

# Staple versus fibrin glue fixation in laparoscopic total extraperitoneal repair of inguinal hernia: a systematic review and meta-analysis

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## Abstract

**Background** Fixation of mesh is typically performed to minimize risk of recurrence in laparoscopic inguinal hernia repair. Mesh fixation with staples has been implicated as a cause of chronic inguinal pain. Our study aim is to compare mesh fixation using a fibrin sealant versus staple fixation in laparoscopic inguinal hernia and compare outcomes for hernia recurrence and chronic inguinal pain.

**Methods and procedures** PubMed was searched through December 2010 by use of specific search terms. Inclusion criteria were laparoscopic total extraperitoneal repair inguinal hernia repair, and comparison of both mesh fibrin glue fixation and mesh staple fixation. Primary outcomes were inguinal hernia recurrence and chronic inguinal pain. Secondary outcomes were operative time, seroma formation, hospital stay, and time to return to normal activity. Pooled odds ratios (OR) were calculated assuming random-effects models.

**Results** Four studies were included in the review. A total of 662 repairs were included, of which 394 were mesh fixed by staples or tacks, versus 268 with mesh fixed by fibrin glue. There was no difference in inguinal hernia

recurrence with fixation of mesh by staples/tacks versus fibrin glue [OR 2.13; 95% confidence interval (CI) 0.60–7.63]. Chronic inguinal pain (at 3 months) incidence was significantly higher with staple/tack fixation (OR 3.25; 95% CI 1.62–6.49). There was no significant difference in operative time, seroma formation, hospital stay, or time to return to normal activities.

**Conclusions** The meta-analysis does not show an advantage of staple fixation of mesh over fibrin glue fixation in laparoscopic total extraperitoneal inguinal hernia repair. Because fibrin glue mesh fixation with laparoscopic inguinal hernia repair achieves similar hernia recurrence rates compared with staple/tack fixation, but decreased incidence of chronic inguinal pain, it may be the preferred technique.

**Keywords** Laparoscopic · Total extraperitoneal · Inguinal hernia · Staple · Fibrin glue · Mesh fixation

Laparoscopic inguinal hernia repair, whether by transabdominal (TAPP) or total extraperitoneal approach (TEP), has been available as an alternative to open repair since the early 1990s. The laparoscopic approach offers the advantages of lesser postoperative pain and earlier return to normal activity. However, even though the laparoscopic repair significantly reduces postoperative chronic pain [11, 16], the problem is still reported in about 22.5% of patients [11]. This pain has been attributed to nerve entrapment syndromes and osteitis pubis due to the mechanical fixation of the mesh, be it by suturing or stapling [2, 8, 27, 32, 35]. This led to the concept of total abandonment of any kind of fixation [9, 19, 31, 37]. However, although data exist about equal efficacy of this approach [2, 33, 38], it remains a controversial topic. Concerns about mesh folding or

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displacement, and hence a higher chance of hernia recurrence, remain. This concern led to the emergence of atraumatic mesh fixation, using tissue glues.

Helbling and Schlumpf reported the use of cyanoacrylate glue in open sutureless Lichtenstein repair in 1993 [10], and the first attempt at using cyanoacrylate glue in laparoscopic hernia repair for mesh fixation was described by Jourdan and Bailey [13] in 1998. However, concerns about its cytotoxicity [24] and physical characteristics, such as quick hardening and indiscriminate binding to body surfaces and instruments, precluded its success.

Fibrin glue has emerged as a very effective alternative to cyanoacrylate glue for atraumatic mesh fixation, with its efficacy, tolerability, and lack of adverse effects already proved in various other procedures [4]. Fibrin is a coagulation cascade protein with adhesive properties. When applied to tissue surfaces, fibrinolysis occurs and the glue is substituted by fibrotic tissue, facilitating repair. Katkhouda et al. [15] in 2001 used fibrin glue from human origin (Tisseel) for TEP repair in an animal model, which paved the way for its use in humans. However, its efficacy in comparison with staples in laparoscopic inguinal hernia is a matter of debate, and data regarding its benefit in laparoscopic TEP inguinal hernia are sparse.

We aimed to carry out a meta-analysis comparing mesh fixation using a fibrin sealant, versus staple fixation, in laparoscopic TEP repair of inguinal hernia and to address whether it affords an advantage over traditional mechanical stapling in terms of recurrence, chronic pain, or any other outcomes.

## Materials and methods

### Search strategy

The PubMed database was searched through December 2010. The search string was: inguinal AND (hernia OR hernioplasty) AND (laparoscopic OR endoscopic) AND mesh AND (fibrin glue OR Tisseel OR Tissucol). No language restrictions were applied. The electronic search was supplemented by a manual search of reference lists in the articles and the “related articles” function in PubMed, revealing no additional studies.

### Inclusion and exclusion criteria

A total of 30 studies were found and individually scrutinized by the two authors (AK and SH) to determine eligibility for inclusion in the meta-analysis. Studies in which the inguinal hernia repair was done by laparoscopic TEP approach, with traditional mechanical mesh fixation compared with glue fixation, were included. Studies where the

hernia repair was done by traditional “open approach,” laparoscopic transabdominal preperitoneal (TAPP) approach, case reports and reviews, or involving animals, were excluded. We specifically excluded TAPP repair because we did not want to confound the results due to the requirement of additional tacks/sutures to reperitonealize the dissected extraperitoneal space. A total of four studies were finally included in the meta-analysis.

### Outcomes

The primary outcomes of interest for the meta-analysis were recurrence and chronic pain. Chronic groin pain was defined as pain persisting at 3 months to 1 year after operation. Secondary outcome measures were operative time, seroma formation, postoperative pain, length of hospital stay, days to resume normal outdoor activities and work, wound infection, and cost. Operative time was defined as time from skin incision to placement of the last suture. Seroma was defined as clinical presence of palpable fluid collection over the groin in the absence of bruising during follow-up. Length of hospital stay refers to the total number of nights spent in hospital after operation.

### Quality assessment

The methodological quality of the included studies was evaluated according to the published guideline of the Scottish Intercollegiate Guidelines Network (SIGN) and Rangel et al. [23, 28]. The included studies scored from 10 to 13, indicating fair quality of each study (Table 1). Consequently, the methodological quality of the studies was considered inadequate and the results of our review may be considered biased.

### Statistical analysis

Pooled odds ratio (OR) were calculated using a DerSimonian and Laird random-effects model for categorical outcomes (recurrence, chronic pain, and seroma). Odds ratios represent the odds of an adverse event occurring in the staple fixation group compared with the fibrin glue fixation group. The higher the OR, the greater the odds of occurrence of the event in the stapled group. A value of one indicates that the odds of occurrence of the event were equal in the two groups. The point estimate of the odds ratio was considered to be statistically significant if the 95% confidence interval did not include the value of one. Data for continuous outcomes (operating time, hospital stay, and return to normal activity) were not included in the meta-analysis, because standard deviations or standard errors of the mean were not reported or could not be calculated. Statistical heterogeneity, the variation in outcomes

**Table 1** Methodological quality of included studies, adapted from the Scottish Intercollegiate Guidelines Network [23] and Rangel et al. [28]

Quality variable	Schwab et al.	Novik et al.	Topart et al.	Lau et al.
Inclusion criteria	0	0	0	1
Exclusion criteria	0	0	0	0
Demographics comparable?	1	1	1	1
Can the number of participating centers be determined?	1	1	1	1
Can the number of surgeons who participated be determined?	1	1	1	1
Can the reader determine where the authors are on the learning curve for the reported procedure?	0	0	0	0
Are diagnostic criteria clearly stated for clinical outcomes if required?	0	0	0	1
Is the surgical technique adequately described?	1	1	1	1
Is there any way that they have tried to standardize the operative procedure?	1	1	1	1
Is there any way that they have tried to standardize perioperative care?	1	1	1	1
Are the age and range given for patients in the stapled group?	1	1	1	1
Do authors address whether there are any missing data?	0	0	0	0
Are the age and range given for patients in the fibrin glue group?	1	1	1	1
Were patients in each group treated along similar timelines?	0	1	0	1
Did all the patients asked to enter the study take part?	1	1	1	1
Dropout rates stated?	0	1	1	0
Outcomes clearly defined?	1	1	1	1
Blind assessors?	0	0	0	0
Standardized assessment tools?	0	0	0	0
Analysis by intention to treat?	0	0	0	0
Score	10	12	11	13

Total 21; less than 8, poor quality; 8–14, fair quality; 15 or more, good quality

between studies, was assessed using the chi-squared distributed  $Q$ -statistic. The analysis was conducted using MetaAnalyst, beta 3.1 software [36] for Windows.

## Results

Figure 1 shows the flowchart of the selection of studies. Out of the 30 studies, four were found to be eligible for inclusion in the meta-analysis. One of these papers was a randomized clinical trial (RCT), two were retrospective studies, and one was a prospective study. The three observational studies [25, 30, 34] were meta-analyzed together, while the one RCT [18] was compared with the meta-analysis. A total of 662 repairs in 367 patients were analyzed, of which 394 hernias were fixed with staples/tacks and 268 fixed with fibrin glue. Lau's study [18] included only bilateral hernias. Schwab's study [30] included primary hernias only, and the two other studies [25, 34] included primary as well as recurrent hernias. Two studies [25, 30] had no female patients, while the other two studies [18, 34] had predominantly male patients. Tables 2 and 3 provide a tabular description of the characteristics of the included studies.

All the included studies used a flat sheet of mesh, except one [25] in which mesh was split from the cranial edge down to the center of the mesh, with a hole in the center for passage of spermatic vessels in one of the included studies. None of the studies documented how close to the deep ring the tacks were placed.

### Primary outcome measures

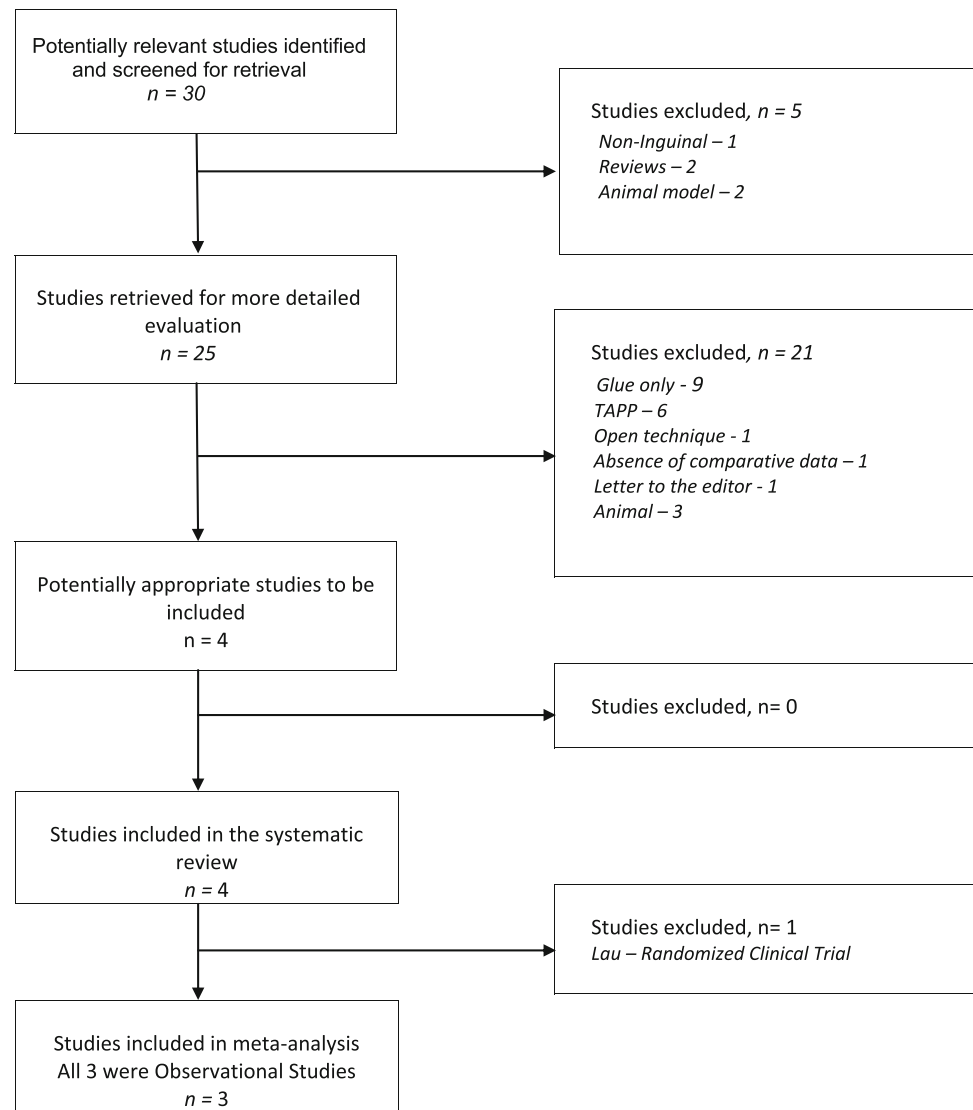
#### Recurrence

All three papers reported hernia recurrence after surgery [25, 30, 34]. There was no significant difference in terms of recurrence after surgery between the staple fixed and glue fixed mesh groups [OR 1.609; 95% confidence interval (CI) 0.403–6.42]. Lau's study [18] did not have any recurrence in either of the groups (Fig. 2).

#### Chronic groin pain

The outcome of chronic pain (3 months postoperatively) was reported by all three observational studies [25, 30, 34], but only two could be included in the analysis [30, 34]. The third study [25] reported the chronic pain in varying degrees and

**Fig. 1** Flowchart showing study methodology. TAPP trans abdominal pre peritoneal



hence could not be meta-analyzed with the other two, and the effect on chronic pain due to the mesh split in this study could also not be ascertained. The staple fixed mesh group had significantly higher incidence of chronic pain as compared with the glue fixed mesh group (OR 4.509; CI 1.932–10.522). Novik et al. [25] reported a greater number of patients with absent chronic pain in the glue fixed mesh repair group compared with the staple fixed group (77.8 and 64.58%, respectively). The staple fixed group had 3–11.5% incidence of mild to moderate degree of chronic pain, while none of the patients in the glue fixed group had that degree of chronic pain. Schwab et al. [30] reported that none of their patients with chronic postoperative pain required reoperation, but 56% of their staple group patients required local anesthetic infiltrations, as compared with none in the fibrin glue group. Lau et al. [18] reported higher incidence of chronic groin pain (1 year postoperatively) in the staple group compared with the fibrin glue group (20 vs. 13.2%,

respectively) (Fig. 3). Chronic pain was not specifically attributed to any named nerve in the included studies. No details about the chronic pain were given except the mention of chronic inguinal pain postoperatively, duration as per the definition they were following.

#### *Subgroup analysis of analgesic requirement in the immediate postoperative period*

Only one study [18] made a note of this, reporting much lower analgesic requirement in the fibrin glue group than the staple group. They reported that the total number of analgesic tablets consumed by the fibrin glue group was significantly less than that of the staple group [4.5 (2–10) tablets vs. 7 (4–10) tablets, respectively]. Also, the absolute number of patients who did not require any analgesia after returning home was higher in the fibrin glue group, being 9 versus 8 in the staple group, but that was not statistically significant.

**Table 2** Characteristics of the studies and the patients included in the analysis

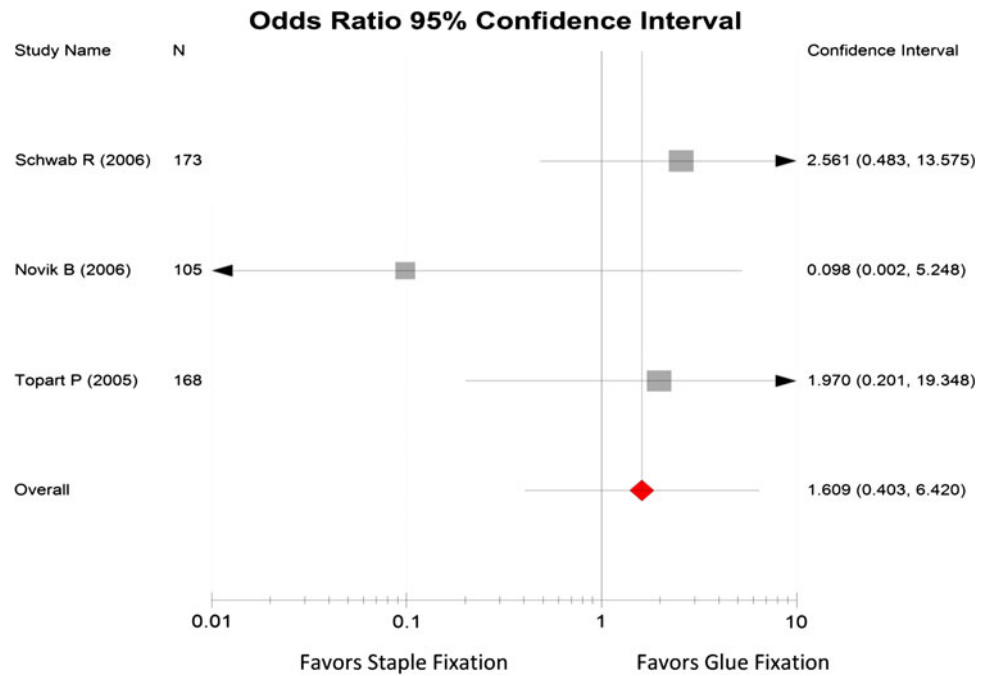
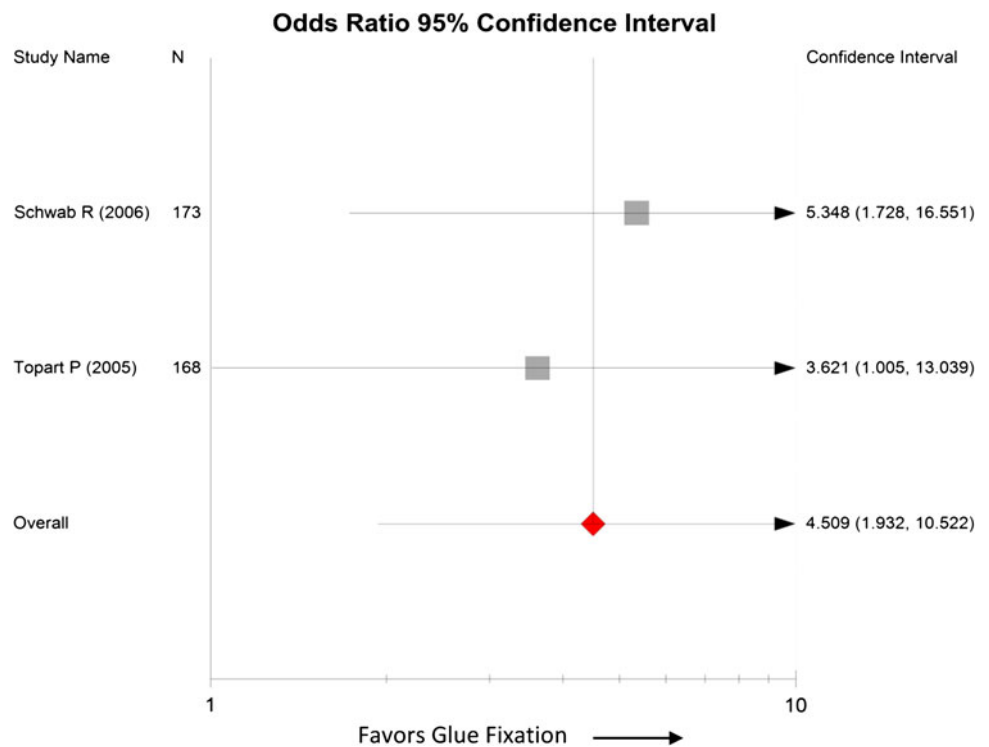
Study	Study type	Recruitment periods for the two groups		Total number		Mean age (years)		Sex (M/F)		Follow-up period (months)		Country
		GFx	SFx	Patients	Repair	SFx	GFx	SFx	GFx	SFx	GFx	
Schwab (2006)	Retrospective case-control study	2002–2004		125	173	57	54.7	125/0	17–47	11–21	Germany	
Novik (2006)	Prospective cohort	Dec 2000	Aug 2000 to May 2001	74	105	58	61	68/0	6/0	7–43	Sweden	
Topart (2005)	Retrospective cohort	Jan 2001–July 2003	Jan 1997 to Dec 1999	168	198	55.8	55.6	86/16	64/2	28.3 ± 10.9	23.9 ± 11.3	France
Lau (2005)	Randomized prospective clinical trial	July 2002–Feb 2004		93	186	66	64	47/0	45/1	8–27	China	

GFx glue fixed; SFx staple/tack fixed

**Table 3** Characteristics of the hernia repairs in the included studies

Study	Repairs, <i>n</i>		Type of hernia				Mechanical fixation				Glue fixation		Mesh	
			Unilateral		Bilateral		Recurrent							
	SFx	GFx	SFx	GFx	SFx	GFx	SFx	GFx	SFx	GFx	SFx	GFx	Type	Size (cm)
Schwab et al. (2006)	87	86	77	48	48	Excluded	4	Titanium tacks (AutoSuture, ProTack 5 mm, Tyco Healthcare)	1	ml Tisseel for unilateral repairs, 5 ml for bilateral repairs; Duplotip 6 laparoscopic applicator, Baxter	10 × 15	Polypropylene		
Novik et al. (2006)	96	9	40	3	28	3	11	1	5–6	Spiral tacks (ProTack, Tyco/AutoSuture)	10 × 15	Polypropylene		
Topart et al. (2005)	117	81	87	51	15	15	7	2–3	Tacks; 5-mm Tacker, US Surgical Corp.	2	ml Tisseel for unilateral repairs, 5 ml for bilateral repairs; Duplotip 6 laparoscopic applicator	10 × 15	Polyester	
Lau et al. (2005)	94	92	0	0	47	46	9	5	Endoscopic Stapler (EMS Hernia Stapler, Ethicon Ltd.)	2	ml Tisseel VH, Baxter; Duplocath 35 MIC, Baxter; laparoscopic applicator	10 × 15	Polypropylene	

GFx glue fixed; SFx staple/tack fixed

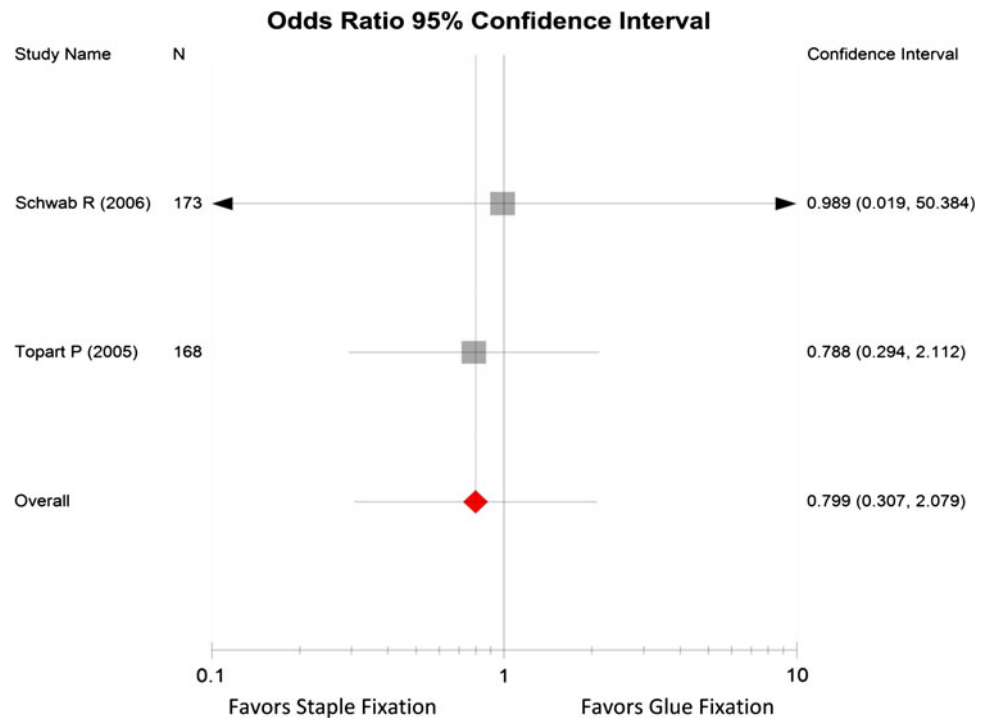
**Fig. 2** Pooled odds ratio for recurrence**Fig. 3** Pooled odds ratio for chronic pain

### Secondary outcome measures

#### Operating time

Three studies reported operating times. Novik et al. [25] reported equal operating times of 33 min for both the glue and staple fixed groups when compared per groin, but longer

operating time for the glue fixed group when compared per person, being 49 and 39 min, respectively. Lau et al. [18] reported nearly equal mean operating times for bilateral hernias in the two groups, being 75 and 76 min, respectively. Topart et al. [34] reported operating time for the glue fixed group only, with a mean of 54 min. The operating time for the stapled group was not reported in the study.

**Fig. 4** Pooled odds ratio for seroma

### Seroma formation

Two studies reported on seroma formation [18, 34]. Pooled analysis did not show a statistically significant difference in incidence of seroma formation between the staple and the fibrin glue groups (OR 0.799; 95% CI 0.307–2.079). Lau et al. [18] found significantly higher incidence of seroma in the fibrin group compared with the staple group (17.4 vs. 5.3%, respectively). Topart et al. [34] noted higher incidence of seroma and less hematoma in the fibrin glue group as compared with the staple group, which was not statistically significant (Fig. 4). Higher rates of seroma were attributed to more intense inflammatory reaction incited by the fibrin glue, which possibly increases exudation and hence seroma formation.

### Wound infection

Two studies reported this outcome [18, 30], finding no difference in its incidence between the staple or fibrin glue group.

### Hospital stay

Three studies reported hospital stay. Two studies [18, 30] noted no difference between the staple or fibrin glue groups, but the third study reported a relatively longer hospital stay in the staple group [34] of 1.9 days compared with  $1.5 \pm 1.7$  days in the fibrin glue group.

### Time to return to normal activity

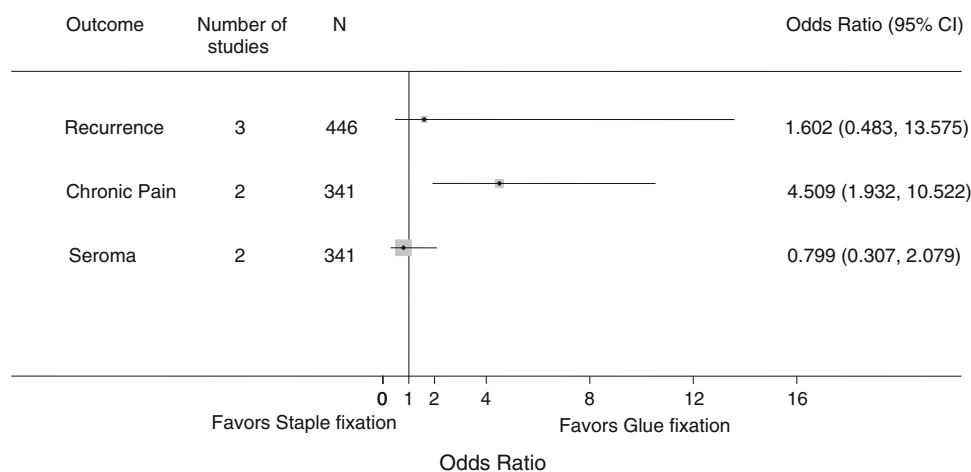
Only one of the included studies [18] reported time to return to normal activity, finding comparable results between the fibrin glue and the staple group. Novik et al. [34] gave information about return to normal activity for the fibrin glue group only, with no comparative information given.

### Cost

Two studies looked into the cost difference, comparing the two modes of fixation [18, 25]. Novik et al. [25] found a marginal difference in cost between the two groups in unilateral repairs, with glue fixation in bilateral repairs costing US \$100 more than staple/tack fixation. Lau et al. [18] reported the cost of fibrin glue fixation to be more than double that of staple fixation. Glue fixation costed a total of US \$270 (including the Duplocath applicator), while staple fixation cost US \$130, with the other expenses in both types of fixation being equal. Cost of treatment of chronic pain was not documented by any of the included studies.

### Discussion

The results of our analysis indicate that fixation of mesh using fibrin glue is equivalent to staple fixation in terms of hernia recurrence in laparoscopic total extraperitoneal

**Fig. 5** Summary pooled analysis

(TEP) repair of inguinal hernia. Fibrin glue mesh fixation also proved better in terms of incidence of chronic pain after surgery compared with staple fixation. There was no significant difference in operating time, seroma, or hospital stay between the two groups (Fig. 5).

Postoperative groin pain can be neurogenic due to direct nerve entrapment by a staple/suture or involvement in perineural fibrosis. It can also be nonneurogenic due to periosteal response to trauma by sutures/staples, or excessive scarring from repeated hernia surgery [3, 5, 14, 15, 18, 20, 26, 34]. The placement of the staple/tack is critical to avoid neurogenic impingement in the area. The only thing mentioned in our included studies was that tacks were put on Cooper's ligament, and none lateral to it and below the iliopubic tract. However, to avoid nerve entrapment syndromes, some surgeons purport total nonfixation of the mesh, relying on pure surgical technique and anatomy. Their thought being, if the mesh coverage of the myopectineal orifice is adequate, the mesh will hold itself in place [2, 9, 33, 37, 38]. We, as well as the included papers, acknowledge these studies reporting favorable results with "no fixation" of mesh, but concerns remain regarding certain hernias, such as with large direct defects, hematoma, and inadequate inferomedial and inferolateral mesh fixation, which represent the most common causes of mesh folding and lifting, and hence may lead to recurrence [22]. However, to ensure mesh fixation and at the same time avoid fixation-related neuralgia, use of fibrin glue was proposed.

Fixation of mesh in laparoscopic hernia repair using mechanical devices such as staples, tacks, endoanchor, etc. leads to regional nerve injury, and postoperative groin pain has been well documented [1, 2, 7, 8, 17, 27, 32, 35]. Alternative methods of nontraumatic mesh fixation such as with fibrin glue have shown promising results in terms of both decreased postoperative chronic groin pain as well as

comparable hernia recurrence rates [6, 21, 29]. Our meta-analysis supports these observations, suggesting that use of fibrin glue for mesh fixation in laparoscopic TEP repair of inguinal hernia is an effective alternative to staple fixation.

Due to the paucity of comparative literature on use of fibrin glue or staples for mesh fixation in laparoscopic TEP repair of inguinal hernia, we carried out this meta-analysis to address the issue, being the first on the topic to the best of our knowledge. Additionally, we would definitely have liked to compare glue fixation to no fixation in these repairs, but did not find a direct one-to-one comparison for the two, in one patient cohort, and it would be inappropriate to compare two different such studies. We aimed to compare both staples and tacks (mechanical fixation) versus glue fixation, the concept being that nerve entrapment can occur due to both direct impingement as well as the perineural fibrosis which occurs with both forms of mechanical fixation. However, outcomes may ideally be reported separately for staples and tacks in comparison with glue when the literature is sufficiently populated with studies making such comparisons.

Our meta-analysis included three observational studies and one randomized clinical trial. Meta-analyses of observational studies have their own unique challenges because of inherent biases and differences in study design [12]. Despite these challenges, meta-analyses of observational studies continue to be one of the few methods for assessing efficacy and effectiveness, and are being published in increasing numbers. Methodological diversity as well as potential biases are sources of weakness in our study. Moreover, there are other variabilities which add to these biases. The follow-up periods for the two compared groups were different in three of the four selected studies [25, 30, 34], and on the whole the period of follow-up was short to opine definitively regarding recurrence numbers. The definition of chronic pain as persistent groin pain after



postoperative periods ranging from 3 months to 1 year [18] is an important limitation of our study. Hernia size was not mentioned, but could have an important bearing on the observed hernia recurrence. One study [34] compared groups from two different time periods, reflecting the shift in practice of the group from staple fixation to glue fixation only, whenever fixation was required. There is a potential surgeon experience bias also, whereby the same surgeon's experience with this advanced laparoscopic technique over time may impact on differences in patient outcomes. No information was provided in the included studies about surgeon experience in terms of number of cases, or their status with respect to the learning curve, though one study [25] documents the “senior author” to be in charge of the surgical procedures. The amount of fibrin glue used in the glue fixation group also varied among the studies, which could alter the results. One of the studies [34] used a different type of mesh than the other three, which may have an effect on outcomes. The variation in the types of hernia in the included studies as well as the gender distribution adds to the inhomogeneity of the compared groups.

The cost difference between the two groups would be one of the main factors driving the decision regarding choice of fixation. There are studies reporting that fibrin glue fixation is less expensive than staple fixation [21]. The studies included in our analysis had mixed reports, from no difference in costs [25] to fibrin glue usage costing about double that of staple fixation [18]. An explanation of these cost differences may lie in the amount of fibrin glue used in the procedure, which varied a great deal. Operating time differences between the two groups is an important aspect to look into. Some studies suggest that fibrin glue (FG) mesh fixation takes about 10–15 min longer than staple fixation [6, 21] in laparoscopic TAPP repair of inguinal hernia, but another reported 15 min less for the FG group. We could not analyze the operative times in our analysis because of baseline difference in study design, but individually two studies [18, 25] found no significant difference in operating time between the two groups. We do tack the mesh in TEP repair at our institution, but based on the results of this study, there may be a shift in our current practice.

#### Deficiencies in the relevant literature

Our study revealed some deficiencies in the existing literature on this topic, which could pave the way for future studies. We need more prospective randomized trials on the subject, preferably controlled for age and sex. Whether use of different volumes of fibrin glue results in any difference in terms of long-term recurrence needs to be addressed. None of the studies included in our analysis used the absorbable tacker, and also we did not find any published

study comparing the absorbable tacker with other nonabsorbable fixation devices.

## Conclusions

Meta-analysis of laparoscopic inguinal hernia mesh fixation technique comparing fibrin sealant versus staple or tack fixation finds both effective with no difference when measuring inguinal hernia recurrence rates. When postoperative groin pain is compared, however, meta-analysis favors mesh fixation with fibrin glue, with lower incidence of chronic groin pain. Because fibrin glue mesh fixation with laparoscopic inguinal hernia repair achieves similar hernia recurrence rates compared with staple/tack fixation, but decreased incidence of chronic inguinal pain, it may be the preferred technique.

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