Comparison between Lichtenstein procedure using polypropylene mesh and self-fixating mesh for management of primary inguinal hernia in adult male patients in terms of chronic postoperative pain: a prospective randomized controlled trial

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Aim
The aim of this study was to evaluate the self-gripping mesh compared with standard polypropylene mesh (PM) in treating primary inguinal hernia in adult male patients in terms of chronic postoperative pain.
Patients and methods
One hundred male patients with primary inguinal hernia were randomly allocated into two groups: group I included 50 patients (mean age, 35.92±13.21 years) who were treated with the standard PM and group B included 50 patients (mean age, 36.60±13.12 years) who were treated with the self-fixating mesh (SF).
Results
Recurrence was encountered in only one patient in the PM group and in one patient of the SF group. Visual analog scale showed significant less early and late postoperative pain in the SF group compared with the PM group. The operative time for the SF group (47.54±6.51 min) was significantly shorter compared with the PM group (58.82 ±11.90 min). Both PM and SF groups showed no significant differences as regards hospital stay (0.78± 0.53 vs.0.74±0.31 days), time to return to domestic activity (1.96±1.16 vs. 1.66±0.80 days), time to return to work activity (7.34±2.17 vs. 6.98±1.66 days), and early postoperative complications.
Conclusion
After 1 year follow-up, in Lichtenstein repair, using the Self-gripping ProGrip mesh showed significant less chronic postoperative pain compared with the standard PM. The use of Self-gripping ProGrip mesh was also associated with a significantly less operative time.

Keywords:
chronic postoperative pain, inguinal hernia, Lichtenstein procedure, Self-gripping ProGrip mesh

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Introduction

The invention of tension-free mesh repair created a revolution in inguinal hernia surgery outcome. It led to dramatic reductions in recurrence rate. After the establishment of the tension-free repair techniques, criteria of success of inguinal hernia repair have changed [1,2]. As the rate of recurrence with mesh repair has greatly declined, other parameters of success are being considered. Decrease in intensity of chronic postoperative pain is considered one of the most important indicators of success after hernia repairs. Postoperative pain begins after hernioplasty and persists after 3 months of the operation, with an incidence ranging from 1 to 19% [3].

The Lichtenstein procedure using polypropylene mesh (PM) is still considered the standard treatment of inguinal hernia. However, chronic postoperative pain may be one of the complications for this operation [4,5]. Trials to understand and explain this pain resulted in many theories. Possible causes of postoperative chronic pain include intraoperative injury to inguinal nerves, and excessive fibrous tissue scar formation initiated by the mesh, leading to irritation or entrapment of these nerves [6].

Fixation of the mesh to the periosteum of the pubic tubercle was also considered to be a main possible cause of postoperative chronic pain syndrome. Rigidity and stiffness of the abdominal wall may add to the chronic pain felt by the patient [6]. It is suggested that all

complications occurring after mesh repair were found to be related to mesh fixation and to the amount of fibrous tissue formed with a direct relation to the amount of foreign body placed in the field [7]. Hence, nowadays, it is recommended to reduce the amount of foreign body by using lower weight macroporous meshes in addition to limiting the extent of fixation [8]. Different fixation procedures including absorbable sutures, fibrin glue, and skin staples were investigated to clarify to what extent fixation of the mesh is a source of acute and chronic pain [9–11].

Self-gripping mesh is a new trial to reduce chronic postoperative pain syndrome by avoiding most of its causes. Theoretically, it avoids most of the causes of postoperative pain by being low weight, semiabsorbable and of a large porosity, in addition to the lack of need for traditional fixation procedures [12].

The aim of this study is to evaluate the self-gripping mesh compared with standard PM in treating primary inguinal hernia in adult male patients in terms of chronic postoperative pain.

Patients and methods

This study was a prospective randomized controlled study that included 100 patients with primary inguinal hernia who were admitted to Alexandria Main University Hospital. The research was approved by the Institutional Research Board of College of Medicine, Alexandria University (IRB 00007555) and precautions were taken to conceal the identity of patients. The minimal sample size needed for each group was calculated to be 37. The calculation was based on α of 0.05 and a power of 0.80 (with effect size 0.2=19%). It was calculated by using G power program version 3.1.3 2007 [13].

Patients were randomly allocated by closed envelope technique into group A (50 patients), who were treated with the standard PM, and group B (50 patients), who were treated with the self-fixating mesh (SF). A total number of 100 envelopes were divided into 50 polypropylene mesh and 50 self fixating mesh. Envelopes were completely sealed and shuffled. An operating nurse with no clinical involvement in the trial and is blinded to the procedure chose one envelope just before the surgery and informed the surgeon with the procedure to be done.

Eligibility criteria

The study included adult male patients with primary inguinal hernias who were diagnosed as Gilbert's III (indirect inguinal hernia with weakening of the posterior wall), Gilbert's IV (direct inguinal hernia with bulge and weakening of the whole posterior wall), and dual hernia with direct and indirect hernia in the same side [14].

Exclusion criteria

Patients with recurrent, complicated, bilateral, or congenital hernia and patients with muscular or neurological disease were excluded.

Preoperative preparation

All patients were subjected to thorough history taking and clinical examination. Any predisposing factors such as chronic cough, chronic constipation, enlarged prostate, etc., were treated first, and then routine investigations were carried out. Patients with any predisposing factor that is resistant to treatment, patients with complications, or those with recurrent hernias were excluded from the study. Patients with bilateral hernia were also excluded from the study, as we thought they may confuse the results as regards postoperative pain.

All patients were operated upon by the same team of surgeons who are experts in the field of open hernia repair. A dose of cefuroxime (1 g intravenous) was given to all patients just before induction of anesthesia. Type of anesthesia (general or spinal) was decided by the anesthetist and the patient according to the patient's general condition and his preference.

Informed consent was taken from all patients with regard to the operation and participation in the study.

Operative workup

Standard Lichtenstein procedure was performed for all patients using PM in patients of group I and Self-gripping ProGrip (Covidien, Covedien-Medtronic, Dublin, Ireland) mesh in patients of group II. For patients in group I, after performing herniotomy, the PM was tailored and applied to the posterior wall of the inguinal canal. It was fixed with 4-0 polypropylene sutures to the pubic tubercle first then with three interrupted sutures to the inguinal ligament. It was then fixed to the conjoined tendon by two to three sutures and lastly one lateral suture to create a new deep ring. For patients in group II, after herniotomy, the Self-gripping ProGrip^{TM} mesh (Fig. 1) was applied with its gripping side toward the posterior wall of the inguinal canal. The limbs of the mesh were applied around the inguinal cord at the deep ring and attached together laterally (Fig. 2). The medial part of the mesh was applied over the pubic tubercle with 1 cm overlap (Fig. 3).

Trimming off the excess part of the mesh was performed. No sutures were added for more fixation (Fig. 4).

Postoperative work up

Patients were discharged on the same day or one day after surgery unless there was a complication that necessitated keeping them in the hospital. Patients were followed-up in the outpatient clinic 14 days after surgery and after 3, 6, and 12 months by a doctor who was blinded to the type of mesh that was used.

Outcomes

Primary endpoints

(1) Chronic postoperative pain measured by modified visual analog scale [15] at day 0 (baseline) and at 3, 6, and 12 months (at rest and with movement) was assessed by the surgeon during follow-up visits in the outpatient clinic.

Secondary endpoints

(1) Operative time (min) measured by the operative nurse at the time of operation.
(2) Early postoperative complications in the form of urine retention, hematoma, early wound infection and seroma by examination by the surgeon during hospital stay and follow-up visits in the outpatient clinic.
(3) Time to regain domestic and work activities (days) noticed by the patient and recorded by the surgeon during the first visit of the patient to the outpatient clinic at the 14th postoperative day.
(4) Recurrence detected at 3, 6, and 12 months through clinical examination by the surgeon during follow-up visits in outpatient clinic.

The statistical analysis of the data was carried out using the Statistical Package for Social Sciences (SPSS version 25; SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were applied (frequency and percentage for categorical variables, and mean and SD for quantitative variables). To test the significance of differences between both study groups, independent sample t test was applied for quantitative data, whereas the χ^2 test was applied for qualitative data (Fisher's exact test was used when appropriate). A statistically significant difference was considered at P value less than 0.05.

The manuscript was written in accordance with the items of the CONSORT 2010 checklist. The research was approved by the Institutional Research Board of College of Medicine, Alexandria University (IRB 00007555).

Results

No significant differences could be detected between the two groups as regards age, BMI, percentage of smokers, or percentage of affected side or type of inguinal hernia. The demographic and clinical data of the patients are shown in Table 1.

The mean operative time of group I (PM) was significantly longer than group II (SF). In contrast, no significant differences could be detected between the two groups as regards hospital stay. Operative and postoperative data are shown in Table 2.

Patients of group I resumed domestic activities after 1.96±1.16 days and work activities after 7.34±2.17 days. Patients of group II resumed domestic

Table 1 Demographic and clinical data of the patients

	Group I (PM) (*N*=50)	Group II (SF) (*N*=50)
Age (years)		
Range	18–70	18–73
Mean	35.92	36.60
SD	13.212	13.120
BMI (kg/m^2)		
Range	19–45	19–56
Mean	30.14	32.52
SD	6.292	8.440
Smoking [*n* (%)]		
Nonsmoker	22 (44)	21 (42)
Exsmoker	8 (16)	10 (20)
Smoker	20 (40)	19 (38)
Affected side [*n* (%)]		
Right	32 (64)	30 (60)
Left	18 (36)	20 (40)
Type [*n* (%)]		
Indirect	40 (80)	40 (80)
Direct	8 (16)	7 (14)
Dual	2 (4)	3 (6)

PM, polypropylene mesh; SF, self-fixating mesh.

Table 2 Operative and postoperative data of the two groups

	Group I (PM) (*N*=50)	Group II (SF) (*N*=50)	*P*
Operative time (min)			
Range	40–87	33–64	**<0.001**
Mean	58.82	47.54	
SD	11.895	6.513	
Hospital stay (day)			
Range	0.5–4	0.5–2	0.644
Mean	0.780	0.740	
SD	0.5264	0.3071	

Bold values indicate statistical significance ($P<0.05$). PM, polypropylene mesh; SF, self-fixating mesh.

activities after 1.66±0.80 days and work activities after 6.98±1.66 days. As regards these values, no significant difference could be found between the two groups. The early postoperative complication rate in group I showed no significant difference compared with group II. In group I, four patients only had superficial wound infection compared with five patients in group II, and all of them, in both groups, were treated conservatively by local wound care and antibiotics. Seroma was detected in only one patient in group I compared with two patients in group II, and all of them were treated successfully by aspiration under complete aseptic technique. Early postoperative complications are shown in Table 3.

All patients were followed-up after 3, 6, and 12 months. As regards late complications, late wound infection occurred in one patient in group I, 9 months after the operation. The patient was diabetic and experienced a period of uncontrolled diabetes. Drainage of pus was tried but the infection was only controlled after removal of the mesh after which the patient had a recurrent inguinal hernia. In group II, recurrence was encountered in one patient after 4 months. The patient experienced a very bad flu with excessive vigorous sneezing after which he developed the recurrence. No significant difference was detected between the two groups as regards recurrence.

Visual analog scale [14] was used to assess postoperative pain at rest and with movement during the early and late postoperative periods (Table 4). It was found that patients in group II (SF) had significantly less pain sensation compared with patients in group I (PM) during both early and late postoperative periods.

Discussion

Although mesh reinforcement has become the standard of care in open and laparoscopic repair of inguinal hernia [2], the surgeons who deal with inguinal hernia are challenged by the attempt to achieve two goals that are difficult to reconcile: achieve stable mesh fixation [16] and minimize the postoperative acute and chronic pain, which is one of the most common complications after inguinal hernia repair [17,18]. The reason for such pain is not fully understood, but factors such as nerve injury, nerve entrapment by sutures or postoperative adhesion, tissue injury, use of biomaterials, chronic inflammation, and foreign body reaction have all been implicated [19,20].

Lichtenstein technique is the standard open procedure for repair of inguinal hernia [21]. In our study, we compared between Lichtenstein procedure using the PM, which is fixed with nonabsorbable suture, and Lichtenstein procedure using the Self-gripping ProGrip mesh, which requires no fixation. We

Table 4 Visual analog scale for both groups during the early and late postoperative periods

	Group I (PM)	Group II (SF)	*P*
At rest			
VAS at 6 h postoperatively			
Number	50	50	
Mean±SD	46.96±11.212	34.82±6.915	<**0.001**
VAS after 3 months postoperatively			
Number	50	50	
Mean±SD	18.04±5.841	13.28±3.670	<**0.001**
VAS after 6 months postoperatively			
Number	50	49	
Mean±SD	9.44±3.552	5.06±2.653	<**0.001**
VAS after 12 months postoperatively			
Number	49	49	
Mean±SD	4.58±2.942	1.34±1.409	<**0.001**
With movement			
VAS at 6 h postoperatively			
Number	50	50	
Mean±SD	59.54±12.031	46.90±7.095	<**0.001**
VAS after 3 months postoperatively			
Number	50	50	
Mean±SD	22.18±6.288	18.80±3.458	<**0.001**
VAS after 6 months postoperatively			
Number	50	49	
Mean±SD	12.62±3.675	7.70±2.525	<**0.001**
VAS after 12 months postoperatively			
Number	49	49	
Mean±SD	5.54±3.164	1.68±1.435	<**0.001**

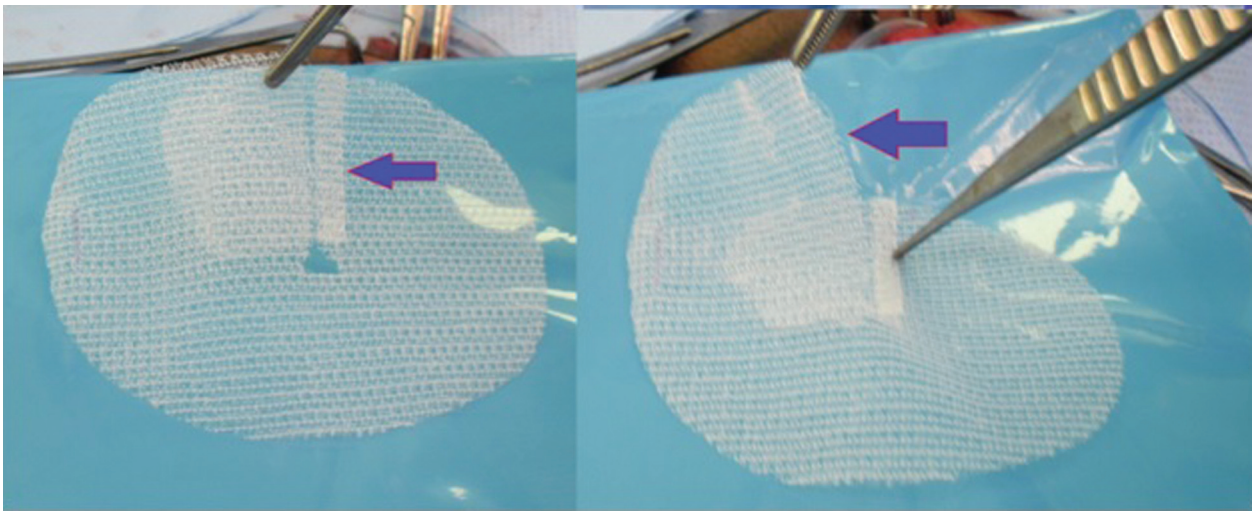
Bold values indicate statistical significance ($P<0.05$). PM, polypropylene mesh; SF, self-fixating mesh.

Table 3 Early postoperative complications

	Group I (PM) [*n* (%)]	Group II (SF) [*n* (%)]	Fisher's exact two-tailed *P* value
Early complications: (within 4 weeks postoperatively)			
Urine retention	2 (4)	0 (0)	0.495
Seroma	1 (2)	2 (4)	1.000
Early wound infection	4 (8)	5 (10)	1.000
Hematoma	1 (2)	0 (0)	1.000

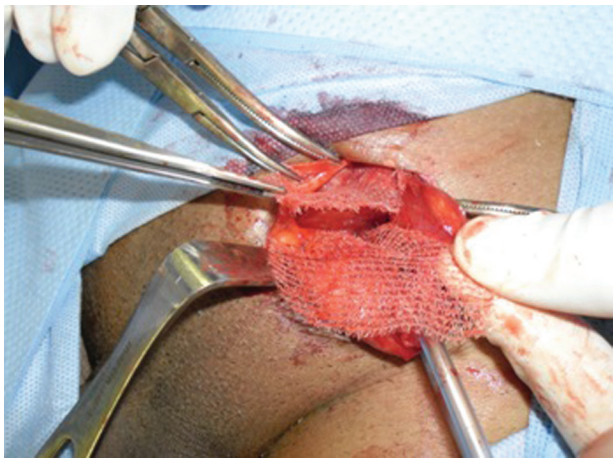
Bold values indicate statistical significance ($P<0.05$). PM, polypropylene mesh; SF, self-fixating mesh.

Figure 1



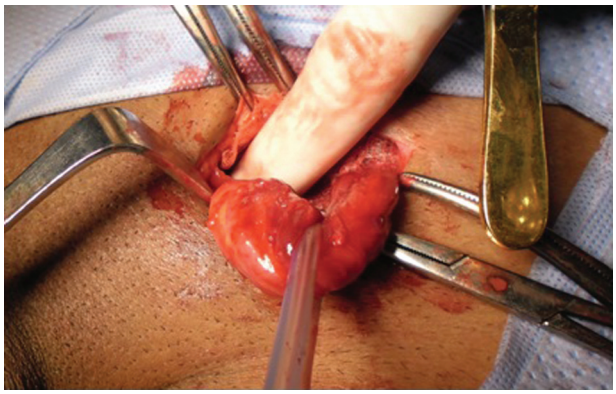
The Progrip mesh with the ready-made flap to allow the application of the mesh around the cord.

Figure 2



The limbs of the mesh were applied around the inguinal cord.

Figure 3



The medial part of the mesh was applied over the pubic tubercle with 1 cm overlap without sutures.

found that early and chronic postoperative pain was significantly less in the Self-gripping ProGrip group.

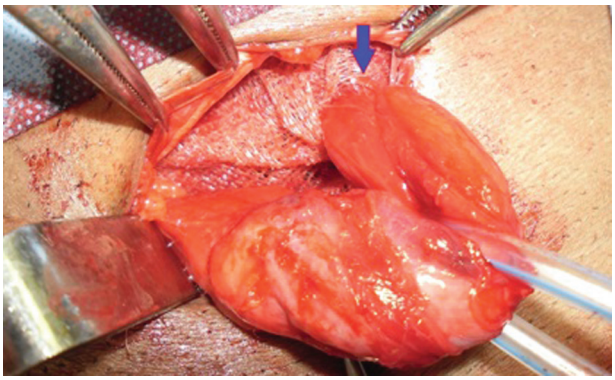
Many studies and meta-analyses comparing fixation of the mesh, during repair of inguinal hernia, with glue and sutures have shown a significant reduction in the incidence of early and chronic groin pain, with glue fixation suggesting suture fixation may be a predisposing factor to increased groin pain [22–25]. This may be explained by less chronic inflammation and foreign body reaction and also less incidence of nerve entrapment.

Similar findings were encountered by Lionetti *et al.* [19] in their study; they found that chronic postoperative pain occurred in 7.8% of the patients after Lichtenstein technique using nonabsorbable mesh and plug anchored with polypropylene suture, which did not happen in any patient after using the sutureless technique.

Kapischke *et al.* [26] reported that the visual analog scale pain score showed, at the first postoperative day, a significantly lower level of pain after placement of SF Parietene progrip mesh than after standard Lichtenstein repair. In addition, they reported that 6 months after the operation, a trend toward a lower pain score was observed after placement of SF Parietene progrip mesh, but this did not reach statistical significance.

Involvement of pubic periosteum was suggested as a cause of postoperative pain [20]. In our study, we did not fix the Self-gripping ProGrip mesh to the pubic bone, which may contribute to less incidence of pain in this group. Kingsnorth *et al.* [27] reported that there was significantly more chronic pain among patients

Figure 4



The Progrip mesh after application with no sutures and creation of new deep ring.

who were treated with Lichtenstein repair with single-suture fixation than among patients treated with Self-gripping ProGrip mesh without fixation. The same study compared also between no stitch versus one stitch in the Self-gripping ProGrip mesh group. They performed 74.5% of the repairs without any sutures, while the remaining 25.5% were performed using a single stitch over the pubic bone, as per protocol. The suture-free patients had less pain at all timepoints of follow-up than sutured patients [27].

Chronic inflammation and foreign body reaction are suggested as a reason for chronic pain [19,20]. Self-gripping ProGrip mesh is a light-weight and partially absorbable mesh, which theoretically decreases the load of foreign body and, consequently, decreases chronic inflammation [4]. This may add to the explanation of less postoperative pain in the SF group in our study. Compared with heavy-weight meshes, light-weight meshes provide excellent surgical repair with fewer long-term complications [28]. Moreover, the large porous textile structure guarantees excellent resistance to intra-abdominal wall pressures. They show better long-term results as regards lesser degree of shrinkage and better abdominal wall compliance [19].

Nienhuijs *et al.* [5], in their multidatabase systematic search, reported that less chronic pain was encountered when a light-weight mesh composed of a combination of polypropylene and polyglactin was used, as compared with heavy-weight PM. This was attributed to the less amount of foreign body and, consequently, a reduced inflammatory response, less scar tissue, and less restriction of abdominal wall movement.

In contrast to our study, in which the nerves were preserved rather than divided, Sanders *et al.* [29], in their study comparing self-gripping mesh with suture fixation of light-weight PM in Lichtenstein repair, found that there was no significant difference in midterm (1 month) and long-term (3 months and 1 year) pain scores between the two groups. However, in their study, most of the patients underwent resection of the iliohypogastric nerve, which was associated with a significant reduction of postoperative pain at all follow-up times. In contrast, their group analysis of the fixation method revealed that when the iliohypogastric nerve was preserved, postoperative pain was significantly higher in the Lichtenstein repair with light-weight PM group than in the self-gripping mesh group in all follow-up points from discharge to 1 year.

In our study, we were careful to preserve the nerves during hernioplasty. We agree with Alfieri *et al.* [30] who stressed the importance of always identifying and preserving the nerves of the inguinal canal, during hernioplastic surgery, to minimize the incidence of chronic postoperative groin pain.

Pandanaboyana *et al.* [31] and Zhang *et al.* [32] conducted two systematic reviews and meta-analyses of self-gripping mesh (progrip) versus sutured mesh in open inguinal hernia repair. Both studies did not find any significant difference between the two types of mesh repairs in chronic groin pain. However, both analyses included a small number of studies (only 5 and 7, respectively). Both analyses do not give any data about the operative technique (nerve resection or preservation and fixing the mesh to the pubic bone). However, the heterogeneous results in the literature raise the need for better designed, multicenter studies with unified technique.

Conclusion

In conclusion, 1 year follow-up in Lichtenstein repair using the Self-gripping ProGrip mesh showed significantly less chronic postoperative pain compared with the standard PM. The use of Self-gripping ProGrip mesh was also associated with significantly less operative time.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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