

# Laparoscopic inguinal hernia repair without mesh fixation, early results of a large randomised clinical trial

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## Abstract

**Background** A new persistent groin pain is reported by a significant number of patients following laparoscopic totally extraperitoneal hernia repair (TEP). Mesh fixation has been implicated as a possible cause, but is widely considered essential for mesh stabilization and early recurrence prevention. This study investigates whether any association exists between mesh fixation by metal tacks and the incidence of new groin pain or early hernia recurrence.

**Methods** A prospective multicenter double-blinded randomised trial was conducted between December 2004 and January 2006. Standardized TEP repair was performed with a rectangular 10 × 15cm polypropylene mesh. Hernia were randomized to either mesh fixation by metal tacks or left entirely unfixated. Clinical review by physical examination was performed by a separate blinded surgeon after a minimum of six months, with another review planned after two years. The incidence of new groin pain and recurrence were compared.

**Results** Five hundred herniae in 360 patients were entered into the study. At the first wave of clinical follow-up (median eight, range 6–13 postoperative months) a new pain was reported by 38 versus 23% ( $p = 0.003$ ), occurring at least once a week in 22 versus 15% ( $p = 0.049$ ), or

several times per week in 16 versus 8% ( $p = 0.009$ ) for fixated versus unfixated repairs, respectively. Patients with bilateral repairs were five times more likely to report the unfixated side being more comfortable ( $p = 0.006$ ). There was one recurrence in the fixated group (1/247) whilst none have yet occurred in the unfixated group. Fixation increased operative costs by approximately 375 AUD.

**Conclusion** Mesh fixation in TEP is associated with increased operative cost and chronic pain but no difference in the risk of hernia recurrence at six months was observed.

**Keywords** Hernia · Clinical papers · Laparoscopy

Repair of groin hernias by the laparoscopic totally extraperitoneal (TEP) method may be associated with less postoperative pain and a more-rapid resumption of usual occupational and leisure activities than conventional open techniques [1, 2]. However whilst usually less problematic than following open repairs, new postoperative groin pain is still reported by approximately one fifth of patients following TEP [2, 3, 4]. Whilst generally mild and nonlimiting, this may be severe in a small percentage of patients who may seek help from chronic pain specialists and suffer significant occupational difficulties [5]. The common practice of using metal staples to fixate mesh to the groin has been implicated as a possible cause. This follows numerous anecdotal reports of new groin pain that is well localized, corresponds with the location of a fixation tack, and is ameliorated by its removal [6]. This has encouraged the development and use of alternative methods of fixation that avoid the use of such tacks including fibrin glues, acrylate adhesives, and absorbable sutures [7, 8, 9]. Patients appear to report less pain than with tacks in such studies [10, 11, 12]. These alternate forms of fixation suffer from their own disadvantages including high cost

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and/or difficulty of use, and the overwhelming majority of surgeons continue to use stapled fixation. However, does a large piece of preperitoneally placed mesh really need fixation at all? Curiously, this requirement is seldom challenged. Instead there appears to exist an entrenched belief within the wider surgical community that mesh fixation is a vital step in the repair which reduces the risk of mesh folding or migration that could lead to early hernia recurrence. This study seeks to test this hypothesis by investigating whether an association exists between stapled fixation and chronic pain or the risk of hernia recurrence.

## Methods

A double-blinded prospective randomized clinical trial was conducted involving four surgeons and three adjacent institutions. Approval for the study was sought and granted from all relevant ethics committees. Both public and privately insured patients with an inguinal or femoral hernia were offered entry to the study. Patients were excluded if under 18 years of age, suffering dementia or other cognitive impairment, or being unable/unwilling to participate in fixation blinding and ongoing clinical follow-up. Patients with hernias considered unsuitable for TEP repair were also excluded (for instance, if difficulty developing the preperitoneal space was anticipated due to previous surgery, or in patients too frail for general anaesthesia).

### Technique

All participating surgeons had performed at least 300 TEP repairs prior to the commencement of the study. All hernias repaired in the study were performed in a standardized way agreed upon by all surgeons and institutions prior to commencement. This involved infra-umbilical access to the preperitoneal space with balloon expansion and insufflation with carbon dioxide. Reduction of the hernial sac and development of a preperitoneal pocket sufficient to accept a 10 × 15 cm polypropylene mesh was performed using a 30° 10 mm videotelescope and two 5 mm laparoscopic graspers. The rectangular mesh was not cut or shaped. The type of hernia was recorded according to the Nyhus classification [13]. In addition, the orificial size of the hernial defect was estimated (using the 5 mm closed diameter and 20 mm open diameter of the laparoscopic graspers as a guide) and recorded as either less than 1 cm, 1 to 2 cm, or greater than 2 cm.

Each participating institution had a unique computer-generated randomization schedule. This consisted of alternating blocks of four and six, and was faithfully reproduced into sealed, ordered envelopes and kept in each operating

theatre area. Following mesh placement, repairs were randomized into either a fixation or nonfixation group as determined by the intraoperative opening of the next envelope in order. When fixation was performed, titanium spiral tacks were used (Autosuture Protack, Norwalk, CT). The number of tacks required for adequate mesh fixation was left to the discretion of the operating surgeon, but placement was limited to areas above the iliopubic tract, and their position and number were recorded diagrammatically. Otherwise, the mesh was left entirely without any form of mechanical fixation and the operation concluded.

### Blinding

Both patients and follow-up clinician were blinded regarding the use of mesh fixation. All patients agreed to be blinded for two postoperative years, after which time they would be informed if requested. In order to prevent accidental unblinding by a curious patient or a well-meaning staff member, it was decided not to record whether mesh fixation had been performed or not in the operation report. Instead, the phrase “mesh fixation: randomized according to trial protocol” was entered for this component of the report. (For legal reasons details of the tack applicator device was recorded on the nursing count sheet.) Follow-up was performed by a different clinician to the operating surgeon. There were no external clues such as differences in the location or size of skin incisions to indicate whether fixation had been performed or not.

### Bilateral hernia repairs

As randomization was performed by hernia rather than by patient, each side was considered separately in bilateral repairs, giving rise to three possible outcomes: fixation performed on both sides, neither side, or one side only. In the last situation, the side randomized to receive fixation was repaired first so that any mesh overlap in the midline would not create inadvertent fixation of the other side. These patients were studied further as a subgroup since they allowed direct comparison between the techniques.

### Trial safeguards

All patients were seen as part of routine postoperative care by their treating surgeon two weeks after surgery. This also provided a safeguard so that, if any acute hernia recurrences began appearing as a result of not fixating the mesh, the trial could be stopped (following statistical

**Table 1** Pain scoring system

Pain impact	Frequency	Score
No discomfort whatsoever		0
Cunningham mild: minor ache not interfering with leisure, occupational or daily activities	Less than once per week	1
	Around once per week	2
	Several times per week	3
Cunningham mod: moderate discomfort interfering with leisure activities but not occupational or daily duties	Less than once per week	4
	Around once per week	5
	Several times per week	6
Cunningham severe: significant pain interfering with occupational and/or basic daily tasks	Less than once per week	7
	Around once per week	8
	Several times per week	9
Severe constant pain		10

confirmation) without exposing further patients to harm. In addition, each patient was provided with the contact details of the trial supervisor and an independent ethics committee liaison officer, and advised of their right to withdraw from trial participation at any time.

#### Follow-up protocol

Patients were recalled for in-person clinical review after a minimum of six months by a separate blinded surgeon. A second wave of review is planned in 2008 to allow comparisons of the two groups after two years.

The severity of any new groin pain was recorded according to a post-herniorrhaphy pain scale devised for the study that took into account both frequency and impact (Table 1). Frequency was categorized as episodes occurring less than once per week, about once per week, or several times per week. Impact was recorded using existing definitions derived from the Cunningham classification of post-herniorrhaphy pain [14]; mild pain was defined as a discomfort or ache that did not interfere with recreational, occupational, or daily activity. Moderate pain was discomfort that imposed some restriction or difficulties with recreational activities such as sport, but did not interfere with occupational or daily activity. Severe pain restricted at least some core occupational duties, or interfered significantly with basic activities of daily life such as showering, changing or walking. A score between 0 and 10 was generated from the combination of frequency and impact, where a higher score reflected more-significant pain.

Patients in whom a bilateral TEP had been performed were additionally asked to indicate which side, if any, felt more comfortable overall.

Physical examination was then performed to detect any areas of groin tenderness, altered sensation, or hernia recurrence. It was a requirement of the trial protocol that any clinically suspected hernia recurrences were confirmed

by laparoscopy to differentiate true recurrences from persistent haematomas or cord lipomas. Where the clinical impression was more equivocal, ultrasound was performed prior to reoperation.

#### Data and statistical analysis

All data was recorded prospectively on a dedicated database (Microsoft Excel, Office 2004 Microsoft Corporation, Washington, USA). Statistical analysis was performed using StatsDirect statistical software [15].

#### Results

Five hundred hernia repairs in 360 patients were enrolled into the trial between December 2004 and February 2006. Patients had a mean age of 59.5 years (range 18–91 years) and 92% were male. Both the mesh fixation and unfixed groups were well matched for age, sex, level of private insurance, type of hernia, size of defect, and incidence of bilateral and recurrent defects (Table 2). The randomized protocol was followed for all hernia repairs entered into the trial, and patient/observer blinding was not knowingly broken at any time.

Eighty-six percent of patients returned for clinical follow-up at a mean of 8.2 months following surgery (range 6–13 months)

There was no difference between the two groups for duration of surgery, intraoperative complications, postoperative morbidity, or duration/participation during follow-up (Table 2).

#### Pain

A new groin pain (all severities) that persisted beyond the initial postoperative period was reported by 38 versus 23%

**Table 2** Group characteristics

		Group 1 tack fixation	Group 2 no fixation
Demographics	Age	59.3 yrs	59.6 yrs
	Private insurance	48%	48%
Presentation	Bilateral	33%	33%
	Incarcerated	6%	6%
Hernia type (Nyhus)	Indirect (type 2)	53%	52%
	Direct (type 3a)	24%	25%
	Mixed (type 3b)	9%	9%
	Femoral (type 3c)	4%	4%
	Recurrent (type 4)	10%	10%
Defect size	<1 cm	27%	26%
	1–2 cm	50%	49%
	>2 cm	23%	25%
Duration of surgery	Mean	27 mins	26.8 mins
	Range	11–83 mins	12–74 mins
Morbidity		11.3%	10.8%
Follow-up attendance		85.5%	86.1%

for herniae repaired with fixation versus nonfixation, respectively ( $p = 0.0003$ ). This pain was reportedly felt at least once per week in 22% of patients in the fixation group versus 15% in the nonfixation group ( $p = 0.049$ ), and experienced several times per week in 16% with fixation compared to 8% without fixation ( $p = 0.009$ ). Pain that was moderate or severe (interfering with leisure or occupational activities) was experienced by 2% of fixated repairs, but not reported by any patient with unfixated mesh ( $p = 0.06$ ) (Table 3).

### Bilateral repairs

One-hundred and twenty patients had bilateral TEP repairs (33%). Eighty-four of these patients had fixation on one side and not the other (following individual randomization of each side). Patients of this subgroup were five times more likely to nominate the nonfixation side as being more comfortable (47 versus 9%,  $p = 0.006$ ).

**Table 3** Incidence of new and persistent groin pain

	Fixation	No fixation	<i>p</i> value
Any new pain	38%	23%	0.0003
Pain score $\geq 2$	22%	15%	0.049
$\geq 3$	16%	8%	0.009
$\geq 4$	2%	Nil	0.06

**Table 4** Pain incidence and number of tacks used

Number of tacks	Proportion	Percentage	<i>p</i> value
$\leq 6$	17/78	22%	0.008
7–10	56/141	40%	0.315
$\geq 11$	14/28	50%	

### Pain and number of fixation tacks

An association was also found between the number of fixation tacks used and the incidence of pain. This association reached statistical significance when more than six tacks were used ( $p = 0.008$ , Table 4).

### Hernia recurrence

One recurrence has thus far been detected after six months (0.2%). This was confirmed by laparoscopy to be a lateral recurrence associated with infolded mesh in a patient in the mesh fixation group, and re-repaired using a laparoscopic transabdominal approach (a 2 cm indirect defect had been repaired with mesh fixated by eight tacks). No recurrent hernias have yet been observed in the nonfixation group.

### Cost

The cost of disposable materials and equipment was approximately 375 AUD less per patient in the nonfixation group. This saving was attributable to the cost of the disposable titanium tack applicator [16].

### Discussion

Many surgeons who perform TEP appear to hold the unproven belief that mesh fixation is necessary for the prevention of hernia recurrence. At the same time it is widely acknowledged that this need for surgical fixation is only temporary, as tissue incorporation into the mesh, characterized by significant cellular ingrowth by two weeks and collagen deposition within two months, achieves effective permanent fixation [17].

It was not the intention of the present study to investigate the long-term recurrence rate of TEP; this has been previously determined to be approximately 1% after five years [3]. Rather, it was to test the hypothesis that, without fixation, the mesh might move or fold before tissue ingrowth has had an opportunity to occur, and lead to recurrence by the uncovering of hernial defects. Recurrence by this mechanism would be expected to be an early

phenomenon, and hence the rationale for the first wave of trial follow-up after six postoperative months. This cohort of patients will continue to be followed, with performance of the two groups after two years available in 2008.

It is perhaps underappreciated that mesh stabilization may occur intrinsically due to the preperitoneal location of the mesh in TEP. Evidence for this exists. Choy et al. found that unfixed mesh could not be induced to move (confirmed on inspection of the mesh by re-laparoscopy of the preperitoneal space) by on-table cycles of hip flexion [18]. This inherent stability was further confirmed by Irving et al. through postoperative X-ray studies [19]. Mesh stabilization may occur through a sandwich effect between the intact peritoneal layer and the body wall, maintaining mesh position by even application of abdominal pressure. Limiting the extent of the preperitoneal dissection may act to further discourage any lateral mesh migration.

Indeed some pioneers in the development of preperitoneal hernia repair including Stoppa and Ferzli advocate that fixation of preperitoneal mesh may be unnecessary [20, 21]. In their view the more important components of a successful long-term repair are adequate dissection (featured by thorough exposure of all potential areas of weakness and parietalization of the cord structures) and avoidance of mesh that is too small.

In clinical experience, more than 6,500 TEP repairs without mesh fixation have now been reported [21, 22, 23, 24, 25, 26, 27, 28]. The mean recurrence rate in these series is less than 1% after two years, comparable with the published recurrence rate of standard repairs involving mesh fixation. Prior to the current trial, two other randomized prospective trials had been conducted attempting to address the need for mesh fixation in TEP [21, 27]. Both trials concluded that mesh fixation was unnecessary and added cost. However, both studies were underpowered with small patient numbers (100 and 170 patients) rendering it difficult to detect anything other than very large differences in recurrence, and also dealt rather lightly with the assessment of chronic groin pain. The current study has attempted to overcome these limitations through larger sample size, clinical follow-up, and detailed pain assessment.

A note of caution is warranted in interpreting the results of this trial. It must be appreciated that the majority of hernial defects (74%) were smaller than 2 cm. Whilst the results suggest that fixation for small defects is unnecessary (provided a 10 × 15 cm mesh is used), the question of whether larger defects (for instance, defects in excess of 4 cm) can be safely repaired without mesh fixation has not yet been adequately answered.

Whilst differences in pain incidence did reach statistical significance, for the overwhelming majority of patients the new groin pain was mild and caused little or no interference with daily life even when tacks were used. Indeed

nearly two-thirds of those with tack fixation reported no persisting groin discomfort whatsoever, even when pushed by direct questioning. Based on this, it would be unreasonable to draw the conclusion that tack fixation was associated with an unacceptable risk of significant pain. More accurately, it is probably more unnecessary than harmful in most cases, but could be associated with significant pain in a small percentage of patients. Fixation may still be appropriate in selected patients where the mesh did not sit well or displayed a tendency to fold, particularly in the sharply angled narrow pelvis. Limiting the number of tacks in such situations appears to reduce the risk of pain.

Finally, use of the popular single-use titanium spiral tack applicator is costly, adding at least 375 AUD to the cost of laparoscopic hernia repair [16]. The higher cost of laparoscopic hernia repair compared with open techniques has been a source of criticism by some surgeons, and has impeded its introduction into many public teaching hospitals in Australia and overseas.

## Conclusion

Mesh fixation appears to be unnecessary in TEP repair of small hernial defects. It is associated with higher operative costs and an increased likelihood of developing chronic groin pain. The omission of mesh fixation did not increase the risk of early hernia recurrence.

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