

## Outcome of Onlay Prolene Mesh Fixation using Skin Staplers in Ventral Hernia

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### Abstract

**Background and Purpose:** Ventral hernia is a common surgical problem, with an annual incidence of 10 - 50%. Repair of the ventral hernia is required to relieve the symptoms, and to prevent incarceration. Mesh repair herioplasty decreases the long term recurrence risk around 50%, when compared to suture repair herioplasty. Both recurrence and chronic postoperative pain etiology are multifactorial, that may be related to mesh application technique, type of mesh, or method of fixation as well. Ongoing refinements in surgical technique and the advancement of mesh technology are essential to have the ideal treatment for incisional hernia repair. losis worldwide.

**Objective of the Study:** The objectives is to compare mesh fixation in ventral hernia using skin staplers with the classic prolene suture fixation in terms of early endpoints like operative time, cost, seroma and late outcome like sinus formation and chronic pain and recurrence.

**Methods:** This study was carried on 40 patients with ventral hernia in two departments, the department of General Surgery, Zagazig University Hospitals, and the department of Hepatobiliopancreatic(HBP) surgery of the National Hepatology & Tropical Medicine Research Institute (NHTMRI) in Cairo, during the period from December 2015 to May 2017. The patients divided into two groups: Group (A): includes 20 patients mesh fixation was done with skin staplers. Group (B): includes 20 patients mesh fixation was done with the classic prolene suture fixation.

**Results:** The age of the studied patients in group (A) ranging from 18 - 50 years old with mean  $33.0 \pm 6.2$  and in group (B) ranging from 20 - 55 years old with mean  $35.4 \pm 6.5$  Group (A) has shorter operative time and less seroma and wound infection and no difference between both groups as regard postoperative sinus formation, pain, recurrence and hospital stay.

**Conclusion:** Conclusions application of skin stapler device to fix the mesh in ventral hernioplasty operations provides staples with good penetration into the tissue and secure fixation of the mesh, so that rendering this method effective and technically easier. The staples can save the operative time than sutures for mesh fixation as it is applied quickly. The use of staples is not associated with any increase in postoperative pain and is not associated with any increase in complications as compared to the use of sutures. The use of staples is cost effective in comparison to the suture.

**Keywords:** Prolene; Skin Staplers; Ventral Hernia

### Background

Ventral hernia is a common surgical problem, with an annual incidence of 10 - 50% [1].

“Ventral hernia” is defined as a protrusion of loops of intestine, fat, or fibrous tissue through a defect or weakened region of the abdominal wall. The protrusion may involve, for example, preperitoneal fat, intestinal contents, or omentum [2].

Ventral hernia is classified according to its cause into primary and secondary types. Primary ventral hernia occurs because of primary defect in abdominal wall fascia, which can cause umbilical hernia, paraumbilical hernia, epigastric hernia, or spigelian hernia. Secondary ventral hernia ‘incisional hernia’ occurs because of herniation through a weak abdominal scar, such as scar of previous operation [3].

A number of risk factors are said to be responsible for ventral hernia formation which include previous surgery, radiation therapy, collagen disorders and syndrome of metastatic emphysema [4].

This incidence may increase due to the large number of laparotomies performed annually. Repair of the ventral hernia is required to relieve the symptoms, and to prevent incarceration [5].

Ventral hernia repair has technical difficulties, high morbidity, and relatively high recurrence rate especially with big defects which, because of lack of sufficient tissues, require defect bridging either by mesh implantation or autologous tissue reconstruction [6].

Although with the increased frequency of ventral herniorrhaphy use, it is somewhat surprising that the question of optimal choice of repair is not yet settled [7].

Mesh repair hernioplasty for ventral incisional hernia decreases the risk of recurrence around 50% compared to suture repair on the long term [8].

Both recurrence and chronic postoperative pain etiology are multifactorial, that may be related to mesh application technique, type of mesh, or method of fixation as well. Ongoing refinements in surgical technique and the advancement of mesh technology are essential to have the ideal treatment for incisional hernia repair [9].

Egger, *et al.* [10] have mentioned a new technique by stapling of the applied mesh repair with good fixation and effective reduction in operative time, they reported no significant increase in the complications rate in the early postoperatively, as well during the follow-up.

We conducted the study to evaluate the efficacy of using skin stapler for mesh fixation in ventral hernia.

### Aim of the Work

To compare mesh fixation in ventral hernia using skin staplers with the classic prolene suture fixation in terms of early endpoints like operative time, cost, seroma and late outcome like sinus formation and chronic pain and recurrence.

### Patients and Methods

#### Study design

It is a Prospective randomized controlled study that was carried out on 40 patients all with primary ventral hernia. All patients signed an informed consent, adequate information was accurately given (the surgical technique, benefits and possible morbidities), simply randomized by closed envelop method in which a comparison was held between 2 groups of patients with ventral hernia:

The 40 patients were randomly classified in to 2 different groups of treatment:

1. **Group (A):** Mesh fixation was done with skin staplers. It includes 20 patients. They were 12 female and 8 male.
2. **Group (B):** It includes 20 patients mesh fixation was done with the classic prolene suture fixation. They were 10 female and 10 male.

**Study setting and time:** This study was conducted in two departments, the department of general surgery, Zagazig University Hospitals, and the department of Hepatobiliopancreatic (HBP) surgery of the National Hepatology and Tropical Medicine Research Institute (NHT-MRI) in Cairo, from December 2015 till May 2017.

#### Inclusion criteria

- Age: between 18 and 60 years old.
- Co-morbidities: ASA class I or II.
- Sign of the informed consent.

#### Exclusion criteria

- Age: less than 18 or above 60 years old.
- Recent history of alcohol or drug abuse, current therapy of any anticonvulsant or immunosuppressive, inability to cooperate with the requirement of the study.
- Female patients with early or late pregnancy.
- Ventral hernia with infection, irreducibility or strangulation.
- Patients participating in other clinical trials.

All our patient are subjected to the following:

### Full history

- **Personal history:** Name, age, sex, residence, date of admission and telephone number; other habits of medical interest.
- **Past history:** Medical and surgical history.

### Full Clinical Assessment

**Presenting symptoms as:** Visible bulge in abdomen especially with cough or strain pain or pressure at hernia site.

### Signs as:

- Ventral hernia (site, size of the defect in the anterior abdominal wall) and hernia complication (irreducible, obstructed and strangulated).
- Digital rectal examination.

### Investigations

#### 1. Routine pre-operative investigations

- CBC, coagulation profile (PT, PTT and INR), Liver and Kidney function tests, random blood sugar and ECG.

#### 2. Imaging studies: Chest x ray and Abdominal ultrasound

### Patient preparation

The technique and possible complications were explained to the patient and informed consent was obtained. The patient was kept NPO for 6 hours prior to the procedure. Prophylactic antibiotics (ceftriaxone I.V 1g) were given with the induction of anaesthesia and continued for the whole following week. Patients were admitted to the hospital on the day of the operation. All patients fulfilled the criteria of the American Society of Anaesthesiology (ASA) for fitness for surgery and anaesthesia.

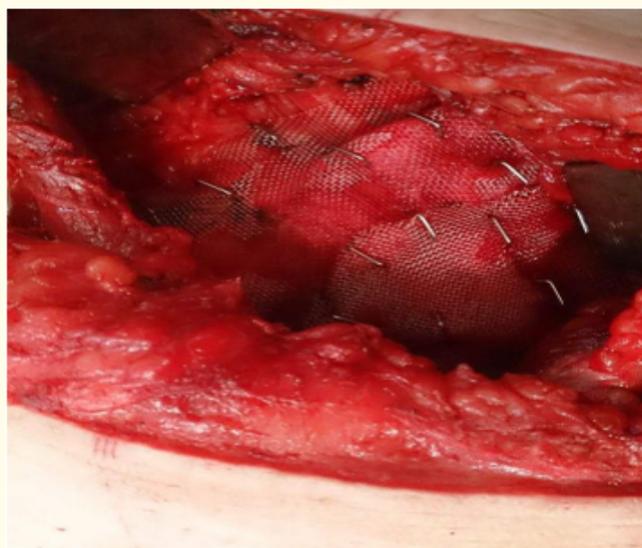
### Methods

Under general anesthesia and endotracheal incubation. Operations were performed with the patient in the supine position. Design of incision was performed according to the status of skin redundancy. transverse skin incision was done with no skin redundancy. Subcutaneous dissection was carried out to expose the hernia sac and its neck. The dissection was extended laterally to 5 cm lateral to hernial defect. Dissection was extended upward till xiphisternum in cases with divaricated recti. Herniotomy was done, and the abdominal wall

The external oblique aponeurosis was closed in all patients(of both groups) using a 0 Prolene (Ethicon), in a continuous manner.

**Group (A):** Include 20 patients; the mesh was fixed by skin staplers (Figure 1). We use a Proximate PX Stapler (Ethicon), it contains 35 preloaded stainless steel staples. All staples have an approximate diameter of 0.53 mm, a span of 5.7 mm, and a leg length of 3.9 mm. The staples were placed 1 - 2 cm apart.





**Figure 1:** Mesh fixation was done with skin staplers.

**Group (B):** Include 20 patients mesh was fixed in position by interrupted sutures of 2/0 Prolene (Ethicon).



**Figure 2:** Mesh fixation was done with the classic prolene suture.

In both groups the subcutaneous tissue were then approximated with 2/0 vicryl. Skin closure was in the staple group, the skin was closed using the remaining staples from the stapler. Closure of the skin with a continuous subcuticular manner using vicryl rapide 3/0 suture (Ethicon) In the polypropylene group.

The operative time from the start of mesh application to completion of skin closure was recorded to the nearest 30 seconds.

**Post-operative care and follow up:** Antibiotics were given postoperatively to all patients for one week. The patients were discharged 24h after the operation. Instructions on discharge included avoidance of straining or carrying heavy objects for the following 3 months. Postoperative patients were made ambulatory the same day of surgery(D0). Normal activity was permitted a week after. Follow-up visits

were scheduled on fifth, seventh, and 14<sup>th</sup> days for assessment of wound complications such as seroma, infection, and prolonged hospital stay, Drain removal was done after minimal output serous discharge (20 ml/day). Further follow-up visits were scheduled at 3, 6 months, 1 year and annually for assessment of sinus formation, chronic pain and hernia recurrence.

**Statistical analysis**

The collected data were computerized and statistically analyzed using Statistical Package for Social Science (SPSS) program version 20. Variables presented as number and percentage (qualitative data) and as mean ± stander deviation (SD) and range (quantitative continues data). Pearson chi-squared (X2) and Fisher exact tests were used to compare categorical variables and Independent t-test (t) used for continuous variables. P values < 0.05 and < 0.001 were considered statistically significant and highly statistical significant respectively.

**Results**

Variables		Group A (skin stapler)	Group B (suture)	Test	P value
Age (years)	(Mean ± SD)	33.0 ± 6.2	35.4 ± 6.5	<sup>a</sup> 1.20	0.24
	(range)	(18 - 50)	(20 - 55)		
Gender (M/F)	No (%)	8/12 (40%/60%)	10/10 (50%/50%)	<sup>b</sup> 0.40	0.53

**Table 1:** Age and gender distribution in both groups.

<sup>a</sup>: Independent t-test (t)

<sup>b</sup>: Chi-square (X<sup>2</sup>)

This table shows no significant difference regard both age or gender between both groups.

		Group A (skin stapler) No (%)	Group B (suture) No (%)	Test	P
Type of hernia	PUH	11/20 (55%)	12/20 (20%)	Fisher	0.99
	Epigastric	4/20 (20%)	3/20 (15%)		
	Umbilical	3/20 (15%)	2/20 (10%)		
	Incisional	1/20 (5%)	1/20 (5%)		
	Recurrent PUH	1/20 (5%)	1/20 (5%)		
Total		20/20 (100%)	20/20 (100%)		

**Table 2:** Type of hernia in both groups.

This table shows that PUH are most common type of ventral hernia no significant difference regard both age or gender between both groups.

	Group A (skin stapler)	Group B (suture)	t	P
Operative time (min) (mean ± SD)	30.6 ± 5.3	46.2 ± 6.5	8.3	< 0.0001**

**Table 3:** Operative time distribution in both groups.

This table shows that Group (A) technique has significantly shorter operative time.

		Group A (skin stapler)	Group B (suture)	Total	Test	P
Wound seroma	No (%)	1/20 (5%)	4/20 (20%)	5/40 (12.5%)	Fisher	0.15

**Table 4:** Postoperative seroma in both groups.

This table shows one case (5.0%) in group (A) and four cases (20.0%) in group (B) associated with postoperative wound seroma. There no significant difference regard wound seroma between both groups.

		Group A (skin stapler)	Group B (suture)	Total	Test	P
Wound infection	No (%)	1/20 (5%)	3/20 (15%)	4/40 (10%)	Fisher	0.29

**Table 5:** Postoperative wound infection in both groups.

This table shows one cases (5.0%) in group (A) and three cases (15.0%) in group (B) associated with postoperative wound infection. There no significant difference regard postoperative wound infection between both groups.

		Group A (skin stapler)	Group B (suture)	Total	Test	P
Sinus formation	No (%)	1/20 (5%)	2/20 (10%)	3/40 (7.5%)	Fisher	0.54

**Table 6:** Postoperative sinus formation in both groups.

This table shows one case in group (A) and two case (5.0%) in group (B) associated with postoperative sinus formation. There is no significant difference as regard sinus formation between both groups.

		Group A (skin stapler)	Group B (suture)	Total	Test	P
Postoperative pain	No (%)	1/20 (5%)	1/20 (5%)	2/40 (5%)	Fisher	1

**Table 7:** Postoperative chronic pain in both groups.

This table shows one case (5.0%) in group (A) and one case (5.0%) in group (B) associated with postoperative chronic pain. There is no significant difference as regard postoperative pain between both groups.

		Group A (skin stapler)	Group B (suture)	Total	Test	P
Recurrence	No (%)	1/20 (5%)	2/20 (10%)	3/40 (7.5%)	Fisher	0.54

**Table 8:** Postoperative recurrence in both groups.

This table shows one cases in group (A) and two case (5.0%) in group (B) associated with postoperative recurrence. There is no significant difference as regard hernia recurrence between both groups.

Hospital stay			Groups		Test	P
			Group A (skin stapler)	Group B (suture)		
Stay	One day	No	19	17	Fisher	0.29
		%	95.0%	85.0%		
	Prolonged	No	1	3		
		%	5.0%	15.0%		
Total		No	20	20		
		%	100.0%	100.0%		

**Table 9:** Hospital stay in both groups.

This table shows one cases (5.0%) in group (A) and three cases (15.0%) in group (B) associated with prolonged hospital stay(3 days) to control postoperative wound infection.

## Discussion

Early treatment of hernia is very important to reduce the risk of obstruction and or strangulation [11].

The optimum treatment method for these hernias is still under debate and there are no guidelines recommend the most appropriate treatment [12].

Mayo described his technique of hernia repair. It was recognized as the classical method for the repair of umbilical hernia [13]. From that time, many advanced techniques have been developed for ventral hernia repair, with not enough evidence still to support a single technique.

Luijendijk, *et al.* [14] reported that mesh repair is superior to suture repair regarding the recurrence of hernia, regardless of the size of the hernia.

Skin staplers use for mesh fixation in inguinal hernia repair has been described by Egger, *et al.* [10] and Mills *et al* [15].

In the present study the age of the studied patients in group (A) ranging from 18 - 50 years old with mean  $33.0 \pm 6.2$  and in group (B) ranging from 20 - 55 years old with mean  $35.4 \pm 6.5$ . There was no significant difference as regard age in both groups.

Also, in our study there was statistically significant difference as regard the operative time as cases managed using the skin stapler technique have shorter operative time with mean  $30.6 \pm 5.3$  minutes than cases managed using the prolene suture technique with mean  $46.2 \pm 6.5$  minutes. The use of skin staples save the operative and anesthetic time, hence reducing the risk of general anaesthesia and the operating theatre cost.

Other studies found that the application of staples for fixation of the mesh in Lichtenstein repair with reduction in the operative time is the main advantage.

About 12 minutes difference was recorded between groups I and II, which was significant ( $P < 0.001$ ). So, the stapling technique for mesh fixation is more quickly than sutures hence save much of the operative time, as well as, reduce the tissue handling, so that reduces the risk of wound infection, and also the risks associated with prolonged anaesthesia [15,16].

As regard Postoperative seroma, group (A) include one case (5.0%) while group (B) include four cases (20.0%) All of them resolved within 2 - 3 weeks with conservative management.

Munghate, *et al.* (2014) found that in Lichtenstein repair Postoperative seroma with using skin staples technique for securing the mesh is less than using polypropylene sutures technique [17] while other authors report that the seroma formation was almost equal in both groups and no significant difference was observed between the two groups. The swelling and induration of wound were transient and settled without intervention [16-19].

As regard Postoperative wound infection there is only one case (5.0%) in group (A) and three cases (15.0%) in group (B) associated with postoperative wound infection.

In group (A) the short operating time reduces the exposure time of the mesh, hence lowering the risk of mesh colonization.

Van der Zwaal [18] and colleagues showed no postoperative wound infection. The inert coating covering the stainless steel staples was possibly suggested as a contributing cause for less infective results. Hence, the rate of wound infection is significantly less with the use of staples, supposed to, but further studies and larger numbers of patients are needed to confirm it. Local use of gentamycin may have a beneficial effect without increasing serum levels [20].

Other studies found that in Lichtenstein repair the infection rate was significantly higher in securing the mesh using polypropylene sutures technique [17,19].

As regard Postoperative sinus formation, This study shows two cases (10.0%) in group (B) after stitch abscess and one case (5.0%) in group (A) associated with postoperative sinus formation. There was no significant difference between both groups.

Other studies found that in Lichtenstein repair stitch abscess was more in securing the mesh using polypropylene sutures technique [17,21].

As regard Postoperative pain This study shows one case (5.0%) in group (A) and one case (5.0%) in group (B) associated with postoperative chronic pain. There is no significant difference as regard chronic pain between both groups.

Other studies stated that in Lichtenstein repair there was no difference in the pain scores in in securing the mesh using polypropylene sutures technique or stapler technique [11,17,18].

In our study there was one case (5.0%) in group (A) and two cases (10.0%) in group (B) associated with postoperative recurrence. No difference between both groups as regard hernia recurrence at 3, 6, 12 months.

Some studies stated that in Lichtenstein repair there was no difference in the recurrence between polypropylene sutures technique or stapler technique [17,19,22].

Van der Zwaal [18] and colleagues reported that in Lichtenstein repair the recurrence was decreased in stapler technique than polypropylene sutures technique [18].

Also all cases were discharged in the 1st post-operative day except one cases (5.0%) in group (A) and three cases (15.0) in group (B) associated with postoperative wound infection was discharged in the 3rd post-operative day.

Munghate., *et al.* (2014) stated that in Lichtenstein repair the hospital stay was decreased in stapler technique than polypropylene sutures technique [17].

Other study stated that in Lichtenstein repair there was no difference in the hospital stay between polypropylene sutures technique or stapler technique [19].

### Conclusion

- Skin stapler provides a very good penetration into the tissues, have a secure fixating technique for the mesh application. So, rendering this method highly effective and technically easier.
- The staples can save the operative time than sutures for mesh fixation as it is applied quickly.
- The use of staples is not associated with any increase in postoperative pain and is not associated with any increase in complications as compared to the use of sutures. The use of staples is cost effective in comparison to the suture.

**From the results obtained from this work:** Staples technique is considered a better option for mesh fixation, when compared to conventional suture technique.

These preliminary results require further evaluation with a larger group of patients to establish and study the impact of shorter operative time on postoperative morbidities regarding postoperative infection and recurrence rates and more.

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