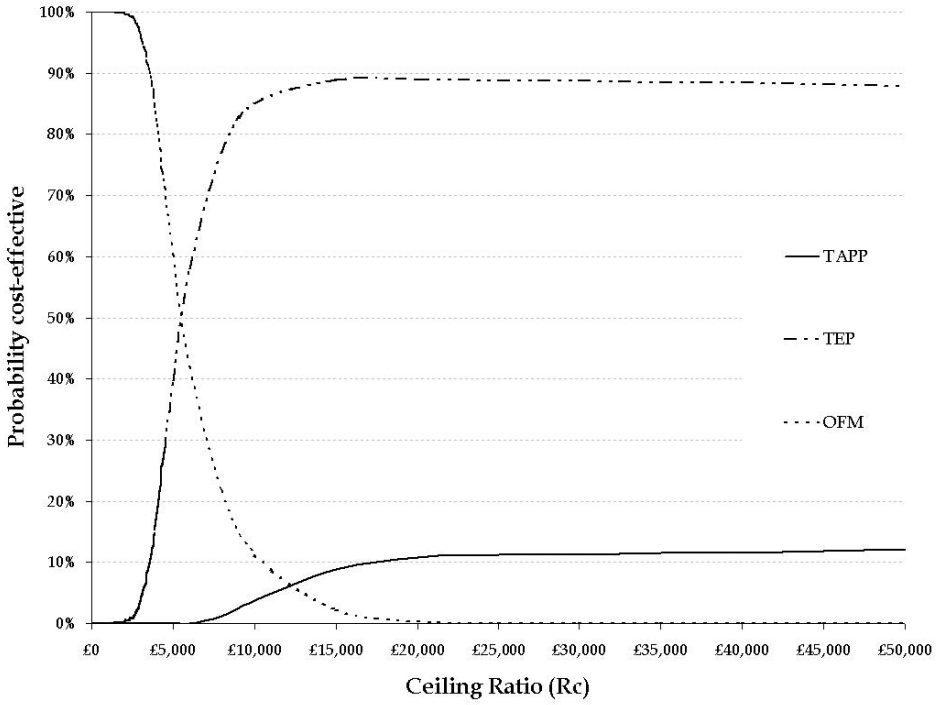
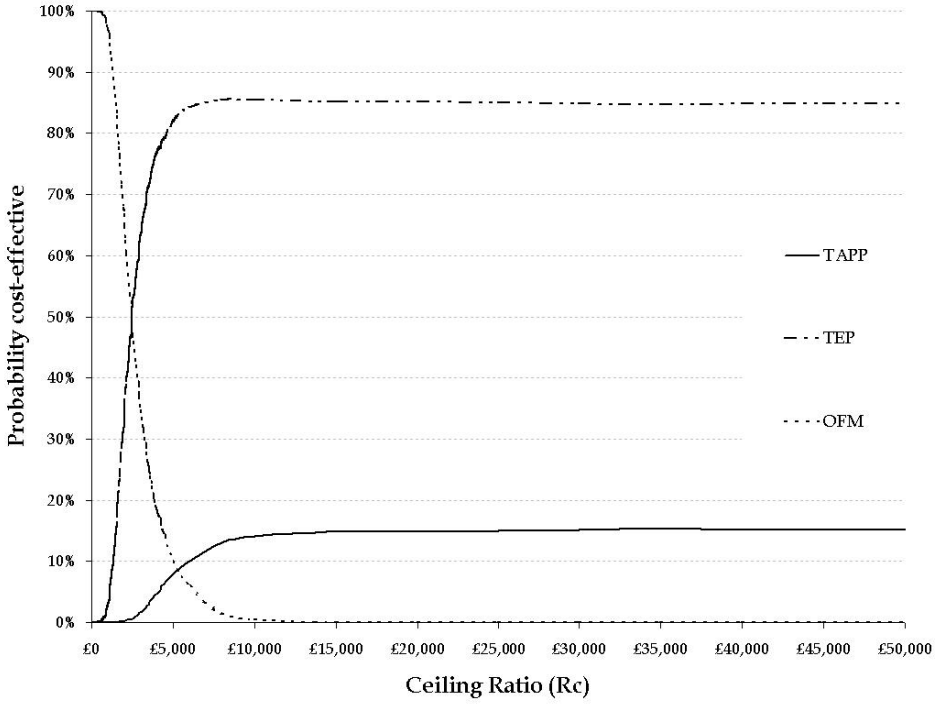


Figure 5.3 **Cost-effectiveness acceptability curves for the comparison of TAPP, TEP and open flat mesh for a twenty five year time horizon**



Sensitivity analysis

Changes to relative effect sizes

Table 5.15 shows that if the length of stay and operation lengths for TAPP and TEP are the same then TAPP becomes very slightly less costly than TEP although TEP has extended dominance over TAPP. Overall, TEP remains the most likely to be cost-effective. Similarly, assuming that there are no meaningful differences in length of stay between procedures TEP is marginally less cost-effective compared to the other interventions. Although there was little difference compared with the base case model.

Changes to the duration over which the relative effect size differ had relatively little effect on cost due to the relatively low rate of recurrences but relatively more on estimates of QALY. Should differences in long-term pain, numbness and recurrence not persist into the long-term then open flat mesh becomes more likely to be considered cost-effective. Nonetheless, it would appear that TEP dominates TAPP and is associated with a relatively low incremental cost per QALY (Table 5.15).

Table 5.15 Results of the sensitivity analysis for variations in length of operation time and length of stay

Sensitivity analysis	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£ 10000	£20,000	£30,000	£50,000
Base case model for a 25 year time horizon	TAPP	£1211	16.23	Dominated	14.1%	14,8%	15.2%	15.1%
	TEP	£1135	16.24	£2093	85.5%	85.2%	84.8%	84.9%
	OFM	£1022	16.19		0.4%	0.0%	0.0%	0.0%
TAPP and TEP have the same operation length and length of stay	TEP	£1121	16.24	£3240 vs OFM (£8 vs TAPP)	77.7%	80.9%	81.9%	82.8%
	TAPP	£1121	16.23	ED (£5218 vs OFM)	20.7%	19.1%	18.1%	17.2%
	OFM	£1022	16.19		0.3%	0.0%	0.0%	0.0%
Assumption that the length of stay for each procedure is the same	TAPP	£1186	16.23	Dominated	17.1%	16.9%	16.1%	16.1%
	TEP	£1144	16.24	£2252	82.6%	83.1%	83.9%	83.9%
	OFM	£1022	16.19		0.3%	0.0%	0.0%	0.0%
Assumption that the duration of effect for pain is five years	TAPP	£1211	16.22	Dominated	23.6%	31.3%	34.2%	36.1%
	TEP	£1135	16.22	£3302	71.5%	68.4%	65.7%	63.9%
	OFM	£1022	16.19		4.9%	0.3%	0.1%	0.0%
Assumption that the duration of effect for pain, recurrences and numbness is five years	TAPP	1211	16.20	Dominated	3.2%	11.3%	14.1%	16.6%
	TEP	1134	16.21	£5471	79.6%	86.3%	85.1%	83.3%
	OFM	1030	16.19		17.25	2.4%	0.8%	0.1%

OFM = Open flat mesh; ED = Extended dominance

Costs

Table 5.16 shows the effect of changing the cost estimates of the model. In the first sensitivity analysis it has been assumed that laparoscopic procedures are conducted using disposable equipment. This has the effect of greatly increasing the cumulative costs of both TAPP and TEP. As a result at lower incremental cost per QALY thresholds (e.g. £10,000) it is unlikely that either laparoscopic procedures are cost-effective. However, at higher thresholds TEP becomes increasingly more likely to be cost-effective as it more likely to provide additional QALYs over open flat mesh.

Also shown in Table 5.16 is the effect on relative cost-effectiveness of using different cost estimates available from one of the other centres included in the MRC Laparoscopic Groin Hernia Trial Group and the estimates from Wellwood and colleagues.[64,131] As these analyses show although the mean incremental cost per QALY of TEP compared with open flat mesh is increased the overall likelihood that TEP is the most cost-effective option at the threshold values for society's willingness to pay for a QALY reported is virtually unchanged.

Table 5.16 Results of the sensitivity analysis for variations in costs

Sensitivity analysis	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£10,000	£20,000	£30,000	£50,000
Baseline model for a 25 year time horizon	TAPP	£1211	16.23	Dominated	14.1%	14,8%	15.2%	15.1%
	TEP	£1135	16.24	£2093	85.5%	85.2%	84.8%	84.9%
	OFM	£1022	16.19		0.4%	0.0%	0.0%	0.0%
TAPP and TEP use disposable equipment	TAPP	£1832	16.23	Dominated	0.2%	5.8%	12.6%	15.1%
	TEP	£1757	16.24	£13,616	6.3%	65.6%	81.4%	84.6%
	OFM	£1022	16.19		93.5%	28.6%	6.0%	0.3%
Alternative unit costs (1) (see Table 5.7)	TAPP	£1110	16.23	Dominated	9.2%	15.4%	15.6%	15.6%
	TEP	£1064	16.24	£5538	75.7%	84.2%	84.4%	84.4%
	OFM	£765	16.19		15.1%	0.4%	0.0%	0.0%
Alternative unit costs (2) (see Table 5.7)	TEP	£1838	16.23	Dominated	13.0%	14.5%	15.0%	15.2%
	TAPP	£1724	16.24	£2107	85.6%	85.5%	85.0%	84.8%
	OFM	£1614	16.19		1.4%	0.0%	0.0%	0.0%

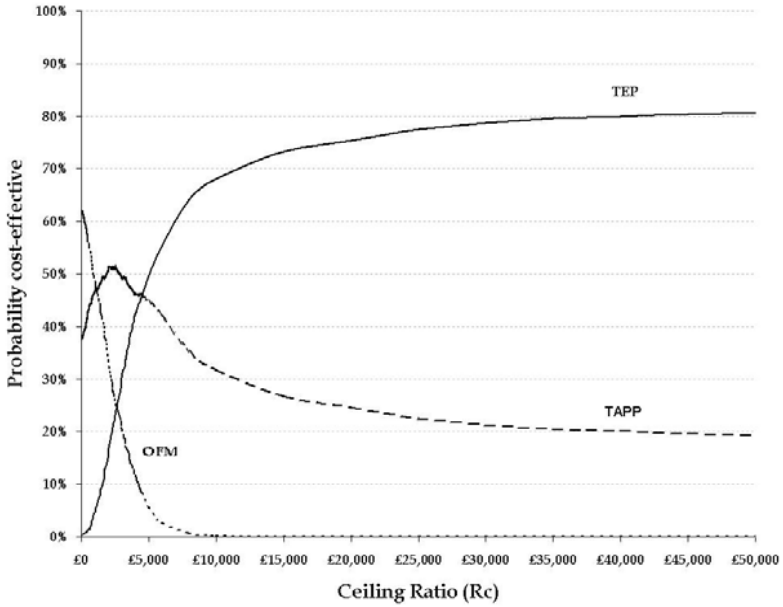
OFM = Open Flat Mesh

Changes to the structure of the model

Considering how the costs of TAPP and TEP might vary for experienced and inexperienced operators was assessed by the impact on cost-effectiveness of learning. The results of this analysis are showed in Figure 5.5. In these figures TAPP becomes more likely to be cost-effective. Nonetheless, even for inexperienced surgeons at threshold values greater than £10,000 per QALY TEP is more likely to be efficient than the other interventions. What these analyses do not reflect is any change in effectiveness or safety nor do they reflect any other impact on cost other than that mitigated through operation time.

Figure 5.4 Cost-effectiveness acceptability curves for the comparison of TAPP; TEP and open flat mesh for surgeons at different levels of experience

1) Experienced laparoscopic surgeons



2) Inexperienced laparoscopic surgeons

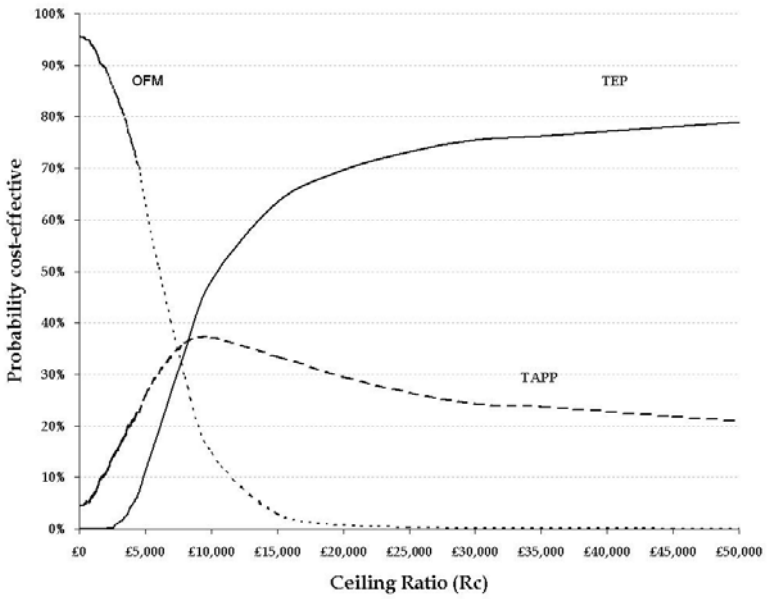


Table 5.17 Results of the sensitivity analysis for variations in the structure of the model

Sensitivity analysis	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£10,000	£20,000	£30,000	£50,000
Baseline model for a 25 year time horizon	TAPP	£1211	16.23	Dominated	14.1%	14,8%	15.2%	15.1%
	TEP	£1135	16.24	£2093	85.5%	85.2%	84.8%	84.9%
	OFM	£1022	16.19		0.4%	0.0%	0.0%	0.0%
Subsequent procedures are all open flat mesh	TAPP	£1213	16.22	Dominated	13.4%	15.1%	15.7	16.3%
	TEP	£1135	16.24	£2180	87.5%	84.9%	84.3	83.7%
	OFM	£1022	16.19		1.1%	0.0%	0.0	0.0%
Inclusion of serious complications as operative mortality	TAPP	£1210	16.09	Dominated	0.6%	0.7%	0.8%	0.9%
	TEP	£1135	16.22	£2190	81.9%	86.4%	87.2%	88.0%
	OFM	£1022	16.17		17.5%	12.9%	12.0%	11.1%

OFM = Open flat mesh; ED = Extended dominance

Changing the structure of the model so that all subsequent procedures are open flat mesh slightly reduces the likelihood that TEP is cost-effective. The reason the impact of this change is small is the relatively low risk that a recurrence will occur (Table 5.17).

Also shown in Table 5.17 is the effect of including all serious complications such as operative mortality. As reported in Section 5.2 the estimated rate of serious complications is higher for TAPP than either TEP or open flat mesh. As a consequence the overall cost-effectiveness of TEP is not greatly changed but TAPP is less likely to be cost-effective and open flat mesh is more likely to be cost-effective.

Changes to utilities

Table 5.18 provides details of the effect of changing the utility associated with a recurrence. In this sensitivity analysis it has been assumed that a recurrence is associated with the same utility as being healthy. This is the same assumption used by Stylopoulos and colleagues in their analysis.[132] As the data show the results do not greatly change. The reason for this is that there is a relatively low risk of recurrence and hence a relatively small risk of a patient suffering the associated disutility.

Also shown in Table 5.18 is the effect of removing the disutility associated with long-term persisting pain and numbness. As the results of these sensitivity analyses show the utility values assumed for people with long-term persisting pain and numbness greatly influence cost-effectiveness. Assuming there is no disutility associated with long-term persisting pain reduced the cost-effectiveness of TEP and leads to a reduction in difference between TAPP and TEP. Indeed in this sensitivity analysis TAPP is associated with a slightly higher estimate of mean QALYs than TEP. An assumption that there is no disutility associated with long-term numbness has less impact, although the mean cost-effectiveness of TEP is again reduced. Nonetheless, at higher threshold values e.g. £20,000, for a cost per QALY TEP is highly likely to be considered cost-effective.

The greatest impact on cost-effectiveness occurs when there is no disutility from either long-term pain or numbness. This sensitivity analysis is essentially the same as assuming that the only differences in QALYs between interventions are caused by differences in the risk of recurrence and the speed of recovery from a procedure. In this

analysis it is unlikely that either TAPP or TEP will be considered cost-effective at threshold values for a cost per QALY deemed affordable by society.

Although the utilities used in the model were derived using the EQ-5D they relate to a single study. Furthermore, these valuations may not match those of patients. In an attempt to explore the importance of this the analysis was repeated using the findings of a discrete choice experiment. The results of this analysis are presented in terms of net benefits for TAPP vs open flat mesh and TEP vs open flat mesh. From these two pairwise comparisons the net benefit of TEP compared with TAPP can be calculated. It should be noted that the discrete choice approach essentially assumes that there are no meaningful differences between interventions other than in the attributes chosen.

The mean net benefit for TAPP compared with open mesh was -£4527 (a negative net benefit means open flat mesh is preferred). The corresponding value for TEP was -£14. Overall, there was a only a 26.2% probability that TAPP was preferred to open flat mesh and a 40.3% chance that TEP was preferred to open flat mesh. The mean net benefit of TEP over TAPP was £4513 and there was only a 2.6% chance that TAPP would be preferred to TEP.

It should be noted that with this analysis the relatively poor performance of TAPP is driven by the relatively high risk of serious complications (0.79% for TAPP compared with 0.16% for TEP). Although it appears likely that TAPP does have a higher rate of serious complications precisely how much higher is uncertain.

Table 5.18 Results of the sensitivity analysis for changes in the utility values

Sensitivity analysis	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£ 10000	£20,000	£30,000	£50,000
Baseline model for a 25 year time horizon	TAPP	£1211	16.23	Dominated	14.1%	14,8%	15.2%	15.1%
	TEP	£1135	16.24	£2093	85.5%	85.2%	84.8%	84.9%
	OFM	£1022	16.19		0.4%	0.0%	0.0%	0.0%
Assuming that the utility associated with recurrent hernias is the same as healthy	TAPP	£1211	16.23	Dominated	9.1%	9.1%	8.2%	8.0%
	TEP	£1135	16.25	£2004	90.8%	90.9%	91.8%	92.0%
	OFM	£1022	16.19		0.1%	0.0%	0.0%	0.0%
Assuming that there is no disutility associated with pain	TAPP	£1211	16.26	£72,671	13.6%	28.8%	37.7%	47.2%
	TEP	£1135	16.26	£8262	42.1%	50.0%	47.1%	41.9%
	OFM	£1022	16.24		44.3%	21.2%	15.2%	10.9%
Assuming that there is no disutility associated with numbness	TAPP	£1211	16.23	Dominated	0.2%	5.8%	7.8%	9.0%
	TEP	£1135	16.25	£4008	81.3%	89.4%	91.0%	90.7%
	OFM	£1022	16.22		16.7%	4.8%	1.2%	0.3%
Assuming that there is no disutility associated with pain or numbness	TAPP	£1211	16.26	£2,173,247	0.0%	0.2%	1.7%	8.6%
	TEP	£1135	16.26	£98,584	0.3%	3.6%	13.4%	30.8%
	OFM	£1022	16.26		99.7%	96.2%	84.9%	60.6%

5.3.2 Management of recurrent hernias

The limited data available suggest that the TEP approach may be associated with a mean lower cost and higher mean QALYs than either TAPP or open flat mesh. The results of the probabilistic analysis indicate that at threshold values for a cost per QALY of £10,000 or greater there is a very small chance that open flat mesh might be considered cost-effective (Table 5.19). However, the data available to assess the management of recurrent hernias are very limited. For example, for comparisons of TAPP with the individual open mesh procedures the data relate to less than 100 patients per randomised group and for TEP the data are considerably more limited. Therefore, the results presented require very cautious interpretation and a judgement about whether the best estimate for the treatment of recurrent hernias is provided by these data or the base case analysis.

5.3.3 Different age groups

Age specific relative risks were not available from the literature and as a result the effect on costs and QALYs arose solely through changes in the risk of mortality. For the younger age group (age 40) operative mortality was the same as baseline but all cause mortality was reduced. For older age groups (age 75) operative mortality increased from 0.1% to 1.6% with the mortality for emergency procedures increasing from 1% to 2.5%. Furthermore, for older age groups all cause mortality also increased. The effect of these changes on cost-effectiveness was minimal (Table 5.19).

5.3.4 Management of occult bilateral hernias

Relatively little data were available to model the cost-effectiveness of the alternative procedures. For the comparison of TAPP, TEP and open flat mesh procedures the limited data available suggest that there is nearly a 90% chance that TEP is cost-effective if society is willing to pay £20,000 per additional QALY. These results are driven by the likelihood of an occult hernia and the likelihood that it will progress. Nonetheless, even if prevalence falls to 10% (the lower end of rates reported in the literature) and the rate of progression falls to five percent (lower than rates reported in the one small study available) there is still over an 83% chance that TEP will be considered cost-effective at a threshold of £20,000 per QALY (Table 5.20). It should be noted that this analysis does not take into account any adverse events caused by the additional dissection required when TEP is used for this sub-group.

Table 5.19 Results of sub-group analysis for recurrent hernias and different age groups

Sensitivity analysis	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£ 10000	£20,000	£30,000	£50,000
Primary unilateral inguinal hernia. Age at first procedure 57 (base case)	TAPP	£1211	16.23	Dominated	14.1%	14,8%	15.2%	15.1%
	TEP	£1135	16.24	£2093	85.5%	85.2%	84.8%	84.9%
	OFM	£1022	16.19		0.4%	0.0%	0.0%	0.0%
Management of recurrent hernia	TAPP	£1131	16.19	Dominated	30%	28.6%	27.7%	26.6%
	OFM	£1126	16.17	Dominated	0.0%	0.0%	0.0%	0.0%
	TEP	£1103	16.23		70%	71.4%	72.8%	73.4%
Age at first procedure 75	TAPP	£1195	8.71	Dominated	13.7%	19.8%	20.1%	21.3%
	TEP	£1119	8.72	£3,489	79.7%	79.9%	79.9%	78.7%
	OFM	£1012	8.69		6.6%	0.3%	0.0%	0.0%
Age at first procedure 40	TAPP	£1215	18.92	Dominated	12.6%	13.4%	13.5%	14.4%
	TEP	£1140	18.94	£1869	87.1%	86.6%	86.5%	85.6%
	OFM	£1026	18.88		0.3%	0.0%	0.0%	0.0%

OFM = Open flat mesh

Table 5.20 Results of sub-group analysis for occult bilateral hernias

Sensitivity analysis	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£ 10000	£20,000	£30,000	£50,000
Base case analysis at 5 years for	TAPP	£1190	4.44	Dominated	3.7%	10.8%	11.3%	12.1%
comparison of TAPP, TEP and	TEP	£1113	4.45	£4928	85.0%	88.9%	88.7%	87.9%
open mesh	OFM	£1009	4.42		11.3%	0.3%	0.0%	0.0%
Management of occult hernias	TAPP	£1377	4.44	Dominated	0.7%	2.9%	5.2%	6.7%
Results of 5 year model	TEP	£1227	4.44	£5294	69.3%	94.6%	94.6%	93.3%
prevalence of bilateral hernias	OFM	£1080	4.42		30.0%	2.5%	0.2%	0.0%
25%								
Management of occult hernias	TAPP	£1375	4.44	Dominated	0.7%	3.8%	7.0%	8.9%
Results of 5 year model	TEP	£1225	4.45	£7887	49.2%	88.6%	92.0%	90.8%
prevalence of bilateral hernias	OFM	£1037	4.42		50.1%	7.6%	1.0%	0.3%
10%								
Management of occult hernias	TAPP	£1375	4.44	Dominated	0.3%	1.8%	5.4%	8.2%
Results of 5 year model	TEP	£1225	4.45	£8952	44.0%	87.3%	93.0%	91.7%
prevalence of bilateral hernias	OFM	£1023	4.42		55.7%	10.9%	1.6%	0.1%
10% and a 14% progression rate								
Management of occult hernias	TAPP	£1374	4.44	Dominated	0.1%	1.9%	5.3%	8.5%
Results of 5 year model	TEP	£1224	4.45	£9732	37.0%	83.3%	91.7%	91.3%
prevalence of bilateral hernias	OFM	£1014	4.42		62.9%	14.8%	3.0%	0.2%
10% and a 5% progression rate								

OFM = Open flat mesh

5.4 Summary of evidence on cost-effectiveness

For the comparison of all five interventions the results indicate that judgements about relative cost-effectiveness are sensitive to the time horizon chosen. The longer the time horizon the more likely it is that laparoscopic procedures will be considered cost-effective. The data used to model the costs and QALYs for open plug and mesh and open preperitoneal mesh are limited and may not be applicable to the UK NHS. As a result, it has been assumed in subsequent analyses that both open plug and mesh and open preperitoneal mesh have costs and effects similar to open flat mesh.

For the comparison of TAPP, TEP and open flat mesh the results were less sensitive to the time horizon. In this analysis open flat mesh was the least costly option but provided less QALYs. The analysis suggests that TEP is the most cost-effective intervention when the amount society is willing to pay for an additional QALY is greater than £10,000.

The results of the analysis were sensitive to whether the laparoscopic procedures were performed using disposable laparoscopic equipment. The use of disposable equipment greatly increases the cost of laparoscopic procedures but does not change estimates of QALYs. As a result, at lower thresholds for society's willingness to pay for an additional QALY (less than £10,000) open flat mesh is more likely to be cost-effective when compared to the base case analysis. Above this threshold level TEP is more likely to be cost-effective.

The results of the analysis are most sensitive to assumptions about the disutility attached to either long-term pain or numbness. The utility data come from only one trial and were extrapolated. They therefore may not represent the true disutility associated with long-term pain and numbness. If there is no disutility associated with long-term pain or numbness or the disutility is reduced then it is highly likely that neither TAPP nor TEP is cost-effective.

Overall, based on the data used in the model TEP appears to dominate TAPP. This analysis was based on indirect comparisons as directly comparative data were sparse. Nonetheless, it is possible that the length of stay TAPP and TEP would be the same in practice and operation time would either be equal or slightly longer for TEP. In such a situation the cost

advantage enjoyed by TEP over TAPP would disappear and TEP may be the more costly procedure. Should there be no meaningful difference in numbness, pain and recurrences (and hence QALYs) then the choice between TAPP and TEP procedures would be determined by the risk of complications and their importance to patients.

The estimation of QALYs may not fully capture the preferences of patients to avoid serious complications. Using data on the strength of patients' preference for the different outcomes from surgery showed that both TAPP and TEP were most likely to be dominated by open flat mesh. This finding is driven principally by the preferences of patients to avoid serious complications.

The base case results were based on the extrapolation of the relative effect sizes over the whole 25 year time horizon. Limiting the duration of effects for pain numbness and recurrence to five years did not greatly alter the results. The results were also not greatly influenced when the analysis was based on alternative unit costs, all subsequent procedures being flat mesh, utility associated with a recurrent hernia, or the inclusion of the risk of serious complications as operative mortality. In the latter analysis, however, TAPP was much less likely and open flat mesh was more likely to be considered cost-effective.

Few data were available to assess cost-effectiveness for the different sub-groups. Based on the very limited data available the analyses suggest that TEP is highly likely to be cost-effective should the threshold value of society's willingness to pay for an additional QALY be greater than £10,000. With respect to age of the patient it was assumed that relative effects would be the same as the base case analysis but operative and all cause mortality would change. There was, however, relatively little impact on estimates of cost-effectiveness.

For the management of occult hernias the limited data available suggests that TEP has over an 80% chance of being cost-effective at a threshold value of society's willingness to pay for an additional QALY greater than £20,000 irrespective of plausible variations in the prevalence and rate of progression of occult hernias. Below threshold values of society's

willingness to pay for an additional QALY of less than £20,000 open flat mesh is increasingly likely to be considered cost-effective.

6 Implications for other parties

6.1 Quality of life for family and carers

The use of a laparoscopic approach to repair inguinal hernia appears to be associated with faster recovery and less pain. Any reduction in the time required to recover after a hernia repair may also reduce the time and effort that a patient's family or other carers devote to care following discharge from hospital. However, open mesh repair also has advantages for patients and carers. There are concerns about rare serious complications associated with laparoscopic repair and it is usually performed under general anaesthesia.

6.2 Financial impact for the patient and others

Less pain after operation is associated with a more rapid return to usual activities, including work. For this reason laparoscopic surgery may sometimes be the preferred technique. Where there are compelling reasons for wanting as rapid a recovery as possible, these benefits may offset the additional costs associated with this method. In particular, those who experience financial hardship as a result of time away from employment may prefer laparoscopic repair. In addition, some employers may welcome an earlier return to work of their employees.

6.3 Impact on other sectors of community

The adoption of laparoscopic repair has been argued to reduce the net costs to society. Such estimates are based on a range of assumptions which may not be realised, wholly or in part, in practice. However, although the precise magnitude of benefit is uncertain, employers may find that the reduction in a patient's absence reduces the disruption to productivity.

7 Implications for the NHS

7.1 Training

Serious complications can occur during laparoscopic hernia repair and, as for other minimal access techniques, the risk of these is likely to be related to operator experience and skill. The largest European series published by Bittner and colleagues in which 12 of the 15 surgeons were trainees, reported that there were 9/8050 (0.11%) bowel injuries and 8/8050 (0.10%) bladder injuries.[137] These complications could be minimised by adequate training. It is difficult to determine the true clinical value of laparoscopic herniorrhaphy when surgeons, in general, are more technically proficient with open techniques.

It can be argued that the skills obtained in laparoscopic hernia surgery can be transferred to other more complex laparoscopic operations, and hence helps to maintain these laparoscopic skills. The high incidence of inguinal hernia has the potential to provide training potential for surgeons since the skills learnt are transferable to other types of minimally invasive surgery. The counter argument is that the number of other applications of laparoscopic techniques (e.g. laparoscopic cholecystectomy) is more than suffice to provide adequate training. The UK training facilities for laparoscopic surgery are currently being enhanced with the development of the National Training Programme for Laparoscopic Surgery with the support of the Royal College of Surgeons of England, the Association of Surgeons of Great Britain and Ireland, the Association of Endoscopic Surgeons of Great Britain and Ireland and the Department of Health (AESGBI submission).

While the nature of the procedure would appear to preclude its use outside specialist centres, if its use is to be extended, appropriate training and supervision would be needed for additional surgeons.

7.2 Fair access and equity issues

Currently only four percent of patients receive laparoscopic repair (RCS submission). Access to this type of surgery must be limited, as expertise and equipment are concentrated in a limited number of specialist centres. It may be difficult for patients to obtain access to

hospitals, where laparoscopic repair is performed, due to the limited availability of this type of surgery and to the cost of travelling to those centres that can provide it.

Seymour conducted a study to examine patterns of inpatient inguinal hernia surgery in men using a mixture of routine hospital data, demographic data and the Carstairs deprivation category.[138] Comparison of data describing men undergoing inguinal hernia surgery in Scotland in 1982-84, 1987-89, and 1992-94 revealed that there was inequality of access to inguinal hernia surgery because of age had decreased, but inequity, on the basis of deprivation category, persisted. The effect of time off work/usual activities, for those who suffer the most deprivation and who have an inguinal hernia, may be reduced if laparoscopic hernia repair was introduced.

8 Discussion

8.1 Main results

Laparoscopic repair is consistently more costly than open repair. The magnitude of the extra cost from studies conducted in the UK appears to be about £300 to £350 per patient. The point estimates of cost provided by the economic model presented in Chapter 5 also suggest that the laparoscopic techniques are more costly (approximately £100 to £200 more per patient after five years). The costs of laparoscopic surgery are sensitive to factors relating to surgeon and hospital preference, such as the use of disposable or reusable equipment or whether patients are treated as inpatients or daycases. In addition to the costs of equipment, the other 'cost driver' is the extra theatre costs associated with the longer operating time.

These cost estimates are similar to those in the HTA report considered by NICE in 2001. That report concluded that laparoscopic repair was unlikely to be cost-effective compared with open mesh repair on the basis that the extra costs were unlikely to be offset by the benefits then identified - short-term advantages, such as in the time to return to usual activities.

This new report is based on a considerably enhanced evidence base, particularly because of new data available through the EU Hernia Trialists Collaboration. This group conducted meta-analyses based on re-analysis of the raw data (including previously unpublished data) from the majority of relevant trials. This has been the basis for a more complete meta-analysis for this report providing estimates of effectiveness which are more precise and arguably more generalisable.

The results of the meta-analyses of data for short-term outcomes have not fundamentally changed the overall picture: convalescence is more rapid after laparoscopic repair.

The main difference between the original HTA report and the present update is in the availability of data describing longer-term persisting pain and persisting numbness. Meta-

analysis of these data suggests the risk of both is reduced by laparosopic repair. These findings are also supported by the five-year follow-up data from one large UK trial.[66]

The results of the updated meta-analyses (including consideration of persisting pain and numbness) have been incorporated into the economic model outlined in Chapter 5. The base case analysis and much of the sensitivity analysis suggest that the mean incremental cost per QALY for TEP compared to open flat mesh repair is less than £10,000 and that there is approximately an 80% chance that TEP is the most cost-effective intervention, should society's maximum willingness to pay for an additional QALY be £20,000. The results were most sensitive to assumptions about the disutility associated with long-term persisting pain and persisting numbness. When long-term persisting pain and persisting numbness are excluded from the model the results are similar to those that formed the basis of the 2001 assessment, that is that it is unlikely that laparoscopic repair would be associated with an incremental cost per QALY of less than £50,000.

A concern with laparoscopic repair is the possible increased risk of rare but serious intraoperative complications. The evidence suggests that the risk of these may be greater during TAPP than TEP.

New evidence has also become available on the strengths of patients' preferences for the various outcomes, based on a discrete choice experiment.[136] This showed that people facing surgical hernia repair wish to avoid, in particular, the risk of serious complications. When the discrete choice experiment preference weights (rather than the utility estimates derived from the MRC Laparoscopic Groin Hernia Trial Group[96]) are incorporated in the model, neither TAPP nor TEP were associated with a mean net benefit compared with open flat mesh and the results of a probabilistic analysis showed that there was a 40% chance that TEP would be preferred to open flat mesh and a 3% chance that TAPP would be preferred to TEP.

The evidence comparing TAPP with TEP directly was sparse. For this reason the economic modelling depended on indirect comparisons. The economic model tended to favour TEP

but minor changes in the assumptions would change the balance. For example, assuming that duration of operation and length of hospital stay were the same for the two procedures removed the cost advantage of TEP.

For the open procedures, most of the data related to comparisons of laparoscopic repair with open flat mesh. Estimates for open preperitoneal mesh repair and open plug and mesh repair were based on very limited data and therefore unlikely to be reliable. There is no clear evidence that the various open approaches differ in respect to comparative performance with laparoscopic repair. For this reason the report has concentrated on the comparison of laparoscopic repair with open flat mesh repair (currently the most commonly used open procedure).

There were some new data for the repair of recurrent hernias. However, these data were still sparse. On the basis of what was available, TEP was the dominant intervention. But the results are unreliable, and in these circumstances extrapolation from the base case for primary hernia repair may provide the best available evidence base.

It is plausible that, for management of symptomatic bilateral hernias, laparoscopic repair would become relatively more cost-effective as differences in operation time (a key cost driver) may be reduced and the difference in convalescence time may become more marked (hence QALYs will increase). For occult contralateral hernias the analysis was conducted for a five-year time horizon only. This analysis showed that on average TEP dominated TAPP but was more costly and more effective than open flat mesh. The mean incremental cost per QALY of TEP compared with open flat mesh was less than £10,000 in sensitivity analyses conducted over a range of plausible estimates of prevalence and progression of occult hernias. Overall, TEP repair is most likely to be considered cost-effective at threshold values for the cost per additional QALY above £20,000. Nonetheless, the results are based on estimates of prevalence and risk of progression of occult hernias for which data are limited.

Little data were available for sub-group analysis by gender or age. There was no specific relative effect size data for age or gender. There is no reason to believe that costs of the procedures will vary by gender, and cost estimates for younger (age 40) and older (age 75) were close to the base case results (age 57).

8.2 Assumptions, limitations and uncertainties

The systematic review of effectiveness was based on meta-analyses using a fixed effects model. This approach assumed that there was little heterogeneity between the study populations and that each study was attempting to assess the same true differences between the trial arms. A sensitivity analysis using a random effects model was conducted and showed that there was little effect on estimated differential effects, although the confidence intervals were widened. The meta-analyses also did not attempt to adjust for variation in study methodological quality as it was concluded that the validity of the results was not seriously threatened.

As mentioned above, the data available were very limited for some of the outcomes and for some of the sub-groups and insufficient to draw firm conclusions about the relative effectiveness of the techniques being compared. Further work could use sources of data other than RCTs to try to address these issues.

In respect of persisting pain and numbness the findings were based on predominantly unpublished data using differing definitions of severity of pain and numbness. Furthermore, few data are available beyond a one year follow-up. Only one report of five-year follow-up was available and these results were consistent with the meta-analyses.[66] It is anticipated that another large multi-centre trial will be reporting these data shortly.[96] A non-randomised study carried out in Scotland using a postal questionnaire to patients who had undergone hernia repair with either TEP or open mesh repair, support the findings of less persisting pain after laparoscopic repair.[139] As was noted above in Section 8.1, long-term outcomes such as these are particularly important in terms of cost-effectiveness where patients may be living many years with such morbidity. Longer follow-up data is required to confirm these findings and provide more reliably estimates of prevalence.

Data describing hernia recurrence were available from the majority of trials. While this showed no evidence of a statistically significant difference between the laparoscopic and open repair the confidence interval did not rule out a clinically important difference. Furthermore, the data mostly relate to only a one-year time horizon. More long-term follow-up data are therefore required before it is certain that there is no difference in this respect.

Very meagre data were available for the direct comparison of TAPP and TEP. Although attempts were made to identify non randomised evidence for the comparison of TAPP and TEP, the data identified were heterogeneous and their ability to control selection biases was limited. The paucity of data highlights the need for more studies for these comparisons.

Laparoscopic repair is technically more difficult than open repair and there is evidence of a 'learning curve' in its performance. The cost effectiveness (and also almost certainly the safety) of laparoscopic repair is influenced by where operators are on their learning curves. The literature on operator learning of laparoscopic methods was reviewed and the effect, for example in terms of length of operation, incorporated into the model in a sensitivity analysis. This showed that for a less experienced surgeon there was over a 70% chance that TEP (and over 20% chance that TAPP) would be considered cost-effective if society were willing to pay more than £30,000 for an additional QALY.

Determining which open mesh repair method is superior was not within the remit of this review. Most of the trial data came from comparison of laparoscopic repair with open flat mesh repair, and data for the other open mesh techniques were too few to be reliable. Access to trial data directly comparing the alternative open mesh techniques might have improved this.

As with any economic evaluation a number of assumptions have been made both with respect to the structure of the model and the data used. One of the main structural assumptions was that an individual would experience a maximum of three operations and that the third operation would not fail. For the rates of recurrence used in this model this

did not appear to cause a problem. A further structural assumption related to the omission of serious complications. However, sensitivity analysis showed even extreme assumptions about the effect of these had a minimal impact on the incremental cost per QALY.

One concern about the economic model is the quantity and quality of data available. As mentioned above the data available for some of the sub-groups and for open plug and mesh as well as open preperitoneal mesh were imprecise and unreliable. While the imprecision has been incorporated into the model, the issue of reliability remains. It is for this reason that it was felt most appropriate to limit the economic evaluation to comparisons of open flat mesh with TAPP and TEP. Ideally more studies are required that compare open plug and mesh and open preperitoneal mesh to TAPP and TEP.

The nature of the data available also had an impact on the economic evaluation. In the base case analysis it was assumed that baseline event rates could be extrapolated for up to 25 years. While these assumptions appeared to be in accordance with the limited data available these were all extrapolated. For this reason the base case results were also presented for a five year time horizon, which is consistent with the time period for which data are available. Further assumptions were made about the duration over which relative effects would persist. These assumptions were tested in a series of sensitivity analyses and it was found that varying them did not substantially alter the results.

There is also a concern about the data chosen for baseline event rates. Ideally, baseline event data should have related to the same intervention for all events of interest, and have come from the same source. Such data were not available and as a result data were identified from the best available source. For all events apart from recurrences the baseline event data related to open flat mesh. For recurrences, superior data were available from the Swedish registry. However, these data related to TAPP. Computationally this does not cause problems as the appropriate relative effect sizes can still be used to estimate the required absolute rates for the other interventions under consideration.

A further concern about baseline rates used in the model relates to rates used for long-term persisting pain and long-term numbness. The baseline rates for these parameters were derived from a single source and were measured on a crude five point scale. For pain this included (i) none; (ii) very mild (iii) mild (iv) severe (v) very severe and for numbness the scale covered (i) not at all (ii) slightly (iii) moderately (iv) quite a lot (v) extremely. Estimates of the risk of pain for the baseline comparator were based on points (iv) and (v). Had a less strict definition of long-term pain and long-term numbness been used (e.g. any vs none) then the laparoscopic procedures would have appeared more cost-effective.

The base case analysis used data on costs and utility weights from a single study. This naturally raises concerns about whether such data are typical after hernia repair. Furthermore, sensitivity analysis showed that the values assumed for the utility weights for long-term persisting pain and numbness were key determinants of cost-effectiveness. The utility weights were extrapolated from data describing patients with pain and numbness at three months postoperatively. Direct measurements of utility at one year (or later) would have strengthened the model. Data from a discrete choice experiment provided information on the strength of patients preferences for a range of parameters. This showed that risk of serious complication, which had limited effect on QALY estimates, was highly important and was the key determinant of net benefit when these data were incorporated into the economic model. This work raises two questions (i) are the utilities used to estimate QALYs generalisable to the UK? and (ii) given the potential increased risk of rare serious complications from TAPP and TEP, are the laparoscopic techniques acceptable to informed patients?

9 Conclusions

9.1 Implications for the NHS

- To an important extent, the use of laparoscopic inguinal hernia repair within the NHS will depend on judgements about the balance of costs, benefits and risks.
- Laparoscopic repair costs more than mesh repair (the current standard). This is principally because it takes longer to perform. Using disposable equipment and keeping patients overnight increase this difference. The difference may be reduced if experienced surgeons perform laparoscopic surgery.
- Both laparoscopic and open mesh methods utilise mesh to reinforce the repair. The chances of hernia recurrence appear to be similar after each type of procedure.
- Laparoscopic repair is associated with short-term benefits, in terms of the postoperative pain and more rapid return to usual activities.
- Data newly available since the HTA report considered by NICE in 2001 show that laparoscopic repair also has longer-term benefits in terms of a lower risk of persisting groin pain and persisting numbness.
- The risk of some potentially serious intraoperative complications appears to be higher during laparoscopic repair, particularly TAPP (overall estimates 7.9 per 1000 versus 1.4 per 1000).
- There is a scarcity of data comparing laparoscopic TAPP and TEP and the choice between laparoscopic approaches would therefore be based on clinical decisions.
- Most data describe open flat mesh repair, but there appear to be no differences in analyses in this report stratified by method of open repair.
- An economic model relating benefits to costs suggested that it was likely that an additional QALY would cost more than £10,000; this is sensitive to whether or not persisting pain and numbness are considered. When they are not, the model suggests that an additional QALY would cost over £50,000.
- There are clinical arguments for the selective use of laparoscopic repair. This may apply to recurrent hernias but the data was too sparse to address this reliably. The use of laparoscopic repair for bilateral hernias avoids two incisions and the recovery advantages may be more marked. Routine identification and repair of 'occult'

contralateral hernias during laparoscopic repair is controversial and the estimates of cost-effectiveness are subject to the assumptions made about prevalence and likely progress to clinical symptoms.

- Increased adoption of laparoscopic hernia repair would require additional surgeons proficient in the technique. It is likely that some of the higher rates of potentially serious complications, e.g. bladder injuries, reported for laparoscopic repair are associated with a 'learning curve'. Appropriate and supervised training will therefore be needed for surgeons new to the operation, in respect of both the technical aspects of the procedure and the choice of patients suitable for the operation.
- The training of surgeons in techniques for laparoscopic hernia repair might also provide useful skills and experience which are transferable to other laparoscopic procedures.

9.2 Implications for patients and carers

- Laparoscopic hernia repair has the advantage that it is less invasive than open mesh hernia repair but is usually performed under general anaesthesia.
- Any reduction in the time required to recover after a hernia repair may reduce the time and effort that a patient's family or other carers devote to care, following discharge from hospital.
- The use of a laparoscopic approach to repair inguinal hernia is associated with an easier convalescence, less pain and a more rapid return to usual activities but possibly an increased risk of serious complications. Those who experience financial hardship as a result of time away from employment may prefer laparoscopic repair. In addition, some employers may welcome an earlier return to work of their employees.

9.3 Implications for research

- Direct measurements of utilities at one year and later are required to confirm the study findings.
- The issue of chronic pain after inguinal hernia repair should be addressed prospectively using standard definitions and allow for the assessment of the degree of pain.
- Rare, serious complications are an important consideration in the context of minor surgery. Even consideration of RCTs involving over 5000 participants gives imprecise

estimates; prospective population-based registries of new surgical procedures may be the best way to address this general issue.

- More data from methodologically sound RCTs comparing laparoscopic TAPP with laparoscopic TEP techniques would be valuable.
- Further research is required relating to whether the balance of advantages and disadvantages of alternative surgical approaches change when hernias are recurrent or bilateral.
- Laparoscopic groin hernia repair, like most other surgical procedures, is technically challenging and performance is likely to improve with experience. This issue is important in its evaluation, and further methodological research related to this is warranted in the context of both trials and meta-analyses of trials.
- Unlike most surgical procedures, laparoscopic inguinal hernia repair has been tested in a large number of RCTs. These provide a reliable evidence base which demonstrates the feasibility and value of RCTs for assessing the effectiveness of surgical interventions.

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APPENDIX 1 LITERATURE SEARCH STRATEGIES

A Search strategies for clinical effectiveness

A.1 MEDLINE (2000 - June Week 1 2003) EMBASE (2000 – Week 23 2003) Ovid Multifile Search
URL: http://gateway.ovid.com/athens

1 hernia,inguinal/su

2 (inguinal or groin).tw.

3 hernioplasty/ use emez

4 herniorrhaphy/ use emez

5 hernioplasty.tw.

6 herniorrhaphy.tw.

7 (hernia adj3 repair).tw.

8 2 and (3 or 4 or 5 or 6 or 7)

9 1 or 8

10 (tapp or transabdominal or preperitoneal or transperitoneal).tw.

11 (tep or totally extraperitoneal).tw.

12 2 and (10 or 11)

13 laparoscopy/

14 laparoscopic surgery/ use emez

15 endoscopy/

16 endoscopic surgery/ use emez

17 Video-Assisted Surgery/

18 (laparoscop$ or endoscop$ or video$).tw.

19 13 or 14 or 15 or 16 or 17 or 18

20 9 and 19

21 12 or 20

22 randomized controlled trial.pt. use mesz

23 controlled clinical trial.pt. use mesz

24 randomized controlled trials/

25 random allocation/

26 double blind method/

27 single-blind method/

28 clinical trial.pt. use mesz

29 22 or 23

30 exp clinical trials/

31 exp controlled study/ use emez

32 (clin$ adj25 trial$).tw.

33 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.

34 random$.tw.

35 research design/ use mesz

36 comparative study/

37 exp evaluation studies/

38 follow up studies/

39 (control$ or prospectiv$ or volunteer$).tw.

40 or/22-39

41 animal/ not human/ use mesz

42 (animal/ or nonhuman/) not human/ use emez

43 40 not (41 or 42)

44 21 and 43

45 remove duplicates from 44

Supplementary search for TAPP vs TEP comparison

1 (tapp or transabdominal or preperitoneal or transperitoneal).tw.

2 (tep or totally extraperitoneal).tw.

3 (inguinal or groin).tw

4 1 and 2 and 3

A.2 MEDLINE Extra (June 13th 2003)

Ovid URL: http://gateway.ovid.com/athens

1 (inguinal or groin).tw.

2 hernioplasty.tw.

3 herniorrhaphy.tw.

4 (hernia adj3 repair).tw.

5 tapp or transabdominal or preperitoneal or transperitoneal).tw.

6 (tep or totally extraperitoneal).tw.

7 1 and (2 or 3 or 4)

8 1 and (5 or 6)

9 (laparoscop$ or endoscop$ or video$).tw.

10 7 and 9

11 8 or 10

A.3 CINAHL (1982 – June Week 1 2003)
Ovid URL: http://gateway.ovid.com/athens

1 hernia,inguinal/su
2 (inguinal or groin).tw.
3 hernioplasty.tw.
4 herniorrhaphy.tw.
5 (hernia adj3 repair).tw.
6 2 and (3 or 4 or 5)
7 1 or 6
8 (tapp or transabdominal or preperitoneal or transperitoneal).tw.
9 (tep or total$ extraperitoneal).tw.
10 2 and (8 or 9)
11 laparoscopy/
12 surgery,laparoscopic/
13 endoscopy/
14 (laparoscop$ or endoscop$ or video$).tw.
15 11 or 12 or 13 or 14
16 7 and 15
17 10 or 16

A.4 BIOSIS (1985 - 18th June2003)
Edina URL: http://edina.ac.uk/biosis/

(((((((al: transperitoneal) or (al: tapp or al: transabdominal or al: preperitoneal))) and
(al: tep or al: extraperitoneal))) and (al: inguinal or al: groin))
or
(((al: random* or al: control* or al: trial*) and
(((((((((al: transperitoneal) or (al: tapp or al: transabdominal or al: preperitoneal))) or (al: tep or al:
extraperitoneal)))and (al: inguinal or al: groin)))or
((((((al: repair) or (al: hernia* or al: hernioplasty or al: herniorrhaphy))) and
(al: laparoscop* or al: endoscop* or al: video*))and(al: inguinal or al: groin))))))))

A.5 Science Citation Index 1981 – 21st June 2003

Web of Science Proceedings 1990 – 19th June 2003
Web of Knowledge URL: http://wok.mimas.ac.uk/

(((inguinal or groin) and (hernioplasty or herniorrhaphy or repair)) and (laparoscop* or endoscop* or video*)) and (random* or trial* or control*)

or

((tapp or transabdominal or preperitoneal or transperitoneal) and (tep or extraperitoneal)) and hernia

A.6 Cochrane Library Issue 2, 2003

URL: http://www.update-software.com/clibng/cliblogon.htm

#1 HERNIA INGUINAL [su] single term (MeSH)

#2 (inguinal or groin)

#3 (hernioplasty or herniorrhaphy)

#4 (hernia near repair)

#5 (#1 or (#2 and (#3 or #4)))

#6 LAPAROSCOPY single mesh (MeSH)

#7 ENDOSCOPY single mesh (MeSH)

#8 VIDEO-ASSISTED SURGERY single term (MeSH)

#9 (laparoscop* or endoscop* or video*)

#10 (#5 and (#6 or #7 or #8 or #9))

#11(tapp or transabdominal or preperitoneal or transperitoneal)

#12 (total* next extraperitoneal)

#13 tep

#14 #2 and (#11 or #12 or #13)

#15 #10 or #14

#16 (#11 and (#12 or #13))

#17 (#1 or #2 or #3 or #4)

#18 #16 and #17

#19 #15 or #18

A.7 DARE and HTA Database (June 2003)
NHS Centre for Reviews & Dissemination
URL:http://nhscrd.york.ac.uk/welcome.htm

Hernia-inguinal

Or

(inguinal or groin) and herni*

A.8 National Research Register (Issue 2, 2003)
URL: http://www.update-software.com/National/

#1 HERNIA INGUINAL [su] single term (MeSH)

#2 (inguinal or groin)

#3 (hernioplasty or herniorrhaphy)

#4 (hernia near repair)

#5 (#1 or (#2 and (#3 or #4)))

#6 LAPAROSCOPY single mesh (MeSH)

#7 ENDOSCOPY single mesh (MeSH)

#8 VIDEO-ASSISTED SURGERY single term (MeSH)

#9 (laparoscop* or endoscop* or video*)

#10 (#5 and (#6 or #7 or #8 or #9))

#11(tapp or transabdominal or preperitoneal or transperitoneal)

#12 (total* next extraperitoneal)

#13 tep

#14 #2 and (#11 or #12 or #13)

#15 #10 or #14

#16 (#11 and (#12 or #13))

#17 (#1 or #2 or #3 or #4)

#18 #16 and #17

#19 #15 or #18

A.9 Clinical Trials (May 2003)URL: http://clinicaltrials.gov/ct/gui/c/r
Current Controlled Trials (May 2003)
URL: http://www.controlled-trials.com/

Research Findings Register (May 2003) URL:
http://tap.ukwebhost.eds.com/doh/refr_web.nsf/Home?OpenForm

Inguinal or groin or herni*

A.10 Journals@Ovid Full Text (July 15h 2003)
Ovid URL: http://gateway.ovid.com/athens

Journals searched:

Annals of Surgery 1996 – July 2003

Archives of Surgery 1995 – June 2003

British Journal of Surgery + Supplements 1995 – June 2003

Surgical Laparoscopy 1996 – June 2003

1 (inguinal or groin).tw.

2 hernioplasty.tw.

3 herniorrhaphy.tw.

4 (hernia adj3 repair).tw.

5 tapp or transabdominal or preperitoneal or transperitoneal).tw.

6 (tep or totally extraperitoneal).tw.

7 1 and (2 or 3 or 4)

8 1 and (5 or 6)

9 (laparoscop$ or endoscop$ or video$).tw.

10 (random$ or control$ or trial$).tw

11 7 and 9 and 10

12 8 or 11

A.11 SpringerLink (July 16th 2003)
URL: http://www.springerlink.com/

Journal searched:

Surgical Endoscopy 1996-June 2003

Hernia* or hernio*

A.12 Handsearching

The following conference proceedings were handsearched:

Association of Endoscopic Surgeons of Great Britain & Ireland (AESGBI)

Autumn Meeting, Bath,UK, 1999

Spring Meeting, Cardiff, UK, 2000

Spring Meeting, Birmingham,UK, 2001

Autumn Meeting, Guilford, UK, 2001

Annual Meeting, Dublin, UK, 2002

Annual Meeting, Edinburgh,UK, 2003

International Congress of the European Association for Endosopic Surgery (EAES)

8th Annual Meeting, Nice, 2000

9th Annual Meeting, Maastricht, 2001

10th Annual Meeting, Lisbon, 2002

Scientific Session of the Society of American Gastrointestinal & Endoscopic Surgeons (SAGES)

Annual Meeting, St Louis, 2001

Annual Meeting, New York, 2002

Annual Meeting, Los Angeles, 2003

Italian Society of Endosopic Surgery

7th Annual Congress, Urbio, 2001

B Search Strategies for Economic Evaluations

B.1 MEDLINE (2000 - July Week 2 2003) EMBASE (2000 – Week 28 2003) Ovid Multifile Search URL: http://gateway.ovid.com/athens

1 hernia,inguinal/su

2 (inguinal or groin).tw.

3 hernioplasty/ use emez

4 herniorrhaphy/ use emez

5 hernioplasty.tw.

6 herniorrhaphy.tw.

7 (hernia adj3 repair).tw.

8 2 and (3 or 4 or 5 or 6 or 7)

9 1 or 8

10 (tapp or transabdominal or preperitoneal or transperitoneal).tw.

11 (tep or total$ extraperitoneal).tw.

12 2 and (10 or 11)

13 laparoscopy/

14 laparoscopic surgery/ use emez

15 endoscopy/

16 endoscopic surgery/ use emez

17 Video-Assisted Surgery/

18 (laparoscop$ or endoscop$ or video$).tw.

19 13 or 14 or 15 or 16 or 17 or 18

20 9 and 19
21 12 or 20
22 economics/
23 exp "costs and cost analysis"/ use mesz
24 exp economics,hospital/ use mesz
25 exp budgets/
26 exp economic evaluation/ use emez
27 exp hospital cost/ use emez
28 ec.fs. use mesz
29 exp models,economic/ use mesz
30 monte carlo method/
31 markov chains/
32 exp quality of life/
33 value of life/ use mesz
34 health status/
35 health status indicators/ use mesz
36 cost of illness/
37 (cost? adj3 (analys?s or evaluat$ or effective$ or utilit$ or benefit$ or minimi$)).tw.
38 cost$.ti.
39 (price or pricing$).tw.
40 (financial or finance or finances or financed).tw.
41 (fee or fees).tw.
42 (value adj2 (money or monetary)).tw.
43 (economic adj3 (analys?s or evaluat$ or effectiveness)).tw.
45 (decision$ adj2 (tree$ or analy$ or model$)).tw.
46 (quality adj2 life).tw.
47 (qol or qaly? or qald? or qale? or qtime?).tw.
48 (euroqol or hql or hqol).tw.
49 (health adj3 (indicator? or status or utilit$)).tw.
50 qwb.tw.
51 or/22-50
52 21 and 51
53 remove duplicates from 52

B.2 MEDLINE Extra (July 17th 2003)

Ovid URL: http://gateway.ovid.com/athens

1 (inguinal or groin).tw.

2 hernioplasty.tw.

3 herniorrhaphy.tw.

4 (hernia adj3 repair).tw.

5 tapp or transabdominal or preperitoneal or transperitoneal).tw.

6 (tep or totally extraperitoneal).tw.

7 1 and (2 or 3 or 4)

8 1 and (5 or 6)

9 (laparoscop$ or endoscop$ or video$).tw.

10 7 and 9

11 8 or 10

12 (cost? adj3 (analys?s or evaluat$ or effective$ or utilit$ or benefit$ or minimi$)).tw.

13 cost$.ti.

14 (price or pricing$).tw.

15 (financial or finance or finances or financed).tw.

16 (fee or fees).tw.

17 (value adj2 (money or monetary)).tw.

18 (economic adj3 (analys?s or evaluat$ or effectiveness)).tw.

19 (decision$ adj2 (tree$ or analy$ or model$)).tw.

20 (quality adj2 life).tw.

21 (qol or qaly? or qald? or qale? or qtime?).tw.

22 (euroqol or hql or hqol).tw.

23 (health adj3 (indicator? or status or utilit$)).tw.

24 qwb.tw.

25 or/12-24

26 11 and 25

B.3 NHS EED (July 2003)

NHS Centre for Reviews & Dissemination

URL:http://nhscrd.york.ac.uk/welcome.htm

Hernia-inguinal

Or

(inguinal or groin) and herni*

B.4 Health Management Information Consortium (July 2003)
Ovid URL: http://gateway.ovid.com/athens

1 Hernia/

2 ((inguinal or groin) and hernia).tw

3 (hernioplasty or herniorrhaphy or hernia adj2 repair$).tw

4 or/1-3

B.5 Journals@Ovid Full Text (July 17h 2003)
Ovid URL: http://gateway.ovid.com/athens

Journals searched:

Annals of Surgery 1996 – July 2003

Archives of Surgery 1995 – June 2003

British Journal of Surgery + Supplements 1995 – June 2003

Surgical Laparoscopy 1996 – June 2003

1 (inguinal or groin).tw.

2 hernioplasty.tw.

3 herniorrhaphy.tw.

4 (hernia adj3 repair).tw.

5 tapp or transabdominal or preperitoneal or transperitoneal).tw.

6 (tep or totally extraperitoneal).tw.

7 1 and (2 or 3 or 4)

8 1 and (5 or 6)

9 (laparoscop$ or endoscop$ or video$).tw.

10 7 and 9

11 8 or 10

12 (cost? adj3 (analys?s or evaluat$ or effective$ or utilit$ or benefit$ or minimi$)).tw.

13 cost$.ti.

14 (price or pricing$).tw.

15 (financial or finance or finances or financed).tw.

16 (fee or fees).tw.

17 (value adj2 (money or monetary)).tw.

18 (economic adj3 (analys?s or evaluat$ or effectiveness)).tw.

19 (decision$ adj2 (tree$ or analy$ or model$)).tw.

20 (quality adj2 life).tw.

21 (qol or qaly? or qald? or qale? or qtime?).tw.

22 (euroqol or hql or hqol).tw.

23 (health adj3 (indicator? or status or utilit$)).tw.

24 qwb.tw.

25 or/12-24

26 11 and 25

C Search strategies for learning curves

C.1 MEDLINE (1966 - July Week 2 2003) EMBASE (1980 – Week 29 2003) Ovid Multifile Search
URL: http://gateway.ovid.com/athens

1 hernia,inguinal/su
2 (inguinal or groin).tw.
3 hernioplasty/ use emez
4 herniorrhaphy/ use emez
5 hernioplasty.tw.
6 herniorrhaphy.tw.
7 (hernia adj3 repair).tw.
8 2 and (3 or 4 or 5 or 6 or 7)
9 1 or 8
10 (tapp or transabdominal or preperitoneal or transperitoneal).tw.
11 (tep or total$ extraperitoneal).tw.
12 2 and (10 or 11)
13 laparoscopy/
14 laparoscopic surgery/ use emez
15 endoscopy/
16 endoscopic surgery/ use emez
17 Video-Assisted Surgery/
18 (laparoscop$ or endoscop$ or video$).tw.
19 13 or 14 or 15 or 16 or 17 or 18
20 9 and 19
21 12 or 20
22 clinical competence/
23 surgical training/ use emez
24 surgery/ed use mesz
25 (learn$ adj3 curve$).tw.
26 (learn$ adj3 (effect$ or rate? or method?)).tw.
27 (skill? adj3 (acquir$ or acquisit$ or develop$)).tw.
28 (competence adj3 (acquir$ or acquisit$ or develop$)).tw.
29 (expertise adj3 (acquir$ or acquisit$ or develop$)).tw.
30 (error? or mistake?).tw.
31 (surgeon? adj3 (experience? or expertise or skill? or competence)).tw.
32 training.tw.
33 or/22-32

34 21 and 33

35 remove duplicates from 34

C.2 Science Citation Index 1981 – 21st June 2003
Web of Knowledge URL: http://wok.mimas.ac.uk/

(((tapp or transabdominal or preperitoneal or transperitoneal or tep or extraperitoneal) and hernia*) or ((hernia* or hernio*)
and (laparoscop* or endoscop* or video*)))
and
((learning same (curve* or effect* or rate* or method*) or
(skill* or expertise or competence) same (acquir* or acquisit* or develop*)
or (surgeon* same (experience or expertise or skill* or competence*))
or (error* or mistake* or training))

The following Websites were searched for evidence-based reports (accessed June 2003):

Alberta Heritage Foundation for Medical Research URL: http://www.ahfmr.ca/

ASERNIP-S URL: http://www.surgeons.org/asernip-s/

Association of Endoscopic Surgeons of Great Britain and Ireland URL:http://www.aesgbi.org/

Blue Cross Blue Shield Technology Evaluation Center URL:
http://www.bcbs.com/tec/tecassessments.html

CCOHTA URL: http://www.ccohta.ca/

Centers for Medicare & Medicaid Services URL:
http://cms.hhs.gov/mcd/index_list.asp?list_type=tech

ECRI URL: http://www.ecri.org/

Ethicon URL:http://www.ethicon.com/

European Association of Endoscopic Surgeons URL:http://www.eaes-eur.org/

Society of American Gastrointestinal Endoscopic Surgeons URL: http://www.sages.org/

SUMSEARCH URL: http://sumsearch.uthscsa.edu

TRIP database URL: http://www.update-software.com/scripts/clibng/usauth.exe?Server=TRIPUSER&Product=TRIP&Guest=YES

APPENDIX 2 STUDY ELIGIBILITY FORM

NICE Review of the Effectiveness and Cost-Effectiveness of Laparoscopic Surgery for Inguinal Hernia Repair

Study ID:_____**Refman ID:**_____

Type of study

Q1. Is the study a randomised controlled trial or a quasi – randomised controlled trial?

Yes ⇩ Go to Next question | Unclear ⇩ | No ⇩ **Exclude**

Participants in the study

Q2. Were the participants in the study adults with a clinical diagnosis of inguinal hernia for whom surgical management is judged appropriate?

Yes ⇩ Go to Next question | Unclear ⇩ | No ⇩ **Exclude**

Interventions in the study

Q3. Did one group receive a laparoscopic repair?

Yes ⇩ Go to Next question | Unclear ⇩ | No ⇩ **Exclude**

Q4. Did another group receive an open mesh repair or a different type of laparoscopic repair?

Yes ⇩ Go to Next question | Unclear ⇩ | No ⇩ **Exclude**

Outcomes in the study

Q5. Did the study report duration of operation, conversions, intra-operative or post-operative complications, post-operative pain, length of hospital stay, return to usual activities, persisting pain or numbness or hernia recurrence

Yes ⇩ **Include**, subject clarification of 'unclear' points | Unclear ⇩ | No ⇩ **Exclude**

Final decision: Included ☐ Unclear ☐ Excluded ☐

If included:

What are the comparisons? Lap vs Open Mesh ☐ TAPP vs TEP ☐

Is the study included in original review? Yes ☐ No ☐

If yes, please indicate data source: IPD ☐ Additional data ☐ Published data ☐

APPENDIX 3 DATA ABSTRACTION & QUALITY ASSESSMENT FORM

NICE Review of the Effectiveness and Cost-Effectiveness of Laparoscopic Surgery for Inguinal Hernia Repair

_____

Reviewer ID: _____

Study Details
Study ID: **Abstract** ☐ **Full text** ☐ **Unpublished** ☐
Authors:
Title:
Publication year or date of interim data collection:
Language:

Study Design
RCT ☐ **Quasi-RCT** ☐ **Observational study** ☐
Other: _____

Study Methods
Allocation concealment:
Central ☐ **Sealed envelopes** ☐ **Computer generated Nos** ☐ **Random Nos table** ☐
Birthdate ☐ **Alternation** ☐ **Coin toss** ☐ **Not reported** ☐
Other (please give details): _____
Outcome assessor-blinded, where possible: **YES** ☐ **NO** ☐ **Unclear** ☐
Participants lost to follow-up: **YES** ☐ **NO** ☐ **Unclear** ☐
If yes, please give details: _____
Analysis by intention to treat: **YES** ☐ **NO** ☐ **Unclear** ☐
Comments

Participants	
Number of participants randomised or included in study:	
Criteria for inclusion:	**Criteria for exclusion:**

Setting and Timing

Setting of study: _____

The number of laparoscopic procedures performed prior to trial entry: _____

Recruitment period: _____

Follow-up period: _____

Intervention

	Surgical technique	Type of anaesthesia	No of patients
Intervention 1 **Intervention 2** **Intervention 3**			

Patient Characteristics

	Intervention 1	Intervention 2	Intervention 3	Overall
Age (years) **Sex (M/F)** **Unilateral (No)** **Bilateral (No)** **Indirect (No)** **Direct (No)** **Femoral (No)** **Recurrent (No)**				

Outcomes				
	Time Recorded	**Intervention 1**	**Intervention 2**	**Intervention 3**
Short term outcomes: **Duration of operation (min)** **Opposite method initiated (No & specify)** **Conversions (No & specify)** **Visceral injuries (No & specify)** **Vascular injuries (No & specify)** **Post-operative pain** **Haematoma** **Seroma** **Wound/superficial infection** **Mesh/deep infection** **Port site hernia** **Length of hospital stay (days)** **Return to usual activity (days)** **Return to work (days)** *Long-term outcomes*				

Hernia recurrence **Persisting pain** **Persisting numbness** **Quality of life**				

Comments

Contact with author

Date: _____ **Signature:** _____

APPENDIX 4 LIST OF INCLUDED STUDIES: LAPAROSCOPIC VS OPEN MESH

Aitola 1998

Primary reference:

Aitola P, Airo I, Matikainen M. Laparoscopic versus open preperitoneal inguinal hernia repair: a prospective randomised trial. *Ann Chir Gynaecol* 1998;87(1):22-25.

Andersson 2003

Primary reference:

Andersson B, Hall AC, Leveau P, Bergenfelz A, Westerdahl J. Laparoscopic extraperitoneal inguinal hernia repair versus open mesh repair: A prospective randomized controlled trial. *Surgery* 2003;133(5):464-472.

Barkun 1995

Primary reference:

Barkun JS, Wexler MJ, Hinchey EJ, Thibeault D, Meakins JL. Laparoscopic versus open inguinal herniorrhaphy: preliminary results of a randomized controlled trial. *Surgery* 1995;118(4):703-709.

Related references:

Barkun JS, Wexler MJ, Fernandez M, Meakins JL. Laparoscopic vs open inguinal herniorraphy, a randomized controlled trial. *Gastroenterology* 1998;114(4 Part 2):A1378.

Barkun JS, Keyser EJ, Wexler MJ, Fried GM, Hinchey EJ, Fernandez M, Meakins JL. Short-term outcomes in open vs laparoscopic herniorrhaphy: confounding impact of worker's compensation on convalescence. *J Gastrointest Surg* 1999;3(6):575-582.

Barkun JS, Mederios LE, Wexler MJ, Fried GM. Convalesence after inguinal hernia repair. *Surg Endosc* 2001;15(Suppl 1):S30.

Beets 1999

Primary reference:

Beets GL, Dirksen CD, Go PM, Geisler FE, Baeten CG, Kootstra G. Open or laparoscopic preperitoneal mesh repair for recurrent inguinal hernia? A randomized controlled trial. *Surg Endosc* 1999;13(4):323-327.

Bostanci 1998

Primary reference:

Bostanci BE, Tetik C, Ozer S, Ozden A. Posterior approaches in groin hernia repair with prosthesis: open or closed. *Acta Chir Belg* 1998;98(6):241-244.

Bringman 2003

Primary reference:

Bringman S, Ramel S, Heikkinen TJ, Englund T, Westman B, Anderberg B. Tension-free inguinal hernia repair: TEP versus mesh-plug versus Lichtenstein: a prospective randomized controlled trial. *Ann Surg* 2003;237(1):142-147.

Champault 1997

Primary reference:

Champault GG, Rizk N, Catheline JM, Turner R, Boutelier P. Inguinal hernia repair: totally preperitoneal laparoscopic approach versus Stoppa operation: randomized trial of 100 cases. *Surg Laparosc Endosc* 1997;7(6):445-450.

Related references:

Champault G, Rizk N, Catheline JM, Riskalla H, Boutelier P. Groin hernia: pre-peritoneal laparoscopic surgery versus open (Stoppa) procedure. *J Chir (Paris)* 1996;133(6):274-280.

Champault G, Barrat C, Catheline JM, Rizk N. Groin hernias: four-year follow-up of two randomised trials comparing laparoscopic totally preperitoneal approach to Shouldice and Stoppa procedures: 361 cases. *Ann Chir* 1998;52(2):132-136.

Colak 2003

Primary reference:

Colak T, Akca T, Kanik A, Aydin S. Randomized clinical trial comparing laparoscopic totally extraperitoneal approach with open mesh repair in inguinal hernia. *Surg Laparosc Endosc Percutan Tech* 2003;13(3):191-195.

Filipi 1996

Primary reference:

Filipi CJ, Gaston-Johansson F, McBride PJ, Murayama K, Gerhardt J, Cornet DA, Lund RJ, Hirai D, Graham R, Patil K, Fitzgibbons R, Jr., Gaines RD. An assessment of pain and return to normal activity. Laparoscopic herniorrhaphy vs open tension-free Lichtenstein repair. *Surg Endosc* 1996;10(10):983-986.

Gholghesaei 2003

Primary reference:

Gholghesaei M, Essink-Bot ML, van't Riet M, Veldkamp R, Jeekel J, Bonjer HJ. Lichtenstein versus endoscopic inguinal hernia repair: differences in quality of life. *Surg Endosc* 2003;17(Suppl 1):S81.

Related reference:

Gholghesaei M, Essink-Bot ML, van't Riet M, Veldkamp R, Jeekel J, Bonjer HJ. Lichtenstein versus endoscopic inguinal hernia repair: differences in quality of life. *Surg Endosc* 2002;16(Suppl 1):S308.

Gontarz 1998

Primary reference:

Gontarz W, Wolanski L, Leksowski K. A comparison of two 'tension free' inguinal hernia repair methods. *Br J Surg* 1998;85(Suppl II):18.

Heikkinen (1) 1998

Primary reference:

Heikkinen TJ, Haukipuro K, Hulkko A. A cost and outcome comparison between laparoscopic and Lichtenstein hernia operations in a day-case unit. A randomized prospective study. *Surg Endosc* 1998;12(10):1199-1203.

Heikkinen (2) 1998

Primary reference:

Heikkinen TJ, Haukipuro K, Koivukangas P, Hulkko A. A prospective randomized outcome and cost comparison of totally extraperitoneal endoscopic hernioplasty versus Lichtenstein hernia operation among employed patients. *Surg Laparosc Endosc* 1998;8(5):338-344.

Heikkinen 1997

Primary reference:

Heikkinen T, Haukipuro K, Leppala J, Hulkko A. Total costs of laparoscopic and lichtenstein inguinal hernia repairs: a randomized prospective study. *Surg Laparosc Endosc* 1997;7(1):1-5.

Jess 2000

Primary reference:

Jess P, Schultz K, Bendtzen K, Nielsen OH. Systemic inflammatory responses during laparoscopic and open inguinal hernia repair: a randomised prospective study. *Eur J Surg* 2000;166(7):540-544.

Khoury 1998

Primary reference:

Khoury N. A randomized prospective controlled trial of laparoscopic extraperitoneal hernia repair and mesh-plug hernioplasty: a study of 315 cases. *J Laparoendosc Adv Surg Tech A* 1998;8(6):367-372.

Koninger 1998

Primary reference:

Koninger JS, Oster M, Butters M. Management of inguinal hernia--a comparison of current methods. *Chirurg* 1998;69(12):1340-1344.

Lal 2003

Primary reference:

Lal P, Kajla RK, Chander J, Saha R, Ramteke VK. Randomized controlled study of laparoscopic total extraperitoneal vs open Lichtenstein inguinal hernia repair. *Surg Endosc* 2003;17(6):850-856.

Laporte 1997

Primary reference:

Laporte E, Miras M, Ramirez JM, Segura J, Semeraro C, Vicens C. Comparison of the anterior approach versus transabdominal laparoscopy in inguinal hernia repair using preperitoneal polypropylene prostheses. *Cirugia espanola* 1997;61(5):325-328.

Mahon 2001

Primary reference:

Mahon D, Decadt B, Cheadle T, Clarke JM, Speakman C, Stebbings SW, Rhodes M. Prospective randomised trial of laparoscopic (transabdominal preperitoneal - TAPP) versus open (mesh) repair for bilateral and recurrent inguinal hernia. *Surg Endosc* 2001;15(Suppl 1):S102.

Related reference:

Mahon D, Decadt B, Cheadle T, Clarke JM, Speakman C, Stebbings SW, Rhodes M. Prospective randomized trial of laparoscopic (trans-abdominal preperitoneal TAPP) versus open (Lichtenstein) inguinal hernia repair for bilateral and recurrent inguinal hernia. *Br J Surg* 2000;87(Suppl 1):35.

Merello 1997

Primary reference:

Merello J, Guerra AG, Madriz J, Guerra GG. laparoscopic TEP versus open Lichtenstein hernia repair. *Surg Endosc* 1997;11:545.

MRC Multicentre 1999

Primary reference:

Laparoscopic versus open repair of groin hernia: a randomised comparison. The MRC Laparoscopic Groin Hernia Trial Group. *Lancet* 1999;354(9174):185-190.

Related references:

Wright DM, Kennedy A, Baxter JN, Fullarton GM, Fife LM, Sunderland GT, O'Dwyer PJ. Early outcome after open versus extraperitoneal endoscopic tension-free hernioplasty. *Surgery* 1996;119(5):552-557.

Wright DM, Paterson CR, O'Dwyer PJ. Early outcome following open and laparoscopic tension-free hernioplasty - a randomised clinical trial. *Gastroenterology* 1997;112(4 Suppl):A49.

Kumar S, Nixon SJ, MacIntyre IM. Laparoscopic or Lichtenstein repair for recurrent inguinal hernia: one unit's experience. *J R Coll Surg Edinb* 1999;44(5):301-302

Wright D, Hall MG, Paterson C, O'Dwyer PJ. A randomized comparison of driver reaction time after open and endoscopic tension-free inguinal hernia repair. *Surg Endosc* 1999;13(4):332-334.

Scott NW, Grant AM, Ross SJ, Smith A, Macintyre IMC, O'Dwyer PJ. Patient-assessed outcome up to three months in a randomised controlled trial comparing laparoscopic with open groin hernia repair. *Hernia* 2000;4(2):73-79.

Hair A, Taylor S, Wright D, Paterson C, O'Dwyer PJ. Five year outcome following laparoscopic and open hernia repair. *Surg Endosc* 2001;15(Suppl 1):S79.

Wright D, Paterson C, Scott N, Hair A, O'Dwyer PJ. Five-year follow-up of patients undergoing laparoscopic or open groin hernia repair: a randomized controlled trial. *Ann Surg* 2002;235(3):333-337.

Paganini 1998

Primary reference:

Paganini AM, Lezoche E, Carle F, Carlei F, Favretti F, Feliciotti F, Gesuita R, Guerrieri M, Lomanto D, Nardovino M, Panti M, Ribichini P, Sarli L, Sottili M, Tamburini A, Taschieri A. A randomized, controlled, clinical study of laparoscopic vs open tension-free inguinal hernia repair. *Surg Endosc* 1998;12(7):979-986.

Payne 1994

Primary reference:

Payne JH, Jr., Grininger LM, Izawa MT, Podoll EF, Lindahl PJ, Balfour J. Laparoscopic or open inguinal herniorrhaphy? A randomized prospective trial. *Arch Surg* 1994;129(9):973-979.

Related reference:

Payne J, Grininger L, Izawa M, Lindahl PJ, Podoll EF. A randomised prospective comparison between a laparoscopic, preperitoneal and anterior tension-free repair of inguinal hernia. *Surg Laparosc Endosc* 1994;4(6):471-472.

Payne 1996

Primary reference:

Payne J, Izawa M, Glen P, Grininger L, Podoll E, Balfour J. Laprascopic or tension-free inguinal hernia repair. *Society of American Gastrointestinal Endoscopic Surgeons* 1996.

Picchio 1999

Primary reference:

Picchio M, Lombardi A, Zolovkins A, Mihelsons M, La Torre G. Tension-free laparoscopic and open hernia repair: randomized controlled trial of early results. *World J Surg* 1999;23(10):1004-1007.

Ramon 1998

Primary reference:

Ramon JM, Carulla X, Serrano A, Roura J, Castillo J, Solsona, J. Ortega, J.M. Sanchez The endoscopic preperitoneal inguinal hernia repair (TEP). *Br J Surg* 1998;85(Suppl 2):48.

Sarli 1997

Primary reference:

Sarli L, Pietra N, Choua O, Costi R, Thenasseril B, Giunta A. [Prospective randomized comparative study of laparoscopic hernioplasty and Lichtenstein tension-free hernioplasty. Acta Biomed Ateneo Parmense 1997;68(1-2):5-10.

Sarli 2001

Primary reference:

Sarli L, Iusco DR, Sansebastiano G, Costi R. Simultaneous repair of bilateral inguinal hernias: a prospective, randomized study of open, tension-free versus laparoscopic approach. *Surg Laparosc Endosc Percutan Tech* 2001;11(4):262-267.

Schrenk 1996

Primary reference:

Schrenk P, Woisetschlager R, Rieger R, Wayand W. Prospective randomized trial comparing postoperative pain and return to physical activity after transabdominal preperitoneal, total preperitoneal or Shouldice technique for inguinal hernia repair. *Br J Surg* 1996;83(11):1563-1566

Related reference:

Schrenk P, Bettelheim P, Woisetschlager R, Rieger R, Wayand WU. Metabolic responses after laparoscopic or open hernia repair. *Surg Endosc* 1996;10(6):628-632.

SCUR 1999

Primary reference:

Johansson B, Hallerback B, Glise H, Anesten B, Smedberg S, Roman J. Laparoscopic mesh versus open preperitoneal mesh versus conventional technique for inguinal hernia repair: a randomized multicenter trial (SCUR Hernia Repair Study). *Ann Surg* 1999;230(2):225-231.

Rel*ated reference:*

Johansson B, Hallerback B, Glise H, Anesten B, Melen K, Holm J, Bergman B. Laparoscopic mesh repair vs open repair w/wo mesh graft for inguinal hernia (SCUR groin hernia repair study) - preliminary results. *Surg Endosc* 1997;11(2):170.

Simmermacher 2000

Primary reference:

Simmermacher RKJ, Van Duyn EB, Clevers GJ, de Vries LS, van Vroonhoven TJ. Preperitoneal mesh in groin hernia surgery. A randomized clinical trial emphasizing the surgical aspects of preperitoneal placement via a laparoscopic (TEP) or Grid-iron (Ugahary) approach. *Hernia* 2000;4(4):296-298.

Snyder 1998

Primary reference:

Snyder S, Frazee R, Smith R, Symmonds R, Hendricks J, Roberts J, Rajab M. A prospective randomised comparison and long-term follow-up of open and laparoscopic mesh inguinal hernia repair. *Proceedings of the 6th World Congress of Endoscopic Surgery* 1998;(Part 1 & 2):A979-A982.

Suter 2002

Primary reference:

Suter M, Martinet O, Spertin F. Reduced acute inflammatory response after bilateral hernia repair with TEPP compared to Stoppa; a prospective randomised study. *Surg Endosc* 2002;16(Suppl1):S10

Related references:

Suter M, Martinet O, Spertin F. Reduced acute phase response after laparoscopic total extraperitoneal bilateral hernia repair compared to open repair with the Stoppa procedure. *Surg Endosc* 2002;16(8):1214-1219.

Suter M, Martinet O. Postoperative pulmonary dysfunction after bilateral inguinal hernia repair: a prospective randomized study comparing the Stoppa procedure with laparoscopic total extraperitoneal repair (TEPP). *Surg Laparosc Endosc Percutan Tech* 2002;12(6):420-425.

Vatansev 2002

Primary reference:

Vatansev C, Belviranli M, Aksoy F, Tuncer S, Sahin M, Karahan O. The effects of different hernia repair methods on postoperative pain medication and CRP levels. *Surg Laparosc Endosc Percutan Tech* 2002;12(4):243-246.

Wellwood 1998

Primary reference:

Wellwood J, Sculpher MJ, Stoker D, Nicholls GJ, Geddes C, Whitehead A, Singh R, Spiegelhalter D. Randomised controlled trial of laparoscopic versus open mesh repair for inguinal hernia: outcome and cost. *BMJ* 1998;317(7151):103-110.

Related references:

Douek M, Smith G, Oshowo A, Stoker DL, Wellwood JM. Prospective randomized controlled trial of laparoscopic versus open hernia mesh repair: 5-year follow-up. *Br J Surg* 2002;89(Suppl 1):37.

Douek M, Smith G, Oshowo A, Stoker DL, Wellwood JM. Prospective randomised controlled trial of laparoscopic versus open inguinal hernia mesh repair: five year follow up. *BMJ* 2003;326(7397):1012-1013.

Zieren 1998

Primary reference:

Zieren J, Zieren HU, Jacobi CA, Wenger FA, Muller JM. Prospective randomized study comparing laparoscopic and open tension-free inguinal hernia repair with Shouldice's operation. *Am J Surg* 1998;175(4):330-333.

Related references:

Zieren J, Zieren HU, Wenger FA, Muller JM. Laparoscopic or conventional inguinal hernia repair with mesh? *Langenbecks Arch fur Chirurgie* 1996;381(5):289-294.

Zieren J, Zieren HU, Said S, Muller JM. Laparoscopic or conventional inguinal hernia repair with or without implant. *Langenbecks Arch fur Chirurgie* 1996;113(Suppl 2):609-610.

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APPENDIX 5 DETAILED QUALITY ASSESSMENT RESULTS FOR INCLUDED PRIMARY STUDIES

Study	Method of randomisation	Concealment of allocation	Blinding of outcome assessor	Loss-to-follow-up	Analysis by intention-to-treat
Aitola 1998[67]	Alternation	Inadequate	Unclear	Yes	No
Andersson 2003[76]	Sealed envelopes	Adequate	Unclear	Yes	Yes
Barkun 1995[104]	Sealed envelopes	Adequate	Unclear	Unclear	Yes
Beets 1999[68]	Sealed envelopes	Adequate	Unclear	Yes	Yes
Bostanci 1998[84]	Not reported	Unclear	Unclear	Unclear	Unclear
Bringman 2003[95]	Sealed envelopes	Adequate	Unclear	Yes	Unclear
Champault 1997[85]	Random number tables	Inadequate	Unclear	Yes	Unclear
Colak 2003[77]	Computer generated numbers	Adequate	Unclear	Unclear	Unclear
Filipi 1996[50]	Computer generated numbers	Inadequate	Unclear	Yes	Unclear
Gholghessaei 2003[78]	Not reported	Unclear	Unclear	Unclear	Unclear
Gontarz 1998[51]	Not reported	Unclear	Unclear	Unclear	Unclear
Heikkinen (1) 1998[52]	Sealed envelopes	Adequate	Unclear	Unclear	No
Heikkinen (2) 1998[80]	Sealed envelopes	Adequate	Unclear	Unclear	Unclear
Heikkinen 1997[53]	Not reported	Unclear	Unclear	Unclear	Unclear
Jess 2000[54]	Sealed envelopes	Adequate	Unclear	Unclear	Unclear
Khoury 1998[93]	Cards	Inadequate	Unclear	Unclear	No
Koninger 1998[55]	Not reported	Unclear	Unclear	Yes	No

Study	Method of randomisation	Concealment of allocation	Blinding of outcome assessor	Loss-to-follow-up	Analysis by intention-to-treat
Lal 2003[81]	Sealed envelopes	Adequate	Unclear	Unclear	No
Laporte 1997[69]	Birthdate	Inadequate	Unclear	Unclear	Unclear
Mahon 2001[56]	Not reported	Unclear	Unclear	Unclear	Unclear
Merello 1997 [82]	Not reported	Unclear	Unclear	Unclear	Unclear
MRC multi-centre 1999[96]	Central computer randomisation	Adequate	Unclear	Yes	Yes
Paganini 1998[58]	Central computer randomisation	Adequate	Unclear	No	Unclear
Payne 1994[59]	Sealed envelopes	Adequate	Unclear	Unclear	Unclear
Payne 1996[83]	Sealed envelopes	Adequate	Unclear	Yes	Unclear
Picchio 1999[61]	Sealed envelopes	Adequate	Unclear	Yes	Unclear
Ramon 1998[88]	Sealed envelopes	Adequate	Unclear	Unclear	Unclear
Sarli 1997[62]	Sealed envelopes	Adequate	Unclear	Yes	No
Sarli 2001[63]	Sealed envelopes	Adequate	Unclear	Yes	Unclear
Schrenk 1996[109]	Sealed envelopes	Adequate	Unclear	Unclear	Unclear
SCUR 1999[70]	Central computer randomisation	Adequate	Unclear	Yes	Yes
Simmermacher 2000[89]	Not reported	Unclear	Unclear	Unclear	Unclear
Snyder 1998[108]	Central computer randomisation	Adequate	Unclear	Yes	Yes
Suter 2002[90]	Sealed envelopes	Adequate	Unclear	Unclear	Unclear
Vatansev 2002[94]	Sealed envelopes	Adequate	Unclear	Unclear	No
Wellwood 1998[64]	Sealed envelopes	Adequate	Unclear	Yes	Yes
Zieren 1998[72]	Computer generated numbers	Adequate	Unclear	Unclear	Unclear

APPENDIX 6 CHARACTERISTICS OF INCLUDED STUDIES FOR EFFECTIVENESS

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Aitola 1998[67]	Single-centre RCT 60 Participants Follow-up = median 18 months Full text IPD available	TAPP (n=29) versus Open Preperitoneal mesh (n=31)	29/29 General Anaesthetic 10/29 Bilateral 10/29 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 54.52 (16.37) 26 Male/3 Female	16/31 General Anaesthetic 14/31 Regional Anaesthetic (1 not known) 4/31 Bilateral 7/31 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 54.39 (18.06) 26 Male/5 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to usual activities Hernia recurrence
Andersson 2003[76]	Single-centre RCT 168 participants Follow-up = 1 year Full text	TEP (n=87) versus Open flat mesh (n=81)	87/87 General Anaesthetic 3/87 Bilateral 15/87 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 49(9) 81 Male/0 Female	General and Regional Anaesthetic 7/81 Bilateral 13/81 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 50(9) 87 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to work/normal activity Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Barkun 1995[104-107]	Multi-centre RCT 92 participants Follow-up = median 54 months Full text IPD available	Mixed laparoscopic (n=43) versus Mixed Open (n=49) (Choice left to surgeon)	43/43 General Anaesthetic Bilateral - Unknown Recurrent - Unknown 23/43 Direct 19/43 Indirect 1/43 Other Age mean (SD) 49.1(14.7) 42 Male/1 Female	18/49 General Anaesthetic, 31/49 Local/Regional Anaesthetic 49 Bilateral - Unknown 49 Recurrent - Unknown 23/49 Direct 25/49 Indirect 1/49 Other Age mean (SD) 51.4(17) 47 Male/2 Female	Duration of operation Conversions Postoperative pain (day 1) Postoperative complications Length of hospital stay Convalescence Hernia recurrence Quality of life Patient satisfaction
Beets 1999[68]	Single-centre RCT 79 participants Follow-up = mean 21 months, range (8-36) Full text IPD available	TAPP (n=42) versus Open preperitoneal mesh (n=37)	42/42 General Anaesthetic 14/42 Bilateral 42/42 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 58.10 (12.26) 41 Male/1 Female	37/37 General Anaesthetic 13/37 Bilateral 37/37 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 57.86 (12.34) 36 Male/1 Female	Duration of operation Postoperative pain (Day 1-7) Postoperative complications Length of hospital stay Return to usual activities Persisting pain Persisting numbness Hernia recurrence Return to physical activities Mortality

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Bostanci 1998[84]	RCT 64 participants Follow-up = mean (SD) 15 (4-24) months Full text	TEP (n=32) versus Open preperitoneal mesh (n=32)	32/32 General Anaesthetic 3/32 Bilateral 1/35 Recurrent (hernias) Direct 3/34 (primary hernias) Indirect 30/34 (primary hernias) Other 1/34 (primary hernias) Age median (range) 25(20-59) 31 Male/1 Female	General Anaesthetic - Unknown 3/32 Bilateral 5/35 Recurrent (hernias) Direct 2/30 (primary hernias) Indirect 27/30 (primary hernias) Other 1/30 (primary hernias) Age median (range) 31 (20-71) 32 Male/0 Female	Duration of operation Conversions Intraoperative complications Post-operative complications Hernia recurrence Mortality

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Bringman 2003[95]	Multi-centre RCT 299 participants Follow-up = mean (SD) 19.8 months (8.6) Full text	TEP (n=92) versus Open plug and mesh (n=104) versus Open flat mesh (n=103)	92/92 General Anaesthetic 0/92 Bilateral 13/92 Recurrent 34/92 Direct 49/92 Indirect 1/92 Other Age mean (SD) 55(12) 92 Male/0 Female	***1.1.1. Open plug and mesh*** 98/104 General Anaesthetic 6/104 Regional Anaesthetic 0/104 Bilateral 17/104 Recurrent 45/104 Direct 54/104 Indirect 1/104 Other Age mean (SD) 55(12) 104 Male/0 Female ***1.1.2. Open flat mesh*** 100/103 General Anaesthetic 3/103 Regional Anaesthesia 0/103 Bilateral 11/103 Recurrent 44/103 Direct 56/103 Indirect 0/103 Other Age mean (SD) 54(11) 103 Male/0 Female	Duration of operation Conversions Post-operative complications Length of hospital stay Return to work/normal activity Hernia recurrence Persisting pain Persisting numbness

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Champault 1997[85-87]	RCT 100 participants Follow-up = TEP: mean 570 days Open: 610 days Full text	TEP (n=51) versus Open preperitoneal mesh (n=49)	51/51 General Anaesthetic 21/51 Bilateral 20/51 Recurrent 36/51 Direct 15/51 Indirect Age mean (SD) 57.2(40.74) 51 Male/0 Female	49/49 General Anaesthetic Bilateral 24/49 23/49 Recurrent 39/49 Direct 10/49 Indirect Age mean (SD) 61.3(43.77) 49 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to work Hernia recurrence
Colak 2003[77]	Single-centre RCT 134 participants Follow-up = TEP: mean (SD) 12.04(2.84) months, Open: 11.1(2.67) months Full text	TEP (n=67) versus Open flat mesh (n=67)	67/67 General Anaesthetic 21/67 Bilateral 7/67 Recurrent Direct - Unknown Indirect - Unknown Age mean (range) 49.4(21-78) 57 Male/10 Female	67/67 General Anaesthetic 6/67 Bilateral 5/67 Recurrent Direct - Unknown Indirect - Unknown Age mean (range) 51.6(16-77) 62 Male/5 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to usual activities Hernia recurrence Persisting pain Persisting numbness

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Filipi 1996[50]	Multi-centre RCT 53 participants Follow-up = mean (range) 11 (1-24) months Full text IPD available	TAPP (n=24) versus Open flat mesh (n=29)	24/24 General Anaesthetic 0/24 Bilateral Recurrent - Unknown Direct - Unknown Indirect - Unknown Age (mean) 58 24 Male/0 Female	General, Regional or Local Anaesthetic 0/29 Bilateral Recurrent - Unknown Direct - Unknown Indirect - Unknown Age (mean) 57 29 Male/0 Female	Duration of operation Postoperative complications Length of hospital stay Hernia recurrence
Gholghessaei 2003[78,79]	RCT 30 participants Follow-up = Unclear Abstract	TEP (n=13) versus Open flat mesh (n=17)	No data reported	No data reported	Quality of Life
Gontarz 1998[51]	RCT 112 participants Follow-up = median (range) 6(3-11) months Abstract	TAPP (n=62 hernia repairs) versus Open flat mesh (n= 73 hernia repairs)	No data reported	No data reported	Postoperative complications Hernia recurrence
Heikkinen (1) 1998[52]	Single-centre RCT 42 participants Follow-up = median 17 months Full text IPD available	TAPP (n=20) versus Open flat mesh (n=20)	20/20 General Anaesthetic 0/20 Bilateral 0/20 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 49.2 (11.0) 19 Male/1 Female	20/20 Local Anaesthetic 0/20 Bilateral 0/20 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 52.7 (13.0) 20 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to usual activities Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Heikkinen (2) 1998[80]	Single-centre RCT 45 participants Follow-up = median 10 months Full text IPD available	TEP (n=22) versus Open flat mesh (n=23)	22/22 General Anaesthetic 0/22 Bilateral 0/22 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 41.55 (11.90) 22 Male/0 Female	2/23 General Anaesthetic 9/23 Regional Anaesthetic 12/23 Local Anaesthetic 0/23 Bilateral 0/23 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 43.61 (12.30) 23 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to normal activities Persisting pain Persisting numbness Hernia recurrence
Heikkinen 1997[53]	Single-centre RCT 38 participants Follow-up = median 10 months Full text IPD available	TAPP (n=20) versus Open flat mesh (n=18)	20/20 General Anaesthetic 2/20 Bilateral 0/20 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 46.50 (13.13) 19 Male/1 Female	18/18 General Anaesthetic 0/18 Bilateral 0/18 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 48.94 (13.89) 17 Male/1 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to work Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Jess 2000[54]	Single-centre RCT 18 participants Follow-up = 4 weeks Full text	TAPP (n=10) versus Open flat mesh (n=8)	10/10 General Anaesthetic 0/10 Bilateral 4/10 Recurrent 6/10 Direct 4/10 Indirect Age median (range) 61(25-77) 10 Male/0 Female	8/8 General Anaesthetic 0/8 Bilateral 0/8 Recurrent 6/8 Direct 2/8 Indirect Age median (range) 62(41-72) 8 Male/0 Female	Duration of operation Return to usual activities
Khoury 1998[93]	Single-centre RCT 292 participants Follow-up = 36 months Full Text IPD available	TEP (n=150) versus Open plug and mesh (n=142)	150/150 General Anaesthetic 19/150 Bilateral 13/150 Recurrent 41/150 Direct 118/150 Indirect 6/150 Other Age median (range) 48(19-76) 140 Male/10 Female	7/142 General Anaesthetic 4/142 Bilateral 17/142 Recurrent 34/142 Direct 103/142 Indirect 4/142 Other Age median (range) 54(18-80) 132 Male/10 Female	Duration of operation Return to work Postoperative complications Persisting pain Persisting numbness Hernia recurrence
Koninger 1998[55]	Single-centre RCT 186 participants included (280 in total) Follow-up = median 18 months Full text (German) Additional aggregated data available	TAPP (n=93) versus Open flat mesh (n= 93) (The third arm of the trial is not relevant to this review)	94/93 General Anaesthetic Bilateral - Unknown 0/93 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 53(30-74) 94 Male/0 Female	93/93 General Anaesthetic Bilateral - Unknown 0/93 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 53(26-74) 93 Male/0 Female	Duration of operation Postoperative complications Return to work Persisting pain Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Lal 2003[81]	Single centre RCT 50 participants Follow-up = mean (range) 13 (9-18) months Full text	TEP (n=25) versus Open flat mesh (n=25)	24/25 General Anaesthetic 0/25Bilateral 0/25 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 36.72(12.08) 25 Male/0 Female	3/25 General Anaesthetic 0/25Bilateral 0/25Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 37.8(12.43) 25 Male/0 Female	Duration of operation Postoperative complications Length of hospital stay Return to usual activities Return to work Hernia recurrence
Laporte 1997[69]	Multi-centre RCT 402 participants Follow-up = 1 month Full text (Spanish)	TAPP (n=209) versus Open pre-peritoneal mesh (n=183)	General Anaesthetic - Unknown 54/209 Bilateral 49/209 Recurrent 128/209 Direct 77/209 Indirect Age mean (SD) 52(14) 195 Male/14 Female	General Anaesthetic - Unknown 35/183 Bilateral 37/183 Recurrent 94/183 Direct 85/183 Indirect Age mean (SD) 54(15) 168 Male/15 Female	Duration of operation Return to usual activities
Mahon 2001[56,57]	Single-centre RCT 90 participants Follow-up = Unclear Abstract	TAPP (n=45) versus Open flat mesh (n=45)	No data reported	No data reported	Duration of operation Length of hospital stay Return to usual activities Return to work Quality of Life

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Merello 1997[82]	Single-centre RCT 120 participants Follow-up = 'short' Abstract IPD available	TEP (n=60) versus Open flat mesh (n= 60)	60/60 General Anaesthetic 0/60 Bilateral 0/60 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 52.08 (12.58) 60 Male/0 Female	60/60 General Anaesthetic 0/60 Bilateral 0/60 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 52.70 (12.23) 60 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to usual activities Persisting pain Persisting numbness Hernia recurrence
MRCmulticentre 1999[96-103]	Multi-centre RCT 928 participants Follow-up = 60 months Full text IPD available	Mixed laparoscopic (n=468) versus Mixed open repair (n=460) (93/468 TAPP, 295/468 TEP. 93% of mixed open repairs were open mesh repairs)	447/468 General Anaesthetic 2/468 Regional Anaesthetic 4/468 Local Anaesthetic (7 not known) 33/468 Bilateral (8 not known) 56/468 Recurrent (9 not known) Direct - Unknown Indirect - Unknown 9/468 Other Age mean (SD) 55.3(16.1) 441 Male/27 Female	399/460 General Anaesthetic 16/460 Regional Anaesthetic 30/460 Local Anaesthetic (15 not known) 37/460 Bilateral (10 not known) 42/460 Recurrent (12 not known) Direct - Unknown Indirect - Unknown 4/460 Other Age mean (SD) 55.7(16.8) 445 Male/15 Female	Duration of operation Conversions Intraoperative complications Post-operative complications Length of hospital stay Return to usual activities Persisting pain Persisting numbness Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Paganini 1998[58]	Multi-centre RCT 108 participants Follow-up = mean 28 months Full text IPD available	TAPP (n=52) versus Open flat mesh (n=56)	48/52 General Anaesthetic 1/52 Regional Anaesthetic 2/52 Local Anaesthetic (1 not known) 13/52 Bilateral 11/52 Recurrent 33/77 Direct (hernias) 30/77 Indirect (hernias) 14/77 Other (hernias) Age mean (SD) 54(15.3) 48 Male/4 Female	10/56 General Anaesthetic 10/56 Regional Anaesthetic 35/56 Local Anaesthetic (1 not known) 16/56 Bilateral (2 not known) 5/56 Recurrent 33/72 Direct (hernias) 37/72 Indirect (hernias) 2/72 Other (hernias) Age mean (SD) 55.6(15.2) 51 Male/5 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Postoperative pain Length of hospital stay Return to usual activities Persisting pain Persisting numbness Hernia recurrence
Payne 1994[59,60]	Single-centre RCT 100 participants Follow-up = median (range) 10 (7-18) months Full text IPD available	TAPP (n=48) versus Open flat mesh (n=52)	48/48 General Anaesthetic 4/48 Bilateral 6/48 Recurrent Direct - Unknown Indirect - Unknown Age (mean) 46 47 Male/1 Female	3/52 General Anaesthetic 6/52 Bilateral 2/52 Recurrent Direct - Unknown Indirect - Unknown Age (mean) 45 50 Male/2 Female	Duration of operation Conversions Length of hospital stay Complications Time to return to work Persisting numbness Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Payne 1996[83]	RCT 100 participants Follow-up = median (range) 20 (4-40) months Abstract IPD available	TEP (n=51) versus Open flat mesh (n=49)	Anaesthetic - Unknown 9/51 Bilateral 4/51 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 46.4(13.6) Sex - Unknown	Anaesthetic - Unknown 6/49 Bilateral 1/49 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 46.5(14.9) Sex - Unknown	Duration of operation Length of hospital stay Complications Time to return to work Hernia recurrence
Picchio 1999[61]	Single-centre RCT 105 participants Follow-up = 4 weeks Full text	TAPP (n=52) versus Open flat mesh (n=52)	52/52 General Anaesthetic Bilateral - Unknown 0/52 Recurrent 40/52 Direct 12/52 Indirect Age mean (SD) 57.5(11.0) 37 Male/15 Female	52/52 General Anaesthetic Bilateral - Unknown 0/52 Recurrent 37/52 Direct 15/52 Indirect Age mean (SD) 55.2(12.4) 40 Male/12 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Hospital Stay
Ramon 1998[88]	RCT 59 participants Follow-up = 30 days Abstract	TEP (n=31) versus Open preperitoneal mesh (n=28)	No data reported	No data reported	Return to work

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Sarli 1997[62]	Single-centre RCT 108 participants Follow-up = Unclear Full text (Italian) Additional aggregated data available	TAPP (n=52) versus Open flat mesh (n=56)	52/52 General Anaesthetic Bilateral - Unknown Recurrent - Unknown Direct - Unknown Indirect – Unknown Age mean (range) 46.3(7-88) 42 Male/10 Female	Local or Regional Anaesthetic Bilateral - Unknown Recurrent - Unknown Direct - Unknown Indirect – Unknown Age mean (range) 45.3(22-83) 45 Male/11 Female	Duration of operation Postoperative complications Length of hospital stay Return to normal activities Persisting pain Persisting numbness
Sarli 2001[63]	Single-centre RCT 43 participants Follow-up = 36 months Full text	TAPP (n=20) versus Open flat mesh (n=23)	20/20 General Anaesthetic 20/20 Bilateral 0/20 Recurrent 11/40 Direct (hernias) 25/40 Indirect (hernias) 3/40 Other (hernias) Age mean (SD) 48.7(14.8) 20 Male/0 Female	8/23 General Anaesthetic 23/23 Bilateral 0/23 Recurrent 15/46 Direct (hernias) 29/46 Indirect (hernias) 2/46 Other (hernias) Age mean (SD) 49.4(15.1) 23 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to work Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Schrenk 1996[109,110] TAPP versus TEP ONLY	Single-centre RCT 52 participants included (86 in total) Follow-up = 3months Full text Additional aggregated data available	TAPP (n=28) versus TEP (n=24)	***1.1.3. TAPP*** 28/28 General Anaesthetic 0/28 Bilateral 0/28 Recurrent 9/28 Direct 19/28 Indirect Age mean (SD) 39.1(14.3) 24 Male/4 Female	***1.1.4. TEP*** 24/24 General Anaesthetic 0/24 Bilateral 0/24 Recurrent 6/24 Direct 18/24 Indirect Age mean (SD) 42.3(11.9) 22 Male/2 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to work Hernia recurrence
SCUR 1999[70,71]	Multi-centre RCT 406 participants included (613 in total) Follow-up = 12 months Full text IPD available	TAPP (n=207) versus Preperitoneal mesh (n=200) (The third arm of the trial is not relevant to this review)	206/207 General Anaesthetic 1/207 Regional Anaesthetic 0/207 Bilateral 23/207 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 55.93 (9.68) 207 Male/0 Female	49/200 General Anaesthetic 150/200 Regional Anaesthetic (1 not known) 0/200 Bilateral 18/200 Recurrent Direct - Unknown Indirect - Unknown Age mean (SD) 56.83 (9.37) (n=199) 200 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to work Persisting pain Persisting numbness Hernia recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Simmermacher 2000[89]	RCT 162 participants Follow-up = Unclear Full text	TEP (n=80) versus Open preperitoneal mesh (n=82)	80/80 General Anaesthetic 0/80 Bilateral 0/80 Recurrent 50/80 Direct 30/80 Indirect Age - Unknown 80 Male/0 Female	82/82 General Anaesthetic 0/82 Bilateral 0/82 Recurrent 65/82 Direct 17/82 Indirect Age - Unknown 82 Male/0 Female	Duration of operation Conversions Intraoperative complications Postoperative complications
Snyder 1998[108]	Single-centre RCT 200 participants Follow-up = median 1 year Full text	Mixed Laparoscopic (n=100) versus Open flat mesh (n=100)	100/100 General Anaesthetic 23/100 Bilateral Recurrent - Unknown Direct - Unknown Indirect - Unknown Age - Unknown Sex - Unknown	'Generally' General Anaesthetic 16/100 Bilateral Recurrent - Unknown Direct - Unknown Indirect - Unknown Age - Unknown Sex - Unknown	Postoperative pain Return to usual activities Hernia recurrence
Suter 2002[90-92]	Single-centre RCT 39 participants Follow-up = Unclear Full text	TEP (n= 19) versus Open preperitoneal mesh (n=20)	19/19 General Anaesthetic 19/19 Bilateral Recurrent - Unknown Direct - Unknown Indirect - Unknown Age mean (range) 63(36-82) 18 Male/1 Female	20/20 General Anaesthetic 20/20 Bilateral Recurrent - Unknown Direct - Unknown Indirect - Unknown Age mean (range) 57(36-91) 20 Male/0 Female	Duration of operation Length of hospital stay Return to usual activities Hernia Recurrence

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Vatansev 2002[94]	Single-centre RCT 65 participants Follow-up = 1 week Full text	TEP (n=20) versus Open flat mesh (n=24) versus Open preperitoneal mesh (n=21)	20/20 General Anaesthetic 0/20 Bilateral 0/20 Recurrent 6/20 Direct 13/20 Indirect 1/20 Other Age mean (SD) 54.6 (12.8) 18 Male/2 Female	**Open Flat Mesh** 24/24 General Anaesthetic 0/24 Bilateral 0/24 Recurrent 5/24 Direct 17/24 Indirect 2/24 Other Age mean (SD) 53.2(12.6) 22 Male/2 Female **Open Preperitoneal Mesh** 21/21 General Anaesthetic 0/21 Bilateral 0/21 Recurrent 4/21 Direct 16/21 Indirect 1/21 Other Age mean (SD) 56.7(15.3) 18 Male/3 Female	Duration of operation

Study	Study Details	Intervention/Comparator	Intervention Population Characteristics	Comparator Population Characteristics	Outcomes
Wellwood 1998[64-66]	Multi-centre RCT 400 participants Follow-up = 60 months Full text IPD available	TAPP (n=201) versus Open flat mesh (n=202)	201/201 General Anaesthetic 23/201 Bilateral 20/201 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 52.11 (15.76) 193 Male/8 Female	202/202 Local Anaesthetic 24/202 Bilateral 25/202 Recurrent Direct - Unknown Indirect - Unknown Age median (range) 49.26 (16.02) 190 Male/12 Female	Duration of operation Conversions Intraoperative complications Postoperative complications Length of hospital stay Return to usual activities Persistent pain Persistent numbness Hernia recurrence
Zieren 1998[72-75]	Single-centre RCT 160 participants included (240 in total) Follow-up = mean (SD) 25(7) months Full text (German) Additional aggregated data available	TAPP (n=80) versus Open plug and mesh (n=80) (The third arm of the trial is not relevant to this review)	80/80 General Anaesthetic Bilateral - Unknown Recurrent – 0/80 Direct – 28/80 Indirect – 52/80 Age mean (SD) 43(12) 72 Male/8 Female	9/80 General Anaesthetic Bilateral - Unknown Recurrent – 0/80 Direct – 24/80 Indirect – 56/80 Age mean (SD) 47(14) 74 Male/6 Female	Duration of operation Intraoperative complications Postoperative pain Postoperative complications Length of hospital stay Limitation of daily activities Persisting pain Persisting numbness Hernia recurrence

APPENDIX 7(1) RESULTS OF META-ANALYSES: LAPAROSCOPIC TAPP VERSUS OPEN MESH REPAIR

Comparison: 01 TAPP versus Open Mesh
Outcome: 01 Duration of operation (minutes)

Study	Treatment n	Treatment mean(sd)	Control n	Control mean(sd)	WMD (95%CI Fixed)	Weight %	WMD (95%CI Fixed)
01 TAPP versus Flat Mesh							
Filipi 1996	24	109.00(23.78)	29	87.00(17.27)		1.2	22.00[10.60,33.40]
Heikkinen (1) 1998	20	73.65(26.93)	20	65.05(11.55)		0.9	8.60[-4.24,21.44]
Heikkinen 1997	20	78.90(25.65)	18	48.00(17.20)		0.8	30.90[17.13,44.67]
Koninger 1998	94	52.00(23.78)	93	48.00(17.27)		4.4	4.00[-1.95,9.95]
Paganini 1998	52	73.75(28.37)	56	55.63(31.97)		1.2	18.12[6.74,29.50]
Payne 1994	51	73.10(20.12)	49	59.86(15.39)		3.1	13.24[6.24,20.24]
Picchio 1999	52	49.60(5.40)	52	33.90(6.20)		30.9	15.70[13.47,17.93]
Sarli 1997	52	73.00(15.00)	56	59.00(11.00)		6.2	14.00[9.01,18.99]
Sarli 2001	20	95.00(32.30)	21	99.00(28.30)		0.4	-4.00[-22.63,14.63]
Wellwood 1998	201	46.42(16.92)	201	46.86(15.67)		15.2	-0.44[-3.63,2.75]
Subtotal(95%CI)	586		595			64.4	10.93[9.38,12.48]
Test for heterogeneity chi-square=89.27 df=9 p<0.00001							
Test for overall effect z=13.83 p<0.00001							
02 TAPP versus Preperitoneal Mesh							
Aitola 1998	27	46.26(15.78)	29	38.48(12.16)		2.8	7.78[0.36,15.20]
Beets 1999	42	79.38(31.67)	37	55.70(16.48)		1.3	23.68[12.73,34.63]
Laporte 1997	209	58.00(25.00)	183	57.00(23.00)		6.8	1.00[-3.75,5.75]
SCUR 1999	207	65.10(25.47)	199	38.01(14.09)		9.7	27.09[23.11,31.07]
Subtotal(95%CI)	485		448			20.7	15.62[12.89,18.36]
Test for heterogeneity chi-square=74.56 df=3 p<0.00001							
Test for overall effect z=11.20 p<0.00001							
03 TAPP versus Plug and Mesh							
Zieren 1998	80	61.00(12.00)	80	36.00(14.00)		9.5	25.00[20.96,29.04]
Subtotal(95%CI)	80		80			9.5	25.00[20.96,29.04]
Test for heterogeneity chi-square=0.00 df=0 p=1							
Test for overall effect z=12.13 p<0.00001							
04 TAPP versus Mixed Mesh							
MRCmulticentre 1999	101	54.60(23.42)	98	41.92(13.96)		5.4	12.68[7.34,18.02]
Subtotal(95%CI)	101		98			5.4	12.68[7.34,18.02]
Test for heterogeneity chi-square=0.0 df=0							
Test for overall effect z=4.66 p<0.00001							
Total(95%CI)	1252		1221			100.0	13.33[12.08,14.57]
Test for heterogeneity chi-square=207.86 df=15 p<0.00001							
Test for overall effect z=21.01 p<0.00001							

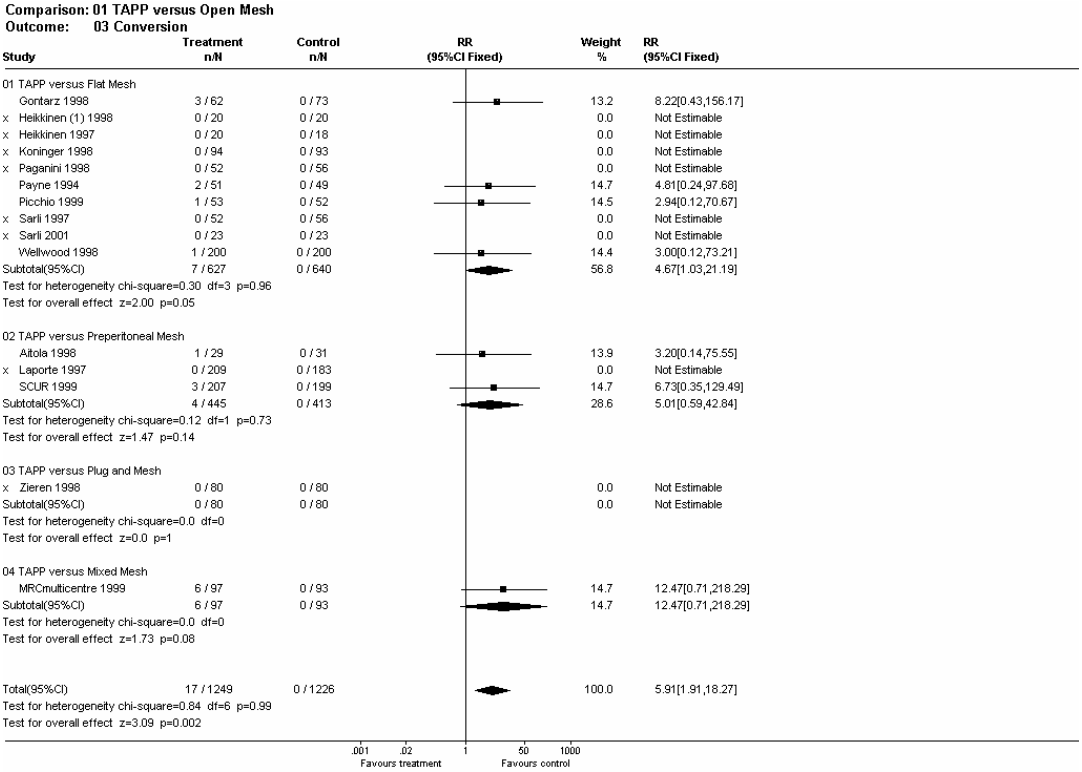
-100 -50 0 50 100
Favours treatment Favours control

Comparison: 01 TAPP versus Open Mesh
Outcome: 02 "Opposite" method initiated

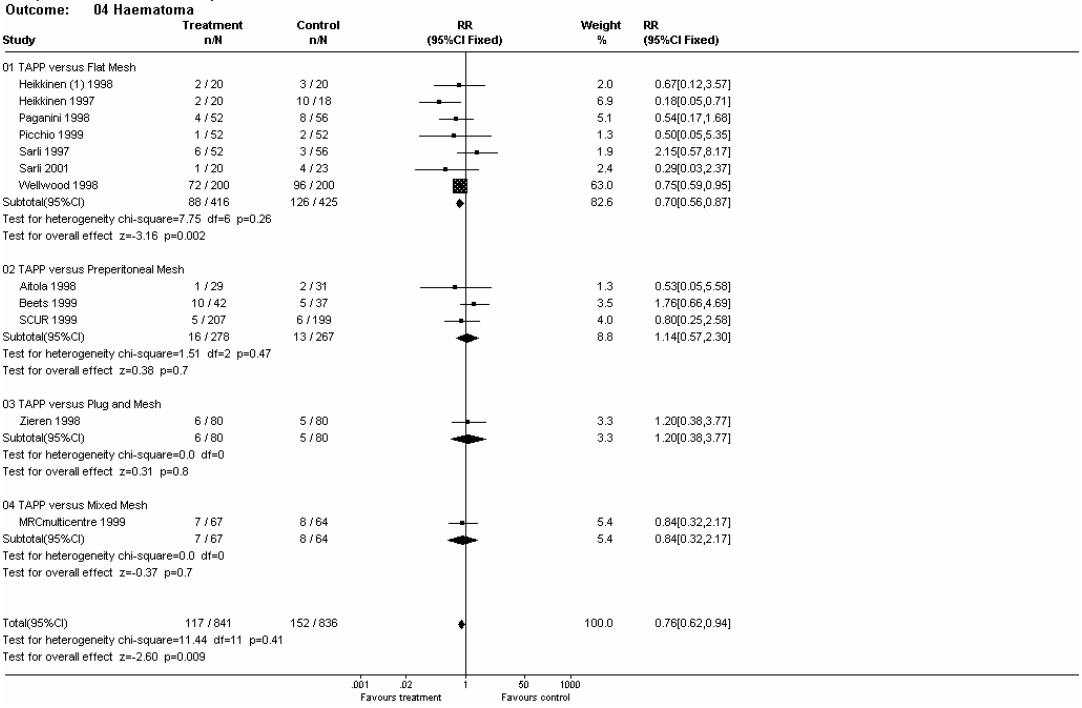
Study	Treatment n/N	Control n/N	RR (95%CI Fixed)	Weight %	RR (95%CI Fixed)
01 TAPP versus Flat Mesh					
Gontarz 1998	3 / 62	0 / 73		18.2	8.22[0.43,156.17]
x Heikkinen 1997	0 / 20	0 / 18		0.0	Not Estimable
x Paganini 1998	0 / 52	0 / 56		0.0	Not Estimable
x Payne 1994	0 / 51	0 / 49		0.0	Not Estimable
Subtotal(95%CI)	3 / 185	0 / 196		18.2	8.22[0.43,156.17]
Test for heterogeneity chi-square=0.0 df=0					
Test for overall effect z=1.40 p=0.16					
02 TAPP versus Preperitoneal Mesh					
Aitola 1998	3 / 29	0 / 31		19.1	7.47[0.40,138.59]
Beets 1999	1 / 42	0 / 37		21.0	2.65[0.11,63.17]
Subtotal(95%CI)	4 / 71	0 / 68		40.1	4.95[0.61,40.33]
Test for heterogeneity chi-square=0.22 df=1 p=0.64					
Test for overall effect z=1.49 p=0.14					
03 TAPP versus Plug and Mesh					
x Zieren 1998	0 / 80	0 / 80		0.0	Not Estimable
Subtotal(95%CI)	0 / 80	0 / 80		0.0	Not Estimable
Test for heterogeneity chi-square=0.0 df=0					
Test for overall effect z=0.0 p=1					
04 TAPP versus Mixed Mesh					
MRCmulticentre 1999	8 / 104	1 / 93		41.7	7.15[0.91,56.13]
Subtotal(95%CI)	8 / 104	1 / 93		41.7	7.15[0.91,56.13]
Test for heterogeneity chi-square=0.0 df=0					
Test for overall effect z=1.87 p=0.06					
Total(95%CI)	15 / 440	1 / 437		100.0	6.46[1.74,24.02]
Test for heterogeneity chi-square=0.35 df=3 p=0.95					
Test for overall effect z=2.79 p=0.005					

.001 .02 1 50 1000
Favours treatment Favours control

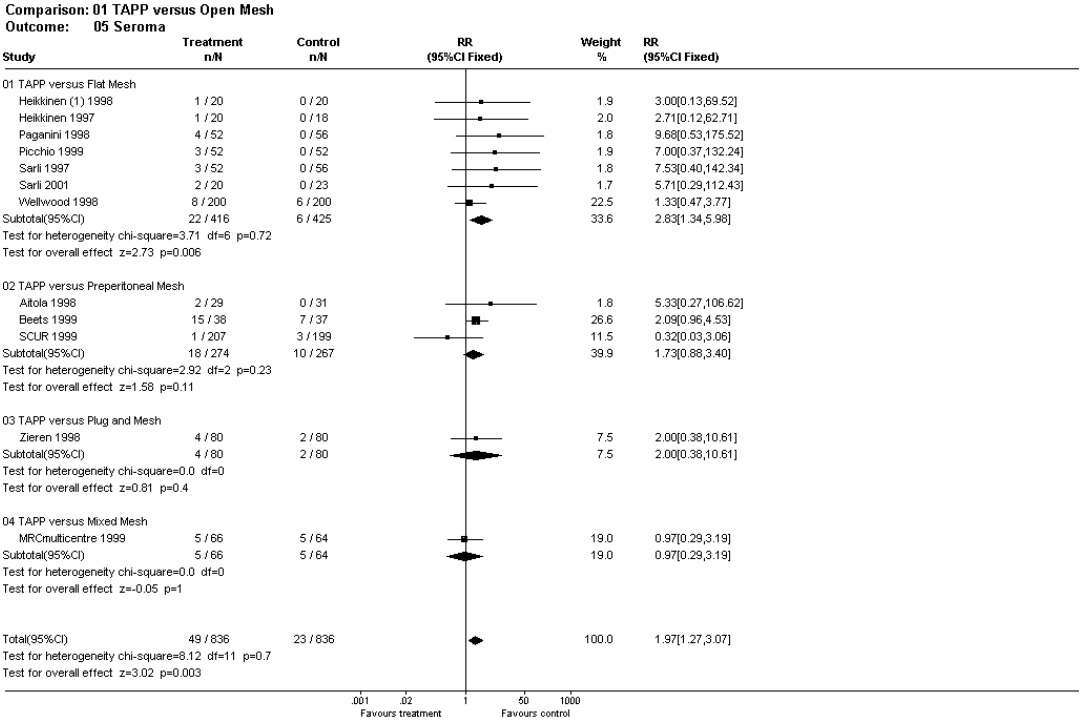
Comparison: 01 TAPP versus Open Mesh
Outcome: 03 Conversion



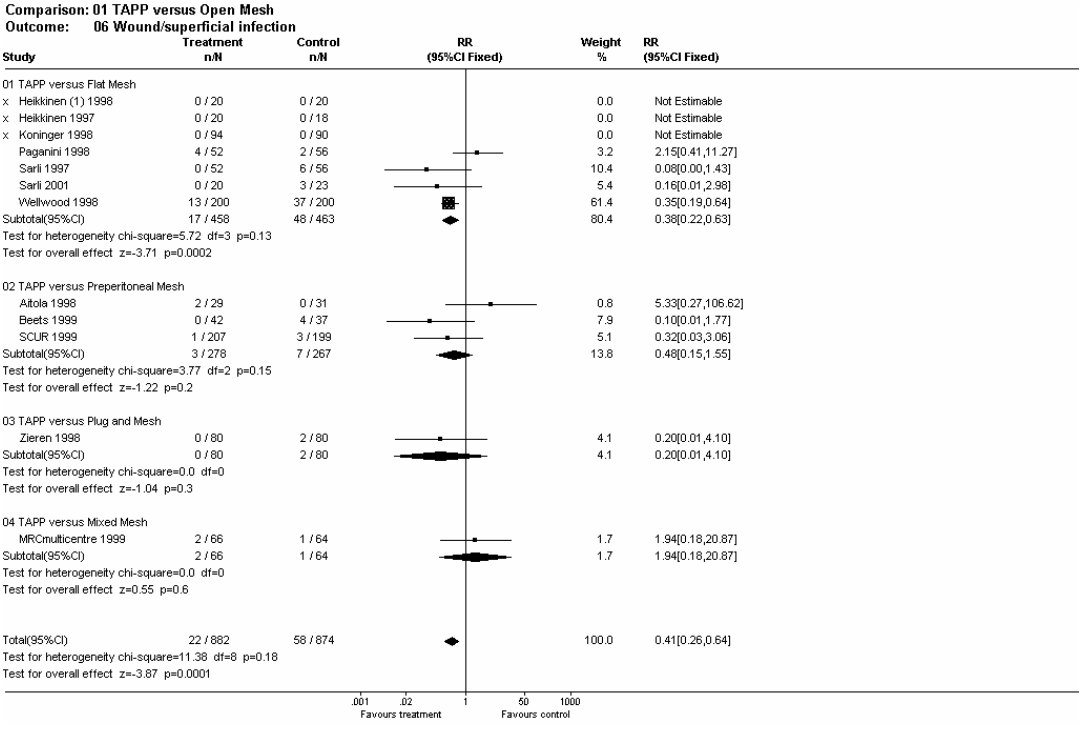
Comparison: 01 TAPP versus Open Mesh
Outcome: 04 Haematoma



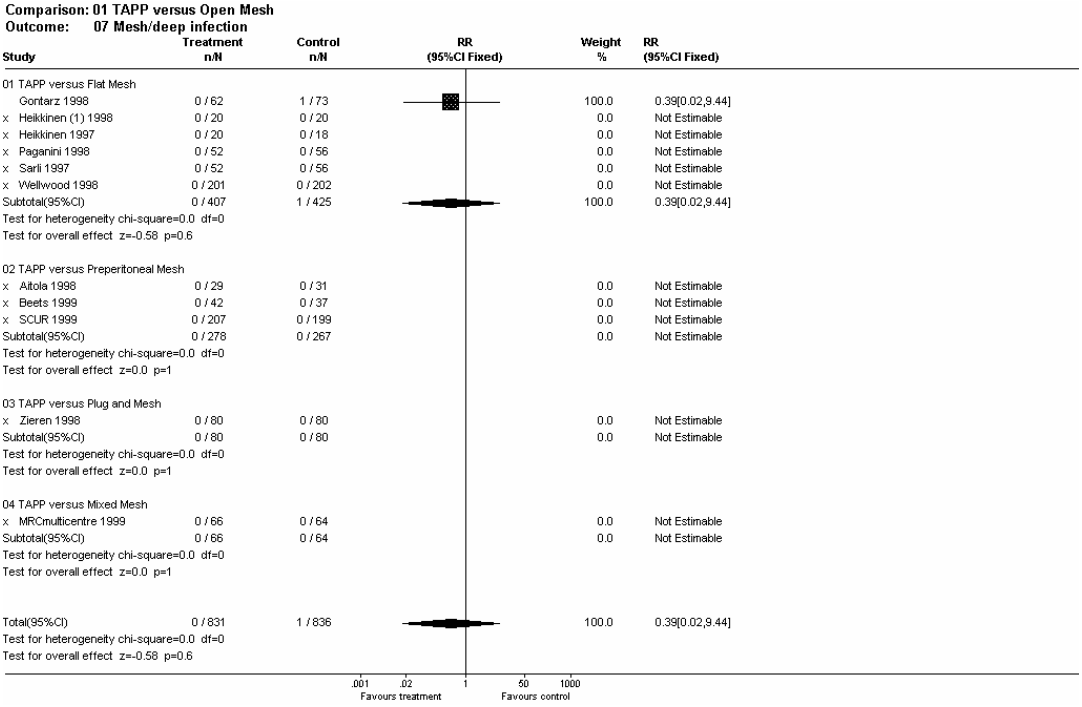
Comparison: 01 TAPP versus Open Mesh
Outcome: 05 Seroma



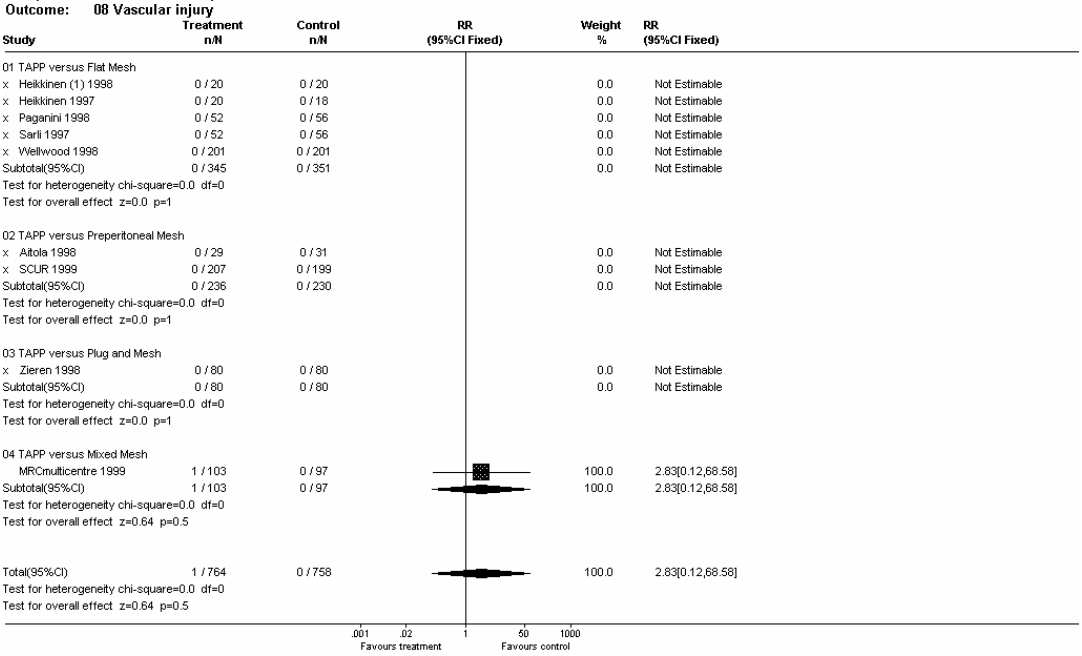
Comparison: 01 TAPP versus Open Mesh
Outcome: 06 Wound/superficial infection



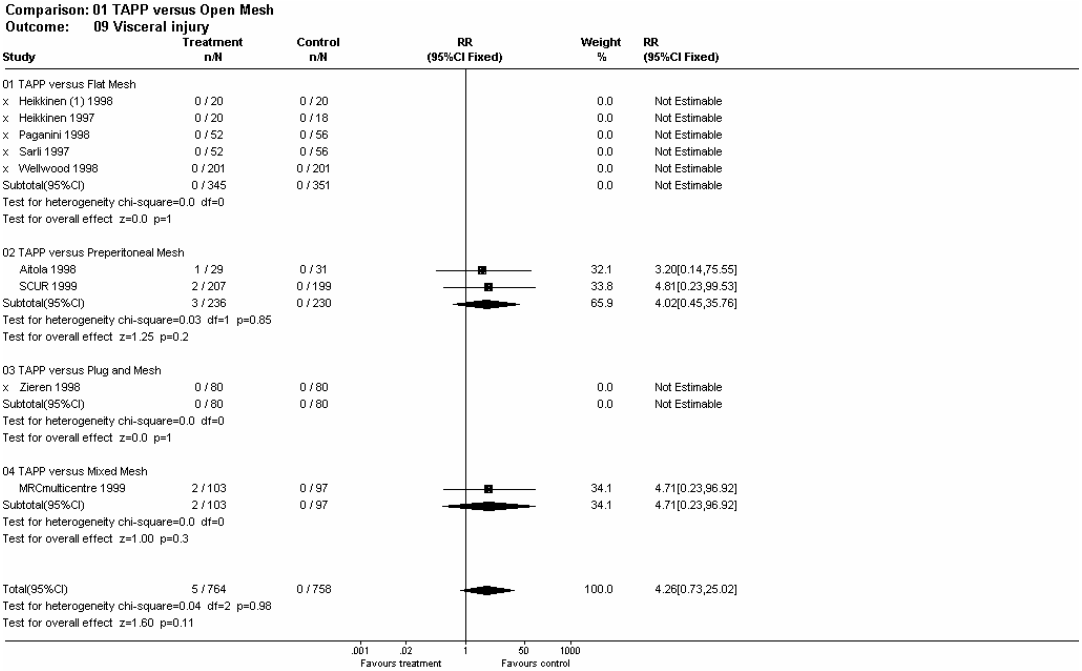
Comparison: 01 TAPP versus Open Mesh
Outcome: 07 Mesh/deep infection



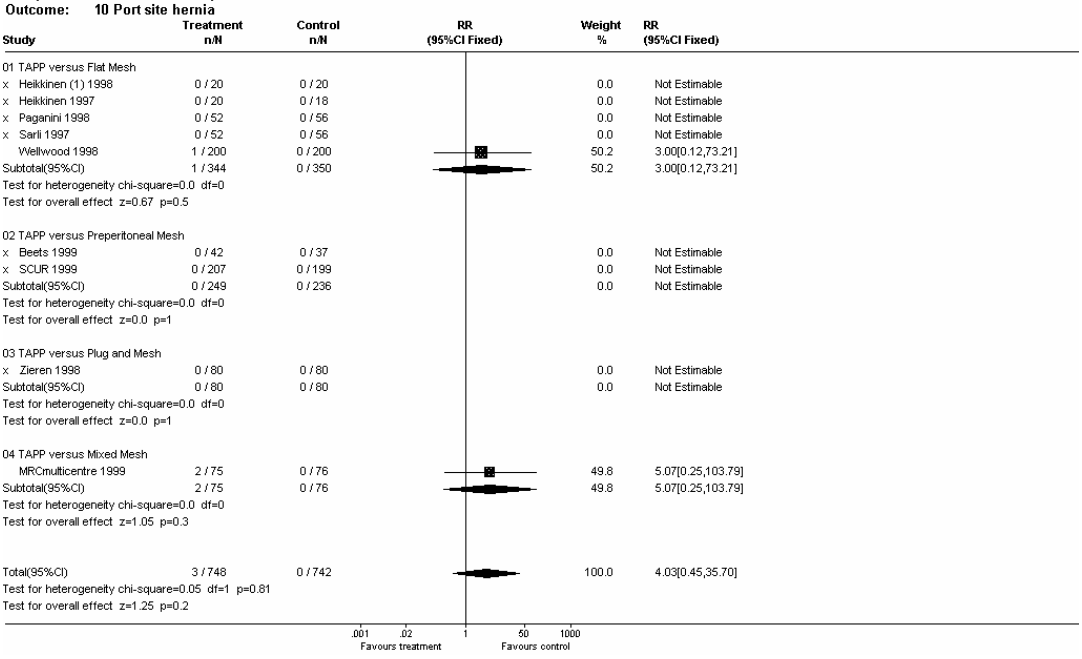
Comparison: 01 TAPP versus Open Mesh
Outcome: 08 Vascular injury

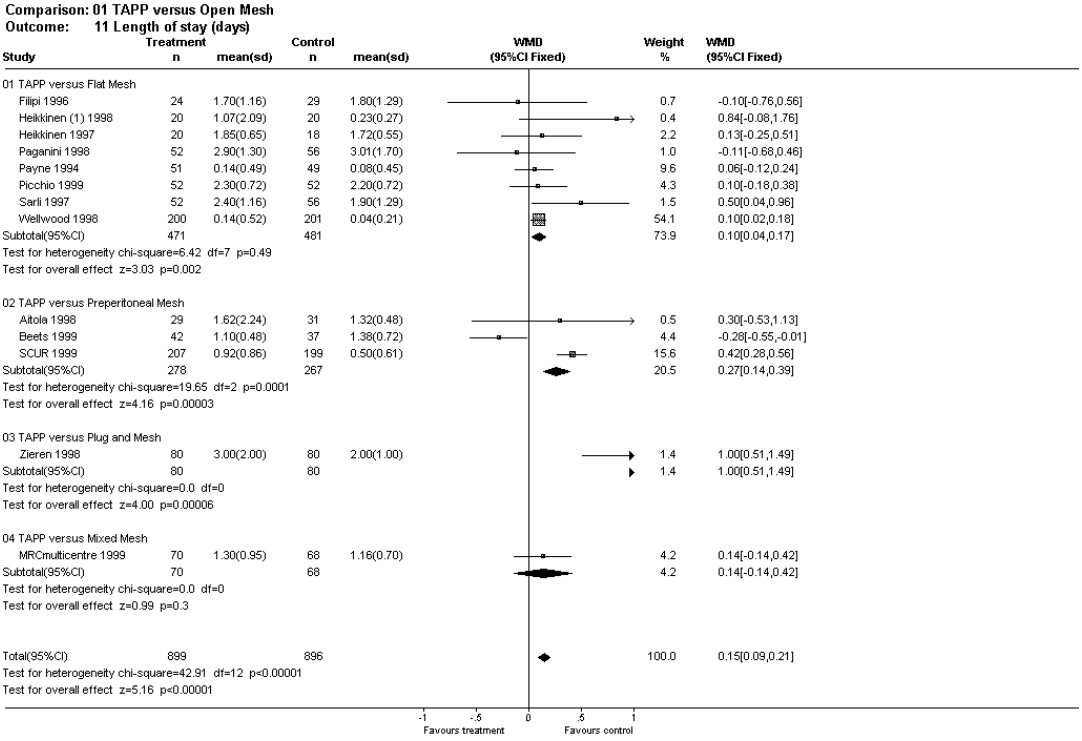


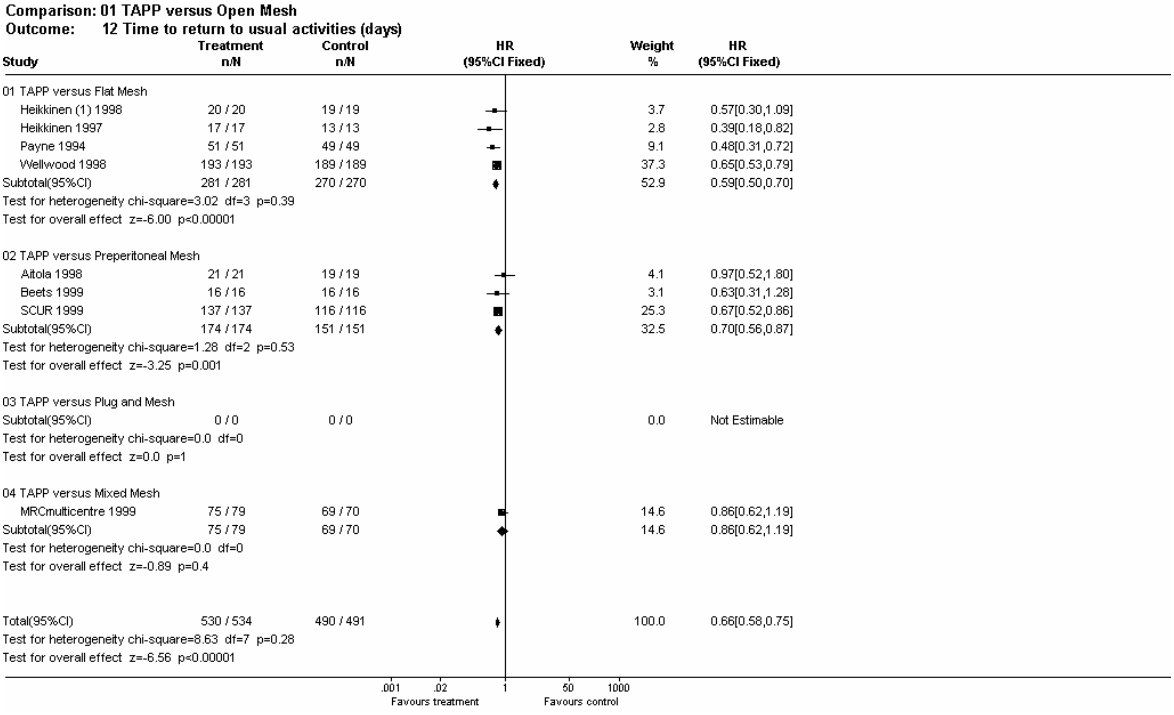
Comparison: 01 TAPP versus Open Mesh
Outcome: 09 Visceral injury



Comparison: 01 TAPP versus Open Mesh
Outcome: 10 Port site hernia

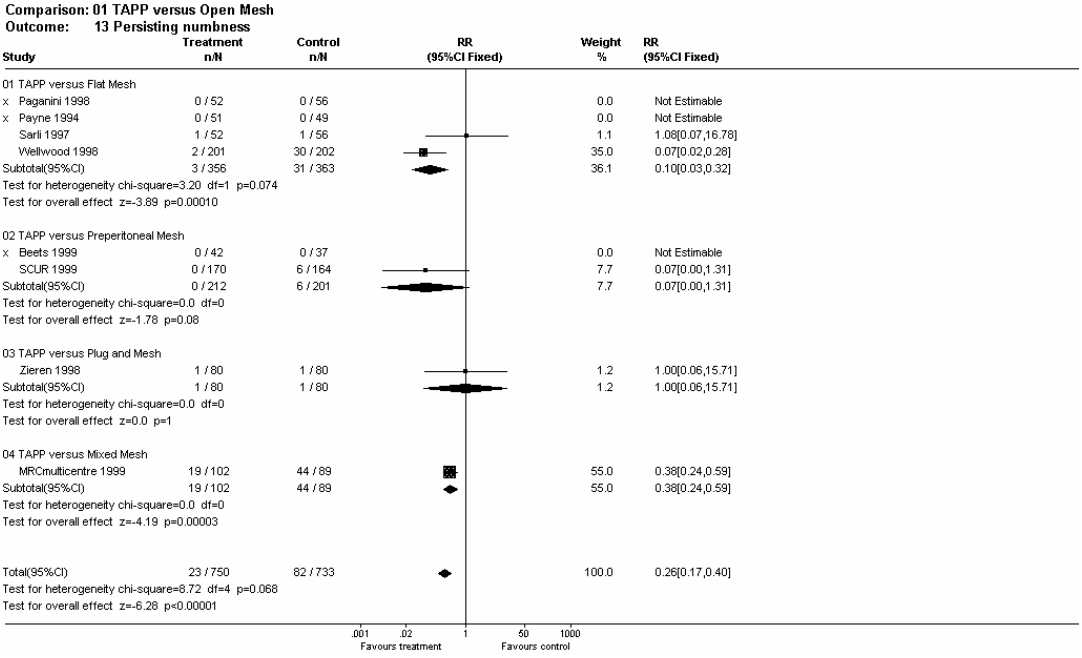




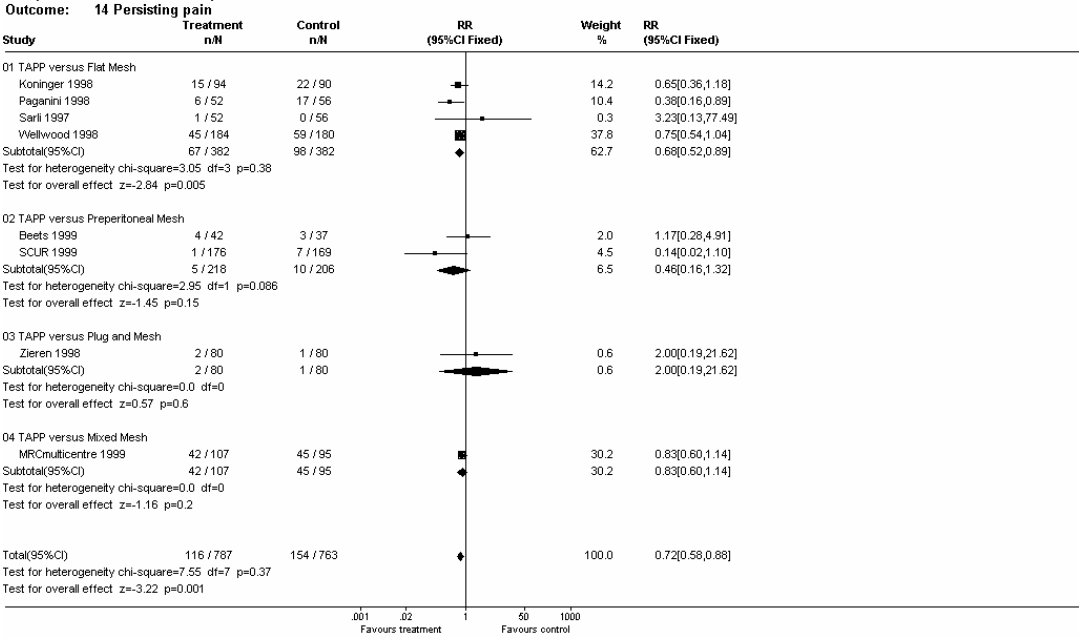


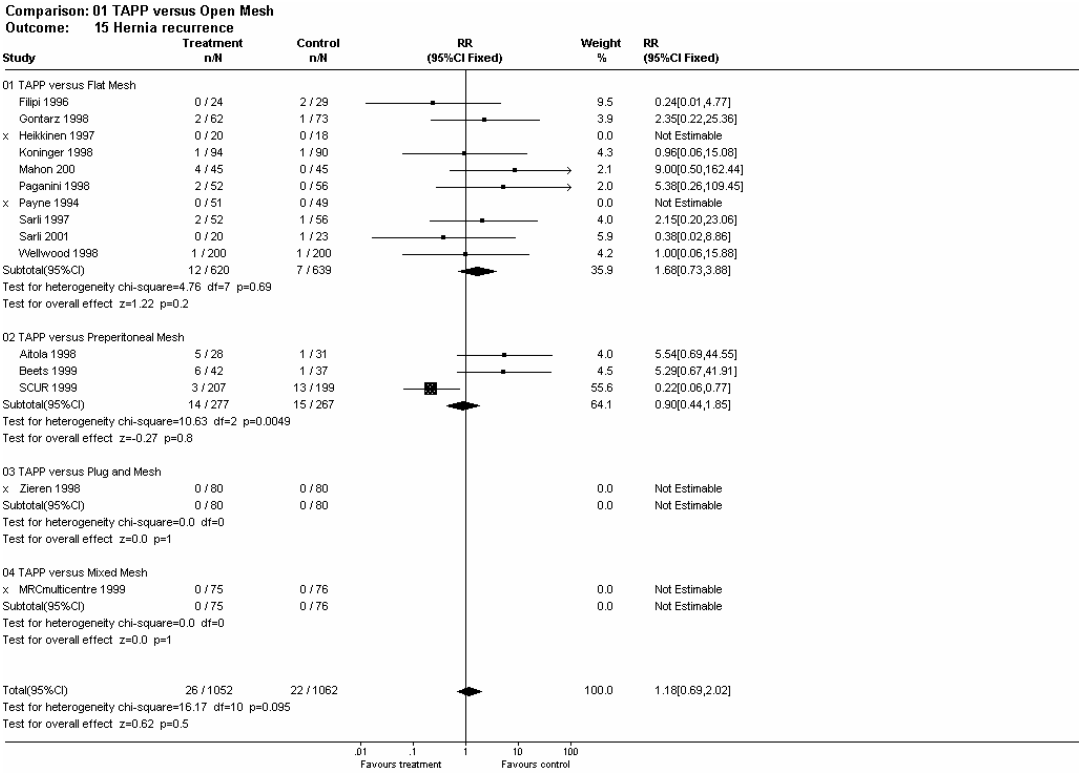
n/N refers to the number who have returned to activities within the follow-up period. The remaining few people are censored, i.e. they have not yet returned to activities at the time of follow-up.

Comparison: 01 TAPP versus Open Mesh
Outcome: 13 Persisting numbness

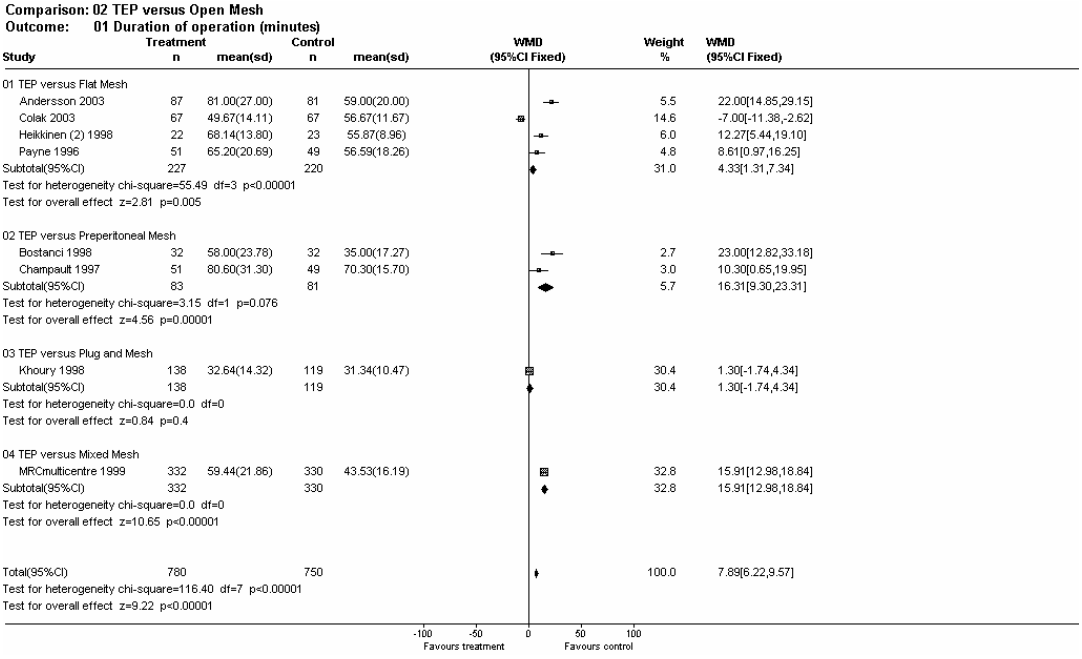


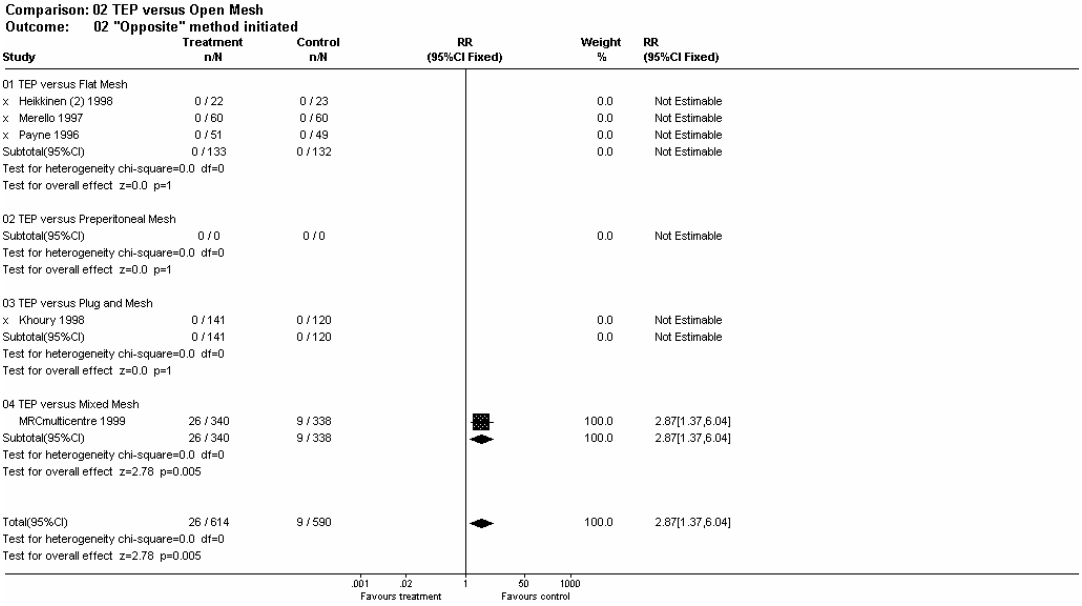
Comparison: 01 TAPP versus Open Mesh
Outcome: 14 Persisting pain



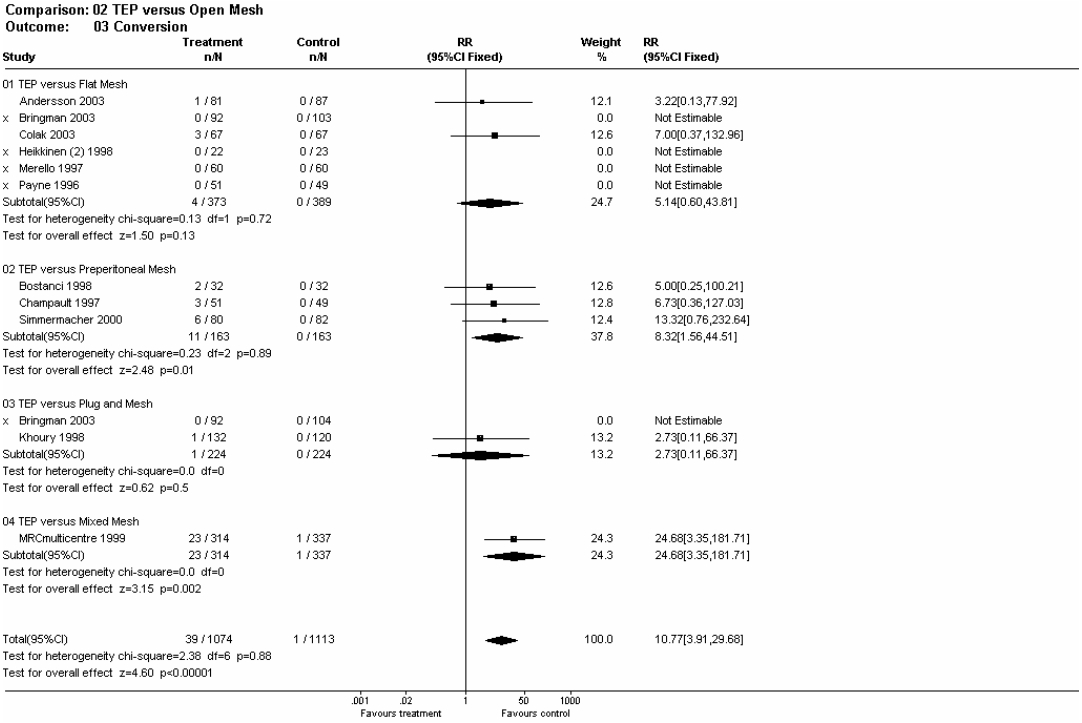

Comparison: 01 TAPP versus Open Mesh
Outcome: 15 Hernia recurrence
Study
Treatment n/N
Control n/N
RR (95%CI Fixed)
Weight %
RR (95%CI Fixed)
01 TAPP versus Flat Mesh
Filipi 1996 0 / 24 2 / 29 9.5 0.24[0.01,4.77]
Gontarz 1998 2 / 62 1 / 73 3.9 2.35[0.22,25.36]
x Heikkinen 1997 0 / 20 0 / 18 0.0 Not Estimable
Koninger 1998 1 / 94 1 / 90 4.3 0.96[0.06,15.08]
Mahon 200 4 / 45 0 / 45 2.1 9.00[0.50,162.44]
Paganini 1998 2 / 52 0 / 56 2.0 5.38[0.26,109.45]
x Payne 1994 0 / 51 0 / 49 0.0 Not Estimable
Sarli 1997 2 / 52 1 / 56 4.0 2.15[0.20,23.06]
Sarli 2001 0 / 20 1 / 23 5.9 0.38[0.02,8.86]
Wellwood 1998 1 / 200 1 / 200 4.2 1.00[0.06,15.88]
Subtotal(95%CI) 12 / 620 7 / 639 35.9 1.68[0.73,3.88]
Test for heterogeneity chi-square=4.76 df=7 p=0.69
Test for overall effect z=1.22 p=0.2
02 TAPP versus Preperitoneal Mesh
Aitola 1998 5 / 28 1 / 31 4.0 5.54[0.69,44.55]
Beets 1999 6 / 42 1 / 37 4.5 5.29[0.67,41.91]
SCUR 1999 3 / 207 13 / 199 55.6 0.22[0.06,0.77]
Subtotal(95%CI) 14 / 277 15 / 267 64.1 0.90[0.44,1.85]
Test for heterogeneity chi-square=10.63 df=2 p=0.0049
Test for overall effect z=-0.27 p=0.8
03 TAPP versus Plug and Mesh
x Zieren 1998 0 / 80 0 / 80 0.0 Not Estimable
Subtotal(95%CI) 0 / 80 0 / 80 0.0 Not Estimable
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.0 p=1
04 TAPP versus Mixed Mesh
x MRCmulticentre 1999 0 / 75 0 / 76 0.0 Not Estimable
Subtotal(95%CI) 0 / 75 0 / 76 0.0 Not Estimable
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.0 p=1
Total(95%CI) 26 / 1052 22 / 1062 100.0 1.18[0.69,2.02]
Test for heterogeneity chi-square=16.17 df=10 p=0.095
Test for overall effect z=0.62 p=0.5
.01
.1
1
10
100
Favours treatment
Favours control

APPENDIX 7(2) RESULTS OF META-ANALYSES: LAPAROSCOPIC TEP VERSUS OPEN MESH REPAIR

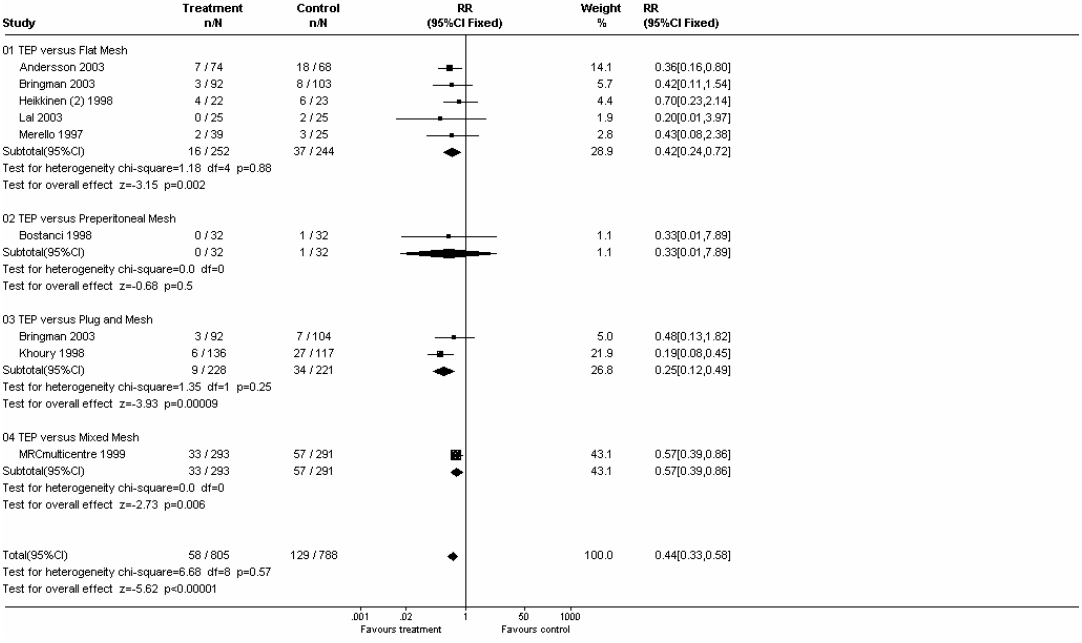




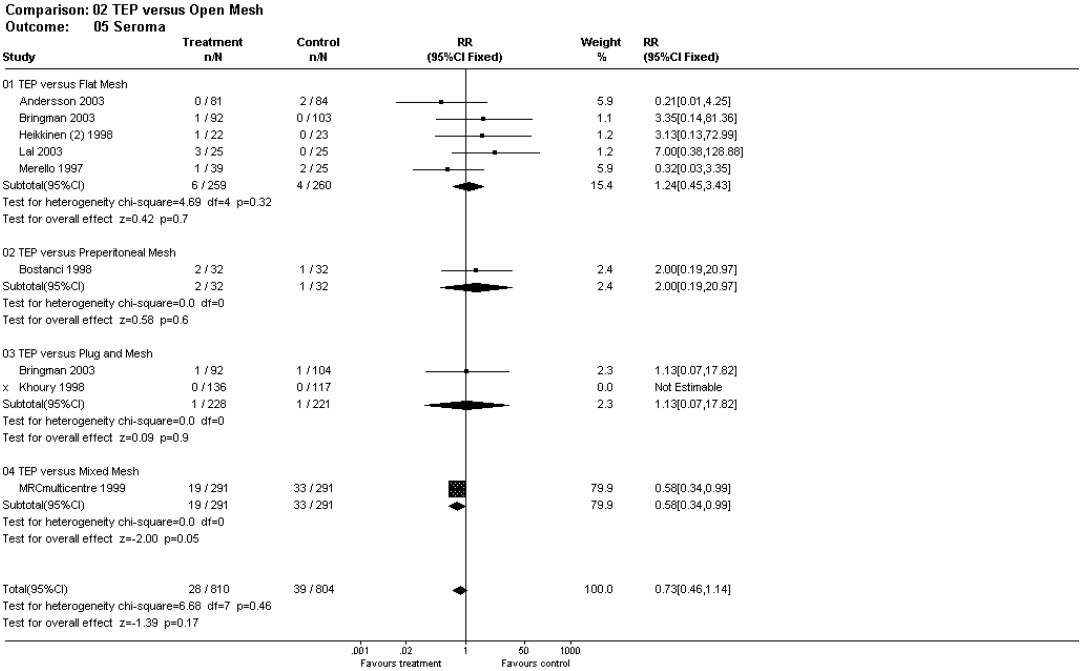
Comparison: 02 TEP versus Open Mesh
Outcome: 03 Conversion



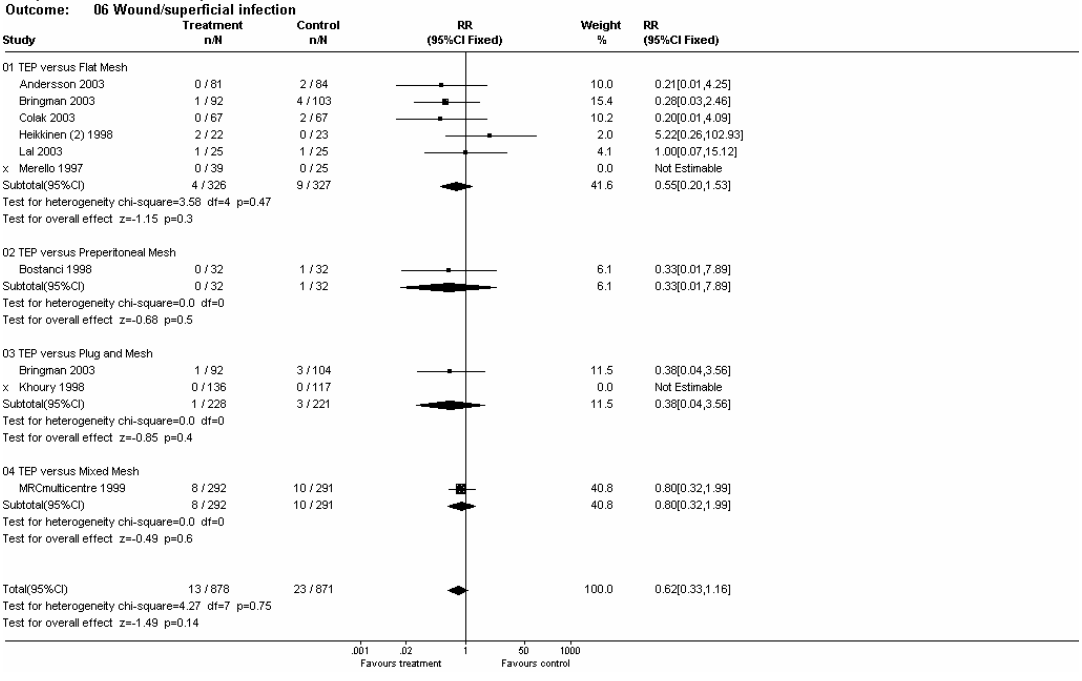
Comparison: 02 TEP versus Open Mesh
Outcome: 04 Haematoma



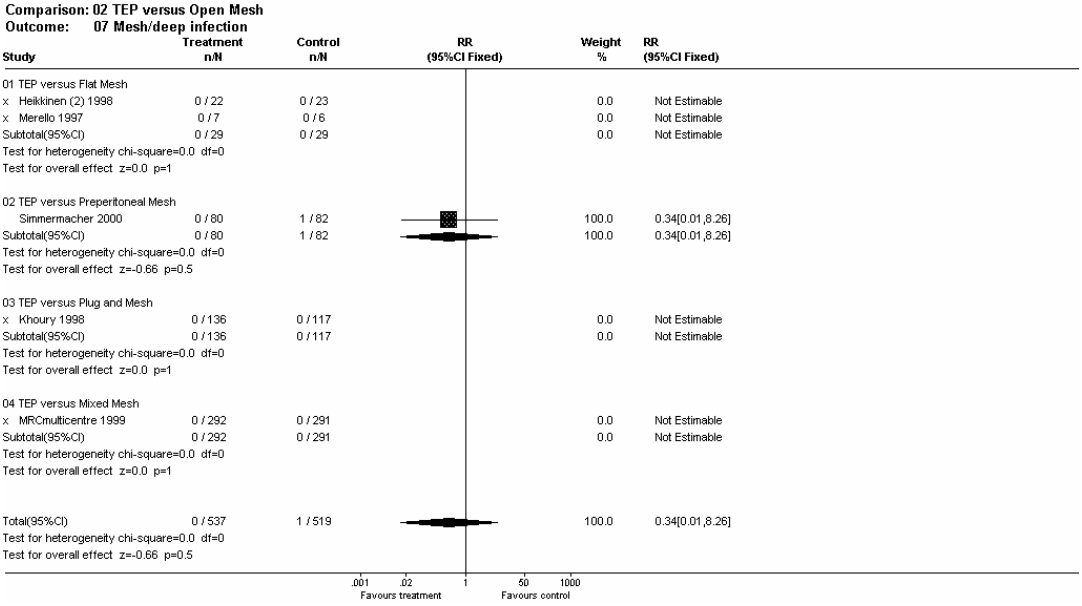
Comparison: 02 TEP versus Open Mesh
Outcome: 05 Seroma



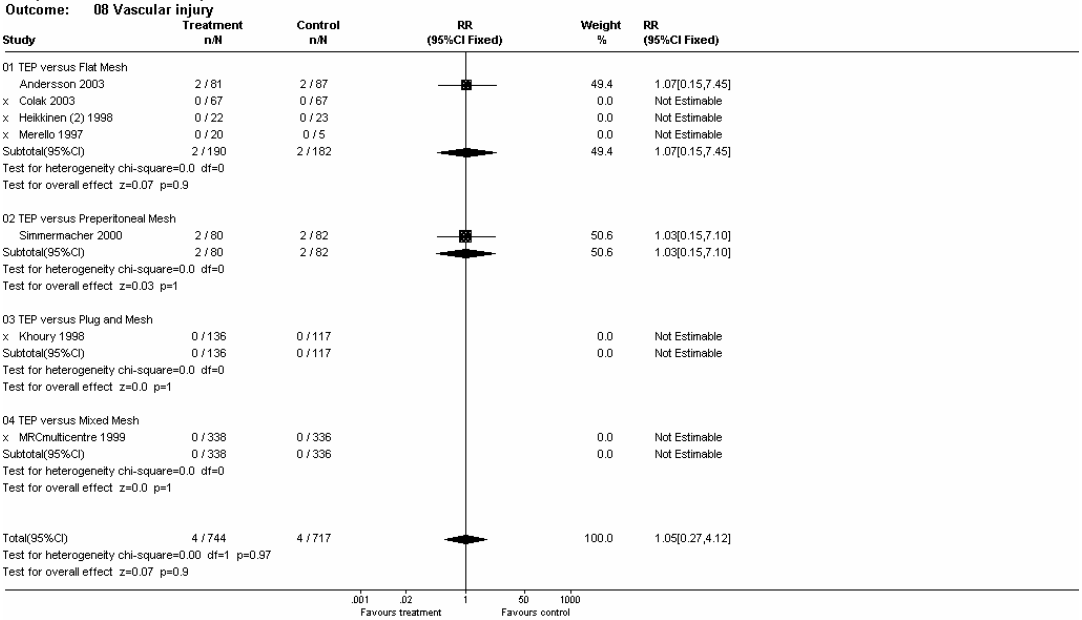
Comparison: 02 TEP versus Open Mesh
Outcome: 06 Wound/superficial infection



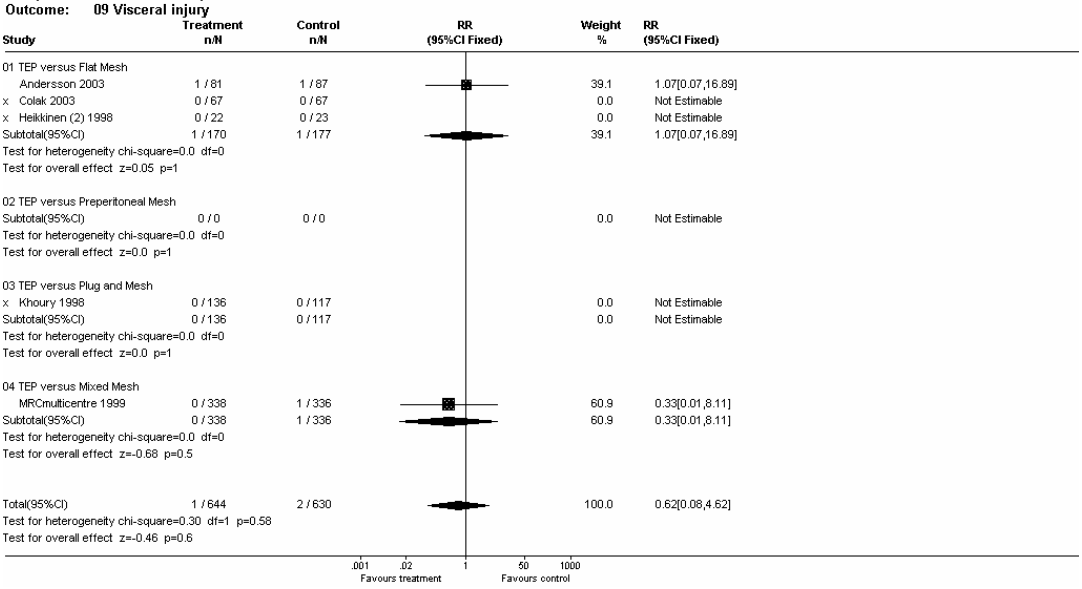
Comparison: 02 TEP versus Open Mesh
Outcome: 07 Mesh/deep infection



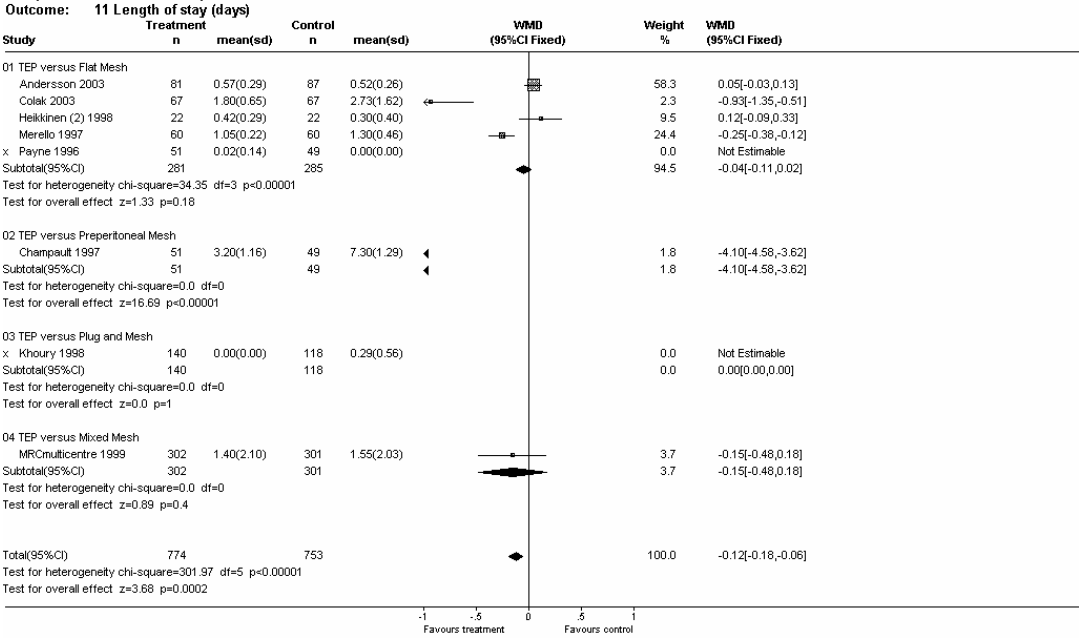
Comparison: 02 TEP versus Open Mesh
Outcome: 08 Vascular injury

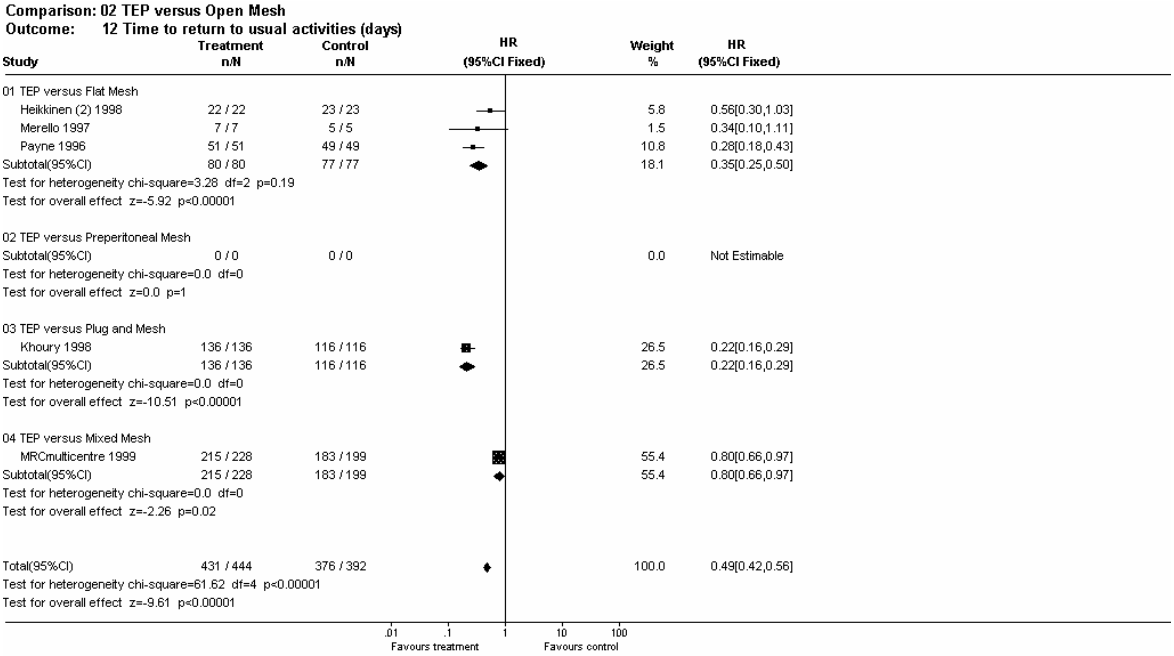


Comparison: 02 TEP versus Open Mesh
Outcome: 09 Visceral injury

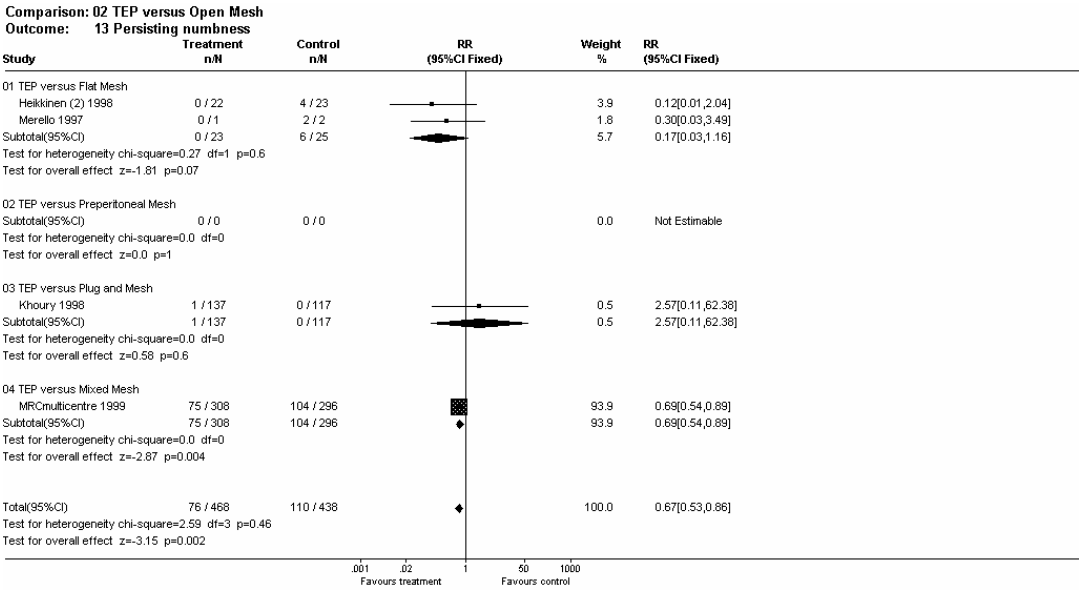


Comparison: 02 TEP versus Open Mesh
Outcome: 11 Length of stay (days)

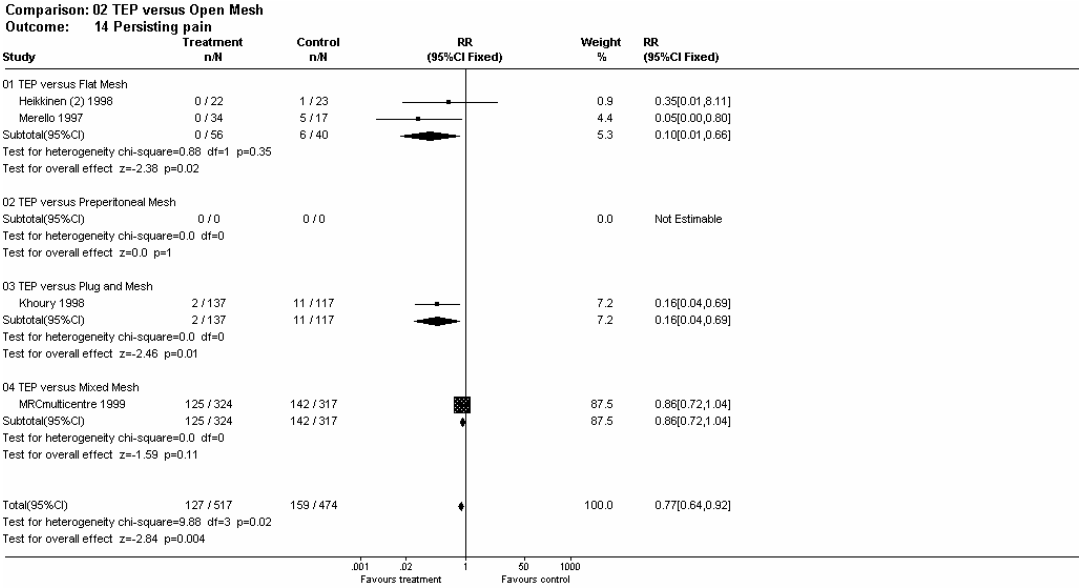




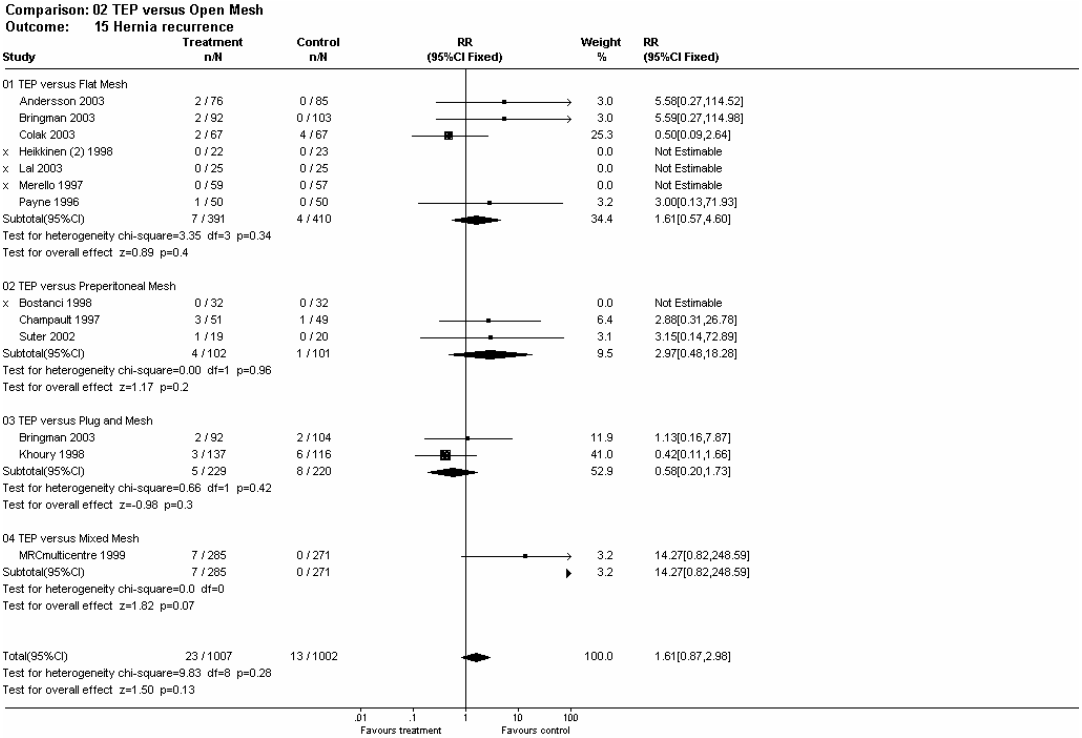
n/N refers to the number who have returned to activities within the follow-up period. The remaining few people are censored, i.e. they have not yet returned to activities at the time of follow-up.



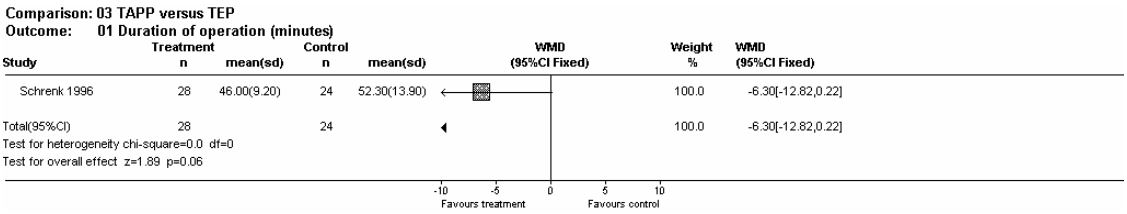
Comparison: 02 TEP versus Open Mesh
Outcome: 14 Persisting pain

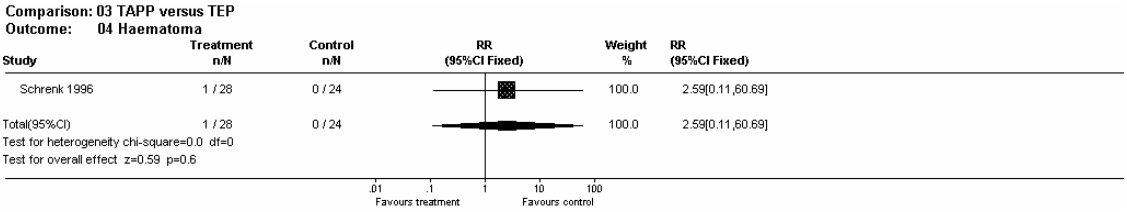


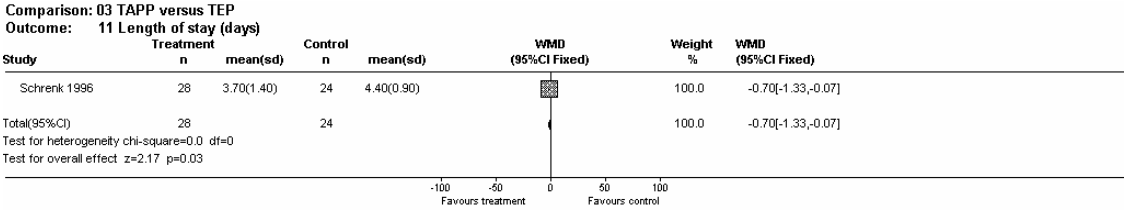
Comparison: 02 TEP versus Open Mesh
Outcome: 15 Hernia recurrence

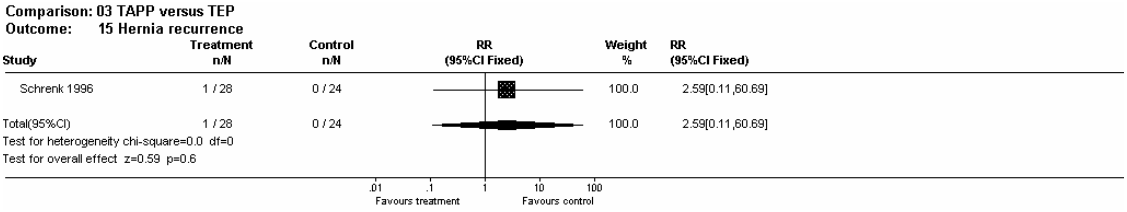


APPENDIX 7(3) RESULTS OF META-ANALYSES: LAPAROSCOPIC TAPP VERSUS LAPAROSCOPIC TEP REPAIR

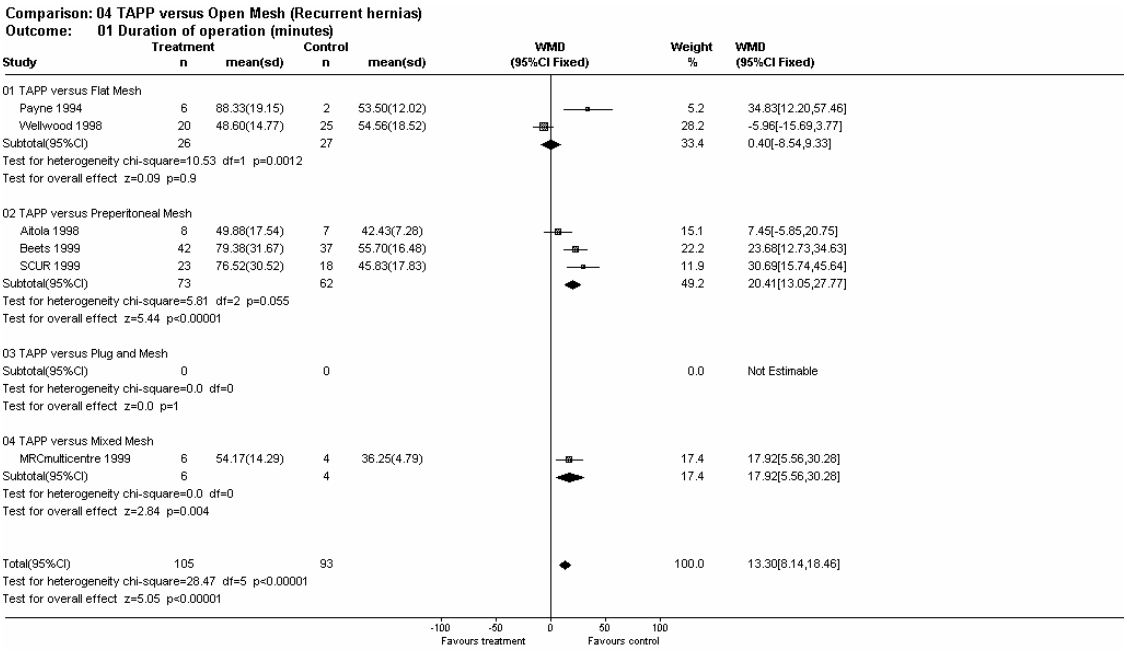


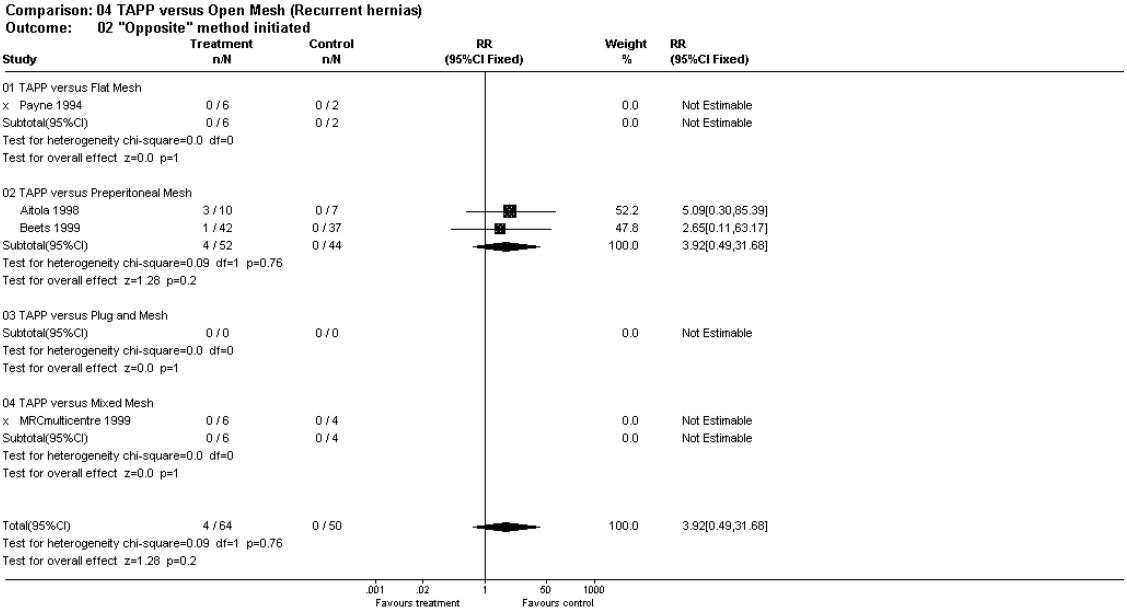




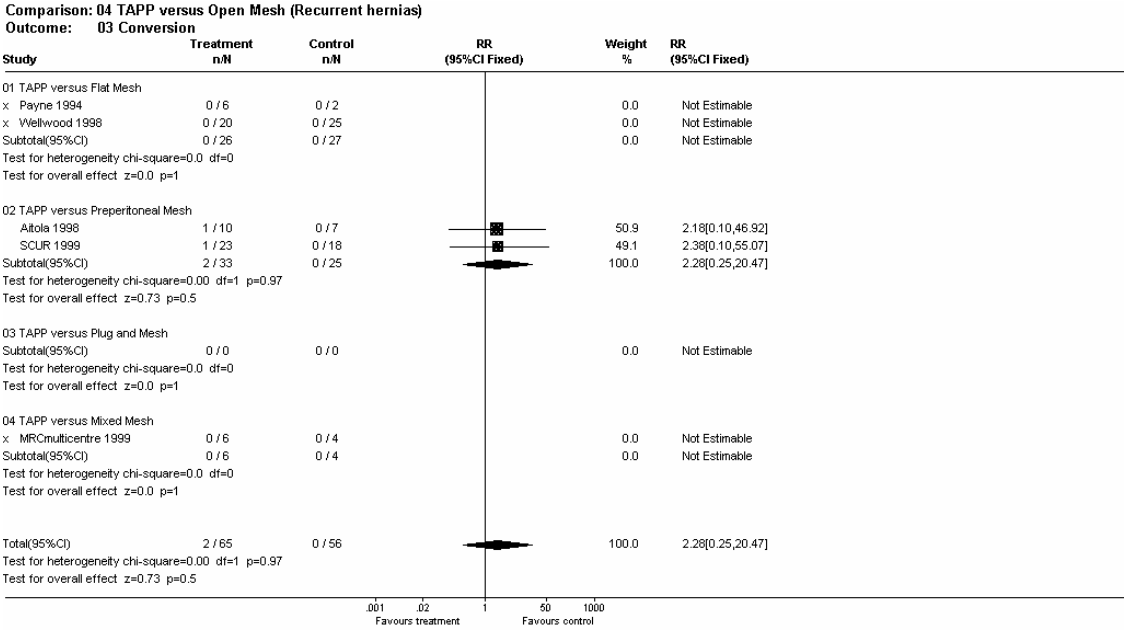

Comparison: 03 TAPP versus TEP
Outcome: 15 Hernia recurrence
Study
Treatment n/N
Control n/N
RR (95%CI Fixed)
Weight %
RR (95%CI Fixed)
Schrenk 1996
1 / 28
0 / 24
100.0
2.59[0.11,60.69]
Total(95%CI)
1 / 28
0 / 24
100.0
2.59[0.11,60.69]
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.59 p=0.6
.01
.1
1
10
100
Favours treatment
Favours control

APPENDIX 7(4) RESULTS OF META-ANALYSES: LAPAROSCOPIC TAPP VERSUS OPEN MESH REPAIR (RECURRENT HERNIAS)

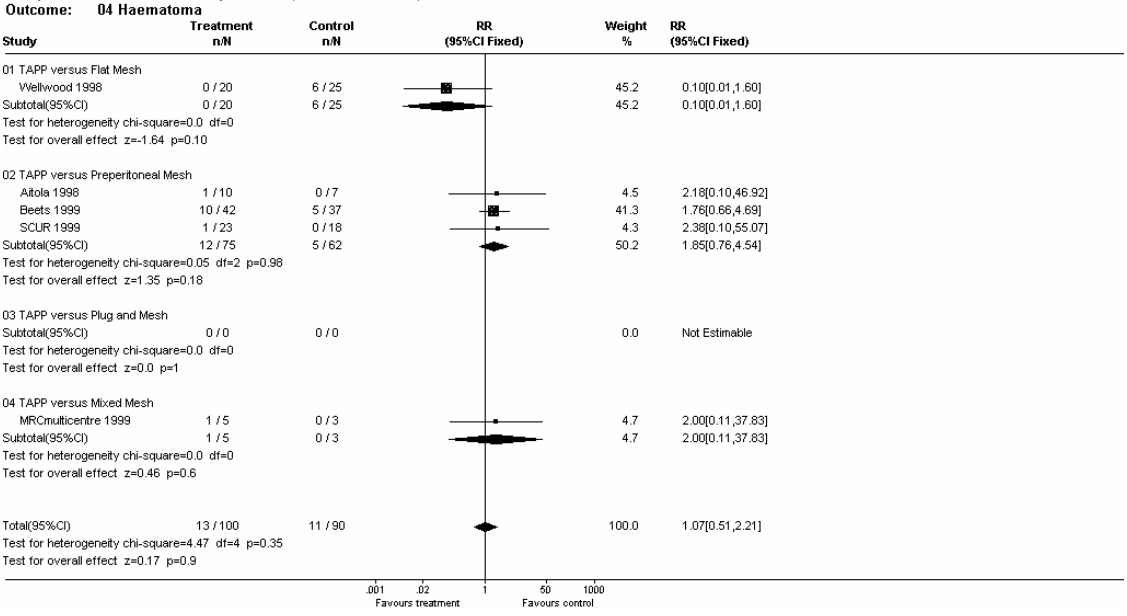




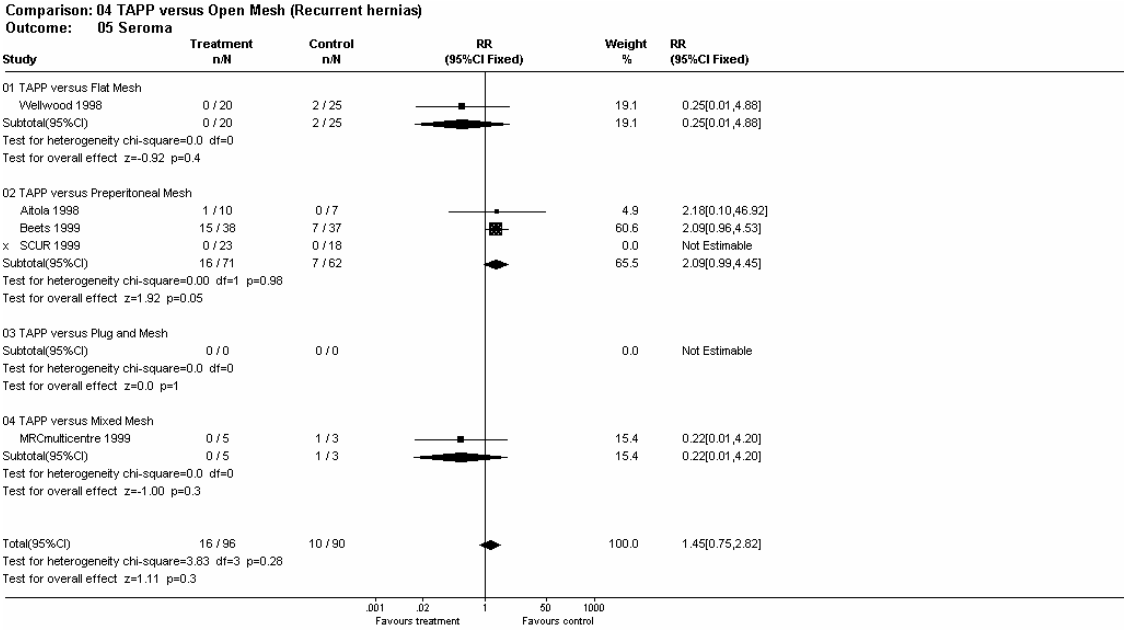
Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 03 Conversion



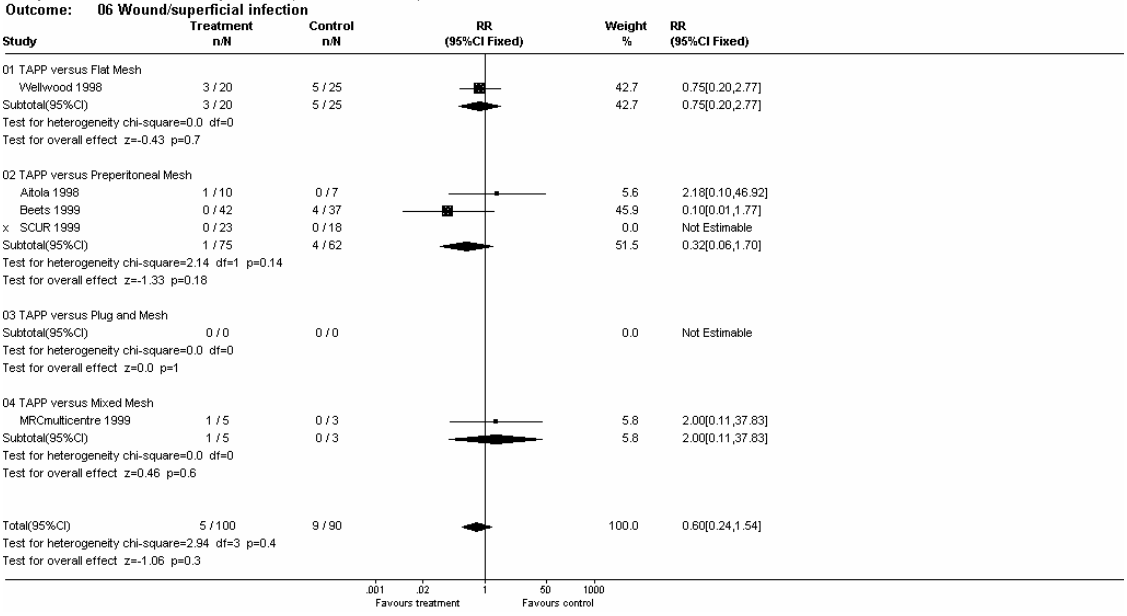
Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 04 Haematoma



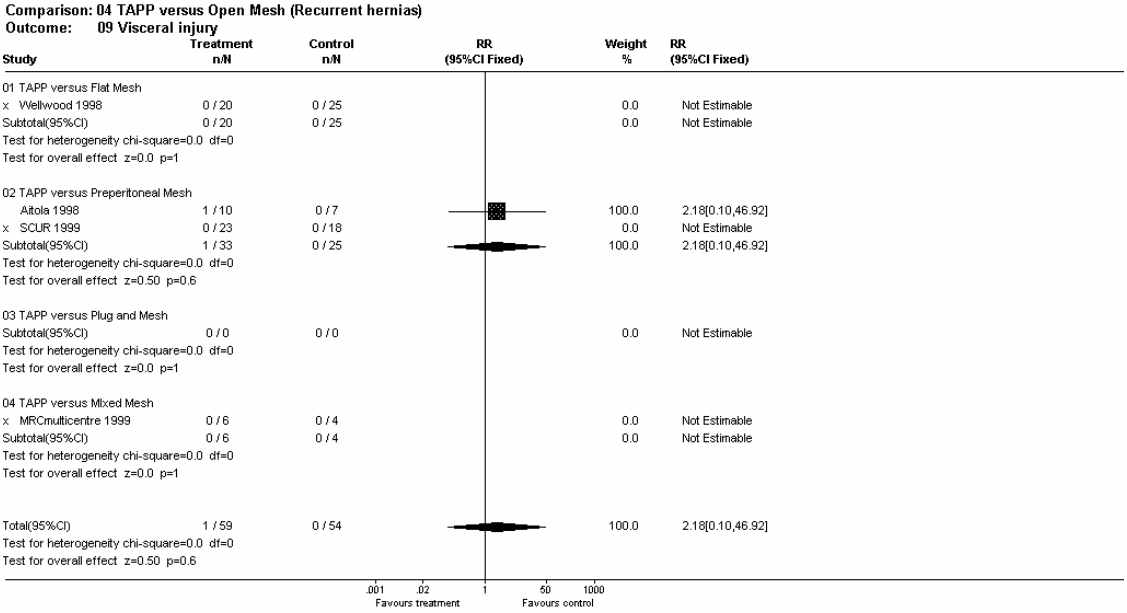
Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 05 Seroma



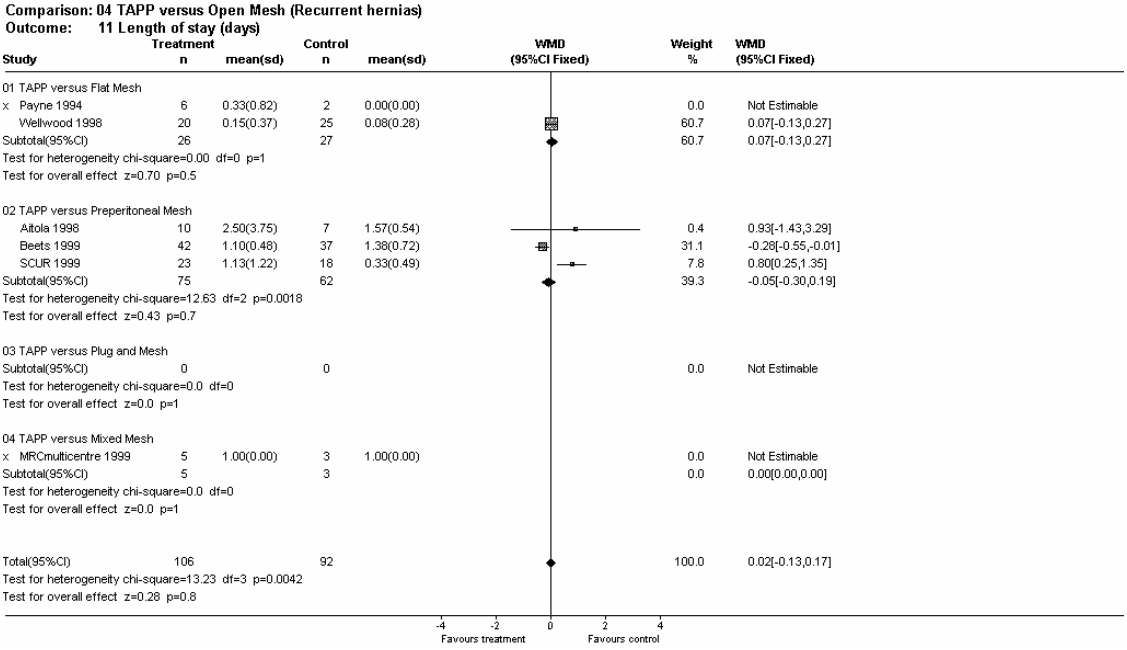
Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 06 Wound/superficial infection

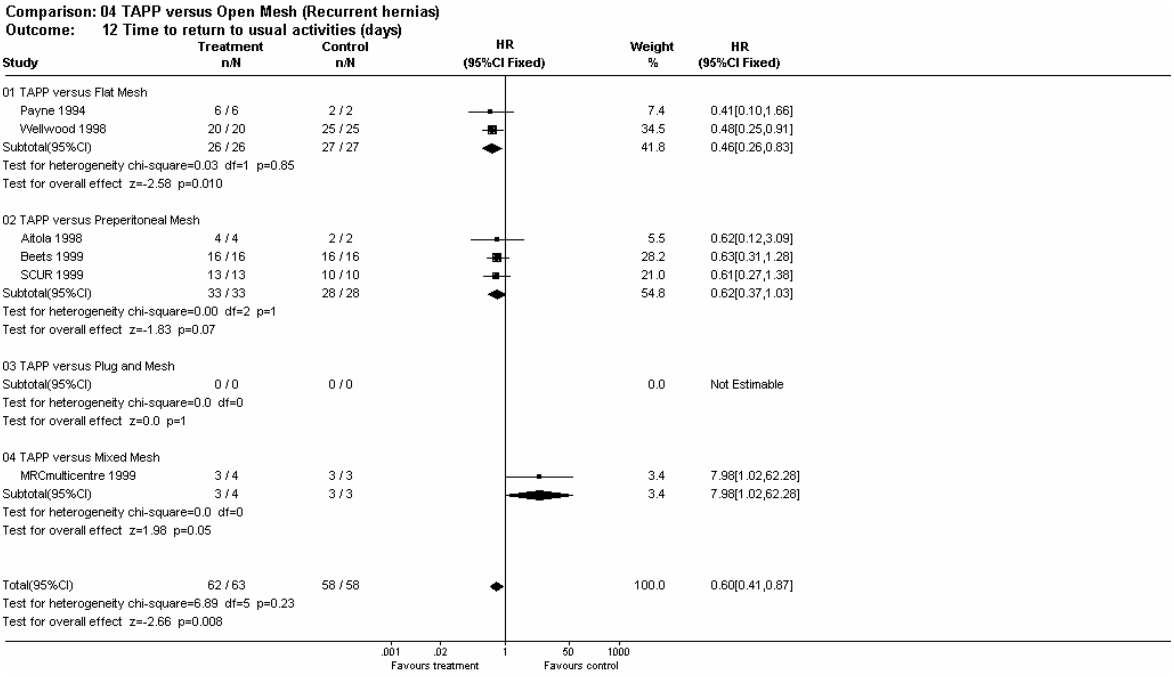


Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 09 Visceral injury

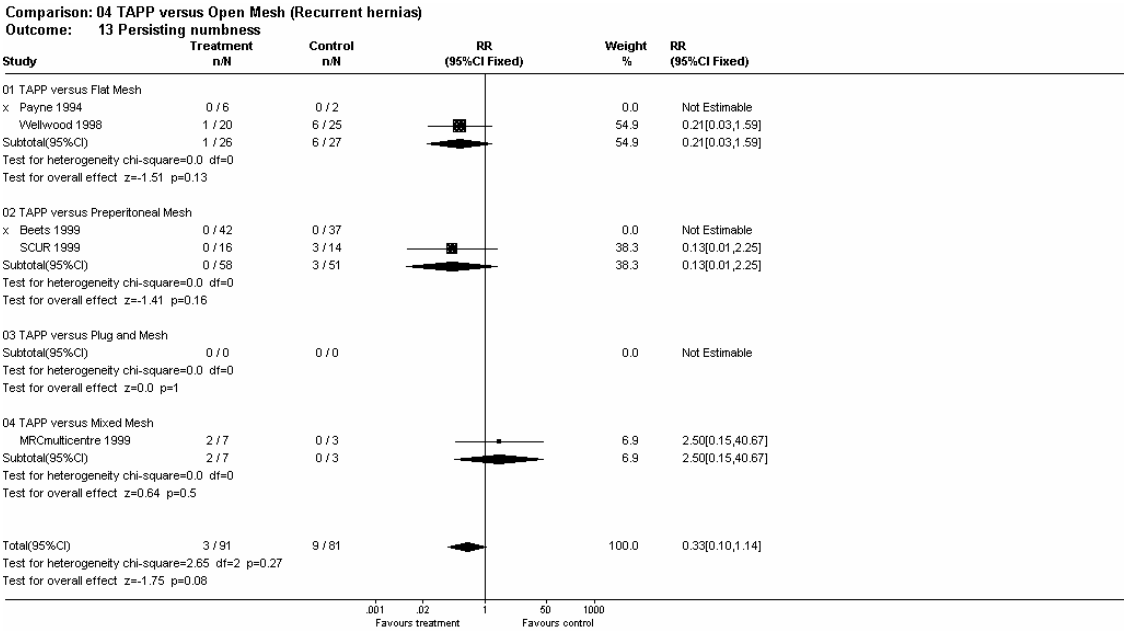


Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 11 Length of stay (days)

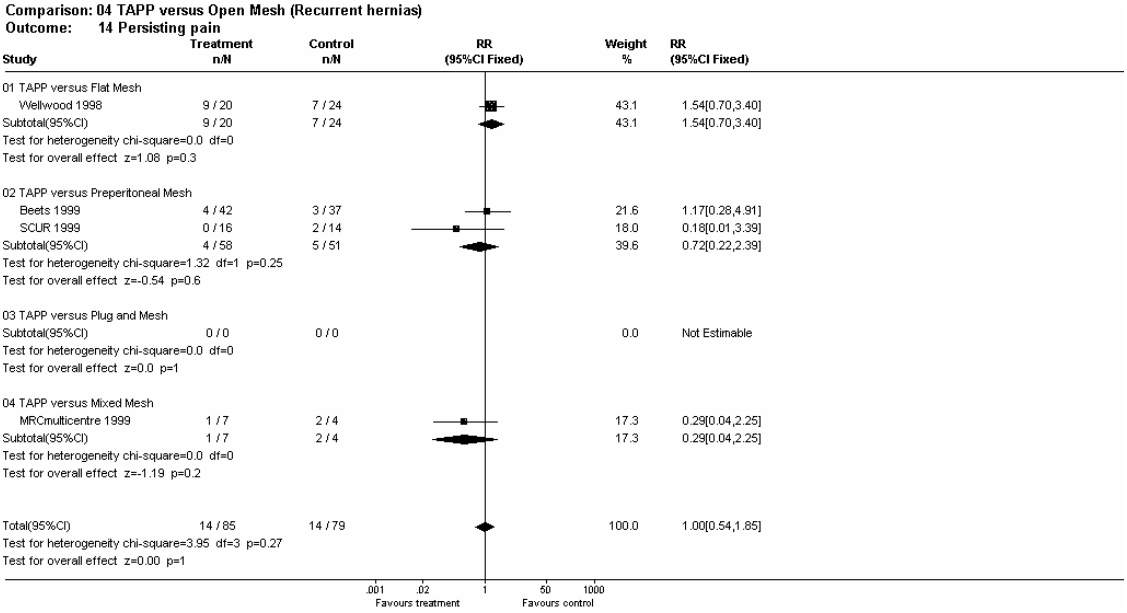




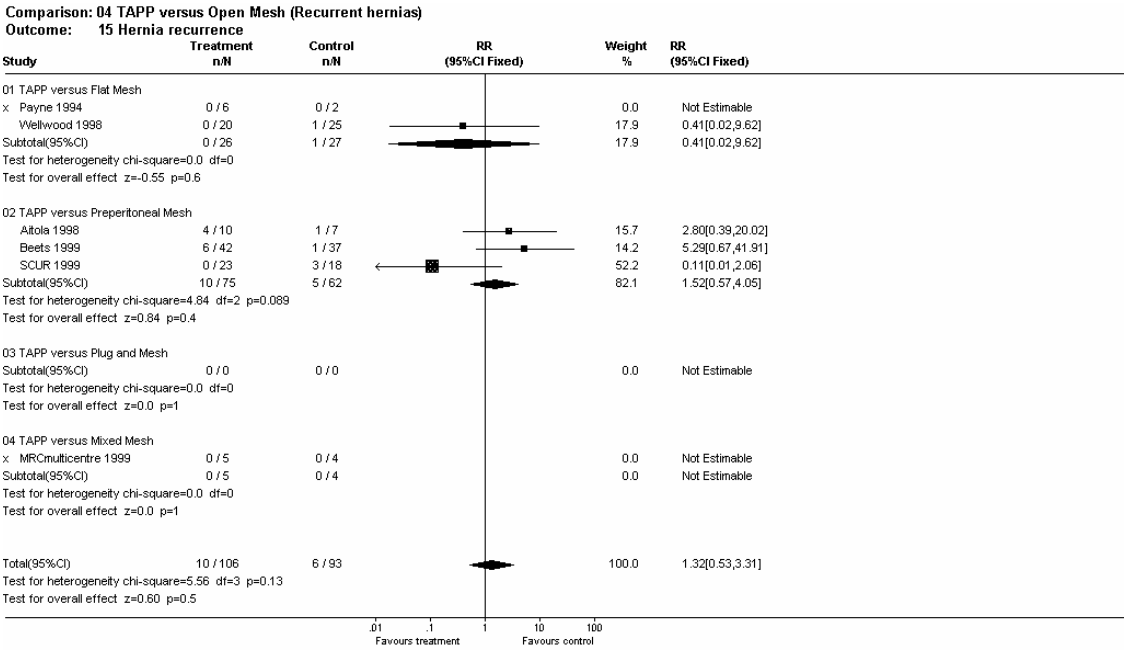
n/N refers to the number who have returned to activities within the follow-up period. The remaining few people are censored, i.e. they have not yet returned to activities at the time of follow-up.



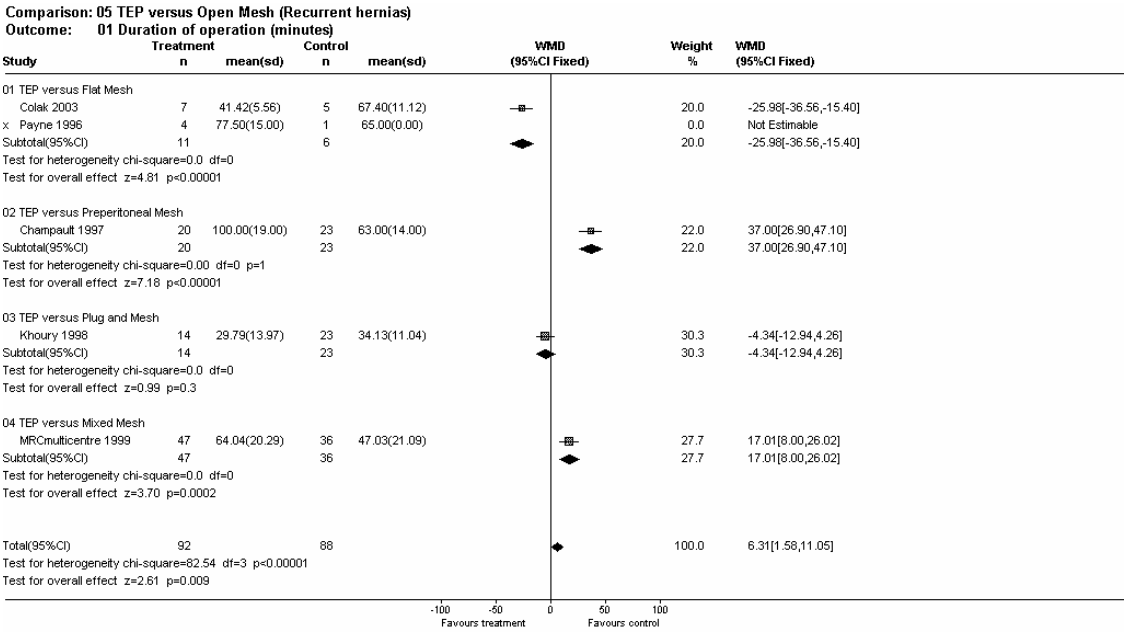
Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 14 Persisting pain

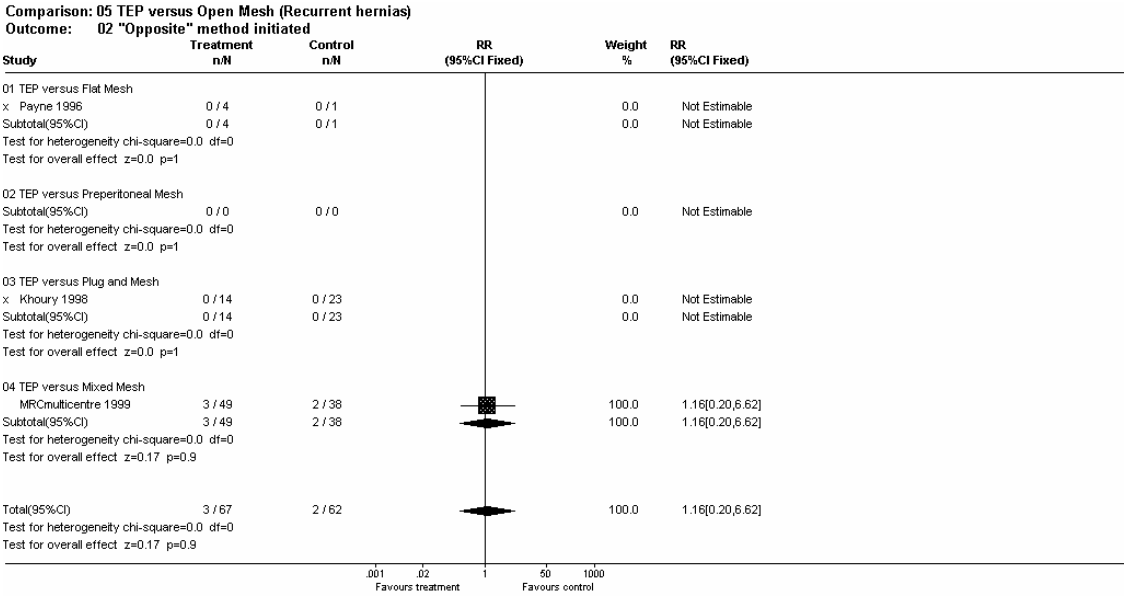


Comparison: 04 TAPP versus Open Mesh (Recurrent hernias)
Outcome: 15 Hernia recurrence

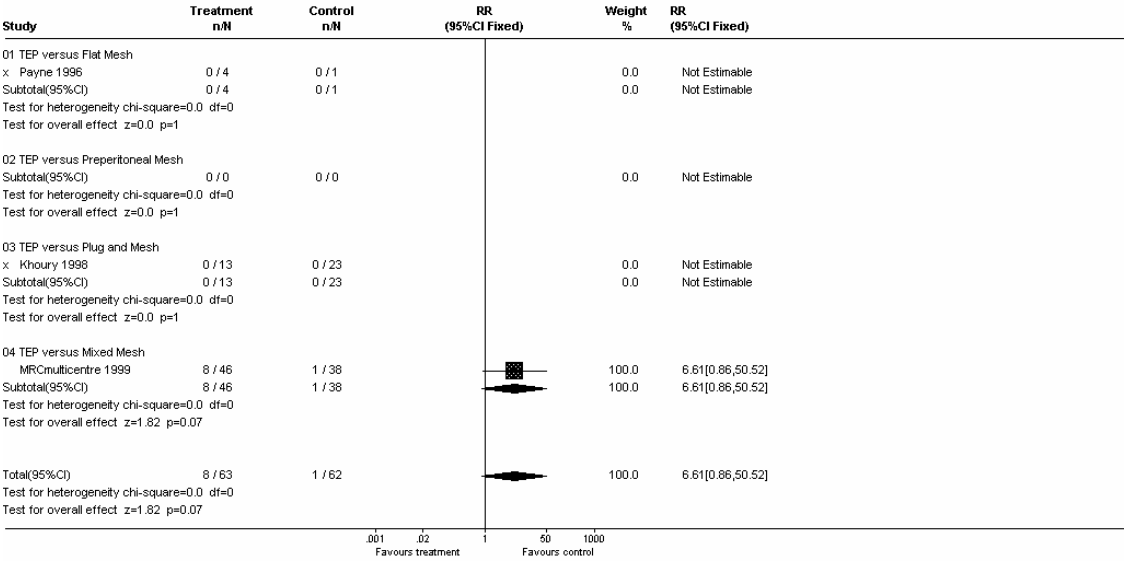


APPENDIX 7(5) RESULTS OF META-ANALYSES: LAPAROSCOPIC TEP VERSUS OPEN MESH REPAIR (RECURRENT HERNIAS)

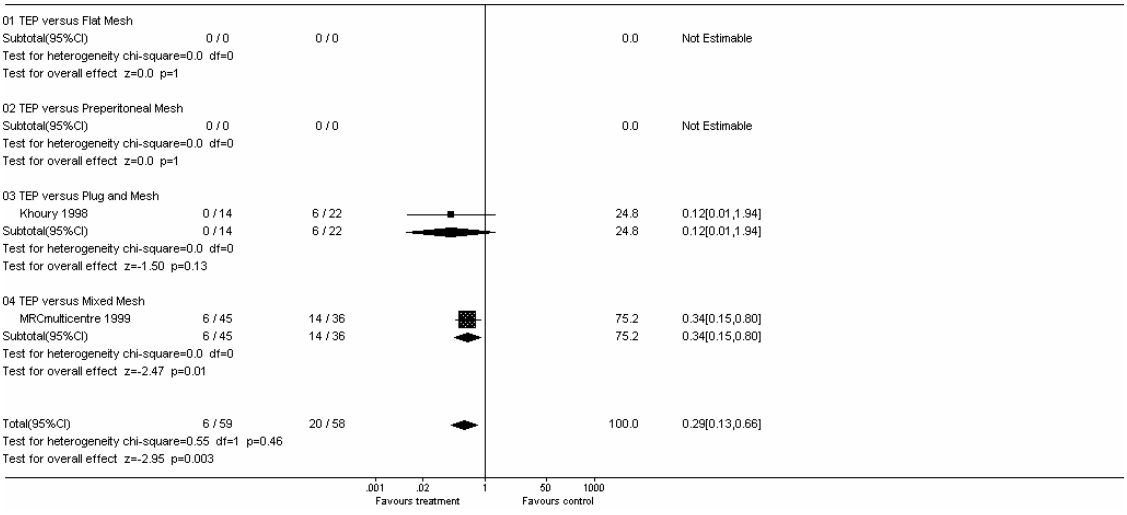




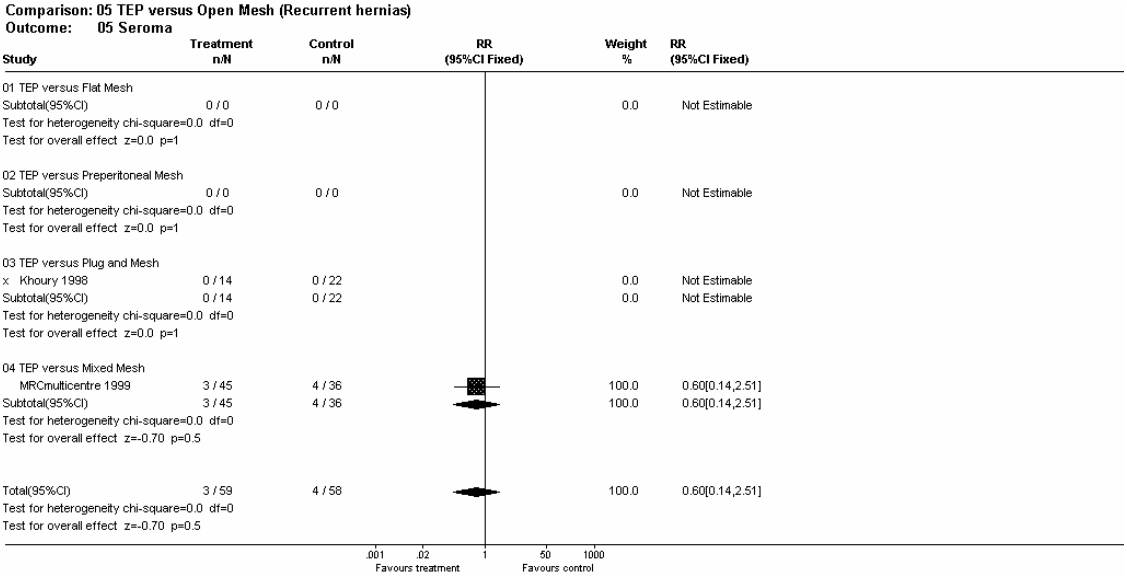
Comparison: 05 TEP versus Open Mesh (Recurrent hernias)
Outcome: 03 Conversion



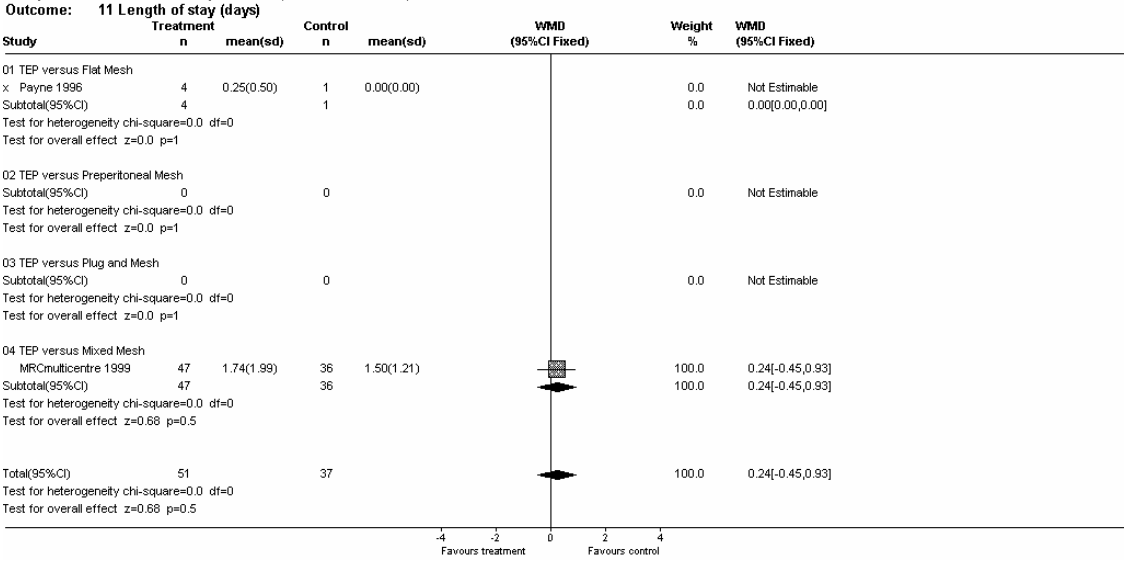
Comparison: 05 TEP versus Open Mesh (Recurrent hernias)
Outcome: 04 Haematoma

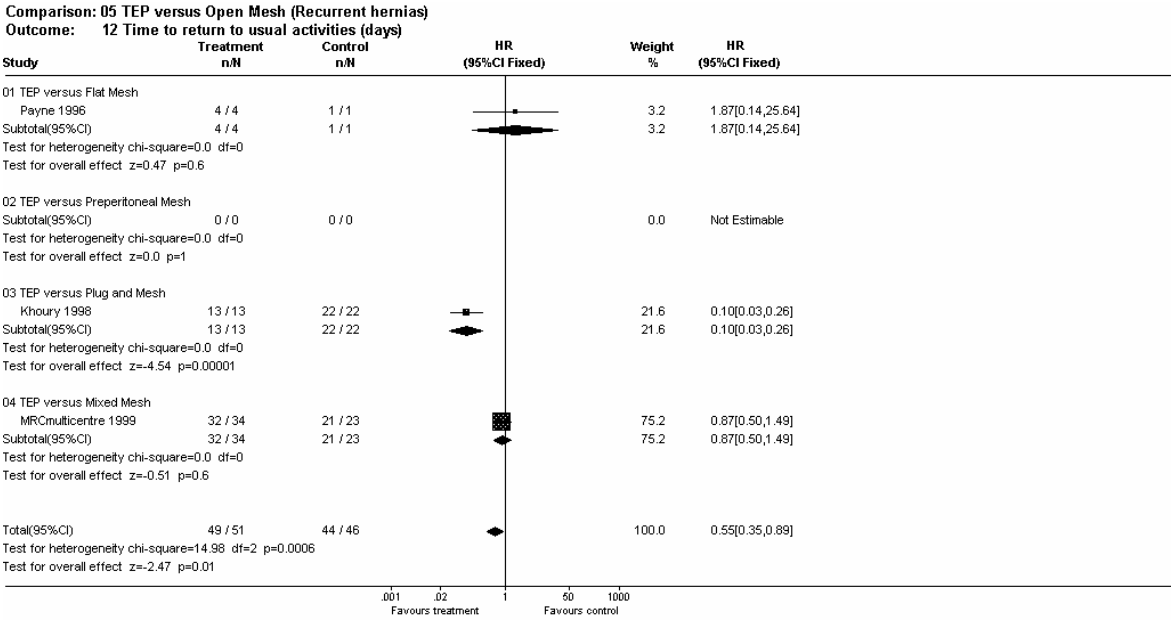


Comparison: 05 TEP versus Open Mesh (Recurrent hernias)
Outcome: 05 Seroma

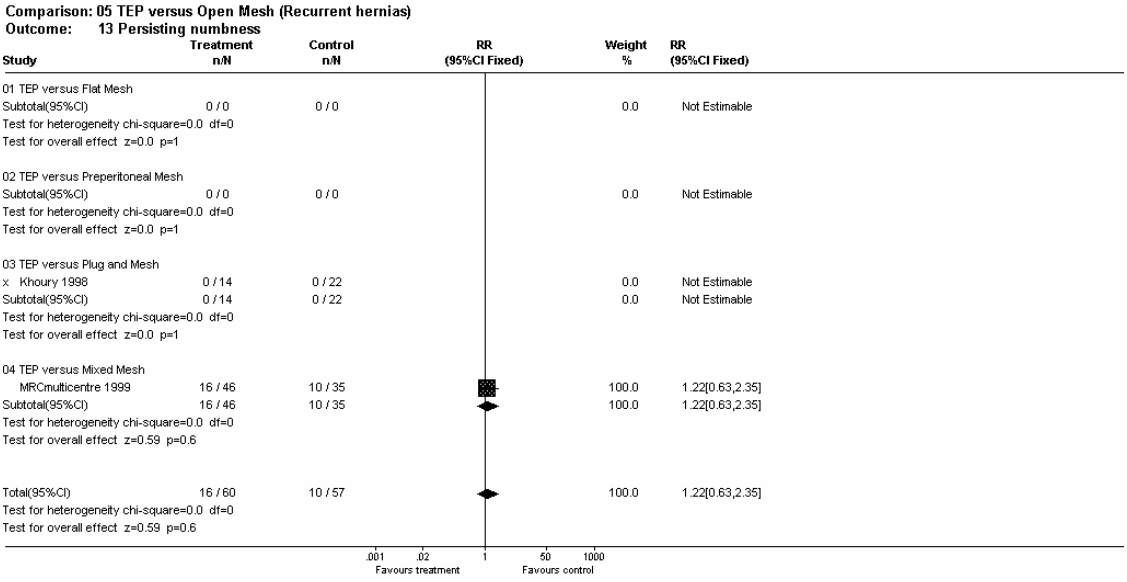


Comparison: 05 TEP versus Open Mesh (Recurrent hernias)
Outcome: 11 Length of stay (days)

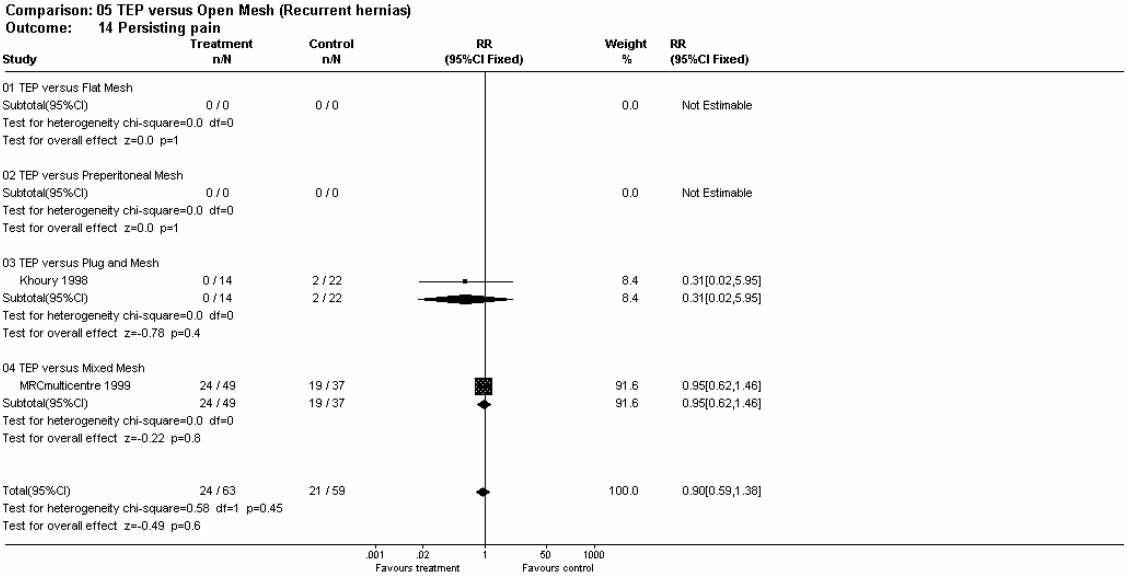




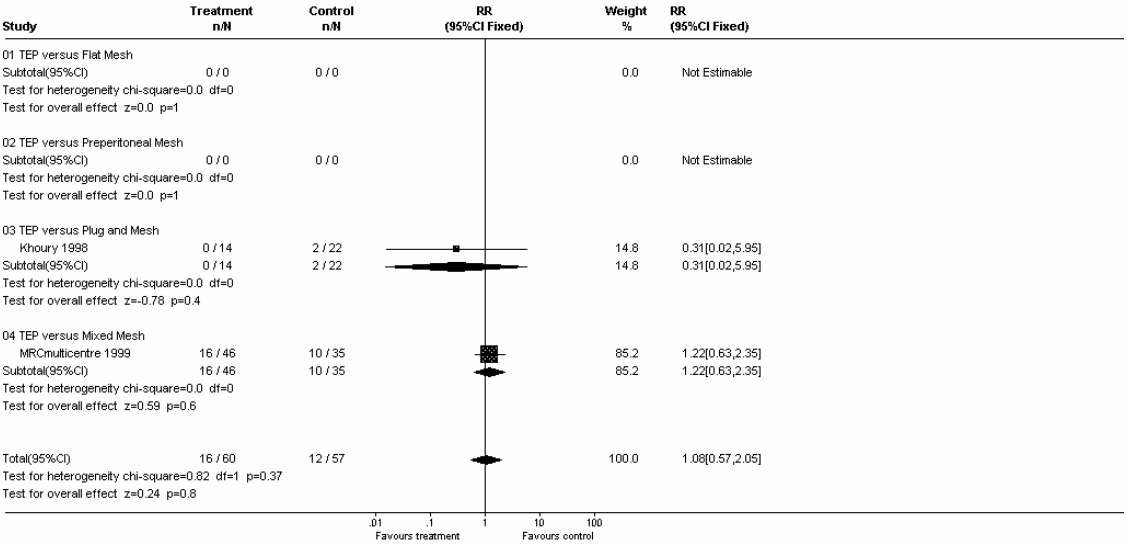
n/N refers to the number who have returned to activities within the follow-up period. The remaining few people are censored, i.e. they have not yet returned to activities at the time of follow-up.



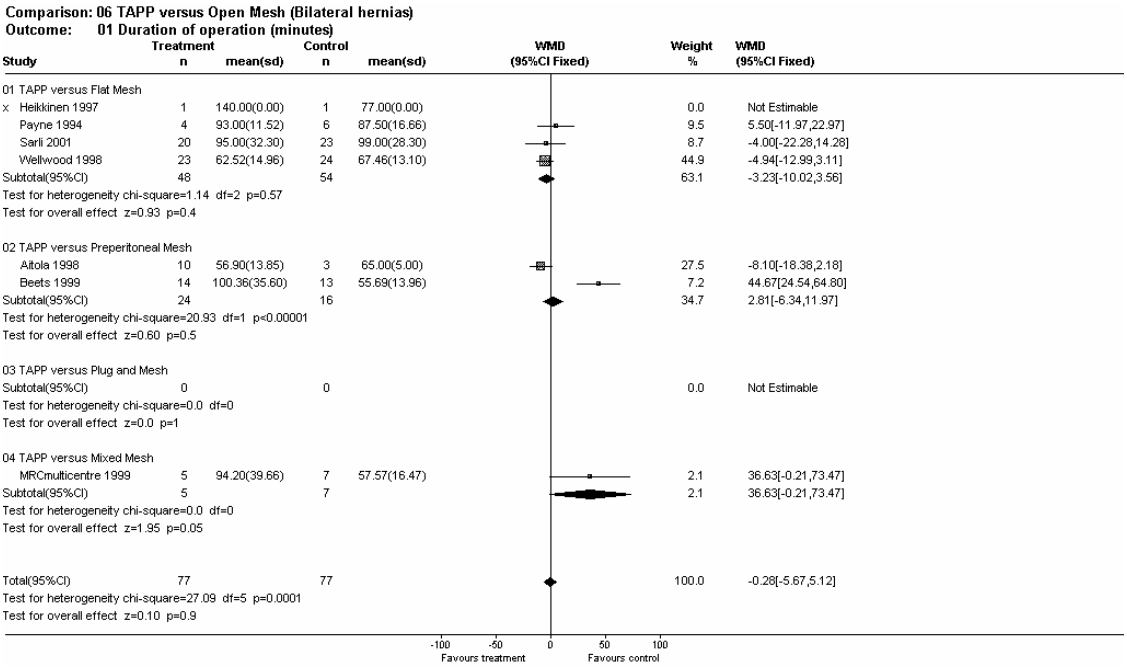
Comparison: 05 TEP versus Open Mesh (Recurrent hernias)
Outcome: 14 Persisting pain

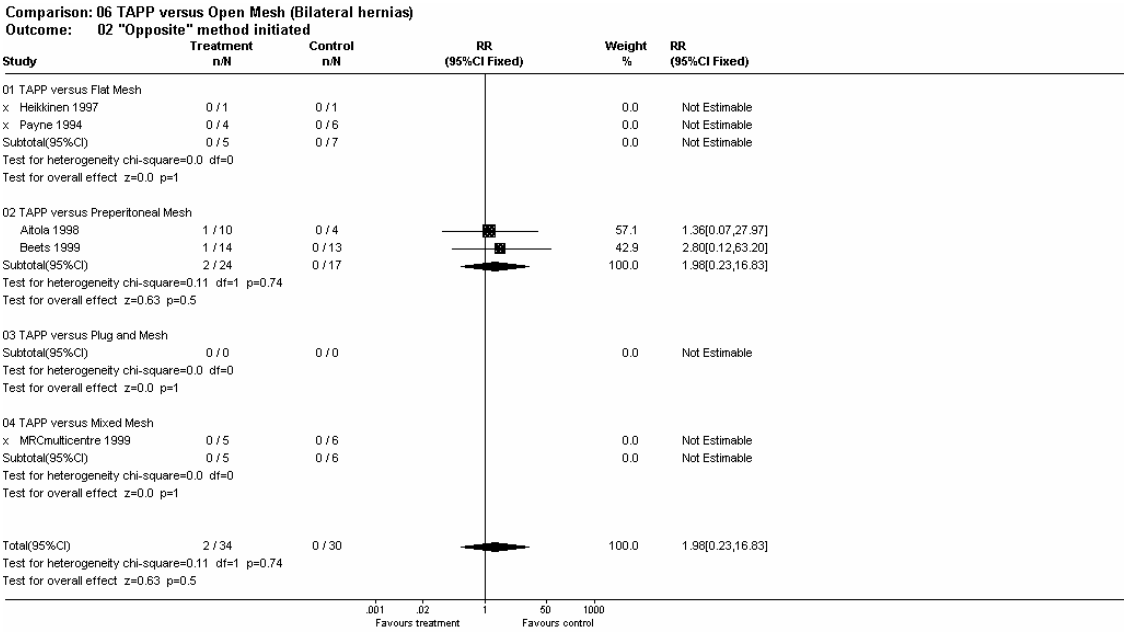


Comparison: 05 TEP versus Open Mesh (Recurrent hernias)
Outcome: 15 Hernia recurrence

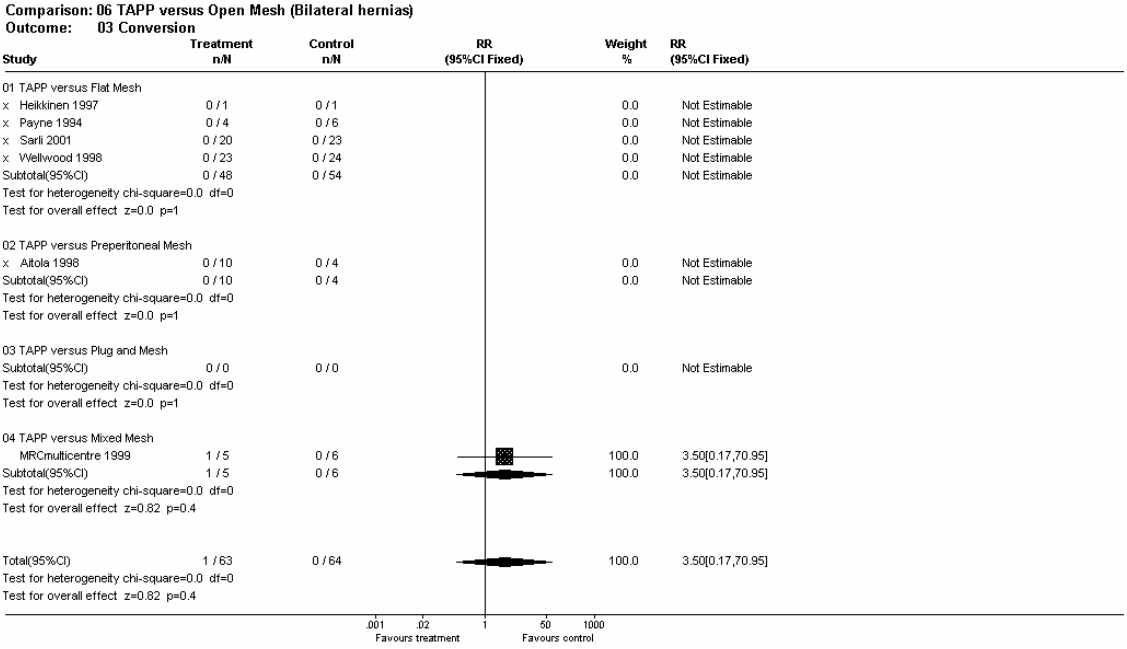


APPENDIX 7(6) RESULTS OF META-ANALYSES: LAPAROSCOPIC TAPP VERSUS OPEN MESH REPAIR (BILATERAL HERNIAS)

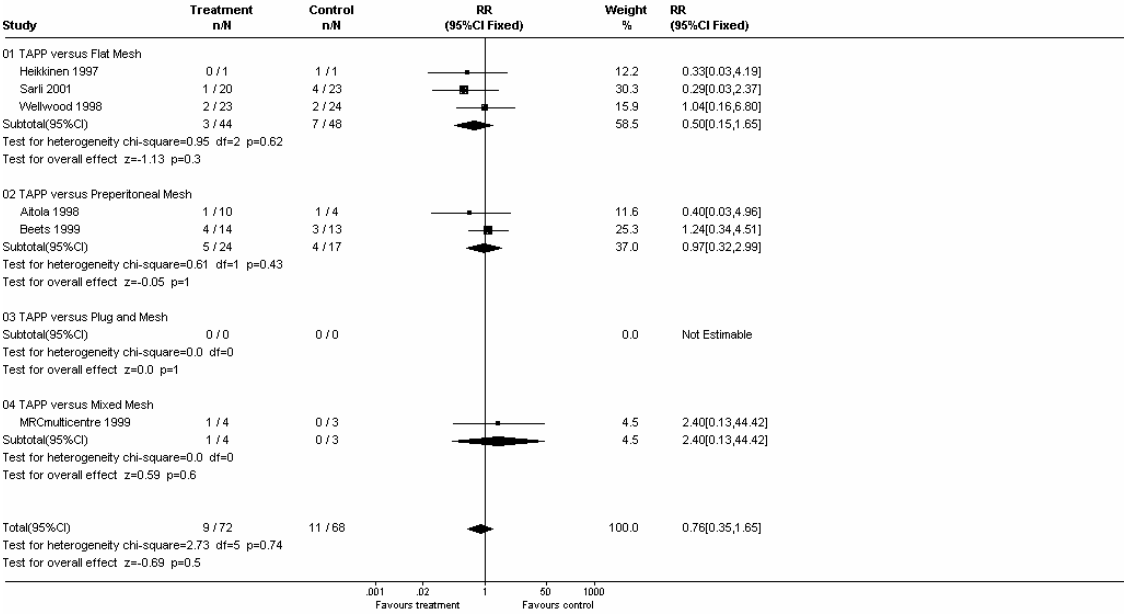




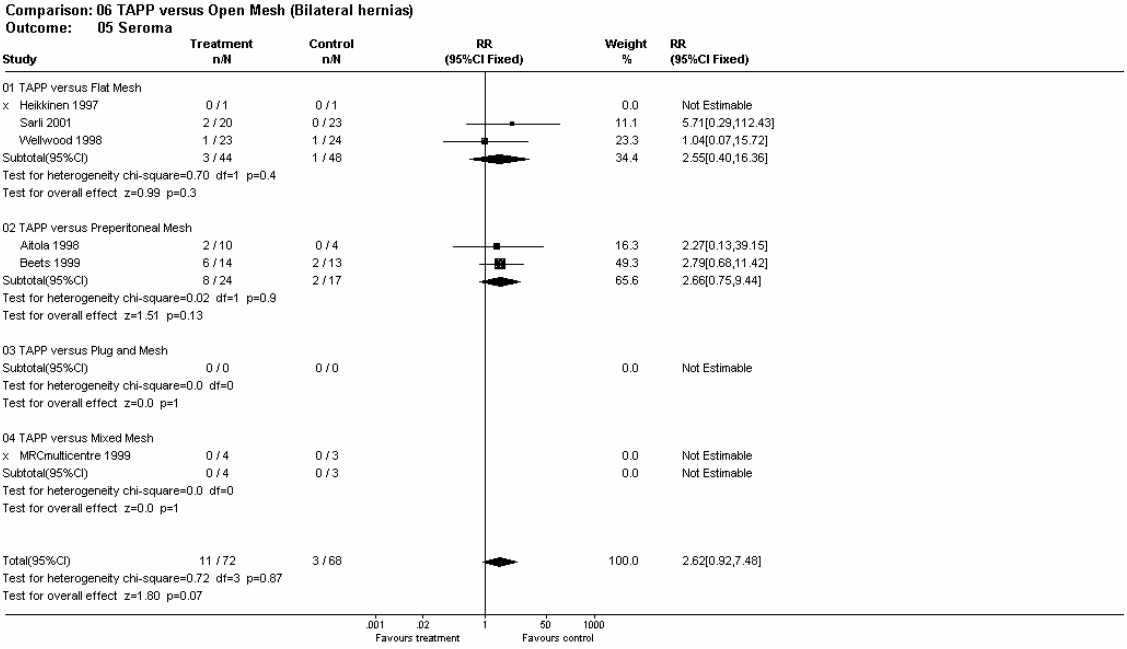
Comparison: 06 TAPP versus Open Mesh (Bilateral hernias)
Outcome: 03 Conversion



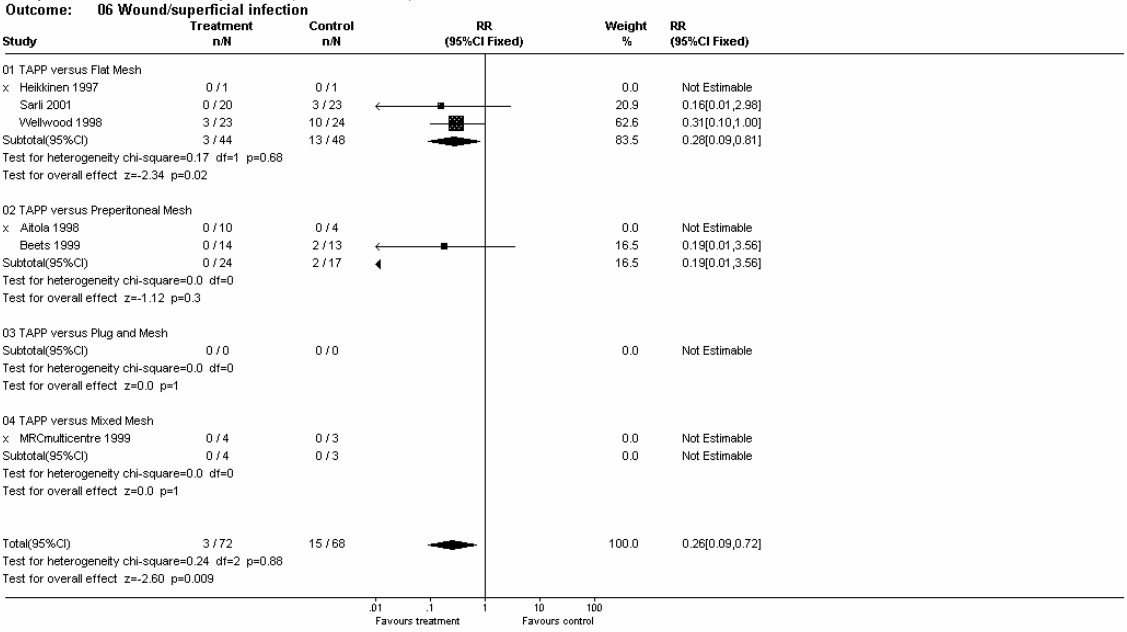
Comparison: 06 TAPP versus Open Mesh (Bilateral hernias)
Outcome: 04 Haematoma

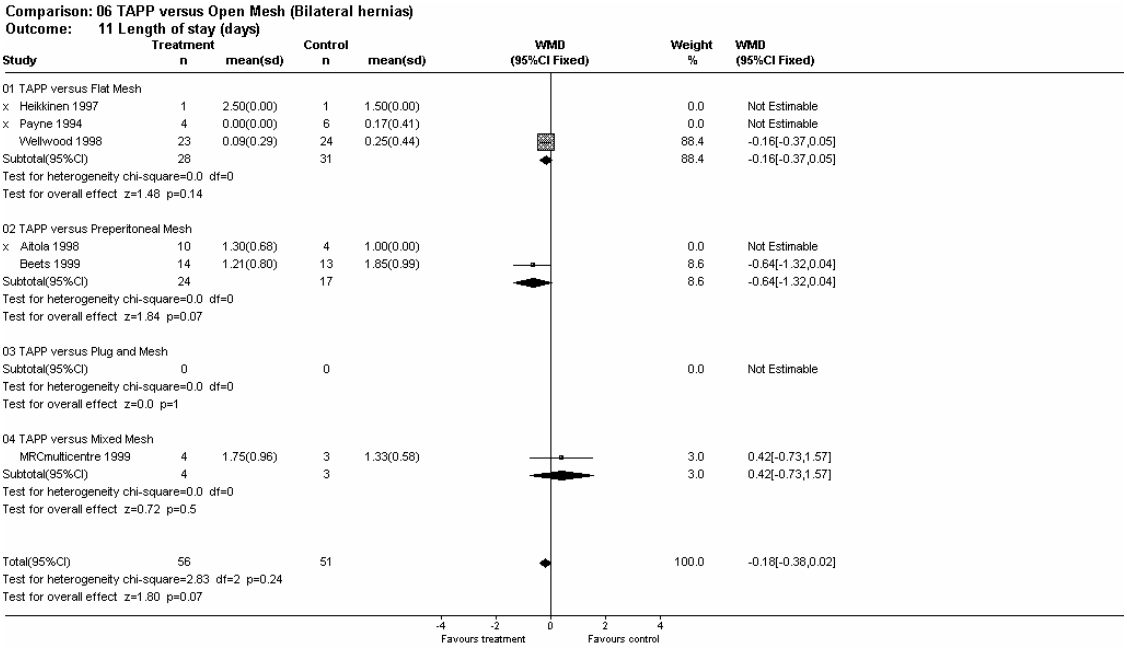


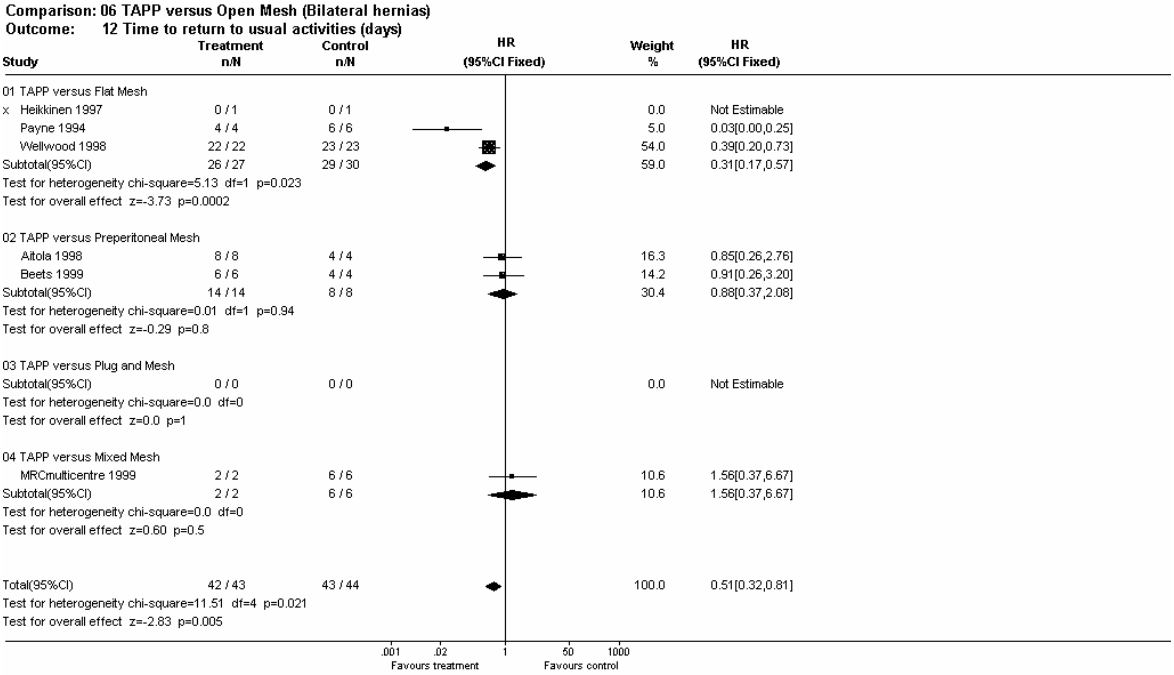
Comparison: 06 TAPP versus Open Mesh (Bilateral hernias)
Outcome: 05 Seroma



Comparison: 06 TAPP versus Open Mesh (Bilateral hernias)
Outcome: 06 Wound/superficial infection

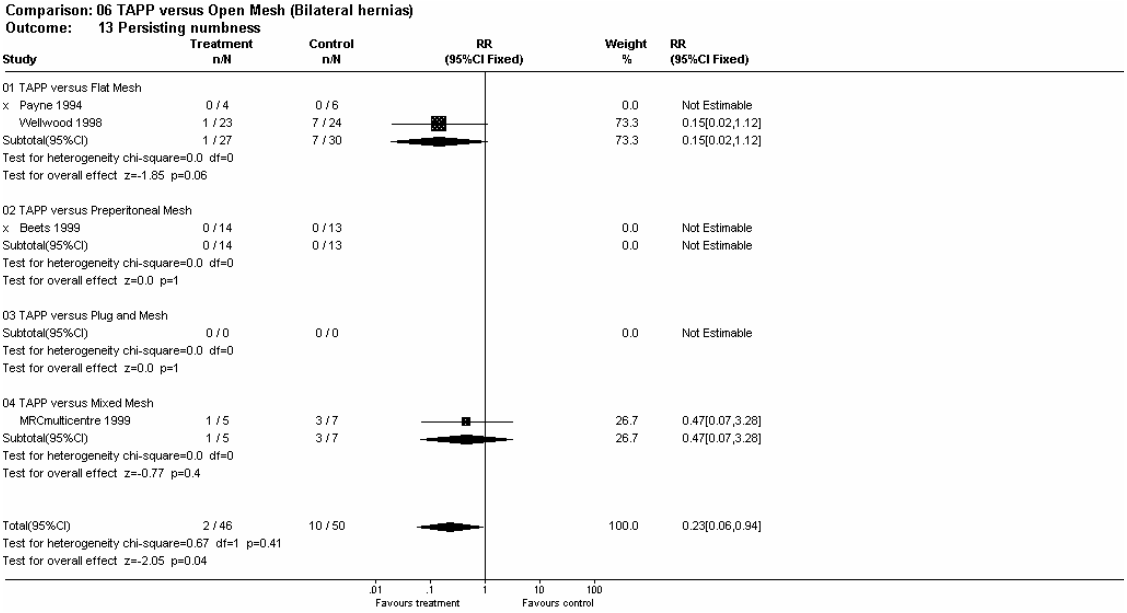




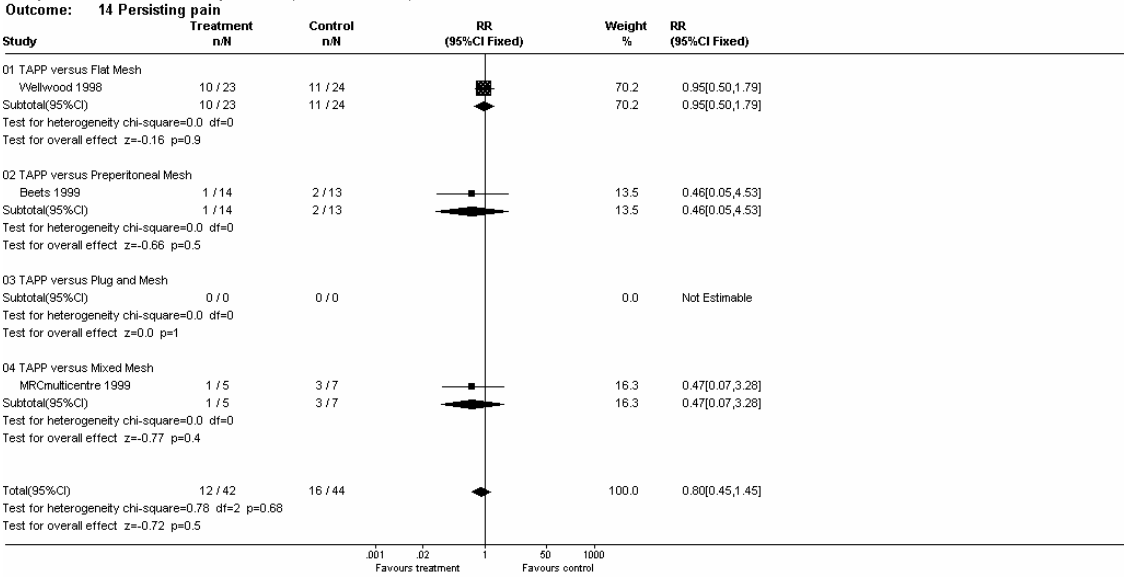


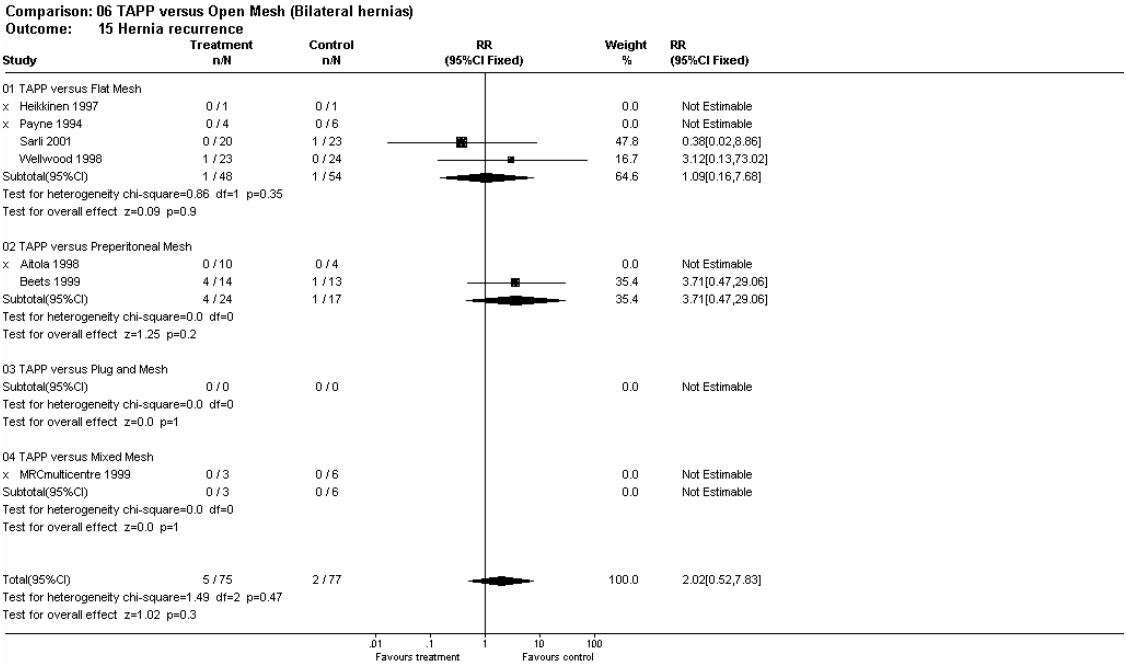
n/N refers to the number who have returned to activities within the follow-up period. The remaining few people are censored, i.e. they have not yet returned to activities at the time of follow-up.

Comparison: 06 TAPP versus Open Mesh (Bilateral hernias)
Outcome: 13 Persisting numbness

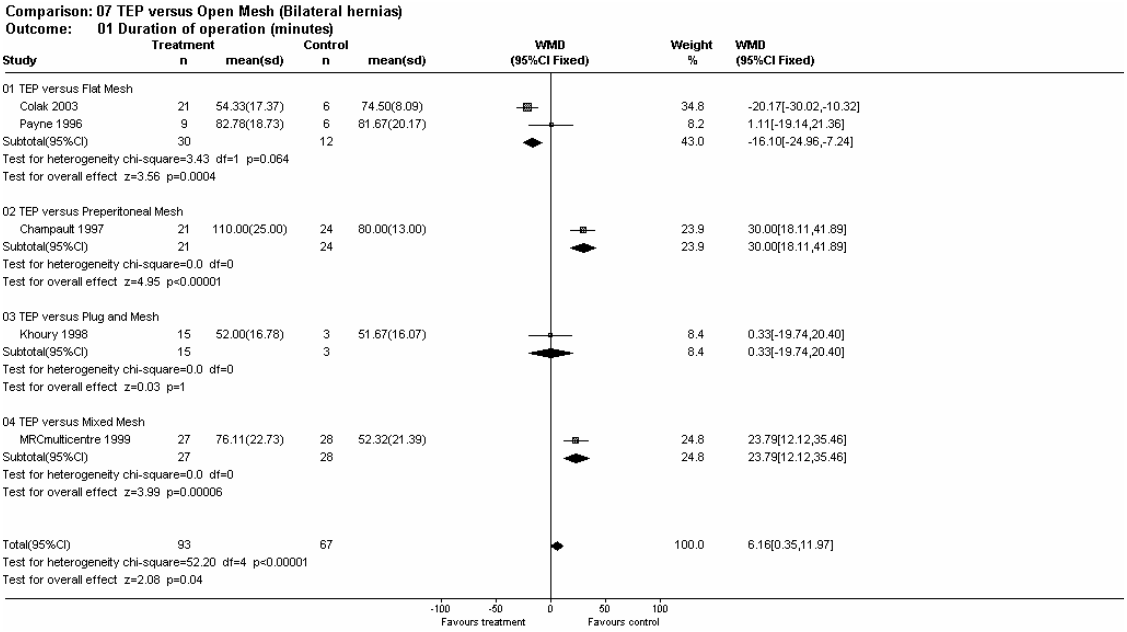


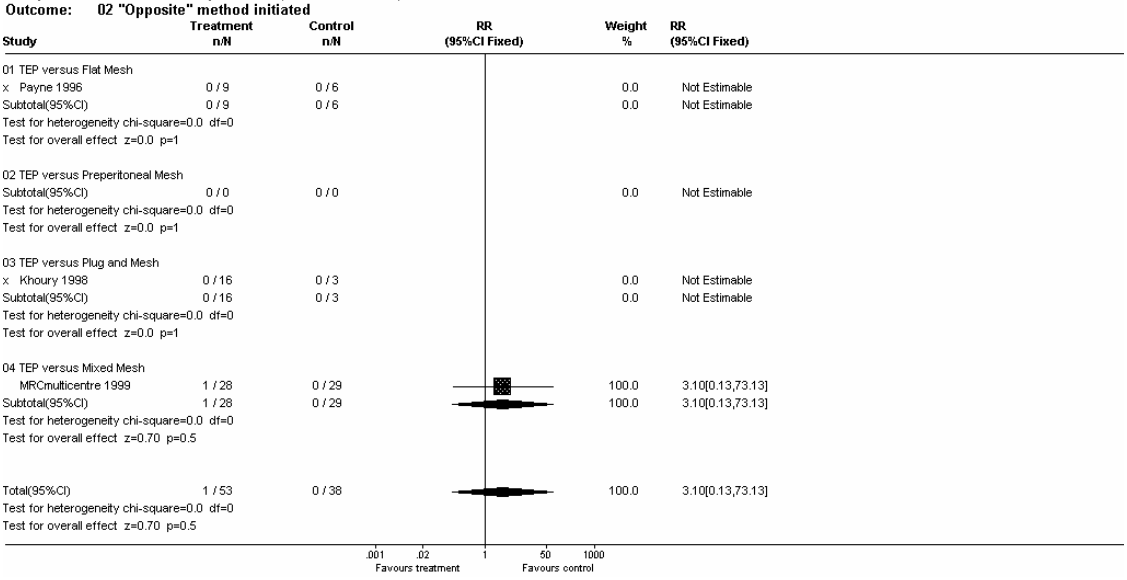
Comparison: 06 TAPP versus Open Mesh (Bilateral hernias)
Outcome: 14 Persisting pain



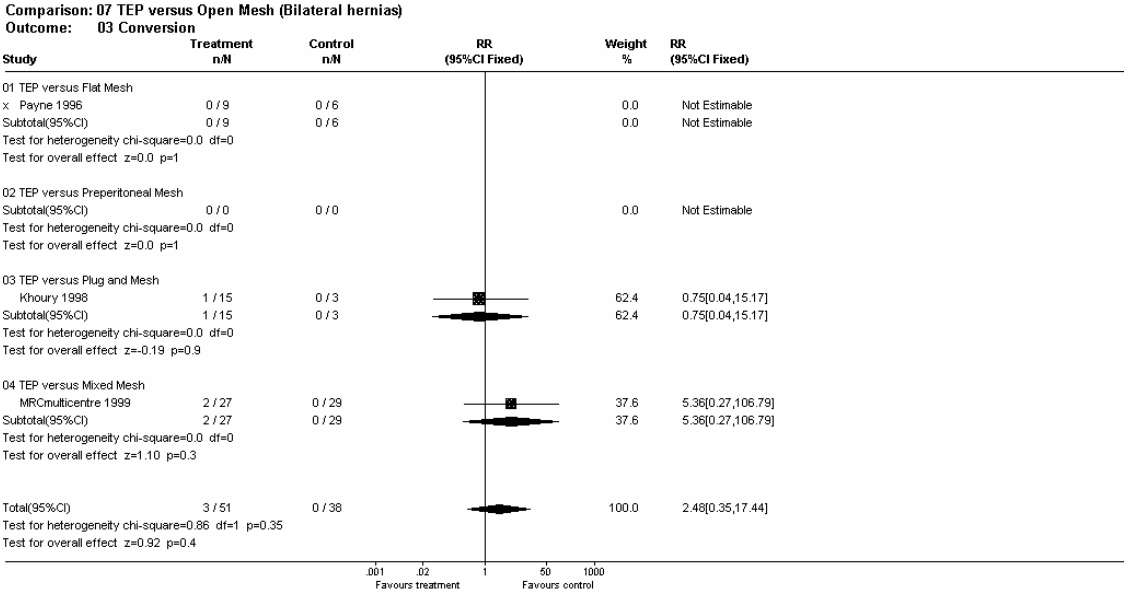

Comparison: 06 TAPP versus Open Mesh (Bilateral hernias)
Outcome: 15 Hernia recurrence
Study
Treatment n/N
Control n/N
RR (95%CI Fixed)
Weight %
RR (95%CI Fixed)
01 TAPP versus Flat Mesh
x Heikkinen 1997 0 / 1 0 / 1 0.0 Not Estimable
x Payne 1994 0 / 4 0 / 6 0.0 Not Estimable
Sarli 2001 0 / 20 1 / 23 47.8 0.38[0.02,8.86]
Wellwood 1998 1 / 23 0 / 24 16.7 3.12[0.13,73.02]
Subtotal(95%CI) 1 / 48 1 / 54 64.6 1.09[0.16,7.68]
Test for heterogeneity chi-square=0.86 df=1 p=0.35
Test for overall effect z=0.09 p=0.9
02 TAPP versus Preperitoneal Mesh
x Aitola 1998 0 / 10 0 / 4 0.0 Not Estimable
Beets 1999 4 / 14 1 / 13 35.4 3.71[0.47,29.06]
Subtotal(95%CI) 4 / 24 1 / 17 35.4 3.71[0.47,29.06]
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=1.25 p=0.2
03 TAPP versus Plug and Mesh
Subtotal(95%CI) 0 / 0 0 / 0 0.0 Not Estimable
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.0 p=1
04 TAPP versus Mixed Mesh
x MRCmulticentre 1999 0 / 3 0 / 6 0.0 Not Estimable
Subtotal(95%CI) 0 / 3 0 / 6 0.0 Not Estimable
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.0 p=1
Total(95%CI) 5 / 75 2 / 77 100.0 2.02[0.52,7.83]
Test for heterogeneity chi-square=1.49 df=2 p=0.47
Test for overall effect z=1.02 p=0.3
.01
.1
1
10
100
Favours treatment
Favours control

APPENDIX 7(7) RESULTS OF META-ANALYSES: LAPAROSCOPIC TEP VERSUS OPEN MESH REPAIR (BILATERAL HERNIAS)

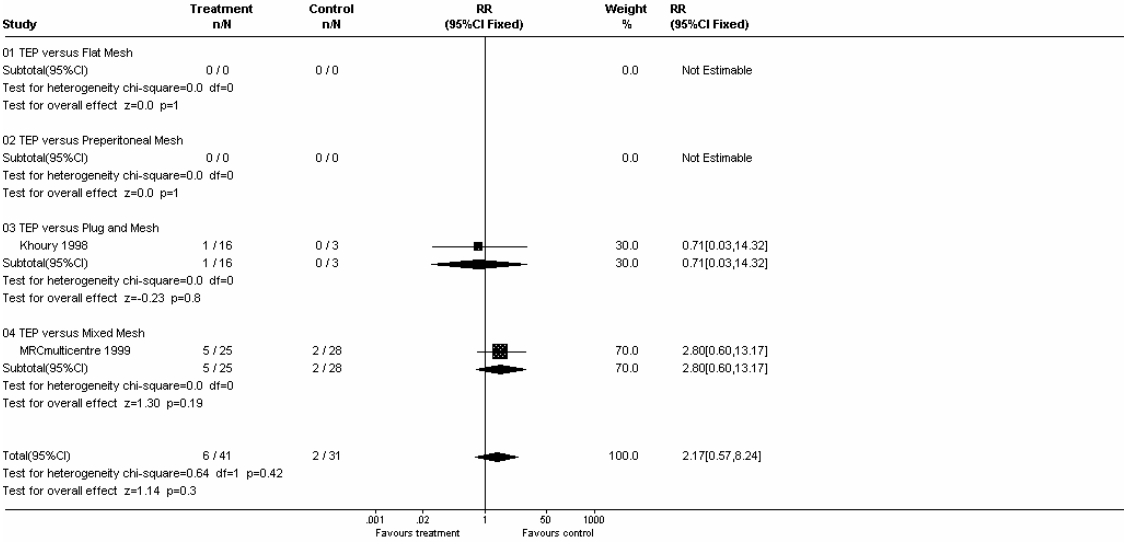




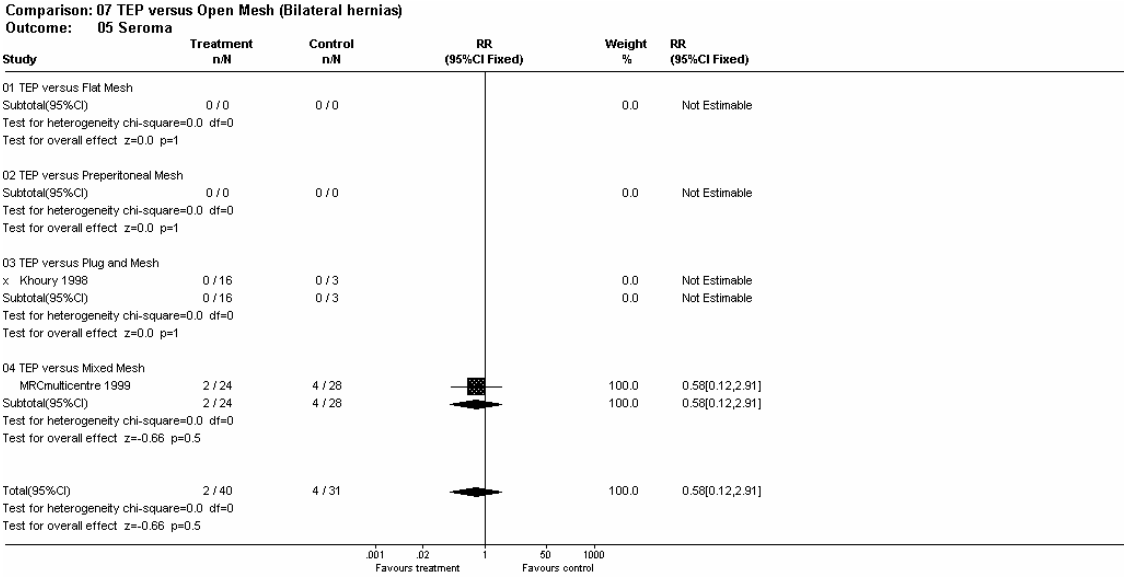
Comparison: 07 TEP versus Open Mesh (Bilateral hernias)
Outcome: 03 Conversion



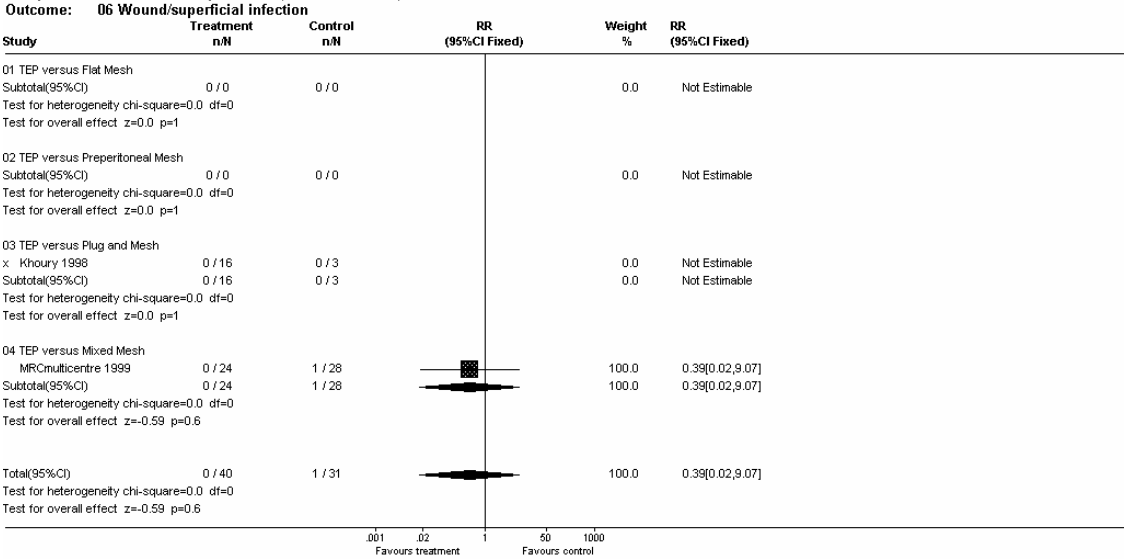
Comparison: 07 TEP versus Open Mesh (Bilateral hernias)
Outcome: 04 Haematoma

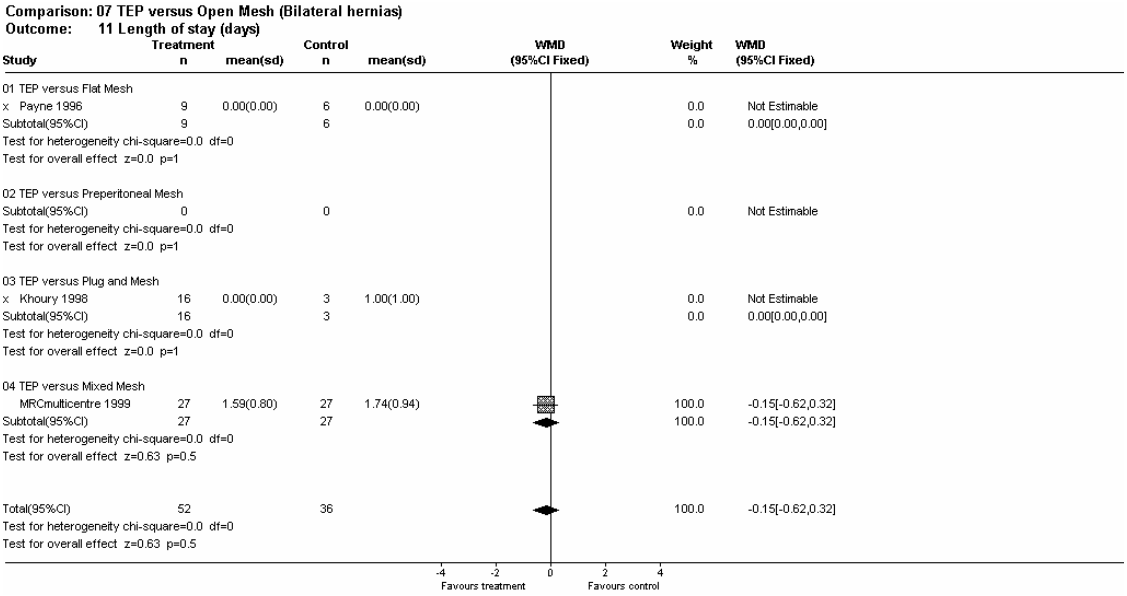


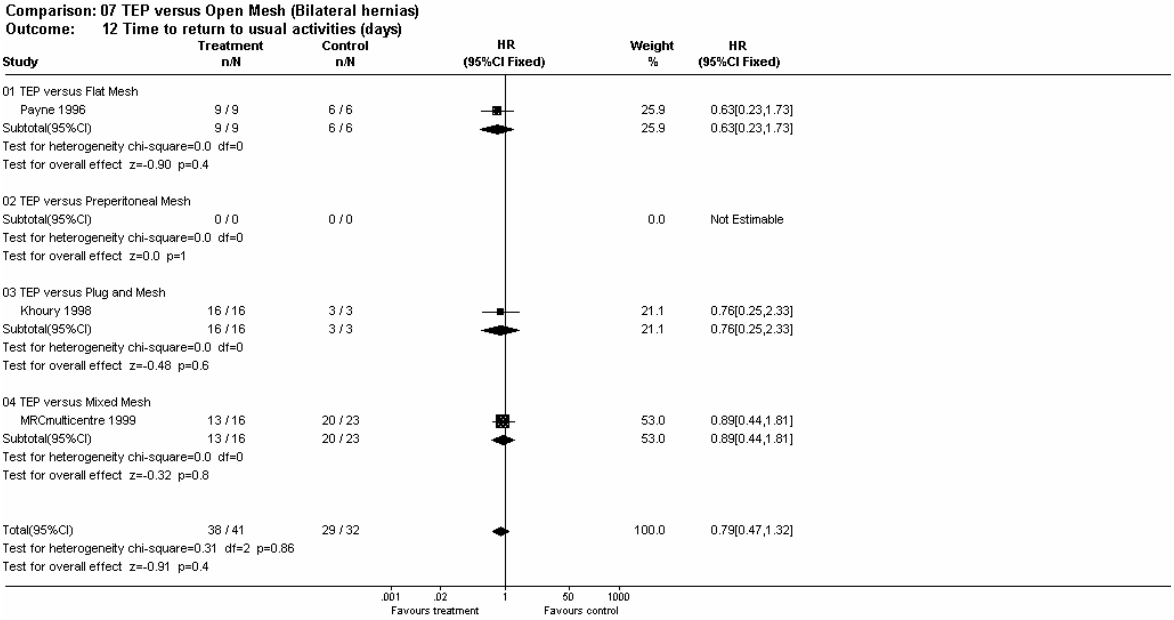
Comparison: 07 TEP versus Open Mesh (Bilateral hernias)
Outcome: 05 Seroma



Comparison: 07 TEP versus Open Mesh (Bilateral hernias)
Outcome: 06 Wound/superficial infection

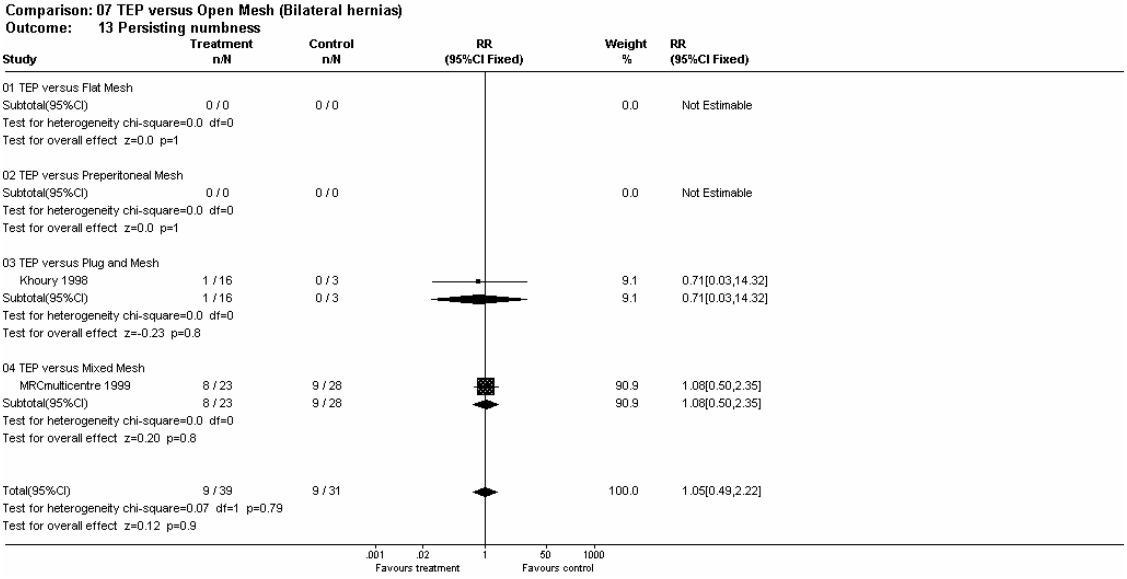




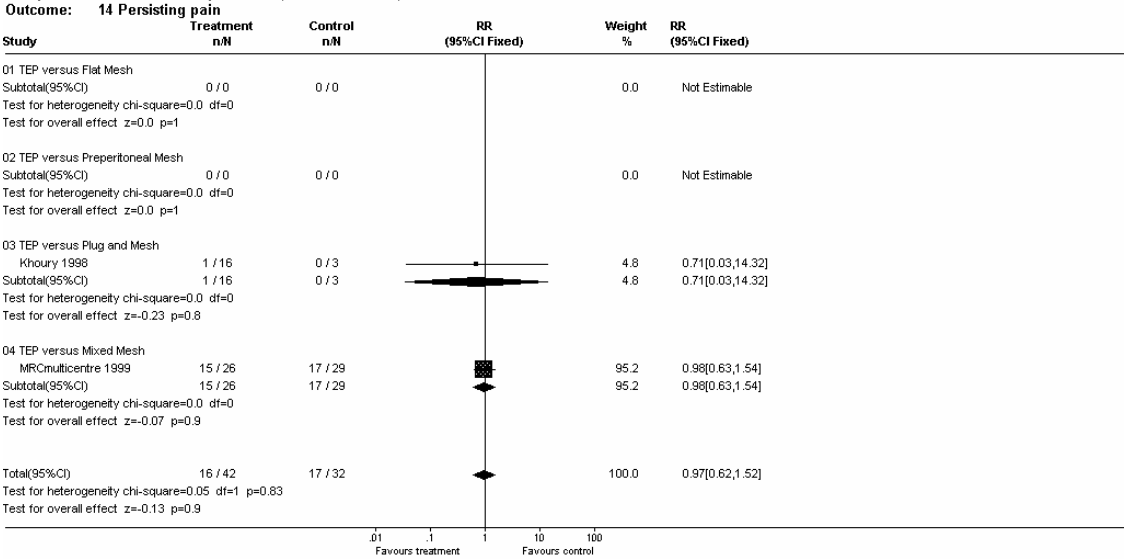


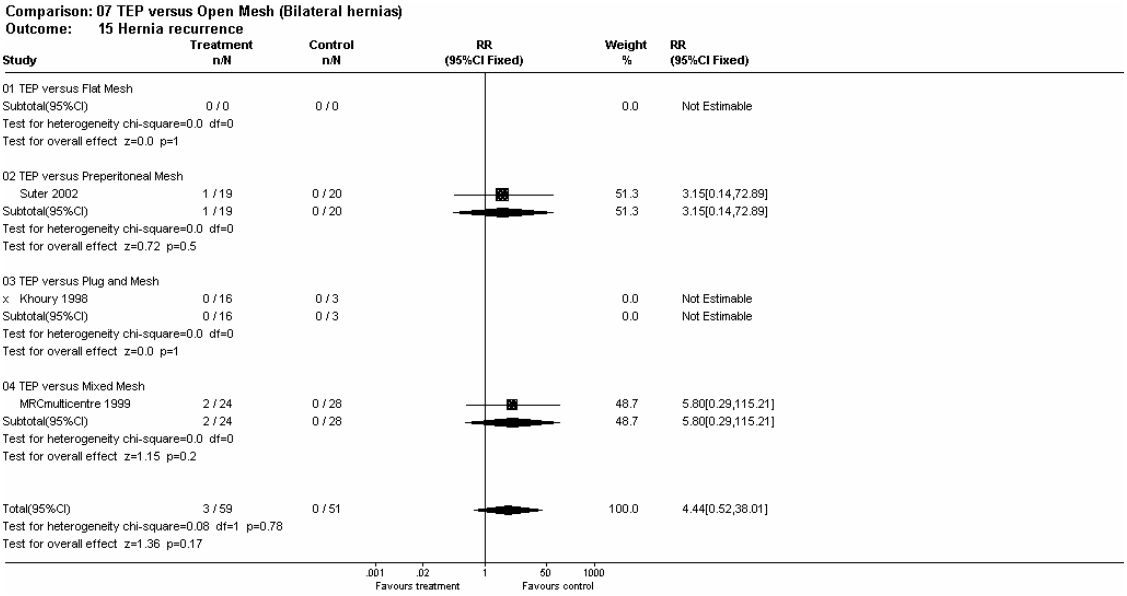
n/N refers to the number who have returned to activities within the follow-up period. The remaining few people are censored, i.e. they have not yet returned to activities at the time of follow-up.

Comparison: 07 TEP versus Open Mesh (Bilateral hernias)
Outcome: 13 Persisting numbness



Comparison: 07 TEP versus Open Mesh (Bilateral hernias)
Outcome: 14 Persisting pain




Comparison: 07 TEP versus Open Mesh (Bilateral hernias)
Outcome: 15 Hernia recurrence
Study
Treatment n/N
Control n/N
RR (95%CI Fixed)
Weight %
RR (95%CI Fixed)
01 TEP versus Flat Mesh
Subtotal(95%CI) 0 / 0 0 / 0 0.0 Not Estimable
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.0 p=1
02 TEP versus Preperitoneal Mesh
Suter 2002 1 / 19 0 / 20 51.3 3.15[0.14,72.89]
Subtotal(95%CI) 1 / 19 0 / 20 51.3 3.15[0.14,72.89]
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.72 p=0.5
03 TEP versus Plug and Mesh
x Khoury 1998 0 / 16 0 / 3 0.0 Not Estimable
Subtotal(95%CI) 0 / 16 0 / 3 0.0 Not Estimable
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=0.0 p=1
04 TEP versus Mixed Mesh
MRCmulticentre 1999 2 / 24 0 / 28 48.7 5.80[0.29,115.21]
Subtotal(95%CI) 2 / 24 0 / 28 48.7 5.80[0.29,115.21]
Test for heterogeneity chi-square=0.0 df=0
Test for overall effect z=1.15 p=0.2
Total(95%CI) 3 / 59 0 / 51 100.0 4.44[0.52,38.01]
Test for heterogeneity chi-square=0.08 df=1 p=0.78
Test for overall effect z=1.36 p=0.17
.001
.02
1
50
1000
Favours treatment
Favours control

APPENDIX 8 DETAILS OF FURTHER STUDIES USED FOR CLINICAL EFFECTIVENESS OF TAPP VERSUS TEP (NON-RCTS)

First author (date)	Country of Study	Study design	Data Collection	Number of repairs	Patient Characteristics - TAPP	Patient Characteristics - TEP
Baca (2000)[112]	Germany	Case Series	Retrospective	2500 TAPP	92% Male Average age 59 (range 19-88) 32% Direct, 37% Indirect, 2% Femoral, 12% Combined, 17% Recurrent, 22% Bilateral Mean Follow-up 39 months (range 4 weeks to 7 yrs) 87% patients included in analysis	Not Applicable
Cohen (1998)[113]	Brazil	Concurrent Comparison?	Prospective	108 TAPP 100 TEP	100% Male Mean age 35 (range 21-73) – Overall only 28% Unilateral, 38% Bilateral, 33% Recurrent	100% Male Mean age 35 (range 21-73) – Overall only 9% Unilateral, 49% Bilateral, 42% Recurrent
Felix (1995)[114]	USA	Concurrent Comparison	Retrospective	733 TAPP 382 TEP	87% male Mean age 49 (range 12-89) Median follow-up: 24 month (TAPP) and 9 months (TEP) 60% indirect, 23.6% direct, 15.3% pantaloon, 1% femoral	
Khoury (1995)[115]	Canada	Concurrent Comparison	Prospective	60 TAPP 60 TEP	91% Male Age range (20-76) 67% indirect, 28% direct, 3% femoral, 2% combined	Used a distension balloon 93% Male Age range (20-73) 68% indirect, 27% direct, 2% femoral, 3% combined
Leibl (2000)[116]	Germany	Case Series	Retrospective	5707 TAPP	Not reported	
Lepere (2000)[117]	France	Concurrent Comparison	Retrospective	1290 TAPP 682 TEP	87% Male overall 63% unilateral, 37% bilateral, 9% recurrent	87% Male overall 74% unilateral, 36% bilateral, 8% recurrent
Tamme (2003)[118]	Germany	Case Series	Retrospective	5203 TEP	Median age 53 (range 15-89) 91% male 32% direct, 57% indirect, 8% combined, 3% femoral, 13% recurrent, 35% bilateral	
Van Hee (1998)[119]	Belgium	Concurrent Comparison?	Prospective	37 TAPP 69 TEP	100% Male, Mean age 58, range (20-79) 78% unilateral, 22% bilateral, 43% direct, 54% direct, 3% combined, 5% recurrent	97% Male, Mean age 59 range (21-84) 68% unilateral, 32% bilateral, 29% direct, 59% indirect, 12% combined, 10% recurrent

First author (date)	Country of Study	Study design	Data Collection	Number of repairs	Patient Characteristics - TAPP	Patient Characteristics - TEP
Weiser (2000)[120]	Germany	Non-concurrent Comparison	Retrospective	1216 TAPP 1547 TEP	Not reported	Not reported

APPENDIX 9 LEARNING CURVE STUDY ELIGIBILITY FORM

NICE Review of the Effectiveness and Cost-Effectiveness of Laparoscopic Surgery for Inguinal Hernia Repair

Study ID:_____**RefmanID:**_____

Q1. Is data reported for an individual operator rather than an institution?

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Q2. Is data reported for at least 3 points on the learning curve?

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Q3. Are the procedures consecutive?

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Q4. Is data reported for at least one of the relevant 'learning' outcomes?

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Final decision: Included ☐ Unclear ☐ Excluded ☐

APPENDIX 10 LEARNING CURVE DATA COLLECTION AND QUALITY ASSESSMENT FORM

NICE Review Of The Effectiveness And Cost-Effectiveness Of Laparoscopic Surgery For Inguinal Hernia Repair

Reviewer ID: _____

Study Details
Study ID: **Abstract** ☐ **Full Text** ☐
Authors:
Title:
Publication year or date of interim data collection:
Language:
Type of study:

Setting and Timing
Setting of study: _____
Number of clinics _____**Number of operators** _____
No. lap procedures performed prior to study entry_____
Recruitment period: _____
Follow-up period: _____
Other details :

Intervention

	Surgical Technique	**Type of Anaesthesia**	**Nº of patients**
Intervention 1			
Intervention 2			

Patient Characteristics			
	Intervention 1	**Intervention 2**	**Overall**
Age (years)			
Sex (M/F)			

Outcomes								
Duration of operation	Time point							
	Mins							
	Time point							
	Mins							
Visceral injury	Time point							
	Number							
Vascular injury	Time point							
	Number							
Length of stay	Time point							
	Days							
Return to usual activity	Time point							
	Days							
Hernia recurrence	Time point							
	No							
Persisting pain	Time point							
	No							
Persisting Numbness	Time point							
	No							

APPENDIX 11 CHARACTERISTICS OF LEARNING CURVE STUDIES

	Study Type	Surgical Technique	Patients (n)	Repairs (n)	Setting	Clinics (n)	Operators (n)	Lap. Procedures prior to study (n)	Follow-up period	Characteristics of patients	Characteristics of hernias
Aeberhard 1999[121]	Prospective audit	TEP	1186	1605 (767 unilateral, 419 bilateral)	Multi centre, Switzerland	29	29?	594	> 3m	Age (mean/SD) 54.6 (14.4) 1095 male/90 female	819 indirect, 338 direct, 231 recurrent, 28 femoral
Lau 2002[20]	Retrospective analysis	TEP	120	120	Single centre, Hong Kong	1	1	14 TAPP, No TEP	1 week	Age (mean/SD) 63 (13.9) 116 male/4 female	80 indirect, 31 direct, 11 recurrent, 2 femoral
Leibl 2000[116]	Retrospective analysis	TAPP	778	778	Single centre, Germany	10 (2 groups: experts and trainees)	1	Median 30.5	Median 23 m	Age (range) 59 (16-97) – Experts, 58 (18-92) learners	No translation
Liem 1996[123]	Pilot study	TEP	120	122	Multi centre, Netherlands	4	4	Only one had done 15 TAPP	Unknown	Age (range) 54 (21-57). 113 male/7 female	92 indirect, 26 direct, 14 recurrent, 2 bilateral
Ramsay 2001[124]	Systematic review	TAPP and TEP	702	702	Multi centre, UK	Unknown	27	At least 10 but 'still learning'	Unknown	Unknown	Unknown
Voitk 1998[125]	Prospective analysis	TAPP	98	164 (First 100 consecutive TAPP procedures	Single centre, Canada	1	1	>50 chole, no lap hernias	2 weeks/3m	Age (mean/range) 57 (24-88) 90 male/ 8 female	62 unilateral, 38 bilateral, 21 pantaloon. 58% indirect, 42% direct
Wright 1998[126]	Report of 2 RCTs	TEP	Unknown	Given for 30 repairs	2 multi centre RCTs – Netherlands and UK	Unknown	7	Unknown	Unknown	Unknown	Unknown

APPENDIX 12 CHARACTERISTICS AND SUMMARY OF RESULTS OF THE STUDIES REPORTING BOTH COSTS AND OUTCOMES

Models

Study	**Study characteristics**	**Treatment Groups**	**Baseline characteristics and follow up**	Results	Conclusions
BARD 2003 (BARD Industry submission 2003)	To assess the cost-effectiveness of the Perfix Plug approach *Design:* Decision analytic model making indirect comparisons using pooled data from randomised and non-randomised studies Cost reported in 2002 UK £	**Perfix Plug (form of open mesh) Laparoscopic repair**	Characteristics of patient population not described Time horizon of model not stated Cost based on NHS National reference costs for 2002 for hernia repair plus the cost of the Prefix plug. Key assumption relates to proportion of patients managed as less costly daycases (91% Perfix Plug, 60% laparoscopic repair)	*Costs:* Perfix Plug £809 Laparoscopic £894 *Recurrence probabilities:* Prefix Plug 0.5 Laparoscopic 2.2 One and two way analysis performed to look at thresholds. In two way analysis cost neutrality occurs when the laparoscopic daycase rate is 76% and the recurrence rate is 1.8%	Perfix Plug approach is cost saving and more effective but the results are driven by number of people managed as daycases and to very much lesser extent estimates of recurrence

Study	Study characteristics	Treatment groups	Baseline characteristics and follow up	Results	Conclusions
Eno[135]	To compare outcome of patients who had an open hernia repair or a laparoscopic hernia repair *Design*: Retrospective observational study *Setting:* Australia teaching hospital *Country*: Australia *Costing:* Costs obtained using the Trendstar Decision Support Information System (John Hunter Hospital). Costs included an average of nursing, medical, allied health, dispensed drugs, imaging, pathology, theatre and prosthesis costs. Costs reported AUS $. Year not stated	*Number of patients in each group:* Laparoscopic 69 Open 35 Conversion laparoscopic to open 4 All patients having laparsocopic had general anaesthesia but only 84% of those in the open group Data for the costs of consumables were obtained from the New South Wells Inpatient Statistics Collection 1996/1997, 1997/1998. Effectiveness data retrieved from patients between June 1997 and May 1998.	Patients were between 26 and 80 for laparoscopic average 50 and between 17 and 91 for open mesh, average 59. Patients included those who had an elective hernia repair between 1 June 1997 and 31 May 1998 at John Hunter hospital. Follow up only during hospitalisation period.	*Average length of stay:* Laparoscopic 1.1 days (median 1.0 range 0-4) Open repair 1.8 days (median 1.0; range 0-7) *P*=0.001 Mann-Whitney U Test) *Operation duration:* Laparoscopic average 68 minutes (range 40-155) Open average 51 minutes (range 30-80) *P*=0.0001, Man Whitney U-test *Complications:* Laparoscopic 2 Open group 13 *P*=0.08 Fisher's exact Test). *Postoperative analgesia:* Laparoscopic: Median number of doses 1 (range 0-3) Open repair: Median number of doses 2 (range 0-5) *P*=0.022, Man Whitney U-test *Hospital costs:* Laparoscopic: AU$ 3,106 Open: AU$ 2,342 No sensitivity analysis was performed	The study identified that only length of stay and the use of analgesia was significantly higher in the open than in the laparoscopic. The author states that despite only considering in hospital costs the additional cost of laparoscopic would fund the performance of at least 13 extra open repairs in the audited hospital.

Study	Study characteristics	Treatment groups	Baseline characteristics and follow up	Results	Conclusions
Ethicon Endo-Surgery (2003)(Ethicon Endo-Surgery Submission, 2003)	Same as MRC Laparoscopic Groin Hernia Trial but modified to consider the management of bilateral hernias. The MRC trial was a multicentre trial based in 26 centres in the UK country UK Costing: Method of Bottom-up. Cost reported in 1998 UK £	Same as MRC Laparoscopic Groin Hernia Trial Laparoscopic 468 Open mesh 460 Various regimes of anaesthesia and equipment were used	Same as MRC Laparoscopic Groin Hernia Trial QALY scores are based on EQ5D given at 1 week, 1 month and 3 months Utilities calculated using power curves and UK tariffs for the EQ5D Assumed that 30% of all patients would have occult contralateral hernias and that these could be identified and treated by laparoscopic repair. Thus presenting the need for subsequent operations	Allowing for treatment of occult contralateral hernias reduced incremental cost per QALY to £ 15,000 cost per QALY (£55,548 in the previous MRC trial).	Use of laparoscopic repair may be considered cost effective. Includes an impact for the NHS: £1.3 million pounds and 6,900 secondary interventions.
Papachristou 2002[133]	To compare the costs and effectiveness of TAPP compared to TEP and standard open mesh *Design*: Observational Setting: Not stated *Country*: Greece *Costing:* Method of costing not reported. Cost reported in Euros	*Number of patients in each group:* TAPP 60 TEP 174 Open 86	Patients were between 21 and 82 and presented with inguinal hernia No other inclusion/exclusion criteria were stated Follow up 6 months. Only costs relating to the operative episode were collected. These costs included inpatient room, operation room, pharmacy, intravenous fluids, anaesthesia supplies, and nutrition services.	*Post operative complications:* TAPP: 13 TEP:9 Open:10 *Recurrences:* TAPP: 2 TEP:1 Open:0 *Time to normal activities, in days* (median, range): TAPP: 8 (6-16) TEP: 6 (4-10) Open: 12 (10-21) Total average costs: TAPP: 763.20 euros TEP: 572.50 euros Open: 489 euros No sensitivity analysis was performed	Laparoscopic and open mesh comparable for complications. TEP less operative pain and more rapid return to normal activities. Choice between TEP and open mesh depending on surgeons experience

Study	Study characteristics	Treatment groups	Baseline characteristics and follow up	Results	Conclusions
Pikoulis 2002[134]	To compare two modern mesh based "tension free" hernioplasties, laparoscopic repair and mesh plug technique. *Design:* Observational (prospective) Setting: Two major medical centres *Country*: Greece **Costing:** Based on hospital charges Costs reported US $. Year not stated	*Number of patients in each group:* TAPP 237 Open 234 TAPP general anaesthesia Open, local, epidural, or spinal anaesthesia All TAPP patients were kept overnight. OPEN patients under local discharged a few hours later, the remaining patients kept overnight.	Patients were between 29 and 78 for laparoscopic and 18 and 87 for open mesh. Patients were excluded if: -were at high risk for general anaesthesia -were pregnant -had multiple lower abdominal operations -had second recurrences Patients with bilateral groin hernias, femoral hernias, and those with both inguinal hernias and cholelithiais were encouraged to undergo laparoscopic Mean follow up in the study was 17 months.	**Median operating time:** TAPP 57 (56.37-60.08) Open 33 (33.2-35.7) *Return to light activities in days:* Mean(SD) TAPP 5.4(2.4) Open 3.4 (1.5) **Return to full time work (days):** TAPP Median 8 Range(4-10) Open Median 8 Range(4-9) **Return to heavy physical activities in days:** Mean(SD) TAPP 19.6(5.9) Open 18.7(4.3) **Complications:** TAPP 117 Open 9 **Recurrences:** TAPP 6 Open 1 **Cost:** TAPP Mean US$ 1,200 Open Mean US$ 500 No sensitivity analysis was performed	Mesh repair faster, cheaper, technically easier and does not require general anaesthesia, and resulted in fewer short or long-term complications and reduced the recurrence rate.

Study	Study characteristics	Treatment groups	Baseline characteristics and follow up	Results	Conclusions
Stylopoulos 2003[132]	To study the cost-effectiveness of laparoscopic surgery *Design:* Markov model using data from 51 randomised controlled trials and two databases **Costing:** Cost reported in 2002 USA $ and discounted at 3% rate	Expectant management Laparoscopic Open mesh Open non mesh	Patients were between 18 and 65+ No other inclusion/exclusion criteria were stated The cohort of patients was modelled for five years. Costs were Medicare charges, all direct medical costs were included, productivity costs were included following guidelines of the Washington Panel. QALYs based on Quality well being index and US population valuations	**Costs:** Laparoscopic: $4,086 Open Mesh: $4,290 Open No mesh: $6,200 **QALYs:** Laparoscopic: 9.04 QALYs Open Mesh: 8.975 QALYs Open No mesh: 8.546 QALYs *Early Recurrence Proabability (2 years):* Laparoscopic: 2.192% Open Mesh: 2.329% Open No mesh: 4.737% I*ncremental costs per* QALY *relative to expectant management:* Laparoscopic $605, Open Mesh $697, Open No Mesh $1,711 One way and two way sensitivity analysis was performed on the assumptions of the model. Ambulatory facility cost and recurrence rate for laparoscopic appeared to be the most influential values.	From a societal perspective the laparosopic approach may be cost-effective and greater efforts to make it easier to perform could reduce health care costs.

Study	Study characteristics	Treatment groups	Baseline characteristics and follow up	Results	Conclusions
Vale 2003 (Unpublished)	To study the cost-effectiveness of laparoscopic surgery *Design*: Markov model using data from 3 Cochrane reviews conducted as part of the same project *Costing:* Cost reported in 2001 and discounted at 6% rate	TAPP TEP Open non mesh Open flat mash	Model based on a male patient age 45 The cohort of the patients was modelled for five years Costs were based on the bottom up costs estimated alongside three recent economic evaluations. Cost data from three sources not pooled but rather the analysis were repeated for each data source Probability sensitivity analysis conducted along for a number of scenarios including different cost data sources and type of laparoscopic equipment (reusable or disposable)	Open mesh associated with lower cost, less pain, fewer recurrences, and less time from usual activities Open flat mesh vs lap **Costs:** TEP Mean saving £101; 95% CI £63 TO £177 Vs TAPP Mean saving £161; 95% CI £138 to £203 **Recurrence:** TEP 2 fewer recurrences per 1000 patients. 95% CI – 49.5 to 109.0; TAPP 1 additional recurrences per 1000 patients over 5 years. 95% CI –30.8 to 56.4. **Return to usual activities:** TEP: 4.3 (95% CI 0.4 to 8.2) More days TAPP: 3.2 (95% CI 1.8 to 4.5) More days **Pain:** TEP: 67 (95% CI 41 to 107) Fewer TAPP: 32 (95% CI 12 to 57) fewer people per 1000	Open non-mesh was dominated Laparoscopic repair is not cost-effective compared with open mesh repair in terms of cost per recurrence avoided. The extra costs of laparoscopic repair are unlikely to be offset by the short-term benefits (reduced pain, earlier return to usual activities)

APPENDIX 13 COST ESTIMATES USED IN THE MODEL

Note: The cost for each item may not sum to the totals reported due rounding

Table 1 Staff and theatre costs

TAPP and TEP	
Staff	***Cost (£) per minute***
Consultant anaeth.	£0.56
Consultant	£0.56
Senior Registrar	£0.30
Staff nurse *2	£0.36
Theatre Orderly	£0.12
Auxiliary	£0.12
Total	£2.00
Theatre Cost	***Cost (£) per minute***
Overheads	£4.40
Staff and theatre costs	**£6.40**

OFM, OPM and OPPM	
Staff	***Cost (£) per minute***
Consultant anaeth	£0.56
Consultant	£0.56
Registrar	£0.24
Staff nurse *2	£0.36
Theatre Orderly	£0.12
Auxiliary	£0.12
Total	£1.94
Theatre Cost	***Cost (£) per patient***
Overheads	£4.40
Total staff and theatre costs	**£6.34**

Table 2 Equipment costs, general anaesthetics reusables

TAPP and TEP	
	Cost per patient
Drugs	£10.36
Other	£2.50
Prophylactic antibiotics	£7.28
Equipment costs	£9.67
Consumables	£32.93
Cleaning and sterilisation	£59.38
Other laparoscopic equipment	£44.46
Total	**£166.58**

Table 3 Operation equipment costs, general anaesthetics, disposables

TAPP and TEP	
	Cost per patient
Drugs	£9.09
Other	£2.50
Prophylactic antibiotics	£7.28
Consumables	£637.96
Cleaning and sterilisation	£86.73
Other laparoscopic equipment	£44.46
Total	**£788.02**

Table 4 Operation equipment costs, local anaesthetics

OFM, OPM and OPPM	
	Cost per patient
Drugs	£5.37
Other items	£3.13
Prophylactic antibiotics	£7.28
Consumables	£41.74
Cleaning and sterilisation	£33.15
Medium basic tray and self retaining retractors	£1.32
Diathermy machine	£5.00
Total	**£96.99**

Table 5 Hospitalization costs

All modalities	**Cost per patient**
Hospital "hotel costs" per day	£236.57

APPENDIX 14 DETAILS OF THE DISCRETE CHOICE EXPERIMENT

This section is based on work conducted by Emma McIntosh and colleagues.

Outline of the discrete choice experiment

The Discrete Choice Experiment (DCE) approach breaks the commodity being valued (in this case the process and outcomes for a particular type of hernia repair) into a series of attributes. Individuals are then presented with a number of discrete choices and, for each choice, respondents must say which option they prefer. Each type of repair offers both potential advantages and disadvantages in relation to the varying attributes. For example, for each type of surgical repair there may be trade-offs occurring between quality of life, return to usual activities, recurrence rates, pain scores and cost. Furthermore, each individual intervention is associated with different levels for each attribute. It is unclear what 'value' patients place on each of these attributes. Hence, it is unclear which method of inguinal repair provides the greatest welfare gain to patients.

The study was carried out at two centres – London and Glasgow. The attributes and levels for the study were based on the available literature (substantially reported in Chapter 3) and consensus meetings with clinical collaborators. The attributes and levels outlined had to be representative of the main 'trade-offs' between laparoscopic and open groin hernia repair. In order to obtain welfare estimates, a payment vehicle was also included in the DCE. The DCE used a strength of preference response variable. This variable allows for a graded response rather than a dichotomous choice, which as is more usual with DCEs, as it was hypothesised that the strength of preference format may produce more accurate estimates of welfare.

Following the selection of attributes and levels choice scenarios for presentation to respondents were developed. The main design criteria were orthogonality of design (there is no correlation between the levels of an attribute included in a DCE) and level balance (the levels of an attribute occur with equal frequency in the questionnaire). Design software (SPEED, Hague Consulting) was used to identify an orthogonal matrix of scenarios.

A pilot study was conducted to assess the appropriateness of the attributes and levels chosen. This study was also used to determine whether there was evidence that respondents perceived that attributes were correlated i.e. measuring the same thing or that were interactions between attributes i.e. whether preferences for one attribute were influenced by the levels of the other interacting attribute. Based on the results of the pilot study the design and content of the postal questionnaire used was finalised. Table 1 summarises the attributes and levels used to develop the scenarios.

Table 1 Attributes and levels used in the DCE

Attribute	**Levels**
Type of anaesthetic	0=general, 1=local
Risk of serious complications	0.1%, 0.5%, 1%
Days in pain following surgery	3 days, 7 days, 14 days
Chance of long term pain up to 1 year	3%, 5%, 13%
Chance of recurrence within 4 years	4%, 16%, 20%
Cost	£500, £1000, £1500

Devising welfare estimates

To estimate benefits from alternative types of hernia repair a benefit equation was first derived from the response data where the independent variables were the difference in the levels of the attributes within each choice and the dependent variable was the strength of preference score. The following equation was thus estimated:

$$\Delta B = \beta_0 + \beta_1'\text{Anaesthetic}' + \beta_2'\text{Complications}' + \beta_3'\text{Postoperativepain}' + \beta_4'\text{Longtermpain}' + \beta_5'\text{Recurrence}' + \beta_6'\text{Cost}' + e + u$$

where ΔB is the change in benefit in moving from treatment option A to treatment option B, and all independent variables are the differences in the attributes of the choice experiment. e and u are the unobservable error terms where, e is the error term due to differences amongst observations and u is the error term due to differences amongst respondents. The coefficients β_0 to β_6 are the parameters of the model to be estimated. They indicate the relative importance, or weight, of a unit change in that attribute on overall benefit. β_0 is the constant term in the model,

reflecting the overall preference for B over A when there is no difference between the levels of attributes across scenarios.

How much of one attribute respondents are willing to give up for improvements in other attributes, i.e. the rate at which individuals trade between these attributes, is shown by the ratio of the coefficients. For example β_1/β_6 shows how much an individual is willing to pay to have their preferred type of anaesthetic (assuming others things equal). Given the strength of preference responses are ordinal ratings of utility differences between attribute level pairs, a random effects ordered probit was used to estimate the regression equation using the LIMDEP package. Confidence intervals for the welfare estimates were obtained by bootstrapping from the multivariate normal distribution of coefficients and their variance-covariance matrix. The 95% confidence intervals are the 2.5th and 97.5th percentile values from the bootstrapped distribution.

1.1.5. Sample size

The sample of patients for the main postal survey was identified from hospital records as having had a hernia repair in the past. In total, 658 patients were identified from existing databases, the majority of those had been involved in the MRC trials. These patients were then sent a covering letter, information sheet and copy of the DCE questionnaire for self-completion and freepost reply. A reminder was sent after two weeks.

Results of DCE

Of the 658 questionnaires sent out, 320 were returned, a response rate of 49%. Of those returned, 258 were completed (39%). Of those returned uncompleted, 40 provided some form of reasoning for non-response, either by letter or telephone call and 41 questionnaires were uncompleted with no reason given.

Of a possible total of 3354 (n=258*13) response variables there were 250 missing dependant 'response' variables. These were removed from the analysis of choices, leaving 3,104 choice responses for analysis, from n=246 respondents (these 246 respondents had total responses ranging from only 1 to the full 13 questions). The results of a consistency test included in the strength of preference questions (based

on dominance criteria) showed that 30 respondents (comprising 386 observations in total; 26 respondents*13 observations and 4 respondents*12 observations) were 'inconsistent' in choosing the 'incorrect' scenario, this is an inconsistency rate of 12.25%. These individuals were identified by a dummy variable in the analysis ('inconsis' = 1) such that the choice models estimated could be tested to see whether the inclusion of these individuals affected the results.

The coefficients and welfare results of the ordered probit model for the strength of preference format are shown in Table 2.

Table 2 Random effects ordered probit model – all responders

Variable	**Attribute Unit**	**Coefficients (95% CIs)**	**SE**	**P**	**WTP (£) per unit (95% CI's)**
Type of anaesthetic (0=General, 1=Local)	Categorical	-0.1660 (-0.12541, -0.1801)	0.02345	0.000	£327.65 (£248, £355)
Risk of serious complications (%)	*0.01%*	-0.3386 (-0.3786, -0.2232)	0.04825	0.000	£668.33 (£441, £747)
Days in pain following surgery (Days)	*1 Day*	-0.0609 (-0.0652, -0.05124)	0.00342	0.000	£120.20 (£101.13, £128.66)
Cost (£)	*£*	-0.0005 (-0.00057, -0.00044)	0.000032	0.000	N/A
Chance of long term pain up to 1 year (%)	*1%*	-0.0432 (-0.043247, -0.0645)	0.00502	0.000	£85.35 (78.87, £127.37)
Chance of recurrence (%)	*%*	-0.0516 (-0.05877, -0.04653)	0.00221	0.000	£101.88 (£91.84, £116.00)
Constant		1.62143 (1.546, 1.711)	0.08834	0.000	N/A

Number of observations: 3,104 Unbalanced panel: 246 individuals Log likelihood function: -3369.97 Restricted log-likelihood: -3714.41 Chi squared: 599 Significance level: 0.000 McFadden's R^2:0.09 % Correct Predictions: 40%

Table 3 shows the results of the analysis when those individuals that give inconsistent responses were excluded.

Table 3 Random effects ordered probit model – 'consistent' responders only

Variable	**Attribute Unit**	**Coefficients**	**SE**	**P**	**WTP (£) per unit**
Type of anaesthetic (0=General, 1=Local)	*Categorical*	-0.1842774	0.025414	0.000	£313.77
Risk of serious complications (%)	*0.01%*	-0.394805	0.050481	0.000	£672.23
Days in pain following surgery (Days)	*1 Day*	-0.0672808	0.003524	0.000	£114.56
Cost (£)	*£*	-0.000587309	0.000035	0.000	N/A
Chance of long-term pain up to 1 year (%)	*1%*	-0.0496271	0.005271	0.000	£84.50
Chance of recurrence (%)	*%*	-0.0599083	0.002601	0.000	£102.00
Constant	/	1.66248	0.09886	0.000	
Number of observations: 2717 Unbalanced panel: 216 individuals Log likelihood function: -2890.618 Restricted log-likelihood: -3154.234 Chi squared: 527.33 Significance level: 0.000 McFadden's R^2: 0.08 % Correct predictions: 41.5%					

HERNIA REPAIR - A SURVEY OF YOUR PREFERENCES

INFORMATION SHEET

In this questionnaire we are trying to find out what is important to people when having hernia repair surgery. We are asking you because you have already had a hernia repair and you are therefore the best person to ask. Your views are important to us.

It is important to note that this questionnaire is not trying to evaluate the operation you actually had (or about to have), but to find out your views about a number of imaginary hernia repair scenarios.

The information you provide will allow us to produce information on how patients value the different characteristics of hernia repair surgery.

The questionnaire will ask you to imagine you need another hernia repair and then to tell us which operation you would choose if you were given the choice. All you have to do is pick the imaginary operation you would prefer from a series of choices.

These imaginary operations differ only in terms of the six features listed in the questionnaire. Please take a moment to read the descriptions of how these imaginary operations vary before completing the choices.

This should only take you a few minutes to complete and will help hernia surgeons and researchers to find out what are the most important features of hernia operations.

Many thanks for your help with this research.

When you have completed the questionnaire
please return it in the Freepost envelope provided.

DISCRETE CHOICE QUESTIONNAIRE

(Note: The questionnaire displayed is not precisely the one used as small formatting edits)

Hernia Repair ~ A survey of your preferences

University of Aberdeen

In collaboration with Professor Paddy O'Dwyer
Department of Surgery
Western General Infirmary, Glasgow

If you would like to ask any questions about completing this questionnaire please contact:

Emma McIntosh
Research fellow

Tel: 01865- 226634

G					

Please read your pink information sheet first.

The imaginary operations will differ only according to the following features, everything else will about the operations will be equal.

Type of anaesthetic
Local *General*

Chance of serious complications giving rise to prolonged hospital stay
This refers to the chance of having a serious complication during surgery, e.g. bladder injury.
0.1% *ρ0.5%* *ρ1%*
(1 per 1000) (5 per 1000) (10 per 1000)

Number of days suffering post-operative pain
This refers to the number of days you may experience pain as a result of your operation. You may have to take painkillers such as Aspirin or Paracetamol and there may be occasional times where the pain in noticeable when the painkillers wear off.
3 days *ρ7 days* *ρ14 days*

Cost (£) to you as a result of this episode of care
This refers to the cost to you of the hernia operation and the following post-operative recuperation. Whilst you would never be asked to pay, please try to think of how much you would value this operation as you would value other items you buy.
£500 *ρ£1000* *ρ£1,500*

Chance of experiencing long-term persisting pain up to 1 year post-operatively
This refers to the chance that you may have pain in your hernia region following surgery for up to 1 year.
3% *ρ5 %* *ρ13 %*

Chance of recurrence following your operation
This refers to the chance that your hernia may recur (come back) and you may have to have another hernia operation within the next 4 years.
4 % *ρ16 %* *ρ20%*

Now we would like you to *choose between* alternative possible hernia repair operations by indicating how *strongly* you prefer your favourite. Please try to imagine that you are about to have a hernia operation and you are deciding between possible operations by looking at how the features of each operation differ.

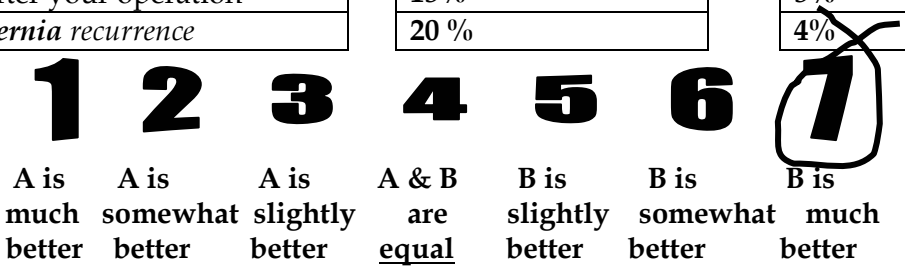
Please look at each imaginary operation and choose between A & B by circling the number which most represents your preference

We are not asking you to find the surgery nearest to the *actual* surgery you had, we are interested in the choices you would make if ever offered these imaginary operations

Please answer every question remembering that there are no right or wrong answers. It is your views that we are interested in.

EXAMPLE

Imaginary Hernia Operation	**A**	**B**
Type of anaesthetic	**Local**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**1%**	**0.1%**
Number of days suffering **post-operative pain**	**14 days**	**3 days**
Cost of operation to you (£)	**£1,000**	**£500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**13%**	**3%**
Chance of a hernia *recurrence*	**20 %**	**4%**



Please circle the number from 1 to 7 which best reflects your preference
In this example, I circled number 7 because if I imagined I had to have another hernia operation, I think operation B would be much better than operation A.

Now please turn over and complete the rest yourself ☛

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.1%**	**0.1%**
Number of days suffering **post-operative pain**	**3 days**	**7 days**
Cost of operation to you (£)	**£500**	**£1,000**
Chance of experiencing **long-term pain** up to 1 year after your operation	**5%**	**13%**
Chance of a hernia *recurrence*	**4%**	**16%**

1	2	3	4	5	6	7
A is much better	**A is somewhat better**	**A is slightly better**	**A & B are <u>equal</u>**	**B is slightly better**	**B is somewhat better**	**B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.5%**	**1%**
Number of days suffering **post-operative pain**	**3 days**	**3 days**
Cost of operation to you (£)	**£1,000**	**£1,500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**13%**	**5%**
Chance of a hernia *recurrence*	**4%**	**16%**

1	2	3	4	5	6	7
A is much better	**A is somewhat better**	**A is slightly better**	**A & B are <u>equal</u>**	**B is slightly better**	**B is somewhat better**	**B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.1%**	**0.1%**
Number of days suffering **post-operative pain**	**7 days**	**3 days**
Cost of operation to you (£)	**£1,500**	**£1,000**
Chance of experiencing **long-term pain** up to 1 year after your operation	**5%**	**3%**
Chance of a hernia *recurrence*	**4%**	**20%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are equal** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.1%**	**0.5%**
Number of days suffering **post-operative pain**	**14 days**	**14 days**
Cost of operation to you (£)	**£500**	**£1,500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**13%**	**13%**
Chance of a hernia *recurrence*	**16%**	**4%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are equal** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**1%**	**0.5%**
Number of days suffering **post-operative pain**	**3 days**	**14 days**
Cost of operation to you (£)	**£1,500**	**£500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**13%**	**5%**
Chance of a hernia *recurrence*	**20%**	**20%**

1	2	3	4	5	6	7
A is much better	**A is somewhat better**	**A is slightly better**	**A & B are <u>equal</u>**	**B is slightly better**	**B is somewhat better**	**B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**Local**	**General**
Risk of a **serious complication** giving rise to prolonged hospital stay	**1%**	**0.5%**
Number of days suffering **post-operative pain**	**7 days**	**7 days**
Cost of operation to you (£)	**£500**	**£1,000**
Chance of experiencing **long-term pain** up to 1 year after your operation	**3%**	**5%**
Chance of a hernia *recurrence*	**4%**	**20%**

1	2	3	4	5	6	7
A is much better	**A is somewhat better**	**A is slightly better**	**A & B are <u>equal</u>**	**B is slightly better**	**B is somewhat better**	**B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**General**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.1%**	**0.1%**
Number of days suffering **post-operative pain**	**3 days**	**7 days**
Cost of operation to you (£)	**£500**	**£1,500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**5%**	**5%**
Chance of a hernia *recurrence*	**4%**	**4%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are <u>equal</u>** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**1%**	**1%**
Number of days suffering **post-operative pain**	**14 days**	**7 days**
Cost of operation to you (£)	**£1,000**	**£500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**3%**	**3%**
Chance of a hernia *recurrence*	**4%**	**4%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are <u>equal</u>** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.5%**	**0.1%**
Number of days suffering **post-operative pain**	**3 days**	**7 days**
Cost of operation to you (£)	**£500**	**£1,000**
Chance of experiencing **long-term pain** up to 1 year after your operation	**3%**	**13%**
Chance of a hernia *recurrence*	**16%**	**16%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are <u>equal</u>** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.1%**	**1%**
Number of days suffering **post-operative pain**	**14 days**	**3 days**
Cost of operation to you (£)	**£1,500**	**£1,500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**3%**	**5%**
Chance of a hernia *recurrence*	**20%**	**16%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are <u>equal</u>** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**1%**	**0.5%**
Number of days suffering **post-operative pain**	**7 days**	**14 days**
Cost of operation to you (£)	**£500**	**£1,500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**13%**	**13%**
Chance of a hernia *recurrence*	**20%**	**4%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are <u>equal</u>** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**General**	**Local**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.5%**	**0.5%**
Number of days suffering **post-operative pain**	**7 days**	**14 days**
Cost of operation to you (£)	**£1,500**	**£500**
Chance of experiencing **long-term pain** up to 1 year after your operation	**3%**	**5%**
Chance of a hernia *recurrence*	**16%**	**20%**

1 2 3 4 5 6 7

A is much better | **A is somewhat better** | **A is slightly better** | **A & B are <u>equal</u>** | **B is slightly better** | **B is somewhat better** | **B is much better**

Imaginary Operations

	A	B
Type of anaesthetic	**Local**	**General**
Risk of a **serious complication** giving rise to prolonged hospital stay	**0.1%**	**1%**
Number of days suffering **post-operative pain**	**3 days**	**14 days**
Cost of operation to you (£)	**£1,000**	**£1,000**
Chance of experiencing **long-term pain** up to 1 year after your operation	**3%**	**5%**
Chance of a hernia *recurrence*	**20%**	**16%**

1	2	3	4	5	6	7
A is much better	**A is somewhat better**	**A is slightly better**	**A & B are <u>equal</u>**	**B is slightly better**	**B is somewhat better**	**B is much better**

How difficult/easy did you find the choices above? *(please circle)*

Very Difficult			**Moderate**				**Very Easy**		
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Now that you have completed the choices please <u>rank</u> the features in the order of importance to you when you were making your choices. Please rank them on a scale of 1-6 where 1 = the most important and 6 = the least important. Or if they were not important to you please leave the box blank.

	Ranking
Risk of a serious complication	❒
Number of days of post-operative pain	❒
Cost of the operation	❒
Chance of long term pain	❒
Chance of a recurrence	❒
Type of anaesthetic	❒

Please tick (✓) whether you would prefer **local** ❒ or **general** ❒ anaesthetic

Finally, we find it very useful to have information about you.
All answers are <u>completely confidential</u>.

Gender Female ❒ **Age** ☐ years
Male ❒

Do you have any children? Yes ❒ No ❒
If *yes*, how many live in your Household? ☐

Qualifications None ❒
O-grade/GCSE ❒
Higher/A-level/SYS/OND ❒ *Please indicate the*
Diploma/HND/HNC ❒ *highest level only*
Undergraduate degree ❒
Post-graduate degree ❒
Other (please specify below) ❒
.....

Income **Could you please estimate the annual income of your household before deducting tax and national insurance (if you receive any benefits or pensions include them as income) (*Please tick ✓ one box only).***

Less than £9,999	☐	**£30,000 - £34,999**	☐
£10,000 - £14,999	☐	**£35,000 - £39,999**	☐
£15,000 - £19,999	☐	**£40,000 - £44,999**	☐
£20,000 - £24,999	☐	**£45,000 - £49,999**	☐
£25,000 - £29,999	☐	**Greater than £50,000**	☐

How many adults are there in your household? ☐

Questions about your <u>actual</u> hernia operation

What type of hernia repair did you have?
Open mesh ❒ Open non-mesh ❒ Key hole ❒
Don't remember ❒

What date did you have your hernia surgery ? (if you can't remember please just note the month and/or year) ___ / ___ / ___

How many days of pain did you suffer after your hernia operation? ☐

How many days did it take you to return to your normal activities? ☐

Finally, on a scale of 1-10, where 1=very *un*satisfied and 10= very satisfied, please state how you rated your hernia operation ☐

Thank you for completing this questionnaire.
Please post it back in the enclosed <u>Freepost</u> addressed envelope