

1 Executive Summary

In the United Kingdom, the most common surgical procedure for the treatment of haemorrhoids is the Milligan-Morgan haemorrhoidectomy. This technique has been subject to numerous modifications over the past years, and more recently adapted by the use of diathermy, laser, ligasure and harmonic scalpel. The underlying principle however of the Milligan-Morgan haemorrhoidectomy has not changed; the preservation of skin bridges between the excised haemorrhoids to prevent stricturing. Wounds are left to heal by secondary intention (open haemorrhoidectomy). The Ferguson technique is a similar, but less frequently used technique in the UK. Here the wounds are sutured closed at the end of surgery.

Improvements in the understanding of the anatomy of haemorrhoids prompted the development of new and innovative methods of treatment. Stapled Haemorrhoidopexy (*also known as the Procedure for Prolapse & Haemorrhoids (PPH), or Stapled Haemorrhoidectomy, or Stapled Anopexy or Circumferential Mucosectomy*), is a technique developed in the late 1990's that reduces the prolapse of haemorrhoidal tissue by excising a band of the prolapsed anal mucosa membrane above the dentate line with the use of a specific circular stapling device. The excess prolapsed tissue is removed, whilst the remaining haemorrhoidal tissue is conserved, unlike in a traditional haemorrhoidectomy where the haemorrhoids are surgically removed. This procedure is referred to as a 'pexy', as the haemorrhoidal tissue is restored to its original anatomical position, it is not excised.

A degree of confusion still exists among lay people and doctors, who misuse the terms "haemorrhoids" and "piles" to cover a variety of complaints. This unfortunately has led to estimates of prevalence for haemorrhoids varying from 4.4% among adults in the United States, to 36.4% in general practice in London. These numbers are not particularly helpful for informing the potential number of patients suitable for surgical intervention.

Data from the Hospital Episodes Statistics database indicates that in the year 2004-2005, there were approximately 23,000 haemorrhoidal procedures conducted in the UK. Of these, approximately 13,000 were rubber band ligation and sclerotherapy, with approximately 8,000 excisional surgical procedures being performed (OPCS code H511).

Haemorrhoidectomy has been a Department of Health target for day case surgery since 2001. However in 2004-2005, still only 1,957 were conducted in the day case setting. This reluctance to move more patients to the day case setting is considered by the Association of Coloproctology of Great Britain and Ireland (ACPGBI) to be a result of the significant level of pain experienced by these patients post surgery, and therefore often requiring a brief in-patient stay. Evidence suggests that the significant reductions in pain reported following a stapled haemorrhoidopexy procedure would enable a greater proportion of patients to be managed in the surgical day-case setting.

Stapled Haemorrhoidopexy has previously been reviewed by NICE as part of their interventional procedures programme (IPG034) which concluded that "Current evidence on the safety and efficacy of circular stapled haemorrhoidectomy appears adequate to support the use of the procedure". Ethicon Endo-Surgery recommends the use of Stapled Haemorrhoidopexy routinely for the surgical treatment of grade three haemorrhoids.

The ACPGBI recommends that any surgeon wishing to undertake stapled haemorrhoidopexy undergo specific training and are preceptored through their first cases during their learning curve (ACPGBI Consensus Document - Monson et al. 2002). In line with this recommendation, Ethicon Endo-Surgery offers a comprehensive training and preceptorship programme to all new surgeons.

1.1 Clinical Effectiveness

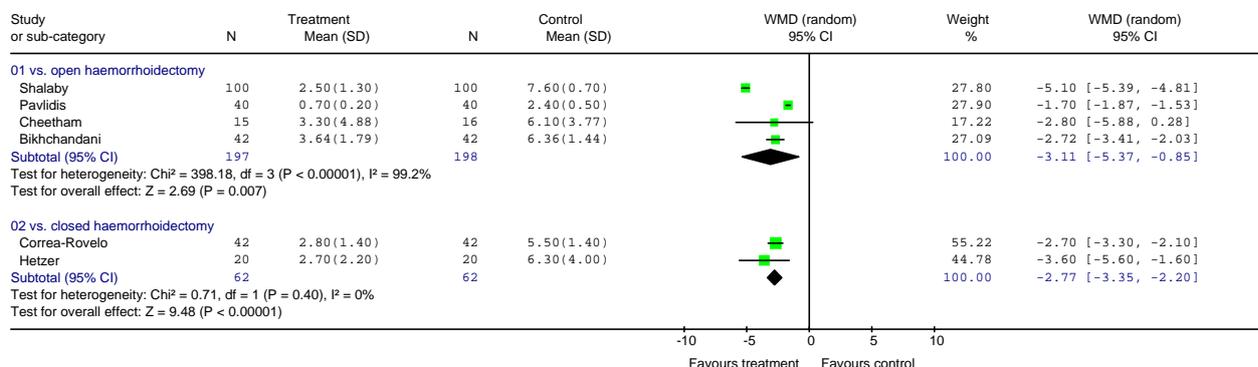
A systematic review of RCTs comparing Stapled Haemorrhoidopexy to other surgical techniques was undertaken. Thirty-four trials were found comparing Stapled Haemorrhoidopexy with either Milligan Morgan or Ferguson. All clinical data relating to stapled haemorrhoidopexy procedures identified through the systematic review, and reported in this submission, have used the “**Proximate* PPH Procedure for Prolapse and Haemorrhoids Set**”. No trials reporting evidence on other device kits were found through our literature search.

1.1.1 Pain

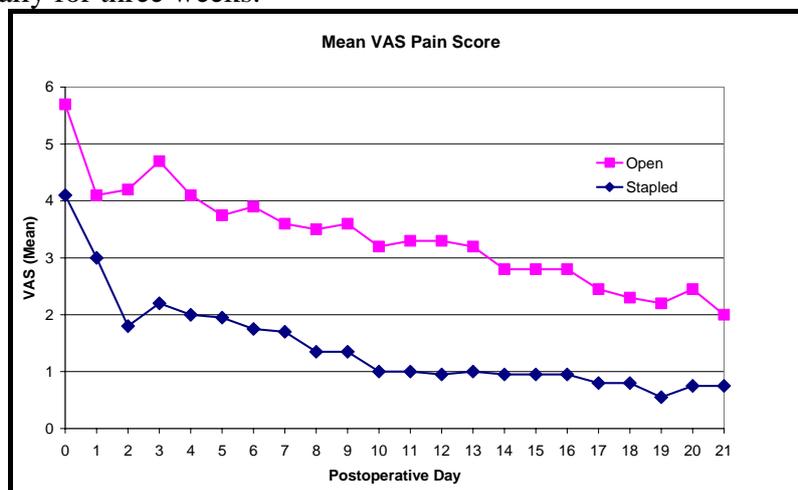
The principle benefit of the stapled haemorrhoidopexy technique compared with Milligan Morgan is the significant reduction in pain, from post surgery throughout the recovery period. Statistically significant and clinically relevant benefits in pain reduction were seen with Stapled Haemorrhoidopexy, both in the short term (24 hour) and mid-term follow up (up to a median 16 months) when compared to traditional techniques.

Perioperative pain at 24 hrs: stapled haemorrhoidopexy vs. Milligan-Morgan/Ferguson - random effects model.

Review: PPH U1680
 Comparison: 01 PPH vs. Conventional
 Outcome: 08 pain VAS 24 h



The sustained benefit in pain reduction can be visualised in the results from one study that reported pain daily for three weeks.



Means VAS scores taken from Van de Stadt et al.

1.1.2 Wound Healing

Another key benefit of the stapled technique is that patients are not left with an open wound post surgery that requires ongoing management. With the stapled procedure patients are left with an internal staple line, whereas patients undergoing traditional surgery are left with a ‘true’ wound, as the procedure creates three external cuts that are then left open to heal naturally over time.



Wound resulting from a Milligan Morgan Procedure



Following a Stapled Haemorrhoidopexy

The one study that reported time to wound healing, Shalaby, demonstrated that 50% of patients who underwent a Milligan Morgan procedure still had an open wound over four weeks after their initial procedure. A reduction in the time to wound healing is instrumental in ensuring patients return to normal activities as quickly as possible after their procedure.

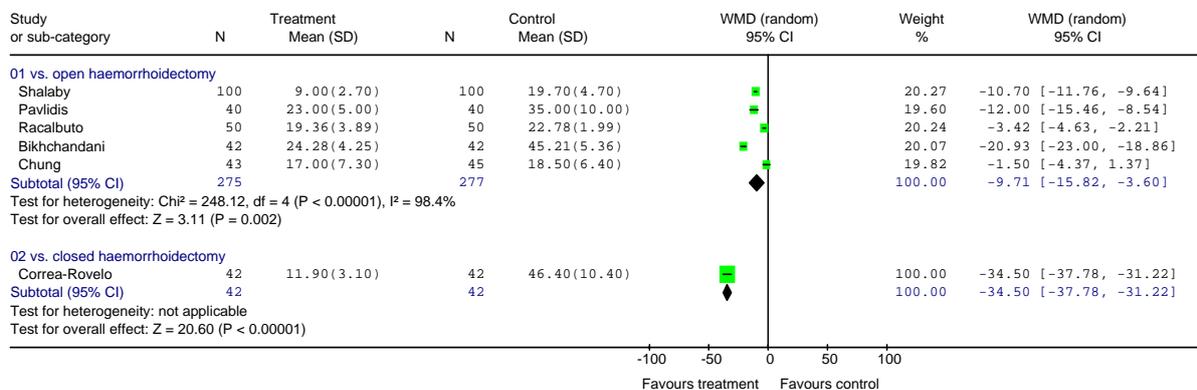
1.1.3 Resource Use

Stapled Haemorrhoidopexy provides benefits in terms of both reduced operating time and reductions in hospital length of stay when compared with the traditional Milligan-Morgan technique. Length of Stay data was not available for Ferguson technique.

1.1.4 Operating Time

Operation time“: stapled haemorrhoidopexy vs. Milligan-Morgan/Ferguson hemorrhoidectomy, random effects model.

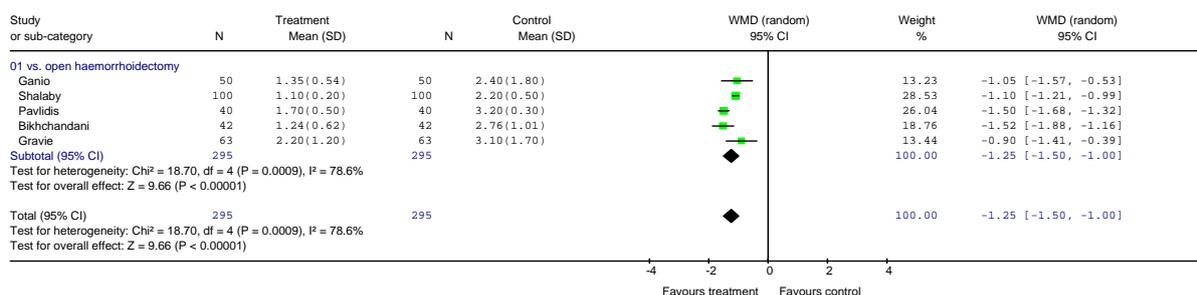
Review: PPH U1680
 Comparison: 01 PPH vs. Conventional
 Outcome: 22 Operation time



1.1.5 Length of Stay

Hospital stay: stapled haemorrhoidopexy vs. Milligan-Morgan – overall, random effects model.

Review: PPH U1680
 Comparison: 01 PPH vs. Conventional
 Outcome: 25 hospital stay



1.1.6 Complications / Adverse Events

No significant differences in postoperative bleeding, anal incontinence, or stenosis were observed between the two techniques.

A significant difference in recurrent prolapse was observed between the stapled haemorrhoidopexy and traditional techniques (combined Milligan Morgan and Ferguson) when considering all patients, however sub-group analysis of patients with grade 3 haemorrhoids did not show statistical significance. Furthermore, no significant difference was observed in the rate of re-do surgery (all patients).

1.2 Cost Effectiveness

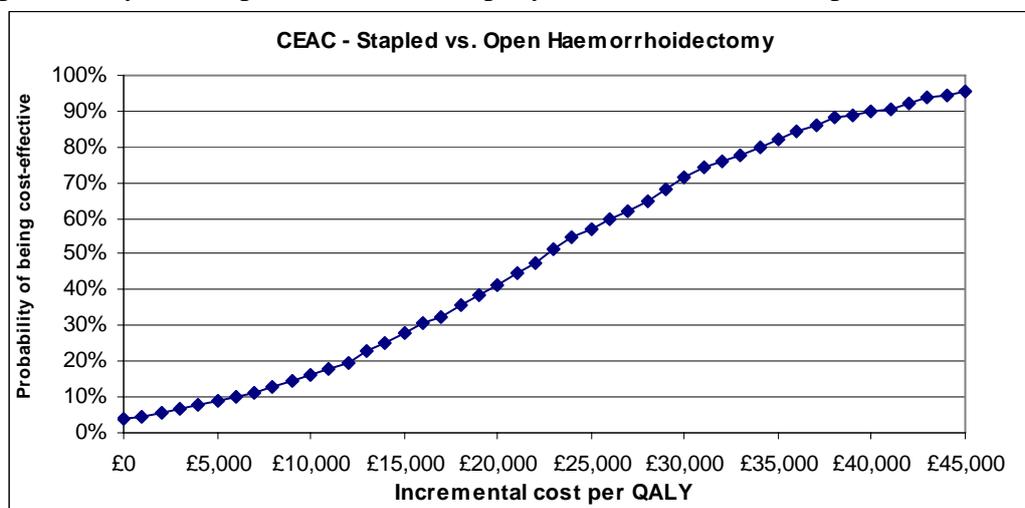
The economic analysis submitted is a probabilistic model based on the combined data set reported in the clinical effectiveness section. The starting point for the model is current NHS practice utilising HES data sets to estimate the current day case/in-patient caseload split. The comparator is Milligan Morgan technique, as this is the ‘gold standard’ in the NHS and this technique appears to be a superior technique to Ferguson and as such is a conservative assumption for our model.

A cohort-based model with a simple decision tree structure was developed to investigate the cost effectiveness of stapled haemorrhoidopexy in the treatment of haemorrhoids. Patients enter the model having undergone either a stapled or an open haemorrhoidectomy. The patient then goes through a recovery period during which a proportion of the patients may suffer a recurrent prolapse. The severity of the recurrent prolapse determines whether the patient is able to self-treat or requires further surgery. Those who require re-surgery are readmitted to hospital and undergo the same procedure they had on entry to the model. List Price for the equipment is used in the model.

1.2.1 Results

The base case gives an incremental cost effectiveness ratio (ICER) of £22,416 /QALY gained.

A cost effectiveness acceptability curve (CEAC) has been generated comparing the cost effectiveness of stapled haemorrhoidopexy to an open haemorrhoidectomy. The CEAC shows that at a cost effectiveness acceptability threshold of £30,000, there is a greater than 70% probability that stapled haemorrhoidopexy is the cost-effective option.



Cost effectiveness acceptability curve (CEAC) for stapled haemorrhoidopexy versus open haemorrhoidectomy

1.2.2 Sensitivity Analysis and limitations

The modelling proved to be robust in its conclusions under sensitivity analysis to all major parameters, giving 95% confidence intervals ranging from stapled haemorrhoidopexy dominating the open procedure, to £49,621 per QALY. Furthermore, the Base Case result is considered a conservative estimate for the following reasons:

- The list price used for the equipment is the maximum price the NHS would pay (and discounting is common).
- The utility mapping undertaken mapped from the SF-36, a technique that is acknowledged to have significant ceiling and floor effects.
- The SF36 evidence used to inform the utility mapping was taken at some point between 6 & 8 weeks post surgery, and is driven by pain scores. We have assumed in the modelling no difference between role physical and general health dimensions in the SF36. The utility estimates are therefore driven by pain, and may not represent other acute QoL impairment post surgery, such as being able to undertake routine activities. These would have been captured had direct utility measures been used in the studies.
- The estimate of day-case surgery for Milligan Morgan taken from HES data is likely to be an over-estimate, as it includes current Stapled Haemorrhoidopexy procedures being undertaken as day-case. For example, Barnet and Chase Farm Hospitals Trust switched to Stapled Haemorrhoidopexy so that it could offer day case surgery as the default option rather than an elective in-patient surgical stay.
- No costs have been included for the follow up management of any difficult to heal open wounds following a Milligan Morgan procedure in Primary Care.

A limitation is that the model is confined to a one year time horizon. This however is not considered a significant limitation as there appears to be convergence in utilities by one year. Clinical opinion also considers that prolapse beyond this point is a new prolapse, not necessarily recurrence.

1.3 NHS Budget Impact

The annual (undiscounted) marginal cost of adopting the stapled haemorrhoidopexy technique is anticipated to be £1.5M in 2007, rising to £2.1M in 2011.

1.4 Conclusion

The safety and efficacy of Stapled Haemorrhoidopexy has been recognised by the NICE Interventional Procedures Programme (IPG034).

This submission demonstrates the clinical and cost effectiveness of the Stapled Haemorrhoidopexy procedure. The evidence presented demonstrates that the use of “**Proximate* PPH Procedure for Prolapse and Haemorrhoids Set**” for haemorrhoidopexy is a cost effective technique that results in less pain & faster healing for the patient; less operative time for the surgeon; and a shorter hospital stay and potential for day-case delivery for the Provider.