Comparison of the clinical outcomes of self-gripping mesh versus staple fixation mesh in laparoscopic inguinal hernia repair

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AIM: *Inguinal hernia repairs are the most common operations performed in general surgery practice worldwide. Different surgical techniques, mesh types and different fixation methods have been developed for hernia repair. The aim of this study was to compare the clinical results of staple fixation and self-gripping meshes used in laparoscopic inguinal hernia repair.*
MATERIAL AND METHOD: *Forty patients who presented with inguinal hernia between January 2013 and December 2016 and underwent laparoscopic hernia repair were analyzed. The patients were divided into two groups according to used staple fixation (SF group, n = 20) and self-gripping (SG group, n = 20) meshes. Operative and follow-up data of both groups were analyzed and compared in terms of operative time, postoperative pain levels, complications, recurrence, and patient satisfaction.*
RESULTS: *The groups were similar in terms of age, sex, BMI, ASA score, and comorbidities. The mean operative time of SG group (52.75 ± 17.58 min) was significantly lower than SF group (64.75 ± 16.66 min) (p = 0.033). The mean postoperative 1st hour and 1st week pain scores was lower in SG group. Long-term follow-up revealed a single case of recurrence in the SF group, and none of the cases in either group had chronic groin pain.*
CONCLUSION: *In conclusion, in our study where we compared two mesh types in laparoscopic hernia surgeries, it was concluded that self-gripping mesh is a fast, effective and safe mesh similar to polypropylene mesh, which can be used without increasing recurrence and postoperative pain rates, when applied by experienced surgeons.*

KEY WORDS: Chronic groin pain, Inguinal hernia, Self-gripping mesh, Staple fixation

Introduction

Laparoscopy has been used in hernia surgery for the last twenty years and its use is becoming more frequent due to its advantages, such as high patient comfort and early return to work and social life. In the Cochrane database, laparoscopy showed superiority in terms of postoperative pain, numbness, hematoma, and surgical site infections, in the comparison of open hernia repair and the laparoscopic method [1].

There are many studies in the literature about mesh types and fixation models used in laparoscopic inguinal hernia repair, but there is no clear consensus. This is because specific results and side effects may occur with each different material. Metallic tacks are used to secure the polypropylene mesh and prevent it from moving in the preperitoneal space. Chronic pain may occur when these tacks invade tissues and nerves. Over time, the most important points of successful laparoscopic hernia repair have been to achieve low chronic groin pain (CGP) and low recurrence rates. Regardless of the technique, the incidence of CGP in patients after these operations was around 5-10% [2]. In order to prevent chronic groin pain,

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different mesh fixation methods such as the use of absorbable tacks, non-fixation mesh, fibrin glue or cyanoacrylate have been tried. While the search for a solution to this issue continues, innovative self-gripping mesh, which does not require fixation, has been introduced. It has been observed that this mesh provides homogeneous continuous adhesion to the tissue with its self-adhesive micro grips consisting of absorbable polylactic acid (PLA) without the need for staple and provides better adhesion than the staple tack on the 5th day [3,4]. However, although it may attach to the tissue by itself, this feature may cause difficulties during insertion. In this respect, surgical experience should be increased.

The aim of our study was to compare the superiority of polypropylene and self-gripping mesh over each other, and comparing the results in terms of clinical outcomes, CGP and recurrence, when used in laparoscopic hernia repair. We will also mention the perioperative and postoperative outcomes of the patients for which we used the visual analog scale (VAS) for early and late pain level evaluation.

Material and Method

A total of 40 adult patients (≥18-years of age) who admitted to Istanbul Faculty of Medicine General Surgery Department with primary, recurrent, unilateral or bilateral inguinal hernia and underwent laparoscopic inguinal hernia repair within the period from January 2013 to December 2016 were included in this study. Exclusion criteria included patients who are under the age of 18, who had previously undergone laparoscopic inguinal hernia repair, who underwent emergency hernia surgery, or those who had an American Society of Anesthesiologists (ASA) score ≥3. All patients were preoperatively informed in detail about the risks related to the surgical techniques and general anesthesia and written informed consent was obtained. Patient information was collected by scanning the archive files of the patients and by phone interviews.

Patients were divided into two groups according to the mesh types used during repair.

– Staple fixation (SF) group (n = 20): Cases where staple fixation standard polypropylene mesh was used.

– Self-gripping (SG) Group (n = 20): Cases where self-gripping (ProGrip™) mesh was used.

Data Analysis

Preoperative data consists of demographic characteristics (age, sex), body mass index (BMI), ASA score, comorbidities, hernia types according to Nyhus classification [5], preoperative pain scores, based on the Visual Analogue Scale (VAS), while resting (VAS-Rest) and during activities (VAS-Act). Perioperative data included surgical technique, length of surgery, intraoperative complications and length of hospital stay. All patients underwent laparoscopic totally extraperitoneal (TEP) or transabdominal preperitoneal (TAPP) technique under general anesthesia. All surgeries and mesh placements were performed by a single surgeon with 20 years of experience in laparoscopy. Postoperative data included VAS scores at postoperative 1st hour, 1st week, 1st month, 6th month, and 1st year follow-up, return to social life or work, postoperative early and late complications, follow-up duration, recurrence, and patient satisfaction. Data such as complications, pain, and patient satisfaction, were obtained via telephone follow-up by using a questionnaire-based form which evaluated them.

Postoperative complications were divided into major and minor complications. Major complications were defined as significant effects requiring hospital follow-up, while minor complications were defined as indeterminate effects with no effect on postoperative evaluation. Return to activity time was obtained based on the first time the patient was able to move and get out of bed, return to work time was obtained by questioning when the patient returned to their occupation, if possible. Postoperative pain was assessed by VAS scores defined by the patients in the 0-10 range. In the determination of the pain scores, it was explained to the patients that the starting point of 0 (zero) meant there was no pain at all and 10 (ten) represented pain which was too severe to withstand. 1-3 was evaluated as mild pain, 4-6 as moderate pain, and 7-10 as severe pain. Chronic groin pain (CGP) was defined as persisting pain even after the 6th month. Recurrence was clarified by a re-examination of the cases based on their expression of swelling or lump presentation. Advanced examination methods such as ultrasound were performed in suspected cases. Patient satisfaction was evaluated by questions such as "Are you satisfied with the surgery" and "Would you recommend this surgery to your relatives".

Operative Steps for Tapp Repair

After capnoperitoneum, infraumbilical 10-mm trocar and two subumbilical 5-mm and 10-mm trocars were entered through the mid-clavicular line in the same transverse plane. In both laparoscopic techniques, a 10 mm 30° angle camera was used during the operation. The peritoneum was incised from the edge of the medial umbilical ligament to the anterior superior iliac spine, a few centimeters above the myopectineal orifice. The peritoneum was dissected until the pubis, Cooper's ligament and iliopubic tract appeared and the preperitoneal area was enlarged. Hernia sac and peritoneum were isolated from vas deferens, spermatic vessels and surrounding tissues. After all possible hernia sites (indirect, direct, and femoral) were made visible, the mesh placement stage was started (see mesh types and placement). After ensur-

ing that the mesh is properly placed, the peritoneal opening is closed with running absorbable sutures or closely spaced tacks.

Operative Steps for Tep Repair

After insufflation of the preperitoneal cavity with a 10-mm Hasson or balloon trocar by incision through the lower umbilicus, two more 5 mm ports were inserted between the symphysis pubis and umbilicus, on the midline. The steps of isolating the peritoneum and hernia sac from the surrounding anatomical structures are similar to those of TAPP. After all possible hernia sites were made visible, the mesh placement stage was started (see mesh placement). After mesh placement, the preperitoneal space was deflated under observation. In both methods, the fascia and skin incisions were closed after CO_2 evacuation.

Mesh Types and Placement

In the SF group, a lightweight polypropylene mesh was used, with a size of 15x12 cm and fixed with staple tacks (Fig. 1). In the SG group, a 15x12 cm, lightweight monofilament ProGrip™ mesh was used, which provides self-gripping to the tissue. This mesh has two components, a micro-grips surface of absorbable PLA, and a non-absorbable monofilament polyester surface. With its self-gripping feature, the micro-grip surface attaches to the surrounding tissues, eliminating the need for tools such as sutures, tack, or stapler, thus eliminating potential nerve damage. For proper placement of the mesh,

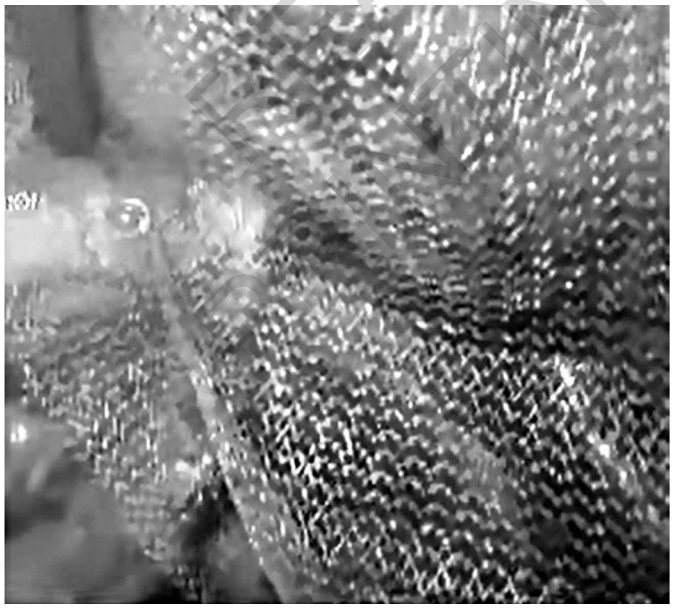

Fig. 1: The laparoscopic view of staple fixation mesh used in one case of SF group.

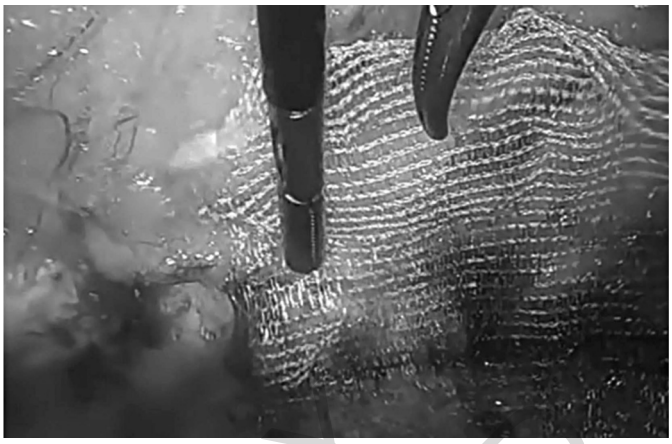

Fig. 2: The laparoscopic view of self-gripping mesh used in one case of SG group.

the medial and lateral aspects of the preperitoneal cavity was dissected to a sufficient width. The meshes are curled to the middle from the upper and lower edges when outside the body. The meshes that were sent from the 10-mm trocar were positioned centrally to cover the inner inguinal ring, and medially to cover the pubic tubercle. With the help of blunt instruments such as a grasper, the upper fold of the rounded mesh was fixed. The lower fold was unrolled until it went below the peritoneal reflection, then the upper fold was opened to cover all potential hernia sites. The self-gripping mesh is gently pressed with the grasper to make it adhere to the surrounding tissues (Fig. 2). Usually 3-4 tacks were sufficient to secure the standard polypropylene mesh to the os pubis, the Cooper ligament, and the top of the iliopubic tract. In some cases of TAPP, tack was also used to close the peritoneal opening. In the SF group, a total number of tacks varying between 3-6 were used.

Statistical Analysis

The data obtained from the study were analyzed using IBM SPSS Statistics for Windows, version 22 (IBM Corp., Armonk, N.Y., USA). Number, percentage, mean, and standard deviation were used as descriptive statistical methods in the evaluation of the data. Independent sample t-test was used to compare the quantitative continuous data between the two groups. The difference between repeated measurements within the group was analyzed by the paired group t-test. The findings were evaluated at 95% confidence interval and a 5% significance level.

Results

Forty patients were included in the study. Self-gripping (SG) mesh and staple fixation (SF) groups consisted of

Table I - *Preoperative data.*

		SF group (n: 20) n (%)	SG group (n: 20) n (%)	p*
Age (min-max)		46,45±12,87 (21-70)	48,50±13,40 (30-75)	0.625
Sex	Male	18 (90.0)	19 (95.0)	0.5
	Female	2 (10.0)	1 (5.0)	
BMI		28,09±4,39 (21,9-43,2)	26,75±3,12 (20,0-33,4)	0.275
ASA score	1	18 (90.0)	16 (80.0)	0.331
	2	2 (10.0)	4 (20.0)	
Hernia characteristics (Nyhus Classification)	Type II	15 (75.0)	14 (70.0)	0.695
	Type IIIA	3 (15.0)	3 (15.0)	
	Type IIIB	1 (5.0)	1 (5.0)	
	Type IVA	0 (0.0)	1 (5.0)	
	Type IVB	0 (0.0)	1 (5.0)	
	Type IVD	1 (5.0)	0 (0.0)	
Preoperative pain scores	VAS-rest	1,350±1,268 (0-4)	1,250±1,209 (0-4)	0.8
	VAS-act	3,650±1,226 (1-6)	4,100±1,021 (2-6)	0.215

BMI: Body mass index (kg/m^2), ASA: American Society of Anesthesiologists. Values are presented as mean ± standard deviation (minimum-maximum) or number (%)

Table II - *Perioperative and postoperative data*

		SF group (n: 20) n (%)	SG group (n: 20) n (%)	p*
Surgical technique	TAPP	7 (35.0)	4 (20.0)	0.24
	TEP	13 (65.0)	16 (80.0)	
Length of Surgery (minute)		64,75±16,66 (40-110)	52,75±17,58 (30-105)	0.033
Postoperative early complications	Seroma	2 (10.0)	0 (0.0)	0.348
	Urinary retention	1 (5.0)	1 (5.0)	
Length of hospital stay (day)		1,25±0,64 (1-3)	1,15±0,37 (1-3)	0.547
Length of return to social life or work (day)		6,55±2,80 (1-10)	6,25±2,59 (1-10)	0.727
Follow-up duration (month)		31,8±13,46 (13-52)	25,8±12,30 (14-48)	0.146

TAPP: Transabdominal preperitoneal, TEP: Totally extraperitoneal Values are presented as mean ± standard deviation (minimum-maximum) or number (%)

an equal number of patients (n = 20). Demographic data, BMI, ASA scores, Nyhus classification, and preoperative pain scores are listed in (Table I). The groups were similar in terms of these parameters. In the SF group there were hypertension in 4 cases, pulmonary disease in 2 cases, diabetes in 1 case, benign prostatic hyperplasia in 2 cases, smoking in 6 cases and obesity in 3 cases.

In the SG group, there were hypertension in 4 cases, cardiac diseases in 2 cases, pulmonary disease in 1 case, diabetes in 2 cases, benign prostatic hyperplasia in 1 case, smoking in 10 cases and obesity in 3 cases. Perioperative and postoperative data are presented in (Table II).

A total of 58 hernia repairs were performed, 30 of which were in the SG group and 28 in the SF group. In the SG group, the mean duration of operation (52.75 min) was shorter than that of the SF group (64.75 min), and this difference was statistically significant (p = 0.033). We did not encounter any perioperative complications

Table III - *Comparison of preoperative and early postoperative VAS scores.*

	SF group (n: 20)	SG group (n: 20)	p*
VAS-rest	1,350±1,268 (0-4)	1,250±1,209 (0-4)	0.8
VAS-act	3,650±1,226 (1-6)	4,100±1,021 (2-6)	0.215
VAS 1st hour	1,050±0,686 (0-2)	0,800±0,616 (0-2)	0.233
VAS 1st week	0,300±0,733 (0-3)	0,200±0,410 (0-1)	0.597

VAS-rest: Visual analog scale while resting, VAS-act: Visual analog scale during activity, Values are presented as mean ± standard deviation (minimum-maximum) or number (%)

in any patient, while early postoperative complications were seen in 4 patients. In the SF group, two patients had seroma and one patient had urinary retention. One patient in the SG group had urinary retention. The seromas resorbed and recovered spontaneously, and the patients were discharged on the third day. All other patients in the study were discharged on the first postoperative day. There was no statistical difference between the two groups in terms of length of hospital stay (p = 0.547). Urinary retention was resolved with a temporary foley catheter. There was no significant difference between the groups in terms of postoperative early complications (p = 0.348).

The time of return to social life or work was 6.55 ± 2.80 and 6.25 ± 2.59 (p = 0.727) days between SF and SG, respectively, and there was no statistically significant difference. The mean follow-up period was 31.8 ± 13.46 (13-52) months in the SF group and 25.8 ± 12.30 (14-48) months in the SG group (p: 0.146).

Comparison of preoperative (VAS-rest and VAS-act) and postoperative (VAS 1st hour, VAS 1st week) pain score averages are listed in (Table III). In both groups, it was observed that preoperative pain was postoperatively significantly reduced. All patients were pain-free from the first month of surgery, therefore the remaining times are not presented in (Table III).

There was no statistically significant difference at any time period between the two groups in terms of acute and chronic pain using VAS.

We did not detect any CGP in either group, a patient in the SG group stated that he felt pain when touching his right testicle, so a follow-up visit was scheduled. It was evaluated clinically and radiologically for CGP and recurrence, but the complaint was not related to these. Recurrence was detected as a chronic complication in only 1 patient in the SF group, at the 42nd month of follow-up.

All patients, interestingly including the recurrent case, reported that they were satisfied with the operation and would recommend this operation to their relatives.

Discussion

Inguinal hernia repairs are the most common operations in the general surgery practice in the world, with 800,000 performed in the United States annually. Although it is seen in 3.8% of the population, the ideal repair technique is still being discussed. Two major developments on this issue are the description of tension-free repair in the 1980s and the introduction of laparoscopic methods in the 1990s [6,7]. Almost all of the studies comparing laparoscopic inguinal hernia repair with open hernia repair in the last 20 years have stated that minimally invasive approach contributes to the early comfort of patients, less postoperative pain, shorter postoperative course, accelerated return to work, lower incidence of wound infection and chronic pain. Laparoscopy has even become the preferred method for bilateral hernias, and recurrent cases with an anterior repair history [8-11].

Despite all advances in open or laparoscopic hernia surgery, complications that prevent successful hernia repair have been recurrence and CGP. Since recurrence rates have decreased to very low levels, CGP has become more important in terms of long-term complications. Compared to open surgery, laparoscopy has been shown to be superior in terms of development of CGP [8-12]. However, it remains as a potential complication for both TEP and TAPP laparoscopic procedures. These acute and chronic pain are thought to be due to surgical techniques with extensive or incomplete dissection, mesh type, tethering of tissues, suture or other fixation devices, and inadvertent injury or entrapment of sensory nerves [13-16]. This multi-factor etiology of CGP makes management of cases difficult and increases costs, so efforts are directed towards the development of alternative fixation methods, optimization of products, and increase of surgical ability. Pain is not a quantitatively measurable symptom, and although VAS pain scoring is also a subjective method, it is still a frequently used method for evaluating pain because of its simple application and satisfactory results [17]. We used VAS scoring for the assessment of acute and chronic pain in laparoscopic surgery in order to reveal the differences between the two types of mesh fixation in terms of pain. We aimed to reveal the advantages and disadvantages of the different types of mesh by comparison of clinical presentation and pain level results.

Stapler materials are known to be one of the most important factors in the formation of acute and chronic pain after repair [14]. Different methods such as non-fixation, absorbable tacks, fibrin glue or cyanoacrylate have been tried in order to cope with this complication and there is no consensus about which method is more effective. In the study conducted by Sözen et al., suture and fibrin glue were compared in open hernioplasty and it was observed that the VAS scores of the fibrin glue group were statistically significantly lower than suture group in

the postoperative acute period and this superiority continued without an increase in recurrence rates even in the first year of the chronic period. But its use has not been popularized in daily practice, even though there is a study showing it to be cost-effective [16,18] Buyukasik et al. compared the standard polypropylene mesh with staple fixation and non-fixation methods, and the level of pain was significantly lower in the non-fixation group at discharge and postoperative 1st month [19]. Taylor et al., in a similar comparison, pointed out the number of fixation materials used and mentioned that the pain was significantly higher in cases with a tack number more than 6, and that the pain increased in direct proportion with the increase of the number of tacks [15]. Recently, self-gripping mesh ProGrip™ has been produced which is attached to the tissue with micro-hooks containing absorbable PLA material without the need for fixing material or fibrin adhesives. It is thought that the potential damage to tissues and nerves can be avoided since the need for fixation is eliminated for this mesh [20]. After the introduction of self-gripping mesh, it was compared with polypropylene mesh in open repair and it was found that the pain was generally lower in discharge and in the first month, but this difference disappeared in the chronic period [13-21]. Even a reduction in the postoperative use of painkillers was observed [22]. In a series of 95 patients using self-gripping mesh for laparoscopic hernia repair, no pain was observed in 14.7% of patients on the first postoperative day and only 1 case of groin pain persisted after 3 months in the follow-up of the patients, but this pain also disappeared in the 1st year follow-up [4].

In our study, it was observed that the pain of both groups was significantly decreased from the postoperative 1st hour and 1st week compared to the preoperative period. However, when the groups were compared, it was found that although there was less pain in the self-gripping mesh group, this difference was not statistically significant. In terms of postoperative late pain levels, pain relief was observed in all patients at the 1st, 6th month and 1st year follow-up.

In our comparison, the pain results in the SF group are similar to the self-gripping group, and one of the reasons for relief may be the low number of tacks (three or six) used during mesh fixation. Another factor is the placement of these tacks in the correct anatomical locations. In our study, we believe that early and late pain levels are low in the SF group because the potential damage to the nerves is minimized by placing a small number of tacks in the correct anatomical points in the operations, which were performed by a surgeon with 20 years of experience in laparoscopic hernia surgery. On the other hand, since the self-gripping mesh has microhooks, it can not only provide homogenous integration with the tissue when it is laid in the anatomical region, but it can also create invasion.

It is stated that it provides 0.5 mm integration into the tissue and provides better fixation performance when compared to tacks on day 5 [4]. It should be kept in mind that although it is not as much pain as when a tack coincides with a nerve, it can cause pain with the minimal negative effect on the nerve during tissue invasion. Therefore, we thought that the use of a low number of tacks and the possibility of nerve invasion of the self-gripping mesh may result in close and parallel early and late pain results. However, it should not be forgotten that the comparison result may be different in larger series.

Another important complication for laparoscopic hernia repair is recurrence. Although very low rates of recurrence have been achieved in laparoscopic hernia repair, it remains a problem, similar to chronic groin pain. The retrospective analysis of Birk et al. was one of the large series with good results in terms of CGP and recurrence rate [23]. There are even a few studies with no recurrence, but Klobusicky et al. stated that longer follow-up periods are needed for better evaluation of recurrence results and therefore they stated their studies will continue in 5th and 10th years [4,24]. In a study with a mean follow-up of 11 months and a comparison of fibrin glue fixation and self-gripping, only one patient in the fibrin glue group had recurrence and it was pointed out that this may be due to incorrect positioning or inaccurate dilution of the glue.

It was also reported that the short 11-month period may be sufficient to show early recurrences but may be insufficient to show late recurrences [25]. In our study, the mean follow-up of the patients in the staple fixation and self-gripping mesh groups was 31.8 and 25.8 months, respectively. In this process, no recurrence was seen in the self-gripping mesh group, while only one case in the staple fixation group had recurrence in the 42nd month of follow-up. Although there are many studies on the recurrence of polypropylene mesh in the literature, it is seen that very good results are obtained in terms of recurrence in the few self-gripping mesh studies [23-25]. While the fact that our follow-up periods are acceptable and there is no recurrence in our self-gripping group as reported in the literature makes us think that this method is advantageous in relation to this problem, it is a fact that longer-term studies are needed to really evaluate recurrence.

Although self-gripping meshes are self-adhering to the tissue, there are difficulties in manipulating and spreading out compared to polypropylene meshes during surgery and therefore they require more experience and skill. Because of the self-gripping feature, the mesh should be properly rounded and the myopectineal orifice closed at once to prevent it from folding over itself or adhering to the inappropriate region. In this respect, the surgeon's anatomical knowledge and laparoscopy experience should be high. Our practice in laying the mesh on the hernia site is to send the mesh to the correct region, while it is folded extracorporeally from the bottom and top, first opening the lower fold and adher-

ing to the tissue, then spreading the upper fold and covering all hernia regions. This avoids the adherence of the mesh to itself or the difficulties caused by environmental adhesions, thus shortening the time. In our study, the mean operative time in the self-gripping mesh group was 52.75 ± 17.58 min and it was 64.75 ± 16.66 min in the polypropylene group. We think that this result, which is a statistically significant difference, is related to the surgeon's experience of mesh placement and the lack of fixation time. In a series of 169 cases using a self-gripping mesh, a result under 1 hour, 54.7 ± 15.8 minutes, was obtained, which is similar to the time we found in our study [23].

Promising results were obtained in terms of patient comfort in the early period after laparoscopic inguinal hernia repair operations performed with this new self-gripping mesh without staple, and even after 1 year, demonstrated by very low pain scores. Recurrence, another cause of failed hernia repair, is a complication that disrupts patient comfort and may even cause chronic pain. In our series, we did not encounter recurrence in the SG group, but there are positive results in the literature showing that chronic pain does not occur even in patients with recurrence related to self-gripping mesh [23]. The only recurrence in the study was in the SF group, and all patients, interestingly including this patient, were satisfied with the operation and would recommend it to their relatives and close ones. In addition to its advantageous results for chronic inguinal pain and recurrence, the short duration of operation and very low complication rates will be effective factors for the choice of self-gripping mesh for patients and surgeons. Although the number of compared cases being low and the retrospective nature of our series were among the limitations of the study, preoperative and postoperative clinical outcomes were compared for both mesh types, depending on our laparoscopic inguinal hernia repair practices and clinical experience. Larger case series and prospective long-term studies will provide clearer results regarding their superiority to each other.

In conclusion, self-gripping mesh is a fast, effective and safe similar to polypropylene mesh, which can be used without increasing recurrence and postoperative pain rates, when performed by experienced surgeons.

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