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A Prospective Randomized Study Comparing Skin Staples and Polypropylene Sutures for Securing the Mesh in Lichtenstein's Repair

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Abstract

Objective: The aim of the study was to compare the duration of surgery and postoperative outcome of securing mesh with skin staples versus polypropylene sutures in Lichtenstein hernia repair.
Method: A total of 96 patients with inguinal hernia undergoing Lichtenstein mesh repair were randomly assigned into two groups. The mesh was secured by using either skin staples (group I) or polypropylene sutures (group II).
Results: Mesh fixation with skin staples is as effective as conventional sutures with the added advantage of significant reduction in the operating time and complications.
Conclusions: The staples can be applied much more quickly than sutures for fixing the mesh, thus saving the operating time. The infection rate is significantly decreased with staples. The staples are not associated with any significant complications or recurrence.

Key words: *Inguinal hernia, hernioplasty, inguinal canal, pain, operative time*

Introduction

Hernia is defined as a protrusion of a viscus or a part of viscus through an abnormal opening in the wall of its containing cavity. The most frequent of all hernias is inguinal hernia, which occurs in 73% of all hernia cases and is 20 times more frequent in males than females [1].

Lichtenstein (1989) reported that excessive tension on the suture line resulted in the high recurrence rate after the primary repair. In 1989, Lichtenstein et al. concluded that with tension-free mesh repair of hernia, recurrence could be completely avoided. Although many new techniques are available today for hernia repair (plug and patch, TEP, TAPP, PHS), Lichtenstein tension-free repair is the most commonly used technique due to cost effectiveness, low recurrence rate, and better patient

satisfaction [2]. The Lichtenstein repair takes into account the important factors identified in the successful outcome of hernia operation — supplementing the strength of transversalis fascia and a tension-free repair. The only disadvantage of the mesh operation is that it requires the use of prosthetic material with attendant risk of infection. Any modification which reduces this threat would be useful.

The main cause of recurrence of hernia is "Suture Line Tension" brought by suturing of overcasting between the annular and ligamentous flap, which are not normally in apposition. The valuable sling and shutter mechanism are destroyed by the tension created by suture material on tissues. A needle hole also causes damage to the tissue [3,4].

The latest trial in this aspect is securing mesh with use of skin staples instead of the usual polypropylene sutures. Staples are applied with a Proximate Plus MD (multidirectional) Release Skin Stapler. Staples are quick to use and reduce the operating time and minimize the risk of wound infection [5].

Materials and Methods

This study was carried out in the tertiary care center from June 2010 to June 2012. Ninety six adult patients (>18 yrs) with primary inguinal hernias were included in the trial, all as elective cases. Inclusion criteria were as follows: age >18 and <70, non-obstructed or strangulated hernia, non-recurrent hernia. Exclusion criteria were as follows: age <18 and >70, strangulated or obstructed hernia, recurrent hernia. After taking the informed consent, patients were randomized either to group I (where the mesh was secured with staples) or group II (where the mesh was sutured with polypropylene sutures) by distributing either a yellow (group I) or red (group II) card. Two patients in each group underwent bilateral inguinal hernia repair, thus making 50 mesh repairs in each group. Most of the operations were done under spinal anesthesia. A single dose of intravenous cefotaxime at 1 g was administered 1 hour prior to surgery. Direct hernia sacs were plicated, while very small ones were reduced or unopened. Small indirect sacs were dissected from the spermatic cord and divided. They were then transfixed and the distal part excised. A sheet of polypropylene mesh (11 x 6 cm) was cut to shape and laid over the posterior wall of the inguinal canal so that it overlapped the pubic tubercle by at least 1 cm medially, and extended superiorly to lay over the conjoint tendon and to a point at least 2 cm lateral to the internal ring. In group II, mesh was fixed in position by interrupted sutures of 2/0 Prolene (Ethicon, Johnson & Johnson, USA) along the inguinal ligament inferiorly from the pubic tubercle to the lateral edge of the mesh. Interrupted polypropylene sutures were then placed medially and superiorly into the internal oblique and transversalis muscles. The spermatic cord was passed through a slit in the mesh. Lateral to it the overlapping free edges of the mesh were sutured together with two interrupted polypropylene sutures. In group I the positioning of the mesh was identical but a Proximate Plus MD (multidirectional) Release Skin Stapler (Ethicon, Johnson & Johnson, USA) containing 35 preloaded stainless steel staples was used to secure it. A staple was placed into the pubic tubercle with between seven and nine staples along the inguinal ligament placed 1–2 cm apart (Figure 1). A further four to five staples were placed in the internal oblique and transversalis muscle medially and superiorly and the overlapping free edges of the mesh were stapled together with two staples lateral to the cord (Figures 2, 3). In both groups the external oblique aponeurosis was closed with a continuous suture of 2/0 Prolene (Ethicon, Johnson & Johnson, USA) and the subcutaneous tissue was then approximated with 2/0 vicryl. Skin closure was completed in group II using interrupted sutures of 3/0 Ethilon (Ethicon, Johnson & Johnson, USA), which were removed 7 days after surgery.

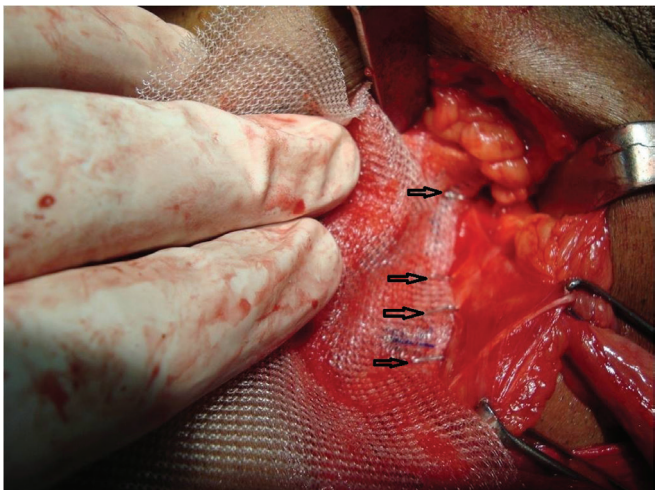

Figure 1. Arrow head showing staples along the inguinal ligament and pubic tubercle.

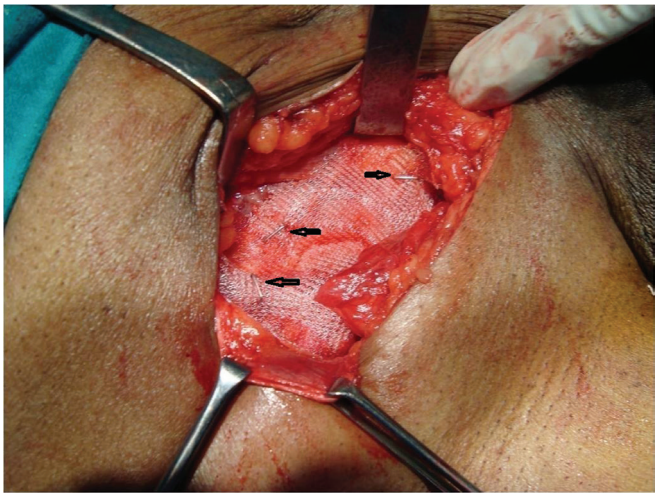

Figure 2. Arrow head showing staples along the Transversalis Fascia and Conjoint Tendon.

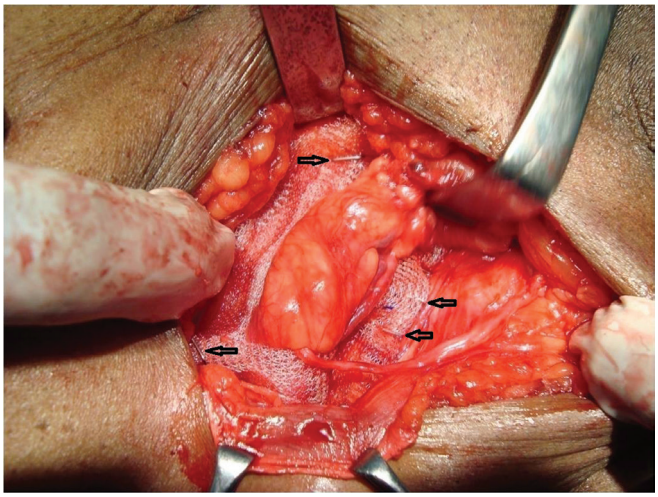

Figure 3. Arrow head showing staples along the inguinal ligament laterally and conjoint tendon and fascia transversalis medially.

In group I, skin closure was completed using staples from the same staple gun. Staples were removed 7 days after operation. The time taken from the skin incision to the beginning of the mesh insertion and from the beginning of the mesh insertion to completion of skin closure was recorded to the nearest 30 seconds. Antibiotics were given post-operatively to all patients for one week. Post-operative patients were made ambulatory the day after surgery. Normal activity was permitted a week after. Strenuous exercise was discouraged for a month. Post-operative complications such as infection, hematoma, requiring drainage or in-patient admission, pain significant enough to cause alteration in lifestyle (assessed by a visual analogue scale), non-infectious urinary complications including acute urinary retention that prolonged the hospital stay, post-operative ileus, and other miscellaneous complications were noted daily. Patients were discharged as soon as possible depending on the post-operative condition of the patient. All cases were performed by an experienced team of surgeons.

Patients were called into the out-patient department on the 7th post-operative day, 2–3 weeks post-op, 1–2 months later, and then for further follow-up till 12–18 months. Check-up for any complication and recurrence was carried out in detail and the observations were recorded.

Statistical analysis was performed using the unpaired "t" test for continuous variables and Pearson chi-square and Fisher's exact test for categorical variables.

Results

Ninety-six adult patients (>18 yrs) with primary inguinal hernias entered into the trial. There was no significant difference in the demographic profile between the two groups (Table 1).

The median duration of surgery in the staple group was 62 mins, whereas in the suture group there was a 74-min difference of 12 mins. This difference was mainly because of the time difference from the mesh insertion to the completion of the surgery. The difference in time from the skin incision to the mesh insertion was not significant between the two groups, but the difference in time from the mesh insertion to completion of the surgery was significant (p=0.0001). The differences in the total operating time between the two groups were also significant (p=0.007) (Table 2).

In the present study, no significant difference was seen in post-operative pain in either group.

Complications: six patients in the staple group and

Table 1. Demographic profile, type of hernia.

	Staple Group (I)	Suture Group (II)	P value
Age in years*	48 (26-68)	46 (24-60)	0.31
Sex :			
M	48	47	1.00
F	0	1	
Type of hernia			
Bilateral	2	2	
Indirect	34	38	0.67
Direct	16	12	

*Mean (min-max)

four patients in the suture group had urinary retention. Wound infection was seen in two patients in the staple group and in 12 patients in the suture group. Of these 12 patients, six patients had serosanguinous discharge, four developed wound gaping, and two patients had minimal discharge. The difference was found to be significant (p=0.0076).

In the suture group, six patients presented with wound seroma. All of them resolved within 2–3 weeks with conservative management. Two patients in the suture group had scrotal swelling and a scrotal hematoma each. Swelling was managed conservatively and hematoma was aspirated. Four patients presented with stitch abscess in the suture group. None of the above complications were seen in the staple group (Table 3).

Table 2. Comparison of Operative Time: Time one (T1), Time two (T2) and Total operative Time (TOT) in two groups.

	Mean	SD
Staple group (I)		
T1	41.3	9.0
T2	20.7*	6.9
Total	62.0**	14.4
Staple group (II)		
T1	41.3	8.8
T2	32.7*	8.3
Total	74.2**	16.2

*p=0.0001 HS **p=0.007 HS
T1-The time (minutes) taken from the skin incision to the beginning of the mesh insertion.
T2- The time (minutes) taken from the beginning of the mesh insertion to completion of skin closure was recorded to the nearest 30 seconds.

Discussion

The treatment of inguinal hernia has evolved over the past 15 years when truss support was used and operation was reserved for life-threatening situations. Now hernia repair is done as an elective outpatient procedure [6].

Pure tissue repairs have a suture line after closure, which is under tension because the defect edges are approximated instead of being bridged. Suture line tension is at the heart of failed hernia repair and solving this problem would largely eliminate the recurrence [7]. Excessive tension on the suture line and the surrounding tissue leads to tissue ischemia, and suture cut out leads to recurrence [8].

In tension-free or mesh-based repair, synthetic mesh is usually used to strengthen the transversalis fascia to create a strong and tensionless repair [9]. Open mesh hernioplasty appears to be the gold standard when managing inguinal hernia [10].

Egger et al. first reported the use of skin staples for securing the mesh in the hernia repair [11]. Mills et al. [7] and Garg et al. [5] reported a similar study to compare the skin staples and polypropylene sutures for securing the mesh in inguinal hernioplasty.

The main advantage with application of staples for securing the mesh in Lichtenstein repair is reduction in the operative time. A difference of 12 minutes was found between the two groups in our study, which was significant. Our study results are comparable with those of previous studies such as Garg et al. [5] and Mills et al. [7]. According to Mills the difference can be important as shorter operation time may be associated with a

Table 3. Comparison of various complications in two groups.

	Staple group (I)	Suture group (II)	P value
Urinary retention	6(12%)	4(8%)	0.74
Wound echymosis	0	0	
Wound infection	2(4%)	12(24%)	0.00
Wound Hematoma	0	0	
Wound Seroma	0	6(12%)	0.02
Wound Abscess	0	0	
Scrotal Oedema	0	2(4%)	0.49
Scrotal Hematoma	0	2(4%)	0.49
Scrotal Abscess	0	0	
Stitch Abscess	0	4(8%)	0.11

reduced wound infection rate and also it decreases the risk of anesthesia [7].

In our study, with regard to previous studies such as Garg et al. [5], the staple used was a Proximate Plus MD (multi-directional) Release Skin Stapler. The staples are made from stainless steel with inert coating. The length of the prongs on the staples is 3.0 mm, which appears to be sufficient enough to provide good penetration into the tissue to fix the mesh. Mills had used a Proximate RH (rotating head) Skin Stapler in which accurate skin staple placement is facilitated by the design of the stapler whose head rotates by 360 degrees, thereby allowing maximum visibility and improved access [7].

Wound infection is a major cause of hernia recurrence [2]. Wound infection was seen in two patients in the staple group and 12 patients in the suture group. Of these 12 patients, six patients had serosanguinous discharge, four developed wound gaping, and two patients had minimal discharge. The difference between the two groups was found to be significant (p=0.0076). The incidence of decreased infection in the staple group could be because of the decreased operating time. The staples can be applied much more quickly than sutures, hence saving the operating time, less tissue handling, and reducing the risk of wound infection.

Van der Zwaal et al. [12] interestingly reported that there was no post-operative wound infection. They suggested that it could possibly be attributed to the inert coating covering the stainless steel staples. Thus, it may be inferred that the rate of wound infection is significantly less with the use of staples, but further studies are needed to confirm it.

There was no intra-operative or immediate post-operative hemorrhage, as well as any bladder/bowel/neurovascular injury in the present study. Gould SW suggested that it is safe to staple the mesh a little higher up on the inguinal ligament than one might with a suture [13]. Mills et al. [7] also said that the risk of damage to a major underlying vessel may be less than with insertion of conventional sutures.

In our study, six patients in the suture group presented with seroma of the wound. All of them resolved within 2–3 weeks with conservative management. None of the patients in the staple group had similar complaints. Garg et al. were the only authors to report this complication in both groups, but the seroma formation was almost equal in both groups [5].

In the present study, none of the patients in either group presented with nerve entrapment, showing there is no increased risk of entrapment neuropathy with the use of staples. Fligestone and Kingsworth stated that the use of staples in the laparoscopic inguinal hernia repair could damage the nerves and small blood vessel with harmful consequences due to relatively unsighted application of staples [14,15]. Cheek also stated that the use of staples is not without the risk of entrapment neuropathy; in early case series of laparoscopic hernia repair, this complication was not reported, but with the use of a stapler in later series, nerve injuries began to be described [16].

In the present study, no significant difference was seen in post-operative pain in both groups. Mills et al. have reported that there was no difference in pain score between the two groups [7]. Garg et al. also stated that there was no difference in the pain duration in both groups of their study [5]. Van der Zwaal et al. also reported that pain scores were similar in both groups [12].

Patients were followed up in the out-patient department on the 7th post-operative day, 2–3 weeks post-op, 1–2 months later, and then for further follow-up till 12–18 months. No recurrence was observed. There was no recurrence in the study conducted by Garg et al. [5] and Mills et al. [7], who followed the patients for 3–24 months and 12 weeks respectively. A very striking finding was by van der Zwaal et al. [12]: a high recurrence rate in the suture group (11%) compared to 1% in the staple group. Other authors have reported a recurrence rate of 0.5–3.7% in the traditional Lichtenstein repair procedure.

It is known that recurrent inguinal hernia occurs in the medial side. Therefore, it is important to position the mesh 1 cm medial to the pubic bone. Furthermore, a tension-free position of the mesh is advocated. Their hypothesis was that staple fixation is able to create a more tension-free position of the mesh than sutures, because sutures are more prone to tensioning than staples [12].

Thus, there is some evidence that securing the mesh with staples instead of sutures might reduce the recurrence rate. But a detailed study with prolonged follow-up is required to comment accurately on the recurrence rate of inguinal hernia in both groups.

Conclusion

The technique of Lichtenstein tension-free repair is simple, relatively easier to learn and less technically demanding.

In our study it was concluded that:

- The staples can be applied much more quickly than sutures for mesh fixation, thus saving the operating time.
- This technique of mesh fixation is as effective as conventional fixation with polypropylene sutures.
- The stapler placement with a skin stapler provides good penetration into the tissue with secure fixation of the mesh, making this method technically easier.
- Infection rate is significantly decreased with use of staples.
- The use of staples is not associated with any increase in post-operative pain.
- The use of staples is not associated with any increase in complications, as compared to the use of sutures.

Thus, in our opinion, staples may be a better option for fixation of mesh than conventional sutures.

This study needs to be evaluated further in a larger group of patients to explore the impact of reduced operative time on post-operative complications and recurrence rate.

Conflicts of Interest

The authors have no conflicts of interest to declare.

References

1. Kingsnorth AN, Porter CS, Bennett DH, Walker AJ, Hyland ME, Sodergren S. Lichtenstein patch or Perfix plug-and-patch in inguinal hernia: a prospective double-blind randomized controlled trial of short-term outcome. Surgery 2000;127:276-283.
2. Lichtenstein IL, Shulman AG, Amid PK, Montllor MM. The tension-free hernioplasty. Am J Surg 1989;157:188-193.
3. Andrews E. A method of herniotomy utilizing only white fascia. Ann Surg 1924;80:225-238.
4. Lytle W. The internal inguinal ring. Br J Surg 1945;32:441-446.
5. Garg CP, Bhatnagar AM, Parmar CD, Darshan JR, Sehgal RA. Comparative study of skin staples and polypropylene sutures for securing the mesh in lichtenstein's tension free inguinal hernia repair: A Prospective randomized controlled clinical trial. Indian J Surg 2004;66: 152-155.
6. Crawford DL, Phillips EH. Laparoscopic repair and groin hernia surgery. Surg Clin North Am 1998;78:1047-1062.
7. Mills IW, McDermott IM, Ratliff DA. Prospective randomized controlled trial to compare skin staples and polypropylene for securing the mesh in inguinal hernia repair. Br J Surg 1998;85:790-792.
8. Stephenson BM. Complications of open groin hernia repairs. Surg Clin North Am 2003;83:1255-1278.
9. Javid PJ, Brooks DC. Hernias. In: Zinner MJ, Ashley SW (eds.) Maingot's abdominal operations. McGraw Hill , New York, 2007; 103-141.
10. Douglas JM, Young WN, Jones DB. Lichtenstein inguinal herniorrhaphy using sutures versus tacks. Hernia 2002;6:99-101.
11. Egger B, Fawcett J, Dowling BL. Use of skin staples for securing the mesh in the Lichtenstein repair of inguinal hernia. Ann R Coll Surg Engl 1996;78:63-64.
12. van der Zwaal P, van den Berg IR, Plaisier PW, Tutein Nolthenius RP. Mesh fixation using staples in Lichtenstein's inguinal hernioplasty: fewer complications and fewer recurrences. Hernia 2008;12:391-394.
13. Gould SW. Use of skin staples for securing the mesh in the Lichtenstein repair of inguinal hernia. Ann R Coll Surg Engl 1996;78:235.
14. Fligelstone L, Wanendeya N, Palmer B. Use of skin staples for securing the mesh in the Lichtenstein repair of inguinal hernia. Ann R Coll Surg Engl 1996;78:398.
15. Kingsnorth AN. Use of skin staples for securing the mesh in the Lichtenstein repair of inguinal hernia. Ann R Coll Surg Engl 1996;78:398.
16. Cheek C. Use of skin staples for securing the mesh in the Lichtenstein repair of inguinal hernia. Ann R Coll Surg Engl 1996;78:398.