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Original Research Article

A comparative prospective randomised controlled study for mesh fixation by cyanoacrylate glue versus prolene sutures in patients undergoing Lichtenstein hernioplasty

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ABSTRACT

Background: Inguinal hernia repair is one of the most commonly performed procedures by general surgeons. Cyanoacrylate is the generic name for a family of fast acting adhesives. The aim of the present study done in Department of General Surgery, Safdarjung Hospital, New Delhi was to compare the newer emerging technique of mesh fixation.
Methods: A total of sixty patients were included in the present study and were allotted in case and control group randomly by sealed envelope technique. In case (study) group, all the patients underwent mesh fixation by cyanoacrylate glue and in control group, by prolene 3-0 sutures.
Results: Most frequency in age group 31-40 yrs, males:females ratio >1 and right sided inguinal hernia was more common. Bi-lateral hernia was common in elderly. Indirect: direct ratio 4.5:1. Operating time period for the patients of the case (study) group is less than control group. P value of post-operative pain in immediate post-operative period (day 1 and 2) and POD 30, 60 and 90 was not of clinical significance whereas the p-value on 6,120,150 and 180 post op day was of clinical significance. In our study, there was a case of incidental observation: a) reaction due to use of cyanoacrylate glue, b) rejection of mesh for which mesh had to be removed.
Conclusions: There is no statistically significant difference between mesh fixation with cyanoacrylate glue and mesh fixation by prolene suture techniques in immediate post-operative pain. Statistically significant difference favoring mesh fixation by cyanoacrylate glue technique was seen with respect to operating time and post-operative groin pain with increasing post-operative duration.

Keywords: Inguinal hernia, Lichtenstein tension free mesh hernioplasty, Cyanoacrylate, Pain

INTRODUCTION

Inguinal hernia repair is one of the most commonly performed procedures by general surgeons. 25% of men and 2% women develop inguinal hernia in their lifetime.[1] Despite the frequency of this procedure, complications such as postoperative pain, nerve injury, infection, and recurrence still remain the topic for discussion.

All modern repair techniques are very effective with regard to recurrence, and traditional end point recurrence has switched to other outcome measures such as patient comfort, satisfaction, and time to rehabilitation. Several

recent studies have shown that up to 10% of patients report moderate to severe pain within two years of surgery.[1] Much evidence suggest that hernia formation and recurrence depends in part on a systemic predisposition due to an abnormal metabolism of connective tissue and in part on the other risk factors, surgical as well as non-surgical.[2] High prevalence of inguinal hernia is well known among patients suffering from connective tissue disorders.[2]

The era of tissue based repair has been supplanted by tension free repair with the wide spread acceptance of prosthesis. Initially developed by Lichtenstein, the repair involved placement of polypropylene mesh over entire floor of inguinal canal and fixing it to the pubic periosteum and inguinal ligament with non-absorbable sutures which lead to risk of hernia recurrence compared with non-mesh methods. Chronic pain has been reported in 10 to 30% of patients.[3] The pain may be caused by irritation or damage to the inguinal nerves by sutures or mesh. Classic causes of chronic pain, such as osteitis pubis and ilio-inguinal nerve entrapment, are reported from a management perspective.[4] The majority of chronic pain has been attributed to ilio-inguinal nerve entrapment.

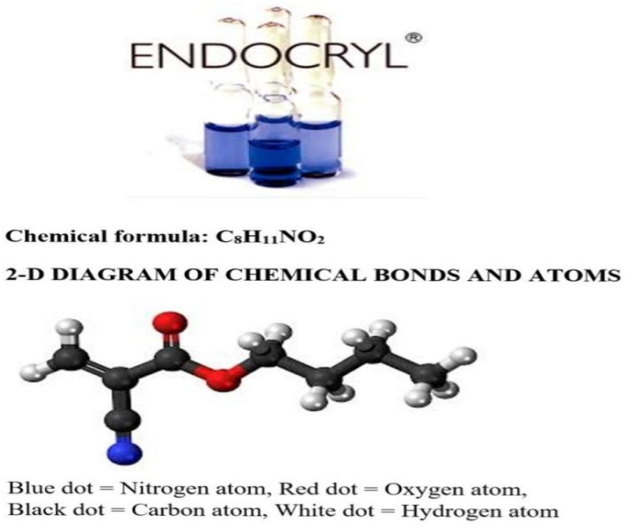

Figure 1: Cyanoacrylate chemical formula and the adhesive vials used in study.[7]

To counter these side effects various technique have been explored including usage of absorbable sutures, self-fixing mesh and various tissue glues. Cyanoacrylate (Figure 1) is the generic name for a family of fast acting adhesives with industrial, medical and household uses. They include methyl-2-cyanoacrylate, ethyl-2-cyanoacrylate, n-butyl cyanoacrylate and 2-octyl cyanoacrylate.[5,6]

Glue fixation may cause less damage to nerves, pubic periosteum or vessels than conventional methods. Sutures, anchors, tacks and staples all have been linked to iatrogenic tissue trauma and neuropathic pain.[3] Mesh fixation by using tissue glue as seen in few of recent studies have shown encouraging results, especially relating to less of nerve damage than conventional method.[7]

Mechanism of polymerization

The chemical reaction that causes curing of instant adhesives is referred to as an anionic polymerization i.e. it causes a reaction to progress rapidly, with polymerization and curing taking place within seconds. Representative examples of chemical groups that have negative ions (anions) are water (H-OH), methanol (CH_3-OH), and caustic soda (NA-OH). The OH-group within molecular structures of these groups acts upon the cyanoacrylates which induces polymerization and curing.

The aim of the present study was to compare the newer emerging technique of mesh fixation using cyanoacrylate glue with the conventional technique of mesh fixation using prolene sutures.

METHODS

The study was conducted in the Department of General Surgery, Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi from October 2011 to April 2013 (1 year and 6 months). A total of sixty patients were included in the study, the control group consisted of thirty patients, in which mesh fixation was done by prolene suture. The study group consisted of thirty patients, in which mesh fixation was done using cyanoacrylate glue. Following variables were evaluated.

Operating time

International norms of calculation were followed in the study (<30 sec, previous minute was taken, >30 sec next minute was taken) (e.g. 4 min 20 sec taken as 4 min, 4 min 42 sec taken as 5 min).

- Operating time for the prolene suture group was recorded from the placement of first prolene stitch for mesh fixation to the application of the last stitch used for mesh fixation.
- Operating time for cyanoacrylate group was recorded from the application of the first drop of the glue to the application of last drop of glue for mesh fixation.

Postoperative pain

Postoperative pain was assessed on the day one, two, six, and at monthly interval for six months by visual analogue scale (VAS), 0 (no pain) to 10 (worst pain).

Follow-up

All the patients of this study were followed, up to 6 month of postoperative period in outpatient department for VAS calculation for pain.

Inclusion criteria

All patients presenting to surgical out patients department with uncomplicated inguinal hernia requiring lichtenstein tension free mesh hernioplasty.

Exclusion criteria

This study excludes patients under the age of 12 year; patients with complicated inguinal hernia; patients with recurrent hernia; patients with femoral hernia; patients with co-morbid conditions as chronic obstructive pulmonary disease, benign prostatic hyperplasia, coagulopathies, diabetes mellitus and hypertension.

Randomization

Patients were allocated to the two different groups by means of sealed, numbered envelops opened in sequence.

Surgery

All patients in both the groups were subjected to Lichtenstein tension free mesh hernioplasty. All surgeries were performed under spinal anaesthesia.

- In prolene suture mesh fixation group (control group), the mesh was fixed to the pubic tubercle, inguinal ligament, conjoint tendon and internal oblique aponeurosis using 3-0 polypropylene suture.
- In cyanoacrylate glue mesh fixation group (study group), 1 ml of cyanoacrylate glue was applied all over mesh with major attention over pubic tubercle, conjoined tendon, internal oblique aponeurosis, inguinal ligament and crossed tails.

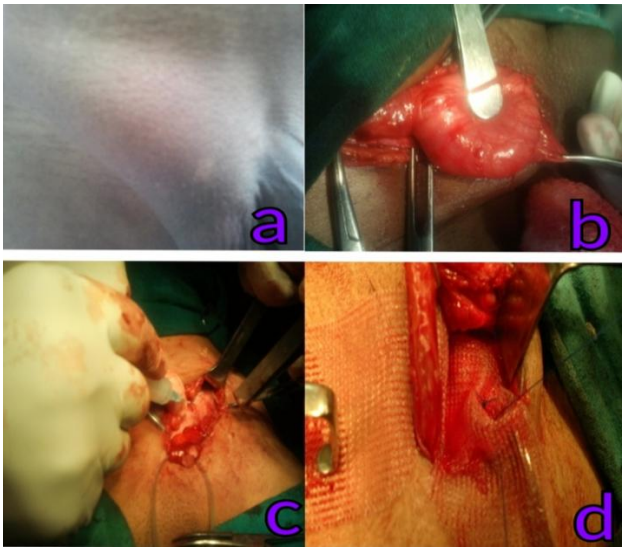

Figure 2: (a) Right sided inguinal hernia; (b) inugunail hernia indirect sac with ilioinguinal nerve lying above it; (c) mesh fixation with cyanoacrylate; (d) mesh fixation with prolene sutures.

All four B/L hernia were operated on right because patients were more symptomatic on right side, on left side only bubonocele was present. Despite of explaining of all the possible consequences and outcomes, all four patients did not give consent for B/L surgery simultaneously (Figure 2).

Relevant data including demographical and clinical, for the proposed prospective study were obtained from both the randomized groups followed by compilation, collation, tabulation and thoroughly analysis of the pertaining variables along with appropriate statistical applications including chi square test and likelihood ratio. The level of statistical significance is taken as probability p value less than or equal to 0.05. This data was analyzed using SPSS statistical software version.

RESULTS

Age distribution of patients

Age group of 31-40 years had 26 patients (43.33%) with 12 case and 14 control group. Age group of 41 to 50 years had 21 patients (35%) with 10 case and 11 control group. Total patients >50 years were 3 comprising 2 in case and 1 in control group (Table 1).

Table 1: Age distribution.

Age group (in years)	Case	Control	Percentage of patients (%)
13-20	0	0	0
21-30	6	4	16.67
31-40	12	14	43.33
41-50	10	11	35
>50	2	1	5

Sex ratio

Our study showed male to female ratio of 29:1. There were total 58 males and 2 females (one in each group).

Table 2: Gender distribution in inguinal hernia.

Sex	Case	Control	Percentage (%)
Male	29	29	96.67
Female	1	1	3.33

Laterality

In this study maximum number of patients was presents with right side inguinal hernia, (38 patients out of 60, 63.33%). Second common presentation was left sided inguinal hernia, (18 out of 60, 30%). Four patients were present with bilateral inguinal hernia (6.67%) (Figure 3).

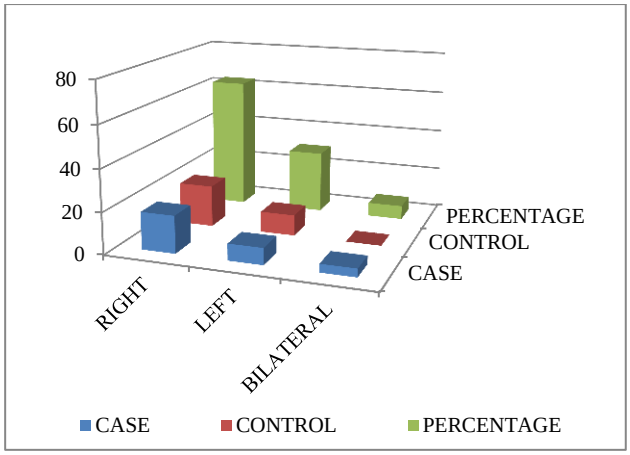

Figure 3: Laterality.

Type of hernia (on the basis of origin)

Forty nine cases total out of sixty were of indirect type (81.67%). Direct hernia type was present in 11 cases total out of 60 (18.33%) (Figure 4).

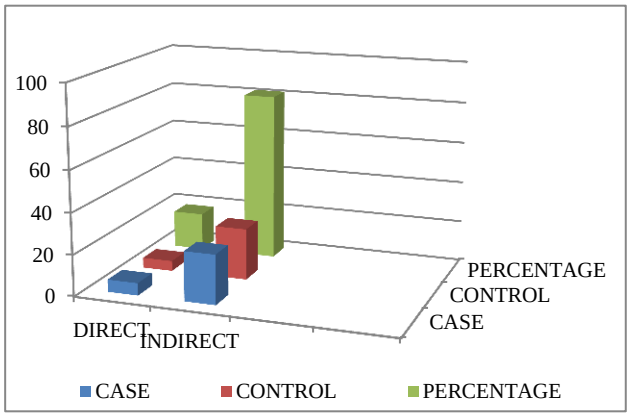

Figure 4: Type of hernia.

Type of hernia on the basis of extent of sac

Most common form of presentation was incomplete inguinal hernia, which accounts for 66.67% of cases (40 cases out of total 60). Complete inguinal hernia was the second most common presentation (28.33%, seventeen cases out of total sixty). Bubonocele was present only in 5% of cases (three cases out of total sixty)

Common symptoms of presentations

Swelling in the groin accounts for forty two cases out of total 60 (70%). Second most common symptom of presentation was swelling in groin with pain, it accounts for 18 cases out of total 60 (30%) (Figure 5).

Operating time/mesh fixation time

In the patients of study group, maximum number of patients was in time period of 6 minute, 19 patients out of total 30 patients in study group (63.33%). In the patients of control group, maximum number of patients was in time period of 8 minute, 15 patients out of total 30 in control group (50%). Only single patient was in time period of 9 minute, (3.33%). P value for this variable (operating time) is 0.000, which is <0.05. Shows that operating time period for study group (mesh fixation by cyanoacrylate glue) was significantly less than, operating time period for control group (mesh fixation by prolene sutures).

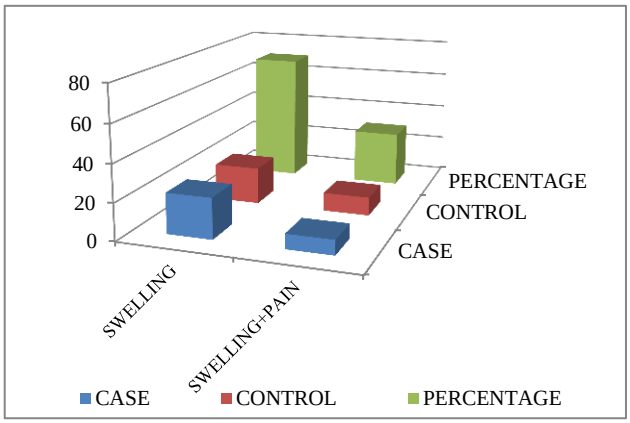

Figure 5: Symptoms of presentation.

Table 3: Operating time case/control cross tabulation.

	Operating time (in minutes)					Total
	5	6	7	8	9	
Case	5	19	4	2	0	30
Control	0	7	7	15	1	30
Total	5	26	11	17	1	60

Postoperative pain

Measurement of the postoperative pain as per VAS score was done for the patients of both groups on postoperative day (POD) 1, 2, 6, 30, 60, 90, 120, 150 and 180 (Table 4).

Postoperative pain on POD-1

P value for postoperative pain at POD-1 is 0.105 (>0.05). Means postoperative pain on POD-1 is not of any clinical significance when compared between case and control group.

Postoperative pain at POD-2

P value for postoperative pain on POD-2 day is 0.178 (>0.05). Means postoperative pain comparison was not of any clinical significance.

Postoperative pain on POD-6

Maximum number of the patients was with VAS score 2, 22 and 24 patients from case and control group

respectively (73.33% and 80%). But, the number of patients were three times more in control group in comparison to patients in case group with VAS score '4'. (6 and 2 patients respectively). Six patients from case group (20%) were free from any kind of pain. P-value for postoperative pain on POD-6 is 0.005(<0.05). Means the comparison of pain in case and control group was of clinical significance on POD-6.

Postoperative pain on POD-30

In case group, 17 out of totals 30 patients, 56.66% were free from pain. Whereas nine patients in the control group were also free from pain (30%). While majority of patients in the control group were with VAS score 2, (17 out of total 30 patients, 56.66%). P value for postoperative pain on POD-30 is 0.071 (>0.05) which is clinically insignificant.

Postoperative pain on POD-60

Majority of patients in both the groups were free from pain (VAS score 0), 19 and 21 patients in the case and control group respectively, out of 30 patients in each group, (63.33% and 70%). P value for postoperative pain On POD-60 is 0.851(>0.851), Which do not have any clinical significance.

Postoperative pain on POD-90

21 and 20 patients out of 30 patients in each, case and control group respectively, were free from pain on POD-90 (VAS score 0), (70% and 66.66%). Seven & nine patients from each group case and control were with VAS score '2', (23.33% & 30%). With recorded VAS score '4', patients in case group were just double than the control group, two and one in each group case and control group respectively, out of 30 patients in each group (6.66% & 3.33%). P value for postoperative pain on POD-90 is 0.735(>0.05) which is not of any clinical significance.

Postoperative pain on POD-120

24 patients in case group out of total 30 patients (80%), were free from pain, while 14 patients in control group out of total 30 patients (46.66%), were also free from pain on POD-120. Patients with VAS score '2' in case and control group were 5 and 13 respectively (16.66% & 43.33% respectively). Patients with VAS score '4' in control group were three times more than patients in case group, one and three patients in case and control group (3.33% & 10%). P value for postoperative pain on POD-120 is 0.025 (<0.05). Means postoperative pain difference based on VAS score on POD-120 is of clinical significance when compared between case and control group.

Postoperative pain on POD-150

Number of patients, free from pain on POD-150 was 23 and 12 in case and control group (76.66% and 40%) respectively, out of totals 30 patients in each group. Patients with VAS score '2' were 6 and 13 in case and control group (20% & 43.33%) respectively. Patients with VAS score '4', were 4 times more in control group than case group (4 and 1, 13.33% and 3.33% respectively). No patient in case group was with VAS score 6 but control group have single patient (3.33%). P-value for postoperative pain on POD-150 is 0.024 (<0.05). It signifies that postoperative pain comparison between case and control group is of clinical significance on POD-150.

Table 4: VAS score and postoperative day pain along with p value.

VAS score	POD 1 (Case/ control)	POD 2 (Case/ control)	POD6 (Case/ control)	POD 30 (case/ control)	POD 60 (case/ control)	POD 90 (case/ control)	POD 120 (case/ control)	POD 150 (case/ control)	POD 180 (case/ control)
0	-/-	-/-	6/0	17/9	19/21	21/20	24/14	23/12	26/13
2	7/3	20/14	22/24	12/17	10/8	7/9	5/13	6/13	3/13
4	23/25	10/15	2/6	1/4	1/1	2/1	1/3	1/4	1/3
6	0/2	0/1	-/-	-/-	-/-	-/-	-/-	0/1	0/1
P value	0.105	0.178	0.005	0.071	0.851	0.735	0.025	0.024	0.004

Postoperative pain on POD-180

On POD-180, majority of patients were free from pain in case group, 26 patients out of total 30 (86.66%), while in control group only 13 patients were free from pain (43.66%). From rest of 4 patients in case group, 3 (10%) patients were with VAS score '2', and one (3.33%) patient was with VAS score '4'. Out of rest 17 patients in control group, thirteen (43.33%) patients were with VAS score '2', three (10%) patients were with VAS score '4' (three times than case), single (3.33%) patient was with VAS score '6'. P value for postoperative pain on POD-180 day is 0.004, (<0.05). P value on POD-180 is statistically significant.

DISCUSSION

The present study was designed to compare and evaluate the clinical outcomes with the reference to the operating time for mesh fixation and postoperative pain between

mesh fixation by cyanoacrylate glue and mesh fixation using prolene suture in Lichtenstein hernioplasty

Results were analyzed concentrating on operating/mesh fixation time in the two techniques of mesh fixation and chronic groin pain. In the case group the operating /mesh fixation time, in 63.33% were in the period of 6 minute. While in the control group, 50% of patients were in time period of 8 minute.

In our study the difference in the operating time for mesh fixation between two groups is statistically significant (p value 0.000), this is in confirmatory with the study conducted by A.H.I. Helmy[5]. This is in our study, the difference age and sex distribution of patients between the two groups (case group in which mesh fixation was done by cyanoacrylate glue, control group in which mesh fixation was done by prolene suture) was not statistically significant ruling out any biases in the present study on above parameters.

We observe that although there is no clinically significant difference in postoperative pain in immediate postoperative period. But p-value for postoperative pain with increasing postoperative duration is clinically significant on post op day 120, 150 and 180 (p value 0.025, 0.024, 0.004 respectively) which also has been observed in clinical trial done by Paajanen et al.[3]

The incidence of osteitis pubis happens to be more where mesh fixation accomplished through sutures. Use of glue could the favorable outcome regarding the chronic groin pain might also be because of decrease incidence of osteitis pubis where mesh fixation was done with cyanoacrylate glue.[6]

In this study we observed that fixation of mesh with cyanoacrylate glue is quicker and also appears with improved pain profile with increasing postoperative duration. Data on cyanoacrylate glues for mesh fixation are still limited, but the capability of such substances to bond with enormous strength in a wet environment, as well as their bacteriostatic activities, have stimulated continuous research on their potential applications.[6-8]

In our study, there was a case of incidental observation: a) reaction due to use of cyanoacrylate glue, b) rejection of mesh (Figure 6).

A patient in case group, who was operated for left inguinal hernia, was asymptomatic, except pain at operating site without any sign of inflammation. After 4 weeks patient develop signs of inflammation, which despite all conservative management, resulted in sinus tract at incision line with serous discharge. Culture sensitivity (c/s) of discharge did not show any growth. Subsequently in a week of time, the discharge become sero-purulent, c/s showing growth of *Staphylococcus aureus* sensitive to clindamycin. Patient was put on antibiotics as per c/s report after which discharge again become serous. Local exploration did not reveal any foreign body in wound. The discharge continued for another one month. MRI was done to see the position of mesh, surrounding inflammatory reaction and also to rule out any other foreign body. MRI report suggested that mesh was in position with gross inflammation around it. The mesh was very much in position with unusual peri-mesh inflammatory tissue. Histopathology report of removed specimen shows that mesh surrounded by inflammatory tissue with abundance of neutrophils, macrophages and lymphocytes (mixed inflammatory response). Subsequently the wound healed. The above findings could be either because of reaction of glue/rejection of mesh.

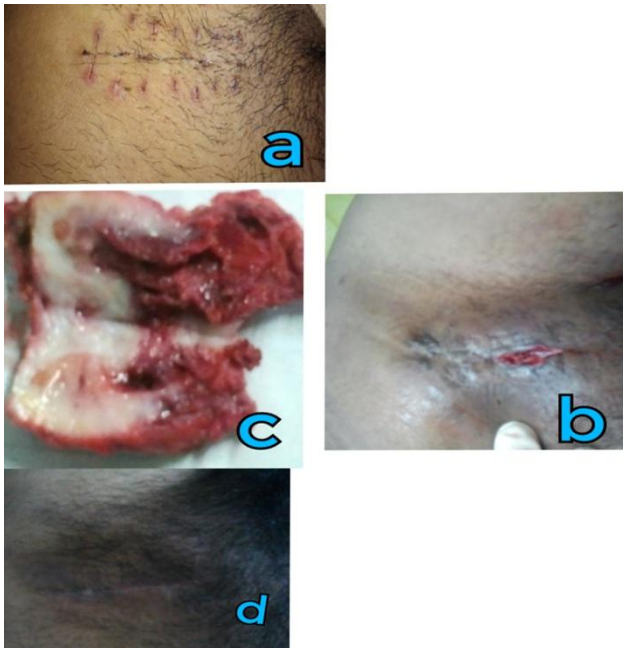

Figure 6: (a) Final scar of incision of inguinal hernia repair; (b) sinus with surrounding induration, inguinal hernia repair scar; (c) removed mesh with surrounding inflammatory tissue; d) healed scar mark of re-do inguinal hernia repair.

A relatively large multi-institutional randomized trial is required to make a definitive statement regarding the clinical outcomes of mesh fixation in terms of operating time and postoperative chronic groin pain as well as the safety profile of cyanoacrylate glue with special reference to severe inflammatory reaction and poor wound healing.

CONCLUSION

In this study it was observed that mesh fixation by cyanoacrylate glue require less time to fix the mesh and is also associated with improved chronic pain profile in comparison to conventional method of mesh fixation by prolene suture. Our results and those in literature are consistent and reassuring, but a relatively large scale multi-institutional trial is suggested to clearly define the superiority of mesh fixation by cyanoacrylate glue over

the conventional method mesh fixation by prolene suture in Lichtenstein hernioplasty.

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