

# Comparison of Absorbable versus Non Absorbable Tackers for Fixation of Mesh in Laparoscopic Midline Anterior Abdominal Wall Hernia Repair: A Randomised Clinical Study

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## ABSTRACT

**Introduction:** Tackers are divided in two broad categories namely, absorbable and non absorbable. Absorbable tackers are believed to achieve sufficient tensile strength compared to conventional non absorbable tackers. It is a matter of debate that which type of tacker has an upper hand over the other especially in terms of postoperative pain and recurrences even after few years of clinical experience with these tackers and available clinical studies.

**Aim:** To compare various aspects of absorbable versus non absorbable tackers for fixation of mesh in Laparoscopic Midline Anterior Abdominal Wall Hernia Repair for short period of follow-up.

**Materials and Methods:** In this prospective randomised clinical study from November 2016 till March 2018 at Atal Bihari Vajpayee Institute of Medical Sciences (ABVIMS) and Dr. Ram Manohar Lohia (RML) Hospital, New Delhi, India. Total of 80 patients of age  $\geq 18$  years with midline anterior abdominal wall hernia were included and randomised into two groups 40 patients each i.e. group 1 absorbable tackers and group 2 non absorbable tackers. Outcomes evaluated were postoperative pain, seroma formation,

paralytic ileus, early recurrence (3 months follow-up) and duration of hospital stay. The data acquired was analysed using Statistical Package for Social Sciences (SPSS) version 22.0. Comparison of ordinal paired data was done using Wilcoxon signed rank sum test. The nominal categorical data was compared using Chi-square or Fisher's-exact test as appropriate. A p-value of  $<0.05$  was considered statistically significant.

**Results:** Out of 80 patients included in this study with a range of 21 to 60 years, the median age was 30 years. There was no statistically significant association noted in terms of postoperative pain (p-value  $>0.05$ ), seroma formation (p-value=1), paralytic ileus (p-value  $>0.05$ ), length of hospital stay (p-value=0.801) and early recurrence (3 months).

**Conclusion:** This study has shown that both non absorbable and absorbable tackers are associated with minimal postoperative complications and have similar postoperative morbidity. Both absorbable and non absorbable tackers are comparable for fixation of mesh in laparoscopic midline anterior abdominal wall hernia with respect to the above mentioned outcomes.

**Keywords:** Hernia complications, Intraperitoneal onlay meshplasty, Protacker, Securestrap, Ventral wall hernia

## INTRODUCTION

Hernia is one of the most commonly encountered surgical problem. Anterior abdominal wall hernia being the most common of all hernias is defined as bulging of part of the viscera of abdominal cavity with peritoneal covering through a defect or weakness in the abdominal wall muscle or its fascia [1-3].

It can be divided into incisional hernia, umbilical/paraumbilical hernia and epigastric hernia. With the evolving understanding of pathophysiology and cause of hernia recurrences, treatment of ventral hernia has also evolved. Primary suture repair of the defect has an extremely high recurrence rates (63%) and is therefore recommended only in some special circumstances [4]. Open meshplasty is an advancement of primary repair where a prosthetic mesh reinforcement is done to augment the repair. This has led to a decrease in recurrence rates to 32.6% [4].

Finally, laparoscopic meshplasty has evolved to be a standard of care for most of the anterior abdominal wall hernias [4]. Leblanc K in 1993 performed the first laparoscopic hernia repair and they documented certain advantages of laparoscopic meshplasty versus open meshplasty [5]. To list, some of the various advantages include smaller incision with better cosmesis, less postoperative-pain, decreased hospital stay, lesser blood loss and low risk of infection [6-8].

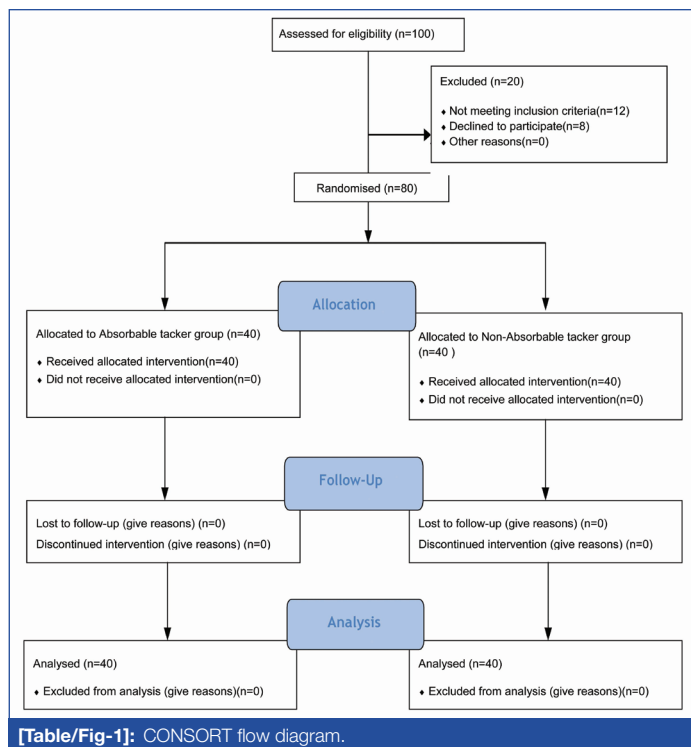
Fixation of mesh is one of the most important steps in laparoscopic ventral hernia repair. It is vitally important to fix the mesh to anterior abdominal wall with a proper technique to prevent mesh migration and to reduce complication like recurrence and postoperative pain [9]. The fixation of mesh in laparoscopic hernia is still debatable in terms of the number, strength, and the type (absorbable or non absorbable). Fixation techniques include glue, sutures or tacking devices. Tackers are one of the commonly used fixative techniques owing to the simplicity. Tackers are either made up of non absorbable material (titanium) or absorbable material (polydioxanone and L(-)-lactide/glycolide copolymer, polyglycolide-co-L-lactide, poly (D,L)-lactide) [10].

The principle of absorbable fixation is that after the mesh is integrated within host tissue, permanent fixation is not needed [11]. With the advent of tacking devices, it is obvious beyond doubt that they reduce the operative time over classical suture fixation techniques which had to be done manually [12]. Absorbable Tackers (AT) are believed to achieve sufficient tensile strength comparable to conventional non absorbable tackers and trans-fascial suture repairs with added advantage of improved biocompatibility, reduced postoperative pain and decreased risk of peritoneal adhesions [13,14]. Both absorbable and Non Absorbable Tackers (NAT) may elicit chronic tissue pain however absorbable tackers are costly [15]. The newer absorbable tackers made with strap principle are

proposed to provide greater tissue holding at acute deployment angles. It is a matter of debate that which type of tackler has an upper hand over the other especially in terms of postoperative pain and recurrences even after few years of clinical experience with these tacklers and available clinical studies. No study has been carried out using the absorbable tackler with strap technology. This study was thus carried out to compare the absorbable tacklers with non absorbable tacklers for mesh fixation in laparoscopic hernia repair to add on to the existing clinical data and help to find a solution for the debate. Authors hypothesised that the absorbable tacklers are associated with lesser postoperative pain, seroma formation, hospital stay and early recurrence when compared to non absorbable tacklers.

## MATERIALS AND METHODS

This prospective randomised clinical trial was conducted at Department of Surgery, ABVIMS and Dr. RML Hospital, North India, from November 2016 to March 2018. The Institutional Ethics Committee's approval for the study was secured prior to the commencement of the study, as it involved human participants with an approval number TP (MD/MS)(95/2019)/IEC/ABVIMS/RMLH. Patients were not involved in planning the study design. All patients were enrolled in the study after their written informed consent was obtained. The proceedings of the study are reported as per the Consolidated Standards of Reporting Trials (CONSORT) guidelines. This was a single centre study with balanced randomisation (1:1); it was single-blinded and used a parallel group design [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

**Inclusion criteria:** All patients above the age of 18 years with midline anterior abdominal wall hernia were invited to participate in the study. Those who consented were enrolled in the study till the study sample size was reached (consecutive sampling).

**Exclusion criteria:** Patients with recurrent hernia, complicated hernia, strangulated hernia, hernia with defect of more than seven centimeters, lateral hernias and patient unfit for general anaesthesia were excluded from the study.

**Sample size calculation:** A total of 80 patients were enrolled, 40 in each group.

$$\text{Sample size} = \frac{\{Z_{1-\alpha/2}\}^2 \times p(1-p)}{d^2}$$

Here,

$Z_{1-\alpha/2}$  = is standard normal variate {at 5% type I error ( $p < 0.05$ ), it is 1.96}

$p$  = 5% based on previous study [15]

$d$  = absolute error of 5%

Using this formula minimum sample size calculated was 60.

## Study Procedure

All patients who presented to the outpatient department with complaints and a history suggestive of ventral wall hernia were evaluated clinically and investigated further using imaging techniques. The size of the defect was detected clinically and by ultrasonography which was recorded on the patient proforma. Patients underwent preanaesthetic checkup and fitness tests for general anaesthesia. Patients were subjected to laparoscopic ventral hernia repair (intraperitoneal onlay meshplasty) with the use of composite mesh under general anaesthesia [15].

Prophylactic antibiotic amoxicillin clavulanate one gram was administered intravenously before the start of the procedure. Ports were inserted as per the size and location of hernia and adhesiolysis was done using harmonic scalpel. Once the defect was demonstrated, composite mesh was opened and inserted into the peritoneal cavity.

Same surgical team was present in all cases and a single main operating surgeon operated all the cases. Patients were randomised using the opaque sealed envelope method, which was opened in the Operating Theatre (OT) just before fixation of the mesh by a resident. One arm which was labelled as group 1 (absorbable tacklers) and the other as group 2 (non absorbable tacklers). Absorbable tacklers used were of SECURESTRAP (Ethicon, New Jersey, United States). Non absorbable tacklers used were of Pro Tacker (Covidien, Dublin, Ireland). In this single blinded study, patient was the blind component while the surgical team which was also the researcher knew the kind of treatment patient was receiving.

Tackers were applied in double crowning fashion. Injection Diclofenac sodium aqueous 75 mg intravenous infusion was given to all patients during reversal of anaesthesia and was repeated after eight hours. It was followed by tablet diclofenac sodium on as and when required basis mostly till 5 days. The present institute is a Government funded tertiary care teaching hospital and cost of tacklers and mesh was born by Government funds so, cost-analysis of tacklers was not carried out.

Outcomes evaluated were postoperative pain, seroma formation, paralytic ileus, early recurrence (3 months follow-up) and duration of hospital stay. The pain was recorded using the Visual Analog Scale that observes verbal score from 1 to 10 [16]. These recordings were made at 6 hours, 24 hours, at the time of discharge, follow-up visits at 1 week, 1 month, 2 months, and 3 months after surgery. Any complications in the immediate postoperative period and during the follow-up visits for three months were recorded.

## STATISTICAL ANALYSIS

The data acquired was analysed using SPSS version 22.0 (IBM SPSS Statistics, International Business Machines Corporation, New York). Categorical variables were presented in frequency (n) and percentage (%), and continuous variables were presented as Mean  $\pm$  Standard Deviation (SD) and median. A p-value of  $< 0.05$  was considered statistically significant. The nominal categorical data was compared using Chi-square, Mann-Whitney test or Fisher's-exact test as appropriate.

## RESULTS

In this study, a total of 80 cases of midline anterior abdominal wall hernia were included. Their mean age was 37.33 years with a range of 21 to 60 years. Mean  $\pm$  SD of age in years in group 1 was 36.25  $\pm$  9.4 and group 2 was 38.4  $\pm$  10.5 with no significant difference between the two groups ( $p$ -value = 0.955). Majority of patients were

females; 55% in group 1 and 60% in group 2 and proportion of males was 45% in group 1 and 40% in group 2 with no significant difference between them (p-value >0.05).

Two patients had epigastric hernia, 22 had incisional hernia, 26 had paraumbilical hernia and 30 had umbilical hernia. The variable defect size (cm) was normally distributed. Thus, parametric test was used for the comparison. No significant difference was seen in defect size (cm) between group 1 and 2 (p-value >0.05). Mean±SD of defect size (cm) in group 1 was 2.05±0.64 and group 2 was 1.83±0.64 with no significant difference between them.

### 1. Comparison of number of tackers between group 1 and 2 [Table/Fig-2]

Mean number of tackers applied in absorbable tackers group and non absorbable tackers group was 29.8±1.36 and 29.75±1.45, respectively with no significant difference (p-value >0.05).

### 2. Comparison of postoperative pain between group 1 and 2 [Table/Fig-3]

Postoperative pain was calculated at 6 hours, 24 hours, at discharge, at 1 week, at 1 month, at 2 months and at 3 months after surgery. In absorbable and non absorbable tackers group, the score was found

Number of tacks	Group 1 (n=40)	Group 2 (n=40)	Total	p-value*
Mean±SD	29.8±1.36	29.75±1.45	29.77±1.39	0.955
Median (IQR)	30 (29-31)	30 (29-31)	30 (29-31)	
Range	28-32	27-32	27-32	

**[Table/Fig-2]:** Comparison of number of tackers between group 1 and 2. IQR: Interquartile range; p-value >0.05, Chi-square test

Postoperative pain	Group 1 (n=40)	Group 2 (n=40)	Total	p-value*
<b>At 6 hours</b>				
Mean±SD	8.1±0.45	7.95±0.51	8.02±0.48	0.325
Median (IQR)	8 (8-8)	8 (8-8)	8 (8-8)	
Range	7-9	7-9	7-9	
<b>At 24 hours</b>				
Mean±SD	6.05±0.94	5.6±1.1	5.82±1.03	0.231
Median (IQR)	6 (5.75-7)	6 (5-6)	6 (5-6.25)	
Range	4-8	3-7	3-8	
<b>At discharge</b>				
Mean±SD	2.3±0.47	2.4±0.5	2.35±0.48	0.512
Median (IQR)	2 (2-3)	2 (2-3)	2 (2-3)	
Range	2-3	2-3	2-3	
<b>After 1 week</b>				
Mean±SD	1.1±0.31	1.05±0.22	1.08±0.27	0.553
Median (IQR)	1 (1-1)	1 (1-1)	1 (1-1)	
Range	1-2	1-2	1-2	
<b>After 1 month</b>				
Mean±SD	1±0	1±0	1±0	1.000
Median (IQR)	1 (1-1)	1 (1-1)	1 (1-1)	
Range	1-1	1-1	1-1	
<b>After 2 months</b>				
Mean±SD	1±0	1±0	1±0	1.000
Median (IQR)	1 (1-1)	1 (1-1)	1 (1-1)	
Range	1-1	1-1	1-1	
<b>After 3 months</b>				
Mean±SD	1±0	1±0	1±0	1.000
Median (IQR)	1(1-1)	1(1-1)	1(1-1)	
Range	1-1	1-1	1-1	

**[Table/Fig-3]:** Comparison of postoperative pain between group 1 and 2. SD: Standard deviation; IQR: Interquartile range; \*Mann-Whitney test; p-value is significant if less than 0.05

to be 8.1±0.45 and 7.95±0.51, 6.05±0.94 and 5.6±1.1, 2.3±0.47 and 2.4±0.5, 1.1±0.31 and 1.05±0.22, 1±0 and 1±0, 1±0 and 1±0, 1±0 and 1±0, respectively. Statistical analysis shows that there was no significant correlation of group 1 and group 2 with postoperative pain (p-value >0.05).

### 3. Comparison of seroma at 3 months between group 1 and 2 [Table/Fig-4]

Seroma at 3 months	Group 1 (n=40)	Group 2 (n=40)	Total	p-value <sup>§</sup>
No seroma developed	38 (95%)	40 (100%)	78 (97.50%)	1.000
Seroma developed	2 (5%)	0	2 (2.50%)	
Total	40 (100%)	40 (100%)	80 (100%)	

**[Table/Fig-4]:** Comparison of seroma at 3 months between group 1 and 2. <sup>§</sup>Fisher Exact test, p-value is significant if less than 0.05

At 3 months follow-up period, in group 1, 2 out of 40 patients developed seroma while none of the patients in group 2 developed seroma. This association was found to be statistically insignificant (p-value=1.000).

### 4. Comparison of paralytic ileus between group 1 and 2.

No paralytic ileus was found in both the groups in any patient.

### 5. Comparison of duration of hospital stay (days) between group 1 and 2 [Table/Fig-5]

Duration of hospital stay (Days)	Group 1 (n=40)	Group 2 (n=40)	Total	p-value
2 days	28 (70%)	28 (70%)	56 (70%)	0.801 <sup>^</sup>
3 days	8 (20%)	10 (25%)	18 (22.50%)	
4 days	4 (10%)	2 (5%)	6 (7.50%)	
Mean±S.D	2.4±0.68	2.35±0.59	2.38±0.63	0.919 <sup>*</sup>
Median (IQR)	2 (2-3)	2 (2-3)	2 (2-3)	
Range	2-4	2-4	2-4	

**[Table/Fig-5]:** Comparison of duration of hospital stay (days) between group 1 and 2. SD: Standard deviation; IQR: Interquartile range; <sup>^</sup>Chi-square test; <sup>\*</sup>Mann-Whitney test; p-value is significant if less than 0.05

Postoperative hospital stay was 2.4±0.68 days in group 1 while it was 2.35±0.59 days in group 2. Maximum number of patients 56 (70%) were discharged on postoperative day 2, 18 (22.5%) were discharged on postoperative day 3 and 6 were discharged on postoperative day 4.

On Mann-Whitney test, no significant association was found between hospital stay duration and type of tackers used.

### 6. Comparison of recurrence at 3 months between group 1 and 2

No significant difference was seen in postoperative pain, seroma formation, occurrence of paralytic ileus, hospital stay duration and early recurrence between group 1 and 2 with p-value >0.05. There were no early recurrences in both the groups.

## DISCUSSION

The mean age of this study sample was 37.33 years with a range of 21 to 60 years, of which 46 patients (57.50%) were females and 34 patients (42.50%) were males. In the study by Colak E et al., 15.6% of non absorbable tackers group and 52.9% of absorbable tackers group were females [17]. In contrast to this, in a study conducted by Bangash A and Khan N males outnumbered females in suture and tackers group [12].

Similar to present study, Bansal VK et al., also did not find any significant difference in the incidence of immediate postoperative and chronic pain over a mean follow-up of 8.8 months (n=90) [15]. Vallabhshai DS et al., also found no significant difference in the mean pain score between AT group and NAT group which were 6.47±1.57 and 6.6±1.19, respectively (p-value >0.5) [18]. Similarly, Colak E et al., also found no significant difference in the mean pain score



between AT and NAT groups at 0, 1 and 2 days [17]. Khan RM et al., in their meta-analysis also concluded that there was no significant difference in the pain with type of tackler used (p-value= 0.64) [19]. Many of the studies conclude recommending a study with larger sample size and long term follow-up to identify any difference in chronic pain [20-23].

At three months follow-up period, in AT group, 2 out of 40 patients developed seroma while none of the patients in NAT group developed seroma. This association was found to be statistically insignificant (p-value=1.000). This result obtained was different from the results obtained by Colak E et al., who found that seroma formation was statistically significantly observed in AT group [17]. Prakash P et al., also concluded that there was no statistically significant difference between groups (AT and NAT group) in terms of seroma formation [20]. A meta-analysis conducted by Khan RM et al., also concluded that there was no significant association of seroma with type of tacklers used (p-value=0.9600) [19]. Contrary to this study, Smith AM et al., in their study found out more seroma formation in non absorbable tackler group [21].

In present study, paralytic ileus was absent in all the patients with no difference in the incidence of paralytic ileus between group 1 and 2. Prakash P et al., also in their study concluded that there was no statistically significant difference between groups (AT and NAT group) in terms of incidence of postoperative paralytic ileus [20]. A meta-analysis conducted by Khan RM et al., concluded that there was no significant association of paralytic ileus with type of tackler used (p-value=0.99) [19]. However, Colak E et al., concluded that there was statistically significant association between the incidence of postoperative paralytic ileus and use of absorbable tackers [17].

Early recurrences were not observed in any of the patients in both group 1 and group 2. Prakash P et al., also in their study concluded that there was no statistically significant difference between groups (AT and NAT group) in terms of hernia recurrences [20]. In contrast, in the study by Colak E et al., as there was statistically significant association between hernia recurrence and the use of absorbable tackers [17]. Comparison of the present study results with previous published literature has been mentioned in [Table/Fig-6] [15, 17, 18, 19, 22, 23].

Authors	Year	Sample size	Recurrence	Pain
Colak E et al., [17]	2015	51	No difference p-value=0.685	No difference p-value=0.079
Christoffersen MW et al., [22]	2015	816	Absorbable tackers associated with recurrence p-value=0.007	No difference p-value=0.765
Bansal VK et al., [15]	2016	90	-	No difference p-value <0.01
Khan RM et al., [19]	2018	1149	No difference p-value=0.47	No difference p-value=0.64
Vallabhshai DS et al., [18]	2018	1091	Absorbable tackers associated with recurrence p-value<0.001	No difference p-value=0.260
Harslof SS et al., [23]	2018	75	-	No difference p-value=0.25
Present study	2021	80	No difference p-value >0.05	No difference p-value >0.05

**[Table/Fig-6]:** Comparison between the present study and other published studies [15, 17, 18, 19, 22, 23].

In present study, mean postoperative hospital stay was 2.4±0.68 days in the AT group while it was 2.35±0.59 days in the NAT group. Maximum number of patients 56 (70%) were discharged on postoperative day 2. In the study conducted by Vallabhshai DS et al., hospital stay duration was 1.5±0.572 days and 1.43±0.679 days in AT and NAT, respectively [18]. It was not found to be statistically significant as in the present study. However, in study by Colak E et al., mean duration of hospital stay was 2.1 days and 2.5 days for AT group and NAT group, respectively, and had no significant difference [17].

## Limitation(s)

The sample size is small. The center being a tertiary care center and referral center, the study may have centripetal bias. The follow-up period of the study is short to pick up only early recurrences.

## CONCLUSION(S)

This study has shown that both non absorbable and absorbable tackers are associated with minimal postoperative complications and have similar postoperative morbidity. It is further concluded that using absorbable tackers or non absorbable tackers during laparoscopic ventral hernia repair have no additional benefit in terms of postoperative pain, seroma formation, duration of hospital stay, early recurrence. As such, both non absorbable and absorbable tackers are safe and feasible for mesh fixation during laparoscopic hernia repair. In an era where absorbable tackers are dominating the market, it is suggested that further multicentric studies with large sample size are needed to evaluate for any advantage of using non absorbable tackers during laparoscopic repair of ventral hernia.

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**PLAGIARISM CHECKING METHODS:** [\[Lain H et al.\]](#)

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