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## Evaluation of efficacy of self-gripping mesh in open and laparoscopic inguinal hernia repair

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### Abstract

**1.1 Background:** Inguinal hernioplasty is one of the most common surgeries performed. With the extensive use of prosthetic mesh implants in open and laparoscopic inguinal hernia repair, recurrence rates have decreased substantially. Therefore, the focus has been shifted from the clinical outcomes, such as recurrence, towards patient-experienced endpoints, such as chronic pain. Use of self adhesive mesh eliminates the complication risk, increased operation time, and expense that come with the mechanical fixation of mesh. Hence this study, to prove the efficacy of self-gripping mesh in open and laparoscopic hernia repair in terms of post-op complications, recurrence rate and cost effectiveness.

**1.2 Methods:** A study was conducted between June 2017 and April 2019. Patients aged between 18 to 60 with primary inguinal hernia were operated either open or laparoscopically using self-gripping mesh. The patients were followed up for 6 months to look for post-operative complications and recurrence.

**1.3 Results:** In total, 60 patients, 30 in open group and 30 in laparoscopic group underwent operation. Postoperative pain was low in both groups in comparison to previous studies on use of simple polypropylene mesh fixed with suture or tacker. Self-gripping mesh was found to be more cost effective as compared to polypropylene mesh with added cost of suture or tacker.

**1.4 Conclusions:** In conclusion use of self-gripping mesh in inguinal hernia repair either in open or laparoscopic method is more efficacious than simple polypropylene mesh.

**Keywords:** Inguinal hernia, self-gripping mesh, self-adhesive mesh, inguinal pain, recurrence

### 2. Introduction

Inguinal hernia repair is one of the most common general surgical operations performed worldwide [1]. Worldwide accounting for about 10–15% of all surgical procedures second only to appendectomy [2]. Worldwide, inguinal hernias comprise 75% of all abdominal wall hernias. Over 20 million repairs of inguinal hernia are carried out annually [3], the specific operation rates varying between countries from around 100 to 300/100,000 population/year [3, 4]. In the United Kingdom, some 100,000 inguinal hernias are repaired each year and approximately 750,000 inguinal hernias are repaired each year in the United States. In India, the estimated annual incidence of inguinal hernias is 1,957,850 [4, 5].

In India, there is a paucity of published data on the clinico-epidemiological profile of patients presenting with inguinal hernia and data on their surgical management and outcomes. In recent times the incidence of inguinal hernia has increased, surgical correction of hernia is the only definitive treatment which leads to hernia repair as one of the most commonly performed elective surgery by a general surgeon [6].

Commonly used open techniques include Lichtenstein tension-free mesh repair, Bassini, Shouldice, and McVay procedure [7, 8]. Tension-free mesh repair is now considered as the gold standard for inguinal hernias repair because of lower recurrence rates and overall better satisfaction [9].

As with the evolution of various open and minimally invasive techniques for inguinal hernia surgeons now focus on various other methods of mesh fixation which doesn't require fixation by suturing or taking the mesh, instead of using different types of glues or meshes [10]. The most commonly used mesh nowadays is polyester or polypropylene mesh, which usually migrates from its original position if not fixed properly. Traditional methods of mesh fixation with the help of sutures, tacks, and clips have resulted in numerous postoperative complications, like bowel perforation, intestinal obstruction, neurovascular injury, and mesh migration into the bladder. Fixation devices are strongly implicated as a cause of postoperative pain and chronic

inguinodynia (inguinal pain) [10, 11].

In recent studies the hernias has been considered as a systemic disorder because of defective collagen III in the tissue obtained from cases operated for hernia which indicates that there is an intrinsic and inherent weakness in the tissue which makes the individual more prone for developing hernia that is primary, incisional or recurrent hernias [12]. The quantitative and staining assessment has proved that primary inguinal hernias are not just caused because of a primary defect but an acquired disorder with respect to collagen distribution [13][14]. Keeping this in mind there is search for a mesh which gets integrated with host tissue to add to its strength.

Self-gripping meshes [15] are the latest advancement in inguinal hernia repair and are suitable for being used in both open and laparoscopic operations. These meshes do not require any other external fixating device, they need to be just put in contact with host tissue. The most important features of these meshes is the integration with host tissue, which provides the desired strength and eliminates the complications associated with mesh fixation as well they reduce overall operation time and cost that comes with the mechanical fixation of mesh [16]. There are few studies regarding the effectiveness of self-gripping mesh in inguinal hernia repair documenting its low rates of postsurgical pain and comparative recurrence rates with other methods of mesh fixation [16, 17].

Glues, such as fibrin tissue glue and cyano-acrylate have also been used as an alternative to the traditional methods of fixation. However, glues have limitations ranging from concerns over availability, cytotoxicity and increased cost as well they interfere with integration of mesh with host tissue [18, 19].

However, there is limited study and published data on the use of self-gripping mesh in laparoscopic and open hernia repair. Based on these considerations, we at our college decided to conduct a non-randomized control trial to study the effectiveness of self-gripping mesh without any fixation device or suture in open and laparoscopic inguinal hernia repair.

The goal of this study, based on single-centre collection of data from the Operated cases of inguinal hernia in M.Y. Hospital Indore, is to demonstrate the safety and efficacy of the use of self-gripping meshes in standardised laparoscopic inguinal hernia repair and open inguinal hernia repair.

### 3. Methods

The study period was 1.5 years (january 2018- june -2019). The study includes 60 patients who attended the General surgery

OPD and were randomized into two groups 'open group' and 'laparoscopic group' and admitted in the general surgical wards of a single surgical unit of M.Y. Hospital Indore, (M.P) with clinically and radiologically diagnosed primary inguinal hernias, requiring surgical intervention and is willing to get operated with self-adhesive mesh. Time taken for mesh fixation was studied intra-operatively while all patients were followed up for 6 Months after surgery to evaluate in terms of and post-operative complications like seroma formation, wound infection, post-operative pain and recurrence.

This randomized clinical trial has received approval by the local Ethical Committee.

#### 3.1 selection criteria

1. Only Incomplete/Complete Inguinal hernias.
2. Patients of age group 18-70yrs, of both sexes.
3. Uncomplicated conditions for elective repair.
4. Medically fit patients.

#### 3.2 exclusion criteria

1. Other hernias of anterior abdominal wall.
2. Unfit for anesthesia.
3. Pediatric and Geriatric population.
4. Unwilling candidates who were reluctant to oblige for the study.
5. Complicated hernia. (Non-reducible, incarcerated inguinal hernia, Strangulated hernia.)
6. Recurrent cases.

#### 3.3 Methodology

- Informed consent was taken from all patients included in the study
- All patients in study underwent a detailed history taking including general examination.
- Records were maintained
- Statistical analysis was done using SPSS software at the end of study period.

Follow-up clinical examination was performed at 1 day, 7 days, 1 month, and 6 months after surgery.

#### 3.4 Self gripping mesh

Self-gripping mesh will be used for hernia repair which consist of a monofilament polyethylene terephthalate mesh (PET), covered by a resorbable layer of microgrips on one side [20-21].

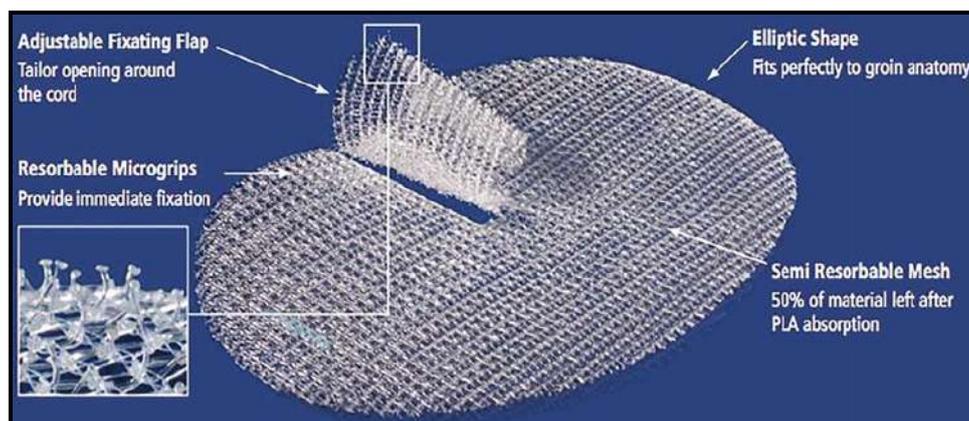


Fig 1: Self-gripping (Pro-grip) mesh

The microgrips are club shaped 1mm projections that are made of biodegradable monofilament PolyLactic Acid (PLA).

Combined with segmental covering of fast resorbing film composition (70% collagen, 30% glycerol). The weight of mesh

before absorption is 82g/m<sup>2</sup> and weight after absorption is 49g/m<sup>2</sup>, with the pore size (mm) 1.8x1.8. according to the manufacturer, the time for degradation of the quickly absorbing layer <1 day and that for the layer with microgrips is >18 days [22, 23, 24].

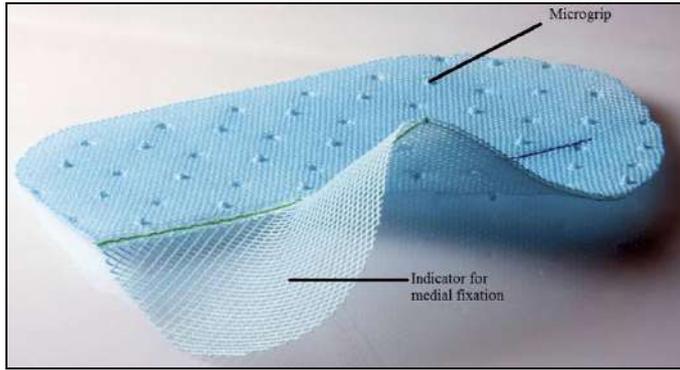


Fig 2: Selfgripping mesh with adhesive microgrips on surface

**3.5 Method of mesh fixation**

In laparoscopic repair self-gripping mesh was folded in half along the long axis and the apex of the anterior side of the mesh was placed on the pubic tubercle with the help of forceps. The posterior side of the mesh was completely unexposed to the tissue until the anterior side of the mesh had been attached to the tissue. Thereafter, the entire mesh was unrolled and affixed to the inguinal canal. The upper edge of the mesh was fixed over the conjoint tendon and the lower edge of the mesh was attached to the inguinal ligament.

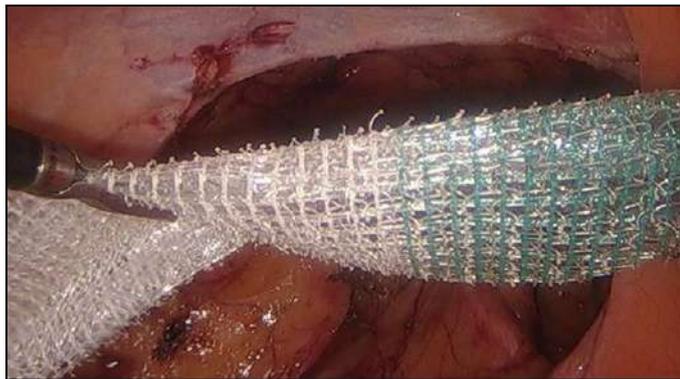


Fig 3: Method of rolling of mesh and insertion through port.



Fig 4: After completion of mesh fixation

**3.6 Pain**

Pain was assessed using the visual analog scale with scores from 0 to 10, where 0 represents no pain and 10 indicates the most severe pain [25].

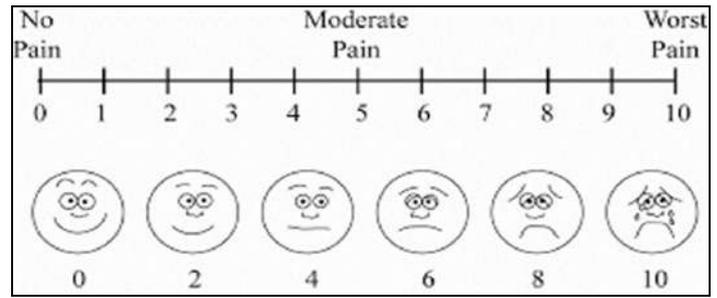


Fig 5: Visual analogue scale (VAS)

**4. Results**

The present study entitled “Evaluation of efficacy of self-gripping mesh in open and laparoscopic inguinal hernia repair” was carried out in M.G.M. medical college and M.Y. Hospital, Indore (M.P.). 60 patients from age group 18-79 years of age were divided into two groups with 30 patients each.

**Group I (OPEN Group):** 30 patients with primary unilateral hernia were operated by “Open Tension Free Mesh repair” by using self-gripping mesh without using sutures for fixation.

**Group II (LAP Group):** 30 patients with primary unilateral hernia were operated by Conventional three port Total Extra Peritoneal (TEP) inguinal hernia repair by using self-gripping mesh without using any fixation device like tacker or suture.

Both groups were evaluated and studied for duration of mesh fixation, post-operative complications like, seroma formation, pain, infection, mesh migration and recurrence.

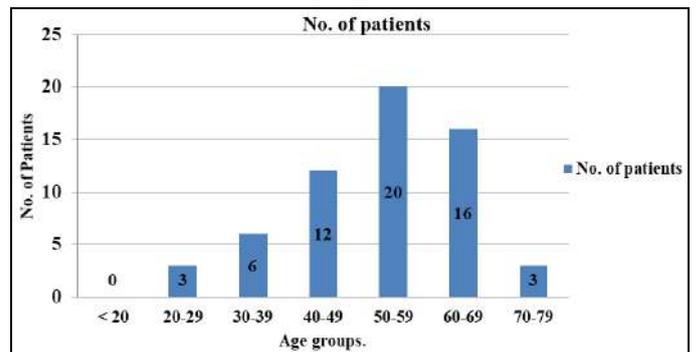


Fig 6: Graph showing age wise distribution of patients

Table 1: Mean age and standard deviation

	N	Minimum	Maximum	Mean	Std. Deviation
Open	30	21	70	52.97	12.430
Laparoscopic	30	22	70	51.47	11.936

Table 2: Type of inguinal hernia.

Inguinal hernia	Open	Laparoscopic
Right inguinal hernia	16 (53.3%)	17 (56.7%)
Left inguinal hernia	14 (46.7%)	13 (43.3%)
Total	30	30

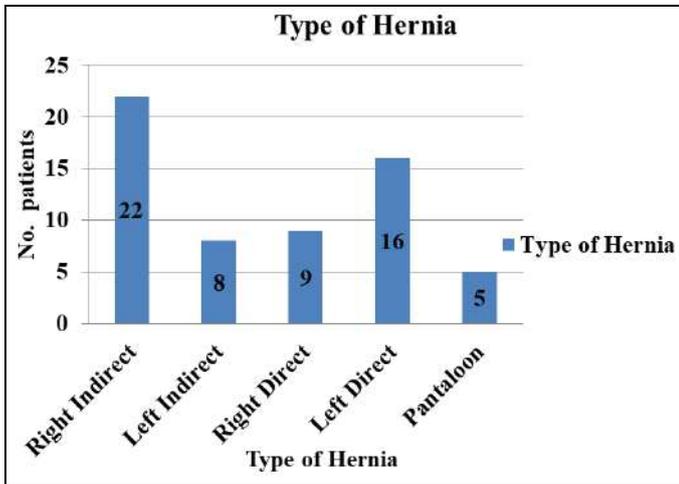


Fig 7: Graph Showing Side wise Incidence of Type of Hernia

Table 3: Time for Mesh Fixation

	N	Minimum	Maximum	Mean	S.D
Open	30	2.00	7.00	3.8667	1.33218
Laparoscopic	30	5.00	10.00	7.36667	1.42594

Table 4: Postoperative Pain

		POD - 1	POD - 7	AT 1 Month	AT 6 Month
Open	Yes	08 (26.7%)	03 (10%)	1 (3.3%)	0 (0.0%)
	No	22 (73.6%)	27 (90%)	29 (96.7%)	30 (100%)
Laparoscopic	Yes	05 (16.7%)	02 (06.7%)	0 (0%)	0 (0.0%)
	No	25 (83.3%)	28 (93.3%)	30 (100%)	30 (100%)

On post op day 1, 08 patients (26.7%) out of 30 were having pain in open group, while in laparoscopic group 05 patients (16.7%) out of 30 were having pain.

On post op day 7, 03 patients (10%) out of 30 were having pain in open group, while in laparoscopic group 02 patients (06.7%) out of 30 were having pain. After 1 month of surgery, 01 patient (3.3%) out of 30 was having pain in open group, while in laparoscopic group none of the patient was having pain. After 6 month of surgery none of the patient in either of the group was having pain.

Table 5: Seroma formation.

		POD - 1	POD - 7	AT 1 Month	AT 6 Month
Open	Yes	02 (6.7%)	01 (3.3%)	0	0
	No	28 (93.3%)	29 (96.7%)	30 (100%)	30 (100%)
Laparoscopic	Yes	01 (3.3%)	0	0	0
	No	29 (96.7%)	30 (100%)	30 (100%)	30 (100%)

On post op day 1, 02 patients (6.7%) out of 30 were having seroma in open group, while in laparoscopic group 01 patient (3.3%) out of 30 were having seroma. In both groups patients were managed conservatively.

On post op day 7, 01 patients (3.3%) out of 30 was having seroma in open group, while in laparoscopic group no patient was having seroma. patients the patient was managed conservatively. At 1 month after surgery and thereafter no patient had seroma.

Table 6: Wound Infection

		POD - 7	AT 1 Month	AT 6 Month
Open	Yes	1 (3.3%)	0	0
	No	29 (96.7%)	30 (100%)	30 (100%)

Laparoscopic	Yes	0	0	0
	No	30 (100%)	30 (100%)	30 (100%)

Only one patient in open group has got wound infection by the post op day 7, which gets cured by broad spectrum antibiotics

Table 7: Recurrence

		POD - 7	AT 1 Month	AT 6 Month
Open	Yes	0	0	0
	No	30 (100%)	30 (100%)	30 (100%)
Laparoscopic	Yes	0	0	0
	No	30 (100%)	30 (100%)	30 (100%)

In our study there was no reported case of recurrence after follow up of 6 months.

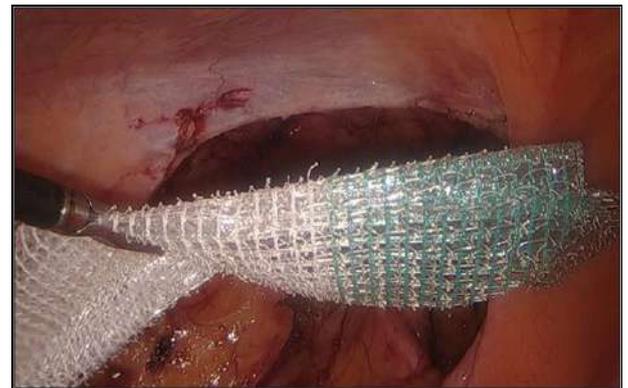


Fig 8: Mesh preparation and introduction into pre-peritoneal space



Fig 9: Unrolling of mesh in pre-peritoneal space.



Fig 10: Final fixation of mesh in pre-peritoneal space.



**Fig 11:** Introduction of mesh in open inguinal hernia repair



**Fig 12:** Placement of mesh in open inguinal hernia surgery



**Fig 13:** Final Fixation of mesh in open inguinal hernia surgery

## 5. Discussion

Currently there is no difference in complication rates of both techniques; however, most complications are due to mesh itself or due to its fixation. To avoid the fixation related complication like post-operative chronic pain which is thought to be due to nerve entrapment in inguinal regional during fixation, a new type of mesh is developed which is called ‘Self Gripping mesh’ which gets adhered to tissue planes by itself within 5 minutes of attachment and need not to be fixed by any fixation device or suture.

The results of our study are comparable with the previous conducted studies in terms of post operative outcomes.

The study by, Alessia Ferrarese *et al.* [26] revealed an average operating time of 74.4 minutes for the polypropylene mesh group and 74.9 minutes for self gripping mesh group. Analysis of surgery-related variables revealed no statistically significant differences between the two groups and in the elderly.

In terms of complications, 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.

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 € 123 (the cost of the mesh alone), whereas the cost of hernioplasty with polypropylene mesh was € 272 (€ 22 for mesh and € 259 for 5 cc of glue).

Pavol Klobusicky and David Hoskovec [27] found that laparoscopic inguinal hernia repair using the trans-abdominal pre-peritoneal technique with implantation of the ProGrip laparoscopic mesh is a fast, effective and reliable method in experienced hands, which according to our results reduces the occurrence of chronic post-operative inguinal pain with simultaneously a low recurrence rate.

No recurrence or chronic postoperative pain was reported.

Luigi Percalli *et al.* [28] found that the mean duration of the surgical procedure using Progrid was significantly shorter than that identified within the polyethylene group. None among patients participating to this study suffered any intra-operative and/or early/late surgical complication.

Preoperative pain assessed by the VAS for ProGrip® group was slightly higher than for polyethylene group, the difference was not statistically significant.

In our study, overall the results shown with the self-gripping mesh in both open and laparoscopic inguinal hernia repairs were satisfactory and were comparable to previous studies. Both methods of using prosthesis either fixation or no fixation using self-gripping mesh are valid and effective.

Cost analysis found the self-gripping mesh superior and more cost-effective to the polypropylene mesh because of the high cost of the fixating device like tackers or biological glue used for fixation. However, further studies with more sample sizes are needed to compare the different methods of fixation to test their cost-effectiveness and actual efficacy.

This study performed at a government tertiary care centre located in central India has some limitations. First, the sample size is small (only 60 patients). Second, this study includes more no. of male patients and only one female patient, although the technique of hernia repair is the same in both sexes still it needs more data to apply outcomes of this study on female patients. Third, the types of patients reporting at our institute are mostly of low socioeconomic status and are mostly elderly having various co-morbidities. Surgery seems to be more difficult in elderly patients and associated co-morbidities may affect the overall long term outcome of the study. Fourth, we have included only primary unilateral uncomplicated hernia in our study; therefore, the outcomes of this study cannot be applied with certainty to patients with a recurring or bilateral defect.

Our study as well as in previous studies showed that inguinal hernia repair using self-fixation mesh both in laparoscopic and open hernia repair is a safe, fast, effective, reliable and economically advantageous method in experienced hands.

The results of this study showed that the risk of wound infection and recurrence is very low. Also, the less time required for mesh fixation results in overall reduced time for surgery and ultimately results in better long term outcomes.

Based on the submitted study it is possible to recommend the use of self-gripping mesh as a standard technique for both open and laparoscopic inguinal hernia repair as it is cost-effective, safe and easy to perform.

However to assess postoperative complications more comprehensively and other long term effects a study with larger sample size is required.

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