

Prospective Randomized Controlled Study of Efficacy of Self Gripping Mesh in Inguinal Hernia Repair

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Abstract

Background: Chronic pain following inguinal hernia repair is a complex problem. Mesh fixation with sutures may be a contributing factor to this pain. A new self gripping mesh (Parietex® Progrid®) was developed to allow sutureless fixation of mesh, avoid chronic pain after hernia surgery and reduce the operative time.

Aim of the Work: The aim of this study was to study the efficacy of self gripping mesh in inguinal hernia repair. Methods: Twenty six male patients with uncomplicated inguinal hernia were randomized into 2 groups. Group A: Included 10 patients subjected to repair with polypropylene mesh. Group B: Included 16 patients subjected to repair with parietex® progrid® mesh. They were followed-up for incidence of pain (with VAS) and integrity of the mesh (with U/S).

Results: There were no statistically significant differences between both groups regarding age, sex, body mass index or incidence of postoperative pain ($p=0.385$). The operative time and mesh fixation time were significantly shorter in self gripping mesh group than the sutured mesh group ($p<0.001$). There were no reported cases of recurrence, haematoma, epididymo-orchitis or testicular atrophy in either group during the follow-up period. Scrotal oedema was detected in 7 cases in group A and 4 cases in group B. Seroma was detected in 3 cases in group A and 2 cases in group B. Wound infection occurred in 2 cases in group A.

Conclusion: The higher price of the parietex progrid mesh makes its use questionable. The smaller number of the studied cases with the short follow-up period make us unable to give solid recommendation to use one mesh type than the other.

Key Words: Inguinal – Hernia repair – Progrid mesh.

Introduction

LICHTENSTEIN tension free mesh repair is the most commonly used technique for open inguinal hernia. The ideal outcome in inguinal hernia surgery is to provide a repair that is free from recurrence, pain, and infection, with minimal scarring and with improvement in patient's quality of life [1]. In the

traditional Lichtenstein procedure, the mesh is fixed in position with sutures to prevent migration [2]. The widespread use of this technique has reduced the hernia recurrence rates to acceptable levels (less than 2%). The rate of chronic pain following hernia repair ranges from 11-40%, so the focus of scientific attention has shifted towards prevention of postoperative pain [3]. The reason for chronic pain is multi-factorial; the type of mesh material, the nerve irritation or injury, the nerve entrapment by the fixation sutures, or the inflammatory reaction by the mesh have all been reported as possible causes. Different fixation procedures using absorbable sutures and skin staples were investigated [4].

Type of mesh may play a role in the post-operative pain. The lightweight mesh did not produce post-operative pain, foreign body sensation or pain during exercise and movement [2]. It is documented that the conventional polypropylene mesh and sutures for fixation are associated with formation of mesh aponeurosis scar tissue complex as an inflammatory response induced by polypropylene material [5]. Any mesh should have the usual properties of any implant, including being non-allergenic, non-carcinogenic, have good incorporation into tissue it is replacing or reinforcing [6].

In 2008, Covidien launched self gripping (parietex® progrid®) mesh indicated for the use in inguinal hernia and incisional hernia repairs, to offer patients greater comfort following surgery, and allow surgeons the ability to position and secure the mesh and reduction of the of the operation time [7]. It is an isoelastic large pore knitted fabric of monofilament polyester that incorporates biodegradable polylactic acid (PLA) progrid®. These microgrid® are club shaped 1mm projections, they integrate into the tissue for 0.5mm below the

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lower rim of the mesh and provide stronger tissue incorporation at 5 days than fixation by staples [8]. Fig. (1) its density is 74g/m^2 at implantation and 38g/m^2 after absorption [9]. It is approximately 45% lighter than standard polypropylene mesh (38g/m^2 versus 85g/m^2) [3].

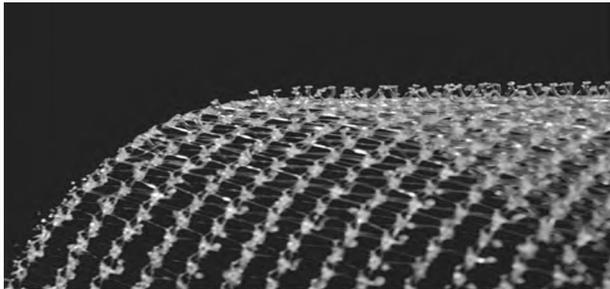


Fig. (1): Parietex® progrid® mesh absorbable microgrips for fixation [2].

Patients and Methods

Patients:

This prospective study was conducted on 26 adult male patients presented with primary reducible inguinal hernia who were admitted into the Surgical Oncology Unit at General Surgery Department, Tanta University Hospital from August 2017 to July 2018. Patients were randomized into 2 groups; Control group, group A. The 1st 10 cases underwent inguinal hernia repair with polypropylene® mesh and group B, the subsequent 16 cases who underwent inguinal hernia repair with self gripping (Parietex®) mesh.

Inclusion criteria:

Adult male patients 18 years or older with primary reducible inguinal hernia.

Exclusion criteria:

- Patients younger than 18 years.
- Complicated inguinal hernia.
- Recurrent inguinal hernia.
- Female patients.

The details of the operation technique and complications were explained to the patient and an informed written consent was obtained. Approval by the ethical committee for research in Tanta Faculty of medicine was obtained before initiating this study.

Preoperative workup:

Every patient was subjected to:

- 1- *History taking:* Age, sex, occupation, special habits, reducibility, duration.

A particular stress was made upon risk factors of inguinal hernia as smoking, heavy weight lifting and the nature of patient's work, chronic cough, chronic constipation, bladder neck obstruction, body mass index (BMI) >25 and history of appendectomy.

2- Examination:

- *General:* Vital data (blood pressure, pulse and temperature) and general condition.
- *Local:* To define type of the hernia and/or complications.

Checking the other hernia orifices, presence of organomegaly and the cardiopulmonary status.

3- Investigation:

a- Laboratory: Routine laboratory investigations as: Complete blood analysis, renal function tests.

b- Imaging:

- Chest X-ray.
- Pelvi abdominal U/S to exclude organomegally, abdominal masses or prostatic enlargement.

Patient preparation:

In every patient, the operative area swabbed with betadine the night before surgery.

Prophylactic antibiotics: (Amoxicillin + clavulanic acid) IV were given 2 hours before induction of anesthesia and a second dose 12 hrs later.

Operative details:

Operations were performed under spinal or general anesthesia with the patients in supine position. Skin disinfection was done with 10% povidine iodine antiseptic solution.

Skin incision was made 1/2 inch above the medial 2/3 of the inguinal ligament to expose the external oblique aponeurosis, then it was divided.

The cord is dissected out of its bed to obtain a suitable space for mesh positioning deep to the external oblique aponeurosis.

Dissection of the hernia sac from the spermatic cord was gently done. In case of indirect oblique hernia, the sac was dissected from the cord till its proper neck, then the sac was excised after transfixing-ligation of its neck by absorbable suture material (Vicryl 0). In case of direct hernia, the sac was reduced without opening.

Mesh fixation:

Group A: A sheet of polypropylene® (PP) mesh tailored to shape the posterior wall of the inguinal canal where it is placed, so that it overlapped the pubic tubercle by at least 1 cm medially. Fixed with interrupted polypropylene 2/0 suture to the inguinal ligament inferiorly and interrupted sutures to the conjoint tendon superiorly. A slit is made for the spermatic cord and the tails secured back together around the cord with permanent sutures (Lichtenstein in 1984)

Group B: A 6x11cm Parietex® progrid® mesh was laid over the posterior wall of the inguinal canal and tailoring of the mesh was done to accommodate the created space overlapped the pubic tubercle minimally by 1 cm. Fixation was done by applying digital pressure on the mesh, starting medially on the pubic bone, then laterally onto the conjoint tendon. To help the mesh positioning, one stitch of absorbable suture to be taken to fix it to the pubic tubercle.

Closure: The external oblique aponeurosis was then closed anterior to the spermatic cord structures by non-absorbable suture. The subcutaneous tissue was approximated by an absorbable sutures (vicryl 2/0) and skin was closed by non absorbable subcuticular sutures. No drainage system was needed.

Recovery and postoperative care:

Patients were monitored in a recovery room for a minimum 2 hours. Non-narcotic injectable analgesic (75mg diclofenac sodium intra muscular) was given routinely to every patients in the immediate post operative period and converted to oral tablets on the next morning.

Follow-up:

Every patient is followed-up monthly for the first 3 months then every 6 months till the end of the study.

On every follow-up visit the patient is:

- 1- *Clinically well assessed for presence of signs of:*
 - Early post-operative complications (that occur within 30 days after surgery) e.g: Local inflammation, swelling as seroma, recurrence or tenderness [10].
 - Late post-operative complications (that occur after 30 days after surgery) e.g: Chronic groin pain, mesh infection or testicular atrophy.
- 2- Inguinal ultra-sonographic study at the 6th month post-operatively to check the stability and integrity of the mesh or excessive scarring.

Methods of evaluation:

A- The surgeon and the surgery:

- 1- Technical difficulties as in cases of disturbed anatomy and obese patients.
- 2- Operative time.
- 3- Mesh fixation time.

B- The patient:

- 1- Post operative pain, using visual analogue scale (VAS) and the needed analgesic dose to kill pain [11].
- 2- Hospital stay.
- 3- Return to normal activity.
- 4- Patient satisfaction.

C- The mesh itself and related complications:

- 1- Seroma detected clinically.
- 2- Hematoma, detected clinically.
- 3- Wound infection (superficial/deep) according to Centre for Disease Control (CDC) definition of Surgical Site Infection (SSI).
- 4- Mesh infection.
- 5- Recurrence. Clinically and as confirmed by U/S.
- 6- Thickening of the spermatic cord and testicular atrophy assessed by U/S.
- 7- Foreign body sensation.
- 8- Mesh shrinkage as assessed by U/S.
- 9- Cost.

Visual analogue scale (VAS):

The pain VAS is self completed by the respondent. The respondents are asked to place a line perpendicular to the VAS line at the point that represents their pain intensity.

Scoring:

Using a ruler, the score is determined by measuring the distance (mm) on the 10cm line between the "no pain" anchor and the patient's mark providing a range of scores from 0-100 and determine the degree of pain as following: None (0-4mm), mild (5-44mm), moderate (45-74mm) and severe (75-100mm) [11] Fig. (2).

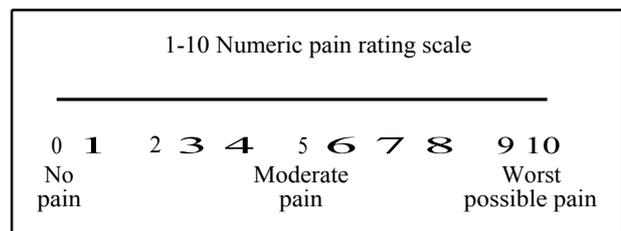


Fig. (2): Visual analogue scale [12].

Results

This study was a prospective, randomized, controlled study. It included twenty six adult male patients who were admitted into the Surgical Oncology Unit at General Surgery Department in Tanta University Hospital for elective repair of uncomplicated inguinal hernia during the period from the 1st of August 2017 to the end of July 2018.

The patients were randomized into group A (Conventional polypropylene® mesh) and group B (Parietex® Progrid® mesh).

Group A: Five patients (50%) had a right side hernia while five patients (50%) had a left side one. Six of them (60%) had an IHH while three patients (30%) had a DIH, and only one patient (10%) had pantaloon hernia. Four patients (40%)

had history of other side hernia repair with polypropylene® mesh.

Group B: Including sixteen patients who underwent inguinal hernia repair with self gripping (Parietex® Progrid®) mesh. Eight patients (50%) had a right sided hernia while eight patients (50%) had a left side one. Fourteen patients (87.5%) had an indirect inguinal hernia (IHH) while two patients (12.5%) had a direct inguinal hernia (DIH). Two patients (12.5%) had a history of other side hernia repair using polypropylene® mesh Tables (1,2).

Pain necessitates administration of non steroidal analgesic in the form of Brufen 400mg tablets one tablet every 8 hrs. They responded well within one week without need to increase dose except only one patient in group A (10%) required increasing the dose to 600mg tablets one tablet every 8 hrs till pain disappeared over 10 weeks.

U/S findings:

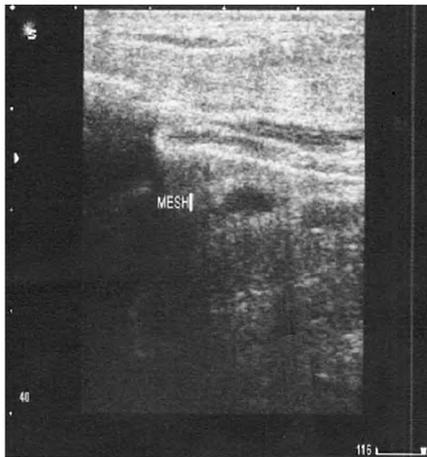


Fig. (3): U/S of the left inguinal region showing self gripping (parietex® progrid®) mesh in 33 yrs old male patient after one month post surgery.

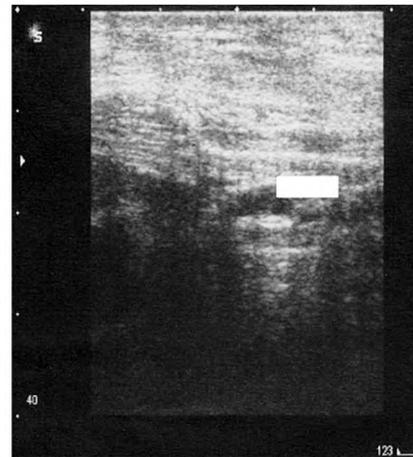


Fig. (4): U/S of the left inguinal region showing self gripping (Parietex® progrid®) mesh in 33 yrs old male patient after 6 months post surgery.

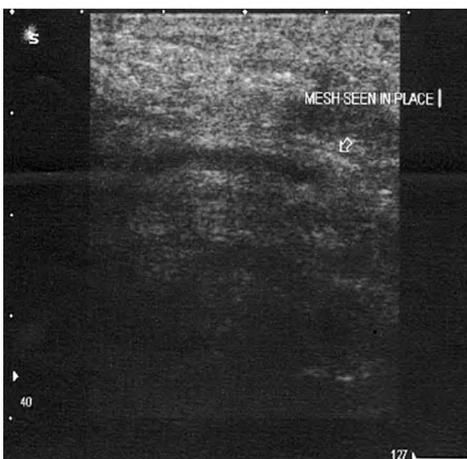


Fig. (5): U/S of right inguinal region showing Polypropylene® mesh in 45 yrs old male patient after one month post surgery.

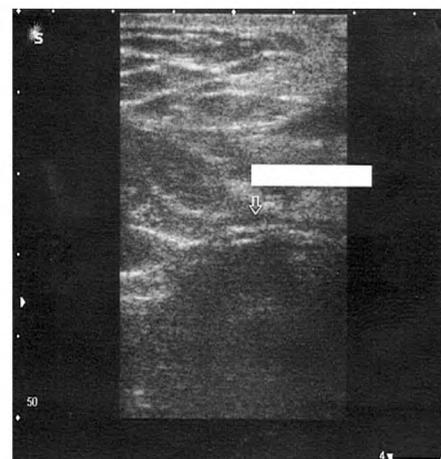


Fig. (6): U/S of right inguinal region showing Polypropylene® mesh in 45 yrs old male patient after 6 months post surgery.

Table (1): Demographic data of the studied cases in both groups.

	Group A (n=10)		Group B (n=16)		Test of significance	p		
	No.	%	No.	%				
Age:								
Min-Max	22.0–63.0		20.0–61.0		t=1.359	0.187		
Mean ± SD	46.40–13.75		39.25–12.61					
Median	47.5		41.0					
BMI:								
Min-Max	24.6–36.0		23.66–38.97		t=0.139	0.890		
Mean ± SD	29.20– 4.13		29.44–4.41					
Median	28.55		28.55					
Occupation:								
Manual worker	8	80.0	11	68.8	$\chi^2=2.650$	MCp=0.250		
Student	1	10.0	0	0				
Employee	1	10.0	5	31.2				
Medical History:								
No	2	20.0	6	37.5	$\chi^2=0.885$	FEp=0.420		
Yes	8	80.0	10	62.5				
DM	3	30.0	1	6.3			$\chi^2=2.666$	FEp=0.264
Chest problems	5	50.0	10	62.5			$\chi^2=0.394$	FEp=0.689
Surgical History:								
No	4	40.0	9	56.3	$\chi^2=5.439$	MCp=0.250		
Appendectomy	2	20.0	1	6.3				
Other hernia side repair	4	40.0	2	12.5				
Other surgeries	0	0.00	4	25.0				

Table (2): Total operative time, mesh fixation time, complications and postoperative pain of the studied cases in both groups.

	Group A (n=10)		Group B (n=16)		Test of significance	p		
	No.	%	No.	%				
Total operative time:								
Min-Max	55.0–75.0		40.0–55.0		t=7.652	<0.001		
Mean ± SD	65.50±7.06		46.81±5.37					
Median	64.0		46.0					
Mesh fixation time:								
Min-Max	13.0–18.0		3.0–7.0		t=20.099	<0.001		
Mean ± SD	15.3 ±1.49		5.13±109					
Median	15.0		5.0					
Early complications:								
No	2	20.0	10	62.5	$\chi^2=4.473$	FEp=0.051		
Yes	8	80.0	6	37.5				
Scrotal oedema	7	70.0	4	25.0			$\chi^2=5.105$	FEp=0.043
Seroma	3	30.0	2	12.5			$\chi^2=1.213$	FEp=0.340
Wound infection	2	20.0	0	0.0			$\chi^2=3.467$	FEp=0.138
Haematoma	0	0.0	0	0.0			–	–
Recurrence	0	0.0	0	0.0	–	–		
Late complications:								
Epididymo-orchitis	0	0.0	0	0.0	–	–		
Testicular atrophy	0	0.0	0	0.0	–	–		
Pain according to VAS:								
None	9	90.0	16	100.0	$\chi^2=1.664$	FEp=0.3 85		
Mild	1	10.0	0	0.0				
Moderate	0	0.0	0	0.0				
Severe	0	0.0	0	0.0				
Analgesia:								
No need	9	90.0	16	100.0	$\chi^2=1.664$	FEp=0.3 85		
Need	1	10.0	0	0.0				
Regular dose	9	90.0	16	100.0				
Over dose	1	10.0	0	0.0				

Discussion

This study was designed to assess the outcome of self gripping mesh versus the conventional sutured mesh.

In group A, the ages ranged from 22-63 years with a median of 47.0 years. In group B, the ages ranged from 20-61 years with a median of 41.0 years. There was no statistically significant difference between both groups regarding age ($p=0.187$). This is the usual age at repair as reported by Maharaul H et al., [1]. Verhagen T and colleagues [3].

In this study BMI $>25\%$ was a risk factor for inguinal hernia in both groups. In group A, it ranged from 24.60-36.0Kg/m² with mean 29.20 \pm 4.13 Kg/m² and median 28.55Kg/m² and In group B, it ranged from 23.66-38.97Kg/m² with mean 29.44 \pm 4.41Kg/m² and median 28.55Kg/m². This is comparable with the findings of Ceith N and colleagues [13]. and Verhagen T et al., [3] who reported that the median BMI in both groups was 25Kg/m².

In the current study: 5 cases (50%) in group A and 10 cases (62.5%) in group B were smokers and had chest problems. Whereas, Verhagen T and colleagues [3] reported 28% of patients in self gripping mesh group and 23.75% in sutured mesh group were smokers and had chest problems. Kingnorth A and his group [2] reported that 27.9% of cases were smokers and had chest problems. In their series, Zhang C and colleagues [4] reported 57.04% in the self gripping mesh group and 29.2% in sutured mesh group were smokers and had chest problems.

As regard co-morbidity, we reported that 3 patients (30%) in group A and one patient (6.3%) in group B were diabetics. This is comparable with the finding of Kingsnorth A et al., [2] who reported that 6% of their cases were diabetics.

As regard the operative time (calculated from skin incision to skin closure); in group A, it ranged from 55-75 minutes with a mean of 65.5 \pm 7.06 minutes. However, in group B it ranged from 40-55 minutes with a mean of 46.81 \pm 5.37 minutes, with reduction in the operative time ranged 15-20 minutes. The operative time in group B was statistically significantly shorter than it in group A ($p<0.001$).

As regard the time needed for mesh fixation; in group A, it ranged from 13-18 minutes with a mean of 15.3 \pm 1.49 minutes, whereas in group B, it ranged from 3-7 minutes with a mean of 5.13 \pm 1.09 minutes. The mesh fixation time was signif-

icantly shorter in group B ($p<0.001$). These results are consistent with the results of Batabyal P et al., [14]. Maharaul H et al., [1]. For surprise, Anadol A Z et al., [1] found no significant difference in the operative time between using self gripping mesh and mesh fixation by conventional sutures.

The incidence of seroma in our study was 3 patients (30%) in group A and 2 patients (12.6%) in group B. All the 5 patients who developed mild seroma had an indirect inguino-scrotal hernia with larger sac that required more distal dissection creating large surface area and large dead space which may be the reasons of seromas formation. These seromas resolved spontaneously without any intervention in all cases during the first few post operative days.

In the present study; 7 cases (70%) in group A and 4 cases (24%) in group B developed mild scrotal edema that resolved spontaneously during the few post operative days. While, Batabyal P et al., [14]. reported that scrotal edema was 2% in patients who underwent inguinal hernia repair with self gripping mesh.

In the present study, we reported wound infection in 2 cases (were diabetics) in group A during the first few postoperative days that resolved on antibiotics. No reported cases with wound infection in group B. In our study, over the short period of follow-up, we reported no recurrence in either group. Therefore, long term follow-up can judge the recurrence as some studies said that if recurrence to occur, most incidence supposed to be within 2 yrs after operation [8,16].

On ultrasound study during the follow-up period, we reported no mesh complications in terms of shrinkage, migration or fragmentation. However, migration to a great extent depends on the nature of mesh and the type of fixation of the mesh. An experimental study in rats comparing polypropylene, polyglactin and mixed polypropylene-polyglactin mesh revealed frequent and deeper penetration of bladder by polypropylene one. It is found erosion of polypropylene into the muscularis mucosa of bladder within 14 days [17].

Regarding postoperative pain and need for analgesia, in our study there was only one patient (10%) in group A had mild pain for 3 months postoperatively that required increasing the dose of analgesia. While, no reported cases of chronic groin pain in group B. There was no statistically significant difference between both groups ($p=0.385$). Zhang C et al., [4]. Junsheng Li and colleagues [8] and Verhagen T et al., [1]. also re-

ported no statistically significant differences in pain intensity between the two groups with p -value =0.40, 0.25, 0.016 respectively.

Contrary to the other reports, El-Komy H and colleagues [18] reported that the mean VAS scores for the self gripping mesh group were consistently significantly higher than those in the sutured mesh group. They found that, after 2 months sutured mesh patients cured from pain whereas 75% of self gripping mesh patients still have pain especially with movement.

Conclusion:

The self gripping mesh proved to be as safe and effective as the conventional sutured polypropylene mesh in Lichtenstein tension free repair of uncomplicated inguinal hernia. There was no difference between the two meshes used as regard to the technical difficulties and surgeons were equally satisfied.

There was no difference between the two meshes used as regard the post operative complications such as seroma, hematoma, wound infection and mesh complications in terms of shrinkage, migration, fragmentation indicates that both types of mesh are effective and safe.

The mesh fixation time and the overall operative time were significantly shorter with self gripping mesh than with the sutured one.

Self gripping mesh hocks proved to be as effective and safe as sutures in fixing the mesh in place. As there was no recurrence was reported in both groups during the follow-up period, also there was no statistically significant difference between both groups regarding postoperative chronic pain and need for analgesia. ($p=0.385$).

The higher price of self gripping mesh compared with conventional mesh makes its use questionable. The self gripping mesh costs 22 times that of the polypropylene mesh; 4500LE vs750 LE. This may be the most limitation factor of its wide spread use.

The smaller number of the studied cases (26) together with the short time of follow-up (6 months) make us unable to give solid recommendation to use one mesh type than the other.

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دراسة مستقبلية في تقييم كفاءة الشبكة ذاتية التثبيت في إصلاح الفتق الإربي

يعتبر إصلاح الفتق الإربي من أكثر الجراحات المنتشرة في العالم حيث يتم إصلاحه إما عن طريق إصلاح الفتحة في جدار البطن عن طريق حياكة العضلات مع بعضها البعض أو وضع شبكة على مكان الفتحة، كما يوجد تقنيات عديدة لوضع الشبكة وأكثرها هو تثبيت الشبكة في مكانها بغرز لمنع حركتها أو تجعدها وعادة يسبب ألم مزمن بعد العملية عن طريق تداخل الغرز مع الأنسجة أو إثارة العصب أو الضغط على العصب.

إن الشبكة ذاتية التثبيت (برياتكس) صممت لتجنب تثبيت الشبكة بالغرز وذلك لتقليل حدوث التليف بعد التثبيت أثناء الإلتئام وتقليل الألم بعد العملية وهي شبكة خفيفة الوزن محبة للماء من مادة البولي إستر كما تتمتع بوجود زوائد خطافية تمكنها من الالتصاق بقوة بالأنسجة والعضلات والإستغناء عن وسائل التثبيت التقليدية.

أجريت هذه الدراسة على ٢٦ مريض ممن يعانون من الفتق الإربي بوحدة جراحة الأورام بقسم الجراحة العامة مستشفى طنطا الجامعي في الفترة من أغسطس ٢٠١٧ إلى يوليو تم ٢٠١٨ تقسيمهم عشوائياً إلى مجموعتين وفقاً لنوع الشبكة المستخدمة، المجموعة الأولى: إشتملت على ١٠ مرضى تلقوا شبكة البرولين وأستخدمت الخيوط الجراحية لتثبيتها والمجموعة الثانية: إشتملت على ١٦ مريضاً حيث تم إستخدام الشبكة ذاتية التثبيت (برياتكس) لإصلاح الفتق الإربي.

كانت مدة تثبيت الشبكة والوقت الكلي للجراحة أقصر بكثير بإستخدام الشبكة ذاتية التثبيت مما كانت عليه بإستخدام شبكة البرولين ولا يوجد فروق ذات دلالات إحصائية في معدل الألم، المضاعفات المبكرة والمتأخرة بعد العملية.