

## Open inguinal hernia repair with self-gripping Parietex ProGrip mesh: a retrospective study of 204 cases

M. DEL PAPA, G. D'AMATA, F. MANZI, P. CARNÌ, G. FLORIO,  
M. CROVARO, L. MUSMECI, C. BUONOCORE

**SUMMARY: Open inguinal hernia repair with self-gripping Parietex ProGrip mesh: a retrospective study of 204 cases.**

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*Chronic pain and recurrence rates are the main challenge in modern inguinal hernia surgery. Several trials have investigated the role of self-adhesive mesh repair for inguinal hernia, with special attention to the incidence of chronic postoperative inguinal pain and recurrence. The purpose of our study was to retrospectively evaluate the early and long-term results using a self-gripping mesh (Parietex ProGrip®, Covidien) in our institution. A total of 204 patients, mean age 50.3 standard deviation (SD) 15.3, was included in the study. The repair was performed under local anaesthesia in 159 (78%) cases and locoregional anaesthesia in remaining 45 (22%). Mean operative time was  $39 \pm 20$  minutes. The time for self-gripping mesh placement ranged from 5 to 9*

*minutes (mean  $7 \pm 2$  minutes). There were no intraoperative complications. Clinical follow-up was performed at 1 month, 1 year and 2 years and consisted in the evaluation of complications, discomfort/pain and recurrence. One case of cutaneous infection and three cases of seroma were observed at one-month follow-up and were all treated conservatively. 8 patients were lost at one year follow-up, and another 4 were lost at 2 years. 3 patients died for other causes during follow-up. At 1 year and 2 years follow-up no cases of seroma, testicular complications or mesh infection were observed. Two cases of recurrence were recorded at 2 years follow up. No patient reported VAS score  $> 2$  at one month, 1 year and 2 years follow-up. There were no readmissions, systemic complications or death during 2 years follow-up. Lichtenstein open repair using Parietex ProGrip® mesh is a simple, rapid, effective and safe method for inguinal hernia repair. The main advantage of self-fixing mesh is the reduced operative time. A suturless fixation seems to prevent the development of postoperative chronic pain, without increasing recurrence rate in the majority of the trials.*

KEY WORDS: Inguinal hernia - Open repair - Pain - Parietex ProGrip.

### Objectives

Chronic pain and recurrence rates are the main challenge in modern inguinal hernia surgery. The current widespread of mesh technique has reduced hernia recurrence rates to acceptable levels (less than 2%), and though the prevention of postoperative pain has become the principal focus of scientific research. Post-operative chronic pain incidence varies from 11 to 40%, depending on the diagnostic criteria which are used (1, 2). Since the first description of Chastan of open inguinal hernia repair using an innovative self-gripping semi-reabsorbable mesh (3), several trials

have investigated the role of self-adhesive mesh repair for inguinal hernia, with special attention to the incidence of chronic postoperative inguinal pain and recurrence. The search for optimal mesh is still an open challenge, as the use of foreign body material is potentially associated with long-lasting postoperative pain in some patients. The purpose of our study was to retrospectively evaluate the early and long-term results using a self-gripping mesh (Parietex ProGrip®, Covidien) in our institution.

### Patients and methods

A retrospective study evaluating the outcomes of inguinal hernioplasty with Parietex ProGrip® self-gripping mesh was carried out. The inclusion criteria

"Leopoldo Parodi Delfino" Colferro Hospital, Colferro (Roma), Italy

Corresponding author: Gabriela D'Amata, e-mail: gabridamata@gmail.com

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were: patients 18 years or older with unilateral primary or recurrent inguinal hernia operated between January 2014 and December 2017 at a single community hospital in Collevero, Italy. Patients with inguino-scrotal or femoral hernia and patients who underwent emergency operation were excluded from study. All patients provided written informed consent.

### ***Surgical technique (modified technique of mesh placement)***

Local anesthetic infiltration was performed using 15 ml of ropivacain 7,5 mg/ml (long-acting local anesthetic) and 10 ml of lidocaine 20 mg/ml. Local anesthetic was performed by injection in the subarachnoid space of 12 mg of hyperbaric marcaine 5 mg/ml. The intervertebral space which was used varied in base of patient characteristics between L2-L3 and L5-S1. The landmarks for the skin incision were the pubic tubercle, the anterior superior iliac spine and the inguinal ligament. We performed an horizontal skin incision one centimeter above the pubic tubercle to have direct access to the main operating site. The traditional division of the external oblique aponeurosis offered the advantage of a wider access to the inguinal ligament which facilitated the closure and resulted in a stronger repair. In this part of the operation we always paid attention to avoid the section of the ilioinguinal nerve. The space for implant was created, in all cases, sideways, from the iliac crest up to pubic tubercle along the inguinal ligament and medially by the aponeurosis of the external oblique muscle and conjoint tendon. Non-vascular space was also smoothly dissected behind the internal inguinal ring to release the inguinal ligament as high as possible. The ilioinguinal nerve was always singled out and, like the other two nerves in the inguinal canal (iliohypogastric nerve and genital branch of the genitofemoral nerve) preserved. It was often necessary to resect the cremaster muscle because it was difficult to position the flap around the spermatic cord with a voluminous funicle. The hernia sac was always identified without being opened and repositioned in the abdomen. In case of direct hernia a running suture was used to perform plication of the transversalis fascia. The mesh was then placed and fixed with a single absorbable superficial stitch in correspondence of the pubic tubercle, in order to get an adequate overlap infero-medially and to prevent dislocation of the mesh, as recommended by Chastan. To prevent mesh from engaging tissues prematurely and incorrectly, the mesh was opened and folded in half along the

long axis (Figure 1). The Blue mark, on the inside of the mesh, was useful to orient the prosthesis correctly (Figure 2). The inguinal nerves were preserved in most of the cases, but in case of accidental damage or interference with the mesh they were cut, and nerve endings buried (4). The mesh was then unfolded, allowing the gripping side to block it against the transversalis fascia, closing the flap around the spermatic cord without using any additional fixation (Figure 3). The aponeurosis of the external oblique muscle was then closed leaving the funicle in contact with the upper side of the mesh and the skin was closed with absorbable stitches.

### ***The mesh***

A 12 x 8 cm, macroporous, lightweight (40 g/m<sup>2</sup>) self-fixing polypropylene mesh with absorbable polylactic acid microgrips on one side was used in all cases (Parietex ProGrip®). The microgrips of polylactic acid were able to adhere immediately to the underlying tissues without sutures, and were reabsorbed over time with the advantage of reducing the foreign material that remained in the inguinal canal.



**Figure 1 - To prevent mesh from engaging tissues prematurely and incorrectly, the mesh is opened and folded in half along the long axis.**



Figure 2 - The Blue mark, on the inside of the mesh, is useful to orient the prosthesis correctly.



Figure 3 - The mesh is then unfolded closing the flap around the spermatic cord without using any additional fixation.

### **Patients characteristics**

A total of 204 patients, mean age 50.3 standard deviation (SD) 15.3, was included in the study (Table 1); 30 (14%) women and 174 (86%) men. Five different surgeons performed all the operations hernia repair using a 12 x 8 cm Parietex Progrid® Mesh. The patients were all classified ASA I-II-II. The EHS groin hernia classification was used (Table 2). Data collection was performed with standardized clinical report forms. Pain/discomfort was assessed by the VAS score (0-10) and the type of hernia and collar diameter was recorded. The operation time and peri-operative complications were documented. Clinical follow-up was performed at 1 month, 1 year and 2 years and consisted in the evaluation of complications, discomfort/pain and recurrence.

### **Results**

The repair was performed under local anaesthesia in 159 (78%) cases and locoregional anaesthesia in remaining 45 (22%). Mean operative time was  $39 \pm 20$  minutes. The time for self-gripping mesh placement ranged from 5 to 9 minutes (mean  $7 \pm 2$  minutes). There were no intraoperative complications. Day surgery was achieved in almost all cases, only 4 (2%) patients were hospitalized one night due to comorbidities. No perioperative complications were observed. One case of cutaneous infection and three cases of seroma were observed at one-month follow-up and were all treated conservatively. 8 patients were lost at 1 year follow-up, and another 4 were lost at 2 years. 3 patients died for other causes during follow-up. At 1 year and 2 years follow-up no cases of seroma, testicular complications or mesh infection were observed. Two cases of recurrence were recorded at 2 years follow-up (Table 3). Only 3 patients reported post-operative discomfort in the groin area (VAS 2/10) and were all treated conservatively. No patient reported VAS score  $> 2$  at 1 month, 1 year and 2 years follow-up. There were no readmissions, systemic complications or death during 2 years follow-up.

### **Discussion**

Nowadays the first goal in hernia surgery is to reduce the incidence of postoperative chronic inguinal pain, because it poses a major health issue, while im-

TABLE 1 - PATIENT CHARACTERISTICS AND SURGICAL DETAILS

	All Patients (n = 204)
Age	52.7 , SD 15.3 (23-84)
Gender	
Female	30
Male	174
mean BMI (Kg/m <sup>2</sup> )	28.3
Smoker	
Yes	25 (12%)
No	179 (88%)
Hernia location	
Left	89 (44%)
Right	115 (56%)
ASA score	
1	170 (83%)
2	30 (15%)
3	4 (2%)
EHS classification	
LP1	90 (44%)
LP2	20 (10%)
LP3	3 (1%)
MP1	75 (37%)
MP2	12 (6%)
MP3	4 (2%)
Surgical time (min)	39 ± 20
Mesh placement time (min)	7 ± 2

ASA = American Society of Anesthesiologists; BMI =body mass index; SD = standard deviation

TABLE 2 - EHS CLASSIFICATION FOR INGUINAL HERNIA.

P= Primary hernia
R= recurrent hernia
0= no hernia detectable
1=< 1.5 cm (one finger)
2=< 3 cm (two fingers)
3=> 3 cm (more than two fingers)
L= lateral/indirect hernia
M= medial/direct hernia

provement of effective therapeutic options is very slow. The definition of Chronic postoperative inguinal pain (CPIP) provided by the IASP, which is “pain that persists beyond three months post-operatively”

TABLE 3 - RESULTS.

<b>Short term results</b>	
Hospitalization	4 (2%)
Mean pain (VAS/10)	1.2
Early complication	0
<b>At one month</b>	
Mean pain (VAS/10)	0.2
Haematoma-seroma	3 (1.5%)
Cutaneous infection	1 (0.5%)
Testicular pain	0
Induration	0
Recurrence	0
<b>One year results</b>	
Mean pain (VAS/10)	0.02
Seroma Induration	0
Testicular pain	0
Recurrence	0
Mesh sepsis	0
<b>Two years results</b>	
Mean pain (VAS/10)	0.02
Seroma	0
Induration	0
Testicular pain	0
Recurrence	2 (1%)
Mesh sepsis	0

is the most common used in the Literature (5). Otherwise in a recent systematic review of literature 22 different definitions of CPIP have been identified (6), diverging with respect to duration, intensity, and severity of the pain. It appears that expert opinions differ regarding the cutoff points between acute and chronic pain. Some Authors (7) argued that given the possibility of an ongoing inflammatory reaction to a prosthetic mesh, CPIP should be measured at least 6 months postoperatively, while others used a follow-up at 12 months (8). There is high heterogeneity in CPIP definition, assessment and presentation of outcomes, making it hard to compare incidence rate in Literature. Moreover, the cause of chronic pain is not clearly understood. The pathophysiology of CPIP is estimated multifactorial due to patients-related and surgery-related risk factors. The most important patients-related risk factors are moderate to severe preoperative pain >1 month, female sex, younger age, psychologic vulnerability and genetic predisposition, the last two being very vague. The surgical-related factors are the repair technique, nerve handling, oncoming postoperative complications, type of prosthetic material and fixation. The CPIP is

thought to be primarily of a neuropathic origin. A nerve-recognizing approach improves operative outcomes by avoiding iatrogenic nerve injury, suture entrapment of the nerves, and mesh-stimulated scarring with resultant nerve damage (9). Planned prophylactic ilioinguinal resection has not been demonstrated to reduce chronic pain incidence, while it increases the incidence of postoperative sensory loss (10). However, pragmatic neurectomy of a nerve that is at risk can be recommended if unwanted nerve injury occurs or if the nerves interfere with the mesh position (11). Development of chronic pain after inguinal hernia surgery has often been linked to the weight and structure of mesh. Several meta-analyses have shown that lightweight meshes are associated with less CPIP and less foreign body feeling because of a reduced inflammatory response and a less foreign body reaction, although the incidence of severe CPIP is not significantly lower (12, 13). Another possible reason for the development of CPIP is non-absorbable fixation of mesh to avoid dislocation. Less traumatic fixation modalities, like self-gripping meshes, glue fixation and absorbable sutures, have been elaborated in order to reduce the rate of chronic post-hernioplasty pain (14, 15). The self-adhering Parietex Progrid® mesh was developed to avoid suture fixation and also to diminish the formation of excessive fibrosis during healing. The unique concept of a low-density, macroporous, self-gripping mesh has been very attractive in this context (16). This mesh is made of low-weight knitted polypropylene that incorporates resorbable polylactic acid micro hooks, providing atraumatic anchorage of the mesh on the underlying tissue bed. The resorbable micro hooks provide tissue-gripping properties of the mesh during the first 12 months after surgery. Several randomized trials have compared the traditional Lichtenstein technique with the repair using Progrid® mesh. Chastan published the first report on the use of a self-adhesive prosthetic material on 52 patients (3, 11). He concluded that the use of a self-adhesive mesh could probably reduce the adverse effects of fixation, notably the CPIP. In the following years, several randomized controlled trials have investigated the role of this mesh in inguinal hernia repair (17-23). The first meta-analysis published by Zhang et al. concluded that no significant differences were found in terms of chronic pain, recurrence, hematoma, seroma formation and wound infection, but the mean operative time was shorter in the self-gripping mesh group (24). Other metanalyses (24-26) found the same

results. Zwaans et al. (18) in their trial found that recurrences were significantly more prevalent in the self-gripping mesh after 3 years of follow-up. Due to its semi-resorbable, lighter, and self-gripping characteristics, Progrid® was postulated to have a relative intrinsic weakness when compared with a conventional polypropylene mesh. However, prospective studies and meta-analyses comparing Progrid® and conventional meshes failed to confirm different recurrence rates (24, 27-31). A meta-analysis on long-term results (32) concluded that the self-gripping mesh has comparable results with a sutured mesh regarding to the incidence of chronic postoperative inguinal pain, recurrence and foreign body sensation. However, long-term results are still based on relatively small patient series and outcomes measures are heterogenic.

## Conclusions

Lichtenstein open repair using Parietex Progrid® mesh is a simple, rapid, effective and safe method for inguinal hernia repair. The main advantage of self-fixing mesh is the reduced operative time. A suturless fixation seems to prevent the development of postoperative chronic pain, without increasing recurrence rate in the majority of the trials. However, it has not been demonstrated a clear advantage in reducing the rates of early and chronic postoperative pain, and further studies are needed to assess whether this construction design may affect the incidence of long-term complications. The retrospective nature of this study may be viewed as a limitation; however, the surgical technique was standardized, and careful postoperative follow-up was carried out to assess the hernia recurrence rate, pain, general health status, and patient quality-of life. Although self-gripping meshes are easy to use, they have some disadvantages. The most important one is that they fix themselves to any structure that is near the operating field. A technique to avoid mesh fixation to undesired structures has been described in the present study. We noticed that after a short learning curve the mesh positioning becomes significantly easier and faster, with clear benefits in terms of mean operating time.

## Conflict of interests

The Authors declare no conflict of interest.

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