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RESEARCH ARTICLE

COMPARATIVE STUDY BETWEEN "SELF-FIXATING" AND "SUTURE FIXATING" POLYPROPYLENE MESH IN INGUINAL OPEN HERNIOPLASTY

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ABSTRACT

Objective: The aim of this study is to perform analysis between self-fixating mesh and sutured mesh in open inguinal hernioplasy. ***Method:*** This study has been conducted in Aswan University Hospitals on 40 patients, the patients will be classified blindly into two groups each group include 20 patients Group A for self-fixating mesh and Group B for suture fixating mesh. ***Result:*** From the results of our study and the certain points we tried to modify in the standard technique of self-fixation mesh at inguinal hernioplasty, we collecting data which suggestive that self-fixation mesh has some advantages more than suture fixation mesh. ***Conclusion:*** Self fixation mesh is a simple, rapid, effective, and safe method for inguinal hernia repair, and may reduce postoperative pain, improve patient general health, and quality of life.

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INTRODUCTION

Inguinal hernia is a very frequent pathology. The life time risk for men is 27% and for women 3% (Kingsnorth *et al*., 2012). Consequently hernia repair is one of the most commonly performed interventions in general surgery. In the United States the incidence of hernia repair is 28 per 100 000 persons (Gould, 2008). The open tension free Lichtenstein repair is a well standardized surgical technique that is easy to learn and can usually be performed in day clinic. Lichtenstein mesh repair is generally considered the gold standard technique for inguinal hernia repair (Amid, 2001), Although hernia recurrence rates have significantly reduced over the years, the levels of chronic groin pain after elective hernia repair have not reduced to the same extent, ranging between 19 and 29% (Koch *et al*., 2008). Chronic groin pain can be debilitating with impact on convalescence and return to work, Several factors can affect the incidence of groin pain such as type of mesh used and fixation of mesh (Fountain, 2006).

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A recent study comparing conventional sutured fixation of the mesh with mesh fixation with fibrin glue has shown a reduction in chronic pain at 12 months with fibrin glue fixation (Canonico *et al*., 2013). This suggests that the pain after mesh repair may be related to suture fixation of the mesh. Subsequent to this, a new self-gripping mesh, that provided a Velcro like adherence to underlying tissues was developed with significant improvement in recurrence rates and chronic groin pain (Chastan, 2009). The major concern is the chronic pain reported after mesh suture fixation. Several reasons are known to cause this chronic pain like nerve entrapment by sutures for mesh fixation, anterior approach of the groin, accidental surgical neuropraxia and tissue inflammatory reaction and fibrosis. To limit these factors, large pore meshes and self-fixating meshes have been introduced (Shah *et al*., 2009).

PATIENTS AND METHODS

This study has been conducted in Aswan University Hospitals from Aug 2017 to Aug 2018 on 40 patients, the patients will be classified blindly into two groups each group include 20 patients Group A for self-fixating mesh and Group B for suture

fixating mesh. The period of follow up is about 6 month. The clinical diagnosis of inguinal hernia was based on symptoms and signs elicited during clinical examination. All patients presented to us in the outpatient clinic. None of the patients presented with an emergency of the hernia. Preoperative preparation for our inguinal hernial repair procedure is straight forward and focus on evaluation for fitness for surgery and an aesthesia and elimination of any evident underlying cause for hernia. Patients arrive at the hospital on the morning of surgery, after fasting from midnight. Immediately prior to surgery, patients receive prophylactic antibiotics. Primary consideration must be given to a through diagnostic workup and an evaluation of surgical options available to treat a patient's underlying pathology. The essence of the workup begins with a complete history, including an understanding of the time course of disease, contributing features leading to the patient's morbidity, and their effect on individual pathophysiology. Evaluation of past medical and operative history, a medication history and adverse reactions to both surgical and medical intervention are also important components of the preoperative evaluation. Particular attention must be directed toward ascertaining a history of previous abdominal surgery. Bleeding tendencies and coagulopathies, if uncorrected, may represent relative contraindications to surgery, as well as a family or personal history of problem with anaesthesia. Allergic responses to medications and a patient's functional status will also contribute to the decision-making process (Unger, 2009).

The patient is placed in the supine position. The groin is prepared in the usual fashion, Incising the skin 3 cm incision is done above and parallel to the medial three fifths of the inguinal ligament, Incision of subcutaneous tissue and ligation of three superficial veins, Opening of external oblique aponeurosis, Delivary of the spermatic cord, the cord is elevated from the posterior wall of the inguinal canal the hernial sac is identified, dissected to the internal ring and opened to allow examination of its contents, The sac is ligated and its distal portion is usually excised. In suture fixation mesh A polypropylene mesh (3 × 5 inch) is trimmed to fit the floor of the inguinal canal, and its apex is first sutured to the public tubercle using a No 3–0 Prolene suture. The same continuous suture then sutures the lower border of the mesh to the free edge of the inguinal ligament, after an opening is made into its lower edge to accommodate the spermatic cord. The continuous suture extends up just medial to the anterior superior iliac spine. Interrupted Prolene sutures then suture the two cuted edges of the mesh together around the spermatic cord. The infero-medial corner of the mesh is then attached well overlapping the pubic tubercle. The mesh is then anchored to the conjoined tendon by interrupted sutures (Prolene 3–0) Fig (1).

While in self fixation mesh The (Progrip mesh) about 12 × 8 cm applied on the floor of inguinal canal and closed around the cord. The mesh is spread down carefully to its final position with color stitch orientated towards and overlapping > 2 cm the pubic bone, fixation of the mesh is immediate. No additional stitch fixation was applied (Fig.2). After meticulous hemostasis, a closed suction drain is placed beneath the external oblique aponeurosis, especially in large inguinal hernias, where an extensive dissection was performed during the plastic reconstruction. The aponeurosis of external oblique is then closed sing absorbable sutures (Vicryl No 2).

Before the closure of the surgical incision, its edges are infiltrated with a long-acting local anesthetic

RESULTS

This study has been conducted in Aswan University Hospitals over a 24 month period from June 2017 to June 2018 on 40 patients which classified into two group each group has 20 patients:-

- Group 1 (Self- fixation mesh inguinal hernia repair).
- Group 2 (Suture fixation mesh inguinal hernia repair).

The period of follow up is about 6 month.

Patient characteristics

1-For group (1)

Mean age was 57 years old (36.5-68.5), number of males was18 patients (90%) while number of females was 2 patients (10%). Patients with oblique inguinal hernia was 15 patients (75%), while number of patients with direct inguinal hernia was 5 patients (25%). Tab (1) & Fig (3) Demographic data and type of hernia for whole group Figure (3)

2- For group (2)

Mean age was 58.5 years old (45-73.5), number of males was 19 patients (95%) while number of females was 1 patient (5%). Patients with oblique inguinal hernia was 17 patients (85%), while number of patients with direct inguinal hernia was 3 patients (15%) Tab (2) & Fig (4).

For groups (1): The operative time was be ranging between (57.5-80) minutes with a mean time 69.5 minutes. Tab (3) &Fig (5)

For group (2): The operative time was be ranging between (89-102) minutes with a mean time 95.45 minute **Tab (4) & Fig (6)**

For group (1)

Wound infection: No infection was happened in 18 patiants (90%), While mild infection was happened in 2 patiants (10%) Tab (5) & Fig (7)

Wound seroma: No seroma was happened in 18 patiants (90%), while mild seroma was happened in 2 patiants (10%). Tab (5) & Fig (7)

Chronic pain: No chronic pain was happened in 9 patiants (45%), mild chronic pain was happened in 10 patiants (50%), while moderate chronic pain was happened in 1 patiant (5%). Tab (5) & Fig (7)

Recurranc: NO recurrence was happened . Tab(6)&Fig(8)

For group (2)

Wound infection: No infection was happened in 16 patiants (80%), mild infection was happened in 3 patiants (15%),while moderate infection was happened in 1 patiant (5%). Tab (5) & Fig (7)

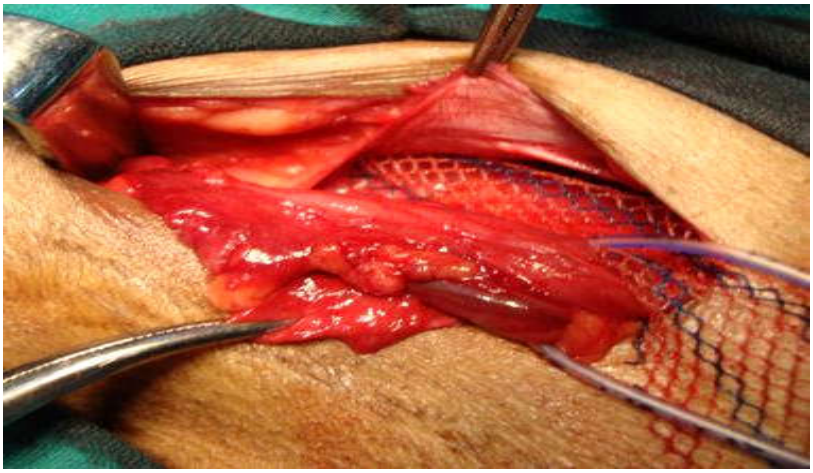

Fig. 1. Application of polypropylene mesh on the floor of inguinal canal

Fig. 2. Closure of the self-gripping flap around the cord (B) Spreading mesh under of the external oblique aponeurosis (C) The mesh anchors to the tissue with the micro-grips immediately with no need for suture fixation

Table 1. Demographic data and type of hernia for whole group

		Mean / N	SD / %	Median (IQR)
Age		55.63	17.22	57 (42.5 - 72)
Sex	Male	37	92.5%	
	Female	3	7.5%	
Direct or oblique	Direct	8	20.0%	
	Oblique	32	80.0%	

Table 2. Demographic data and type of hernia between 2 groups

		Group						Fisher's Exact test of significance	
		Self-fixation mesh			Suture fixation mesh				
		Mean / N	SD / %	Median (IQR)	Mean / N	SD / %	Median (IQR)	P-value	Sig.
Age		52.55	18.43	57 (36.5-68.5)	58.7	15.77	58.5 (45-73.5)	0.264(T)	NS
Sex	Male	18	90%		19	95%		1.00	NS
	Female	2	10%		1	5%			
Direct or oblique	Direct	5	25%		3	15%		0.695	NS
	Oblique	15	75%		17	85%			

Table 3. Time of operation for whole group

Median (IQR)	SD	Mean	
85 (67.5 - 95.5)	17.28	82.48	Time of Operation by mins

Time of operation for whole group Figure (5)

Table 4. Time of operation between 2 groups

	Group						test of significance	
	Self-fixation mesh			Suture fixation mesh				
	Mean	SD	Median (IQR)	Mean	SD	Median (IQR)	P-value	Sig.
Time of Operation by mins	69.5	12.84	67.5 (57.5-80)	95.45	9.69	95.5 (89-102)	<0.001(T)	HS

Table 5. Post operative complication for each group

		Group				Fisher's Exact test of significance	
		Self-fixation mesh		Suture fixation mesh			
		N	%	N	%	P-value	Sig.
Wound infection	No	18	90%	16	80%	0.661	NS
	Mild	2	10%	3	15%		
	Moderate	0	0%	1	5%		
Seroma	No	18	90%	16	80%	0.661	NS
	Mild	2	10%	4	20%		
Chronic pain	No	9	45%	16	80%	0.041	S
	Mild	10	50%	3	15%		
	Moderate	1	5%	1	5%		

Table 6. Recurrence rate for each group

	Group				Fisher's Exact test of significance	
	Self-fixation mesh		Suture fixation mesh			
	N	%	N	%	P-value	Sig.
Recurrence	0	0%	1	5%	1.00	NS

Post operative complication for each group Figure (7)

Table 7. Post hospital stay for each group

	Group						test of significance	
	Self-fixation mesh			Suture fixation mesh				
	Mean	SD	Median (IQR)	Mean	SD	Median (IQR)	P-value	Sig.
Hospital stay by days	1.9	0.64	2 (1.5-2)	3.1	0.72	3 (3-4)	<0.001(M)	HS

Wound seroma: No seroma was happened in 16 patiants (80%), while mild seroma was happened in 4 patiants (20%). Tab (5) & Fig (7)

Chronic pain: No chronic pain was happened in 16 patiants (80%), mild chronic pain was happened in 3 patiants (15%), while moderate chronic pain was happened in 1 patiant (5%) Tab (5) & Fig (7) f

Recurrance: Recurrance was happened in 1 patiant (5%). Tab (6) & Fig (8)

For group (1): The time of hospital stay was be ranging between (1.5-2) days with mean time 1.9 days. Tab (7)

For group (2): The ideal outcome in inguinal hernia surgery is to prevent a recurrence, free repair tension, minimizing the morbidity, disability and both acute and chronic pain that the patient may experience. At the present time, this outcome must be definitively achieved after more than 100 years of hernia surgery. The introduction of mesh prosthesis helped surgeons to decrease recurrence rate of less than 5%. On the contrary, chronic pain (of neuralgic origin) has elicited as one of the most important negative clinical sequel which can follow inguinal hernia repair. The pathogenesis of chronic pain which is defined as sustained discomfort and/or pain after 3 months of surgery is not clearly understood (Shin *et al*., 2005). A prosthetic mesh has certain features like elasticity, density, material, strength, and pore size. Standard heavy weight polypropylene mesh is the most frequently used one because it is affordable, available in most hospitals, inert, non-absorbable, and have tensile strength enough to prevent recurrence. Nevertheless, there are actual problems with mesh usage as foreign body sensation at the site of surgery and chronic postoperative pain or discomfort. This created a disagreement about standard heavy weight polypropylene mesh. Mesh made of Polyester might be an appropriate alternative, but it is not popular as polypropylene mesh (Earle, 2008). Newer light weight meshes have been manufactured to overcome those problems. Nevertheless, all light weight meshes are very expensive than standard heavy weight meshes. There are also coated and composite polyester and polypropylene meshes in the market. The aim of the coating is to prohibit host response to the prosthesis, yet still provide adequate strength for repair. The absence of tension during positioning of the mesh and closure of the prosthesis around the cord can decrease pain created by tension on surrounding tissues and more particularly if sutures can be avoided. The grip provides the advantage of obtaining uniform fixation on the whole surface of the mesh that can decrease the like hood of hernial sac sliding between the prosthesis and the transversalis fascia. The development of chronic pain is of ongoing concern, as its onset is unpredictable. Chronic pain rates vary from 11 to 40 per cent, depending on definition (Nienhuijs *et al*., 2007).

With this mesh, improved quality of life of the patients was expected by reducing post-operative pain. The lightweight mesh can contribute to reduce this adverse outcome , in case of neurological pain, the resorption of fixating grip in about one and half year should allow reduction and disappearance of the pain (Khan *et al*., 2006). To the best of my knowledge, this report is the first study evaluating the use of Parietex ProGrip low density monofilament polyester mesh in open inguinal hernia repair in in the Egyptian population. The results of the current short-term study suggests that repair of inguinal hernia with the Lichtenstein technique using self-gripping mesh is efficient and safe procedure for the Egyptian patients. Similar conclusions were drawn from previous studies conducted in China and Western countries. The suture less Pro Grip mesh is a revolutionary modification as it can be secured without sutures, avoiding any risk for nerve entrapment, and preserving relationship of anatomical structures.

Moreover, the resorbable PLA micro-grips of the ProGrip mesh (poly lactic acid micro-grips of the ProGrip mesh) are substantially blunt to prevent damage to the surrounding tissues including delicate ductus deferens and nerve fibers, examined the impact of ProGrip mesh on fertility in rat models and found that self-gripping mesh posed no harm to the ductus deferens. Given the larger dimensions of the human ductus deferens, there is little or no risk for a detrimental effect on fertility by application of a ProGrip mesh on exposed tissue (Kolbe, 2010). In general, the ProGrip mesh is kept flat during placement. This, however, can make operative manipulation +less difficult, particularly if the size of the incision is kept to > 6 cm for aesthetic reasons. For obese patients, more than one attempt may be needed to attach the mesh in place through the incision in deep fat layers. Repeated manipulation of mesh placement should be avoided as it may reduce the adherence of the mesh to the tissues, thus increasing the risk of mesh dislocation or migration which may predispose to hernia recurrence and chronic pain after surgery. The mean operation time in present study was (67.5 - 95.5) minutes, which is comparable to times reported in other clinical trials using the laparoscopic or open approach. There were also no reports of hernia recurrence or postoperative complications among the present cohort. The self-gripping mesh provides the advantage of obtaining fixation without using any sutures entrapping nerves in the groin. Furthermore, this method of mesh placement minimized the time of operative manipulation. This may have contributed to the significantly lower pain VAS scores in the current study compared with those described in previous studies (Asencio *et al*., 2009). Potential advantages of a self-gripping mesh need to be balanced against a possible disadvantage of higher recurrence rates in the long term. Other ProGrip™ studies have shown recurrence rates of up to 2 per cent after 1 year. Unlike these, the present study protocol did not allow for a medial stitch to fix the mesh, which has been shown to result in more postoperative pain.

All patients reported no/slight pain with good health status after 3 month follow-up. While there were decreases in the SF-36 dimension scores(Short Form-36) at 3 weeks and 3 months after surgery compared with baseline scores, the SF-36 values showed a remarkable improvement at 6 and 12 months of follow-up. Scores in all eight health parameters of the SF-36 were above baseline at 6 months of follow-up assessment, demonstrating the actual benefits of using the ProGrip mesh on postoperative health and quality of life (Post *et al*., 2004). The prospective nature of this study may be viewed as an advantage; as 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. Further long-term follow-up studies in Egyptian populations need to be undertaken.

Conclusion

The aim of this study is to perform analysis between self-fixating mesh and sutured mesh in open inguinal hernioplasy.
From the results of our study and the certain points we tried to modify in the standard technique of self-fixation mesh at inguinal hernioplasty, we collecting data which suggestive that self-fixation mesh has some advantages more than suture fixation mesh.

Advantages of self-fixation mesh at inguinal hernioplasty: Minimize the size of the incision and facilitate operative manipulation.

- Less operative time (57.5-80 min), while the suture fixation mesh (89-102).
- Less post-operative wound infection and wound seroma.
- Less post-operative chronic pain.
- Less post-operative hospital stay.
- Self-gripping mesh is made of lightweight isoelastic large-pore knitted monofilament polypropylene fabric that incorporates resorbable microgrips to provide self-gripping fixation during the first few months after implantation.

Finally, lichtenstein open inguinal hernia repair using Parietex Pro Grip low density polyester mesh is a simple, rapid, effective, and safe method for inguinal hernia repair, and may reduce postoperative pain, improve patient general health, and quality of life.

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