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SURGICAL ENDOSCOPY
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Tisseel vs tack staples as mesh fixation in totally extraperitoneal laparoscopic repair of groin hernias

A retrospective analysis

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Abstract
Background: The laparoscopic repair of groin hernias generally involves mesh fixation to avoid displacement and recurrence. Fixation usually uses staples that can lead to nerve injury and chronic postoperative pain. Laparoscopic repairs are associated with a risk of chronic pain of up to 22.5%. The use of fibrin glue (Tisseel) may represent an alternative method of mesh fixation preventing the risk of nerve injury.
Methods: Sixty-six patients had groin hernia repair using a totally extraperitoneal (TEP) laparoscopic procedure. Mesh fixation was achieved using 2 ml of fibrin glue. Comparison was made with an earlier series of 102 patients operated on according to the same procedure in which mesh fixation used tack staples. Complications, length of stay, recurrence, and postoperative chronic pain were assessed.
Results: No difference was found between the two series, except there was a significantly higher rate of postoperative chronic pain in the staples series (14.7 vs 4.5%, $p = 0.037$) and there was one recurrence (1.5%) in the fibrin glue group of patients.
Conclusions: Fibrin glue achieved an adequate mesh fixation with a lower incidence of chronic postoperative pain. Although a prospective randomized study is needed, Tisseel appears to be an alternative to staples for mesh fixation and may help reduce the postoperative pain problems after hernia repair.

Key words: Inguinal hernia — TEP repair — Chronic pain — Fibrin glue

Laparoscopic hernia repair under its two forms, transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP), is an effective technique of groin hernia repair with recurrence rates comparable to those of open mesh techniques [6]. Although some data suggest that mesh fixation is unnecessary in laparoscopic repair [1, 19, 20] preserving satisfactory long-term results, stapling of the mesh to avoid displacement and reduce the risk of recurrence prevails among surgeons. The chronic pain that may persist in the groin area postoperatively is one of the most serious problems that may affect the results of hernia surgery [3]. Postoperative chronic pain is defined as pain persisting more than 3 months after the operation [5, 9]. Overall, the prevalence of chronic postoperative pain after hernia surgery ranges from 3% [10] to 54% [15]. Although laparoscopic repair appears to be significantly less likely to induce postoperative chronic pain [8, 12], this type of complication is still reported up to 22.5% of patients [8]. Stapling of the mesh, which may lead to nerve injury and osteitis pubis, has been identified as one of the possible causes of the persistence or development of pain after hernia surgery [1, 15].

Apart from avoiding any mesh fixation, the alternative is to use atraumatic fixation by means such as glues. The first attempt at polypropylene mesh fixation in laparoscopic hernia repair was described by Jourdan and Bailey [10] in 1998 using a cyanoacrylate glue. Recently, Katkhouda et al. [11] proposed the use of a fibrin glue from human origin (Tisseel) for mesh fixation in TEP repair in an animal model. Tisseel fibrin glue is a combination of human deactivated fibrinogen, factor XIII, and thrombin. It is a biodegradable adhesive reproducing the last step of the coagulation process that leads to the formation of a stable fibrin clot. Among the properties of Tisseel are its adhesivity and hemostatic action as well as promotion of wound healing [17]. Tisseel has had Food and Drug Administration approval for clinical use since 1998 and is available commercially worldwide along with various application devices from the same manufacturer (Baxter Healthcare, Hyland Immuno Division, Deerfield, IL, USA).

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Table 1. Characteristics of the fibrin glue patients

	No. of patients (%)
Unilateral	51 (77.2)
Right	31 (46.9)
Left	20 (30.3)
Bilateral	15 (22.7)
Indirect	46 (69.7)
Direct	16 (24.2)
Combined	4 (6)
Recurrent	7 (10.6)
Total	66

Materials and methods

From January 2001 to July 2003, 66 patients were treated for groin hernia using a standard laparoscopic (TEP) procedure. The two women and 64 men were aged 55.6 ± 17 years. They presented with unilateral ($n = 51$) or bilateral ($n = 15$) groin hernias. Seven patients (10.6%) had a recurrent hernia after open repair (mesh or herniorraphy) (Table 1). All procedures were elective and only one surgeon was involved.

The standard TEP procedure was routinely performed under general anesthesia with a single-dose antibiotic prophylaxis of cephalosporin. A 2- or 3-cm transverse incision was made approximately 3 cm below the umbilicus, and the anterior rectus major fascia was opened transversely for 2 cm on the right side. After blunt dissection of the preperitoneal space behind the right rectus major muscle, a lubricated dissection ballon was inserted down to the pubis, where it was inflated. After removal, the balloon was replaced by a 10-mm blunt-port balloon seal trocar with carbon dioxide preperitoneal insufflation to 11 mmHg. Under direct vision (0° laparoscope), one 5-mm port was inserted on the rnidline midway between the umbilicus port and the pubis. After dissection of the inguinal area, a second 5-mm was inserted on the side of the hernia medially from the anterosuperior iliac spine. While the hernia sac was reduced, 2 ml of Tisseel was prepared by the operating room nurse and circulator (5 ml in case of bilateral hernia) and the dual syringe was connected to the Duplotip 6 laparoscopic applicator. Once the hernia-sac was reduced and the peritoneum freed from the spermatic cord and vessels, a 10 × 15-cm coated polyester mesh (A2 mesh, Cousin Biotech, Wervicq Sud, France) was inserted through the umbilical trocar. After correct positioning of the mesh with the medial edge lying on the middle of the pubis, the fibrin glue was applied on several locations in between the mesh and the abdominal wall (Fig. 1). No drainage or urinary catheters were used.

The comparison was made with a series of 102 patients operated on for groin hernia between January 1997 and December 1999 (unpublished data) and involving the same surgeon. There were 16 women and 86 men aged 55.8 ± 15.7 years. Of these, 14.7% presented with a bilateral hernia and in two patients the operation was done as an emergency procedure for a strangulated hernia (Table 2). The same TEP procedure as previously described was used for these patients, except the mesh fixation was done using two or three helicoidal (tack) staples delivered using a 5-mm stapler (Tacker, U.S. Surgical Corp., Norwalk, CT, USA) on the cooper ligament. For both groups, patients who were not eligible for TEP repair or who had a conversion from TEP to open repair were not included. Patients in the fibrin glue group were clinically reviewed at 1 and 6 months postoperatively and at the time of study completion (September 2003) by the surgeon in charge of the surgical procedures (senior author). An update (September 2004) was conducted by phone calls to the patients or their family doctors. Patients in the tack staples series were also reviewed by the same surgeon involved in the surgical procedures with the help of a surgeon in training, although this review was performed earlier (2001). Patients were encouraged to mention any pain or tenderness in the operated groin area following the surgery when examined at regular intervals. In addition, analogue visual scale was used to evaluate pain in the fibrin glue group. Statistical comparison between the two series used the chi-square test (significance $p < 0.05$).

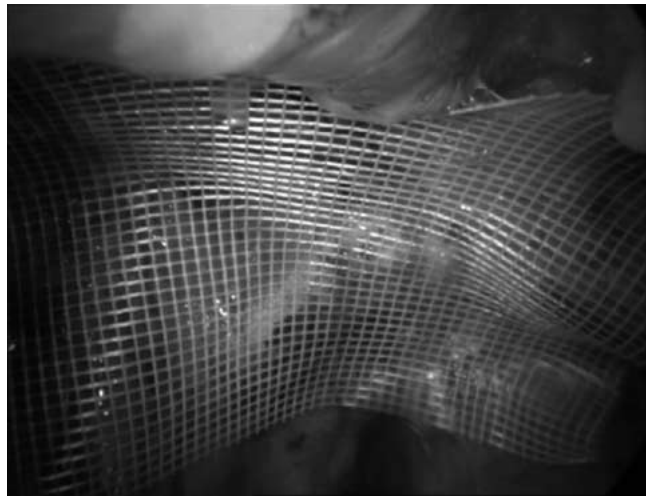

Fig. 1. Appearance of Tisseel on a mesh (left inguinal hernia) secured in position.

Table 2. Characteristics of the tack staples patients

	No. of patients (%)
Unilateral	87 (85.3)
Right	55 (53.9)
Left	32 (31.4)
Bilateral	15 (14.7)
Inguinal	96 (95)
Femoral	5 (5)
Strangulated	2 (1.96)
Recurrent	15 (14.7)
Total	102

Results

Comparison between the two series showed significantly more women in the tack staples group. Also, the percentage of patients operated on for recurrence was higher in the tack staples group (14.7 vs 10.6% in the fibrin glue group), although this was not statistically significant (Tables 1 and 2). Aside from these differences, the two series were comparable and showed no statistical difference with respect to age, type (inguinal or femoral), or side of the hernia.

For the fibrin glue group, the operative time was 54 ± 23 min and no difficulty was encountered during preparation or application of the fibrin sealant. There were no reoperations or postoperative deaths. The postoperative course was uneventful for 53 patients (80.3%). Eight patients (12%) had a seroma, which did not require any dedicated treatment in the majority of cases. Three patients (4.5%) had a hematoma: one patient had to remain on calciparin at the time of the operation, and two patients (3%) had a small bowel obstruction. No fever or inflammation were reported after surgery. Overall, patients were discharged 1.5 ± 1.7 days after the operation.

Two patients were lost to follow-up after the first visit 1 month after surgery; all other patients were

Table 3. Postoperative complications in the tack staples group

Complication	No. (%)
Wound healing problem	1 (0.9)
Pain	12 (11.8)
Hematoma	8 (7.8)
Orchitis	1 (0.9)
Urine retention	1 (0.9)
Seroma	10 (9.7)
Total	27 patients (26.4)

clinically assessed, except for seven who had a follow-up of at least 8 months (two died of unrelated causes and the other five were later lost to follow-up). Overall, the follow-up of the fibrin glue group was 23.9 ± 11.3 months. At the time of the study completion in September 2003, one patient had a recurrence on one side of a bilateral repair (large direct hernia) and three patients (4.5%) with a follow-up of more than 3 months were still complaining of pain in the groin area. No change in the recurrence rate was reported after the follow-up update in September 2004. One more patient died during this 1-year period and 14 patients are now lost to follow-up (half of them had less than 1 year of follow-up).

In the tack staples series, the operation duration was not assessed. There were three patients who had additional procedures, which included ventral hernia repair, hemorroidectomy, and drainage of ascites. Complications are detailed in Table 3 and occured in 26.4% of the patients. Ten patients (9.8%) had a seroma and eight (7.8%) had a hematoma. No major complications or deaths were reported. The length of stay was a mean of 2.3 days (1.9 days when the additional procedures were excluded). The follow-up was 28.3 ± 10.9 months, during which three patients (2.9%) developed a recurrence at a mean of 16.3 months after surgery. When reviewed, 15 patients (14.7%) complained of pain in the groin area more than 3 months after surgery. The postoperative results were compared between the two groups and there was no difference in the overall complication rate. There were slightly more seromas but less hematomas in the fibrin glue group compared to the tack staples group, but this was not statistically significant. However, the postoperative chronic pain rate was significantly reduced in the fibrin glue group ($p = 0.037$).

Discussion

During the past few years, attention has focused on the pain that may arise after groin hernia surgery. Chronic pain after hernia surgery is a complex and controversial problem that affects not only open but also laparoscopic procedures. Three pain syndromes have been identified: somatic, neuropathic, and visceral pain. Besides nerve damage during dissection, thermal injury due to electrocautery, and inflammatory and/or mechanical reaction to the mesh, stapling of the mesh is the most frequent evocated mechanism [1, 12, 15]. Among other potential factors causing postoperative pain is the repair of recurrent hernias. There is a great variation in the rate of postoperative chronic pain, ranging from 0.1% to 0.4% and 22.5% [8, 12, 16] in laparoscopic repairs for which staples are used to attach the mesh. Among the explanations for such a wide discrepancy are the range of pain evaluation methods used, which include clinical examination of the patients, phone calls, and mailed questionnaires and tools to score the severity of the pain. Some studies have reported only cases of pain clinic attendance, possibly underestimating the problem [8]. The rate of chronic postoperative pain we observed in the tack staples group (14.7%) is among the highest reported in the literature [12, 14], but we included all patients who reported even transient or mild pain in the long term.

To date, the series reporting the lowest postoperative chronic pain rates have not used any means of mesh fixation [1, 2, 19]. Tamme et al. [19] and Beattie et al. [1] observed 2.55 and 0% chronic pain problems, respectively, after TEP repair, with a recurrence rate of less than 0.6%. However, the largest of these two series did not specify the length of follow up and the other one was a rather small series ($n = 89$). Although two randomized studies with a short follow up of nonfixed mesh in laparoscopic repairs (one in TEP and the other in TAPP) did show promising results in terms of recurrence [7, 18], justification for routine nonstapling of the mesh in TEP is not yet substantiated [13]. The low rate of chronic pain complications in these reports was similarly observed in our study by avoiding stapling. This confirms that mesh stapling does play a key role in generating postoperative pain after laparoscopic hernia repair.

Although our comparison had a relatively short follow up with a small number of patients and different evaluation periods, the procedures we compared were identical except for the fixation means in two similar groups of patients. In an animal study in which TEP groin hernia repairs were performed, Katkhouda et al. [11] demonstrated that gaft motion and tensile strength were similar in the staples and fibrin glue groups, and both were significantly superior compared to those of the nonfixed mesh group. In addition, histological examinations revealed that the fibrin glue triggered a stronger fibrous reaction and inflammatory response with more fibroblastic mesh ingrowth in comparison to the other two groups. This again suggests that mesh fixation is preferable and that the fibrin glue meets the requirements for both efficiency and security of fixation. This applies particularly to unilateral TEP repairs but more so to bilateral repairs in which the dissected space for the mesh implantation is the same as the working space, making it larger than needed for mesh placement as opposed to the space in which mesh is placed in TAPP repairs. The recurrence rate in the fibrin glue group was slightly lower than in the tack staples group but did not differ significantly, and the case of recurrence reported in the fibrin glue group is probably related to an inadequate mesh size in a large direct hernia. Overall, the recurrence rate in the fibrin glue group remains within the value range of most of the reports on TEP repairs irrespective of mesh fixation [6, 16, 19].

It is not known if the enhanced inflammatory response induced by fibrin glue [11], may explain the slightly higher rate of seromas in the fibrin glue group (12 vs 9.8%). This minor complication is generally associated with direct hernias; however, only three of the eight patients with seromas had been operated on for direct hernia in the fibrin glue group. In addition, we did not report any other complications (fever or local inflammation) that could be related to an enhanced inflammmatory process. Among the explanations for the increased inflammatory reaction in the animal study is the use of human fibrin glue in pigs [11]. There was no significant difference in the development of postoperative hematomas, although the rate was slightly lower in the fibrin glue group, in which one of the three patients with hematoma had be operated on while on calciparin. In this study, it is impossible to attribute the lower risk of hematoma to the effect of Tisseel on local hemostasis [4]. Although no comparison is available between the tack staples group and the fibrin glue group in terms of operation duration, the use of Tisseel and its application device did not seem to change the mean operative tune of 54 min, which is comparable to that of other series using stapling or not [13, 19], as long as the fibrin glue is prepared during the hernia sac dissection. The only difference in terms of operating costs between the two series was in the fixation devices. Two milliliters of Tisseel is available for 149 USD, whereas the single-use Tacker stapler is 287 USD.

In conclusion, there is no evidence in the literature to support nonfixation of the mesh in TEP repair of groin hernias, whereas the use of staples has been identified as one of the factors for postoperative chronic pain. Although prospective randomized trials should be performed Tisseel fibrin glue for mesh fixation is secure as the tack staples, ensuring an adequate fixation and a low recurrence rate. This new method of mesh fixation is obviously potentially less harmful than stapling the mesh and can help reduce the risk of chronic postoperative pain at a comparative or even lower cost than a stapling device.

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