

# Comparing Fixation versus Non-fixation of Mesh in Laparoscopic Totally Extraperitoneal Repair of Inguinal Hernia: A Prospective Study

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## Abstract

**Introduction:** Inguinal hernia repair is one of the most common surgical procedures done worldwide. Conventional repair involves the usage of a mesh to cover the hernia defect to prevent recurrence. The mesh is fixed securely without tension in open hernia repair. Laparoscopic surgery for inguinal hernia repair is done by two methods, which only vary in approach to the preperitoneal space. They include laparoscopic transabdominal preperitoneal inguinal hernia repair and totally extraperitoneal (TEP) inguinal hernia repair.

**Purpose:** The purpose of this study is to compare the outcomes and complications between fixation using suture and non-fixation of mesh in laparoscopic TEP inguinal hernia repair.

**Materials and Methods:** The study period was 1 year, and all patients were followed up for a period of 1 year following surgery. All the surgeries were performed by a single surgeon, and all the ultrasounds were performed by the same radiologist.

**Results:** The study population was randomized into two groups, 46 patients met with the inclusion criteria and were included in the study. Of the 46 patients, 22 patients were randomized to the group in whom, the mesh was fixed. 24 patients were randomized to the group in which the mesh was not fixed. Out of 46 patients, 36 had unilateral hernia and 10 had bilateral hernia giving a total sample size of 56. Out of 36 patients who had unilateral hernia, 11 had hernia on left side. 25 had hernia on the right side.

**Conclusion:** We conclude that the placement of mesh without fixation results in less post-operative pain, consumes less time for placement of mesh and is cost-effective in comparison to mesh fixation technique. And there is no significant difference in the mesh migration in our study.

**Key words:** Laparoscopic inguinal hernia repair, Mesh migration, Non fixation of mesh, Totally extraperitoneal

## INTRODUCTION

Totally extraperitoneal (TEP) inguinal hernia repair was first described in 1993 by McKernon and Laws. Laparoscopic inguinal hernia repair has many advantages over open

repairs such as less post-operative pain, early return to daily activities and to work, lesser incidence of neurogenic pain, bleeding, infection, and seroma. Laparoscopic inguinal hernia repair is similar to the concept of inguinal hernia repair proposed by Stoppa.

During laparoscopic surgery, the mesh is generally placed and sutured using suture materials or using fixation devices such as staples, tacks, or tissue glue. Stapling can cause scarring and pain at the staple sites. The purpose of this study is to compare the outcomes and complications of non-fixation of mesh in laparoscopic TEP inguinal hernia repair.

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## MATERIALS AND METHODS

### Inclusion Criteria

Patients that were more than 18 years of age, who were willing to participate and provided informed consent, were included in the study. Patients diagnosed clinically with direct and indirect inguinal herniae, unilateral, and bi-lateral inguinal herniae were included in the study.

### Exclusion Criteria

Patients that were unfit for general anesthesia, who were diagnosed to have complicated inguinal herniae such as strangulated and obstructed hernia, were excluded from the study.

They were prospectively randomized by closed envelope method into two groups, one of which underwent laparoscopic TEP inguinal hernia repair with a polypropylene mesh fixed with 2-0 prolene and the other groups underwent surgery without the mesh being fixed.

A 12 cm × 15 cm polypropylene, monofilament, non-absorbable mesh that weighed 80 g/m<sup>2</sup> and had a thickness of 0.50 mm and pore size of 0.5 mm × 0.7 mm was used for all patients.

The study period was 1 year, and all patients were followed up for a period of 1 year following surgery. All the surgeries were performed by a single surgeon, and all the ultrasounds were performed by the same radiologist.

### Ultrasonography

Serial ultra-sonogram analysis of patient was done preoperatively, on post-operative day 1 (POD 1) (Visit 1), on POD 7-9 (Visit 2), and after 6 months (Visit 3) post-operatively. The distance of lateral border of mesh to anterior superior iliac spine was taken as "A," the distance of pubic symphysis to medial border of mesh as "B" and the superior border of mesh to a point of intersection of two imaginary lines, one drawn horizontally through the level of umbilicus and the second drawn vertically up through the mid-inguinal point was taken as "C" were measured on Visit 1, 2 and 3.

Measurement of pain score was done using visual analog scale (VAS score) and a score between 0 and 10 was recorded: 0 - no pain, 1-3 - mild pain, 4-6 - moderate pain, and 7-10 - severe pain. These measurements were taken on Visit 0 - the day of surgery (6 h after surgery), Visit 1, 2 and 3 (Table 2-9).

### Statistical Analysis

The statistical analysis for this study was performed using SPSS software version 15 for windows. A value of  $P <$

0.05 was chosen as the significance level for outcome measures.

The analysis was done for paired  $t$ -test. Continuous variables are expressed as means or medians and were compared using  $t$ -tests, analysis of variance, or Mann-Whitney U-tests as appropriate. Categorical variables are expressed as proportions and were compared using either  $\chi^2$  or Fisher exact tests. A 2-sided  $P < 0.05$  was considered statistically significant.

### Statistical Data

- Total number of patients – 46
- Total number of unilateral hernia - 36
- Total number of bilateral hernia – 10
- Sample size - 56 [36+(10×2)]
- Mesh fixed in - 32
- Mesh was not fixed in - 24.

## RESULTS

The study population was randomized into two groups, 46 patients met with the inclusion criteria and were included into the study. Of the 46 patients, 22 patients were randomized to the group in whom, the mesh was fixed. 24 patients were randomized to the group in which the mesh was not fixed. Out of 46 patients, 36 had unilateral hernia and 10 had bilateral hernia giving a total sample size of 56. Out of 36 patients who had unilateral hernia, 11 had hernia on left side. 25 had hernia on the right side.

### Mesh Migration

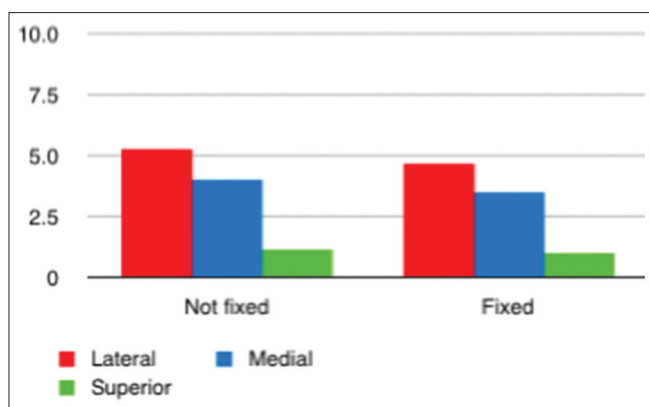
There is minimal movement of mesh in both groups, the group with mesh unfixed showing average movement of 5.31 mm, 4.04 mm and 1.21 mm in lateral, medial and superior directions, respectively. The group with mesh fixation showed average movement of about 4.69 mm, 3.56 mm and 1.02 along lateral, medial and superior directions, respectively. On comparing the values, movement of mesh in group with no fixation was little more than the fixation group. However, the results were not statistically significant. Hence, we conclude that there is negligible mesh migration Table 1 and Graph 1.

### P Value for Mesh Migration

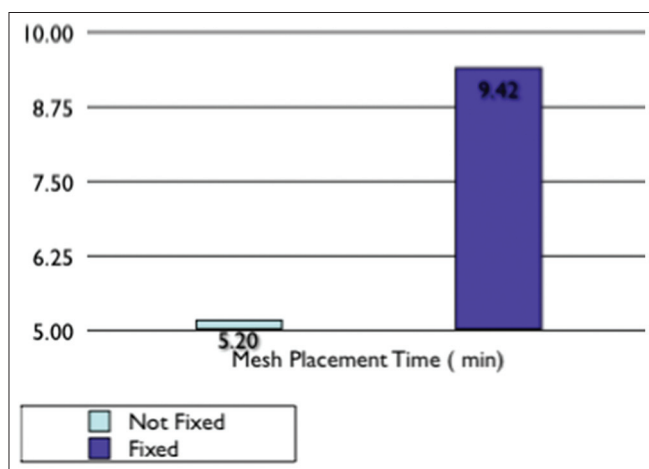
- P value for fixed group - 0.217
- P value for non-fixed group - 0.433. Significant  $P > 0.5$ .

### Time Taken for Mesh Placement

- Average time for mesh fixation
- Average time taken for placement of mesh without fixation - 5 min 20 s



Graph 1: Movement of mesh (in mm)



Graph 2: Time taken for mesh fixation

- Average time taken for placement of mesh with fixation - 9 min 42 s (Graph 2).

### Hernia Recurrence

All patients were followed up for a period of 1 year, and there were no patients with signs and symptoms suggestive of recurrence of inguinal hernia postoperatively.

### Post-operative Pain

Post-operative pain was measured using VAS score; we did not find any difference in pain score between groups on the day of surgery, but there is a statistically significant difference on Visit 1 (POD 1). Average pain score for fixed - 1.73 and unfixed - 1.13. All patients irrespective of the groups did not suffer any pain on Visit 2 and Visit 3 (Table 8 and 9).

## DISCUSSION

In our study, we included patients who were more than 18 years of age and were diagnosed with unilateral/bilateral inguinal herniae which were direct/indirect or both.

**Table 1: Movement of mesh (in mm)**

Group	Lateral (mm)	Medial (mm)	Superior (mm)
Not fixed	5.31	4.04	1.21
Fixed	4.69	3.56	1.02

**Table 2: Group statistics**

Mesh	N	Mean	Standard deviation	Standard error of mean
V1A				
Fixed	32	31.009	7.7735	1.3742
Not fixed	24	32.871	6.7654	1.3810
V3A				
Fixed	32	30.54	7.602	1.344
Not fixed	24	32.34	7.193	1.468

All the procedures (TEP) were standardized. The pre-peritoneal space was created by open technique and blunt dissection of the space was done by the telescope and subsequent insufflation with carbon dioxide, compared to many who advocate the use of balloons. We found that our technique was cost-effective with no difficulty encountered in space creation. The hernial sac is it direct or indirect was completely dissected down up to the point where the vas deferens turns medially.

We placed a 12 × 15 cm mono-filament, non-absorbable polypropylene mesh for both groups. In one group, we placed the mesh without fixation and in another group; we fixed the mesh in two places, viz., Cooper's ligament (medially) and anterior abdominal wall (laterally).

The transversalis fascia, rectus muscle, Cooper's ligament, and the pubic bone have emerged as the traditional safe points of fixation with avoidance of infero medial and inferolateral anchorage that is fraught with dangerous complications according to Parshad *et al.*<sup>1</sup>

Non-fixation of the mesh is based on a principle that when intra-peritoneal pressure is evenly distributed over the large peritoneal surface from the inside the mesh is kept in place without need for fixation as explained by Deerenberg *et al.*

### Mesh Migration

Jamadar *et al.*<sup>2</sup> have experience in using sonography to study the mesh and its behavior in abdominal wall herniae. The mesh most commonly appears as a linear echogenic interface with posterior acoustic shadowing. The mesh is differentiated from adjacent structures by its superficial location and absence of peristalsis which helps in differentiating it from bowel.

**Table 3: Independent samples test**

Group	Levene's test for equality of variances		t-test for equality of means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean difference	Standard error difference	95% confidence interval of the difference	
								Lower	Upper
V1A									
Equal variances assumed	0.004	0.952	-0.936	54	0.353	-1.8615	1.9877	-5.8466	2.1237
Equal variances not assumed			-0.955	52.737	0.344	-1.8615	1.9482	-5.7695	2.0466
V3A									
Equal variances assumed	0.086	0.771	-0.896	54	0.374	-1.798	2.007	-5.821	2.225
Equal variances not assumed			-0.903	51.079	0.371	-1.798	1.990	-5.794	2.198

T: Test for lateral movement; V1A -distance between anterior superior iliac spine to lateral border of mesh on Visit 1; V3A: Distance between anterior superior iliac, spine to lateral border of mesh on Visit 3

**Table 4: Group statistics**

Mesh	N	Mean	Standard deviation	Standard error of mean
V1B				
Fixed	32	16.300	7.1414	1.2624
Not fixed	24	18.504	8.4278	1.7203
V3B				
Fixed	32	16.656	6.6037	1.1674
Not fixed	24	16.800	5.5661	1.1362

**Table 5: Independent samples test**

Group	Levene's test for equality of variances		t-test for equality of means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean difference	Standard error difference	95% confidence interval of the difference	
								Lower	Upper
V1B									
Equal variances assumed	0.000	0.984	-1.058	54	0.295	-2.2042	2.0835	-6.3812	1.9729
Equal variances not assumed			-1.033	44.802	0.307	-2.2042	2.1338	-6.5025	2.0941
V3B									
Equal variances assumed	0.875	0.354	-0.086	54	0.932	-0.1437	1.6696	-3.4912	3.2037
Equal variances not assumed			-0.088	53.203	0.930	-0.1437	1.6290	-3.4108	3.1233

T: Test for medial movement; V1B: Distance between Pubic Symphysis to medial border of mesh on Visit 1; V3B: Distance between Pubic Symphysis to medial border of mesh on Visit 3

**Table 6: Group statistics**

Mesh	N	Mean	Standard deviation	Standard error of mean
V1C				
Fixed	32	53.234	3.1676	0.5600
Not fixed	24	52.675	1.3895	0.2836
V3C				
Fixed	32	52.167	3.2032	0.5662
Not fixed	24	52.796	1.4141	0.2886

According to Crespi *et al.*,<sup>3</sup> sonography is better in identifying mesh than computed tomography in patients with polypropylene mesh who had undergone inguinal hernioplasty.

### Hernia Recurrence

In our study, we evaluated our patients till 1 year after surgery and did not find any signs or symptoms suggestive

of recurrence for any of our patients during the entire course of the study. In general, any recurrence occurring within 6 months of surgery indicates technical failure.

Liem *et al.*<sup>4</sup> elucidate that majority of recurrences following TEP happens in the first year after surgery and are always due to surgeon related factor of either mesh migration or displacement. This is precisely the reason we need to

**Table 7: Independent samples test**

Group	Levene's test for equality of variances		t-test for equality of means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean difference	Standard error difference	95% confidence interval of the difference	
								Lower	Upper
V1C									
Equal variances assumed	8.796	0.004	0.807	54	0.423	0.5594	0.6928	0.8296	1.9483
Equal variances not assumed			0.891	44.959	0.378	0.5594	0.6277	-0.7049	1.8236
V3C									
Equal variances assumed	9.026	0.004	-0.897	54	0.374	-0.6290	0.7011	-2.0347	0.7767
Equal variances not assumed			-0.990	45.099	0.328	-0.6290	0.6356	-1.9090	0.6511

T: Test for vertical movement; V1C - distance between superior border of mesh to a point of intersection of two imaginary lines, one drawn horizontally through the level of umbilicus and the second drawn vertically up through the mid inguinal point on Visit 1; V3C - distance between superior border of mesh to a point of intersection of two imaginary lines, one drawn horizontally through the level of umbilicus and the second drawn vertically up through the mid inguinal point on Visit 3

**Table 8: Group statistics**

Mesh	N	Mean	Standard deviation	Standard error of mean
VAS 0				
Fixed	22	2.91	0.294	0.063
Not fixed	24	2.79	0.415	0.085
VAS 1				
Fixed	22	1.73	0.550	0.177
Not fixed	24	1.13	0.680	0.139
VAS 2				
Fixed	22	0.00	0.000 <sup>a</sup>	0.000
Not fixed	24	0.00	0.000 <sup>a</sup>	0.000
VAS 3				
Fixed	22	0.00	0.000 <sup>a</sup>	0.000
Not fixed	24	0.00	0.000 <sup>a</sup>	0.000

<sup>a</sup>t cannot be computed because the standard deviations of both groups are 0

**Table 9: Independent samples test**

Group	Levene's test for equality of variances		t-test for equality of means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean difference	Standard error difference	95% confidence interval of the difference	
								Lower	Upper
VAS 0									
Equal variances assumed	5.335	0.026	1.098	44	0.278	0.117	0.107	-0.098	0.333
Equal variances not assumed			1.114	41.487	0.272	0.117	0.105	-0.095	0.330
VAS 1									
Equal variances assumed	0.585	0.448	3.284	44	0.002	0.602	0.183	0.233	0.972
Equal variances not assumed			3.314	43.371	0.002	0.602	0.182	0.236	0.969

figure out whether fixing or not fixing the mesh makes any difference to these factors. The same point was highlighted by Parshad *et al.*<sup>1</sup> What we are trying to achieve in our study is to bring about a quantitative and objective assessment with respect to mesh migration.

Davis and Arregui<sup>5</sup> recommend that a mesh of size 10 cm × 15 cm is sufficient for laparoscopic hernia repairs without fixation.

Taylor *et al.*<sup>6</sup> stated that they had one recurrence in the fixated group (1/247) whilst none in the unfixated group. Fixation increased operative costs by approximately 340\$ US. They conclude that mesh fixation in TEP is associated with increased operative cost and chronic pain

Koch *et al.*<sup>7</sup> stated that eliminating fixation does not lead to increase in rate of recurrence. They recommend placement of mesh without fixation for hernia defect <3 cm.

### Post-operative Pain

In our study, patients reported mild pain which corresponded to a VAS score of 3 or 2 on the day of surgery after about 6 h immediately after surgery, but the pain reduced significantly at 24 h post-surgery. Almost all of them returned to normal activities on POD 1. There was no difference in pain in the fixed or non-fixed group.

Ferzli *et al.*<sup>8</sup> states that there were no significant difference in pain between fixation and non-fixation group for a 12-month follow-up period. They added that fixation presents an inherent risk of nerve damage.

Burcharth *et al.*<sup>9</sup> say the descriptive and quantitative equivalence with VAS is an accepted system of measurement.

Koch *et al.*<sup>7</sup> state that foregoing the need for fixation, reduces the necessity and use of post-operative narcotic analgesic, results in reduction in length of hospital stay and lessens the probability of developing urinary retention postoperatively. It does not lead to significant reduction in post-operative pain.

Beattie *et al.*<sup>10</sup> have concluded that post-operative pain after mesh fixation in laparoscopic hernia repair is due to injury of genitofemoral nerve.

We infer that non-fixation of mesh is safe alternative to fixation, considering the cost effectiveness, and ease of the technique.

### CONCLUSION

The outcomes of techniques of mesh fixation over non-fixation of mesh were studied in respect to mesh migration, hernia recurrence, time of mesh placement, and post-operative pain.

#### 1. Mesh migration

In both groups, there was no statistically significant mesh migration.

#### 2. Hernia recurrence

The patients were monitored for 1 year postoperatively on a regular basis. There were no cases of clinically evident hernia recurrence

#### 3. Time taken for mesh placement

The average time taken for mesh placement with fixation was longer than non-fixation.

#### 4. Post-operative pain

Fixation of mesh showed significantly more pain on POD “1” compared to non-fixation. However, there was no difference in pain between both groups on POD “7.”

Hence, we conclude that the technique of mesh fixation is NOT superior for prevention of mesh migration and hernia recurrence.

We also conclude that the placement of mesh without fixation results in less post-operative pain consumes less time for mesh placement and is cost-effective in comparison to mesh fixation technique.

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