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# Self-gripping mesh versus fibrin glue fixation in laparoscopic inguinal hernia repair: a randomized prospective clinical trial in young and elderly patients

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**Abstract:** Laparoscopic transabdominal preperitoneal inguinal hernia repair is a safe and effective technique. In this study we tested the hypothesis that self-gripping mesh used with the laparoscopic approach is comparable to polypropylene mesh in terms of perioperative complications, against a lower overall cost of the procedure.

We carried out a prospective randomized trial comparing a group of 30 patients who underwent laparoscopic inguinal hernia repair with self-gripping mesh versus a group of 30 patients who received polypropylene mesh with fibrin glue fixation.

There were no statistically significant differences between the two groups with regard to intraoperative variables, early or late intraoperative complications, chronic pain or recurrence.

Self-gripping mesh in transabdominal hernia repair was found to be a valid alternative to polypropylene mesh in terms of complications, recurrence and postoperative pain. The cost analysis and comparability of outcomes support the preferential use of self-gripping mesh.

**Keywords:** Inguinal hernia; Laparoscopic repair; Transabdominal hernia repair

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Abbreviations and acronyms: TAPP = Transabdominal Pre-Peritoneal, ASA = American Society of Anesthesiology, BMI= Body Max Index, PM Group = Polypropylene-Mesh Group, SGM Group = Self-Gripping Mesh Group, SD = Standard Deviation

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## 1 Introduction

Inguinal hernia is one of the most common diseases, with an incidence of 700,000 cases each year in the United States and a male-to-female preponderance of 9 to 1 [1,2].

Hernia repair is one of the most frequently performed general surgical procedures in the world [1].

Laparoscopic transabdominal hernia repair was first performed in the early 1990s by F. Ger, in Germany [3-6], and consisted of nickel clips to close the defect through an intra-abdominal approach. The first laparoscopic transabdominal pre-peritoneal hernia repair (TAPP) was performed in 1992 in France by Arregui and Doin, who fixed a mesh in the peritoneal space after making an incision through the parietal peritoneum [7,8].

The advantages of laparoscopic over open mesh repair in terms of improved intraoperative diagnosis, better aesthetic result and reduced postoperative pain have been demonstrated in literature [9-13].

Laparoscopic inguinal hernia repair through a transabdominal preperitoneal approach has been described in literature as a difficult procedure; this difficulty is linked to the intrinsic complexity of the anatomical area to be dissected and also to the patient's habitus and the characteristics of the abdominal wall defect [14].

Laparoscopy is always performed under general anesthesia and, according to some authors, carries a higher risk of intraoperative complications.

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Current indications for laparoscopic repair are bilateral inguinal hernias and recurrent hernias following a previous anterior repair (grade B of recommendation) [15-22].

Despite developments in prosthetic materials and improvements to methods of fixation, polypropylene mesh with fibrin glue fixation still sets the standard for laparoscopic repair [21,23-38].

The use of fibrin glue to fix the mesh in hernia repair was first described in 2001 by Katkhouda et al. using a pig model [39].

Numerous new meshes have been developed in recent years; however, none of these have been able to match polypropylene mesh for ease of handling and efficacy, nor can they replace it as the new gold standard [40-42].

One of the most recent meshes to have come onto the market features a self-gripping technology. According to the literature, these self-gripping meshes have excellent properties of fixation and efficacy [43]; self-gripping mesh is composed of a layer of large-pore polyester coated with a layer of polylactic acid self-gripping micro hooks. The mesh exhibits intrinsic and atraumatic fixation so to close the hernia safely and effectively, considerably reducing the level of chronic pain.

In 2006 Chastan was the first to describe a new hernia repair procedure through the inguinal approach using a Velcro®-like self-gripping mesh without tacking systems [44].

Inadequate mesh fixation has been reported to be the main cause of recurrences following laparoscopic hernia repair.

Chronic pain is an infrequent, but serious, potential complication of mesh fixation with tacks [49-51].

Tekit et al. described two instances in which further surgery was required due to debilitating pain following TAPP repair [46].

The International Endohernia Society (IEHS) guidelines of 2011 and European Hernia Society guidelines of 2009 defined endoscopic inguinal hernia techniques as safe, providing specific technical steps are followed [21,22]; in 2012 a randomized prospective study comparing TAPP versus totally extraperitoneal laparoscopic hernia repair defined the two methods as similar in terms of overall perioperative outcome and found the totally extraperitoneal approach to be significantly advantageous in terms of postoperative pain.

At the time of preparing the guidelines and conducting the study cited above, there was no standardized tech-

nique for applying self-gripping mesh in laparoscopic procedures [52].

In 2012, Fumagalli et al. conducted a study to compare the TAPP approach with self-gripping mesh versus fixation with clips, and the authors concluded, within the limits of a retrospective study, that the use of self-gripping mesh could be a valid alternative to the other techniques [53].

In a retrospective study of 2012, Birk et al. concluded that laparoscopic hernia repair using self-gripping mesh was a rapid, effective and safe technique, with fewer cases of recurrence and reduced incidence of chronic pain; they reported that the costs of fixation systems required with other non-self-gripping meshes were superfluous [54].

The aim of this study was to compare laparoscopic surgical procedure using self-gripping mesh versus the procedure using polypropylene mesh with fibrin glue fixation.

The end point of the trial was to test the hypothesis that self-gripping mesh is comparable to polypropylene mesh in terms of perioperative complications against a lower overall cost of the procedure in young and elderly (> 65 years old).

# 2 Methods

#### 2.1 Study design

This non-stratified, monocentric study with balanced randomization (1:1) used a parallel group design to compare the TAPP approach with self-gripping mesh to the TAPP repair with polypropylene mesh with biological fibrin glue fixation.

## 2.2 Eligibility criteria

Patients eligible for inclusion were men with primary or recurrent unilateral inguinal hernia, aged 25 to 70 years, with a BMI (body mass index) of < 18 and ASA (American Society of Anesthesiology) class <= 3. The purpose of recruiting a male-only cohort was to standardize the surgical setting as far as possible in terms of anatomy and technical problems encountered in performing the inguinal dissection.

Exclusion criteria were glaucoma, previous retinal detachment or relevant cardiovascular co-morbidity.

#### 2.3 Setting

The study was conducted at the General Surgery Unit, Department of Oncology, San Luigi Gonzaga School of Medicine, University of Turin in Orbassano, Italy, between 1 January 2014 and 1 January 2015.

#### 2.4 Surgical procedures

Patients were randomized to receive laparoscopic inguinal hernia repair with either self-gripping mesh or polypropylene mesh with glue fixation.

Self-gripping mesh was a lightweight, monofilament, two-dimensional mesh with an upper layer of resorbable polylactic acid micro hooks on the adhesive side. This was compared with a medium-weight, large-pore polypropylene mesh fixed by means of 1-2 cc of biological fibrin glue.

The procedures were performed by two surgeons, both of whom were specialists in laparoscopy, having performed at least 500 cholecystectomies and a further 300 laparoscopic surgical procedures (including at least 70 TAPP procedures).

The mean at follow-up is currently 11 months. Eligible patients were recruited between March 2013 and December 2013. All participants underwent a surgical and anesthesiological evaluation at the time of randomization into the study. They also underwent a postoperative evaluation at one day, seven days and three months after surgical procedure.

All the operations were performed as day surgery procedures: patients were admitted to hospital on the morning of the operation and discharged the first or second day after surgery, following a physical examination of the abdomen and monitoring of gas canalization.

**Ethical approval:** The research related to human use has been complied with all the relevant national regulations, institutional policies and in accordance the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

Informed consent: Informed consent has been obtained from all individuals included in this study.

## 2.5 Details of the surgical technique

The same laparoscopic technique was used for both groups, with access by umbilical incision, Veress assisted,

and two operating trocars. A preperitoneal pocket was created by performing medial, lateral and midline dissection with reduction of the hernial sac. In all cases, the funicular elements were parietalized, and hemostasis was secured.

In all cases the mesh was cut to a size of 10 x 12 x 8 cm with incision of the funicular portion. Self-gripping mesh was inserted rolled up, and the polypropylene mesh was inserted flat; the latter was fixed using 1-2 cc of biological fibrin glue prepared by diluting the thrombin component in a ratio of 1:10 with respect to the fibrin after appropriate thawing.

#### 2.6 Variables evaluated

For both groups, we evaluated perioperative variables (operating time and postoperative length of hospital stay), intraoperative complications (vascular lesions, deferential lesions), early postoperative complications (hematoma, seroma, orchitis, wound infection, neuralgia, difficulty with urination), and late postoperative complications (testicular phlogosis, testicular atrophy, deferential lesions, chronic local pain, mesh infection, recurrence).

Post-operative pain was evaluated with a visual analogue scale (VAS) one-dimensional numerical rating scale (NRS) graded from 0 to 10 [55]. The evaluation was performed at one day, seven days and three months in both groups (Table 4); we used the definition coined by other authors and proposed in the guidelines for the prevention of chronic postoperative pain [56]. These authors defined chronic pain as pain that persists for more than six months after the operation and that is due to synthetic material used to repair the defect [57,58].

#### 2.7 Outcomes

The primary end point of this study was a comparison of the two techniques based on analysis of the previously defined parameters, given the known reduction in the overall cost of the implantable systems (reduction in the total cost of the operation).

For the equivalence study, to establish the similarity of the perioperative complications of recurrence and chronic pain associated with two surgical procedures, we calculated a sample size of 30 patients per group, given an incidence of recurrence of approximately 5% with a TAPP procedure [59], a fixed chronic pain rate of 28.7 % [10] and a formal estimated power of the study of 80%. After that,

we studied surgery-related variables in the subgroup of elderly patients, and we commented on its incidence.

#### 2.8 Method of randomization

Participants were assigned to one of the two treatment groups by simple randomization generated with the on-line software available at www.randomization.com.

After we obtained patients' informed consent, they were allocated to the groups by a researcher who was not clinically involved in the trial, and randomization was concealed by use of sealed envelopes held in a specific part of the Department. The researcher informed the surgeon which prosthesis was to be used only when the envelope was opened. The patients were told which mesh had been used at the end of the study.

# 2.9 Statistical methodology

Statistical proportions of dichotomic variables (classification and type of hernia, number of complications) were compared with the Chi-square test and Fisher's exact test.

Continuous variables (age distribution, BMI distribution, mean operative time, postoperative length of hospital stay, operating time, American Society of Anesthesiologists [ASA] evaluation) were expressed as the average (range) and analyzed with the Mann-Whitney U test. Patient distribution according to the two teams was verified. All statistical analyses were performed with R software (vers. 2.6.2); a P value of <0.01 was considered statistically significant.

## 3 Results

During the study period, hernioplasty was indicated for 142 patients. Eighty-two patients were excluded from the study: 65 because they did not meet eligibility criteria, 13 because they did not give their consent to take part in the trial and 4 for other reasons (refusal of general anesthesia) (Figure 1).

Sixty patients were randomized: 30 were assigned to surgical treatment with polypropylene mesh with fibrin glue fixation (PM group) and 30 to surgical treatment with self-gripping mesh (SGM group).

None of the patients recruited into the study was excluded, withdrew from or died during the course of the trial, and thus all patients were included in the analysis.

Table 1 summarizes the participants' basic characteristics; study groups were compared on demographic and clinical characteristics. Primary outcome variables are shown in Tables 2a and 2b in the total group and in the elderly.

Intention-to-treat analysis revealed an average operating time of 74.4 minutes for the PM group and 74.9 minutes for SGM group. Analysis of surgery-related variables revealed no statistically significant differences between the two groups (Table 2a) and in the elderly (Table 2b).

In terms of complications, Table 3 shows the data of intention-to-treat analysis. No surgical wound infection, mesh superinfection, urogenital or other complications occurred.

The assessment of chronic pain, using the VAS, showed no statistically significant differences at one day, seven days and three months in either group (Table3a) (Figure 2); there were no differences in the elderly (Table 3b).

The comparison between complications did not reveal any statistically significant differences between two groups.

Cost analysis of the implantable systems found that the total cost of hernia repair with self-gripping mesh was  $\in$  123 (the cost of the mesh alone), whereas the cost of hernioplasty with polypropylene mesh was  $\in$  272 ( $\in$  22 for mesh and  $\in$  259 for 5 cc of glue).

## 4 Discussion

We believe that laparoscopic transabdominal hernia repair is an effective procedure that can achieve excellent results in terms of aesthetics, morbidity and postoperative pain [9-13,60-61].

These are fundamental aspects, since the incidence of chronic pain and disability following inguinal hernia repair through open or laparoscopic procedures is not negligible [62-66].

In agreement with Bittner et al., we are convinced that the application of a strictly standardized technique is an essential precondition for reducing the risk of intraoperative complications to a minimum [14].

The procedure must be performed by a laparoscopic surgeon with extensive experience of open abdominal-wall surgery and an excellent knowledge of abdominal-wall anatomy.

The results achieved with the self-gripping mesh and the polypropylene mesh were comparable, as both are

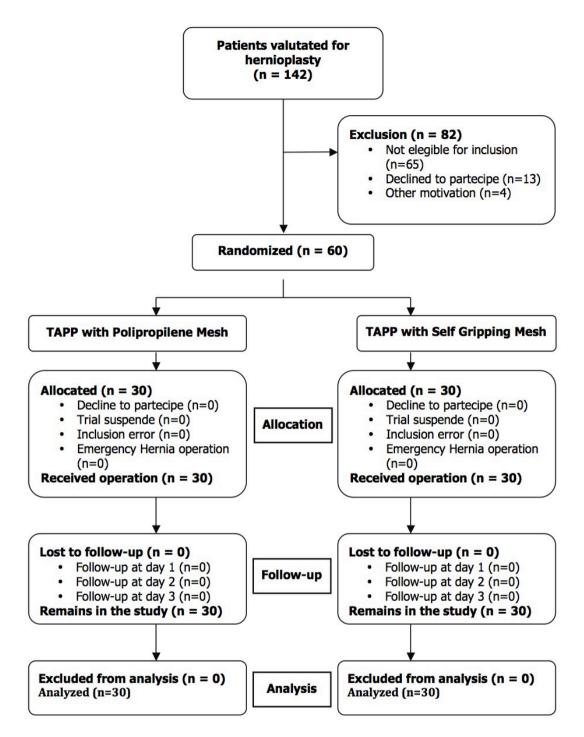


Figure 1: Flowchart

working prostheses and both methods of fixation are valid and effective.

Operating times were comparable, despite the surgeons initially finding it more difficult to position the self-gripping mesh; however, both surgeons confirmed that they found the mesh easy to handle after first ten procedures. Moreover, for the SGM group, there was no need to consider the time required to prepare and apply the fibrin glue.

The postoperative length of hospital stay was comparable for both procedures; both were performed as day surgery with one night in hospital and only a very small number of patients (3 in the PM group, 2 in the SGM group) had to stay two nights. Analytical comparison of post-operative length of hospital stay revealed no statistically sig502 — A. Ferrarese et al. DE GRUYTER

Table 1: Patient Baseline Characteristics

Patient Baseline Characteristics	PM Group	SGM Group	P
Total			
Male [no. (%)]	30	30	
Female [no. (%)]	0	0	
Mean age (yr), mean (± SD)	53,3 (± 10,9)	53 (11,0)	0,906
Hernia type			
Indirect [no. (%)]	27 (90%)	26 (86,6%)	0,687
Direct [no. (%)]	3 (10%)	4 (13,3%)	0,687
Recurrence			
Recurrence [no. (%)]	4 (13.3%)	5 (16.6%)	0,717
Primitive [no. (%)]	28 (86.6%)	25 (83.3%)	0,717
ASA			
I [no. (%)]	5 (16,6%)	5 (16,6%)	1
II[no. (%)]	24 (80%)	23 (76,6%)	0,754
III [no. (%)]	1 (3,3%)	2 (6,6%)	0,553
BMI (Kg/m <sup>2</sup> ), mean (± SD)	24,5 (± 1,2)	24,1 (± 1,6)	0,315

PM Group: Polypropylene Mesh Group SGM Group: Self-Gripping Mesh Group

ASA: American Society of Anesthesiologists' physical status score

BMI: Body Mass Index

Table 2a: Surgery-Related Variables

Sugery-Related Variables	PM Group	SGM Group	Р
Operative time (min), mean (± SD)	74,4 (± 12,8)	74,9 (± 14,8)	0,882
Mean Postoperative Hospitalisation Stay (day), mean (± SD)	1,1 (± 0,2)	1,0 (± 0,2)	0,647

PM Group: Polypropylene Mesh Group SGM Group: Self Gripping Mesh Group

Table 2b: Surgery-Related Variables in elderly

Sugery-Related Variables	PM Group	SGM Group	Р
Operative time (min), mean (± SD)	72,4 (± 10,8)	77,9 (± 13)	0,782
Mean Postoperative Hospitalisation Stay (day), mean (± SD)	1,0 (± 0,2)	1,0 (± 0,2)	0,777

PM Group: Polypropylene Mesh Group SGM Group: Self-Gripping Mesh Group

nificant differences between two groups. The analysis of elderly group showed no significant difference.

A review of the Food and Drug Administration sets the incidence of hematoma after laparoscopic repair of inguinal hernia at < 1%, seroma at 4% and infection at 42%.

Table 3: Complications

Complications	PM Group	SGM Group	Р	RR (95% CI)
Intraoperative complications				
Vascular lesions	0	1	0,313	0 (nv)
Deferential lesions	0	0	-	-
Early postoperative complications				
Hematoma	1	0	0,313	0 (nv)
Seroma	0	0	-	-
Orchitis	0	0	-	-
Wound infections	0	0	-	-
Neuralgia	0	0	-	-
Urinary problems	0	0	-	-
Late postoperative complications				
Testicular problems	0	0	-	-
Chronic pain	0	0	-	-
Mesh infection	0	0	-	-
Recurrence	1	0	0,313	0 (Nv)
Totale	2	1		

PM Group: Polypropylene Mesh Group SGM Group: Self-Gripping Mesh Group

Nv: not evaluable

Table 4a: VAS Scale evaluation

Timing of valutation [Vas scale (cm)]	PM Group	SGM Group	P	
Day 1 mean (± SD)	2,5 (± 0,8)	2,4 (± 0,8)	0,881	
Day 2 mean (± SD)	1,1 (± 0,9)	1,0 (± 1,0)	0,701	
Day 3 mean (± SD)	0,2 (± 0,6)	0,6 (± 0,9)	0,121	

PM Group: Polypropylene Mesh Group SGM Group: Self-Gripping Mesh Group

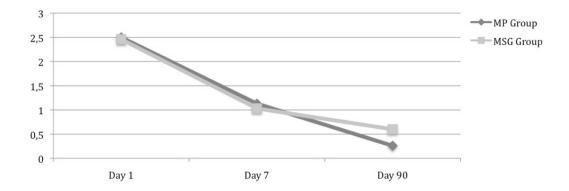
SD: standard deviation

Table 4b: VAS Scale evaluation in elderly

Timing of valutation [Vas scale (cm)]	PM Group	SGM Group	Р	
Day 1 mean (± SD)	2,2 (± 0,7)	2,5 (± 0,6)	0,671	
Day 2 mean (± SD)	1,1 (± 0,6)	1,0 (± 0,9)	0,698	
Day 3 mean (± SD)	0,1 (± 0,6)	0,3 (± 0,9)	0,211	

PM Group: Polypropylene Mesh Group SGM Group: Self-Gripping Mesh Group

SD: standard deviation



MP Group: Mesh Polypropilene Group MSG Group: Mesh Self Gripping Group

Figure 2: VAS Scale valutation

The incidence of intraoperative complications reported in our study was in line with those reported in the literature (Table 3).

The most worrying complication is infection of the mesh. In some cases treatment with antibiotics is not sufficient to solve the problem and another operation may be needed to remove the mesh; this complication is made worse by a high rate of sepsis and mortality [72-76].

In our study there were no cases of mesh superinfection in either group.

Another serious complication that has been reported in the literature associated, above all, with open inguinal hernia repair is erectile dysfunction and subsequent inability to procreate [77-78].

None of the patients in either of our two groups reported sexual dysfunction or urological complications.

One typical complication of inguinal hernia repair is recurrence. In the literature, the recurrence rate following hernia repair has been reported from 8 to 17% of cases [17,79].

A meta-analysis to compare inguinal hernia repair with open and laparoscopic techniques revealed an incidence of recurrence of 2.7% with an open approach versus 5.5% with laparoscopy (transabdominal or totally extraperitoneal approach) with an average follow-up of 28 months [61].

In our study, there was one case of recurrence in the PM group; this occurred on the fifteenth day after surgery and was thus attributable to an erroneous technique with incorrect positioning of the mesh or inaccurate dilution of the glue.

Chronic postoperative pain was measured according to the modified definition of the International Association for the Study of Pain (IASP) [56].

Comparison of postoperative pain in the two study groups (assessed on the VAS) did not reveal any statistically significant differences during the hospital stay or at follow-up after seven days and three months; we believe this reflects the atraumatic nature of both fixation methods.

Cost analysis found the polypropylene mesh to be less cost-effective, owing to the high cost of the biological glue used for fixation. The cost of this system could be reduced by using smaller quantities of fibrin glue or alternative products such as cyanoacrylate [41], which has been found to guarantee good fixation even when only very small amounts are used; however, further prospective studies are needed to compare the different methods of fixation to test their actual efficacy and benefits.

This study has some limitations. First, the sample includes only male patients within a given age range.

Since it is reasonable to assume that hernia defects in females are similar, and possibly also easier to repair, women might also benefit from this type of procedure. Provided there are no co-pathologies that are contraindications for laparoscopic surgery, this technique could also be used equally effectively on patients aged more than 75 years.

Moreover, our sample included patients with just one primary or recurring defect; these findings cannot thus be applied with certainty to patients with a bilateral defect.

The study was limited to a small sample with an average follow-up of just 11 months. An average time of 11 months is reasonable for detecting early recurrences but prevents us from evaluating late recurrences.

Another limitation regards the use of two different surgeons, albeit from the same school and with similar experience; both surgeons used the same verified standard technique, although the evaluation of their similarity was based on their own self-assessment and was therefore not objective. Hopefully, the presence of specialized surgical tutors will make it possible for this operation to be performed by a large number of surgeons in different surgical settings, even during training [14,80-84].

Surgery seems to be more difficult in elderly patients [85], but we consider laparoscopy as feasible in emergency [86-89]. It is a secure technique in both young and elderly patients [90-96] and in repair of wound defects. The constant improvement of open and laparoscopic surgical procedures [97-104] and diagnostic techniques [105-118] have allowed a significant development in the field of wall defects.

In conclusion, the laparoscopic approach for inguinal hernia repair is a safe and effective procedure. The TAPP technique with self-gripping mesh has been found to be a valid alternative to TAPP repair with polypropylene mesh with fibrin glue fixation in terms of the incidence of recurrence, complications and chronic pain.

The lower cost of the procedure using self-gripping mesh also weighs in favor of this type of mesh.

**Conflict of interest statement:** Authors state no conflict of interest.

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