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Comparative Study Between Lightweight Meshes Versus Traditional Heavyweight Meshes for the Repair of Inguinal Hernia

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Abstract

Background and aim: 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**: this study aimed to compare light weight poliglecaprone (Ultrapropolypropylene/Monocryl), UltraPro™ mesh with the standard heavy weight polypropylene mesh in tension free Lichtenstein inguinal hernia repair. **Patients and methods**: the current study included 40 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, 20 patients received the standard polypropylene mesh. Group II, 20 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.

Keywords: hernia, inguinal, Lichtenstein, mesh, UltraPro™, polypropylene.

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 around 80,000 repairs performed each year in the UK and 800,000 repairs each year in the US [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 non-mesh techniques [4].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 [5]. The incidence of foreign body sensation is reported to occur in around 40% [5] and chronic pain in around 30% of patients [5, 6]. There is growing interest in the use of lighter weight 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™ [Ethicon, Inc, Somerville, NJ] is a recently introduced mesh that is composed of two weaves of light weight polypropylene and poliglecaprone, which is a monofilament, gives the mesh additional stiffness for handling and dissolves in approximately 90 days [10,11].

The aim of the present work was to compare light weight poliglecaprone (Ultrapropolypropylene /Monocryl), UltraProTM mesh with the standard heavy weight polypropylene mesh in tension free Lichtenstein inguinal hernia repair.

Patients and methods:

The present study included forty patients, presented to Al-Azhar University Hospitals, for elective repair of uncomplicated inguinal hernia, during the period from March 2018 till September 2018. **The study was approved by the Ethics Board of Al-Azhar University.**

The study was randomized using close-envelope into two groups:

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Group I: 20 patients underwent elective inguinal hernia repair using standard Prolene™ mesh.

Group II: 20 patients underwent elective inguinal hernia repair using UltraPro™ mesh.

A) **Inclusion criteria**: age over 14 years , primary inguinal hernia

B)**Exclusion criteria**: patients were excluded if:

Hernia was irreducible, strangulated or recurrent,

Pregnancy or desire of pregnancy was present, which could be allowed only after stability of their condition.

Patients at high risk for anaesthesia, class 4 and 5 according to physical status classification of the (ASA) American Society of Anaesthesiologists.

History for drug abuse, psychiatric illness, uncontrolled depression and suicidal attempt.

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 anaesthesia. Tension free inguinal hernia repair for both groups was done as described by Lichtenstein [10].

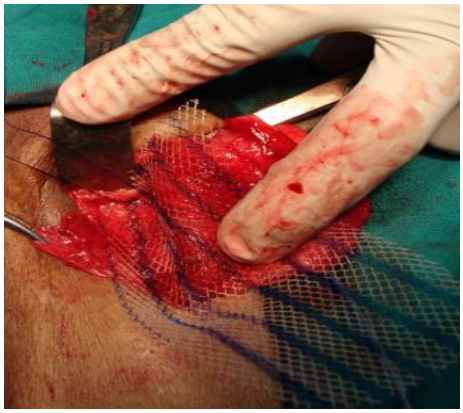

Figure 1: first medial most stitch in mesh, fixed about 1 cm medial to pubic tubercle

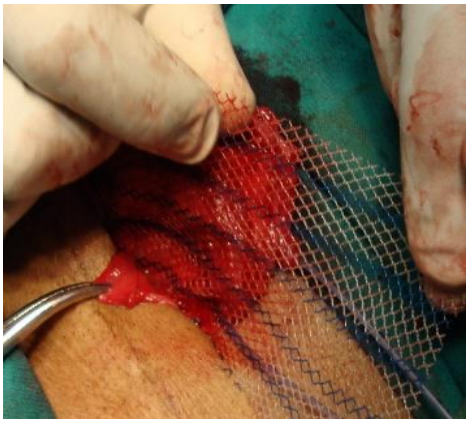

Figure 2: lower edge of mesh sutured to inguinal ligament up to internal inguinal ring.

Results:

There was no statistical significant difference between both groups as regard age, hernia side and type as illustrated in tables I and II. The difference between the two groups as regard to mesh fixation time, overall operative time, technical difficulties, surgeon satisfaction, nerves preservation, cremasteric muscle cutting and the posterior wall repair were illustrated in table III. As regards to the time needed for mesh fixation, there was statistically significant difference between the two groups. The mesh fixation time was shorter in group II with p value = ($p < 0.0057$).As regard to the operative time (Calculated from skin incision to skin closure), the operative time in group II was little significantly shorter than it in group I, with p value = ($p < 0.0009$).There was no statistical significance between the two groups as regard technical difficulties. The surgeons were almost equally satisfied with the procedure in both groups (in 95% of patients in each group). There were no statistical significant differences. There was no statistical significant difference between the two groups as regard nerves preservation, cremasteric muscle cutting and the posterior wall repair.

The hospital stay was equal in both groups to one day. As regard to pain, evaluation of the post-operative pain was done using the VAS, as illustrated in table VIII and figure (3). The pain score was significantly higher in group I in comparison to group II with a P value = ($p <0.0001$). The impact of pain on patient's need of analgesia illustrated in table (IX). Group I showed higher incidence of post-operative pain, 17 patients (85%) showed a continuous need of analgesia compared to only 2 patients (10%) in group II with P value = ($p<0.0001$).As illustrated in tables X and XI cutting the iliohypogastric nerve did not significantly affect the severity of post-operative pain in the two groups or the incidence of chronic pain in group I.As regards to the cost, in group II; UltraPro costs 1400 LE, while in group I; Prolene mesh cost 400 LE, add to this the price of sutures needed for mesh fixation and wound closure (about

70 LE). So, the total cost is about 1470 LE and 470 LE, subsequently.

Table I: distribution of the studied cases according to the age

Age (years)	Group I Prolene (n=20)	Group II UltraPro (n=20)	Test of Sig.
Min - Max	14 – 62	15 - 60	P = 0.5158
Mean ± SD	38 ± 24	37.5 ± 22.5	

Table II: distribution of the studied cases according to the demographic data

	Group I Prolene (n=20)		Group II UltraPro (n=20)		Test of Sig.
	No.	%	No.	%	
Type					
OIH	19	95	18	90	P = 0.2828
DIH	1	5	2	10	
Side					
Right	15	75	16	80	P = 0.4985
Left	5	25	4	20	
History of opposite side repair	4	20	2	10	P = 0.0734

Table III: comparison between the two studied groups according to the surgical technique

	Group I (n=20)		Group II (n=20)		Test of Sig.
	No.	%	No.	%	
Technical difficulties					
no	18	90	18	90	P = 1.0
yes	2	10	2	10	
Causes for technical difficulties					
Not-yet-familiar é mesh type	0	0	2	10	P = 0.594
Obese patient	1	5	0	0	
Anatomy (unclear)	1	5		0	
Surgeon Satisfaction					
Not Satisfied	1	5	1	5	P = 1.0
Satisfied	19	95	19	95	
Operative time (min)					
Min - Max	35.0 - 90.0		30.0 - 70.0		P<0.0009
Mean ± SD	51.25 ± 12.55		45.25 ± 12.55		
Mesh-Fixation time (min)					
Min - Max	8.20- 18.0		7.0 16.0		P<0.0057
Mean ± SD	12.11 ± 2.20		11.05 ± 3.09		
Nerves					
Not Clear	0	0	1	5	P = 1.0
Preserved	17	85	17	85	
Cutting iliohypogastric	3	25	2	10	
Repair of post wall	4	20	4	20	P = 1.0
Cremasteric MS					
Cut	4	20	3	3	P = 0.457
Preserved	16	80	17	85	

Table IV: comparison between the two studied groups according to post-operative complications

	Group I (n=20)		Group II (n=20)		Test of Sig.
	No.	%	No.	%	
Seroma	4	20	2	10	P = 0.0734
Haematoma	2	10	1	5	P = 0.2828
Wound infection	2	10	2	10	P = 1.0
Mesh infection	0	0	0	0	P = 1.0
Recurrence	0	0	0	0	P = 1.0
Thickening of spermatic cord and testicular atrophy	0	0	0	0	P = 1.0
Epididmo-orchitis	2	10	0	0	P = 0.0015
Scrotal oedema	6	30	3	15	P = 0.0004
F.B. Sensation	0	0	0	0	P = 1.0

Table V: comparing the hernia and contra lateral side as regard to testicular volume and RI in group I

	Hernia		Contra-lateral side	
	Pre	Post	Pre	Post
Testicular Volume				
Min - Max	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				
Min - Max	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	

Table VI: comparing the hernia and contra lateral side as regard to testicular volume and RI in group II

	Hernia		Contra-lateral side	
	Pre	Post	Pre	Post
Testicular Volume				
Min - Max	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				
Min - Max	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	

Table VII: comparison between the two groups according to testicular volume and RI, post-operative

	Group I	Group II	P
Testicular Volume			
Min - Max	8.50 – 17.0	10.0 – 19.60	0.0001
Mean ± SD	13.10 ± 2.50	14.74 ± 3.41	
RI			
Min - Max	0.49 – 0.80	0.50 – 0.72	0.0053
Mean ± SD	0.67 ± 0.08	0.64 ± 0.07	

Table VIII: comparison between the two groups according to pain

	Group I	Group II	P
1st Day	(n=20)	(n=20)	
Min - Max	4.0 – 9.0	3.0 - 6.0	< 0.0001*
Mean ± SD	7.10 ± 1.40	3.90 ± 0.85	
2 Weeks	(n=20)	(n=20)	
Min - Max	3.0 – 10.0	1.0 - 7.0	< 0.0001*
Mean ± SD	6.75 ± 1.89	2.85 ± 1.23	
1 Month	(n=20)	(n=20)	
Min - Max	0.0 – 9.0	0.0 - 4.0	< 0.0001*
Mean ± SD	5.55 ± 2.16	0.85 ± 1.23	
2 Months	(n=19)	(n=20)	
Min - Max	2.0 – 8.0	0.0 – 0.0	< 0.001*
Mean ± SD	4.26 ± 2.47	0.0 ± 0.0	
3 Months	(n=19)	(n=20)	
Min - Max	2.0 – 7.0	0.0 – 0.0	< 0.0001*
Mean ± SD	2.63 ± 2.43	0.0 ± 0.0	
6 Months	(n=19)	(n=20)	
Min - Max	3.0 – 5.0	0.0 – 0.0	< 0.0007*
Mean ± SD	1.16 ± 1.83	0.0 ± 0.0	
6 Months	(n=19)	(n=20)	
Min - Max	0.0 – 7.0	0.0 – 0.0	< 0.0016*
Mean ± SD	1.11 ± 2.05	0.0 ± 0.0	

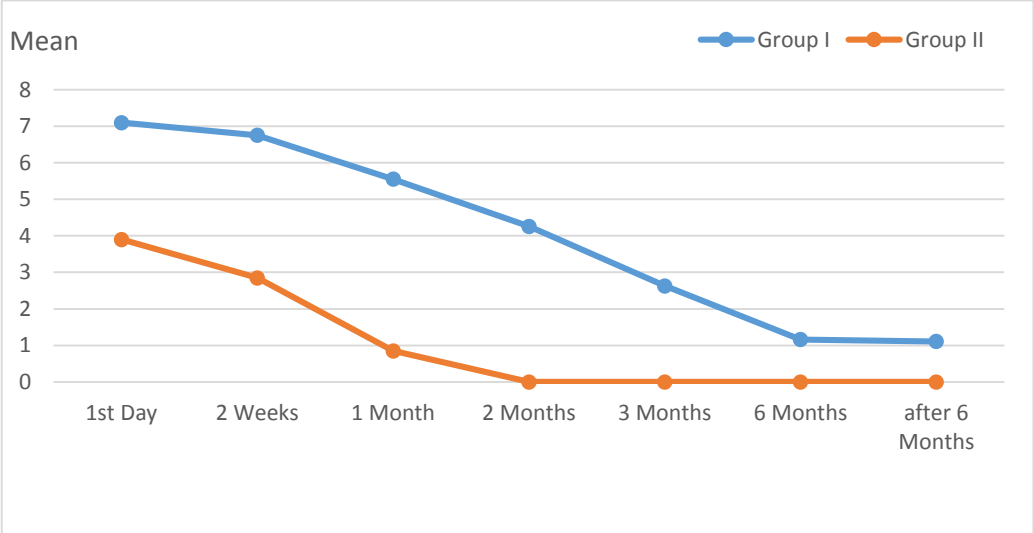

Figure 3: comparison between the two studied groups according to pain

Table IX: comparison between the two studied groups according to the impact of pain

	Group I (n=20)		Group II (n=20)		Test of Sig.
	No.	%	No.	%	
Post-operative pain on VAS					
Min - Max	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	5	25	1	5	P < 0.0001*
Satisfied	15	75	19	95	
Return to normal activity and work					
Min - Max	1.43 – 12.0		1.0 – 3.0		P < 0.0001*
Mean ± SD	4.97 ± 3.71		1.51 ± 0.64		
Improvement					
Improved	14	70	20	100	P = 0.022*
Partially improved	4	20	0	0	
Lost in follow up	1	5	0	0	
Not improved	1	5	0	0	
Duration (weeks)	(n=18)		(n=20)		
Min - Max	10 – 32.0		1.43 – 4.0		P < 0.0001*
Mean ± SD	13.39 ±7.54		2.02 ± 0.78		
Need for analgesia	17	85	2	10	P < 0.0001*
Chronic pain	2	10	0	0	P < 0.0015*

Table X: relation between nerves and postoperative pain on VAS

Post-operative Pain	Nerves			Test of Sig.
	Not Clear	Preserved	Cutting Iliohypog.	
Group I	(n=0)	(n=17)	(n=3)	
Min - Max	-	4.0 – 9.0	7.0 – 9.0	P < 0.0001*
Mean ± SD	-	6.88 ± 1.36	8.33 ± 1.15	
Group II	(n=1)	(n=17)	(n=2)	
Min - Max	4.0 – 4.0	3.0 – 6.0	3.0 – 0.0	P < 0.0001*
Mean ± SD	4.0 ± 0.0	4.0 ± 0.87	3.0 ± 0.0	

Table XI: relation between chronic pain and nerves

Nerves	Chronic Pain				Test of Sig.
	No		Yes		
	No.	%	No.	%	
Group I					
Not clear	0	0	0	0	P = 1
Preserved	17	85	16	80	
Cutting iliohypogastric	3	15	4	20	
Group II					
Not clear	1	5	0	0	-
Preserved	17	85	0	0	
Cutting iliohypogastric	2	10	0	0	

Discussion:

Regarding the type of mesh, a recent literature review to establish an evidence base for lightweight mesh found some advantages with respect to postoperative pain, foreign body sensation, and pain during exercise and movement, and also advantage with respect to

alleviating severe chronic pain [7- 9].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 seven minutes (7.0 - 16.0 min).These results are consistent with those of **Chastan**[17].who reported a mesh fixation time about 7 minutes [17].That was obvious earlier in our study when the surgeons were yet familiar with the mesh and its handling. In those first 2 cases the mesh took longer time for its fixation (65, 69 minutes) compared to (30 minute) later in the study.Shorter surgery time may be beneficial in terms of cost and reduced infection incidence [13]. However, in our study there was no difference between the two groups as regard wound infection. Superficial wound infection presented in 2 patients (10%) in each group that 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% (4 patients) in group I and 10% (2 patients) in group II. This is higher than **Chastan's** results, which showed zero% seroma (70 hernias) with LWM Progrip ™ [17] and by **Hidalgo** et al who reported 17 seromas out of 256 (6.5%) received light weight mesh [14].In our study, seromas resolved spontaneously without any intervention in all cases during the first two post-operative weeks except for one case in group I who had a relatively larger seroma that needed aspiration.In the present study, we had 6 cases (30%) of minimal scrotal oedema in group I and 3 cases (15%) of minimal scrotal oedema in group II. Scrotal oedema has been found to be in patients with indirect hernias and who had a large hernia sac. It resolved spontaneously during the first 10 post-operative days.Epididmo orchitis occurred in 2 patients (10%) in group I, whereas none of group II patients suffered from it.The aim of this prospective study was to evaluate the effect of mesh implantation and peri-mesh fibrosis on testicular flow. The assessment was done by using grey-scale sonography and colour Doppler sonography was performed to evaluate testicular arterial impedance, perfusion, and venous flow. Measurements were made bilaterally at the level of the inguinal canal 1 day before and at the end of the 3rd 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 contra lateral side in group I and reached significance in group II. Also, the RI on the hernia side was higher than it on the contra lateral 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 [12].

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 post-operative while 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 to the prolene group, although 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 contra lateral side post-operative. In the UltraPro group the testicular volume which was bigger than the healthy side pre-operatively had decreased post-operative to become significantly smaller than the other side with a significant increase in the RI between the repaired side and the contra lateral side. Unlike with the HWM prolene group and although there was a decrease in the testicular volume post operatively, but it was still bigger than the contra-lateral side. The difference in the RI between the two sides reach a significant value (P=0.0053).The change in testicular volume in both groups remain 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 light weight mesh would result in less chronic pain and discomfm1 in comparison with the standard heavy weight mesh. Different studies report the rate of prolonged pain after light weight mesh 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 heavy weight mesh were consistently

significantly higher than those in the light weight mesh. By VAS, pain ranged from 4-9 on VAS in group I, while ranged from (3-6) 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 two weeks and ranged from (3-10) on VAS unlike group II which showed good improvement with a pain score ranged from (I -7) on VAS.After one month a degree of improvement as regard to pain in group I which ranged from (0-9) on VAS compared to a mild degree of pain and discomfort in group II which ranged from (0-4) on VAS.Patients in the HWM group who reported higher level of pain during the first month had other complication such as wound infection, hematoma, seroma and scrotal oedema.The severity of pain during the first month in group I, reflected on the patient's need of analgesia. 85% reported a daily use of analgesia compared to only 10% in group II. One patient in group I, admitted to the ER suffering from gastritis secondary to excessive use of analgesia. He responded well later to medical treatment.At the second post-operative month there was a significant difference between the two groups as 75% of patient still report having pain especially with movement while 100% of patient in group II reported being a pain free.As regards to chronic pain at 6th months, 12 patient (60%) reported variable degree of pain specially during movement but on continuing the follow up only 5 patients (25%) complained from having different degree of pain.

One of these 5 patients had gradual improvement as regard to his pain, he experienced a deterioration at the 6th month with increase to the intensity of his pain from 3-4 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 [15]. In this respect, the idea of fixing the mesh to the pubis without sutures is very logical. Nerve damage occurs during surgery appears to be the most common cause of post hernia repair pain because sensory disturbances are frequently seen in these patients. Pain usually presents in the distribution of the affected nerve [15]. In the present study, the three nerves were identified and preserved in 85% of patients in both groups. Accidental cut of the Ilia hypogastric never occurred in 3 patients (15%) in group I and 2 patients (10%) in group II. While clear identification of the 3 nerves failed in one patients in group II. Cutting the Ilio-hypogastric never did not significantly affect the post-operative 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 unidentified nerve has generally been performed distal to its origin, leaving the site of the injured nerve intact to continue to generate a pain signal and exposing it to neuroma formation. Also, there were no sensory loss along distribution of the nerve 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 didn't significantly affect the incidence of chronic pain.

However, it slightly increased the severity of post-operative pain but not significantly. In the present study, there was no difference between the two groups as regard to other risk factors for pain such as age, BMI and type of anaesthesia.Preoperative pain seemed to be a risk factor, with multiple studies showed that those, who report pain before, are more likely to develop chronic pain afterward [16]. Unfortunately, preoperative pain was not assessed in the current study and I 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, specially as regards to 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 U/S on the 6th month post operatively. Knowing that poliglecaprone echogenicity is close to that of prolene U/S 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 U/S or by CT and MRI was recommended but it was not available.The poliglecaprone mesh costs about 2 - 3 times more than the comparable mesh of pure polypropylene with the sutures needed for its fixation, 1470 LE vs 470 LE. From an economical point of view, these increased costs are compensated by the reduced utilization of the operating room due 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 as regard to the technical difficulties, surgeons were equally satisfied and post-operative complications such as seroma, hematoma, wound infection, mesh infection, F.B sensation except epididmo-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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