

## Original Research Article

# Self-gripping polyester mesh with absorbable polylactic acid microhook versus polypropylene mesh for open inguinal hernioplasty

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## ABSTRACT

**Background:** Inguinal hernias are frequently encountered disease. The hernia surgery has gone through a major evolution from Bassini's heralding of the modern era to today's mesh-based open and laparoscopic repair. The Purpose of this study is to compare clinical outcomes following sutureless repair with Self gripping polyester mesh incorporating absorbable polylactic acid microhook (Progrid) to traditional Lichtenstein repair with polypropylene mesh secured with sutures for open inguinal hernioplasty.

**Methods:** 60 patients with diagnosis of inguinal hernia underwent open hernioplasty, after being randomized into two groups, one half of them using Progrid mesh and other group, using Polypropylene mesh over a period of one year at Department of General Surgery at Sir Sayajirao Gaekwad (SSG) Hospital, Baroda. Operative data were recorded, and the patients were followed-up accordingly. Independent assessors were assigned to obtain post-operative pain scores, other secondary outcomes.

**Results:** The present study concluded that Self gripping mesh (Progrid™) repair is superior to Polypropylene mesh in short term outcomes and in certain long-term outcomes like chronic groin pain.

**Conclusions:** Open Inguinal hernioplasty using Self Gripping mesh (Progrid) mesh has better outcome in terms of operative time, post-operative pain, hospital stay, early return to professional life, and chronic pain.

**Keywords:** Open hernioplasty, Operative time, Progrid mesh, Polypropylene mesh, Post-operative pain

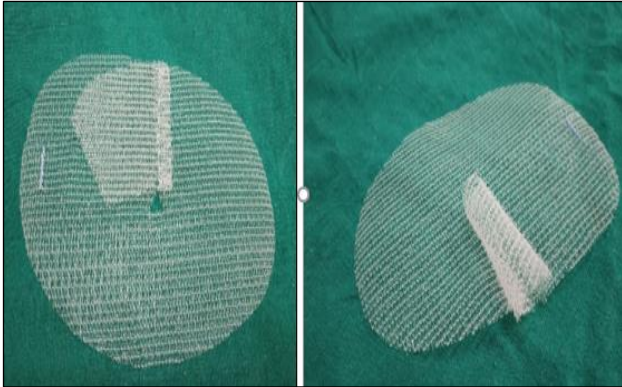
## INTRODUCTION

The surgical treatment of inguinal hernias has evolved through several stages to reach a modern and successful era. Hernia repair is one of the most commonly performed general surgical procedures worldwide. Since the time Bassini described his technique the search for an Ideal inguinal hernia repair is still on. An ideal hernia repair should be tension free, tissue based, with no potential damage to vital structures, no Long-term pain or complications and no recurrence.<sup>1</sup> Inguinal hernias are frequently encountered disease. When not treated may Lead to their complications like obstruction and

strangulation. The hernia surgery has gone through a major evolution from Bassini's heralding of the modern era to today's mesh-based open and laparoscopic repair.<sup>2,3</sup> To address surgeons' concerns over postoperative pain, a new low-density, macroporous polyester mesh with self-gripping properties was developed for tension-free open hernia repair.

The Polyester Self-gripping mesh is made of a low-weight monofilament polyester knitted fabric that incorporates resorbable polylactic acid (PLA) micro hooks. The resorbable polylactic acid micro hooks in the Polyester structure provide tissue-gripping properties at

application of the mesh and during the following 12 months. The self-fixation of the mesh to the underlying tissue bed is instantly achieved at application.



**Figure 1: Progrid mesh: covidien.**

The flap is made of the same fabric as the mesh, i.e. Polyester and PLA micro hooks. After resorption of the PLA part of the mesh, only the low-weight Polyester fabric (40 g/m<sup>2</sup>) remains in the groin area, providing the long-term wall reinforcement (Figure 1 and 2).<sup>4</sup>

## METHODS

This study was a single-centre, randomized, comparative two group study. It compares between two meshes used in hernia repair by Self Gripping mesh (Progrid) mesh and Polypropylene mesh. It was conducted on 60 patients admitted with the diagnosis of inguinal hernia. The present study was done at Department of General Surgery at SSG hospital Baroda Medical College, between August 2016 to August 2017 with a follow up period of 3 months. The study was approved by the Institutional Research and Ethical Committee.

The diagnosis of primary inguinal hernia was made on basis of history of reducible groin swelling and essentially on clinical examination.<sup>5</sup> Detailed history was collected including age, chief complaints and duration, other associated conditions like chronic cough, chronic constipation, urinary complaints etc, history of previous abdominal surgeries, family history, occupation, marital status etc. Detailed physical examination was conducted by any experienced surgeon. Telephonic contact numbers and detailed address were collected for follow up, patients with age <18 years, complicated inguinal hernia, obstructed or strangulated inguinal hernia, local skin infection and those not giving informed consent were excluded.

Routine haematological evaluation was done in all the patients and a written informed consent was taken. 60 sealed envelopes containing a number indicative of the group assignment (even number = Progrid, uneven = Polypropylene) was used to randomly allocate patients into two groups: A: Progrid™ (PG), and B:

Polypropylene (PPL). The surgeon was not blinded to the method used.

**Self-Gripping mesh (Progrid) Group:** This group included 30 patients in whom Self gripping Polyester mesh with absorbable polylactic acid microhook will be used without suture fixation for inguinal hernia repair.

**Polypropylene Group:** This group included 30 patients in whom Polypropylene mesh will be used and mesh will be fixed with polypropylene suture 1-0 for inguinal hernia repair.

## Operative technique

Under spinal anaesthesia, the operation was performed with the patient in the supine position.



**Figure 3: Progrid mesh in its final position.**

After a 5-8 cm skin incision kept, the external oblique aponeurosis is divided. The necessary space for the mesh is created laterally along the inguinal ligament from the pubic tubercle towards the anterior superior iliac spine, and then between the external oblique aponeurosis and the conjoint tendon to exhibit the rectus muscle aponeurosis. The hernia sac is isolated, indirect sac is opened and contents reduced, and sac transfixed and reduced, and direct sac repositioned along its course without any suturing.<sup>6-7</sup> The self-gripping flap of the mesh is released and loosely closed around the cord away from the deeper part of the wound. The mesh is carefully oriented to its final position (Figure 3).

The fixation is achieved by applying pressure on the mesh, starting caudally on the pubic bone, then medially onto the internal oblique structures. No sutures are taken to fix the mesh. The cranial part of the mesh is fixed under the external oblique aponeurosis by digital manipulation, exercising care in order to avoid folding the mesh. Lastly, the mesh is pushed down to towards the inguinal ligament and the lateral part is then allowed to fold onto the deep aspect of the divided external oblique aponeurosis. In its final position, the mesh is anchored into the tissue both at the transversalis structures, as well as to the ligament and external aponeurosis.

### Post-operative care and follow-up

Inj. Ceftriaxone 1gm intravenously was given for all patients half an hour prior to the surgery. Post operatively analgesia in the form of Inj. Diclofenac single dose and then Tab. Diclofenac 50mg twice a day for next 2 days was given to all patients.

Operating time was measured as the time of total procedure i.e. starting from the skin incision till the final suture taken for skin closure.

The patients were followed up for postoperative pain which was evaluated using visual analogue scale, wound hematoma, seroma, wound infection, scrotal swelling, chronic pain.

Time for return to routine daily activities done by the patient pre-operatively, postoperative duration of hospital stays, and recurrence rate was also documented.

Presence of any swelling at wound site, discharge, discoloration or scrotal swelling was documented. Patients were assessed for postoperative pain using visual analogue scale on day 1, day 3 and on day 7. Patient was asked to ambulate as early as possible after effect of spinal anesthesia wore off.

Patients were discharged if there was no wound infection, were ambulatory, were taking orally, felt comfortable and requested for discharge. Sutures were removed on the 8th to 10<sup>th</sup> postoperative day. Chronic pain was defined as pain persisting beyond the normal tissue healing time: 3 months.

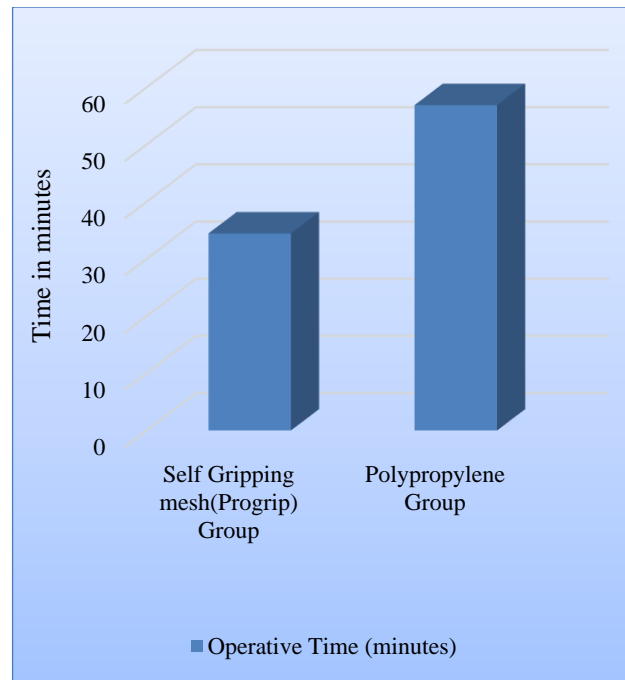
Patients were followed up at 1 and 3 and 6 months to record any late complications such as Seroma and recurrence. Primary outcomes included operative time, post-operative pain. Secondary outcomes included timing of return to normal daily activity, duration of hospital stay and early and late complications.

### Statistical analysis

Data analysis was performed using MedCalc version 17.9.7 software. Categorical variables were analyzed with chi-squared test and continuous variables were analyzed with 't' test and fisher's exact test. Values were reported as mean  $\pm$  standard deviation or median (extremes) or percentages as and when required. P value of less than 0.05 was considered significant.

## RESULTS

Total 60 patients of inguinal hernia were admitted and divided by blind envelope method in Self Gripping mesh (Progrid™)(PG) and Polypropylene group (PPL). The observations made in this study between Self Gripping mesh (Progrid™) and Polypropylene group were as follow.

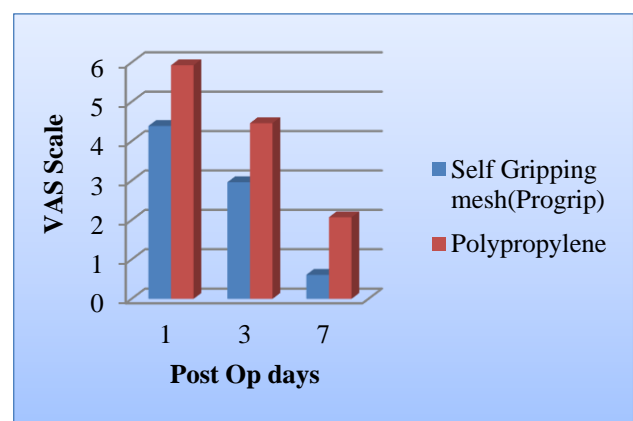


**Figure 4: Operative time (minutes).**

The mean duration of the total surgery in Polypropylene Group group was 56.90  $\pm$  13.8 mins while that in Self Gripping mesh (Progrid) Group was 34.46  $\pm$  12.12 mins. There was a statistically significant difference of nearly 22 minutes with a P value of <0.0001 (Table 1, Figure 4).

Similarly, the mean pain scores in PPL group were seen consistently higher compared to PG group on post-operative day 1, day 3 and day 7. On day 1, the mean pain score in PPL group was 5.93  $\pm$  1.12, compared to PG group, which was 4.39  $\pm$  1.03. On day 3, the mean pain score in PPL group was 4.46  $\pm$  1.10, compared to PG group, which was 2.96  $\pm$  0.84.

On Post-Operative Day 7 the mean VAS Score in PPL Group was 2.07  $\pm$  1.30, while that in PG Group was 0.61  $\pm$  0.88. This difference is statistically significant with a P value of <0.0001 (Table 1, Figure 5).



**Figure 5: Post-operative pain.**

Similarly, early complications like, Seroma was seen in 1 (3.3%) of patients in PG group and 4 (13.33%) patients in Polypropylene group.

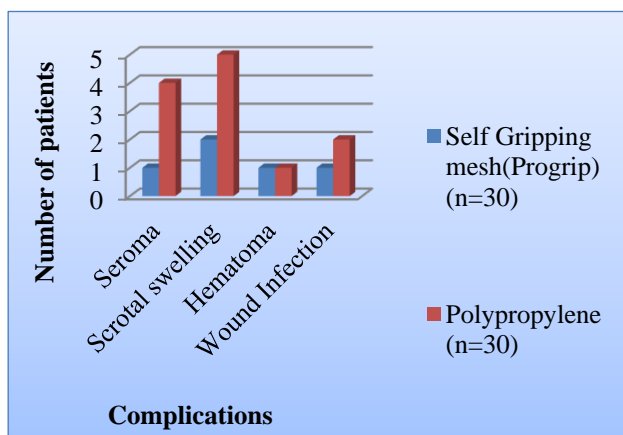
**Table 1: Comparison of outcomes in PG group and PPL group.**

Outcomes	PG group	PPL group	P value
Operative time(minutes)	34.46±12.12	56.90±13.8	<0.0001
<b>Post-op pain scores(vas)</b>			
Day 1	4.39±1.03	5.93±1.12	<0.0001
Day 3	2.96±0.84	4.46±1.10	<0.0001
Day 7	0.61±0.88	2.07±1.30	<0.0001
Seroma	1	4	0.35
Scrotal swelling	2	5	0.42
Hematoma	1	1	1
Wound infection	1	2	0.56
Postoperative hospital stay	2.73±2.22	4.43±2.94	<0.0001
Return to daily activities(days)	5.26±2.28	6.10±3.4	0.0309

The P Value was 0.35, which is considered statistically not significant. Scrotal swelling was seen in 2 (6.6%) of patients in PG group and 5(16.6%) in PPL group. The P value on comparison was 0.42, which is considered statistically not significant.

Hematoma was seen in 1 (3.3%) of patients in PG group and 1(3.3%) in PPL group. The P value on comparison was 1, which is considered statistically not significant.

Wound infection was seen in 1 (3.3%) patient in PG group and 2 (6.6%) in the PPL group. The P Value was 0.56, which is considered statistically not significant (Table 1, Figure 6).

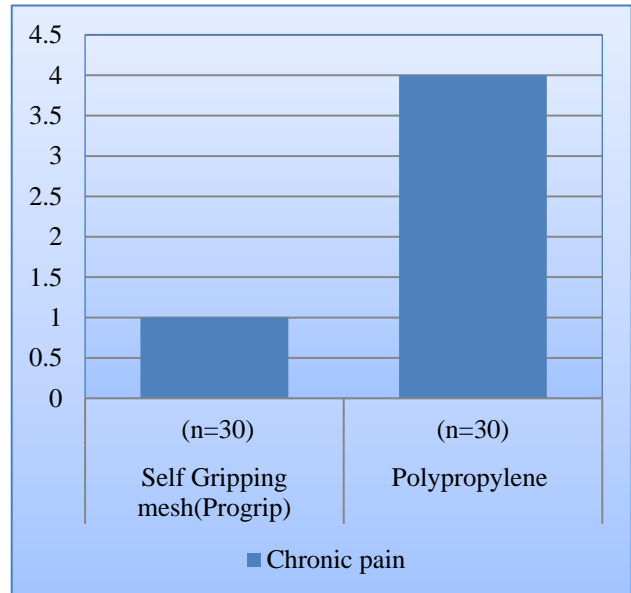


**Figure 6: Early post op complications.**

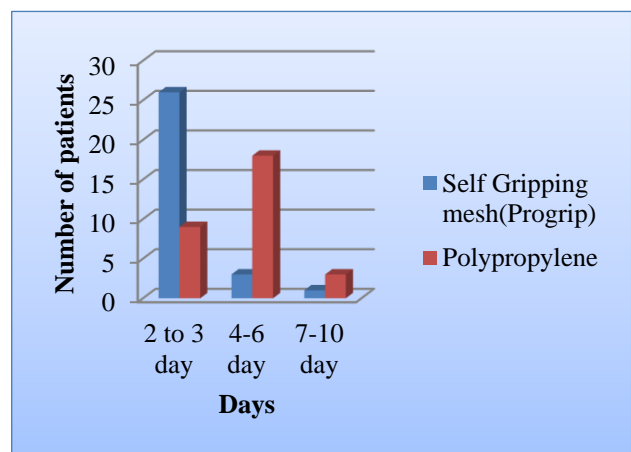
The patients in both groups were followed up after discharge for a period of 3 months with regular OPD

checkups. The overall incidence of chronic groin pain in PPL group was 14.3% while that in PG group was 3.6%. The difference between the two groups is statistically significant  $P=0.012$  (Table 1, Figure 7).

The mean duration of Postoperative Hospital stay in PPL group was  $4.43 \pm 2.94$  days. While that in PG Group was  $2.73 \pm 2.22$ , with a statistically significant difference of 1.7 days with a P value  $< 0.0001$  (Table 1, Figure 8).



**Figure 7: Chronic pain.**



**Figure 8: Post-operative stay.**

The mean duration (in days) to return to the routine light sedentary job work (occupation) was  $6.10 \pm 3.4$  in the PPL group and  $5.26 \pm 2.28$  in the PG group. On statistical calculation the P Value is 0.0309, which is considered statistically significant. (Table 1)

Post-operative follows up for complication like seroma, mesh sepsis, pain, induration at 1 month and 3 month has P value of 0.08 and 0.51 respectively which is considered statistically not significant (Table 1).

## DISCUSSION

The use of mesh has now become the standard of care in repair of inguinal hernia because mesh implantation is known to reduce recurrence by 50%. It has been observed that choice of the prosthesis in hernia repair is far more important than technique as a determinant of outcome.

It is described that polypropylene meshes, as a hydrophobic material, cause some degree of contraction and scar formation in the long-term follow-up. Polypropylene meshes give high risk of recurrence, owing to overall decrease in the size of mesh, as well as an increased subjective foreign body feeling from contracture and scarring. Polyester seems not to suffer from these limitations because it is described as hydrophilic. Other advantages are the softness of polyester without loss of memory, making placement easier and its lack of tendency to stick to fat.

The present study was carried out at SSG Hospital and Baroda Medical College, Vadodra comparing these two meshes in various clinical scenarios and comparing the outcome in immediate post-operative period and by following up these patients for 3 and 6 months. The results were analyzed and compared to various other studies done in this field.

In the present study, total operative time taken was  $56.90 \pm 13.8$  minutes for Polypropylene and  $34.46 \pm 12.12$  minutes for Self Gripping mesh repair with P value  $<0.0001$  which is statistically significant. The mean difference between the two groups with respect to operative time in the current study is 22 minutes. The duration of surgery was shorter in the PG group. However, it is variable and individual surgeon dependent (Table 2).

**Table 2: Comparison of operative time (mean  $\pm$  2SD / median in range) with other studies.**

Studies	PPL (min)	PG (min)	P value
Philippe Chastan et al <sup>11</sup>	-	19 $\pm$ 4	-
LN Jorgensen et al <sup>9</sup>	30	29	$<0.0001$
Yilmaz A et al <sup>10</sup>	58.3 $\pm$ 15.2	24.9 $\pm$ 4.2	$<0.01$
DL Sanders et al <sup>8</sup>	43	35.4	$<0.0001$
Present study	56.90 $\pm$ 13.8	34.46 $\pm$ 12.12	$<0.0001$

In DL Sanders et al study Operative time in PPL Group was 43 minutes and in PG group it was 35.4 minutes.<sup>8</sup> LN Jorgensen et al and Yilmaz A et al in their study found statistically significant difference between the two group. In Yilmaz A et al study Operative time in PPL Group was 58.3 $\pm$ 15.2 minutes and in Self Gripping mesh group it was 24.9 $\pm$ 4.2 minutes. With P value in Yilmaz et al was

$<0.01$  while it was  $<0.0001$  in LN Jorgensen et al (Table 2).<sup>9,10</sup>

The present study has a mean postoperative pain score of  $5.93 \pm 1.12$  in PPL group and  $4.39 \pm 1.03$  in PG group. Lower pain scores are reported among patients in PG group in present study. Self-gripping mesh has less tissue dissection requirement. Polypropylene mesh repair requires more dissection, tissue handling. This may contribute to significant less post-operative pain after the Self Gripping mesh, compared to Polypropylene. Present findings are consistent with the literature (Table 3).

**Table 3: Comparison of post-op pain (mean  $\pm$  2SD / median in range) with other studies.**

Post-op pain (VAS scores)	PPL	PG	P value
Present study	5.93 $\pm$ 1.12	4.39 $\pm$ 1.03	$<0.0001$
Philippe Chastan et al <sup>11</sup>	-	1.1 $\pm$ 1.2	-
Yilmaz A et al <sup>10</sup>	1.43 $\pm$ 1.04	2.07 $\pm$ 1.20	0.052
DLSanders et al <sup>8</sup>	8.6	1.3	0.033

Chastan P et al found post-operative pain score in self gripping mesh group it was 1.1 $\pm$ 1.2.<sup>11</sup> In Yilmaz A et al study post-operative pain score in polypropylene Group was 1.43 $\pm$ 1.04 and in self-gripping mesh Group it was 2.07 $\pm$ 1.20.<sup>10</sup> In Sanders DL et al study post-operative pain score in polypropylene Group was 8.6 and in self-gripping mesh Group it was 1.3 with P value 0.033 which is statistically significant, while it was 0.052 in Yilmaz A. et al which was not statistically significant (Table 3).<sup>8,10</sup>

In Present study the mean duration of postoperative hospital stay in PPL group was  $4.43 \pm 2.94$  days while that in PG Group was  $2.73 \pm 2.22$  days, with a statistically significant difference of 1.7 days and a P value of  $<0.0001$ . Though some patients had to stay for prolonged duration due to complications it was not statistically significant as complications occurred in both groups. Jorgensen LN et al, Yilmaz A et al, Sanders DL et al found duration of hospital stay in polypropylene Group and in self gripping mesh group was not statistically significant (Table 4).<sup>8-10</sup>

**Table 4: Comparison of duration of hospital stay with other studies.**

Duration of hospital stay	PPL	PG	P value
Present study	4.43 $\pm$ 2.94	2.73 $\pm$ 2.22	$<0.0001$
Philippe Chastan et al <sup>11</sup>	-	1	-
L.N.Jorgensen et al <sup>9</sup>	4	4	0.681
Yilmaz A et al <sup>10</sup>	1	1.2	0.492
DL Sanders et al <sup>8</sup>	0.44	0.38	0.452

The time taken to resume to the daily activities like getting dressed, walking, bathing and returning to job work and doing light sedentary work like sitting, desk bound stationary and accounting work.

In the present study the time taken to resume to the daily activities is  $6.10 \pm 3.4$  days in PPL group and  $5.26 \pm 2.28$  days in PG group.

This difference was statistically significant, suggesting patients operated with self-gripping mesh (Progrid-Covidien) get ambulatory sooner and return to the routine activities before the patients operated with Polypropylene mesh repair. Chastan P et al found the time taken to resume to the daily activities in Self Gripping mesh group it was  $5.5 \pm 3.6$  days (Table 5).<sup>11</sup>

**Table 5: Comparison of return to routine daily activities with other studies.**

Return to routine daily activities	PPL	PG	P value
Philippe Chastan et al <sup>11</sup>	-	$5.5 \pm 3.6$	-
Present study	$6.10 \pm 3.4$	$5.26 \pm 2.28$	0.0309

Present findings are consistent with the literature. The cause of this early return to basic activities may be less postoperative pain due to less tissue handling and dissections.

### Wound infections

The present study had 6.6% infection rate in PPL and 3.3% in PG group, with no statistical difference.

Yilmaz A et al found Incidence of Wound Infections in PPL Group was 0% and in self gripping mesh group it was 3.3%.<sup>10</sup>

In Sanders DL et al the incidence of wound infections in PPL Group was 4.9% and in self gripping mesh group it was 2.6%. With P value in Yilmaz A et al and DL Sanders et al was 0.612 and 0.255 respectively which was statistically not significant (Table 6).<sup>8,10</sup>

**Table 6: Comparison of early complications with other studies.**

Studies	Early complications (%)							
	Seroma		Scrotal swelling		Hematoma		Wound infection	
	PPL	PG	PPL	PG	PPL	PG	PPL	PG
Yilmaz A et al <sup>10</sup>	-	-	-	-	3.3	10	0	3.3
Sanders DL et al <sup>8</sup>	2.4	1.9	-	-	2.4	4.4	4.9	2.6
Present study	13.3	3.3	16.6	6.6	3.3	3.3	6.6	3.3

### Scrotal swelling

In the present study the incidence of scrotal swelling was 16.66% in PPL group and 6.6% in PG group. The P Value is 0.42 with no statistical difference. Yilmaz A et al and Sanders DL et al found no incidence of scrotal swelling in PPL Group and in Self Gripping mesh group.<sup>8, 10</sup> Tab Chymoral Forte was given to these patients and scrotal elevation was advised. None of the patients required re-exploration (Table 6).

**Table 7: Comparison of chronic pain in mean  $\pm$  2SD / median with other studies.**

Chronic pain	PPL	PG	P value
Chastan P et al <sup>11</sup>	-	0%	-
Present study	13.33%	3.3%	0.012

### Hematoma

The present study had hematoma in 6.6% in PPL group and 3.3% in PG group. The P Value is 1 which is not statistically significant. Yilmaz A et al found the incidence of hematoma in PPL Group was 3.3% and in Self Gripping mesh group it was 10%.<sup>10</sup>

In Sanders DL et al study the incidence of hematoma in PPL Group was 2.4% and in Self Gripping mesh group it was 4%, which was statistically not significant (Table 6).<sup>8</sup>

### Seroma

The present study had seroma in 13.33% in PPL group and 3.3% in PG group. The P Value is 0.35 which is not statistically significant. In Sanders DL et al study the incidence of seroma in PPL Group was 2.4% and in Self Gripping mesh group it was 1.9% with P value 0.7783, which was statistically not significant (Table 6).<sup>8</sup>

In the present study had 14.3% incidence of chronic pain in PPL group and 3.3% in PG group with P value 0.012. It is found to be of statistical significance. In the present study, an internationally accepted standard definition of pain (pain beyond 3 months) was used.<sup>12-14</sup>

Chastan P et al found there is no incidence of chronic pain in self gripping mesh group (Table 7).<sup>11</sup> Strong foreign body fibrous reactions are seen at the mesh placement sites after inguinal hernia repair.

This causes spermatic cord and nerve entrapment leading to chronic pain. The exact cause of post-herniorraphic pain is not known. The patients were managed with oral analgesics.

### CONCLUSION

Open inguinal hernioplasty using Self Gripping mesh (Progrid-Covidien<sup>TM</sup>) mesh has better outcome in terms

of operative time, post-operative pain, hospital stay, early return to professional life and chronic pain, but a greater number of Randomized control trials and multicenter trials need to be undertaken to study the pros and cons of this procedure in future.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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