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ORIGINAL ARTICLE

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Prolene Hernia System compared with Lichtenstein patch: a randomised double blind study of short-term and medium-term outcomes in primary inguinal hernia repair

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Abstract *Background*. Refinements in the configuration of mesh may ease handling and placement and reduce postoperative discomfort.
Material and Methods. A total of 206 patients were randomly and blindly allocated to receive the Prolene Hernia System (PHS) or Lichtenstein patch. Collected data included: surgical incision size, procedure time, pain scores, analgesic medication, complications, return to activity and work, and quality of life as measured by Short-Form 36 on days 3 and 14.
Results. Immediate post-operative pain was significantly lower with PHS than with the patch. The proportion of PHS patients taking longer than 3 days to return to normal activity was 15.5%, compared to 28.4% of patch patients. Operating time was significantly shorter with PHS (34.1 vs. 38.3 min). There was no treatment effect on any of the quality of life scales as measured by Short-Form 36. There were two recurrences in the patch group.
Conclusions. The study indicates a reduction in operating time (4 min) and postoperative recovery with the PHS compared with patch.

Keywords Inguinal hernia · Herniorrhaphy · Mesh · Lichtenstein

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Introduction

This study compared the widely used method of mesh repair for inguinal hernioplasty, the Lichtenstein patch, with a newly designed configuration of mesh the Prolene Hernia System (PHS).

Ageing and tobacco consumption contribute to structural and functional changes in connective tissue which can affect the transversalis fascia increasing the risk of inguinal herniation [21, 22]. Recreating the transversalis fascia laminar and replacing it with an artificial mesh by the Lichtenstein method is an effective method of inguinal herniorrhaphy. The mesh can be placed by the preperitoneal route (posteriorly) or by the interfascial route (anteriorly). Nyhus [20] has been the main protagonist for the open unilateral posterior preperitoneal approach to repair recurrent inguinal hernias. In France the open preperitoneal approach has been in use for more than 30 years [23, 26] but has failed to gain universal popularity due to technical difficulty [12, 13].

Lichtenstein perfected the anterior open mesh tension-free repair for inguinal hernia more than 15 years ago [17]. Numerous other surgeons have developed techniques for placement of a Lichtenstein-type mesh in the interfascial (between external and internal oblique) plane with mesh of various shapes and sizes designed to cover the myopectineal orifice [1, 2, 5, 6, 18, 28].

Over a period of 10 years Gilbert has been developing the concept of an anterior approach operation in which mesh is placed in the preperitoneal space and further reinforced with a second swatch of mesh placed in the interfascial plane [7, 8]. In the development stage Gilbert was selective in his use of opening the posterior wall to enter the preperitoneal space. Gilbert's present solution, applicable to all types of primary inguinal hernia, is the Prolene Hernia System (PHS). This device incorporates a flat circular mesh for placement in the preperitoneal space, a connector placed in the direct or indirect defect and a lozenge-shaped flat mesh which lies in the interfascial plane and is tacked down to the conjoint tendon/

internal oblique and inguinal ligament. The present trial was designed to compare the outcome after PHS with the more traditional Lichtenstein patch, which lies in the interfascial plane alone. This report represents the findings of this clinical study, examining clinical and patient outcomes at up to 12 months post-operatively.

Patients and methods

This study was carried out in a single institution by a Hernia Service which treats approximately 250 patients per year [15]. Operations were performed or supervised by one specialist surgeon and a number of junior surgeons in training. Consecutive consenting patients with primary uncomplicated unilateral hernia were entered into the study, which was approved by the local research and ethics committee.

Patients

A total of 206 patients over the age of 18 years with an uncomplicated unilateral inguinal hernia were selected as being eligible for the study. Exclusion criteria were irreducible inguino-scrotal hernia, failure to consent for randomisation and recurrent hernia. Patients then received a physical examination and pre-operative investigations consistent with their physical status. They were provided with a patient information leaflet and consent form for entry into the study, along with an information sheet normally given to patients who are being treated on the Hernia Service. The latter information contained guidance on rehabilitation and return to normal activity (usual activities of daily living, dressing, climbing stairs, cleaning the house and going shopping) and return to work. All patients were operated on under local anaesthesia except three who received general anaesthesia.

Patients were prepared for the operating theatre by the research nurse and reviewed by the operating surgeon prior to entry to the operating theatre. The research nurse did not enter the operating theatre and was unaware of the activity therein and the operative procedures being carried out. After application of a standardised local anaesthetic inguinal regional block, randomisation was carried out. Summaries of baseline data are presented in Table 1. Demographic characteristics and medical history were similar in the two treatment groups. The type of hernia defect and its size were essentially the same for each group of patients. Incision size, hernial sac excision and transection were also similar. Local anaesthesia was used with all patients except three (two PHS and one patch).

Surgical techniques

Following reduction of the hernial sac, the size of the defect was classified according to the Aachen classification [24]. For the Lichtenstein method the technique used was that described by Shulman and Amid [25], and for the PHS repair was that described by Gilbert (personal communication): Briefly, the preperitoneal space is opened by division of the transversalis fascia to allow the placement of the inner, circular flat mesh, if necessary a few sutures are placed around the connector to ensure a snug fit and the outer flat mesh then lies in the interfascial plane. In each case the interfascial component was trimmed to cover the differing dimensions of

Table 1. Patient characteristics

	Patch ($n = 103$)	PHS ($n = 103$)	P
Age (years)	59 ± 25.7 (21–29)	59 ± 15.4 (24–86)	0.95
BMI	25 ± 3.9 (16–43)	24 ± 2.4 (19–31)	0.08
Sex: M/F	103/0	99/4	0.25
Employment status			0.93
Full time	47 (45.6%)	42 (40.8%)	
Part time	4 (3.9%)	4 (3.9%)	
Retired	47 (45.6%)	50 (48.5%)	
Not employed	5 (4.9%)	6 (5.58%)	
Missing	0 (0%)	1 (1.0%)	
Self employed	6 (5.8%)	6 (5.8%)	1.00
Occupational type (employed only)			0.01
Largely sedentary	2 (3.9%)	10 (22.7%)	
Predominantly sedentary	11 (21.6%)	7 (15.2%)	
Active work	13 (25.5%)	3 (6.5%)	
Always on feet	16 (31.4%)	12 (26.2%)	
Very labour intensive	9 (17.6%)	14 (30.4%)	
Home activities			0.98
Largely sedentary	6 (5.8%)	5 (4.9%)	
Fairly sedentary	11 (10.7%)	12 (11.7%)	
Moderately active	37 (35.9%)	40 (38.8%)	
Very active	34 (33.0%)	31 (30.1%)	
Always on feet	15 (14.6%)	15 (14.6%)	
Co-existent disease			
Endocrine	15 (14.6%)	6 (5.8%)	0.07
Respiratory	7 (6.8%)	11 (10.7%)	0.46
Cardiovascular	27 (26.2%)	27 (26.2%)	1.00
Skin	1 (1.0%)	2 (1.9%)	–
Genito-urinary	14 (13.6%)	11 (10.7%)	0.67
Muscoskeletal	20 (19.4%)	11 (10.7%)	0.63
CNS	14 (13.6%)	7 (7.8%)	0.17
Other	8 (7.8%)	11 (10.7%)	0.63

the individual patients' posterior inguinal wall [30]. Following hernioplasty and reconstitution of the external oblique the skin incision was closed with an absorbable subcuticular suture and a standard-sized opaque adhesive wound dressing applied. Prophylactic antibiotics were not utilised due to lack of evidence of efficacy [9, 27]. According to the standardised protocol, all patients received rectal administration of a non-steroidal anti-inflammatory drug just prior to operation and an out-patient prescription was supplied for analgesic medication to be taken as required. Summaries of surgery details are given in Table 2.

Data collection and follow-up

Data were collected on standardised questionnaires and case report forms. The research nurse carried out all preoperative investigations and post-operative follow-ups. In the operating theatre the surgeon performing the procedure filled in a standardised operating theatre form which included classification of hernia type, operating time and the procedure performed. To ensure blinded follow-up the operating theatre forms were placed in a sealed envelope (not available to the research nurse) and sent to the data management unit for processing and analysis. All patients were discharged on an ambulatory basis. They were given instructions to complete and record visual analogue scores for pain assessment during the first 14 days after operation and Short-Form 36 (SF36) to assess quality of life at day 3 and day 14 after operation. Patients were also sent further SF36 forms to return at the 6- and 12-month visits. SF36 has been previously validated for inguinal herniorrhaphy [3, 16].

Statistical analysis

The primary outcome measure was time to return to normal activity. In the original protocol the planned analysis for this primary outcome was to apply the Mann-Whitney U test. Using this test, the planned sample size of 100 in each treatment group gave 95% power of detecting a probability of 0.650 that an observation in one group is less than an observation in the other using a 0.050 two-sided significance level. Repeated measures analysis of variance was applied to data on pain scores and SF36 dimensions. Censored data on pain medication days was analysed using the log-rank test. Baseline variables in Table 1 were compared using the t test or χ^2 test as appropriate. Regression analysis was used to investigate the dependency of surgery time on case order and treatment group.

Table 2. Operating procedure details

	Patch ($n=103$)	PHS ($n=103$)	P
Type of hernia			0.93
Direct	39 (37.9%)	39 (37.9%)	
Indirect	61 (59.2%)	60 (58.3%)	
Combined	3 (2.9%)	4 (3.9%)	
Defect size			0.56
Less than 1.5 cm	12 (11.9%)	13 (12.7%)	
1.5–3 cm	52 (51.5%)	45 (44.1%)	
Greater than 3 cm	37 (36.6%)	44 (43.1%)	
Sac Excised	2 (1.9%)	3 (2.9%)	–
Sac transected	14 (13.6%)	6 (5.8%)	0.10
Anaesthesia			–
General	1 (1.0%)	2 (1.9%)	
Local	102 (99%)	101 (98.1%)	
Incision size (cm)	7.8 ± 0.88 (5–12)	7.6 ± 0.74 (5–9)	0.10
Surgery Time (min)	38.3 (21.0–69.0)	34.1 (17.0–63.0)	0.09

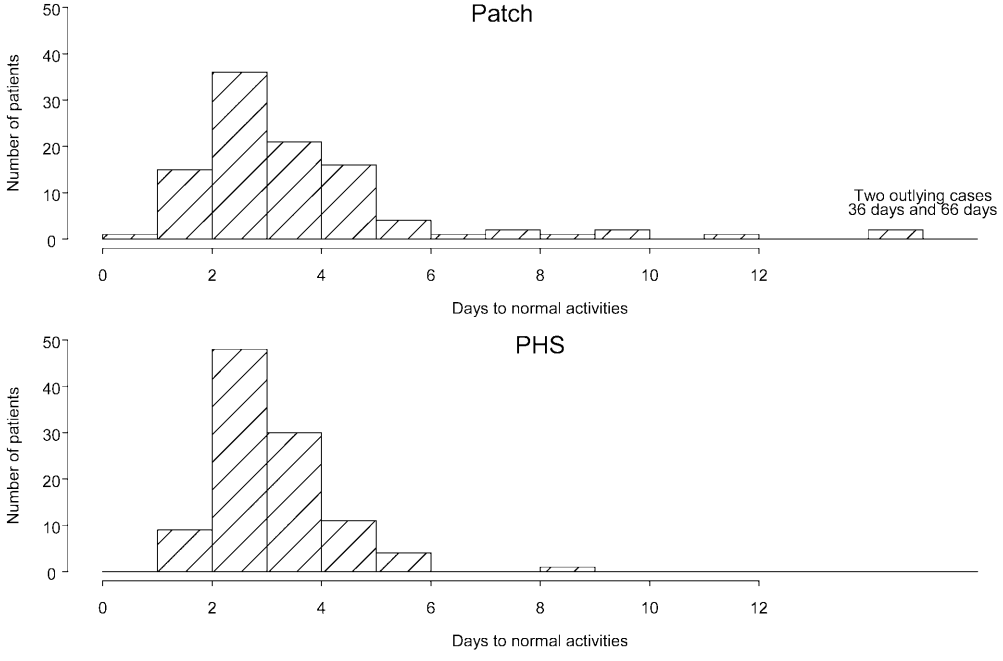

Fig. 1. Histograms of time (days) to return to normal activity by treatment group

Table 3. SF-36 Scores by period and treatment group (*n* number of valid responses)

Dimension	Baseline		3 days		14 days		6 months		12 months	
	n	Mean ± SD	*n*	Mean ± SD	*n*	Mean ± SD	*n*	Mean ± SD	*n*	Mean ± SD
Physical functioning										
Patch	103	79.8 ± 23.3	96	66.2 ± 27.6	95	77.4 ± 24.6	94	83.0 ± 23.5	87	84.1 ± 23.6
PHS	103	77.5 ± 24.1	99	64.7 ± 26.0	97	74.6 ± 24.8	100	81.2 ± 26.3	96	83.0 ± 24.1
Role physical										
Patch	102	69.6 ± 41.1	94	39.4 ± 43.9	94	38.6 ± 44.7	94	82.8 ± 33.6	87	83.8 ± 35.3
PHS	103	62.4 ± 43.3	97	33.1 ± 40.1	96	30.1 ± 38.3	100	77.4 ± 36.7	96	78.2 ± 37.9
Role emotional										
Patch	102	81.2 ± 34.8	94	69.9 ± 40.3	93	73.8 ± 39.3	94	85.7 ± 32.4	87	86.2 ± 31.0
PHS	103	81.2 ± 34.5	97	67.0 ± 42.4	95	64.9 ± 42.8	100	85.5 ± 31.3	96	88.0 ± 29.5
Social functioning										
Patch	102	87.3 ± 19.7	95	74.8 ± 25.7	95	77.3 ± 22.2	94	86.7 ± 23.4	87	88.2 ± 22.9
PHS	103	84.1 ± 24.0	99	74.7 ± 24.8	97	72.0 ± 24.8	100	87.3 ± 22.9	96	88.7 ± 18.6
Mental health										
Patch	100	78.6 ± 16.6	95	78.4 ± 17.4	95	78.8 ± 18.4	94	81.5 ± 16.4	87	81.2 ± 17.9
PHS	102	78.3 ± 16.6	98	78.7 ± 17.1	96	80.2 ± 16.0	100	82.6 ± 16.2	96	82.0 ± 15.8
Vitality										
Patch	100	66.4 ± 19.2	95	60.8 ± 16.9	95	63.2 ± 18.7	94	69.2 ± 19.9	87	70.6 ± 17.7
PHS	102	64.8 ± 21.6	99	59.5 ± 21.6	97	59.4 ± 20.4	100	70.2 ± 21.6	96	69.6 ± 22.1
Bodily pain										
Patch	102	68.1 ± 24.5	95	54.1 ± 25.5	95	51.9 ± 22.6	94	85.0 ± 22.6	87	82.3 ± 25.4
PHS	103	68.1 ± 23.9	99	51.7 ± 22.3	97	51.0 ± 21.9	100	83.9 ± 23.7	96	85.8 ± 21.3
General health										
Patch	103	72.4 ± 20.7	96	70.6 ± 20.8	95	73.2 ± 21.0	94	72.7 ± 22.4	87	74.6 ± 20.8
PHS	103	75.6 ± 17.6	100	72.2 ± 17.5	97	73.7 ± 17.8	100	76.5 ± 19.5	96	75.5 ± 19.0

Results

The median number of days between surgery and return to normal was 2 days in each group. Using the Mann-Whitney test, there is no evidence of a difference in times to return to normal activity between the two treatments ($P = 0.433$). For those patients in employment, 47 in the PHS group and 51 in the patch group, the median number of days of employment missed was 10 and 13, respectively. There was no evidence of a difference in number of days employment missed ($P = 0.309$). The median number of days to return to work after surgery was 14 days with the PHS and 19 days with the patch; ($P = 0.354$). The proportion of patients taking longer than 3 days to return to normal activity was 28.4% in the patch group and 15.5% in the PHS group ($P < 0.05$; Fig. 1); this significant finding was identified after examination of the data and could be spurious. The operating time was shorter in the PHS group (34.1 vs. patch 38.3 min; $P = 0.0008$).

SF36 results are presented in Table 3. In addition, Fig. 2 shows the mean of the SF36 dimensions at baseline and follow-ups. There is no evidence of any treatment effect on the level of the eight SF36 health status dimensions ($P > 0.05$). Pain and role physical dimensions at 12 months show a marked improvement over baseline.

Daily mean levels of postoperative visual analogue scale pain scores are shown in Fig. 3. Repeated-measures analysis of variance showed no evidence of any treatment effect for the 15 days as a whole ($P = 0.564$). However, there was a significant interaction between treatment and day ($P = 0.014$) which was accounted for by the difference in treatments on day 0 (the day of surgery) when PHS patients had significantly less pain than patch patients (PHS 19.2 vs. patch 28.1, $P < 0.05$). Both groups of patients took analgesic medication for a median of 6 days after operation, and the majority had ceased taking pain medication by day 14. The log-rank test provided no evidence of a difference in time on pain medication ($P = 0.82$).

Discussion

This study shows that the use of the PHS results in a similar or better postoperative recovery in patients undergoing primary inguinal hernia repair than the use of a traditional Lichtenstein patch. In PHS patients there was a 10% reduction in operating time, immediate postoperative pain was reduced, and more patients returned to normal activity and work earlier. This was achieved with no more than the anticipated levels of post-operative complications and with no recurrences at up to 1 year after the surgery.

Because this study was carried out in a single institution, and the operations were performed or supervised by one surgeon, external validity needs to be tested in other centres before its true effectiveness and generalis-

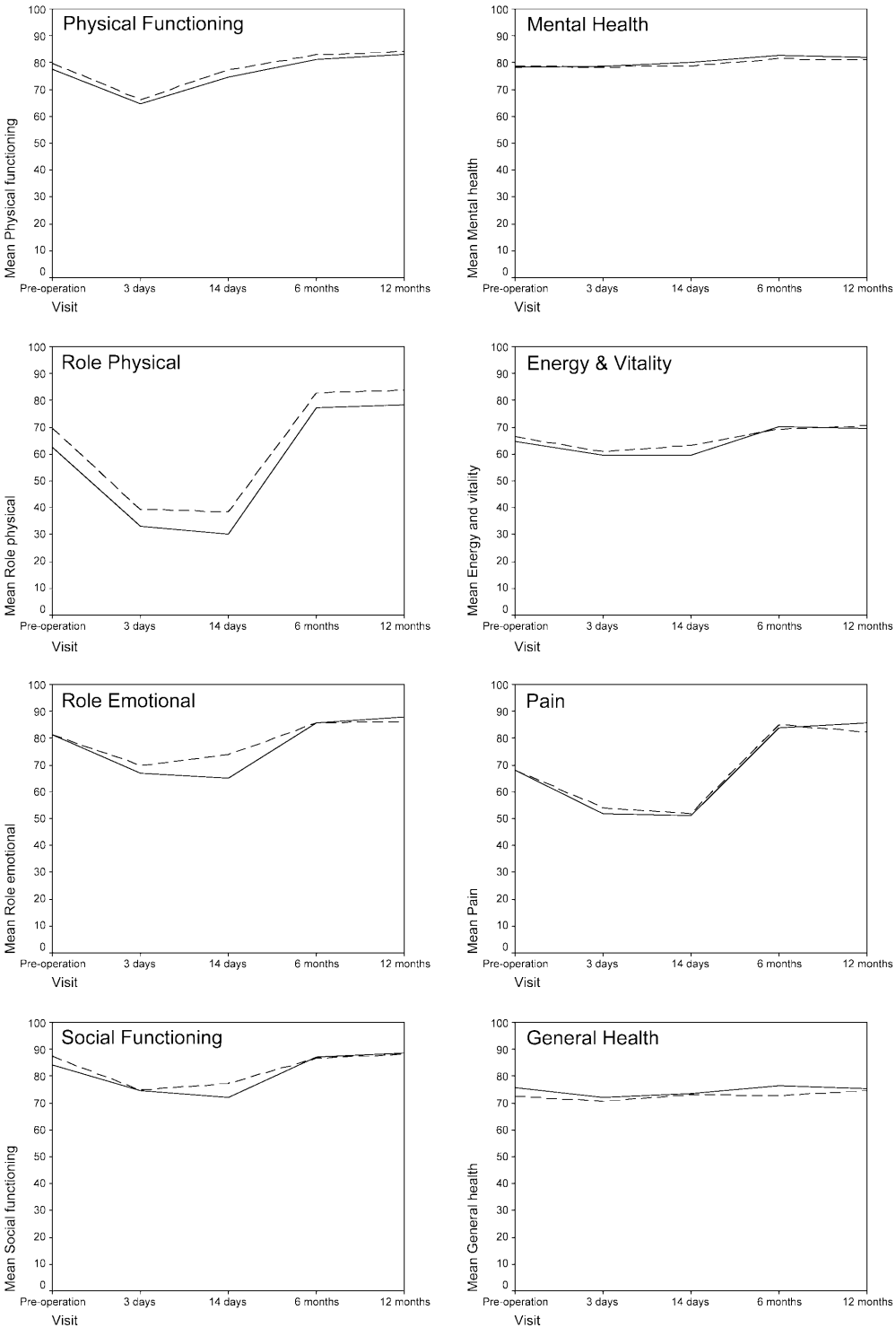

Fig. 2. Mean SF36 scores by visit and treatment group (- - - = Patch, — = PHS)

ability can be established [29]. The introduction of a new surgical technique should proceed in a structured way, which incorporates formal training courses and assistance from expert practitioners of the technique [10].

For considerations in cost-effectiveness, any additional cost of the PHS compared with the Lichtenstein patch must be taken into account [19]. Because inguinal herniorrhaphy is a high volume operation even a small increase in cost increment due to mesh expense will have a significant impact on total healthcare expenditure. Any increased costs compared with the Lichtenstein patch should be equivalently small. On the other hand, the study has demonstrated small but real savings in surgery time and potentially greater social benefits in earlier rehabilitation of patients having had a PHS repair. Few patients were experiencing groin pain at 1 year, but the

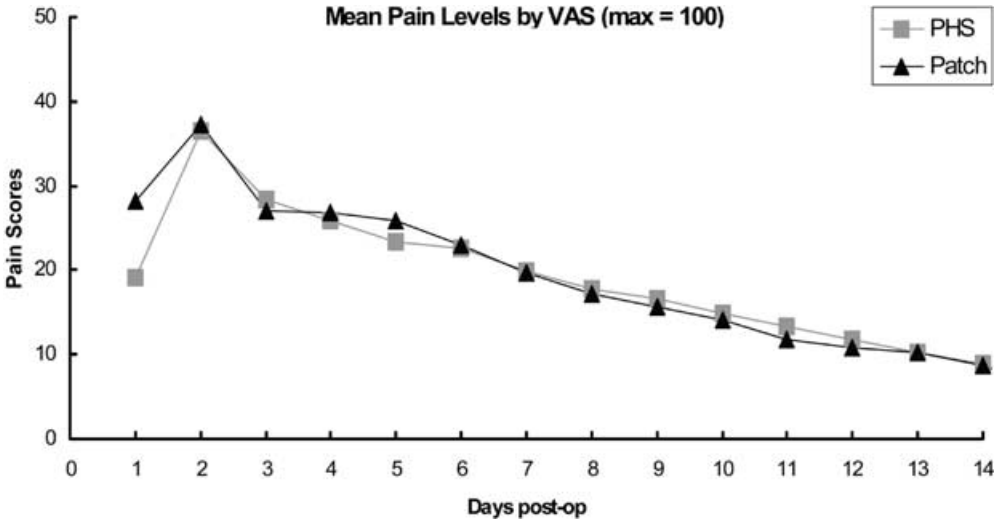

Fig. 3. Mean visual analogue scale pain scores by day and by treatment group

rate was more than twice as high in patch as in PHS patients. Long-term follow-up will determine whether this trend is a real effect.

Postoperative pain in this study was minimised by the application of balanced analgesia combined with patient education [14]. In this context, local anaesthesia is the most important adjunct because it provides fast recovery on the day of surgery, good pain relief in the early postoperative period and immediate return to activity [4]. Long-term studies are required to test the efficacy of mesh in general, both in terms of recurrence rates which have been dramatically reduced by its use, and in terms of chronic groin pain which may be increasing due to mesh inguinodynia [11]. In the medium term, PHS has a similar clinical outcome to Lichtenstein patch and, because of the additional protective patch in the preperitoneal space, may provide additional safeguards against recurrence.

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