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**A SYSTEMATIC REVIEW OF
STAPLED
HAEMORRHOIDECTOMY**

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The Royal Australasian College of Surgeons

A Systematic Review of Stapled Haemorrhoidectomy

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The Safety and Efficacy Classification for the Systematic Review of the Circular Stapled Haemorrhoidectomy Procedure for the Treatment of Haemorrhoids was ratified by:

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EXECUTIVE SUMMARY

Background

The aim of this review was to compare the safety and efficacy of circular stapled haemorrhoidectomy against conventional haemorrhoidal techniques based on a systematic assessment.

Methods

Search strategy - All original, published human studies on stapled haemorrhoidectomy were identified by searching Current Contents, Embase, Medline, HealthStar and the Cochrane Collection Library from when the databases began inputting data (1966 or later) until June 2001. National Institutes of Health Clinical Trials database between 12/06/2001 and 13/06/2001, and The National Coordinating Centre for Health Technology Assessment on the 14/06/2001 were also searched. The search terms used were haemorrhoid* and (stapl* or convent*) or hemorrhoid* and (stapl\$*or convent*). This was supplemented by hand-searching recent conference proceedings from specialist societies and conducting internet searches. Additional articles were identified through the reference sections of the studies retrieved.

Study selection - Articles reporting randomised-controlled trials were included if they compared stapled and conventional haemorrhoidectomy and provided relevant safety and efficacy outcome information. Patient safety outcomes were assessed in terms of common end-points for conventional haemorrhoidectomy, which included major and minor complications. Efficacy outcomes were assessed to determine whether stapled haemorrhoidectomy produced at least equivalent clinical outcomes, in comparison to conventional haemorrhoidectomy.

Data collection and analysis - A profile of each study was produced, including information on the institution, authors and publication year, intervention, methodology, study population characteristics, inclusion/exclusion criteria, length of follow-up and loss to follow-up, and surgical experience. Methodological assessment for the identified outcomes was performed. Meta-analysis was conducted on studies which were comparable in outcome and follow-up period. Measures of effect (pooled relative risks or weighted/standard mean differences) and 95% confidence limits were calculated. Tests for statistical heterogeneity were performed.

Results

Due to variability between the end points used to assess patient outcomes, meta-analysis was unable to be carried out on much of the extracted data. Despite this, the comparative risk of postoperative bleeding was lower in the stapled group. Within trials, significant results supporting the stapled procedure were found. These related to wound healing, pain, anal discharge, pruritis, tenderness to per rectal examination, incontinence and an earlier return to bowel function. There were very few cases of haemorrhoidal recurrence or prolapse within the stapled treatment groups, but the lack of data concerning long-term follow-up made definitive evaluations difficult.

Conclusion and recommendations

On the basis of the evidence presented in this systematic review, The ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of stapled haemorrhoidectomy.

Classifications:

Evidence rating - Average. The level II evidence was limited by small sample size and short follow-up times. Few studies assessed similar end-points and there was incomplete reporting of important outcomes.

Safety - Safe as compared to comparator procedure.

Efficacy - Efficacy cannot be determined. The long-term data on efficacy outcome measures are awaited.

Recommendations:

There is a need for larger randomised controlled trials to be conducted to increase the power of meta-analysis. **Standardisation of outcome measures, particularly for pain, bleeding and long-term evaluation of postoperative complications and symptoms would allow more accurate comparison of data.**

It was recommended that surgeons practicing stapled haemorrhoidectomy should conduct a careful audit of their results with this technique. It was also suggested that as a minimum requirement, surgeons wishing to use the stapled technique of haemorrhoidectomy should undergo appropriate training and supervised instruction.

It was deemed that The Colorectal Surgical Society of Australasia should develop guidelines for training on this procedure. The ASERNIP-S Review Group will conduct an update and reappraisal of this review when any new evidence becomes available that may contribute to a change in these recommendations.

Stapled haemorrhoidectomy may be a viable addition to the therapy options available for treating haemorrhoids but more rigorous studies with longer follow-up periods and larger sample sizes must be pursued.

Important note The information contained in this report is a distillation of the best available evidence located at the time the searches were completed as stated in the protocol. Please consult with your medical practitioner if you have further questions relating to the information provided, as the clinical context may vary from patient to patient.

THE ASERNIP-S CLASSIFICATION SYSTEM

Evidence Rating

The evidence for ASERNIP-S systematic reviews is classified as Good, Average or Poor, based on the quality and availability of this evidence. High quality evidence is defined here as having a low risk of bias and no other significant flaws. While high quality randomised controlled trials are regarded as the best kind of evidence for comparing interventions, it may not be practical or ethical to undertake them for some surgical procedures, or the relevant randomised controlled trials may not yet have been carried out. This means that it may not be possible for the evidence on some procedures to be classified as good.

Good

Most of the evidence is from a high quality systematic review of all relevant randomised trials or from at least one high quality randomised controlled trial of sufficient power. The component studies should show consistent results, the differences between the interventions being compared should be large enough to be important, and the results should be precise with minimal uncertainty.

Average

Most of the evidence is from high quality quasi-randomised controlled trials, or from non-randomised comparative studies without significant flaws, such as large losses to follow-up and obvious baseline differences between the comparison groups. There is a greater risk of bias, confounding and chance relationships compared to high-quality randomised controlled trials, but there is still a moderate probability that the relationships are causal.

An inconclusive systematic review based on small randomised controlled trials that lack the power to detect a difference between interventions and randomised controlled trials of moderate or uncertain quality may attract a rating of average.

Poor

Most of the evidence is from case series, or studies of the above designs with significant flaws or a high risk of bias. A poor rating may also be given if there is insufficient evidence.

Safety and Efficacy Classification

SAFETY

- *Safe compared to comparator* procedure(s)*
This grading is based on the systematic review showing that the new intervention is at least as safe as the comparator.
- *Safety cannot be determined*
This grading is given if the evidence is insufficient to determine the safety of the new intervention.
- *Unsafe compared to comparator* procedure(s)*
This grading is based on the systematic review showing that the new intervention is not as safe as the comparator.

EFFICACY

- *Efficacious compared to comparator* procedure(s)*
This grading is based on the systematic review showing that the new intervention is at least as efficacious as the comparator.
- *Efficacy cannot be determined*
This grading is given if the evidence is insufficient to determine the efficacy of the new intervention.
- *Not efficacious compared to comparator* procedure(s)*
This grading is based on the systematic review showing that the new intervention is not as efficacious as the comparator.

RESEARCH RECOMMENDATIONS

It may be recommended that an audit or a controlled (ideally randomised) clinical trial be undertaken in order to strengthen the evidence base.

CLINICAL RECOMMENDATIONS

Additional recommendations for use of the new intervention in clinical practice may be provided to ensure appropriate use of the procedure by sufficiently qualified/experienced centres and on specific patient types (where appropriate).

* A comparator may be the current "gold standard" procedure, an alternative procedure, a non-surgical procedure or no treatment (natural history).

We aim for continuous improvement and therefore welcome comments on our classification scheme.

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A SYSTEMATIC REVIEW OF STAPLED HAEMORRHOIDECTOMY

1.0 OBJECTIVE

To make recommendations on the safety and efficacy of haemorrhoidectomy using the circular stapled procedure, in comparison to conventional haemorrhoidectomy, on the basis of a systematic assessment and meta-analysis (were appropriate data exists) of the peer-reviewed literature. Information on cost effectiveness will also be sought.

2.0 INTRODUCTION

2.1 Haemorrhoids

Haemorrhoidal tissues are part of the normal anatomy of the distal rectum and anal canal. The disease state of haemorrhoids exists when the internal complex becomes engorged or the tissue prolapses into the anal canal as the result of laxity of the surrounding connective tissue and engorgement of blood vessels.¹ Haemorrhoids are caused by or found in association with increased intra-abdominal pressure, for example, resulting from prolonged straining during defecation and pregnancy.²

External haemorrhoids are aggregations of congested external perianal vascular plexus covered by perianal skin. Whereas, internal haemorrhoids are vascular cushions originating from the subepithelial plexus of the anal canal above the dentate line.¹

2.1.1 Symptoms and Classification

With external haemorrhoids, in particular skin tags, there may be perianal irritation, as well as difficulty in cleaning the perianal area after a bowel motion. They should be treated if symptoms are bothersome.³

Internal haemorrhoids, which occur most frequently in the left lateral, right posterior and right anterior positions of the anal canal (3, 7, and 11 o'clock) are classified according to their symptoms and size.²

The most common symptom of internal haemorrhoids is the passing of bright red blood from the rectum. Prolapse may occur, recognised by soft protrusions from the anus (usually after a bowel motion). It may be associated with a mucous leak, sometimes stained with blood or faeces, which causes perianal irritation and discomfort.³ Anal pain is not a common symptom, unless haemorrhoids become thrombosed or strangulated.

Table 1: Internal Haemorrhoids^{2, 3}

Classification	Symptoms	Treatment
First degree	small; bleed at defecation; no prolapse	No intervention
Second degree	bleed and prolapse from anus at defecation but reduce spontaneously	Elastic band ligation; Sclerosis
Third degree	bleed, prolapse, and require manual reduction; mucous discharge	Haemorrhoidectomy
Fourth degree	bleed, incarcerate, and cannot be reduced; mucous discharge	Haemorrhoidectomy

2.2 Conventional Surgical Techniques of Haemorrhoidectomy

The surgical management of third and fourth degree haemorrhoids is to perform haemorrhoidectomy. These techniques may be classified by the method used for dissection and whether or not the wounds are left open or closed at the end of the procedure.

2.2.1 Excision-ligation Haemorrhoidectomy

Milligan and Morgan describe this as the excision of haemorrhoidal tissue using sharp dissection with suture ligation of the vascular pedicle⁴. Conventionally the wounds are left open and an anal pack is inserted to maintain haemostasis. A variation of this technique has been described where the excision tends to be more conservative and the wounds are closed using an absorbable suture.⁵

2.2.2. Diathermy Haemorrhoidal Dissection

Diathermy haemorrhoidectomy is carried out entirely using electrocautery dissection.¹ The dissection is essentially the same as for the Milligan-Morgan operation. Ligation of the pedicle is not usually required, and haemostasis is complete. The wounds are usually left open at the conclusion of the procedure, although a closure modification has been described.⁶ This procedure is proposed to be less painful for the patient than surgery carried out with sharp dissection.

2.2.3. Laser Haemorrhoidal Dissection

Laser Haemorrhoidectomy using a carbon dioxide laser is essentially similar to the diathermy operation, with the haemorrhoids excised by the laser and the resulting wounds left open.

2.2.4 Submucosal Haemorrhoidectomy

Parks⁷ described a procedure that consists of intra-anal incisions directly over each haemorrhoid. Anodermal flaps are raised to either side of each incision and the underlying haemorrhoidal tissue is excised. The flaps are loosely sutured together at the end of the operation. There is no anodermal tissue excised with the haemorrhoids and as such it is believed to be less painful for the patient compared to excision-ligation haemorrhoidectomy.⁸

2.2.5 Other Haemorrhoidal Interventions

The following techniques are not considered conventional by most colorectal surgeons.

Haemorrhoidal artery ligation (HAL) and suture-only haemorrhoidectomy do not involve anal canal incision and as such, post-operative pain is thought to be reduced. HAL utilises an ultrasound probe to identify terminal branches of the superior haemorrhoidal artery, which are then suture-ligated through a purpose built proctoscope.⁹

Suture-only haemorrhoidectomy is a similar procedure to HAL, such that the base of each haemorrhoid is transfixed and ligated without excising any tissue. The haemorrhoidal tissue gradually shrinks due to its reduced vascularity.⁹

2.3 Stapled Haemorrhoidectomy

Stapled haemorrhoidectomy uses a purpose-designed circular stapling device. The essential technique is to draw the enlarged sagging haemorrhoids into the anal canal by creating a neo-suspensory ligament.¹⁰ Excision of a cuff of mucosa above the haemorrhoidal tissue reduces the vascularity by dividing the haemorrhoidal vessel.¹¹ Thereby, reduction of the mucosal prolapse restores the normal anatomical relationship between the anal mucosa and the haemorrhoidal masses with the anal sphincters. The stapling technique does not involve an incision into the anoderm and is reported to avoid a painful cutaneous wound while reducing the prolapsed haemorrhoid(s) into the anal canal.¹²

2.4 Summary

While it seems that the stapling method of haemorrhoidectomy may offer a good initial functional result for patients, it is possible that there may be a new range of problems and pitfalls not associated with conventional haemorrhoidectomy. Additionally, the long-term outcomes of both these techniques need to be considered. In Australia, the only circular stapling devices available are those marketed by Ethicon Endo-surgery, a Johnson & Johnson company.

3.0 METHODS

3.1 Inclusion Criteria

Articles were selected for inclusion in this systematic literature review of stapled haemorrhoidectomy on the basis of the following criteria.

• Participants

Human studies on individuals with all levels of haemorrhoids were included in this review.

• New Intervention

If the article included concerned the new intervention, it related to:

- circular stapled haemorrhoidectomy for the treatment of haemorrhoids.

No bias was made against the various brands of stapling devices used as long as they were circular staplers.

• Comparative Intervention(s)

If the article included concerned the comparative intervention of conventional haemorrhoidectomy, it related to one or more of the following:

- haemorrhoidectomy as defined as –
 1. excision-ligation, or
 2. closed haemorrhoidectomy, or
 3. diathermy which may or may not be ligated

• Outcomes

The articles included must have contained information on at least one of the following outcomes of the new intervention as compared to the conventional intervention:

1. Post-operative factors for patients included either;
 - pain
 - analgesic requirement

2. Post-operative complications of patients included either;
 - bleeding at the wound
 - wound discharge
 - sphincter fragmentation
 - faecal incontinence
 - constipation
 - urinary retention
 - stenosis
 - prolapse
3. Convalescence course of patients included either;
 - convalescence period
 - wound healing time
4. Efficacy evaluation included either;
 - reduction of residual skin tags
 - return to normal bowel function
 - anal resting and squeeze volumes
 - re-admission
 - re-operation rate

• **Types of Studies**

Articles included in the review were in the following form:

- Randomised controlled clinical trials (RCTs)

Excluded articles were used as background information if they were isolated case reports or studies that did not compare the new intervention to conventional haemorrhoidectomy. Additional relevant published material in the form of letters, commentary and discussions were included as background information.

• **Search Restrictions**

There was no restriction on date of publication. Searches were conducted without language restriction. Foreign language articles were not considered if the findings supported those reported in well-designed studies published in the English language.

3.2 Exclusions

The ASERNIP-S Researcher and the Protocol Surgeon excluded references that clearly did not meet the inclusion criteria.

4.0 LITERATURE SEARCH STRATEGIES

• Databases Searched:

- PubMed Medline and PreMedline
- Ovid Current Contents
- Ovid Embase
- Ovid HealthStar
- The Cochrane Library (The Cochrane Library CD Year 2001, Issue 2)
- National Research Register (UK and USA)

• Search Terms

A search strategy was devised by the ASERNIP-S Researcher and the Protocol Surgeon. It was expected that few articles would be retrieved on stapled haemorrhoidectomy. Therefore, very broad search terms were used to ensure that the maximum number of relevant articles was retrieved across all of the databases.

Search terms used:

haemorrhoid* and (stapl* or convent*)
or
hemorrhoid* and (stapl* or convent*)

• The Cochrane Library

The ASERNIP-S Researcher used a different, broad strategy for The Cochrane Library database as the restricted searches turned up very few references. The simple search term was:

'haemorrhoid*'
or
'hemorrhoid*'

NB: *is a truncation symbol, which retrieves variations of the indicated text.

Stapl* retrieves eg. stapled, stapling

- **Pearling**

Additionally, the reference list of each article included in the database as a result of the electronic search was hand searched to find other articles not identified in the electronic search.

5.0 LITERATURE DATABASE

Table 2: The number of articles retrieved from the searches

Intervention	No. Publications			
	RCTs	Non-RCTs	Abstracts	Other
Circular Stapled Haemorrhoidectomy	10	11	6	13

Abbreviations: RCT – randomised controlled trial

Additional background articles References have also been included for background information on haemorrhoids and the technique of haemorrhoidectomy

- **Exclusions by the ASERNIP-S Researcher**

The RCT published by Helmy *et al.*¹³ was excluded as it appeared to be a direct copy of the work published by Mehigan *et al.*¹⁴ Another RCT employed linear stapling¹⁵ and one other article was a report on a suspended RCT as such all failed to meet the inclusion criteria.²¹ Other comparative studies, case studies, abstracts, commentaries and letters were also excluded.

- **Inclusions by the ASERNIP-S Researcher**

None

- **Exclusions by the Protocol Surgeon**

In agreement with the ASERNIP-S researcher

- **Inclusions by the Protocol Surgeon**

None

6.0 ASSESSMENT METHODS

The Protocol Surgeon and ASERNIP-S Researcher assessed the articles based on the inclusion criteria and a consensus was reached regarding their inclusion. Seven articles were included and a summary of the them is given in Appendix C.1. The included articles were evaluated according to the Hierarchy of Evidence¹⁶ in Appendix A Table 1.

Outcome measures and data extraction

For this review, the question of safety was addressed in terms of whether stapled haemorrhoidectomy was more or less likely to cause harm or injury to the patient in comparison to conventional haemorrhoidectomy.

Therefore, safety outcomes for stapled haemorrhoidectomy were assessed in terms of common end-points reported for conventional haemorrhoidectomy which include; bleeding; faecal impaction; urinary retention; anal discharge; wound discharge; fever; sphincter damage; stenosis. In addition, any other reported outcome that affected patient safety was also tabulated (Appendix C.2).

In terms of efficacy, the question was whether stapled haemorrhoidectomy produced at least equivalent clinical outcomes, in comparison to conventional haemorrhoidectomy. The post-operative indicators chosen to assess the efficacy of the treatment of haemorrhoids via the stapling procedure included; pain; analgesia requirement; readmission; pruritus; prolapse; skin tags; incontinence; tenderness to per rectal examination and anal manometry. Peri-operative efficacy included operating/anaesthesia time and the length of hospital stay. If any other efficacy outcomes were reported in the study it was also tabulated (Appendix C.3).

Grey literature

Six relevant abstracts^{17,18 19, 20, 21, 22} were identified by the researcher. Four abstracts^{19, 20, 21, 22} were in the most recent proceedings of the conference, ‘Colon and Rectal Surgery Regional Society’ published in *Diseases of the Colon and Rectum*; 2001. One abstract¹⁸ was identified through a search of the National Research Register. Another abstract¹⁷ was part of the proceedings of the annual meeting of the Association of Surgeons of Great Britain and Ireland and Surgical Research Society 2001 that was identified in the *British Journal of Surgery – Supplement*; 2001. A critical appraisal of the six studies could not be conducted due to the lack of adequate methodological information (Appendix B Table 1).

Other studies

A randomised trial assessing patient outcome after stapled haemorrhoidectomy has recently been published in the *British Journal of Surgery*.²³ This study was not included in the review as it fell outside of the search time allocated to the retrieval of literature.

There are numerous clinical trials currently being conducted on the procedure of stapled haemorrhoidectomy. To date the results of these trials have not yet been published and as such are not included in this review (Appendix B Table 2).

7.0 RESULTS

Data was only extracted if it was stated in the text, tables, graphs or figures of the article, or could be accurately extrapolated from the data presented. Conversely, if a particular complication was not reported, it was assumed by this reviewer to be unreported rather than not having occurred. For example, if the re-operation rate was not reported in a study, no value was tabulated. This was done to avoid the bias caused by incorrectly assigning a value of zero to an outcome measurement on the basis of an unverified assumption by this reviewer. All methodological assessment and data extraction results are tabulated in Appendices C.2 and C.3.

Designation of Levels of Evidence and Study Methodology Appraisal

Literature documenting the stapled haemorrhoidectomy technique was identified via the search procedure outlined in the Review Protocol. After applying the selection criteria, a number of articles were retrieved (Table 2 Review Protocol). The exclusion process was based on an examination of each article. The excluded articles were not used to formulate the evidence base for the methodological assessment, however, relevant information contained within these excluded articles was used to inform and expand the review discussion.

Many of studies retrieved from the search protocol were either case series or non-randomised trials. These studies form a lower quality of evidence and given the number of RCT's available plus the fact that the other studies did not contribute any more than the data found in the RCT's, it was decided, in consultation with the Protocol Surgeon, that non-RCT's would not be included in the Methodological Assessment.

A total of ten RCT's were identified, three were excluded from the review. One article¹³ appeared to be a direct reproduction of the work of Mehigan *et al.*¹⁴ Another article was a report on a suspended RCT²⁴ and one RCT employed a linear stapling technique¹⁵ (Appendix B Table 3).

Of the seven RCTs that met the inclusion criteria, only one was conducted as a multi-centre trial. In all included studies, the patients were blinded to their treatment avoid outcome bias. Randomisation was by sealed envelopes^{11, 12, 14, 25, 26, 27} or by a table of random numbers.²⁸ Follow-up periods varied between the studies with the longest clinical follow-up time being one year post-operative.^{25, 28} All seven RCTs were assessed with respect to the level of evidence they represented and were all assigned a level II evidence (Appendix A Table 1).

Study Methodology Appraisal

In all included RCTs the two patient groups were appropriately selected, in that all patients were eligible to undergo surgical haemorrhoidectomy. Participants were blinded to the procedure they were undergoing and in addition, the method of randomisation was specified in all of the included RCTs minimising possible bias and confounding factors. The participation rate of the patients approached to enter the studies was not stated. Thus, it was not clear if any self-selection bias occurred on the part of the patients. The main focus of the included RCTs were to assess the effect of stapled haemorrhoidectomy on the primary end-points of post-operative pain, hospital stay, return to normal activity and evaluations such as bowel function. This meant that the data reported at the follow-up times was primarily concerned with efficacy outcomes rather than examination of safety such as bleeding.

The article by Ganio *et al*¹¹ had some discrepancies in the results section with respect to the persistence of prolapse. Unfortunately, it was difficult to discern which were the correct values and as such that the results for that particular complication was not included in the review.

Many factors may change over the period in which studies are undertaken such as operative technique, indications for surgery, and post-operative care protocols, which may influence patient outcomes and bias the results. Rowsell *et al*²⁷ and Mehigan *et al*¹⁴ both report that either one of two of circular haemorrhoidal staplers were used in their respective studies. Details relating to the sample size split between the two stapler groups was not stated in either of these studies. Thus, it was unclear whether there were differences with respect to patient outcome the use of either of the stapler types. The operative techniques did not report to change with the different stapler types, however this does not discount the potential for bias in the reporting of the patient outcomes. As the selection criteria for the inclusion of RCTs did not discriminate against stapler types, as long as the stapler was circular, these studies were included.

Patient groups in the included studies were operated on by surgeons who were experienced and specialised in colorectal disease and that had prior experience using the stapling procedure.^{11, 12, 14, 25, 26, 27, 28} However undoubtedly there is a learning curve associated with this procedure as there is with all new techniques and this would affect patient outcome measurements. Two of the included RCTs^{14, 26} addressed the contribution of the learning curve to an outcome bias.

The total number of patients undergoing stapled haemorrhoidectomy in the reviewed studies was 293, with the largest RCT contributing 100 patients²⁸ and the smallest contributing 11 patients.²⁷

Unfortunately, few of the studies used similar end-points to assess patient outcome and of those that did, on occasion, it was not clearly stated how the outcomes were measured eg pain, visual analog scale (VAS), and follow-up times varied. This made it difficult to objectively assess and compare the pre-operative and post-operative outcomes of patients, either within or between the studies.

Data analysis and statistics

A meta-analysis was conducted on the RCTs if the studies had comparable outcomes and follow-up periods. Results of statistical testing of differences between the conventional and stapled haemorrhoidectomy groups are presented in Figure 1 and Figure 2. The level II evidence was limited by the small sample size and short follow-up period. The heterogeneity between trials was analysed with Chi-squared tests. Since statistical tests of heterogeneity lack power, $p < 0.1$ was used to indicate significant heterogeneity. When there was no significant heterogeneity a fixed effects model was used to calculate summary relative risks (RRs), weighted mean differences (WMDs) or standardised mean differences (SMDs) and the 95% confidence intervals (CIs), otherwise a random effects model was used. Results were interpreted such that the stapled procedure was better than the conventional when the upper limit of the 95% CI of the RR, WMD or SMD was < 1 . RRs, WMDs or SMDs and Chi-squared tests were calculated with RevMan 4.1 (Update Software Ltd 13 June, 2000).

SAFETY

Safety data obtained from the included RCTs is presented in Appendix C.2. Meta analysis of this data was performed where possible and is presented in Appendix C.4. There was heterogeneity in the pooled safety outcome for bleeding at six weeks, but overall none between any of the other pooled safety outcomes.

Bleeding

Bleeding during hospitalisation was comparable in both treatment groups, two patients in the stapled group and one in the conventional treatment group displayed bleeding that prolonged hospital stay for more than one day.²⁶

Two studies reported on the rates of bleeding at two and six weeks post-operatively.^{12,26} At two weeks, stapled haemorrhoidectomy conferred a 45% (CI, 18-63%) reduction in the risk of bleeding as compared to the conventional technique.

With bleeding six weeks post-operatively, there was heterogeneity between the pooled data this may have been due to differing post-operative care regimens and wound healing rates. Analysis of this data was inconclusive due to wide CIs for the comparison between stapled and conventional treatments.

At long-term post-operative follow-up, the rate of bleeding was marginally lower in the stapled treatment group, however the relative rate of bleeding was high in both treatment groups.^{11, 28}

Bleeding requiring medical consultation, transfusion or re-hospitalisation¹² also tended to be less common in the stapled treatment group.^{12, 14, 26}

Haemostatic sutures

There was an operative requirement for haemostatic sutures^{11,14} in both treatment groups. The pooled relative risks were inconclusive but suggest a trend toward a higher requirement of intervention with the stapled procedure.

Haemorrhage

Early post-operative haemorrhage²⁵ was comparable between the two treatment groups however late haemorrhage was more prevalent in the conventional group. Pooled results suggest a trend towards reduced risk of secondary haemorrhage requiring blood transfusion^{25, 12, 14} following stapled haemorrhoidectomy.

Faecal impaction

Unpooled data at two and six weeks, and three months follow-up, showed the rate of faecal impaction to occur more frequently in patients who underwent conventional haemorrhoidectomy as compared to those who received stapled haemorrhoidectomy.²⁶

Urinary retention

Four studies examined post-operative urinary retention.^{14, 25, 26, 28} The pooled relative risk of three of the studies were inconclusive due to wide CI values. However there was a trend to a lower proportion of patients in the stapled group presenting with this outcome. This trend was influenced by the results of one large study.²⁸

Anal stricture and stenosis

The incidences of anal stricture and stenosis in the early post-operative period, and at long-term follow-up, were similar between the stapled and conventional treatment groups however, there was a trend towards a lower incidence in the stapled group.^{12, 25, 26, 28}

Anal fissure

There was a low incidence of anal fissure in both the stapled and the conventional haemorrhoidectomy groups. Early anal fissure was more prevalent in patients in the conventional group as compared to patients in the stapled group,²⁸ however later assessment found comparable incidence in both treatment groups.¹⁴

Thrombosis of the external haemorrhoidal plexus varied between the studies.^{25, 26, 28} One incidence was reported in a patient within the stapled group but did not occur in any patients from the conventional treatment group.²⁶ Pooled data was inconclusive but did suggest a trend towards a lower incidence with stapled haemorrhoidectomy.

Sphincter damage

External sphincter damage was measured in two studies. One study did not find a treatment-dependent difference in internal sphincter damage.¹² However, another study found that it occurred less frequently in the stapled group.²⁶ It should be noted that internal sphincter damage was present in one patient from each treatment group prior to surgery in the later study. Pooled rates of internal sphincter damage were inconclusive but suggestive of a trend to a lower risk with stapled haemorrhoidectomy.

Total number of complications

The total number of complications were assessed in one study.²⁶ Patients in the conventional group had higher rates than patients in the stapled group, however difference in the nature, seriousness, and severity of the complications was not made. High fever occurred in one patient in the conventional treatment group during hospitalisation.²⁶

EFFICACY

Efficacy data obtained from the included RCTs is presented in Appendix C.3 . Meta-analysis of this data was performed where possible and is presented in Appendix C.5. There was heterogeneity for the efficacy outcomes of operating time, length of hospital stay, resumption of usual activities and pain in hospital (visual analog score). There was no overall heterogeneity between any of the other pooled efficacy outcomes.

Perioperative outcomes

Operating time

Mean operating time was reported in four studies.^{25,26, 27, 28} There was heterogeneity between the studies, this may result from variations in the measurement methods by which the time taken to perform surgery was recorded. The pooled mean operating time from these studies was inconclusive. A median time of 15 minutes was reported for either of the treatment methods.¹²

Anaesthesia time was similar between the two treatment groups.¹⁴

Other outcomes

Convalescence

Length of hospital stay was similar in both treatment groups,^{11,12,14,25, 26, 25,28} however there was heterogeneity in the pooled data.^{25, 26, 25,28} This may be a reflection of differences in hospital discharge protocols and the way in which the length of hospital stay was determined in these studies. Pooled mean data for length of hospital stay was inconclusive.

Resumption of normal activities, including employment, was on average quicker in the stapled groups with a mean range of 8-17 days compared to a mean range of 15-53 days for the conventional groups.^{25, 26, 28} SMD was used to combine the results as there was variability in the definition of usual activities between the studies. Pooled mean data was heterogeneous possibly due to patient interpretation and assessment of the outcome and was inconclusive upon analysis. A median 5-17 days was reported for members of the stapled group compared to a median 13-34 days for the conventional haemorrhoidectomy groups.^{11, 12,14}

Readmission rate

Two weeks after surgery none of the patients undergoing stapled haemorrhoidectomy required readmission, whereas 5-20% of patients undergoing conventional haemorrhoidectomy had been readmitted.^{12,26} Pooled data was inconclusive due to low event rates and low patient numbers, but suggested a strong trend towards a lower risk of readmission after stapled haemorrhoidectomy. The need for examination within 10 days of surgery was assessed in one study.²⁵ In the conventional haemorrhoidectomy group, 5% patients required a transfixed suture under local anaesthetic.

Pain

Pain was assessed in terms of duration or severity, which was scored on a visual analogue scale (0 indicating no pain and 10 indicating severe pain). One study found that both severe and moderate pain was experienced for a significantly shorter period following stapled haemorrhoidectomy.¹¹

Three studies reported on the severity of pain experienced during hospital stay.^{12, 28, 26} One reported significantly lower pain scores over the first 24 hours following the stapled technique.²⁸ Similarly reported was a lower maximal pain during hospitalisation for the stapled group.²⁶ Pooled data from these studies was heterogenous and inconclusive possibly due to differing methods for measuring pain. Conversely, it was reported in the third study that stapling led to greater pain in the immediate post-operative period.¹²

Post-discharge pain scores were collected at various stages of recovery. One week after surgery the mean pain scores were 2.6 and 0.4 for conventional and stapled techniques respectively ($p < 0.001$).²⁸ Cumulative pain score over one week was higher for conventional than for stapled haemorrhoidectomy.²⁷ Average pain over ten post-operative days was 6.5 for conventional, and 2.1 for stapled surgery ($p < 0.0001$).¹⁴ Over the same ten-day period, patients in the stapled group were found to have experienced less pain relative to what was expected ($p < 0.0001$).¹⁴ The findings for patients up to two weeks after surgery followed these general trends.¹² Pain at two weeks was significantly less following the stapled technique. The same study investigated the presence of pain six weeks post-surgery. Its findings indicate that a significantly lower proportion of patients who underwent the conventional technique were completely pain-free. Other studies assessed long-term pain at six weeks,²⁶ three months²⁶ and 16 months.¹¹ In each case, fewer patients reported the presence of persistent pain after stapled haemorrhoidectomy.

During hospitalisation, there was no clear trend in pain experienced at stool.^{12, 26, 28} However, two weeks after surgery, pain scores were significantly lower in the stapled groups.^{12, 26} The degree of pain experienced at passage of first motion after surgery, was less for patients following stapled haemorrhoidectomy than for those after conventional treatment ($p < 0.001$).²⁸ This may be partly responsible for the earlier return of bowel function that followed stapled haemorrhoidectomy.^{12, 26, 14} A larger proportion (21%) of patients had opened their bowels before discharge, than those undergoing conventional surgery (11%).²⁶ Similarly, stapled patients were almost twice as likely to have opened their bowels within 24 hours of surgery.¹⁴

Analgesic requirement

In general, less analgesia was required following stapled haemorrhoidectomy. This was shown in numerous studies^{11, 12, 25, 26, 27, 28} although one study demonstrated no difference in analgesic requirements between the two treatment groups.¹⁴

Anal discharge

Anal discharge at two weeks was more prevalent following conventional haemorrhoidectomy.¹² However, discharge had ceased in both groups by six weeks. At six months anal discharge also found that it was significantly more prevalent following conventional haemorrhoidectomy.²⁸

Wound discharge

Two studies, reported that wound discharge at two weeks was more prevalent following conventional haemorrhoidectomy.^{12, 26} At six weeks wound discharge had ceased in all patients that presented symptoms in one study¹² but in the other study continued for up to three months in conventional haemorrhoidectomy patients.²⁶ Results of meta-analysis data obtained at two and six weeks post-operative were

inconclusive. Wound healing took significantly longer following conventional intervention ($p < 0.001$)²⁸ with less patients healed at 6-10 weeks.^{26, 27}

Tenderness to per rectal examination

Significantly more patients in the conventional cohort experienced moderate or severe tenderness to per rectal examination six weeks post-operatively.²⁶ At three months, tenderness had decreased substantially in both groups, with neither intervention yielding more favourable outcomes.

Incontinence

The incidence of incontinence to gas, liquid or solid was extremely rare in both groups of patients when assessed pre-operatively and at various points in their post-operative recovery. Conclusive data regarding its incidence was therefore not obtainable. However, two studies measured incontinence scores.^{11, 26} Only one of these studies found a significant difference between treatment.²⁶ This trial, concluded that post-operative incontinence was more severe in the conventional group. The onset of new faecal urgency occurred in two patients from each treatment group.¹⁴

Change in anal resting and squeeze pressures

Anal resting and squeeze pressures were measured both pre-operatively and postoperatively in four studies^{11, 25, 26, 28}. There were no significant functional variations between the measurements in the two treatment groups,^{11, 25, 26} however in the conventional group at 6 months both pressures were significantly reduced ($p < 0.05$).²⁸

Prolapse

Patient-reported prolapse at two weeks post-operatively occurred in one patient in the stapled group.¹² At one year follow-up prolapse was more common in the stapled group being significant for rare episodes ($p = 0.001$) but not for frequent episodes.¹¹ One other group found with a low incidence at one year follow-up in both treatment groups.²⁸

Skin tags

One study reported a variation between patient perceived postoperative skin tags and that reported by independent assessment at three follow up times. In all instances, the presence of skin tags reported by patients was equal to or less than that noted by independent assessment.²⁶ Pooled relative risks for patient perceived skin tags at 2-3 months were inconclusive due to wide CIs.^{14, 26, 28}

Pruritus

Fewer patients experienced pruritus after stapled haemorrhoidectomy at two and six weeks post-operatively. At three months, the proportion of patients with pruritus in both treatment groups was equal.²⁶

Patient satisfaction and Quality of life

Several studies assessed the level of patient satisfaction after completion of surgery.^{14, 26, 28} Members from the stapled groups perceived a higher rate of operative success than patients that underwent one of the conventional haemorrhoidectomy procedures. Quality of life measures were similar in both treatment groups.²⁶

8.0 DISCUSSION

All seven included studies were randomised controlled trials conducted over the past six years. However, one of the major issues encountered in this review was the lack of comparability of outcomes measures reported. There was wide variation in patient characteristics, stapling equipment used, surgery protocol, post-operative care, postoperative assessment and outcome measures between trials. These factors must be taken into account when considering the recommendations.

Stapled haemorrhoidectomy, based on this systematic literature review, appears to be at least as safe as conventional haemorrhoidal surgical techniques. The efficacy of stapled haemorrhoidectomy in comparison to conventional techniques could not be determined. This was due to the limited data available, the lack of comparability between the efficacy outcome measures and times used by the studies. Patient satisfaction with overall postoperative symptom control was similar in both treatment groups.^{14,26,28}

Due to the variability in outcome measures, meta-analysis was unable to be carried out on much of the extracted data. Despite this, significant results supporting the stapled procedure were found within some of the trials. These related to pain, bleeding, pruritis, anal discharge, wound healing, tenderness to per rectal examination, incontinence scores, and earlier return of bowel function. On the other hand, one trial showed that prolapse occurred at significantly lower rates in the conventional group. Since this is one of the indications for surgery, its persistence may be seen as treatment failure and as such, prospective randomised studies including long-term evaluation of postoperative complications and symptom recurrence need to be conducted. There was support in terms of patient outcome for the stapled technique with analgesic requirement, convalescence and return to normal activities.

Outcome measures for pain and bleeding varied greatly between studies, so very few conclusions could be made. This is of concern as both of these symptoms are of primary importance for patients undergoing haemorrhoidectomy. It would be desirable for future studies to assess pain and bleeding using consistent data collection protocols.

In general, there were very few cases of haemorrhoidal recurrence or prolapse, but the quality of data concerning long term follow-up was generally quite low. As such, prospective randomised studies including long-term evaluation of post-operative complications and symptom recurrence need to be conducted.

Serious complications following stapled surgery have been reported in the literature, including one case of life threatening pelvic sepsis.²⁹ This has led some clinicians to support the use of prophylactic antibiotics.^{29, 30} There has also been one reported case of recto-vaginal fistula³¹ which has led to the proposal that vaginal examination should be carried out routinely after closure and prior to firing of the stapler.³² Evidence documenting the incidence of severe pain and faecal urgency following stapled haemorrhoidectomy also exists.²⁴ It has been suggested that this can be attributed to the misplacement of the purse-string suture in relation to the dentate

line.³³ This complication is likely to be avoided by standard placement of the purse-string suture at 4cm above the dentate line, at which level the rectal mucosa is much less sensitive to pain. In any event, the high proportion of patients with these complications resulted in the suspension of the trial.²⁴

With any stapling procedure, there is always a small possibility of instrument failure. One report has documented a case of intra-operative failure due to a device error.³¹ The authors recommend the routine checking of staplers for defects prior to the commencement of surgery.

Economic aspects and medical costs

As further long-term studies are required to assess efficacy, it is not yet possible to perform a cost-effectiveness analysis of the stapled procedure. It should also be noted that that overseas economic analysis performed in two centres cannot be applied directly to the Australian health system due to major differences in overseas patterns of health resource utilisation and cost units.^{26, 28}

The cost of the stapler is approximately \$600. This compares to a cost of approximately \$25 for sutures with an open haemorrhoidectomy (personal communication, Robyn Johnston, 23th October 2001, The Queen Elizabeth Hospital, Adelaide, Australia). As the length of hospital stay was similar in both treatment groups,^{11, 12, 14, 25, 26, 25,28} the price of the stapling device adds dramatically to the cost of this intervention method. This does not however take into account the shorter convalescence period and earlier return to normal activities that is seen in patients after haemorrhoidectomy.^{25, 26, 25,28} In Australia the procedure of stapled haemorrhoidectomy is predominantly performed in the private health system where patients are completely reimbursed for the cost of the stapler.

These results have recently drawn attention to the suitability of stapled haemorrhoidectomy performed under regional anaesthesia as a day-case procedure.^{9, 34} It has been proposed that such an approach would decrease medical related costs as well as anaesthesia-related complications such as urinary retention. Four studies³⁴⁻³⁷ have examined the feasibility of this, and all have reported favourable results for the stapled technique.

Despite these findings supporting stapled haemorrhoidectomy as a day procedure, the experience of one public hospital in South Australia indicates that both stapled and conventional haemorrhoidectomies can be adequately carried out as a day surgery procedure (personal communication, Dr Shevvy Perera, 24th October 2001, The Queen Elizabeth Hospital, Adelaide, Australia). The generalisability of this hospital's experience must therefore be determined in order for a more accurate assessment of the costs of both techniques. In addition, future studies should ideally contain a standardized protocol for cost appraisal, and data specific to the Australian medical system should be obtained.

The devices used in the seven RCT's included in this review are all marketed by Ethicon Endosurgery, a division of Johnson and Johnson.^{11, 12, 14, 25, 26, 27, 28} The results from three of the RCT's are also included in the technical information and promotional booklet "Procedure for Prolapse and haemorrhoids" produced by Ethicon

Endosurgery.^{14, 26, 27} One of the included studies acknowledges the use of equipment donated by Ethicon Endosurgery.²⁷ Further, the reader should be aware of the fact that, although seven studies were included, two of these were conducted at the same hospital, and two authors had made contributions to both studies.¹² This may mean that the views of these authors have had an undue influence on the findings of this review.

Four RCTs were not included in this review as only the abstracts from conference proceedings could be obtained. However, their conclusions tended to concur with the data extracted from the included trials. Pope *et al.*²¹ found that stapled haemorrhoidectomy reduced rectal discharge and allowed a shorter rehabilitation. Correa and his colleagues¹⁹ reported equal safety between the two procedures, but less bleeding and more pain following conventional haemorrhoidectomy. Doran *et al.*²⁰ found that neither procedure adversely effected continence or anorectal manometry and is independent of anal dilatation or the presence of muscle in the resected specimen. Cheetham *et al.*¹⁷ concluded that stapled haemorrhoidectomy is less painful in the short-term, but also found that it was accompanied by a high incidence of new and residual symptoms at long-term follow-up.

None of the trials in this review thoroughly assessed the long-term safety and efficacy of the procedure. Several prospective studies have followed up patients for up to three years.^{10,33,39} One retrospective clinical study has evaluated patient outcomes at up to ten years after surgery.⁴⁰ Recently, other haemorrhoidal techniques such as Sapimed Transanal Mucosectomy⁴¹ and transcutaneous electrical nerve stimulation for pain relief⁴² have been developed and are awaiting clinical evaluation.

Conclusions and future research

Many of the studies retrieved from the search protocol were either case series or non-randomised trials that represent a lower level of evidence. All of the RCTs available for review were of level II evidence providing the best source of evidence for effect of intervention, minimising confounding factors that may influence the clinical outcomes under study. However, the small number of patients included in the RCTs emphasises the need for further larger studies to be conducted.

Stapled haemorrhoidectomy, based on this systematic literature review, appears to be a safe addition to the therapy options available for treating haemorrhoids. Most notably, stapling was accompanied by a significantly shorter operating time and convalescence, and an earlier return to normal activities. While some researchers argue that the cost of the stapling apparatus does not justify its introduction into surgical practice, this may be balanced, if not outweighed, by savings to the health system and the community

Despite these findings in favour of the stapled technique, it must be borne in mind that there will inevitably be a learning curve associated with its introduction. Thus, the potential benefits may only appear after surgeons have gained experience with the procedure.

Since this review reports inconclusive outcomes for the efficacy of circular stapled haemorrhoidectomy, it must be stressed that further research must be conducted in the following areas:

1. Its costs, in particular, data specific to the Australian medical system, should be obtained.
2. Before this can occur, the feasibility of both techniques as day-case procedures must be assessed, as this will influence cost analysis.
3. Long-term outcomes are yet to be thoroughly assessed in a randomised controlled trial. This is necessary before any recommendations can be made with confidence.
4. New studies should ideally derive data from a large sample size, to increase the power of meta-analysis.
5. As previously mentioned, standardisation of outcome measures, particularly for pain and bleeding, is required. This is likely to facilitate more accurate comparison of data

Safety and efficacy classifications

The Council of RACS endorsed the following ASERNIP-S safety and efficacy classification of Stapled Haemorrhoidectomy:

Evidence rating

- Average.

The level II evidence was limited by small sample size and short follow-up times. Few studies assessed similar end-points and there was incomplete reporting of important outcomes.

Safety

- Safe as compared to comparator procedure.

Efficacy

- Efficacy cannot be determined. The long-term data on efficacy outcome measures are awaited.

Recommendations

Research recommendations

There is a need for larger randomised controlled trials to be conducted to increase the power of meta-analysis. **Standardisation of outcome measures, particularly for pain, bleeding and long-term evaluation of post-operative complications and symptoms would allow more accurate comparison of data.**

Clinical recommendations

1. It is recommended that surgeons practicing stapled haemorrhoidectomy should conduct a careful audit of their results with this technique.
2. As a minimum requirement, surgeons wishing to use the stapled technique of haemorrhoidectomy should undergo appropriate training and supervised instruction.
3. The Colorectal Surgical Society of Australasia should develop guidelines for training on this procedure.

The ASERNIP-S Review group will conduct an update and re-appraisal of this review when any new evidence becomes available that may contribute to a change in these recommendations.

9.0 ACKNOWLEDGMENTS

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APPENDICES

Appendix A:

Table 1: Hierarchy of evidence¹⁶

Level of Evidence	Study Design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time-series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case-series, either post-test or pre-test/post-test.

Appendix B:

Table 1: Grey Literature

Study	Country	Sample Size	Level of Evidence
Cheetham et al. (2001) ²⁴	United Kingdom	CNV=16; St=15	Conference abstract
Correa et al (2001) ¹⁹	Mexico	CNV=40; St=41	Conference abstract
Docherty et al. (2001) ¹⁸	United Kingdom	CNV=20; St=26	Conference abstract
Doran et al. (2001) ^{20*}	United Kingdom	CNV=30; St=59	Conference abstract
Pope et al (2001) ^{21*}	United Kingdom	CNV=34; St=59	Conference abstract
Singer et al (2001) ²²	USA	St=53	Conference abstract

*There is a likely duplication of patients between these studies. CNV, Conventional; St, Stapled.

Table 2: Clinical Trials

Trial	Study Type	Sample group	Project Status
STOPP Trial – Stapled or Open Pile Procedure. Study of haemorrhoid excision and stapled anopecty for the treatment of prolapsing haemorrhoids	Multi-centre RCT	200 patients	Complete but not yet published
An Open Prospective Multicentre Randomised Study of Haemorrhoid Excision (Milligan-Morgan) and Stapled Anoplexy (Longo) for the Treatment of Prolapsing Haemorrhoids	Multi-centre randomised study	20 patients	Complete but not yet published
Prospective randomised controlled trial of closed haemorrhoidectomy verses circular stapled prolapsectomy	Randomised study	Not Stated	Complete but not yet published
Prospective randomised controlled trial of closed haemorrhoidectomy verses circular stapled prolapsectomy	RCT	60 patients	Complete but not yet published
Prospective assessment of the function al and endoscopic effects of circular stapled prolapsectomy	Clinical Trial without Randomisation	40 patients	Complete but not yet published

RCT, randomised controlled trial.

Table 3: Excluded RCTs

Study	Country	Sample size	Level of Evidence
Cheetham et al. (2001) ¹⁷	United Kingdom	St=22(stapled patients)	Report on suspended RCT
Helmy (2000) ¹³	Saudi Arabia	CNV=20; St=20	RCT
Khalil et al. (2000) ¹⁵	United Kingdom	CNV=20; St=20	Linear Stapling Device

RCTs, randomised controlled trials; CNV, Conventional; St, Stapled.

**APPENDIX C – METHODOLOGICAL ASSESSMENT
AND DATA EXTRACTION TABLES**

Appendix C.1: Study profiles

Authors	Institution	Intervention	Study Design	Level of Evidence	Study Population	Inclusion/Exclusion Criteria	Follow-Up	Operator Details/Skills
Boccoasanta <i>et al</i> ²⁵ 2001	Department of General and Oncological Surgery; Department of General and Thoracic Surgery, IRCCS Ospedale Policlinico, Milano, Italy.	Haemorrhoidectomy: Stapled vs Conventional (modified Milligan-Morgan). <i>Pre-operative assessment -</i> All patients assessed via structured questionnaire, proctological examination, defecography and rectoanal manometry <i>Clinical features -</i> <u>Stapled</u> Bleeding 82.5% Rectal dyschezia 55.0% Incomplete evacuation 52.5% Constant pain 27.5% Soiling 65.0% Pruritus 22.5% <u>Conventional</u> Bleeding 77.5% Rectal dyschezia 60.0% Incomplete evacuation 50% Constant pain 30.0% Soiling 57.5% Pruritus 20.0% <i>Anaesthesia -</i> <u>Stapled</u> General 70% Spinal 30% <u>Conventional</u> General 60% Spinal 40% <i>Operation position -</i> Lithotomy <i>Stapler type -</i> Ethicon	Randomised controlled trial Prospective Double blinded with sealed envelope	II	<u>Sample size</u> - n=80 <u>Stapled</u> n=40 (15M/25F) <u>Age</u> - Mean = 51.0 yrs (range 21-92 yrs) <u>Conventional</u> =40 (18M/22F) <u>Age</u> - Mean = 50.5 yrs (range 21-82 yrs) <u>Study period</u> - December 1996 - December 1990 <u>Diagnosis</u> - Fourth degree haemorrhoids and external mucosal prolapse. <u>Duration of symptoms</u> - Not stated <u>Previous haemorrhoidal surgery</u> - Not stated	<u>Exclusions</u> - Not stated	1 and 6 weeks and long-term at 6 months and 1 year after surgery. No loss to follow-up at 1 and 6 weeks and 6 month. Loss to follow up at 1 year: <u>Stapled</u> 5% <u>Conventional</u> 20%	<u>Experience</u> - Not stated
Continued...								

Authors	Institution	Intervention	Study Design	Level of Evidence	Study Population	Inclusion/Exclusion Criteria	Follow-Up	Operator Details/Skills
Boccoasanta <i>et al.</i> ²⁵ 2001		Endosurgery 33-mm Haemorrhoidal circular stapler (PPH). <i>Intra-operative testing</i> – Not stated <i>Post-operative assessment</i> - In hospital and at 1,2,4,12, and 54 weeks after surgery- Structured questionnaire, patient self-assessment and clinical examination. Excised tissue sent for histopathological assessment						
Brown <i>et al.</i> ¹² 2001	Department of Colorectal Surgery, Singapore General Hospital, Singapore	Haemorrhoidectomy: Stapled vs Conventional (open diathermy). <i>Pre-operative assessment</i> - All patients were assessed for the presence of circumferential, oedematous prolapsed haemorrhoids <i>Clinical features</i> - <u>Stapled</u> Bleeding 40% <u>Conventional</u> Bleeding 60% <i>Anaesthesia</i> -General. <i>Operation position</i> - Lithotomy <i>Stapler type</i> – Ethicon Endosurgery 33-mm Haemorrhoidal circular stapler (PPH01). <i>Intra-operative testing</i> – Prior to stapler firing in female patients the	Randomised controlled trial Prospective Patient blinded (sealed envelopes)	II	<u>Sample size</u> - n=30 <u>Stapled</u> n=15 (9M/6F) <u>Age</u> - Median = 44 yrs (range 32-77) <u>Conventional</u> n=15 (11M/4F) <u>Age</u> - Median= 46 yrs (range 16-60) <u>Study period</u> – 6 months. Specific dates not stated <u>Diagnosis</u> – Circumferential, oedematous prolapsed piles with no evidence of infection or necrosis of the haemorrhoid. <u>Duration of symptoms</u> - All patients had symptoms for over 6 months. <u>Previous haemorrhoidal surgery</u> – Not stated	<u>Exclusions</u> - 5 patient <u>Reasons</u> - <ul style="list-style-type: none"> Failed to attend for follow-up and were excluded from analysis Patients with infection or necrosis of the haemorrhoid were ineligible for study entry 	2 and 6 weeks after surgery Mean length: Not stated No loss to follow-up.	<u>Experience</u> - Not stated.
Continued								

Authors	Institution	Intervention	Study Design	Level of Evidence	Study Population	Inclusion/Exclusion Criteria	Follow-Up	Operator Details/Skills
Brown <i>et al.</i> ¹² 2001		vagina was palpated. <i>Post-operative assessment</i> - In hospital and at 2 weeks after discharge - Structured questionnaire, blinded observer assessment and patient self-assessment; 6 weeks - Clinical review, incontinence score, anorectal manometry and endoanal ultrasound; 3 months - As above for 6 weeks plus quality-of-life questionnaire.						
Ganio <i>et al.</i> ¹¹ 2000	Department of General Surgery, Colorectal Eporediensis Centre, Ivrea; Department of General Surgery and Liver Transplantation Units, University of Bari, Bari; Institute of General Surgery, University of Milan, Milan; Institute of Surgery, University Tor Vergata, Rome; Colorectal Unit, Riccione, Italy.	Haemorrhoidectomy: Stapled vs Conventional (open diathermy). <i>Pre-operative assessment</i> - 1 week prior to surgery all patients underwent clinical examination, including proctoscopy and anaorectal manometry, and were asked to complete a clinical diary. <i>Clinical features</i> - <u>Stapled</u> - Bleeding 34% Pain 26% Pruritus 6% <u>Conventional</u> - Bleeding 26% Pain 22% Pruritus 14% <i>Anaesthesia</i> - General, spinal or	Randomised controlled trial Multi-centre (5) Prospective Patient blinded (sealed envelopes)	II	<u>Sample size</u> - n=100 <u>Stapled</u> n=50 <u>Age</u> - Mean 47 (SD 14) <u>Conventional</u> n=50 <u>Age</u> - Mean = 48 yrs (SD 13 yrs) <u>Study period</u> - May 1998 - April 1999. <u>Diagnosis</u> - Symptomatic haemorrhoids; <u>Stapled</u> - third- degree 70% fourth-degree 30% <u>Conventional</u> - third- degree 72% fourth-degree 28% <u>Duration of symptoms</u> - Not stated <u>Previous haemorrhoidal surgery</u> - Not stated	<u>Exclusions</u> - Proportion excluded not stated. <u>Reasons</u> - <ul style="list-style-type: none"> Concomitant anal disease, fissure, abscess, dermatitis, fistula, Crohn's disease, ulcerative colitis, rectal cancer Patients on treatment with oral anticoagulants 	10 and 30 days after surgery Loss to Follow-up not stated.	<u>Experience</u> - Multi-centre study: 5 hospitals in Italy No information on experience of operators
Continued...								

Authors	Institution	Intervention	Study Design	Level of Evidence	Study Population	Inclusion/Exclusion Criteria	Follow-Up	Operator Details/Skills
Ganio <i>et al.</i> ¹¹ 2000		<p>posterior perineal block. <u>Stapled</u> – General 38% Spinal 36% Posterior perineal block 26% <u>Conventional</u> - General 54% Spinal 32% Posterior perineal block 14% <i>Operation position</i> – Not stated <i>Stapler type</i> – Ethicon Endosurgey 33-mm Haemorrhoidal circular stapler (ILS33). <i>Intra-operative testing</i> – None stated. <i>Post-operative assessment</i> - In hospital - Structured questionnaire and patient self-assessment; 10 days and 30 days after surgery – Structured questionnaire, patient self-assessment, clinical evaluation and anaoscopy; Long-term – Telephone interview and structured questionnaire.</p>						
Ho <i>et al.</i> ²⁶ 2000 Continued...	Departments of Colorectal Surgery and Histopathology, Singapore General Hospital, Singapore.	Haemorrhoidectomy: Stapled vs Conventional (open diathermy). <i>Pre-operative assessment</i> - All patients were assessed with faecal incontinence score,	Randomised controlled trial Prospective Patient blinded (sealed envelopes)	II	Sample size - n=119 <u>Stapled</u> n=57 (29M/28F) Age - Mean = 44 yrs (SD 11.3 yrs) <u>Conventional</u> n=62 (30M/32F) Age - Mean = 46.3 yrs (SD 12.6 yrs) Study period – October	<u>Exclusions</u> - Proportion excluded not stated. <u>Reasons</u> - <ul style="list-style-type: none"> • Previous perianal surgery • Acutely thrombosed internal 	2, 6 weeks and 3 months after surgery. <u>Stapled</u> Mean length: 18.9 weeks (range 12.9- 29.9) <u>Conventional</u>	<u>Experience</u> - Multiple operators of specialist colorectal grade (performed at least five stapled haemorrhoidecto mies without

Authors	Institution	Intervention	Study Design	Level of Evidence	Study Population	Inclusion/Exclusion Criteria	Follow-Up	Operator Details/Skills
Mehigan <i>et al.</i> ¹⁴ 2000		Lithotomy <i>Stapler type</i> – Ethicon Endosurgey 33-mm Haemorrhoidal circular stapler (CDH33 or HCS 33). <i>Intra-operative testing</i> – Not stated <i>Post-operative assessment</i> - In hospital and at 1 and 3 weeks after discharge - Structured questionnaire, and patient self-assessment; (patient blinded for first 10 days) 6 - 10 weeks after discharge - Structured questionnaire and patient self-assessment, plus quality-of-life questionnaire.			prolapsing haemorrhoids. <u>Duration of symptoms</u> – Not stated <u>Previous haemorrhoidal surgery</u> – Not stated	(proportion excluded not stated)	Mean length of follow up 125 days (range 80-206) No loss to follow-up	
Rowse <i>et al.</i> ²¹ 2000	Department of Gastrointestinal and General Surgery, Leicester Royal Infirmary, Infirmary Square, Leicester, UK.	Haemorrhoidectomy: Stapled vs Conventional (open diathermy). <i>Pre-operative assessment</i> - Not stated. <i>Clinical features</i> – Not stated <i>Anaesthesia</i> -General. <i>Operation position</i> - Prone <i>Stapler type</i> – Ethicon Endosurgey 33-mm Haemorrhoidal circular stapler (CDH33/PPH01). <i>Intra-operative testing</i> – Not stated	Randomised controlled trial Prospective Patient blinded (sealed Envelopes)	II	<u>Sample size</u> - n=22 <u>Stapled</u> n=11 (7M/4F) <u>Age</u> - Mean = 52.7 yrs (SD 7 yrs) <u>Conventional</u> n=11 (6M/5F) <u>Age</u> - Mean = 58.2 yrs (SD 15.3 yrs) <u>Study period</u> – Not stated. <u>Diagnosis</u> - Symptomatic third-degree haemorrhoids. <u>Duration of symptoms</u> - Not stated <u>Previous haemorrhoidal surgery</u> - <u>Stapled</u> Mean 0.82 (SD 1.1) <u>Conventional</u> Mean 1.5 (SD 2.0)	<u>Exclusions</u> - 1 patient <u>Reasons</u> - • Unable to undergo general anaesthesia	1 and 6 weeks after surgery Mean length: Not stated No loss to follow-up.	<u>Experience</u> - Not stated
Continued...								

Authors	Institution	Intervention	Study Design	Level of Evidence	Study Population	Inclusion/Exclusion Criteria	Follow-Up	Operator Details/Skills
Rowse et al. ²⁷ 2000		<i>Post-operative assessment -</i> In hospital, 6 and 10 weeks after discharge – Structured questionnaire. Excised tissue sent for histopathological assessment						
Shalaby and Desoky ²⁸ 2001	Surgical Department, Al-Arhar and Ain Shams University, Cairo, Egypt	Haemorrhoidectomy: Stapled vs Conventional (Milligan-Morgan). <i>Pre-operative assessment -</i> Clinical Examination, routine laboratory investigations and rectoanal manometry using standard manometric equipment and techniques. <i>Clinical features -</i> Stapled Constipation 60% Bleeding 69% Discharge 39% Itching 34% Prolapse 17% Conventional Constipation 64% Bleeding 62% Discharge 30% Itching 30% Prolapse 20% <i>Anaesthesia –</i> General <i>Operation position -</i> Lithotomy <i>Stapler type –</i> Ethicon Endosurgery 33-mm Haemorrhoidal circular stapler (Proximate®).	Randomised Prospective Patient blinded (table of random numbers)	II	<u>Sample size</u> - n=200 <u>Stapled</u> n=100 (60M/40F) <u>Age</u> - Mean = 44.1 yrs (SD 3.2 yrs) <u>Conventional</u> =100 (64M/36F) <u>Age</u> - Mean = 49.1 yrs (SD 12.2 yrs) <u>Study period</u> – March 1997 – December 1998 <u>Diagnosis</u> – Symptomatic prolapsing haemorrhoids - differing degrees of severity <u>Stapled</u> Second degree= 13 Third degree= 32 Fourth degree= 37 <u>Conventional</u> Second degree= 10 Third degree= 30 Fourth degree= 40 <u>Duration of symptoms</u> – Not stated <u>Previous haemorrhoidal surgery</u> – Not stated	<u>Exclusions</u> - Proportion excluded not stated <u>Reasons</u> - <ul style="list-style-type: none"> • Prolapsed thrombosed piles • Prolapse of one haemorrhoidal cushion • Associated anal fistulas and anal fissures 	1,2,4,12, and 54 weeks after surgery. No loss to follow-up not stated	<u>Experience</u> - Not stated
Continued...								

Authors	Institution	Intervention	Study Design	Level of Evidence	Study Population	Inclusion/Exclusion Criteria	Follow-Up	Operator Details/Skills
Shalaby and Desoky ²⁸ 2001		<p><i>Intra-operative testing –</i> In women, posterior vaginal wall checked before stapler firing.</p> <p><i>Post-operative assessment -</i> In hospital and at 1 and 6 weeks, 6 months and 1 year after surgery - Structured questionnaire, and patient self-assessment; At 6 months after surgery, rectoanal manometry was repeated for all patients Excised tissue sent for histopathological assessment</p>						

Appendix C.2: Safety Results

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
SAFETY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100;St=100
Bleeding							
<i>In hospital</i>							
Conventional				1.6%			
Stapled				3.5%			
<i>2 weeks post-op:</i>							
Conventional		67%		53.3%			
Stapled		20% [†]		33.3 [†]			
<i>6 weeks post-op:</i>							
Conventional		27%		11.3%			
Stapled		0% [†]		15.8%			
<i>2-3 months post-op:</i>							
Conventional				3.2%			2%
Stapled				1.8%			1%
<i>Long-term (range 8-19 months) post-op:</i>							
Conventional			32%				
Stapled			28%*				
<i>Persistent (>10 weeks)</i>							
Conventional					5%		
Stapled					5%		
<i>Bleeding (median days)</i>							
Conventional			6				
Stapled			5*				

[†] p<0.05 compared to Conventional, * not statistically significant compared to Conventional

Abbreviations: CNV – Conventional; St - Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowsell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
SAFETY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100;St=100
Bleeding <i>continued</i>							
<i>Bleeding requiring medical consultation, intervention or re-hospitalisation at 2 weeks post-op</i>							
Conventional		13%		16.1%	5%		
Stapled				5.3%			
<i>From internal sphincter</i>							
Conventional	5%						
Stapled							
Haemorrhage							
<i>Early:</i>							
Conventional	7.5%						
Stapled	5% [*]						
<i>Late (< 1 year):</i>							
Conventional	5%						
Stapled	0% [*]						
<i>Requirement for haemostatic sutures</i>							
Conventional			6%		15%		
Stapled	12.5%		6%		25%		
<i>Requirement for transfixated suture</i>							
Conventional	5%						
Stapled							
<i>2° haemorrhage requiring transfusion</i>							
Conventional	2.5%						
Stapled							
<i>Thrombosis of external piles</i>							
Conventional	15%			1.8%			3%
Stapled	5% [†]						3%

*not statistically significant compared to Conventional; † p<0.034 compared to Conventional; † p<0.05 compared to Conventional

Abbreviations: CNV – Conventional; St - Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
SAFETY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100;St=100
Urinary retention							
Conventional	5%				5%		14%
Stapled	5%*			1.8%	5%		7%
<i>Urinary Catheter</i>							
Conventional			10%				
Stapled			6%*				
High fever							
Conventional				1.6%			
Stapled							
Internal sphincter damage							
<i>Before Surgery:</i>							
Conventional				1.6%			
Stapled				1.8%			
<i>6 weeks- 3 months post-op:</i>							
Conventional		13%		6.5%			
Stapled		13%		3.5%			
External sphincter damage							
<i>Before Surgery:</i>							
Conventional				0%			
Stapled				0%			
<i>6 weeks – 3 months post-op:</i>							
Conventional		0%		0%			
Stapled		0%		0%			
Anal stenosis and stricture							
<i>2 - 6 weeks post-op:</i>							
Conventional		7%		8.1%			
Stapled		7%*		8.8%			
<i>< 1 year – 1 year post-op:</i>							
Conventional	7.5%						6%
Stapled	5%*						2%

*not statistically significant compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
SAFETY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100;St=100
Anal fissure							
<i>Early</i>							
Conventional					5%		3%
Stapled					5%		1%
Anal sphincter muscle removed							
Conventional				0%			
Stapled				0%		36.4%	
No. patients with wounds healed							
<i>6 –10 weeks</i>							
Conventional				85.5% [†]		27.3%	
Stapled				100%			
<i>3 months</i>							
Conventional				100%			
Stapled				100%			
Days till wounds healed							
Conventional							30.5±5.8 [‡]
Stapled							7.0±1.2 ^{‡§}
No patients with wound discharge							
<i>2 weeks</i>							
Conventional		20%		22.6%			
Stapled		7% [*]		8.8%			
<i>6 weeks</i>							
Conventional		0%		4.8%			
Stapled		0% [*]		0%			
<i>3 months - > 10 weeks</i>							
Conventional				3.2%	5%		
Stapled				0%	5%		
Total complications							
Conventional				25.8%			
Stapled				17.5%			

[†]values are mean ± standard deviation; [§]p<0.001 compared to Conventional; ^{*} not statistically significant compared to Conventional; [†] p<0.05 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

Appendix C.3: Efficacy Results

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Peri-operative Outcomes							
<i>Operating time (mins)</i>							
Conventional	50 ± 5.3 [‡]	15 (5-25) ^{**}		11.4± 9.8 ^{‡*}		14.8±3.3 [‡]	19.7± 4.7 [‡]
Stapled	25 ± 3.1 ^{‡*}	15 (10-40) ^{**§§}		17.6± 7.1 [‡]		14.1±6.5 [‡]	9.0 ± 2.7 ^{‡*}
<i>Anaesthesia time (mins)</i>							
Conventional					22 (15-25) ^{**}		
Stapled					18 (9-25) ^{**¶¶¶}		
Convalescence							
<i>Length of hospital stay (days)</i>							
Conventional	3 ± 0.4 [‡]	2 (2-4) ^{**}	2 (0-12) ^{**}	2.0± 0.8 [‡] (1-4) ^{††}	1 (0-3) ^{**}	2.82± 0.3 [‡]	2.2± 0.5 [‡]
Stapled	2 ± 0.5 ^{‡†}	2 (1-5) ^{**§}	1 (0-3) ^{**†}	2.1± 0.76 [‡] (2-6) ^{††}	1 (0-4) ^{** a}	1.09± 1.0 ^{‡*}	1.1± 0.2 ^{‡*}
<i>Post-surgery inpatient stay (nights)</i>							
<i>1 night:</i>							
Conventional						9.1%	
Stapled						90.9%	
<i>2 nights:</i>							
Conventional						27.3%	
Stapled						9.1%	
<i>3 nights:</i>							
Conventional						36.4%	
Stapled							
<i>4 nights:</i>							
Conventional						27.3%	
Stapled							
<i>Resumption of usual activities including employment (days)</i>							
Conventional	15 ± 1.4 [‡]	28 (14-81) ^{**}	(n=37)13 (3-25) ^{**}	22.9±14.2 [‡] (2-52) ^{††}	34 (14-90) ^{**}	16.9±7.70	53.9± 5.8 [‡]
Stapled	8.0 ± 6.9 ^{‡*}	14 (5-43) ^{**§§}	(n=35) 5 (1-16) ^{**¶¶¶}	17.1±14.3 [‡] (0-40) ^{††§§}	17 (3-60) ^{**b}	8.10±5.10	8.2± 0.9 ^{‡*}

[‡]values are mean ± standard deviation; * p<0.001 compared to Conventional; †p=0.01 compared to Conventional; ** values are median (range); ††range; §§ p<0.05 compared to Conventional; ¶¶p=0.07 compared to Conventional; ^ap=0.376 compared to Conventional; ^bp=0.0002 compared to Conventional; *** p=0.04 compared to Conventional.

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowsell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Pain							
<i>During hospitalisation:</i>							
Conventional		1 (0-10) [*]		5.0±3.1 [‡] (0-10) ^{††}			
Stapled		5 (2-10) ^{***}		4.5±13.0 [‡] (0-10) ^{††}			
Mean pain scores for the first 24 hours post-surgery:							
Conventional							7.6± 0.7 [‡]
Stapled							2.5± 1.3 ^{‡*}
Pain 1 week post-surgery:							
Conventional							0.4± 0.7 [‡]
Stapled							2.6± 0.6 ^{‡*}
Average pain over 10 days post-surgery:							
Conventional					6.5 (1-8.5) ^{**}		
Stapled					2.1 (0.2-7.6) ^{**c}		
Total pain over 10 days post-surgery:							
Conventional							
Stapled							
Pain 2 weeks post-surgery							
Conventional				4.8±3.1 [‡] (0-10) ^{††}			
Stapled				3.8±3.8 [‡] (0-10) ^{††}			
Pain 6 weeks post-surgery							
Conventional		33%					
Stapled		0% ^{§§}					
Pain relative to what was expected							
Conventional					0.7(-1.8-3.4) ^{**}		
Stapled					-2.8 (-4.4-1.3) ^{**c}		
Cumulative pain score							
7 days:							
Conventional							44.8±16.7 [‡]
Stapled							20.64±16.5 ^{‡¶¶}

††p<0.02 compared to Conventional; § not statistically significant compared to Conventional; §§ p<0.05 compared to Conventional; °p<0.0001 compared to Conventional; ‡values are mean ± standard deviation; *p<0.001 compared to Conventional; ** values are median (range); ††range; ¶¶p=0.003 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Pain <i>continued</i>							
Cumulative pain score							
<i>Unspecified:</i>							
Conventional			15 (0-82) ^{**}				
Stapled			11 (0-67) ^{**¶}				
<i>Pain >5 (VAS)</i>							
Conventional	42.5%						
Stapled	17.5% [*]						
Persistent pain							
<i>6 weeks post-surgery:</i>							
Conventional				14.5%			
Stapled				5.3%			
<i>3 months post-surgery:</i>							
Conventional				4.8%			
Stapled				1.8%			
Long term pain (range 8-19 months)							
<i>Occasionally:</i>							
Conventional			28%				
Stapled			18%				
<i>Frequent:</i>							
Conventional			2%				
Stapled			2%				
Pain at stool							
<i>During hospitalisation:</i>							
Conventional		3 (0-7) ^{**}		3.0±1.9 [‡] (0-5) ^{††}			6.6± 1.2 [‡]
Stapled		6 (1-10) ^{**§§}		3.0±2.1 [‡] (0-7) ^{††}			1.1± 0.3 ^{‡*}
<i>2 weeks post-surgery:</i>							
Conventional		6 (1-10) ^{**}		5.1±3.2 [‡] (0-10) ^{††}			
Stapled		0 (0-7) ^{**¶¶}		2.6±3.0 [‡] (0-10) ^{††¶}			

[‡]values are mean ± standard deviation; ^{*} p<0.001 compared to Conventional; ^{**} values are median (range); ^{††}range; [¶]p=0.03 compared to Conventional; ^{¶¶} p<0.005 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Requirement for 1 additional dose of analgesia on 1st post-operative night							
Conventional						9%	
Stapled						9%	
Patients requesting longer stay because of perianal pain							
Conventional		20%					
Stapled		26.7%					
Pain score (1-10) 2 weeks post-surgery							
Conventional		5.5 (0-10) ^{**}					
Stapled		0 (0-7) ^{**§§}					
Days in moderate pain							
Conventional			5.3 (0-19) ^{**}				
Stapled			3.1 (0-10) ^{**†}				
Days in severe pain							
Conventional			2.3 (0-24) ^{**}				
Stapled			1 (0-14) ^{**¶}				
Analgesic requirement							
<i>No. of doses per day</i>							
Conventional							3.7± 0.8 [‡]
Stapled							0.8± 0.1 ^{‡*}
<i>No Analgesic required</i>							
Conventional							51%
Stapled							0
<i>Some Analgesic required</i>							
Conventional							49%
Stapled							100%

‡values are mean ± standard deviation; *p<0.001 compared to Conventional; ** values are median (range); ¶p=0.03 compared to Conventional; §§ p<0.05 compared to Conventional; †p=0.01 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Analgesic requirement <i>continued</i>							
<i>Composite pain score (no. of analgesics / no. of days of consumption)</i>							
Conventional			1.5± 05 [‡]				
Stapled			1.4± 05 ^{‡§}				
<i>IM Meperidine (1mg/kg body weight)</i>							
Conventional				0.3±0.8 [‡] (0-2) ^{††}			
Stapled				0.6±0.8 [‡] (0-1) ^{††}			
<i>Ketoprofen (100 mg tablet)</i>							
During hospitalisation:							
Conventional				2.8±9.4 [‡] (0-15) ^{††}			
Stapled				2.7±9.8 [‡] (1-8) ^{††}			
2 weeks after surgery:							
Conventional				19.0±18.9 [‡] (0-64) ^{††}			
Stapled				16.7±11.3 [‡] (0-40) ^{†††}			
6 weeks after surgery:							
Conventional				1.1±5.5 [‡] (0-42) ^{††}			
Stapled				0 ^{§§}			
3 months after surgery:							
Conventional				0			
Stapled				0			
<i>Co-codamol tablets taken over 7 post-op days</i>							
Conventional						22.9± 18.8 [‡]	
Stapled						10.6± 19.3 ^{‡e}	
<i>NSAID tablets</i>							
Immediately post-surgery							
Conventional		3 (0-6) ^{**}					
Stapled		2 (0-7) ^{**§}					

[‡]values are mean ± standard deviation; ^{**} values are median (range); ^{††}range; ^{†††} p<0.005 compared to Conventional; [§] not statistically significant compared to Conventional; ^{§§} p<0.05 compared to Conventional; ^ep=0.14 compared to Conventional; ^{†††} p<0.005 compared to Conventional; ^{††}range

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowsell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Analgesic requirement <i>continued</i>							
<i>2 weeks post-surgery</i>							
Conventional		10 (1-28) ^{**}					
Stapled		8.5 (2-28) ^{***§}					
<i>6 weeks post-surgery</i>							
Conventional		0 (0-28) ^{**}					
Stapled		0 ^{**§}					
No. of pethidine injections immediately post-surgery							
Conventional		0 (0-1) ^{**}					
Stapled		0 (0-4) ^{***§}					
Severe and persistent symptoms post-op requiring examination under anaesthesia							
Conventional					10%		
Stapled					5%		
Readmission							
Conventional		20%			4.8%		
Stapled		0% [§]			0%		
Skin Tags							
Independently Observed							
<i>2 weeks post-surgery:</i>							
Conventional				16.1%			
Stapled				19.3%			
<i>6 weeks post-surgery:</i>							
Conventional				4.8%			
Stapled				8%			
<i>3 months post-surgery:</i>							
Conventional				3.2%			
Stapled				3.5%			

^{**} values are median (range); [§] not statistically significant compared to Conventional;

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i>²⁵	Brown <i>et al.</i>¹²	Ganio <i>et al.</i>¹¹	Ho <i>et al.</i>²⁶	Mehigan <i>et al.</i>¹⁴	Rowsell <i>et al.</i>²⁷	Shalby and Deskoy²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Skin Tags							
Patient Observed							
2 weeks post-surgery:							
Conventional				9.7%			
Stapled				12.3%			
6 weeks post-surgery:							
Conventional				4.8%			
Stapled				7.0%			
2-3 months post-surgery:							
Conventional	5%			1.6%	5%		1%
Stapled	2.5% [§]			1.8%	20%		4%
Pruritis							
2 weeks post-surgery:							
Conventional				43.5%			
Stapled				15.8% ^{§§}			
6 weeks post-surgery:							
Conventional				17.7%			
Stapled				8.8%			
3 months post-surgery:							
Conventional				3.2%			
Stapled				3.5%			
Anal Discharge							
Conventional							14%
Stapled							2% [†]
New passage of slime/mucus PR							
Conventional					10%		
Stapled					10%		
Reintervention within 10 days							
Conventional	5%						
Stapled	0%						

[§] not statistically significant compared to Conventional; [†] p<0.002 compared to Conventional; ^{§§} p<0.05 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowsell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Wound Discharge							
2 weeks post-surgery							
Conventional		20%		22.6%			
Stapled		7% [§]		14.0%			
6 weeks post-surgery							
Conventional		0%		4.8%			
Stapled		0% [§]		0%			
3 months post-surgery							
Conventional				3.2%			
Stapled				0%			
Recurrence of haemorrhoids (<1 year)							
Conventional	0%						
Stapled	0% [§]						
Time to wound healing (days)							
Conventional							30.5±5.8 [‡]
Stapled							7.0±1.2 ^{‡*}
Constipation Score							
Pre-op:							
Conventional			1.03± 2.02 [‡]				
Stapled			0.05 ± 1.19 [‡]				
Post-op:							
Conventional			0.27± 0.84 [‡]				
Stapled			0.14±0.35 ^{‡§§§}				
Tenderness to PR examination							
Moderate							
6 weeks post-surgery:							
Conventional				32.3%			
Stapled				18%			

§ not statistically significant compared to Conventional; §§§p=0.02 compared to Conventional; ‡values are mean ± standard deviation; *p<0.001 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowsell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Tenderness to PR examination <i>continued</i>							
3 months post-surgery:							
Conventional				3.2%			
Stapled				3.4%			
<i>Severe</i>							
6 weeks post-surgery:				16.1%			
Conventional				0% ^{§§}			
Stapled							
3 months post-surgery				3.2%			
Conventional				0%			
Stapled							
New onset faecal ‘urgency’							
Conventional					10%		
Stapled					10%		
Incontinence							
<i>Temporary (to flatus and liquid) at 10 weeks</i>							
Conventional					15%		
Stapled					5%		
<i>To Gas</i>							
<i>Prior to surgery</i>							
Conventional				0%			
Stapled				0%			
6 weeks post-surgery							
Conventional				3.2%			
Stapled				1.7% [§]			

§ not statistically significant compared to Conventional; §§§ p=0.02 compared to Conventional;

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Incontinence							
<i>continued</i>							
3 months post-surgery							
Conventional				1.6%			
Stapled				0% [§]			
<i>To Liquid</i>							
Prior to surgery							
Conventional				1.6%			
Stapled				0%			
6 weeks post-surgery							
Conventional				3.2%			
Stapled				0% [§]			
3 months post-surgery							
Conventional				1.6%			
Stapled				0% [§]			
<i>To Solid</i>							
Prior to surgery							
Conventional				0			
Stapled				0			
6 weeks post-surgery							
Conventional				0			
Stapled				0 [§]			
3 months post-surgery							
Conventional				0			
Stapled				0 [§]			
Incontinence Score							
Preoperative							
Conventional			1.0 ± 0 [‡]	0.06 ± 0.47 [‡] (0-4) ^{††}			
Stapled			1.0 ± 0 [‡]	0			

***p=0.04 compared to Conventional; §not statistically significant compared to Conventional; ‡values are mean ± standard deviation; *p<0.001 compared to Conventional; ††range; §§ p<0.05 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	RowSELL <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Incontinence Score <i>continued</i>							
6 weeks postoperative							
Conventional			1.04 ± 0.2 [‡]	0.3 ± 0.2 [‡] (0-6) ^{††}			
Stapled			1.0 ± 0 ^{***}	0.06 ± 0.47 [‡] (0-2) ^{††§}			
3 months postoperative							
Conventional				0.0 ± 2.36 [‡] (0-6) ^{††}			
Stapled				0 [§]			
Soiling (<1 year post-surgery)							
Conventional	2.5%						
Stapled	2.5% [§]						
Anal Resting Pressure (mmHg)							
<i>Before Surgery:</i>							
Conventional	47.2±39.8 [‡]		79±18 [‡]	73.2± 34.6			60.1±6.1 [‡]
Stapled	51.4±45.5 [‡]		86±14 [‡]	67.2± 22.6 [‡]			61.9±7.1 [‡]
<i>6 Weeks after Surgery:</i>							
Conventional			78±16 [‡]	55.3± 29.9 [‡]			
Stapled			83 ±17 [‡]	77.2± 163.1 ^{‡§}			
<i>3 months after Surgery:</i>							
Conventional	45.2±36.6 [‡]			52.7±63.0 [‡]			
Stapled	49.9±40.5 [‡]			59.9±36.2 ^{‡§}			
<i>6 months after Surgery:</i>							
Conventional							42.7±4.6 [‡]
Stapled							60.3±6.3 ^{‡¶}
Anal squeeze pressure (mmHg)							
<i>Before Surgery:</i>							
Conventional	97.4±23.4 [‡]		146±45 [‡]	172.3±86.6 [‡]			147.2±20.7 [‡]
Stapled	99.3±32.9 ^{‡§}		150±45 [‡]	199.7±80.8 [‡]			145.4±24.1 [‡]

§not statistically significant compared to Conventional; ‡values are mean ± standard deviation; †p=0.01 compared to Conventional; §§p<0.05 compared to preoperative; ***p=0.04 compared to Conventional; ††range

Abbreviations: CNV – Conventional; St – Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Anal squeeze pressure (mmHg) <i>continued</i>							
<i>6 Weeks after Surgery:</i>							
Conventional			143±47 [‡]	176.4±70.1 [‡]			
Stapled			154±50 [‡]	172.9±102.7 ^{‡§§}			
<i>3 months after Surgery:</i>							
Conventional	94.7±22.8 [‡]			181.2±246.5 [‡]			
Stapled	96.7±30.4 ^{‡§§}			229.9±167.6 ^{‡§§}			
<i>6 months after Surgery:</i>							
Conventional							116.4±14.3 ^{‡§§}
Stapled							142.8±22.2 ^{‡*}
Prolapse							
<i>At 2 weeks post-surgery:</i>							
Conventional		0%					
Stapled		7% [§]					
<i>At 6 weeks post-surgery:</i>							
Conventional		0%					
Stapled		0% [§]					
<i>At 1-year follow-up:</i>							
Conventional							2.5%
Stapled							1.1%
<i>Self-reported, at mean 16 (range 8-19) months:</i>							
Rare:			16%				
Conventional			6% ^{†††}				
Stapled							
Frequent:							
Conventional			4%				
Stapled							

§not statistically significant compared to Conventional; ‡values are mean ± standard deviation; * p<0.001 compared to Conventional; §§p<0.05 compared to preoperative; †††p=0.001 compared to Conventional
Abbreviations: CNV – Conventional; St - Stapled

	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowsell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Bowel movements per week (mean)							
2 weeks post-surgery				11.4±7.1 [‡]			
Conventional				12.3±8.3 [‡]			
Stapled							
6 weeks post-surgery				9.6±5.5 [‡]			
Conventional				10.7±6.8 [‡]			
Stapled							
3 months post-surgery				10.2±11.0 [‡]			
Conventional				8.5±5.3 [‡]			
Stapled							
Bowel movement before discharge							
Conventional				22.8%			
Stapled				11.3%			
Time to first bowel movement (days)							
Conventional					2 (0-5) ^{**}		
Stapled					1 (0-6) ^{**}		
Proportion opened bowels within 24 hours							
Conventional					30%		
Stapled					55%		
Proportion discharged within 24 hours							
Conventional					75%		
Stapled					60% ^d		
Mean total related medical cost							
Conventional	Lira1,546±241 [‡]			\$1,283.09±238.50 [‡]			
Stapled	Lira1,380±201 ^{‡§}			\$921.17±132.70 ^{‡! !}			
Quality of life 3 months post-surgery							
Conventional				126.4±29.1 [‡]			
Stapled				120.0±44.5 ^{‡§}			

[‡]values are mean ± standard deviation; [§] not statistically significant compared to Conventional; ^{**} values are median (range); ^{††} range; ^{! !} p<0.005 compared to Conventional; ^d p=0.05 compared to Conventional

Abbreviations: CNV – Conventional; St – Stapled

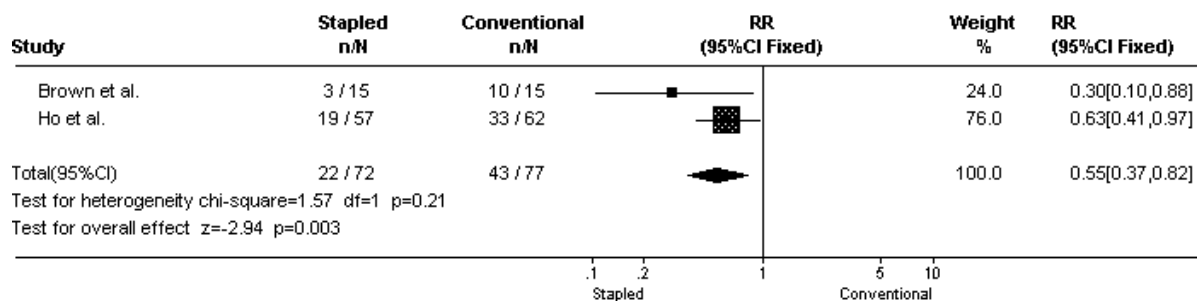
	Boccasanta <i>et al.</i> ²⁵	Brown <i>et al.</i> ¹²	Ganio <i>et al.</i> ¹¹	Ho <i>et al.</i> ²⁶	Mehigan <i>et al.</i> ¹⁴	Rowell <i>et al.</i> ²⁷	Shalby and Deskoy ²⁸
EFFICACY OUTCOMES	CNV=40;St=40	CNV=15; St=15	CNV=50; St=50	CNV=62; St=57	CNV= 20; St=20	CNV=11; St=11	CNV=100; St=100
Patient satisfaction							
<i>During hospitalisation:</i>							
Conventional				7.4±0.8 [‡]			
Stapled				7.3±0.8 [‡]			
<i>1-2 weeks post-surgery:</i>							
Conventional				6.7±1.6 [‡]			92%
Stapled				6.8±1.5 [‡]			80%
<i>6 weeks post-surgery:</i>							
Conventional				8.3±5.5 [‡]			
Stapled				8.0±6.8 [‡]			
<i>3 months post-surgery:</i>							
Conventional				8.6±4.7 [‡]			
Stapled				8.2±6.0 [‡]			
<i>10 weeks or more post-surgery:</i>							
Conventional (median 136 days)							
Unsatisfactory					5%		
Satisfactory					20%		
Good					35%		
Excellent					40%		
Stapled (median 125 days)							
Unsatisfactory					5%		
Satisfactory					10%		
Good					30%		
Excellent					55%		

[‡]values are mean ± standard deviation

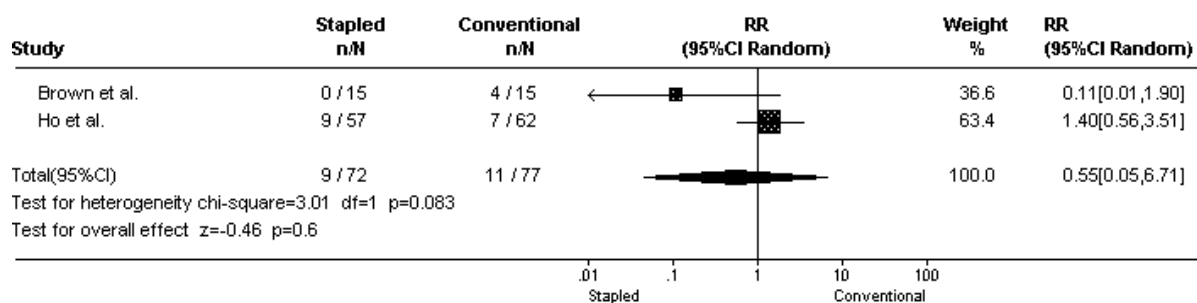
Abbreviations: CNV – Conventional; St – Stapled

Appendix C.4: Safety Meta-analysis

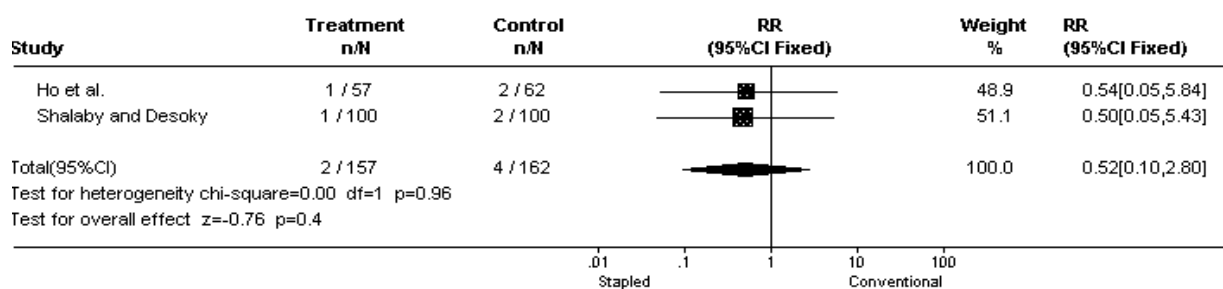
Bleeding at 2 weeks post-operative



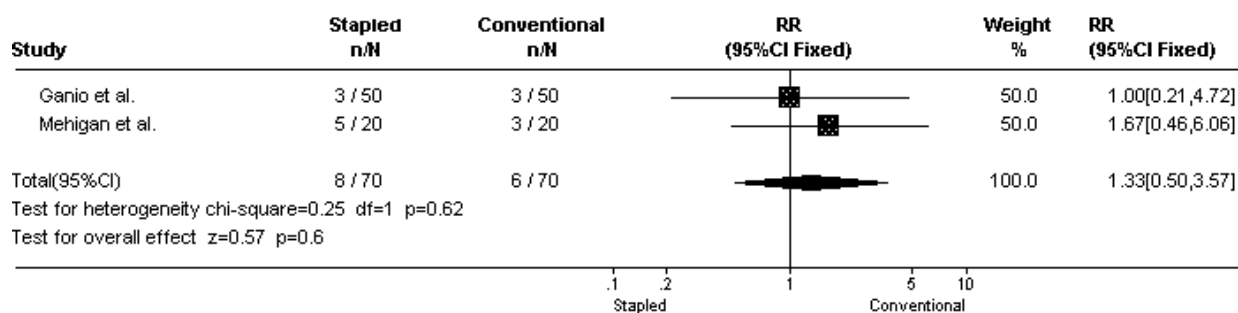
Bleeding at 6 weeks post-operative



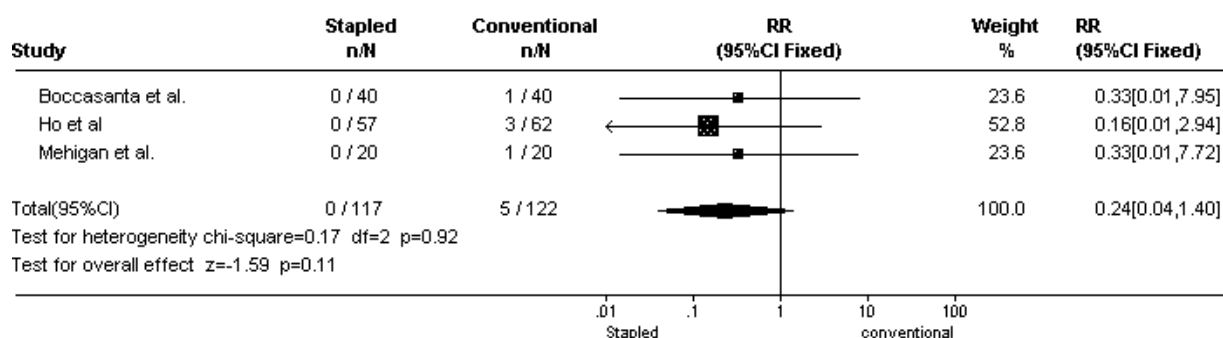
Bleeding at 2-3 months post-operative



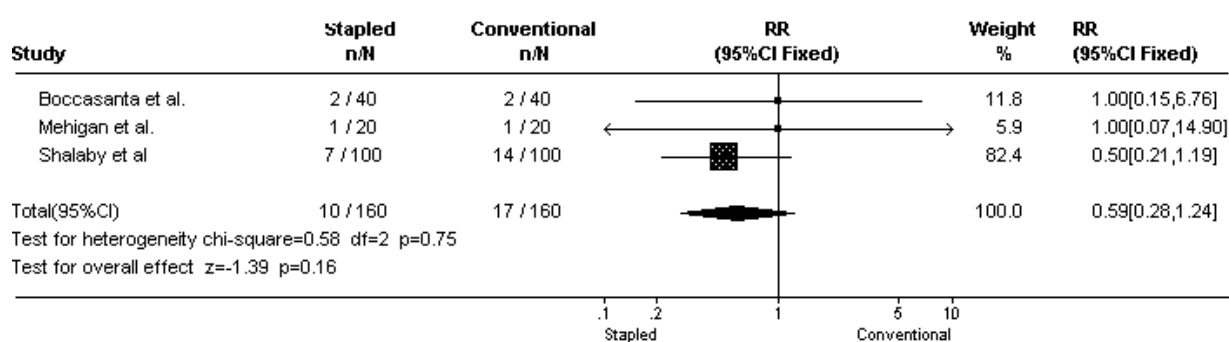
Haemorrhage requiring sutures



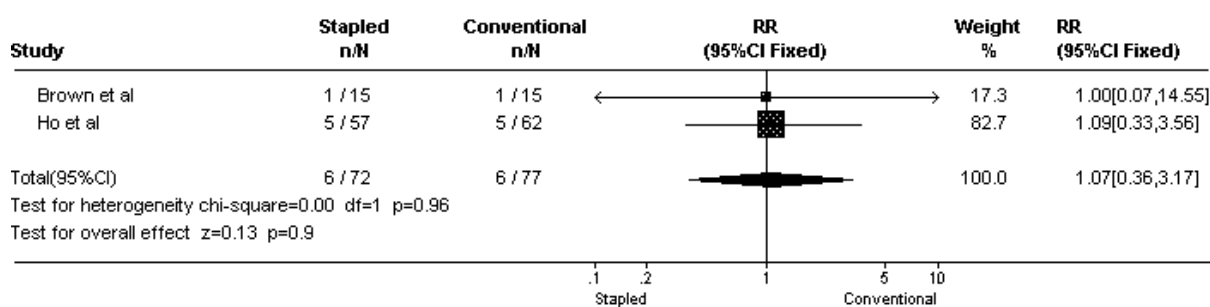
Secondary haemorrhage requiring transfusion



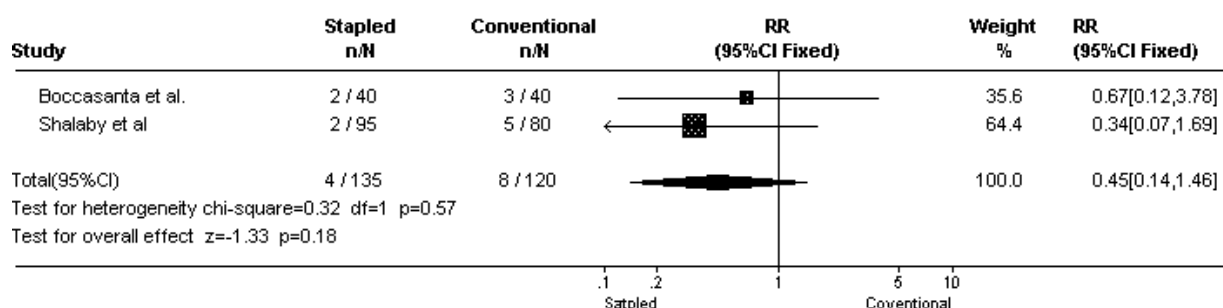
Urinary retention



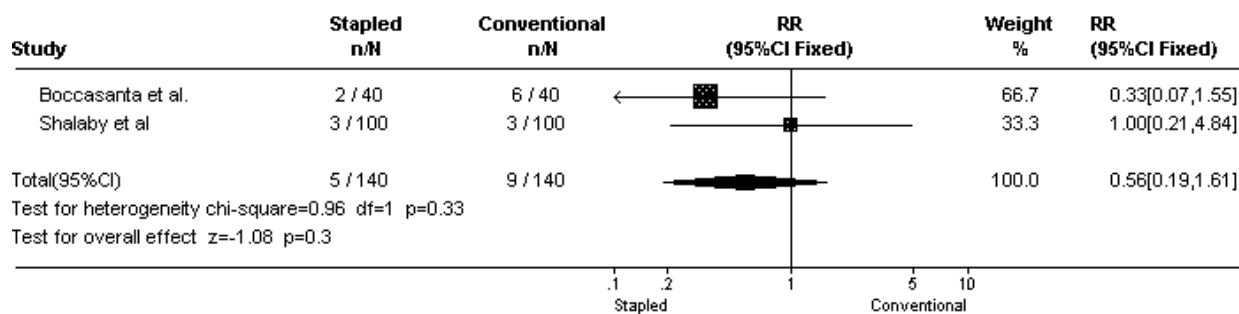
Anal stenosis at 2-6 weeks



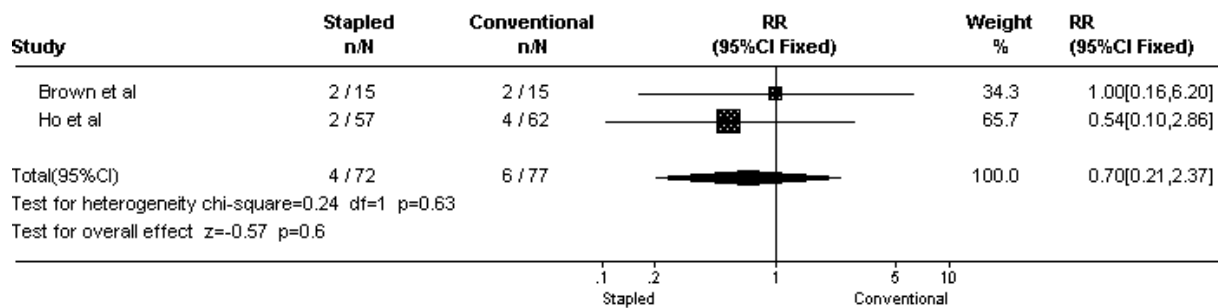
Anal stenosis at late follow-up



Thrombosis of external piles

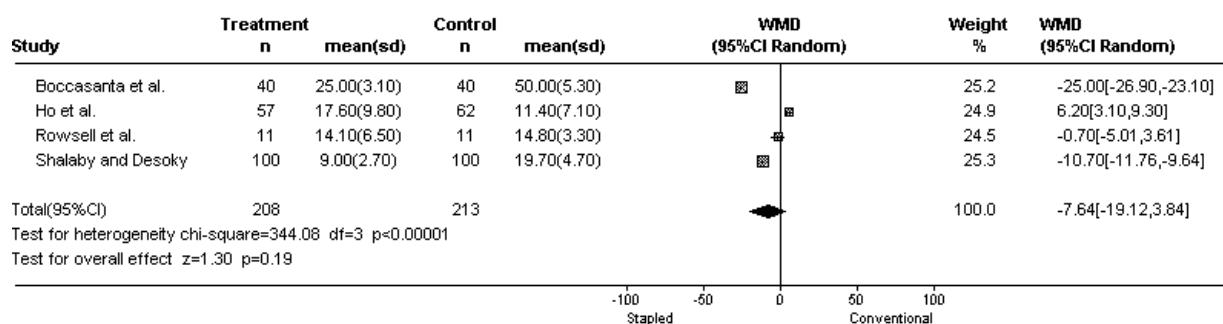


Internal sphincter damage at 6 weeks

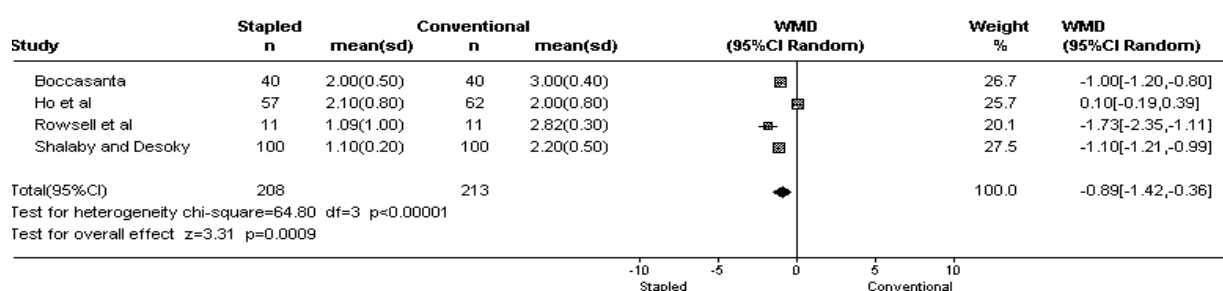


Appendix C.5: Efficacy Meta-analysis

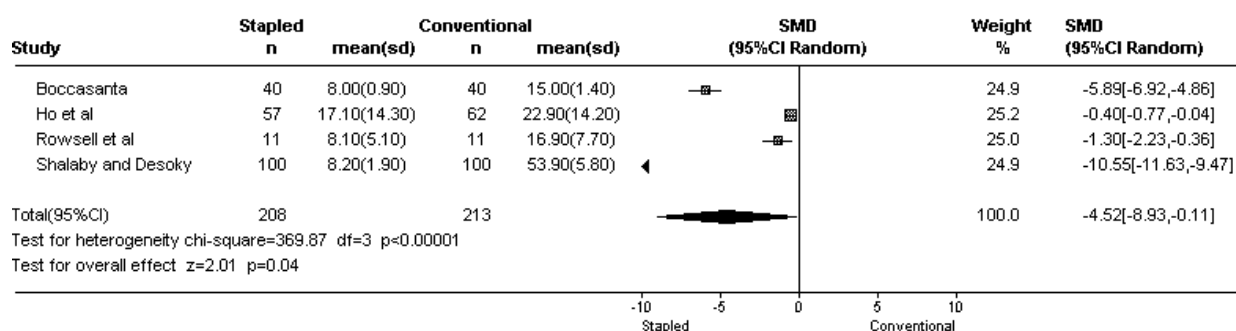
Operating Time



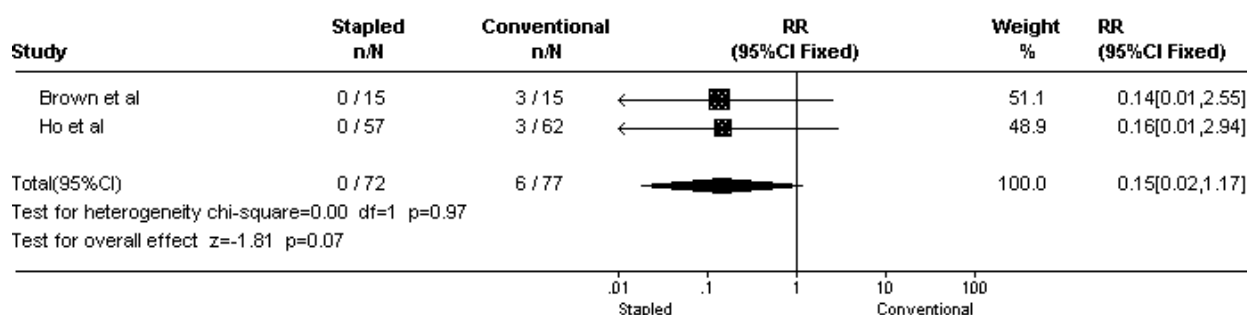
Length of hospital stay



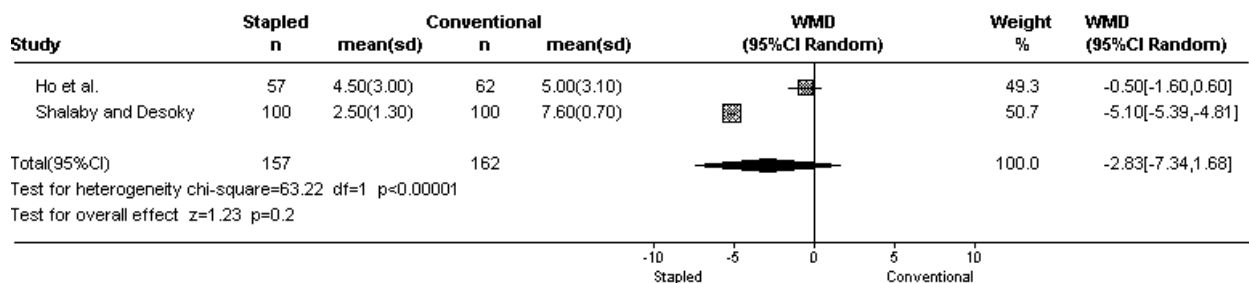
Resumption of usual activities



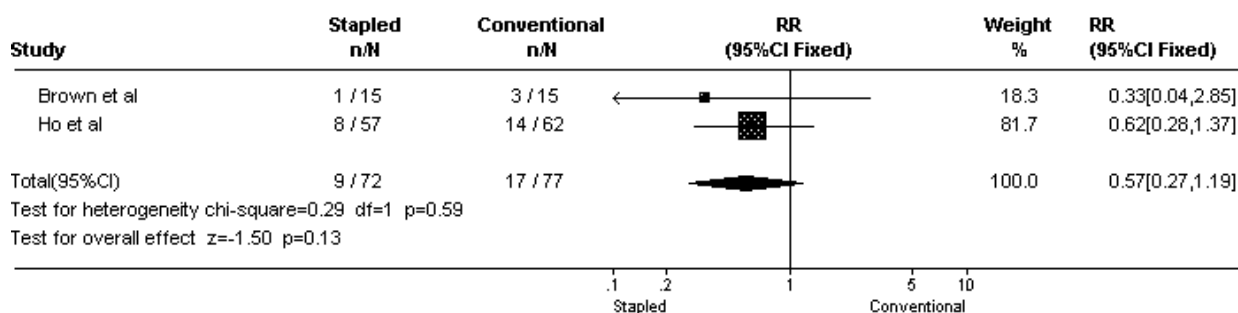
Readmission



Pain in hospital (VAS score)



Wound discharge at 2 weeks



Skin tags at 2-3 months

