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ORIGINAL ARTICLE

Comparison of polypropylene versus polyester mesh in the Lichtenstein hernia repair with respect to chronic pain and discomfort

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Abstract
Background Inguinal hernias are the most common operative procedure performed by general surgeons, and tension-free mesh techniques have revolutionized the procedure. While hernia recurrence rates have decreased, chronic postoperative pain has become recognized more widely. New mesh products offer the potential to decrease pain without compromising recurrence rates. Polyester mesh is a softer material than traditional polypropylene and may offer the benefit of causing less postoperative pain and improved quality of life.
Methods Prospective, single-blind, randomized controlled trial involving 78 patients assigned to receive Lichtenstein type repair with either polyester ($n = 39$) or polypropylene ($n = 39$) mesh. Attempt was made to identify ilioinguinal, iliohypogastric, and genitofemoral nerves intraoperatively and document their handling. Patients were interviewed and examined preoperatively and postoperatively at 2 weeks and 3 months. Inguinal Pain Questionnaire (IPQ) and VAS scores were obtained and analyzed using two sample t test for continuous variables and Chi-square test for categorical variables.
Results VAS scores at 3 months were 0.46 for the polyester group versus 0.56 for the polypropylene group ($P = 0.6727$). At 3 months, 82.3% of the polyester and 76.4% of the polypropylene group had VAS = 0 ($P = 0.5486$). There was no significant difference between the two groups' VAS scores at 3 months. IPQ did not show any difference between the two groups with the exception of "catching or pulling" being reported in 34.3% of polyester and 5.7% of polypropylene groups ($P = 0.0028$).
Conclusions Polyester mesh does not decrease the amount of chronic pain at 3 months. Outcomes with polyester mesh are comparable to polypropylene mesh for Lichtenstein inguinal hernia repair with regards to postoperative pain and quality of life. The sample size in this study was small and limits the significance of the results. Further studies are needed to find the optimal mesh for inguinal hernia repair.

Keywords Polyester · Chronic pain · Inguinal hernia · Lichtenstein · Polypropylene

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Introduction

Inguinal hernia repair is the most common general surgery procedure, and several hundred thousand are performed every year in the United States. Countless studies have been done in attempts to improve outcomes, and the procedure has evolved greatly, especially over the last few decades. Hernia recurrence was a significant problem in the past; however, with the advent of the tension-free mesh repair as described by Lichtenstein and colleagues [1], recurrence rates have dropped significantly and are

consistently reported as 1–10% [2–6]. Concomitant with this drop in recurrence, researchers and clinicians have noted an increase in the rate of chronic pain following hernia repair.

The definition of chronic pain, as set forth by the International Association for the Study of Pain, and referenced by Poobalan et al. [7], is pain that persists at the surgical site and nearby surrounding tissues beyond 3 months. Despite the frequency with which the procedure is performed and the extensive research that has been done, chronic postoperative pain continues to be a significant problem in inguinal herniorraphy. Multiple studies have been performed documenting the pain associated with inguinal hernia repair. The incidence of chronic pain has been reported to range from 13% up to 57% of subjects, depending on the study and level of severity of the pain studied [2, 7–14].

Unlike some surgical diseases, which disproportionately affect the elderly population, inguinal hernia is a problem that affects young and middle aged adult populations as well as the elderly. Studies have shown that younger patients undergoing herniorrhaphy experience more postoperative pain than elderly patients [7, 11, 15]. Given that a fair number of the annual hernia repairs are preformed on active, productive adults, the societal costs in terms of lost productivity due to postoperative pain and missed work are potentially great. Additionally, more than 50% of patients reported that their postoperative pain affected their social activities [11, 15].

Polyester mesh is a soft, pliable, lightweight material that has recently been introduced in the United States for use in hernia repair. Studies using polyester mesh have been limited thus far to laparoscopic inguinal and incisional hernia repairs [3, 16]. The published results of these studies are favorable, with side effect and complication rates comparable to standard practice, i.e., approximately 7–12% [3–6, 16, 17]. However, no comparison study between polyester and polypropylene mesh used in open inguinal hernia repairs has been performed. Polyester mesh has been shown to incite an early, intense inflammatory reaction that stimulates greater tissue ingrowth and integration. Along with this higher degree of connective tissue integration, it has less mesh contraction, less fibrous encapsulation, and less stiffness around the mesh than polypropylene mesh [18]. With better tissue integration, less encapsulation, and less contraction, the sensory nerves of the groin may potentially be less affected—less likely to be pulled or stretched, less likely to be in a field of a chronic inflammatory reaction, or less likely to be constantly irritated by a firm piece of mesh or capsule surrounding the mesh—translating into less chronic pain. Implanted prosthetic meshes used in hernia repairs are much stronger than they need to be to resist intraabdominal pressures. A recent study [19] showed the tensile strength of the polypropylene mesh to be more than five times stronger than the native abdominal wall. While there may be concerns over the strength of the lighter-weight polyester meshes, the tensile strength of polyester mesh was shown to be approximately four times stronger than maximum intraabdominal pressure (Tensile strength of Parietex mesh. Personal communication from Matt Thomas, AutoSuture/United States Surgical. 16 July 2006).

Given the aforementioned properties, polyester mesh has the potential to be a suitable alternative to polypropylene mesh, and may offer improvements in terms of pain and postoperative quality of life.

Methods

Approval for the proposed study was obtained from the local Institutional Review Board. Seventy-eight patients were enrolled prospectively in the study through the outpatient clinic, and were randomized to undergo standard anterior Lichtenstein hernia repair with either "heavyweight" polypropylene mesh or polyester mesh. Patients were blinded to the mesh they received and remained blinded throughout the follow-up period. Patients were 18 years old or older, not pregnant, had no previous history of anterior mesh hernia repair on the planned operative side, had no other concomitant surgical procedures planned, and were cognitively able to discuss the study. All underwent elective inguinal hernia repairs.

The study was conducted as a part of the Scott & White Outcomes and Effectiveness Research Group—a program for performing effectiveness studies comparing the effectiveness of different treatments in the course of usual clinical care. Effectiveness studies are designed to evaluate outcomes of care in realistic practice situations, in contrast to efficacy studies performed in highly selected populations under ideal conditions [20–22].

Subjects were given a study folder that included copies of the VAS (visual analog scale) [23], the Inguinal Pain Questionnaire (IPQ) [24], and several surgery-specific questions created by the investigators based on common complaints listed in previous research [8, 15] (see "Appendix" for these instruments). Both the VAS and IPQ have been previously validated [23, 24]. These three measurement tools were to be completed by patients at 2 weeks, and 3, 12, and 24 months. A research nurse coordinator called study patients to collect this data. If the follow-up call dates fell on a weekend or holiday, the subject was called on the next business day. At any time postoperatively, if the patient reported a possible hernia recurrence, intractable nausea/vomiting/pain, or signs/symptoms of a wound infection or other complication, he

or she was scheduled for an office visit evaluation. At the clinic visit approximately 14 days after surgery (the only routinely scheduled visit), study patients were instructed that they could return to full activity. This visit could be ±7 days of the 14 day visit, at the discretion of the operating surgeon. All subjects were given a prescription for 30 tablets of hydrocodone/APAP 5/500. Those with an allergy or intolerance of hydrocodone/APAP were given a similar prescription for propoxyphene/APAP.

Self assessment schedule

Instrument	Preoperative	2 weeks	3 months	1 year	2 years
VAS	X	X	X	X	X
IPQ		X	X	X	X
Surgery specific questions		X	X	X	X

VAS Visual analog scale, *IPQ* inguinal pain questionnaire

The primary endpoint was chronic pain (measured by VAS) and effect on lifestyle (measured by IPQ) at 3 months; secondary endpoints included operative and anesthesia time, duration of hospital stay or postoperative stay, degree of pain at 2 weeks, and at 12 and 24 months, hernia recurrence, and other complications such as infection, hematoma, seroma, need for readmission.

Intra-operative and/or post-operative adverse events were managed, documented, and reported appropriately. For any patient who developed chronic groin pain related to the surgery, the surgeon managed this complication. Possible treatments for chronic pain included long-term narcotic pain medication, other prescription medications accepted as treatment for chronic non-nociceptive pain (e.g., amitriptyline, gabapentin, pregabalin), nerve blocks by members of the anesthesia department, referral to the pain clinic run by the department of anesthesiology, or reoperation with possible neurolysis or removal of mesh.

Statistical analysis

Baseline characteristics of the study participants were summarized using descriptive statistics for two groups, and differences assessed using two-sample *t* test for continuous data and either chi-square or Fisher's exact test for categorical variables. If data were strongly skewed, the Wilcoxon or other appropriate non-parametric tests was used. All statistical comparisons were made using 0.05 level of significance. SAS 9.1.3 (SAS Institute, Cary, NC) was used for statistical analysis.

Sample size and power analysis

The reported incidence of postoperative pain at 3 months following hernia repair using the polypropylene mesh (our control) was 0.57 [7]. The sample size required to detect a benefit for the new mesh of 25% reduction in pain at 3 months following hernia repair (from 57% to 32% of patients), with alpha 0.05 and power 90 is a minimum of 81 randomized patients per group. The accrual goal was increased to 85 per group to account for dropouts.

Results

A total of 78 patients were enrolled and randomized to receive either polyester or polypropylene mesh, with 39 in each group. One patient received polypropylene mesh instead of polyester which was their original randomized allocation. This patient was included in the polyester mesh group for intention to treat (ITT) analysis and in the polypropylene mesh group for per protocol analysis. Preoperative demographics were similar, with no statistical differences in terms of gender, age, lifting in current job, previous anterior hernia repair, or VAS score (Table 1).

The two groups were also similar with respect to intraoperative variables. The majority of both groups underwent repair under general anesthesia. Anesthesia time for the groups was 118 min for polyester and 125 min for polypropylene repairs (difference not statistically significant). Operative times were also statistically equivalent, with polyester repairs lasting on average 77 min and polypropylene repairs lasting 88 min (Table 2).

There was no difference in rate of admission to the hospital, incision length, defect type, or rate of identification of ilioinguinal, iliohypogastric, or genitofemoral nerves. There was a statistically higher rate of iliohypogastric nerve division in the polypropylene group, with 11% nerve transection rate in the polyester group and 32% transection rate in the polyester group. Rates of nerve transection of the ilioinguinal and genitofemoral nerves were equivalent (Table 3).

Of the initial 78 patients, 77 completed the 2-week follow-up (one patient in the polypropylene group did not), and 70 (35 patients from each group) completed the 3 month follow-up. At 2 weeks, the mean ± SD VAS score in the polyester group was 1.18 ± 1.42, and the mean VAS score for the polypropylene group was 1.39 ± 1.36 ($P = 0.4989$). When the patients are dichotomized into groups of those with any pain (VAS > 0) and those with no pain (VAS = 0), there remains no statistical difference between the two mesh products, with equal numbers of patients having some pain at 2 weeks ($P = 0.2821$). At 3 months, the mean VAS score in the polyester group was

Table 1 Preoperative demographics

	Polyester ($N = 39$)	Polypropylene ($N = 39$)
Material	39 (50.00%)	39 (50.00%)
Gender		
Male	38 (97.44%)	38 (97.44%)
Female	1 (2.56%)	1 (2.56%)
Age at surgery		
Mean (±SD)	54 (±17.9)	56 (±16.4)
Median (min–max)	57 (25–81)	60 (20–78)
Occupation		
Professional/technical	16 (41.03%)	8 (20.51%)
Manager/sales	2 (5.13%)	6 (15.38%)
Craft/skilled	8 (20.51%)	6 (15.38%)
Unskilled	3 (7.69%)	7 (17.95%)
Clerical	0 (0.00%)	0 (0.00%)
Student	0 (0.00%)	0 (0.00%)
Housewife	0 (0.00%)	1 (2.56%)
Retired	9 (23.08%)	11 (28.21%)
Other	1 (2.56%)	0 (0.00%)
Does work involve activity/lifting?		
Yes	27 (69.23%)	30 (76.92%)
No	12 (30.77%)	9 (23.08%)
If yes, which activity?		
Work	4 (14.81%)	7 (23.33%)
Leisure	16 (59.26%)	10 (33.33%)
Both	7 (25.93%)	13 (43.33%)
Previous anterior hernia w/o mesh		
Yes	8 (20.51%)	10 (25.64%)
No	31 (79.49%)	29 (74.36%)
Pre-op VAS	0.58 (±1.23)	0.86 (±1.90)
(Two sample t test: P value = 0.4393)	0 (0–5)	0 (0–8)
(Wilcoxon test: P value = 0.7450)		

Table 2 Intraoperative anesthesia characteristics

	Polyester	Polypropylene
Type of anesthesia		
General	35 (89.74%)	36 (92.31%)
Local mac	3 (7.69%)	1 (2.56%)
Spinal	0 (0.00%)	0 (0.00%)
Other	1 (2.56%)	2 (5.13%)
Type of anesthesia		
General	35 (89.74%)	36 (92.31%)
Other	4 (10.26%)	3 (7.69%)
Time under anesthesia (min)	118.53 (±38.30)	125.29 (±41.41)
Time in surgery (min)	77.56 (±34.29)	88.23 (±38.28)

Table 3 Intraoperative characteristics. *PACU* Postanesthesia care unit

	Polyester	Polypropylene
Admissions		
PACU		
Yes	28 (73.68%)	29 (74.36%)
No	10 (73.68%)	10 (25.64%)
Day surgery		
Yes	37 (97.37%)	39 (100.0%)
No	1 (2.63%)	0 (0.00%)
Hospital		
Yes	2 (5.13%)	0 (0.00%)
No	37 (94.87%)	39 (100.0%)
Ilioingual nerve identified		
Yes	37 (94.87%)	36 (94.74%)
No	2 (5.13%)	2 (5.26%)
If yes, nerve divided?		
Yes	14 (35.90%)	14 (36.84%)
No	25 (64.10%)	24 (63.16%)
Iliohypogastric nerve identified		
Yes	20 (54.05%)	23 (60.53%)
No	17 (45.95%)	15 (39.47%)
If yes, nerve divided?		
Yes	4 (11.43%)	12 (32.43%)
No	31 (88.57%)	25 (67.57%)
Genitofemoral nerve identified?		
Yes	7 (17.95%)	6 (16.22%)
No	32 (82.05%)	31 (83.78%)
If yes, nerve divided?		
Yes	5 (13.89%)	3 (8.33%)
No	31 (86.11%)	33 (91.67%)
Incision length (centimeters)	8.36 (±1.10)	8.46 (±1.24)
Defect type		
Direct	15 (39.47%)	14 (37.84%)
Indirect	19 (50.00%)	17 (45.95%)
Combination	4 (10.53%)	6 (16.22%)

0.46 ± 1.22, and in the polypropylene group was 0.56 ± 1.13 ($P = 0.7213$). When patients are dichotomized into those with any remaining pain and those with no pain at 3 months, there is no significant difference between the two mesh products ($P = 0.5486$) (Tables 4, 5).

At 2 weeks, reporting rates for author-created pain descriptors were equivalent between the two groups. There was no statistical difference in complaints of "throbbing, stabbing, aching, or burning," "catching, pulling, tugging, or tearing," or "numbness or dullness" (all $P > 0.1$). This equivalence remained after dichotomizing reports into "any complaint" versus "no complaints" (all $P > 0.1$). There was no difference in the rate of patients reporting performing some activities more slowly, with about 90% of both groups affirming this. An equivalent number of patients reported being unable to perform some activities

Table 4 Mean VAS pain scores at 2 weeks and 3 months postoperatively

	Polyester ($N = 39$)	Polypropylene ($N = 39$)	P value[a]	P value[b]
VAS score				
2 weeks	1.18 (±1.42)	1.39 (±1.36)	0.3740	0.4989
3 months	0.46 (±1.22)	0.56 (±1.13)	0.6727	0.7213

[a] Wilcoxon's test

[b] Two-sample t test

Table 5 Number of patients reporting any pain at 2 weeks and 3 months postoperatively

	Polyester ($N = 39$)	Polypropylene ($N = 39$)	P value[a]
VAS score			
2 weeks	VAS = 0 18 (47.37%)	13 (35.14%)	0.2821
	VAS ≥ 1 20 (52.63%)	24 (64.86%)	
3 months	VAS = 0 28 (82.35%)	26 (76.47%)	0.5486
	VAS ≥ 1 6 (17.65%)	8 (23.53%)	

[a] Chi-squared test

due to pain. There were no recurrences in either of the two groups. There were three complications in the polyester group, and one in the polypropylene group in the first 2 postoperative weeks. Complications included hematoma, rash, chest pain and dyspnea, urinary retention, and dizziness with syncope. Each group had two hospitalizations, which occurred due to the following problems: respiratory insufficiency, hypotension with bradycardia, chest pain and dyspnea, and dizziness with syncope (Table 6).

At 3 months, reporting rates for complaints of "throbbing, stabbing, aching, or burning," and "numbness or dullness" were equivalent ($P > 0.4$). This equivalence remained after dichotomizing reports into "any complaint" versus "no complaints" ($P > 0.1$). In contrast to the 2-week data, at 3 months, there were statistically more complaints of "catching, pulling, tugging, or tearing" in the polyester group than in the polypropylene group ($P = 0.0189$). The statistical significance remained after dichotomizing the patients into "any complaint" versus "no complaint" ($P = 0.0028$). There was no difference in the rate of patients reporting performing some activities more slowly, with about 15% of both groups affirming this. An equivalent number of patients reported being unable to perform some activities due to pain. There were no recurrences in either of the two groups. There were three complications in the polyester group and one in the polypropylene group between the 2 week and 3 month follow-ups. Complications included erectile dysfunction, osteitis pubis, abdominal wall strain, and postoperative pain requiring referral to pain clinic. There were no new hospital admissions in this follow-up period (Table 7).

Table 8 shows a breakdown of responses to the IPQ completed at 3 months. There were no statistically significant differences between the two groups on any of the questions.

Table 6 Postoperative complaints, 2-week follow up

	Polyester	Polypropylene	P value[a]
Throbbing, stabbing, aching, and burning			
None	14 (35.90%)	16 (42.11%)	0.1527
1–2	11 (28.21%)	8 (21.05%)	
3–5	1 (2.56%)	6 (15.79%)	
>5	13 (33.33%)	8 (21.05%)	
Catching, pulling, tugging, or tearing			
None	18 (46.15%)	24 (63.16%)	0.1104
1–2	10 (25.64%)	6 (15.79%)	
3–5	2 (5.13%)	5 (13.16%)	
>5	9 (23.08%)	3 (7.89%)	
Numbness or dullness			
None	25 (64.10%)	22 (57.89%)	0.8447
1–2	5 (12.82%)	7 (18.42%)	
3–5	1 (2.56%)	2 (5.26%)	
>5	8 (20.51%)	7 (18.42%)	
Perform some activities more slowly			
Agree	35 (89.74%)	35 (92.11%)	1.0000
Disagree	4 (10.26%)	3 (7.89%)	
Unable to perform some activities			
Agree	28 (71.79%)	33 (86.84%	0.1037
Disagree	11 (28.21%)	5 (13.16%)	
Reoccurrence of hernia			
Yes	0 (0.00%)	0.00 (0%)	–
No	39 (100.00%)	38 (100.00%)	
Complications since last survey?			
Yes	3 (7.69%)	1 (2.63%)	0.6151
No	36 (92.31%)	37 (97.37%)	
If Yes, describe			
Excessive pain	0 (0.00%)	0 (0.00%)	
Hematoma	0 (0.00%)	0 (0.00%)	
Seroma	0 (0.00%)	0 (0.00%)	
Neuropathy	0 (0.00%)	0 (0.00%)	
Wound Infect	0 (0.00%)	0 (0.00%)	
Other	3 (7.69%)	1 (2.63%)	
Hospital admissions since last survey?			
Yes	2 (5.13%)	2 (5.26%)	
No	34 (87.18%)	36 (94.74%)	
N/A	3 (7.69%)	0 (0.00%)	

[a] Chi-squared or Fisher's exact test

Table 7 Postoperative complaints, 3-month follow up

	Polyester	Polypropylene	*P* value[a]
Throbbing, stabbing, aching, and burning			
None	22 (62.86%)	27 (77.14%)	0.5858
1–2	5 (14.29%)	4 (11.43%)	
3–5	6 (17.14%)	3(8.57%)	
>5	2 (5.71%)	1 (2.86%)	
Catching, pulling, tugging, or tearing			
None	23 (65.71%)	33 (94.29%)	0.0189
1–2	6 (17.14%)	1 (2.86%)	
3–5	5 (14.29%)	1 (2.86%)	
>5	1 (2.86%)	0 (0.00%)	
Numbness or dullness			
None	23 (65.71%)	28 (80.00%)	0.4109
1–2	6 (17.14%)	5 (14.29%)	
3–5	1 (2.86%)	0 (0.00%)	
>5	5 (14.29%)	2 (5.71%)	
Perform some activities more slowly			
Agree	5 (14.71%)	6 (17.14%)	0.7822
Disagree	29 (85.29%)	29 (82.86%)	
Unable to perform some activities			
Agree	4 (11.76%)	7 (20.00%)	0.3502
Disagree	30 (88.24%)	28 (80.00%)	
Reoccurrence of hernia			
Yes	0.00 (0%)	0 (0.00%)	–
No	35 (100.00%)	35 (100.00%)	
Complications since last survey?			
Yes	3 (8.57%)	1 (2.86%)	0.6139
No	32 (91.43%)	34 (97.14%)	
If yes, describe			
Excessive pain	0 (0.00%)	0 (0.00%)	
Hematoma	0 (0.00%)	0 (0.00%)	
Seroma	0 (0.00%)	0 (0.00%)	
Neuropathy	0 (0.00%)	0 (0.00%)	
Wound infect	0 (0.00%)	0 (0.00%)	
Other	3 (8.57%)	1 (2.86%)	
Hospital admissions since last survey?			
Yes	0 (0.00%)	0 (0.00%)	
No	15 (42.86%)	20 (58.82%)	
N/A	20 (57.14%)	14 (41.18%)	

[a] Chi-squared or Fisher's exact test

In the majority of patients, the ilioinguinal nerve was identified. The nerve was identified and protected in 45 patients, identified and divided in 28 patients, and not identified in 4 patients. The mean ± SD VAS score in patients whose ilioinguinal nerve was protected was 0.64 ± 1.43 at 3 months. The pain score in patients whose ilioingunal nerve was divided was 0.50 ± 1.09, and the mean pain score in those who the nerve was not identified was 0. There was no statistically significant difference between the groups with respect to mean pain score ($P = 0.5594$). When the groups are dichotomized into "any pain" versus "no pain," the complaint rates between those with divided nerves is statistically equivalent to those with preserved nerves ($P = 0.7971$) (Table 9).

The iliohypogastric nerve was identified and protected in 27 patients, identified and divided in 16 patients, and not identified in 32 patients. The mean ± SD VAS score in patients whose iliohypogastric nerve was protected was 0.22 ±0.68 at 3 months. The pain score in patients whose iliohypogastric nerve was divided was 0.81 ± 1.58, and the mean pain score in those who the nerve was not identified was 0.68 ± 1.33. There was no statistically significant difference between the groups with respect to mean pain score ($P = 0.2448$). When the groups are dichotomized into "any pain" versus "no pain," the complaint rates between those with divided nerves is statistically equivalent to those with preserved nerves ($P = 0.2643$) (Table 10).

The genitofemoral nerve was identified infrequently on patients in this study, being identified and protected in 5 patients, identified and divided in 7 patients, and not identified in 55 patients. The mean ± SD VAS score in patients whose genitofemoral nerve was protected was 0.51 ± 0.71 at 3 months. The pain score in patients whose genitofemoral nerve was divided was 1.14 ± 2.04, and the mean pain score in those who the nerve was not identified was 0.45 ± 1.08. There was no statistically significant difference between the groups with respect to mean pain score ($P = 0.2448$). When the groups are dichotomized into "any pain" versus "no pain," the complaint rates between those with divided nerves is statistically equivalent to those with preserved nerves ($P = 0.2643$) (Table 11).

Discussion

Hernia repairs were first described by Bassini in the late 1800s, and an innumerable list of unique techniques have been developed and described. Almost 100 years after Bassini's description, Lichtenstein's repair was described, and his tension-free open inguinal hernia repair with onlay mesh is arguably the current standard of care. Great progress has been made with respect to recurrence rates, which were initially very high. Unfortunately, chronic pain following inguinal herniorrhaphy is now seen frequently; this problem continues to frustrate surgeons, with little progress being made over the last few decades, despite new techniques and materials.

Table 8 Summary of IPQ findings at 3-month follow up

	Polyester	Polypropylene	*P* value
Question 2: Pain feel right now in the groin on the same side as the operation			
No pain	29 (82.86%)	26 (74.29%)	
Pain present but could easily be ignored	4 (11.43%)	7 (20.00%)	
Pain present, could not be ignored, but did not interfere with everyday activities	1 (2.86%)	2 (5.71%)	
Pain present, could not be ignored, interfered with concentration on chores and daily activities	1 (2.86%)	0 (0.00%)	
Pain present, could not be ignored, interfered with most activities	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, necessitated bed rest	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, prompt medical advice sought	0 (0.00%)	0 (0.00%)	
Question 3: Worst pain you felt in the operated groin during this past week			
No pain	24 (75.00%)	25 (75.76%)	
Pain present but could easily be ignored	5 (15.63%)	4 (12.12%)	
Pain present, could not be ignored, but did not interfere with everyday activities	2 (6.25%)	4 (12.12%)	
Pain present, could not be ignored, interfered with concentration on chores and daily activities	1 (3.13%	0 (0.00%)	
Pain present, could not be ignored, interfered with most activities	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, necessitated bed rest	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, prompt medical advice sought	0 (0.00%)	0 (0.00%)	
Question 4: If answered no pain to question 3, when the pain in the operated groin disappeared after the operation			
Within 1 month after the operation	13 (59.09%)	10 (40.00%)	
1–3 months after the operation	9 (40.91%)	15 (60.00%)	
4–6 months after the operation	0 (0.00%)	0 (0.00%)	
7–12 months after the operation	0 (0.00%)	0 (0.00%)	
13–24 months after the operation	0 (0.00%)	0 (0.00%)	
Recently	0 (0.00%)	0 (0.00%)	
Question 5: How often have you felt pain in the operated groin during the past week?			
Once a week	2 (22.22%)	4 (44.44%)	
2–5 times a week	3 (33.33%)	5 (55.56%)	
Every day	2 (22.22%)	0 (0.00%)	
Every day and also during night time	0 (0.00%)	0 (0.00%)	
Whole week, both day and night	2 (22.22%)	0 (0.00%)	
Question 6: How long have the episodes of pain lasted in the past week?			
1 min to 1 h	9 (81.82%)	10 (100.00%)	
1 to 5 h	1 (9.09%)	0 (0.00%)	
The whole day	0 (0.00%)	0 (0.00%)	
Day and night	0 (0.00%)	0 (0.00%)	
The pain has lasted the whole week, day and night	1 (9.09%)	0 (0.00%)	
Question 7: Do you find difficult getting up from a low chair because of pain in the operated groin?			
No	32 (91.43%)	34 (97.14%)	0.6139
Yes	3 (8.57%)	1 (2.86%)	
Question 8: Do you find it difficult sitting down for more than half an hour because of the pain?			
No	32 (91.43%)	35 (100.00%)	0.2391
Yes	3 (8.57%)	0 (0.00%)	
Question 9: Do you find difficult standing up for more than half an hour because of the pain?			
No	32 (91.43%)	34 (97.14%)	0.6139
Yes	3 (8.57%)	1 (2.86%)	
Question 10: Do you find difficult going up or down stairs because of the pain?			
No	34 (97.14%)	33 (94.29%)	1.0000
Yes	1 (2.86%)	1 (2.86%)	
I don't know	0 (0.00%)	1 (2.86%)	

Table 8 continued

	Polyester	Polypropylene	*P* value
Question 11: Does driving a car cause you pain?			
No	32 (91.43%)	33 (94.29%)	1.0000
Yes	3 (8.57%)	2 (5.71%)	
I don't know	0 (0.00%)	0 (0.00%)	
Not applicable	0 (0.00%)	0 (0.00%)	
Question 12: Has the pain limited your ability to exercise and perform sports?			
No	11 (31.43%)	13 (37.14%)	0.8832
Yes	2 (5.71%)	1 (2.86%)	
I don't know	2 (5.71%)	1 (2.86%)	
Not applicable	20 (57.14%)	20 (57.14%)	
Question 13: Have you taken pain-killers for pain in the operated groin during the past week?			
No	31 (88.57%)	35 (100.00%)	
Yes	4 (11.43%)	0 (0.00%)	
Question 14: To what extent has pain in the groin limited your working capability in the last 2 months?			
Not needed to take sick leave	20 (60.61%)	21 (67.74%)	
Take 1–7 days sick leave during last 2 months	1 (3.03%)	2 (6.45%)	
Take sick leave for 1–4 weeks during the last 2 months	0 (0.00%)	0 (0.00%)	
Take sick leave for the whole of the last 2 months	0 (0.00%)	0 (0.00%)	
Disability pension because of pain in the groin	0 (0.00%)	0 (0.00%)	
I am not gainfully employed	12 (36.36%)	8 (25.81%)	
Question 15: Estimate the severity of pain you feel right now in the groin opposite to the operated side			
No pain	34 (97.14%)	35 (100.00%)	
Pain present but could easily be ignored	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, but did not interfere with everyday activities	1 (2.86%)	0 (0.00%)	
Pain present, could not be ignored, interfered with concentration on chores and daily activities	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, interfered with most activities	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, necessitated bed rest	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, prompt medical advice sought	0 (0.00%)	0 (0.00%)	
Question 16: Estimate the worst pain you felt in the groin opposite to the operated side during the past week			
No pain	34 (97.14%)	35 (100.00%)	
Pain present but could easily be ignored	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, but did not interfere with everyday activities	1 (2.86%)	0 (0.00%)	
Pain present, could not be ignored, interfered with concentration on chores and daily activities	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, interfered with most activities	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, necessitated bed rest	0 (0.00%)	0 (0.00%)	
Pain present, could not be ignored, prompt medical advice sought	0 (0.00%)	0 (0.00%)	
Question 17: To be answered by male patients: have you experienced testicular pain on the same side as the operated groin since the operation?			
No	32 (91.43%)	31 (91.18%)	
Yes	3 (8.57%)	3 (8.82%)	
Question 18: Have you operated on for hernia or had an abdominal operation			
No	33 (94.29%)	33 (97.06%)	
Yes	2 (5.71%)	1 (2.94%)	

In this study, polyester mesh was compared to standard polypropylene mesh in Lichtenstein herniorrhaphy. The study was single-blinded and randomized, performed in an effectiveness study format, which aims to compare results that would be expected in real-world practice. We employed commonly used and validated outcomes measures to evaluate pain and effect on quality of life. Groups were well-matched through the randomization process. The premise was that subjectively softer mesh material would cause less postoperative discomfort.

Table 9 Ilioinguinal nerve; postoperative pain at 3 months with respect to nerve handling

	Not identified ($n = 4$)	Divided ($n = 23$)	Preserved ($n = 42$)	P value
Pain score (mean ± SD)	0.00	0.64 ± 1.43	0.50 ± 1.09	0.5594[a]
VAS = 0	4	17	32	0.7971[b]
VAS > 0	0	5	10	

[a] Kruskall–Wallis test

[b] Fisher's exact test; missing data = 2

Table 10 Iliohypogastric nerve; postoperative pain at 3 months with respect to nerve handling

	Not identified ($n = 28$)	Divided ($n = 14$)	Preserved ($n = 25$)	P value
Pain score (mean ± SD)	0.68 ± 1.33	0.81 ± 1.58	0.22 ± 0.68	0.2448[a]
VAS = 0	20	9	22	0.2643[b]
VAS > 0	8	4	3	

[a] Kruskall–Wallis test

[b] Fisher's exact test; missing data = 4

Table 11 Genitofemoral nerve; postoperative pain at 3 months with respect to nerve handling

	Not identified ($n = 56$)	Divided ($n = 7$)	Preserved ($n = 5$)	P value
Pain score (mean ± SD)	0.45 ± 1.08	1.14 ± 2.04	0.51 ± 0.71	0.5762[a]
VAS = 0	44	5	3	0.4548[b]
VAS > 0	11	2	2	

[a] Kruskall–Wallis test

[b] Fisher's exact test; missing data = 3

Patients were well-matched, with average ages, employment type, activity level, non-mesh repair, preoperative pain scores, incision length, and defect type being statistically equivalent. None of the preoperatively measured variables should confound the data or conclusions. Duration of operation and time under anesthesia were similar. Operative time was slightly longer than 1 hour, and time under anesthesia was about 2 h. While these times may be longer than those of other operators, they are likely reflective of the fact that the study was performed at a teaching institution, where residents of varying levels assisted on cases. Similarly, the majority of the cases were performed under general anesthesia. While this finding is unlikely to be representative of general clinical practice in the United States today, it is again likely related to the cases being performed at a teaching institution. The more relaxed atmosphere of a procedure under general anesthesia, lack of patient movement, and opportunity to provide more instruction to the trainee are all benefits of performing this procedure with general anesthesia.

Several studies have shown that handling of ilioinguinal, iliohypogastric, and genitofemoral nerves may affect postoperative pain, with one study showing a benefit to routine division of the ilioinguinal nerve [25]. Understanding that there is reluctance to adopt routine neurectomy, even though it is an accepted treatment for chronic inguinodynia, our study did not dictate how nerves should be handled but rather attempted to describe how they were handled. Ilioinguinal and genitofemoral nerve identification and division rates were similar between the polyester and polypropylene groups. At 3 months, there were no statistical differences between the pain scores of the group that had the nerves preserved compared to the group that had the nerves divided. However, there were statistically more iliohypogastric nerves divided in the polyester mesh group. This did not translate into any difference in mean pain scores nor in frequency of pain complaints at 3 months. We feel that this analysis negates or minimizes the pre-analysis difference between the two groups. The equivalence in postoperative pain despite different rates of iliohypogastric nerves should not be taken as evidence to support this practice, as our study population was small, and the study was not specifically designed to evaluate this outcome. Studies designed to elucidate the effects of routine iliohypogastric nerve division on postoperative pain and discomfort have not been performed.

There were no statistical differences between reported VAS pain scores between the two groups. Additionally, when looking at those reporting any pain at all, no difference in rates were seen at both 2 weeks and 3 months postoperatively. Researcher-designed pain questions showed no differences at 4 weeks, but did show increased complaints of "catching, pulling, tugging, or tearing" pain in the polyester group at 3 months. In explaining this difference, we return to the fact that in vitro studies have shown a vigorous inflammatory reaction around polyester, as opposed to the encapsulation that forms around polypropylene. The inflammatory reaction may involve more surrounding tissue and create the pulling or tugging sensation in the groin of these patients.

The validated IPQ asks detailed questions regarding common pain and discomfort complaints following inguinal herniorrhaphy and offers more detail about discomfort that the numeric VAS. There were no differences between the two mesh groups for any of the IPQ questions.

This study was not able to achieve the enrollment goals set forth in our study design protocol due to funding limitations. Overall enrollment was about half of the proposed goal. Given this smaller than planned size, there is significant possibility of type II (beta) error, or failure to reject a null hypothesis. Thus, any findings of equivalence between the mesh products may have been a failure to identify a difference. However, one may conclude from our study that there is an absence of large, highly significant differences between the two mesh products, but our study size was insufficient to detect small differences between the groups. In this regard, further study is needed to confirm our findings.

Conclusion

Compared to standard polypropylene mesh, polyester mesh placed in open inguinal hernia repair does not reduce postoperative pain or discomfort significantly, nor does it improve quality of life as measured by a standardized questionnaire. There are slightly higher rates of some types of pain complaints with the polyester mesh at 3 months. While polyester mesh appears to be a comparable alternative to polypropylene, it cannot be recommended over polypropylene. Further studies are needed to confirm these findings and to find the optimal mesh for inguinal hernia repair.

Appendix

Inguinal Pain Questionnaire

Inguinal Pain Questionnaire

Name: ……

Date: ……

Check one of the boxes for each of the questions.

1. Estimate the severity of pain in the operated groin you felt before the operation
   1. No pain ☐
   2. Pain present but could easily be ignored ☐
   3. Pain present, could not be ignored, but did not interfere with everyday activities ☐
   4. Pain present, could not be ignored, interfered with concentration on chores and daily activities ☐
   5. Pain present, could not be ignored, interfered with most activities ☐
   6. Pain present, could not be ignored, necessitated bed rest ☐
   7. Pain present, could not be ignored, prompt medical advice sought ☐

2. Estimate the pain you feel right now in the groin on the same side as the operation
   1. No pain ☐
   2. Pain present but can easily be ignored ☐
   3. Pain present, cannot be ignored, but does not interfere with everyday activities ☐
   4. Pain present, cannot be ignored, interferes with concentration on chores and daily activities ☐
   5. Pain present, cannot be ignored, interferes with most activities ☐
   6. Pain present, cannot be ignored, necessitates bed rest ☐
   7. Pain present, cannot be ignored, prompt medical advice sought ☐

3. Estimate the worst pain you felt in the operated groin during this past week
   1. No pain ☐
   2. Pain present but can easily be ignored ☐
   3. Pain present, cannot be ignored, but does not interfere with everyday activities ☐
   4. Pain present, cannot be ignored, interferes with concentration on chores and daily activities ☐
   5. Pain present, cannot be ignored, interferes with most activities ☐
   6. Pain present, cannot be ignored, necessitates bed rest ☐
   7. Pain present, cannot be ignored, prompt medical advice sought ☐

If you have answered that you have pain felt pain during the last week, please continue with questions 5 – 18

If you have answered no pain in question 3, please continue with question 4 and then questions 15 -18

4. If you answered "no pain" to question 3 try to remember when the pain in the operated groin disappeared after the operation
   1. The pain in the operated groin disappeared within 1 month after the operation ☐
   2. The pain in the operated groin disappeared 1-3 months after the operation ☐
   3. The pain in the operated groin disappeared 4-6 months after the operation ☐
   4. The pain in the operated groin disappeared 7-12 months after the operation ☐
   5. The pain in the operated groin disappeared 13-24 months after the operation ☐
   6. The pain in the operated groin disappeared recently ☐

If you have felt pain in the operated groin during the past week, please answer the following two questions:

5. How often have you felt pain in the operated groin during the past week?
   1. Once a week ☐
   2. 2-5 times a week ☐
   3. Every day ☐
   4. Every day and also during night time ☐
   5. I have had pain the whole week, both day and night ☐

6. How long have the episodes of pain lasted in the past week?

1. 1 minute to 1 hour ☐
2. 1 to 5 hours ☐
3. The whole day ☐
4. Day and night ☐
5. The pain has lasted the whole week, day and night ☐

7. Do you find it difficult getting up from a low chair because of pain in the operated groin?

1. No ☐ 2. Yes ☐ 3. I don't know ☐ 4. Not applicable ☐

8. Do you find it difficult sitting down for more than half an hour because of the pain?

1. No ☐ 2. Yes ☐ 3. I don't know ☐ 4. Not applicable ☐

9. Do you find it difficult standing up for more than half an hour because of the pain?

1. No ☐ 2. Yes ☐ 3. I don't know ☐ 4. Not applicable ☐

10. Do you find it difficult going up or down stairs because of the pain?

1. No ☐ 2. Yes ☐ 3. I don't know ☐ 4. Not applicable ☐

11. Does driving a car cause you pain?

1. No ☐ 2. Yes ☐ 3. I don't know ☐ 4. Not applicable ☐

12. Has the pain limited your ability to exercise and perform sports?

1. No ☐ 2. Yes ☐ 3. I don't know ☐ 4. Not applicable ☐

13. Have you taken pain-killers for pain in the operated groin during the past week?

☐ No ☐ Yes

14. To what extent has pain in the groin limited your working capability in the last 2 months?

1. I have not needed to take sick leave ☐
2. The pain made me take 1-7 days´ sick leave during the last 2 months ☐
3. The pain made me take sick leave for 1-4 weeks during the last 2 months ☐
4. The pain has made me take sick leave for the whole of the last 2 months ☐
5. I have a disability pension because of pain in the groin ☐
6. I am not gainfully employed ☐

Please answer questions 15-18 irrespective of you answers to the previous questions

15. Estimate the severity of pain you feel right now in the groin opposite to the operated side

1. No pain ☐
2. Pain present but can easily be ignored ☐
3. Pain present, cannot be ignored, but does not interfere with everyday activities ☐
4. Pain present, cannot be ignored, interferes with concentration on chores and daily activities ☐
5. Pain present, cannot be ignored, interferes with most activities ☐
6. Pain present, cannot be ignored, necessitates bed rest ☐
7. Pain present, cannot be ignored, prompt medical advice sought ☐

16. Estimate the worst pain you have felt in the groin opposite to the operated side during this past week

1. No pain ☐
2. Pain present but can easily be ignored ☐
3. Pain present, cannot be ignored, but does not interfere with everyday activities ☐
4. Pain present, cannot be ignored, interferes with concentration on chores and daily activities ☐
5. Pain present, cannot be ignored, interferes with most activities ☐
6. Pain present, cannot be ignored, necessitates bed rest ☐
7. Pain present, cannot be ignored, prompt medical advice sought ☐

17. To be answered by male patients: have you experienced testicular pain on the same side as the operated groin since the operation?

No ☐ Yes ☐

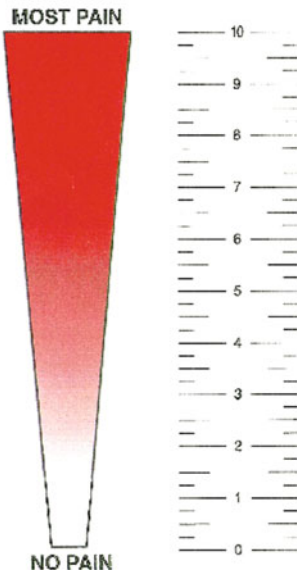
18. Have you been operated on for hernia or had an abdominal operation since the hernia operation?

No ☐ Yes ☐

SCOTT & WHITE

Patient Name: _____

Date: _____



In the last week, how often have you felt throbbing, stabbing, shooting, aching, burning sensation in your groin in the area of surgery? ..... None 1 ○
..... 1-2 2 ○
..... 3-5 3 ○
..... more than 5 4 ○

In the last week, how often have you felt a catching, pulling, tugging, or tearing sensation in your groin in the area of surgery? ..... None 1 ○
..... 1-2 2 ○
..... 3-5 3 ○
..... more than 5 4 ○

In the last week, how often have you felt numbness, dullness, in your groin in the area of surgery? ..... None 1 ○
..... 1-2 2 ○
..... 3-5 3 ○
..... more than 5 4 ○

I currently perform some activities more slowly than I did before surgery
..... Agree 1 ○
..... Disagree 2 ○

Which activities?_____

_____

I am currently unable to perform some activities that I was able to do before surgery ..... Agree 1 ○
..... Disagree 2 ○

Which activities?_____

_____

Was there a recurrence of the hernia?
..... Yes 1 ○
..... No 2 ○

COMPLICATIONS:

IMMEDIATE COMPLICATIONS: ..... YES 1 ○
NO 2 ○

IF YES, (Fill in all that apply)
A. EXCESSIVE PAIN ..... ○
B. HEMATOMA ..... ○
C. SEROMA
D NEUROPATHY ..... ○
E. WOUND INFECTION ..... ○
F. OTHER ..... ○

IF OTHER, SPECIFY_____

WERE THERE ANY COMPLICATIONS
AFTER THE IMMEDIATE POSTOP PERIOD? ..... YES 1 ○
IF YES, DESCRIBE: NO 2 ○

_____

_____

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