#### **ORIGINAL ARTICLE**



# The effect of mesh fixation on migration and postoperative pain in laparoscopic TEP repair: prospective randomized double-blinded controlled study

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## Abstract

**Purpose** The development of chronic pain is one of the major post-surgery problems after inguinal hernia repair. Although the possibility of chronic pain formation decreases with laparoscopic methods, pain may develop due to the staples used. It is thought that absence of mesh fixation in total extra-peritoneal (TEP) repair does not increase the recurrence rate. This study aims to investigate the absence of mesh fixation in the TEP on the development of postoperative pain, mesh displacement, and recurrence rate.

**Methods** Between December 2019 and December 2020, 100 patients who underwent TEP repair due to unilateral inguinal hernia in the General Surgery Clinic of Hitit University were included in the study. Study was registered at http://Clinicaltrials.gov (NCT05152654). Patients were divided into two groups as repairs in which the mesh was fixed with a tacker and no-fixation (NF) was used. The mesh is marked with radiopaque clips. Patients were compared in terms of postoperative pain, mobilization time, hospital stay, return to work, chronic pain, early–late mesh displacement, and recurrence.

**Results** While there was no significant difference between the groups in terms of mesh displacement and recurrence, it was observed that the NF group developed significantly less pain in the early and late postoperative period compared to the other group. The time-dependent reduction rate of postoperative pain was higher in NF group than in other group. In addition, operation time was shorter in the NF group.

**Conclusion** While the absence of mesh fixation in TEP hernia repair does not increase the recurrence rate, it can be used safely, because it causes less acute and chronic pain.

Trail registration Clinicaltrials number: NCT05152654.

Keywords Chronic pain · Hernia · Fixation · Mesh displacement · No-fixation

# Introduction

Inguinal hernias are one of the most common diseases in general surgery practice. In a multicenter study conducted in Germany, inguinal hernia repair is one of the most common operations [1]. Until the last 20 years, after Lichtenstein described tension-free mesh hernia repair, this method was the gold standard in inguinal hernia surgery [2]. This method

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<sup>1</sup> Faculty of Medicine, Department of Surgery, Hitit University, Çorum, Turkey was advantageous in terms of both less recurrence and less postoperative pain compared to tension methods. With the development of minimally invasive surgery, laparoscopic hernia surgery was first described by Dr. Ger in 1992 [3]. Laparoscopic inguinal hernia repair is based on the principles of preperitoneal repair described by Stoppa in open surgery. Its advantages over open surgery are; Less postoperative pain, rapid recovery, reduction in nerve damage and chronic pain, and reduced recurrence rate [4-6]. However, the disadvantage is that the learning curve is longer and higher cost [7]. Two commonly used laparoscopic inguinal hernia surgeries are Trans Abdominal Pre-Peritoneal (TAPP) and totally extraperitoneal (TEP) methods. Although both are preperitoneal repair methods, less intraperitoneal organ damage, less intra-abdominal adhesion formation, and no need for peritoneal sheath repair are the advantages of the

TEP method [8, 9]. For this reason, TEP method has been the preferred method today. Various methods have been tried in order not to change the location of the mesh placed in the TEP method. Laparoscopic inguinal hernia is one of the most debated issues. The most common methods for fixation are tacker, tissue adhesive, or suturing the mesh. However, fixing the mesh using a tacker can cause chronic pain. Tissue adhesives are not preferred, because they have high costs and sometimes cause allergic reactions. The method in which the mesh is sewn to the pubic bone is avoided by surgeons, because it prolongs the operation time [10, 11]. To avoid chronic pain after surgery, the idea was not to fix the mesh. The major drawback of this method is that the mesh may slip and cause recurrence [12, 13]. This study aimed to reveal the difference between the amount of migration and the amount of post-operative pain between fixing the mesh and not fixing it.

# **Methods**

The study was conducted as a prospective two-armed, double-blind, randomized controlled study in the general surgery clinic of a university hospital between December 2019 and December 2020. This double-blind randomised control trial was approved by Hitit University, Faculty of Medicine, Clinical Research Ethics Committee (N:113) and was registered at http://Clinicaltrials.gov (NCT05152654). Power analysis was performed for Student's t test, which will be used in testing the main hypothesis. As a result of Cohen's power analysis, which was calculated under expert view, to reach 80% power with 0.50 effect size (medium effect) and 5% error (alpha = 0.05), it was decided to include a total of 100 patients, 50 in each group. The study was continued by taking the consent of the patients and selecting from the volunteer patients. Which method the patients would be operated on is determined by choosing from a total of 100 (50 per group) sealed envelopes containing group names written inside. In the first (Fixation Group) group, inguinal hernia repair was performed with the TEP method, while the mesh was fixed with a stapler. In the second (non-fixation group) group, inguinal hernia repair was performed with the TEP method, while the mesh was not fixed by any method. Exclusion criteria were; being under the age of 18, having comorbidity that prevents him from receiving general anesthesia, having undergone previous lower abdominal surgery, previous surgery for inguinal hernia, bilateral inguinal hernia, scrotal hernia, or strangulated hernia. Also excluded in patients using anticoagulants.

Creation of double-blind; The patients were not told which group of study they were in as a result of the envelope they chose. In the postoperative follow-up of the patients, the researcher who recorded the parameters related to the study and provided the measurements did not know which group the patients were in.

The age, gender, comorbidity, smoking history, and body mass index of the patients were recorded on the forms before the surgery. The surgery was performed by a single surgeon according to the group chosen by the patients. The practicing surgeon was a general surgeon with 5 years of active experience in laparoscopic hernia surgery and had applied both methods more than 200 times. Until the end of the study, only the practicing surgeon knew which group the patients were in.

# Anesthesia and analgesia method

In both groups, patients were operated under standard general anesthesia; 2 mg midazolam, 1 µg/kg fentanyl, 2–3 µg propofol, and 0.6 µg rocuronium were used for induction. 50% air-50%  $O_2$  was given at a rate of 4 lt/min. Anesthesia was maintained with sevoflurane at a MAK of 1–1.3 and remifentanil at a rate of 0.5–4 µg/kg per minute. Intravenous bolus infusion of 1 g paracetamol and 1–2 mg/kg tramadol provided postoperative analgesia.

#### Surgical method

In both methods, the patients were preoperatively infused with 1 gr intravenous cefazolin, followed by sterile staining and draping in the supine position under general anesthesia, and the rectus posterior sheath was detached by opening the fascia before the rectus with a 1 cm infra-umblical incision. A 10 mm trocar was inserted into this opening and insufflation was achieved with 14 mmHg pressure. After opening the appropriate space up to the symphysis pubis with telescopic dissection, 2 working ports of 5 mm were placed between the umbilicus and the pubis in the midline. Dissection should extend to at least the pubic symphysis and at least 2 cm below the pubis at Zone 2, to create sufficient space to accommodate an adequately sized mesh, that overlaps Direct and Femoral Triangles by at least 3–4 cm (Fig. 2) and will not be lifted by the distending bladder. Dissection extend to at least the pubic symphysis and at least 2 cm below the pubis, to create sufficient space to accommodate an adequately sized mesh, that overlaps Direct and Femoral Triangles by at least 3-4 cm. After the hernia sac was reduced by dissection and the appropriate area was opened, a polypropylene mesh prepared with a diameter of  $15 \times 12$  cm and marked with titanium clips at 4 corners was placed. In the first group (Fixation Group), the mesh was fixed with 5 non-absorbable staples starting from the pubic bone to the medial side of the inferior epigastric vein (Fig. 1). The tackers used were non-absorbable made of titanium in a helical structure. The penetration depth of the tackers was 3.8 mm. No fixation (Fig. 2) was performed after the mesh was placed

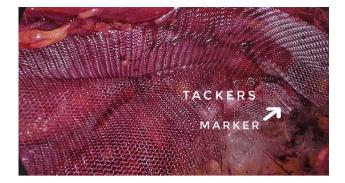


Fig. 1 Fixed mesh with tackers

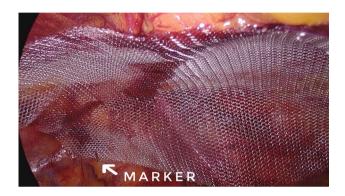


Fig. 2 Non-fixed mesh

on the patients in the second group (non-fixation). Care was taken to prevent the mesh from slipping, while desufflation was achieved in both groups. When calculating the operation times of the patients, the time from the first skin incision to the last suture on the skin was calculated in minutes.

The duration of the operation, the first postoperative mobilization times, the need for postoperative analgesia, postoperative complications, and postoperative 1st-day numerical pain scores were recorded. Direct pelvic radiographs of the patients were taken on the first postoperative day, and the distance of the mark closest to the symphysis pubis from the marks placed on the mesh was recorded. The patients were called for control at the first week and 6 months, and direct pelvic radiographs were taken (Fig. 3). On the same observer side, the patients' numerical pain scores and the amount of migration of the marker fixed to the mesh was recorded in millimeters. At the same time, the patients' return to work times were recorded in the follow-up form. When the registration process of the forms was completed, the patient's group was processed on the registration form by the performing surgeon.

Both groups were compared in terms of demographic data, operative time, postoperative complications, initial mobilization times, postoperative hospital stay, time to return to work, numerical pain scores at the end of



Fig. 3 Post-operative X-ray

post-operative 1st day, 1st week, and 6th month, and mesh migrations at the end of post-operative 1 week and 6 months. In addition, the patients were compared in terms of recurrence between the two groups.

#### **Statistical analysis**

Statistical analysis was carried out using SPSS (Version 22.0, SPSS Inc., Chicago, IL, USA) software. Descriptive statistics were presented as mean  $\pm$  standard deviation for normally distributed continuous data, median ± interquartile range (IQR) for non-normally distributed continuous data, and number and percentage (%) for categorical data. Proportion comparisons between categorical variables were investigated using Chi-square or Fisher's exact tests, based on the sample size in the crosstab cells. The normality distribution of the data was evaluated using the Shapiro-Wilk test. In the comparison of continuous variables between two independent groups, students' t test was used for normally distributed data and Mann Whitney U test was used for non-normally distributed data. Comparison of VAS scores at different time points was performed with the Friedman test, since the data were not normally distributed. For the statistical significance level, p < 0.05 was accepted.

# Results

A total of 100 patients, 50 with fixation and 50 with nonfixation, were included in the study. 92% of the patients were male and 8% were female. The mean age of the patients was  $51.43 \pm 16.91$  (min-max: 18–87). The mean BMI of the

patients was  $26.51 \pm 3.70$  (20.15–39.52). The mean operative time of the patients was  $25.93 \pm 7.95$  (12–52) minutes, the mean hospitalization time was  $1.20 \pm 0.402$  (1–2) days, and the mean time to return to work was  $8.56 \pm 2,82$  (3–17) days. The comparison of the socio-demographic characteristics of the patients and the duration of the operation, hospitalization, mobilization, and return to work among the research groups is presented in Table 1. Gender, ASA, and smoking status were similarly distributed among the research groups (p = 0.715, p = 0.875, p = 0.401, respectively, Table 1). Patient ages and BMI values were statistically similar between the study groups (p = 0.618, p = 0.849, respectively, Table 1). The operation time of the patients in the fixation group was statistically significantly higher than in the non-fixation group (p = 0.005). Duration of hospitalization (day), mobilization time (day), and time of start working (day) times were not statistically significantly different between the groups (p = 0.098, p = 1.000, p = 0.752, respectively, Table 1).

Comparison of additional analgesia, seroma, hematoma, and recurrence among research groups are presented 
 Table 2 Comparison of baseline characteristics between research groups

	Non-fixation $n = 50 (50\%)$	Fixation $n = 50 (50\%)$	<i>p</i> values
Additional	analgesia		
No	47 (94%)	44 (88%)	0.487
Yes	3 (6%)	6 (12%)	
Seroma			
No	46 (92%)	45 (90%)	
Yes	4 (8%)	5 (10%)	1.000
Hematoma	l		
No	48 (96%)	46 (92%)	0.678
Yes	2 (4%)	4 (8%)	
Recurrence	e		
No	48 (96%)	49 (98%)	1.000
Yes	2 (4%)	1 (2%)	

Fisher exact test

Table 1	Comparison of	baseline	characteristics,	operation	time,	duration	of	hospitalization,	mobilization	time,	and	time	of	start	working
between	n research groups														

	Non-fixation <i>n</i> = 50 (50%)	Fixation n=50 (50%)	<i>p</i> values
Gender			
Male	45 (90%)	47 (94%)	0.715 <sup>b</sup>
Female	5 (10%)	3 (6%)	
ASA			
1	11 (22%)	10 (20%)	
2	33 (66%)	31 (62%)	0.875 <sup>b</sup>
3	6 (12%)	8 (16%)	
4	0	1 (2%)	
Smoking			
No	44 (88)	41 (82)	0.401 <sup>a</sup>
Yes	6 (12)	9 (18)	
	$mean \pm SD \text{ or} \\ median \pm IQR$	$mean \pm SD \text{ or} \\ median \pm IQR$	P values
Age (year)	$50.58 \pm 17.3$	52.28 ± 16.64	0.618 <sup>c</sup>
BMI	$26.58 \pm 3.84$	$26.44 \pm 3.60$	0.849 <sup>c</sup>
Operation time (min)	22.5±7	27 ± 11	0.005 <sup>d</sup>
Duration of hospitalization (day)	$1 \pm 0$	$1\pm0$	$0.098^{d}$
Mobilization time (day)	7±2	8±2	$1.000^{d}$
Time of start working (day)	$8\pm4$	8±4	0.752 <sup>d</sup>

The only statistically significant value is indicated in bold

SD standard deviation, IQR Interquartile range, BMI Body Mass Index

<sup>a</sup> Chi-square test

<sup>b</sup>Fisher exact test

<sup>c</sup>Student's *t* test with mean  $\pm$  standard deviation

<sup>d</sup>Mann–Whitney U test with median (IQR)

in Table 2. Additional analgesia, seroma, hematoma, and recurrence distributions were similar between the groups (p=0.487, p=1.000, p=0.678, p=1.000, respectively, Table 2).

Mesh displacement comparison between research groups is presented in Table 3. Mesh displacement values were not statistically different between the groups at the end of the 1st week and 6th month (p=0.743, p=0.926, respectively, Table 3).

Comparison of VAS scores by time and between research groups is presented in Fig. 5. The VAS scores obtained at the end of the 1st day, 1st week, and 6th month were significantly higher in the Fixation group (p=0.001, p<0.001,

Table 3 Comparison of mesh displacements between research groups

	Non-fixation $n = 50$	Fixation $n = 50$	<i>p</i> values		
	$\begin{array}{l} Median \pm IQR \\ (mean \pm SD) \end{array}$	$\begin{array}{l} Median \pm IQR \\ (mean \pm SD) \end{array}$			
Mesh displace- ments 7th day (mm)	$1 \pm 1$ (1.52 ± 1.63)	$1 \pm 1$ (1.44 ± 1.43)	0.743		
Mesh displace- ments 6th month (mm)	$2 \pm 1$ (2.68 ± 2.02)	$2\pm 2$ (2.66±1.90)	0.926		

Mann–Whitney U test with median (IQR) (mean  $\pm$  SD)

IQR Interquartile range, SD standard deviation

Fig. 4 Time-dependent change of pain

p0.001, respectively, Fig. 5). In the non-fixation group, the VAS scores obtained at the end of the 1st day, 1st week, and 6th month were significantly reduced according to time (p < 0.001, p0.001, p = 0.018, respectively, Fig. 5). In the fixation group, while the VAS scores decreased significantly from the 1st day to the 1st week (p = 0.001), no significant difference was found between the VAS score at the end of the 1st week and the VAS score at the end of 6 months (p = 0.690, Fig. 4).

#### Discussion

Inguinal hernia is a very common operation in current surgical practice. The major postoperative problems are relapse, pain in the acute and chronic periods [14]. Tension-free methods are preferred in inguinal hernia repair because of low recurrence. However, chronic pain remains a problem in open surgery. With the development of modern medicine, minimally invasive methods today produce very useful solutions to overcome these problems. Better cosmetic results, early return to work, low recurrence rates, and low postoperative acute and chronic pain rates highlight laparoscopic surgical methods in hernia repair [15].

TAP and TEP applications in laparoscopic inguinal hernia repair not only have the advantages mentioned above but also pose risks of various complications such as injury and bleeding in intraperitoneal organs, mesh migration [16, 17].

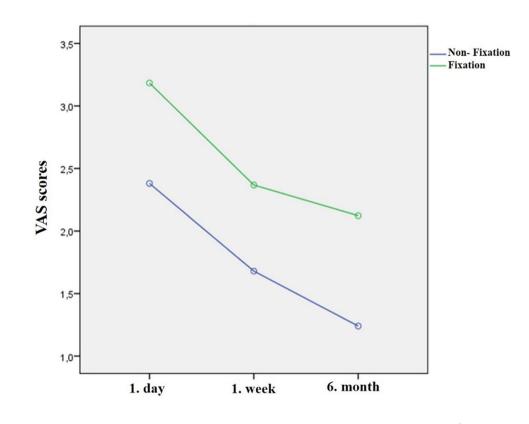
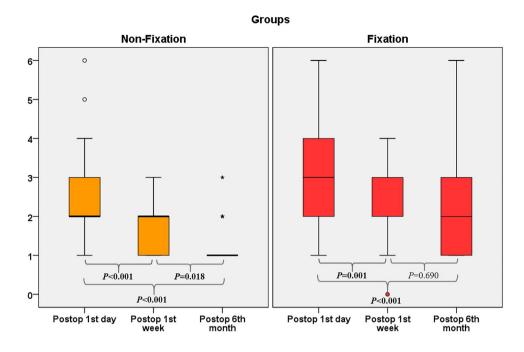


Fig. 5 Comparison of VAS scores between research groups



Although the TEP approach is advantageous in terms of both recurrence and postoperative complications, keeping the mesh placed in the hernia area in the preperitoneal area is of great importance in terms of postoperative complications.

Despite a proper dissection in TEP repair, which is a minimally invasive approach, improperly placed mesh may cause recurrence and pain in the postoperative period [18]. Despite proper dissection and placement, the mesh may displace in the surgical field and cause undesirable complications. In current practice, various methods are used to keep the mesh stable in the surgical field. Methods such as staple fixation and tissue adhesive are the most commonly used fixation methods [19, 20]. Although staple fixation is a very reassuring method in terms of mesh migration, it poses a risk in terms of acute and chronic pain [21]. In an ideal TEP repair, one of the most desirable advantages of the minimally invasive approach is that minimized pain in the postoperative period.

In this study, the demographic characteristics of the patients in both groups showed similar distribution, indicating that the patient groups were homogeneous (Table 1). The most important factors for recurrence in TEP repair are the lack of adequate dissection, the presence of cord lipoma, improper placement of the mesh, and the presence of overlooked femoral hernia as risk factors [22]. Considering the results of this study, it was observed that appropriate and adequate dissection was performed by the same senior surgeon in all patients, and no recurrence was encountered in the early postoperative period (Table 2). A suitable area was created for mesh placement by performing standard and adequate dissection for both groups. Placement of the mesh after appropriate preperitoneal dissection in both fixation

and non-fixation groups is the most important reason for not detecting postoperative recurrence. Although recurrence was detected in both groups in the postoperative 6 month follow-up of the study, no statistically significant difference was found between the groups (p = 1.000). Despite proper dissection and proper placement of the mesh, it is obvious that if mesh migration occurs, it will naturally predispose to recurrence. Due to these reservations, the desire to fix the mesh with staples or tissue adhesives is inevitable by most surgeons. It has been reported in the literature that the fixation methods used reveal undesirable negative situations [22]. Although pain is one of the most important problems. vascular injury and organ injury due to fixation are among the other complications observed [18]. In this study, no complications such as organ injury and vascular injury were observed in the patients in either group (Table 2). It was observed that there were patients who developed superficial hematoma and seroma in both groups, and no statistically and a clinically significant difference was found between the groups in terms of complication development.

Although fixing the mesh in the TEP method used in inguinal hernia repair seems reassuring in terms of recurrence, there are studies in the literature reporting that fixation of the mesh causes acute and chronic pain [23, 24]. When the postoperative acute and chronic pain scores of both groups were examined, it was determined that there was a statistically significant difference between the two groups (Fig. 5). It was observed that all postoperative pain scores on the 1st day, 1st week, and 6th month in the fixation group were clinically and statistically significantly higher than the non-fixation group (p < 0.001). In addition, in the data obtained in the study, it was determined that the pain

scores of the patients in the fixation group at the 1st week decreased compared to the first postoperative day, but did not provide a significant decrease from the first week to the 6th month. However, when the patients in the fixation group were examined, it was determined that the pain pattern showed a continuous decrease. When the duration and reduction pattern of pain were examined, it was observed that non-fixation group had statistically and clinically significantly lower pain scores (Fig. 4). This difference in pain scores between the two groups is of great importance. In a minimally invasive approach such as TEP, which has great advantages compared to open surgery, minimizing acute and chronic pain is the desired result for both the patient and the physician [25]. In this study, achieving the desired low pain levels in the non-fixation group highlights the need for reconsideration of the fixation method. The place of fixation and the number of staples used are also factors affecting the acute and chronic pain that may occur [26, 27]. In this study, 5 staples were used as standard in the fixation group. A staple was applied to the medial part of the Cooper ligament and epigastric vessel, and no staples were applied in the pain triangle. The theories that can explain the pain are that the staples used for fixation are foreign bodies themselves, the trauma caused during the application, and the granulation tissue it creates causes pain.

Even though the fixation method carries such a risk that it may even cause pain and injury, the biggest reason why it is desired to be used intraoperatively is the concern whether the used mesh will be lost from its place, cause recurrence, or fold and cause chronic pain. In the literature, there are studies reporting mesh migration [28]. However, studies reporting that fixation is not necessary to have begun to take their place in the literature [13, 29-31]. In this study, the postoperative migration of the mesh was evaluated by taking X-ray and control radiographs of the patients in the postoperative period. No clinically or statistically significant difference was found in terms of mesh migration in both groups at the postoperative 7th day and 6th-month evaluations (Table 3). In addition, in the measurements made, it was determined that the mesh showed a maximum deviation of 1 mm in both groups. In the light of these results, it appears that the properly placed mesh does not migrate after good dissection. Considering that the main purpose of detecting the mesh is to prevent recurrence that may occur as a result of migration, we see that a safe and comfortable surgical and postoperative period can be obtained in patients without using the fixation method, considering the disadvantages of fixation in the light of the findings of the study. In addition, the fact that recurrence rates are similar and mesh migration is not detected even in patients with recurrence highlights the need to focus on other factors affecting recurrence.

Considering the other results of the study, no statistically significant difference was found between the two groups in

terms of returning to work and hospital stay, but there was a difference in terms of operation time (Table 1). It was observed that the operation time in the fixation group took approximately 5 min longer depending on the procedure performed. This statistical difference between the operative times did not lead to any clinically significant results. This small period, which does not contribute to the postoperative follow-up of the patients or the development of complications, is a negligible period.

## Conclusion

As a result, in the TEP approach, which is applied as a minimally invasive method in inguinal hernia surgery, placing the mesh without fixation does not pose a risk for early and late recurrence. The absence of fixation after proper dissection and proper mesh placement increases the comfort of the patients in terms of pain in the postoperative return and protects the patients from the complications that come with fixation. Keeping in mind that the most important factor in recurrence and postoperative pain in inguinal hernia surgery is inadequate and improper dissection, mesh fixation is not necessary in the TEP method.

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#### Declarations

**Conflict of interest** Authors declares that they have no conflict of interest.

Ethical approval Ethical approval was obtained from The Hitit University Faculty of Medicine Clinical Research Ethics Committee.

Human and animal rights This study was conducted in accordance with the WMA DECLARATION OF HELSINKI and ethical rules. Animal and human rights are respected.

Informed consent Informed consent was obtained from all patients.

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