Comparative study between lightweight poliglecaprone meshes versus traditional heavyweight polypropylene meshes for the repair of inguinal hernia

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Introduction The ideal outcome of 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.

Aim of the work Is to compare lightweight poliglecaprone (Ultrapropolypropylene/Monocryl), UltraPro™ mesh with the standard heavyweight polypropylene mesh in tension free Lichtenstein inguinal hernia repair.

Patients and methods The current study included 200 patients complained of uncomplicated inguinal hernia and they were randomized into two groups according to the type of mesh used in tension free Lichtenstein inguinal hernia repair. Group I, 100 patients received the standard polypropylene mesh. Group II, 100 patients received light weight UltraPro™ mesh, using sutures for their fixation.

Results The UltraPro™ (LWM) mesh proved to be as safe and effective as the standard (HWM) prolene mesh in repair of uncomplicated inguinal hernia. There was no difference between the two groups as regard to the technical difficulties, operative complications and surgeons were equally satisfied. There was more incidence of chronic pain with prolene mesh (25%) compared to (zero%) with UltraPro™ mesh. The mesh fixation time and the overall operative time were shorter with UltraPro™ mesh.

Conclusion The shorter operative time and the no-need to use analgesics could partially compensate the higher cost of UltraPro™ mesh in the absence of other economic factors such as the duration of patient improvement and return to work.

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Introduction

Inguinal hernia repair is one of the most common operative procedures performed in general surgery. Almost 14% of the population develop an inguinal hernia with ~80 000 repairs performed each year in the UK and 800 000 repairs each year in the USA [1,2]. Lichtenstein hernioplasty is now described as a 'gold standard' for open inguinal hernia repair in the European Guidelines on inguinal hernia [3]. Many trials have been published proving the superiority of mesh repair over nonmesh techniques [3]. Despite reducing the incidence of recurrence compared with sutured tissue repair, the use of prosthetic mesh has been linked with chronic pain and foreign body sensation [4]. The incidence of foreign body sensation is reported to occur in ~40% [5] and chronic pain in ~30% of patients [5,6]. There is growing interest in the use of lightweight meshes (LWM) for all types of hernia repair based upon predicted benefits when compared with heavyweight meshes (HWM). These include accelerated recovery with less postoperative pain and earlier return to normal activity, increased patient comfort with reduced mesh awareness, and less chronic pain with improved quality of life [7–9].

UltraPro is a recently introduced mesh that is composed of two weaves of lightweight polypropylene and poliglecaprone, which is a monofilament, gives the mesh additional stiffness for handling, and dissolves in ~90 days [10].

The aim of the present work was to compare lightweight poliglecaprone (Ultrapropolypropylene/Monocryl), UltraPro mesh with the standard heavyweight polypropylene, Prolene mesh in tension-free Lichtenstein inguinal hernia repair.

Patients and methods

The present study included 200 patients, presented to Al-Hussain University Hospitals, in Cairo, Egypt, for elective repair of uncomplicated inguinal hernia, during the period from November 2017 till March 2019, after obtaining the local ethics committee approval. All patients admitted to the surgery department signed a

written informed consent. They were randomized using closed envelopes into two groups:

Group I: 100 patients underwent elective inguinal hernia repair using standard Prolene mesh. Group II: 100 patients underwent elective inguinal hernia repair using UltraPro (Ethicon Inc., Somerville, New Jersey, USA) mesh.

(1) Inclusion criteria were age over 14 years and primary inguinal hernia.
(2) Exclusion criteria were as follows:
    (a) Patients having hernia that was irreducible, strangulated, or recurrent.
    (b) Patients who were pregnant or had the desire of pregnancy, which could be allowed only after stability of their condition.
    (c) Patients at high risk for anesthesia, classes 4 and 5 according to physical status classification of the American Society of Anesthesiologists.
    (d) Patients with a history for drug abuse, psychiatric illness, uncontrolled depression, and suicidal attempt.
    (e) Patients are unable to understand the questionnaire.

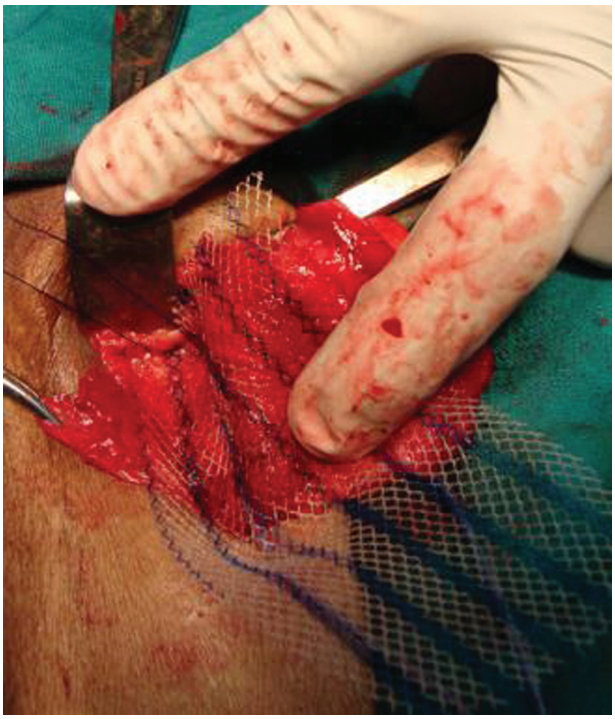
Surgical techniques

Patients were randomized to receive either standard prolene mesh or UltraPro mesh using closed envelopes opened before surgery. Operations were carried out under spinal or general anesthesia. Tension-free inguinal hernia mesh repair for both groups was done as described by Lichtenstein *et al.* [11] (Figs 1 and 2).

Statistical analysis

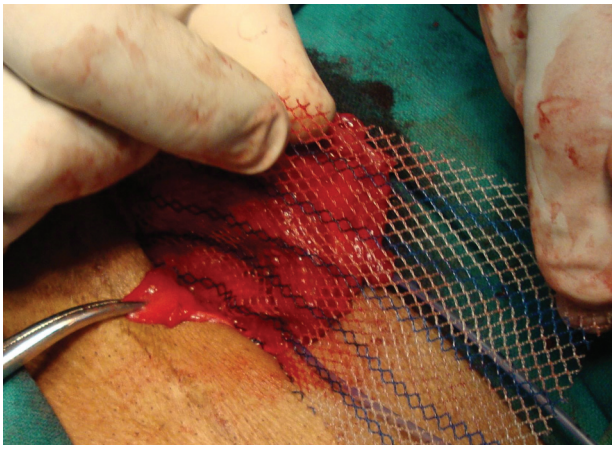
Data were analyzed using IBM SPSS software package version 20.0 (IBM Corporation, Armonk, New York, USA). Quantitative data were presented as mean and SD. Qualitative data were presented as number and percentage. Logistic regression analysis was used to calculate odds ratio and *P* value. *P* value less than 0.05 was considered significant.

Figure 1



First medial most stitch in mesh, fixed ~1 cm medial to pubic tubercle.

Figure 2



Lower edge of mesh sutured to inguinal ligament up to internal inguinal ring.

Results

There was no statistically significant difference between both groups regarding demographic data, including age and hernia side and type. The differences between the two groups regarding mesh-fixation time, overall operative time, technical difficulties, surgeon satisfaction, nerves preservation, cremasteric muscle cutting, and the posterior wall repair are illustrated in Table 1. Regarding the time needed for mesh fixation, there was a statistically significant difference between the two groups. The mesh-fixation time was shorter in group II, with *P* value less than 0.0057. Regarding the operative time (calculated from skin incision to skin closure), the operative time in group II was significantly shorter than in group I, with *P* value less than 0.0009. There was no statistical significance between the two groups regarding technical difficulties. The surgeons were almost equally satisfied with the procedure in both groups (in 95% of patients in each group). There was

Table 1 Comparison between the two studied groups according to the surgical technique

	Group I (*N*=100) [*n* (%)]	Group II (*N*=100) [*n* (%)]	Test of significance
Technical difficulties			
No	90 (90)	90 (90)	1.0
Yes	10 (10)	10 (10)	
Causes for technical difficulties			
Not-yet-familiar with mesh type	0 (0)	10 (10)	0.594
Obese patient	5 (5)	0 (0)	
Anatomy (unclear)	5 (5)	0 (0)	
Surgeon satisfaction			
Not satisfied	5 (5)	5 (5)	1.0
Satisfied	95 (95)	95 (95)	
Operative time (min)			
Minimum–maximum	35.0–90.0	30.0–70.0	<0.0009
Mean±SD	51.25±12.55	45.25±12.55	
Mesh-fixation time (min)			
Minimum–maximum	8.20–18.0	7.0 16.0	<0.0057
Mean±SD	12.11±2.20	11.05±3.09	
Nerves			
Not clear	0 (0)	5 (5)	1.0
Preserved	85 (85)	85 (85)	
Cutting iliohypogastric	15 (15)	10 (10)	
Repair of posterior wall	20 (20)	20 (20)	
Cremasteric muscle			
Cut	20 (20)	15 (15)	0.457
Preserved	80 (80)	85 (85)	

no statistically significant difference between the two groups regarding nerves preservation, cremasteric muscle cutting, and the posterior wall repair. The hospital stay was equal in both groups to 1 day. Regarding the postoperative complications, they are illustrated in Table 2. Regarding the testicular volume and perfusion, evaluation was done using ultrasound (US) and color Doppler preoperatively and 3 months postoperative, as illustrated in Tables 3–5. Regarding pain, evaluation of the postoperative pain was done using the visual analog score (VAS) [12], as illustrated in Tables 6 and 7. The pain score was significantly higher in group I in comparison with group II, with *P* value less than 0.0001. The effect of pain on patients is illustrated in Table 7. As illustrated in Table 8, cutting the iliohypogastric nerve did not significantly affect the severity of postoperative pain in the two groups or the incidence of chronic pain in group I. Regarding the cost at the time of the study, in group II, UltraPro costed 1400 Egyptian Pounds (LE), whereas in group I, prolene mesh costed 400 LE, with addition to this the price of sutures needed for mesh fixation and wound closure (~70 LE). So, the total cost is ~1470 LE and 470 LE, subsequently.

Table 2 Comparison between the two studied groups according to postoperative complications

	Group I (*N*=100) [*n* (%)]	Group II (*N*=100) [*n* (%)]	*P* value
Seroma	20 (20)	10 (10)	0.0734
Hematoma	10 (10)	5 (5)	0.2828
Wound infection	10 (10)	10 (10)	1.0
Mesh infection	0 (0)	0 (0)	1.0
Recurrence	0 (0)	0 (0)	1.0
Thickening of spermatic cord and testicular atrophy	0 (0)	0 (0)	1.0
Epididymo-orchitis	10 (10)	0 (0)	0.0015
Scrotal edema	30 (30)	15 (15)	0.0004
Foreign body sensation	0 (0)	0 (0)	1.0

Discussion

In our study, the advantage of UltraPro mesh clearly emerged with respect to operative time, which was significantly shorter in the fixation time. The time needed for mesh fixation in group II reached 7 min (7.0–16.0 min). These results are consistent with those of Chastan [13], who reported a mesh-fixation time of ~7 min. That was obvious earlier in our study when the surgeons were yet familiar with the mesh and its handling. In those first four cases the mesh took longer time for its fixation (65, 69, 65, and 64 min) compared with 30 min later in the study. Shorter surgery time may be beneficial in terms of cost and reduced infection incidence [14]. However, in our study, there was no difference between the two groups regarding wound infection. Superficial wound infection presented in 10 (10%) patients in each group and responded to antibiotics and resolved within 10–15 days. There were no reported cases with mesh infection.

The incidence of seroma in our study was 20% (20 patients) in group I and 10% (10 patients) in group II. This is higher than the results of Chastan [13], which showed 0% seroma (70 hernias) with LWM Progrip and by García-Ureña *et al* [7], who reported 17 (6.5%) seromas of 256 that received LWM. In our study, seromas resolved spontaneously without any intervention in all cases during the first two postoperative weeks except for one case in group I, which had a relatively larger seroma that needed aspiration. In the present study, we had 30 (30%) cases of minimal scrotal edema in group I and 15 (15%) cases of minimal scrotal edema in group II. Scrotal edema has been found to be in patients with indirect hernias and who had a large hernia sac. It resolved spontaneously during the first 10 postoperative days. Epididymo-orchitis occurred in 10 (10%) patients in group I, whereas none of group II patients experienced it.

Table 3 Comparing the hernia and contralateral side regarding testicular volume and resistive index in group I

	Hernia		Contralateral side	
	Pre	Post	Pre	Post
Testicular volume				
Minimum–maximum	10.0–21.0	8.50–17.0	10.0–21.80	10.50–17.50
Mean±SD	14.74±3.41	13.10±2.50	14.38±3.37	14.57–2.26
P value	0.0001		0.06401	
RI				
Minimum–maximum	0.41–0.79	0.49–0.80	0.43–0.80	0.46–0.75
Mean±SD	0.61±0.08	0.67±0.08	0.61±0.10	0.61±0.09
P value	<0.0001		1.0000	

RI, resistive index.

Table 4 Comparing the hernia and contralateral sides regarding testicular volume and resistive index in group II

	Hernia		Contralateral side	
	Pre	Post	Pre	Post
Testicular volume				
Minimum–maximum	10.20–21.50	10.0–19.60	10.0–19.50	10.20–19.80
Mean±SD	15.55±3.68	14.74±3.41	14.26±3.18	14.42–3.17
P value	0.1080		0.7220	
RI				
Minimum–maximum	0.51–0.72	0.52–0.75	0.50–0.72	0.50–0.70
Mean±SD	0.62±0.06	0.64±0.07	0.60±0.06	0.61±0.05
P value	0.0313		0.2019	

RI, resistive index.

Table 5 Comparison between the two groups according to testicular volume and resistive index postoperatively

	Group I	Group II	*P*
Testicular volume			
Minimum–maximum	8.50–17.0	10.0–19.60	0.0001
Mean±SD	13.10±2.50	14.74±3.41	
RI			
Minimum–maximum	0.49–0.80	0.50–0.72	0.0053
Mean±SD	0.67±0.08	0.64±0.07	

RI, resistive index.

Table 6 Comparison between the two groups according to pain

	Group I	Group II	*P*
1st day	*N*=100	*N*=100	
Minimum–maximum	4.0–9.0	3.0–6.0	<0.0001
Mean±SD	7.10±1.40	3.90±0.85	
2 weeks	*N*=100	*N*=100	
Minimum–maximum	3.0–10.0	1.0–7.0	<0.0001
Mean±SD	6.75±1.89	2.85±1.23	
1 month	*N*=100	*N*=100	
Minimum–maximum	0.0–9.0	0.0–4.0	<0.0001
Mean±SD	5.55±2.16	0.85±1.23	
2 months	*N*=95	*N*=100	
Minimum–maximum	2.0–8.0	0.0–0.0	<0.001
Mean±SD	4.26±2.47	0.0±0.0	
3 months	*N*=95	*N*=100	
Minimum–maximum	2.0–7.0	0.0–0.0	<0.0001
Mean±SD	2.63±2.43	0.0±0.0	
6 months	*N*=95	*N*=100	
Minimum–maximum	3.0–5.0	0.0–0.0	<0.0007
Mean±SD	1.16±1.83	0.0±0.0	
After 6 months	*N*=95	*N*=100	
Minimum–maximum	0.0–7.0	0.0–0.0	<0.0016
Mean±SD	1.11±2.05	0.0±0.0	

This prospective study aimed to evaluate the effect of mesh implantation and peri-mesh fibrosis on testicular flow. The assessment was done by using gray-scale sonography, and color Doppler sonography was performed to evaluate testicular arterial impedance, perfusion, and venous flow. Measurements were made bilaterally at the level of the inguinal canal, one day before and at the end of the third month after the operation for the two groups. Blood flow in the testicle can be represented by vascular resistance or resistive index (RI) (RI=systolic peak velocity–end diastolic peak velocity/systolic peak velocity). In the current study, the presence of hernia itself had an effect on the testicular volume and perfusion. The testicular volume on the hernia side was bigger than the healthy contralateral side in group I and reached significance in group II. Moreover, the RI on the hernia side was higher than it on the contralateral side in both groups, although the difference was not significant. This could be explained by the pressure the hernia itself exerts on the spermatic cord structures [15]. In the present study, the mesh repair had a significant effect on the testicular volume and its blood flow. The testicular volume decreased significantly in both groups

Table 7 Comparison between the two studied groups according to the effect of pain

	Group I (*N*=100) [*n* (%)]	Group II (*N*=100) [*n* (%)]	
Postoperative pain on VAS			
Minimum–maximum	4.0–9.0	3.0–6.0	*P*<0.0001
Mean±SD	7.10±1.41	3.90±0.85	
Patient satisfaction			
Not satisfied	25 (25)	5 (5)	*P*<0.0001
Satisfied	75 (75)	95 (95)	
Return to normal activity and work			
Minimum–maximum	1.43–12.0	1.0–3.0	*P*<0.0001
Mean±SD	4.97±3.71	1.51±0.64	
Improvement			
Improved	70 (70)	100 (100)	*P*=0.022
Partially improved	20 (20)	0 (0)	
Lost to follow-up	1 (5)	0 (0)	
Not improved	1 (5)	0 (0)	
Duration (weeks)	*N*=90	*N*=100	
Minimum–maximum	10–32.0	1.43–4.0	*P*<0.0001
Mean±SD	13.39±7.54	2.02±0.78	
Need for analgesia	85 (85)	10 (10)	*P*<0.0001
Chronic pain	10 (10)	0 (0)	*P*<0.0015

VAS, visual analog scale.

Table 8 Relation between chronic pain and nerves

Nerves	Chronic pain [*n* (%)]		
	No	Yes	
Group I			
Not clear	0 (0)	0 (0)	*P*=1
Preserved	85 (85)	80 (80)	
Cutting iliohypogastric	15 (15)	20 (20)	
Group II			
Not clear	5 (5)	0 (0)	–
Preserved	85 (85)	0 (0)	
Cutting iliohypogastric	10 (10)	0 (0)	

postoperatively, whereas the RI increased also significantly in both groups. The decrease in the testicular volume and the increase in RI was more with the UltraPro group. However, when comparing it with the prolene group, also, the difference was obvious and it reach a significance, with *P*=0.0001 and *P*=0.0053 for the volume and RI, respectively. This difference was obvious when comparing the hernia side and the contralateral side postoperatively. In the UltraPro group, the testicular volume which was bigger than the healthy side preoperatively and had decreased postoperative to become significantly smaller than the other side, with a significant increase in the RI between the repaired side and the contralateral side, which was unlike the HWM prolene group, where although there was a decrease in the testicular volume postoperatively, it was still bigger than the contralateral side. The difference in the RI between the two sides reached a significant value (*P*=0.0053). The change in testicular volume in both groups remains within normal ranges, with a mean of 13.10±2.50 in group I and a mean of 14.74±3.41 in group II, with no cases of testicular atrophy reported.

This study was based on the hypothesis that the LWM would result in less chronic pain and discomfort in comparison with the standard HWM. Different studies report the rate of prolonged pain after LWM repair as from 9.7 to 51.6% [7–9]. In the present study, and during the early postoperative period, the mean VAS scores for the HWM were consistently significantly higher than those in the LWM. By VAS, pain ranged from 4 to 9 on VAS in group I, whereas ranged from 3 to 6 in group II. Pain was in the inguinal region, upper medial thigh, or genitals (penis, scrotum, or testicle) and is most often lancinating or burning in nature. Unfortunately, the pain in group I did not show much improvement during the next 2 weeks and ranged from 3 to 10 on VAS, which was unlike in group II which showed good improvement, with a pain score range from 1 to 7 on VAS. After 1 month, a degree of improvement regarding pain was seen in group I, which ranged from 0 to 9 on VAS, compared with a mild degree of pain and discomfort in group II, which ranged from 0 to 4 on VAS.

Patients, in the HWM group, reported higher level of pain during the first month and had other complications such as wound infection, hematoma, seroma, and scrotal edema. The severity of pain during the first month in group I, reflected on the patient's need of analgesia. Overall, 85% reported a daily use of analgesia compared with only 10% in group II. One patient in group I was admitted to the ER with gastritis secondary to excessive use of analgesia. He responded well later to medical treatment. At the second postoperative month, there was a significant difference between the two groups, as 75% of patients in group I still reported having pain, especially with movement, whereas 100% of patient in group II reported being pain free. Regarding chronic pain at sixth months, 60 (60%) patients reported variable degree of pain, especially during movement, but on continuing the follow-up, only 25 (25%) patients complained from having different degree of pain. One of these five patients had gradual improvement regarding his pain; he experienced a deterioration at the sixth month, with increase in the intensity of his pain from 3 to 4 on VAS with hard work to 7 on VAS, sometimes even at rest. There was an evidence that the cause of pain laid partly in the region of the medial inguinal ligament, where sutures involved pubic periosteal structures and the physiological tensing of

this ligament that leads to pain [16]. In this respect, the idea of fixing the mesh to the pubis without sutures is logical.

Nerve damage occurring during surgery appears to be the most common cause of posthernia repair pain because sensory disturbances are frequently seen in these patients. Pain usually presents in the distribution of the affected nerve [17]. In the present study, the three nerves were identified and preserved in 85% of patients in both groups. Accidental cut of the iliohypogastric nerve occurred in three (15%) patients in group I and two (10%) patients in group II. However, clear identification of the three nerves failed in one patient in group II. Cutting the iliohypogastric nerve did not significantly affect the postoperative pain in both groups. The pain score in those patients was slightly higher than when the three nerves were identified and preserved but not significantly. This could be explained by the fact that resection of the nerve distally leads to neuroma formation. Moreover, there was no sensory loss along distribution of the nerve and this also could be explained by the fact that there is direct communication between branches of the major innervations of the groin, and so sensory loss that may result following nerve cutting might be compensated for by cross-innervation provided by cutaneous nerves from the contralateral side. In the present study, nerves cutting did not significantly affect the incidence of chronic pain. However, it slightly increased the severity of postoperative pain but not significantly. In the present study, there was no difference between the two groups regarding other risk factors for pain such as age, BMI, and type of anesthesia. Preoperative pain seemed to be a risk factor, with multiple studies showing that those who report pain before are more likely to develop chronic pain afterward [16,17]. Unfortunately, preoperative pain was not assessed in the current study, and we may consider it one of the limitations in this study.

There was no recurrence in either group in this present study to date. The lack of recurrences, observed in our study, especially regarding group I, strongly suggests that this mesh follows the key principles of the standard Lichtenstein repair.

In the present study, mesh shrinkage was planned to be assessed using US on the sixth month postoperatively. Knowing that poliglecaprone echogenicity is close to that of prolene, US was the method of choice in the current study. Unfortunately, this failed to be achieved as unlike what we expected the UltraPro mesh was not visualized by US or by computed tomography, and MRI was recommended but it was not available.

The poliglecaprone mesh costs approximately –two to three times more than the comparable mesh of pure polypropylene with the sutures needed for its fixation, 1470 LE versus 470 LE. From an economical point of view, these increased costs are compensated by the reduced utilization of the operating room owing to the significant shorter operative time with the UltraPro. However, duration of sick leave, time to resumption of normal activities, need for analgesia, and other medications were recorded to be more in respect to the UltraPro group, which will add to the overall cost.

Conclusion

The UltraPro (LWM) mesh proved to be as safe and effective as the standard (HWM) prolene mesh in Lichtenstein tension-free repair of uncomplicated inguinal hernia. There was no difference between the two meshes used regarding the technical difficulties. Surgeons were equally satisfied, and postoperative complications included seroma, hematoma, wound infection, mesh infection, and FB sensation, except epididymo-orchitis. The shorter operative time and the no need to use analgesics could partially compensate the higher cost of UltraPro mesh in the absence of other economic factors such as the duration of patient improvement and return to work.

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Conflicts of interest

There are no conflicts of interest.

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