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ORIGINAL ARTICLE

Prolene Hernia System, Lichtenstein mesh and plug-and-patch for primary inguinal hernia repair: 3-year outcome of a prospective randomised controlled trial

The BOOP study: Bi-layer and connector, On-lay, and On-lay with Plug for inguinal hernia repair

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Abstract
Background Dissection requirements differ between various methods for inguinal hernia repair, which may affect operation times, pain response and possibly recovery time. The objectives of this study were to establish if any differences concerning these aspects could be detected following three principally different techniques for primary inguinal hernia repair.
Methods A total of 472 men between 30 and 75 years of age with primary inguinal hernias were included in a prospective controlled study and randomised to Lichtenstein mesh (L), PerFix Plug® (P) or the Prolene® Hernia System (PHS) procedure. All patients were seen and data were collected after 2 weeks, 3 months, 1 year and 3 years.
Results The follow-up rates were 100, 99.8, 98.7 and 95.3%, respectively. The mean operation time was shorter for P (35.5 min, $P < 0.001$) and PHS (37.4 min, $P < 0.02$) versus L (40.4 min). More than 85% of the procedures were performed under local anaesthesia. There were no statistically significant differences between the groups concerning early or late complications, return to full functional ability, early pain response, analgesic consumption or the studied late-outcome parameters after 3 years of observation. Seven (1.5%) evenly distributed recurrences were registered.
Conclusion All of the techniques are suitable for operation under local anaesthesia. The PHS and P techniques can be performed with shorter operation times than the L method. Early and late outcomes are, however, comparable, with no significant differences concerning complication rates, return to full functional status and/or pain response.

Keywords Inguinal hernia · Randomised controlled trial · Surgery · Surgical mesh · Treatment outcome

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Introduction

Mesh-based inguinal hernioplasties are in extensive use today. In the US, more than 90% of the approximately 800,000 hernia repairs performed in 2003 were mesh reinforced [1]. In Sweden, close to 90% of all groin hernia repairs during 2006 involved the use of a mesh prosthesis [2]. There are only a few randomised controlled trials, however, that have focussed on the pros and cons for different mesh methods [3–8]. Three of the most commonly used mesh techniques in North America [1] and Sweden [2] are the Prolene Hernia System (PHS), the most wide-spread Lichtenstein mesh method (L) and the PerFix Plug technique (P). Apart from similarities like being open surgery methods, employing mesh reinforcement and adhering to the "tension-free principles," they also have singularly unique and characteristic features; PHS with its bi-layer mesh, reinforcing both the pre-peritoneal space and the

inguinal floor, together with a connector/plug filling the abdominal wall defect per se [9, 10], L with a single mesh reinforcement of the inguinal floor [11], and P with the plug-and-patch technique with a plug in the hernia defect and a small patch as inguinal canal floor reinforcement [12]. Besides demanding divergent dissection techniques and also the actual need for dissection, they furthermore, in parts, occupy and aim at different anatomical areas and surgical principles. The primary objectives of this randomised controlled trial were to investigate whether these three principally different approaches for inguinal hernia mesh repair, with their various characteristics and demands for dissection, produce any differences in the operation time, postoperative pain response and/or affect the time until full recovery.

Study design

The study was designed as a randomised single blind, multicentre study with patients randomly allocated to one of three principally different surgical techniques for primary inguinal hernia repair; PHS, L or P.

Hypothesis and objectives

The hypothesis of the study was that a diminished need for dissection when performing inguinal hernia repair leads to a shorter operation time and causes less pain in the postoperative recovery period, with fast full recovery. The primary objectives were, thus, to establish if any differences in operation time, postoperative pain response and/or postoperative recovery time and return to full functional ability could be detected when three different mesh techniques for primary inguinal hernia repair were utilised. The secondary objectives were to investigate if any particular technique was relatively inapt for local anaesthesia and/or if postoperative complication patterns or frequencies differed between the techniques.

Patients

Males aged between 30 and 75 years, American Society of Anaesthesiologists (ASA) classification I–III without drug or alcohol abuse, suffering from primary inguinal hernias were eligible for inclusion. Females, men with prior ipsilateral hernia surgery, drug or alcohol abuse, and men with severe illness (ASA > III) were ineligible. The study was carried out at three different institutions (Frölunda Specialist Hospital, Lundby Hospital and Mölndals Hospital/Sahlgrenska University Hospital). The study was approved by the Ethical Committee at the Medical Faculty of the University of Gothenburg. All of the included patients were thoroughly informed and were included after informed consent. A total of 472 patients were included from February 2000 to June 2002. The demographic data and patient characteristics are given in Table 1.

Table 1 Demographics and patient characteristics

	Lichtenstein, $n = 158$	PerFix, $n = 159$	PHS, $n = 155$
Age (years, mean ± SEM)	56 ± 1	55 ± 1	56 ± 1
Weight (kg, mean ± SEM)	80 ± 1	80 ± 1	79 ± 1
BMI (median)	25	25	25
ASA			
I	132	134	135
II	25	24	19
III	1	1	1
Physical activity score ("work-load")			
0	45	49	53
1	75	82	72
2	38	28	30

0 unemployed or retired for any reason, i.e. not working, *1* work not physically demanding, i.e. clerical work, light industrial work, *2* heavy physical work, i.e. furniture removal

Surgical techniques

The participating surgeons were all experienced and interested in hernia surgery. Extensive efforts were made to ensure standardised techniques. As such, close attention to technical details concerning the different surgical procedures was taken. Besides thorough studies of and strict adherence to written descriptions by Robbins and Rutkow [13] considering the PerFix technique, by Gilbert et al. [9] concerning the PHS method and Amid et al. [14] considering the Lichtenstein procedure, all participating surgeons both performed and witnessed inguinal hernia surgery together on several occasions in order to achieve as standardised surgical methods as possible. Furthermore, personal communication and/or surgery witnessed and performed together with some of the above mentioned spokesmen (Gilbert and Robbins) have further clarified issues of details. The surgical key-points of the studied techniques as they were performed in the study are summarised in Table 2. Surgery under local anaesthesia was used as routine, while other types of anaesthesia were chosen for specific reasons, e.g. large hernia size, patient preference and/or considerable overweight. Prophylactic antibiotics were not routinely administered. The fundamental principles for the three techniques are, thus, bi-layer mesh with a connecting plug (PHS), simple on-lay mesh (L) and small on-lay mesh with plug (P). The meshes that were used for the respective hernioplasties were for L Prolene® mesh 10 × 15 cm (Ethicon Inc., Somerville, NJ, USA), for P

Table 2 Surgical key-points for the different methods

General surgical principles for all procedures
Standardised local anaesthesia with 46–60 ml of 5 mg/ml mepivacain with 5 μg/ml adrenaline (Carbocaine® adrenaline, AstraZeneca, Södertälje, Sweden) as the primary choice for routine anaesthesia
Conscious sedation
Oblique or transverse skin incision
Nontraumatic dissection of the spermatic cord and hernia sac
Cremaster fibres routinely spared if possible
Ilioinguinal, iliohypogastric and genitofemoral nerves identified, respected and left unharmed if possible
Indirect hernia sacs dissected free, invaginated and not excised
Subcuticular closure with absorbable suture/sutures
Skin closure of the performing surgeon's choice
Lichtenstein hernioplasty key-points
Single on-lay mesh technique
Medial defect inverted by a running absorbable suture (Vicryl® 3/0, Ethicon Inc., Somerville, NJ, USA)
10 × 15 cm polypropylene mesh (Prolene® mesh, Ethicon Inc.)
Pubic bone overlap >1.5 cm
Lower edge of mesh sutured to the shelving margins of Poupart's ligament with a running non-absorbable running monofilament (Prolene® 2/0, Ethicon) to a point just lateral to the internal ring
Lateral slit in the mesh for the cord, 2/3 upper part, 1/3 lower part
Mesh and slit part secured and sutured to the shelving margin of Poupart's ligament just lateral to the completion knot of the running suture, "sling" mechanism, with a non-absorbable suture (Prolene® 2/0)
Plug-and-patch technique
Small unsutured on-lay mesh with plug
Minimal dissection of the spermatic cord
Cord lipomas allowed to "drop back" through the internal ring
The plug (Bard® PerFix® Plug, BARD/Davol Inc., Murray Hill, NJ, USA) sutured to the margins of the defect with absorbable sutures (Vicryl® 3/0)
Direct hernias repaired with XL plug or two L plugs and sutured with 8–10 interrupted sutures (Vicryl® 3/0)
Indirect plugs secured with 4–8 sutures (Vicryl® 3/0)
The flat mesh routinely not secured unless at the choice of the surgeon
If sutures were deemed appropriate, absorbable sutures were used (Vicryl® 3/0)
Mesh tails brought together with absorbable sutures (Vicryl® 3/0)
PHS
Bi-layer (preperitoneal and on-lay) mesh with connecting plug
Medial defects opened, i.e. the transversalis fascia is opened and circumferentially dissected with scissors or electric cautery, and its protruding contents are dissected from the defect
Creation of a "posterior space," most often by the use of a sponge manipulated into the preperitoneal space
Prolene® (polypropylene) Hernia System Extended (Ethicon Inc., Somerville, NJ, USA) was used
The whole rounded portion was inserted well into the preperitoneal space (like the insertion of a half-closed umbrella with the upper portion in front) and subsequently withdrawn slightly
The round portion is flattened to conform to the inner surfaces of the abdominal wall
The connector remains in the internal ring or in the direct defect
The lateral leaf of the on-lay graft is flattened against the transversus arch and the medial leaf is positioned over the pubic tubercle
The on-lay graft is sutured with non-absorbable sutures (2/0 Prolene) over the pubic tubercle, at the middle of the transversus arch and at the middle of the inguinal ligament
Slit cut for the spermatic cord and secured by non-absorbable sutures
The exact position of the slit could vary from patient to patient, depending on the size of the cord, the position of the cord etc.
Additional sutures placed at the choice of the surgeon

BARD PerFix® plug size Large (DAVOL Inc., Canston, USA) and for PHS Prolene® Hernia System Extended (PHS, Ethicon Inc., Somerville, NJ, USA).

Follow-up

All subjects received a standardised set of postoperative analgesics (Panodil®/paracetamol, GlaxoSmithKline Healthcare, Dexofen®/dextropropoxyphen, AstraZeneca, and Pronaxen®/naproxen, Orion). Perioperative data were collected. Postoperative short-, mid- and long-term data were registered at personal out-clinic appointments after 2 weeks, 3 months, 1 year and 3 years. A specific aim of the study was to attain uniquely high follow-up rates to produce reliable results. A standardised diary was given to the subjects, with a thorough explanation of its purpose and how it should be handled. Postoperative pain response was, thus, self-reported on a 0–10 Visual Analogue Scale (VAS) twice daily in the first 2 weeks and then as a weekly average. Furthermore, analgesic consumption, as a secondary measure of postoperative pain response, was also self-reported in the diary. Left-over tablets were collected on day 14 and checked against the diary. A standardised scored functional ability test protocol was registered preoperatively and at follow-ups. The test consisted of a test-walk of stairs, flexion of the ipsilateral hip, rise from the supine position on stretcher, and bend and rise to and from a squatting position. Each test part was scored as: 0, without problem; 1, with minor discomfort; and 2, with difficulty.

Randomisation

Randomisation was accomplished by a computer programme that stratified for age, ASA classification, weight, length, BMI and "daily activity workload" (no straining activities, moderate straining activities, e.g. office or light industrial work, and heavy work, e.g. furniture removal).

Sample size

With a significance level of 0.05 and a standard deviation of 5–10 min in operation time, 100 patients were calculated to be needed in each arm to demonstrate a 5-min difference in operation time with a power of 97–100%. With a significance level of 0.05 and a standard deviation of 1–2 VAS steps, 100 patients were calculated to be needed in each arm in order to demonstrate a 1–2 VAS step difference in postoperative pain with a power of 97–100%.

Statistical methods

The primary endpoints were operation time, VAS pain score and functional ability score. The data were analysed on an intention-to-treat basis. Student's *t*-test was used when comparing means. Differences in baseline variables were tested by the *t*-test or the χ^2 test, as appropriate. Differences in VAS score, functional ability score and self-reported postoperative complaints were analysed by non-parametric tests (the Wilcoxon, Friedman, Kruskal–Wallis, Median and Mann–Whitney *U*-tests).

Ethics

The local ethics committee had, thus, approved the study protocol and informed consent was obtained from each patient.

Results

The study flow and follow-up rates are shown in Fig. 1. Altogether, 21/472 (4.4%) subjects were lost to follow-up after 3 years (six due to unrelated deaths), giving overall follow-up rates of 94.3, 96.9 and 94.8% for L, P and PHS, respectively, at the end of the study.

Adherence rates to allocated procedures were 99.4% for L, 97.5% for P and 95.5% for PHS (Table 3). The reasons for divergences are also given in Table 3. The perioperative data are given in Table 4. Over 86% of the operations were performed under local anaesthesia, with no statistical difference between the groups (L 89%, P 93% and PHS 86%). There were, as expected, no difference in the distribution of hernia types between the three groups (Fig. 2). Over 94% of the operations were performed as ambulatory procedures (L 97%, P 97% and PHS 94%, Table 4). No perioperative complications were encountered. The median VAS (0–10)

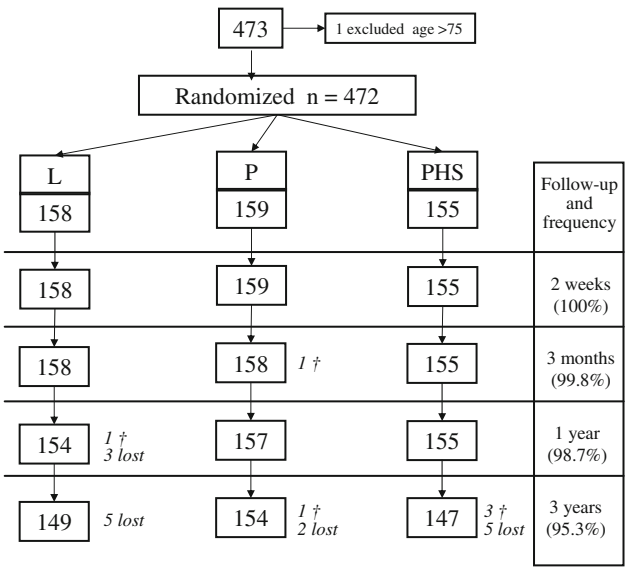

Fig. 1 Study flow and follow-up rates

Table 3 Degree of adherence to allocated procedure

		Ratio of adherence
Lichtenstein		157/158 (99.4%)
PerFix		155/159 (97.5%)
PHS		148/155 (95.5%)
Total		460/473 (97.3%)
Allocated intervention	Performed intervention	Reason for divergence
Reasons for divergence from allocated procedure		
1. Lichtenstein	PerFix	"PerFix deemed more proper"
2. PerFix	PHS	No reason stated
3. PerFix	PHS	"Very large medial defect"
4. PerFix	PHS	"Very large medial defect"
5. PerFix	Double PerFix	"Large medial defect"
6. PHS	PerFix	"Technical problems"
7. PHS	PerFix	"Small indirect hernia sac"
8. PHS	PerFix	No reason stated
9. PHS	PerFix	No reason stated
10. PHS	PerFix	"Small indirect hernia sac"
11. PHS	PerFix	"Combined hernia, PerFix more proper"
12. PHS	PerFix	"Combined hernia, PerFix more proper"
13. PHS	PerFix	"Fragile peritoneum, technical problems"

score considering pain and discomfort during the operation and scored just after the procedure had completed was 1 and 0, respectively, in all groups. The operation time was slightly shorter for P (35.5 ± 1 min, $P < 0.001$ vs. L) and PHS (37.4 ± 1 min, $P < 0.03$ vs. L) compared to L (40.4 ± 1 min, all values means ± SEM, P vs. PHS n.s.). The ranges noted in the operation time between 15 min and close to 2 h (Table 4) indicate that the groups consisted of unselected cohorts of inguinal hernia patients. There were no statistical differences between the groups considering immediate and 30-day complication rates (Table 4). Notable are the few encountered urinary retentions (altogether 5/472, i.e. 1%), no need for any early surgical re-intervention and only one serious event with a deep infection of an L mesh that was removed with subsequent uneventful recovery and no inguinal hernia recurrence during the study period.

The early pain response between day 1 and day 14 after surgery, thus measured by VAS registrations (Fig. 3) on a diary basis and the amounts of consumed analgesics (Fig. 4), were similar in all groups. Morning and evening VAS registrations during the first 14 days are illustrated in Fig. 3, with VAS expressed as means to more clearly visualise the changes in detail over time compared to if they were expressed as median values.

Table 4 Perioperative data

	Lichtenstein	PerFix	PHS
Number of patients	158	159	155
S.c. depth (cm, mean ± SEM)	2.7 ± 0.2	2.7 ± 0.2	2.8 ± 0.2
Type of anaesthesia			
Local anaesthesia	140 (89%)	148 (93%)	133 (86%)
Spinal	4 (2.5%)	2 (1.3%)	5 (3.2%)
General	13 (8%)	5 (3.1%)	12 (8%)
Other	2 (1.3%)	4 (2.5%)	5 (3.2%)
Ambulatory surgery	153 (97%)	154 (97%)	146 (94%)
Prophylactic antibiotics	2 (1.3%)	1 (0.6%)	5 (3.2%)
Perioperative complications	0	0	0
VAS score pain periop. (median)	1	1	1
VAS score discomfort periop. (median)	0	0	0
Operation time (min)			
Mean (±SEM)	40.4 ± 1	35.5 ± 1	37.4 ± 1
Median	40	35	35
Range	18–75	15–80	20–110
Immediate postoperative complications			
Severe	0	0	0
Minor haematoma	1	2	1
Urinary retention	4	0	1
Severe pain (VAS > 7)	2	1	2
Complications of anaesthesia (minor)	1	3	1
Surgical reintervention	0	0	0
Miscellaneous	1	0	2
Late complications (30 days postop.)			
Major	–	–	–
Serious infection	1	0	0
Minor	–	–	–
Haematoma	7	17	14
Infection	2	1	6
Transient neuralgia	0	2	3
Ischaemic orchitis	0	0	0
Miscellaneous	6	4	7

The functional status scores are summarised in Fig. 5. The degree of patients with full functional test scores before surgery was 92% for L, 86% for P and 90% for PHS. At 2 weeks, 71% of L, 77% of P and 79% of PHS (n.s. vs. L and P) achieved full functional test scores. Only a few percent did not achieve full functional test scores from 3 months and onwards (Fig. 5), with no statistical differences between the groups.

No statistical differences between the groups could be detected in the follow-ups at 2 weeks, 3 months, 1 year and 3 years considering the followed parameters, i.e. prickling

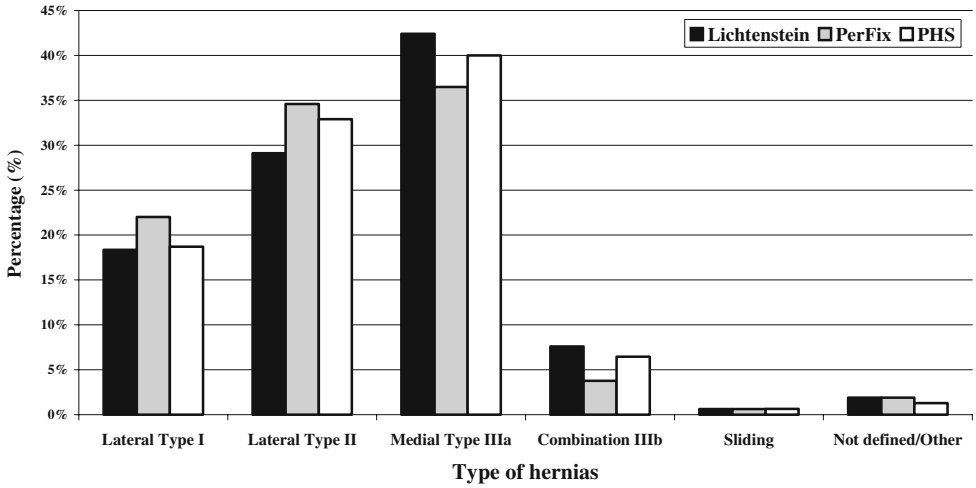

Fig. 2 Distribution of hernia types according to the Nyhus classification. There were no statistical differences between the groups

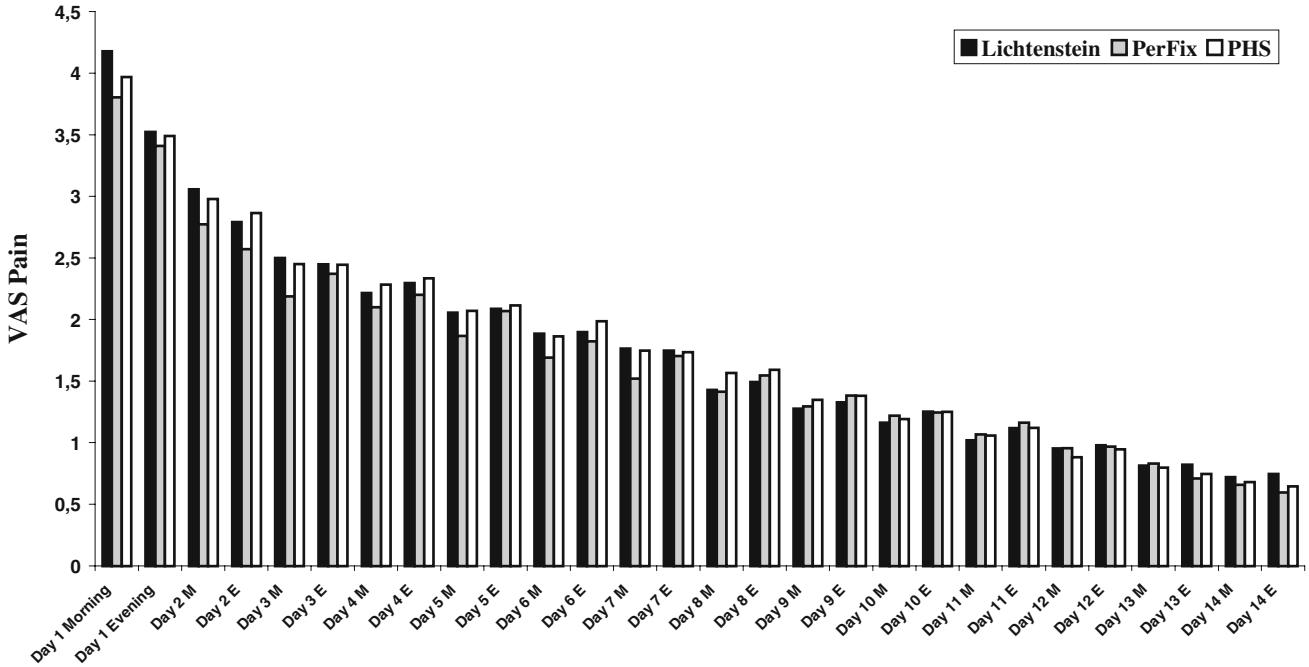

Fig. 3 Mean morning and evening pain during the first 14 postoperative days. There were no statistical differences between the groups

sensation, discomfort, tightness, pain, recurrence, neuralgia, testicular atrophy or other complaints (Table 5). The overall number of complaints was reduced from L 26%, P 35% and PHS 33% at 3 months to L 15%, P 21% and PHS 21% after 3 years ($P = 0.017$, 0.009 and 0.040, respectively). Altogether, seven evenly distributed recurrences were encountered during the 3 years follow-up (Table 5, L 2/158 1.3%, P 2/159 1.3%, PHS 3/155 1.9%).

Discussion

One of the goals of this study was to accomplish a uniquely high follow-up rate to produce as reliable results as possible. The overall follow-up rates were indeed high, reaching above 95% after 3 years (Fig. 1), which is a definite strength of this study. Another strong point of the study is that all patients were personally contacted, interviewed and, if required, examined. The gathered data, even considering clinical findings such as recurrences, could, thus, be regarded, from these view points, as steady and reliable.

We hypothesised that a diminished need for surgical dissection, such as when performing the P and PHS techniques, would lead to a shorter operation time. This was also shown in the present study, in congruence with other recent publications [3–5, 8, 15] but not in all [7]. The difference is, nevertheless, only measured in a few minutes. The clinical implication of this finding is, of course, doubtful.

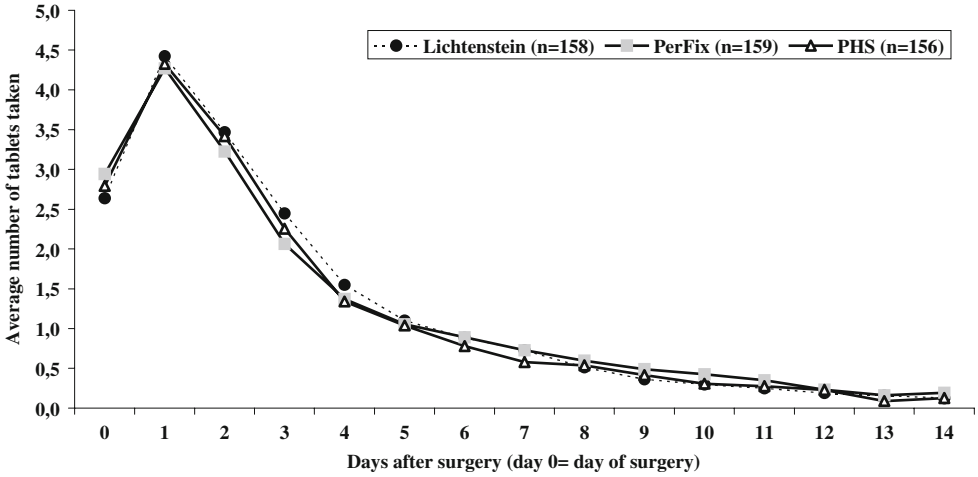

Fig. 4 Average intake of a standardised set of postoperative analgesics during the first 14 postoperative days. There were no statistical differences between the groups

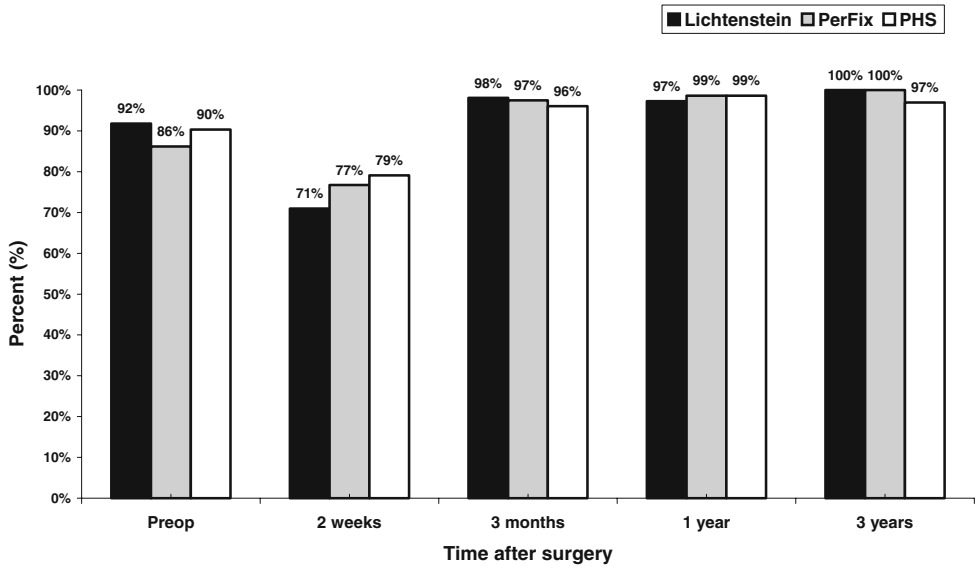

Fig. 5 Percentage of patients reaching full functional ability test scores at follow-ups. There were no statistical differences between the groups

Another hypothesis that we had in the study was that this diminished need for dissection would lead to a more benign and less troublesome postoperative recovery with less pain and also a quicker return to full functional ability after the P and/or PHS techniques. There was, however, neither any statistical difference in the early or late postoperative pain response nor in the measured time until full functional return between the different groups. There was a tendency towards a larger proportion of patients gaining full functional return at 2 weeks in the PHS (79%) and P groups (77%) compared to the L group (71%), a difference that, however, did not reach statistical significance. Kingsnorth et al. [4] have, in a previous study, showed that the PHS technique leads to a somewhat faster return to normal activities versus L. It is possible, speculatively, that this difference would have been apparent also in our study if we had performed the functional status test earlier in the postoperative period. It is, nevertheless, encouragingly notable that about 75% of the patients, regardless of the type of surgical procedure, actually performed the functional status test after 2 weeks without impairment. All procedures, thus, produce a swift return of full functional ability.

There was a trend towards fewer postoperative complaints in the L group versus the other two groups (Table 5), however, it did not fulfil statistical significance criteria. These results could, therefore, also be measured as reassuring for the routine use of any of the studied techniques in the treatment of inguinal hernias. This study clearly shows that reported unwanted postoperative symptoms dissipate, statistically established, over the studied period.

The trial clearly established that all studied procedures are well apt for performance under local anaesthesia (Table 4). Performing inguinal hernioplasties under local anaesthesia has recently been shown to have clear advantages for the patients [16, 17] if compared to regional or general anaesthesia. This should, as we see it, encourage all surgeons to consider this approach if the technique not

Table 5 All of the reported and registered complaints at follow-ups

	At 3 months			At 1 year			At 3 years		
	Lichtenstein, $n = 158$	PerFix, $n = 158$	PHS, $n = 155$	Lichtenstein, $n = 154$	PerFix, $n = 157$	PHS, $n = 155$	Lichtenstein, $n = 149$	PerFix, $n = 154$	PHS, $n = 147$
Prickling sensation	16 (10.1%)	23 (14.6%)	19 (12.3%)	14 (9.1%)	17 (10.8%)	13 (8.5%)	6 (4.0%)	12 (7.8%)	9 (6.1%)
Discomfort	13 (8.2%)	9 (5.7%)	10 (6.5%)	11 (7.1%)	8 (5.2%)	17 (11.0%)	7 (4.7%)	9 (5.8%)	14 (9.5%)
Tightness	5 (3.2%)	5 (3.2%)	9 (5.8%)	7 (4.5%)	7 (4.5%)	6 (3.9%)	4 (2.7%)	1 (0.6%)	4 (2.7%)
Pain	4 (2.5%)	7 (4.4%)	4 (2.6%)	5 (3.2%)	6 (3.9%)	8 (5.2%)	3 (2.0%)	4 (2.6%)	4 (2.7%)
New recurrence	0	1 (0.6%)	0	1 (0.6%)	1 (0.6%)	2 (1.3%)	1 (0.7%)	1 (0.6%)	0
Neuralgia	1 (0.6%)	6 (3.8%)	3 (1.9%)	0	2 (1.3%)	1 (0.6%)	1 (0.7%)	3 (1.9%)	0
Testicular atrophy	0	0	0	0	0	1 (0.6%)	0	0	0
Other complaint	2 (1.3%)	5 (3.2%)	6 (3.9%)	2 (1.3%)	1 (0.6%)	2 (1.3%)	1 (0.7%)	2 (1.3%)	0
Total	25.9%	35.4%	32.9%	26.0%	27.1%	32.4%	15.4%	20.8%	21.1%

Recurrences are registered as recurrences occurring during the actual time period and not as accumulated numbers. All differences between the groups were not of statistical significance. The overall amount of complaints was statistically significantly reduced over time in all groups (3 months vs. 3 years L $P = 0.017$, P 0.009 and PHS 0.040, respectively)

already has been adopted. The low frequency of urinary retentions in the present study (1%) and the low VAS registrations during operation considering pain and discomfort (median values 1 and 0 among all patients) further stress the advantages of local anaesthesia when performing inguinal hernia repair.

Long-lasting pain has been reported as an unwanted and troublesome result after hernioplasties [18, 19] in up to 25–30% of all operations, and severe, chronic pain in about 4% [20]. Detailed pain evaluation was not a specific objective in the present study, but the results are, nevertheless, interesting. The answer to the direct question "Do you experience any type of pain in the region of the inguinal hernia repair?" was, after 3 years, answered with "No" in more than 97% of the patients (Table 5). The evaluation of pain is a complex task when it comes to grading, quantitative measurements and inter-individual comparisons. The statements in the present study that less than 3% of the cases experience any pain after 3 years is, however, encouraging. A watchful attitude is, nevertheless, advisable, as pain could be severely incapacitating for each individual. We, therefore, plan to arrange for a prolongation of the follow-up to a minimum of 5 years and we will, this time, more specifically focus on and thoroughly analyse the presence and characteristics of any long-standing pain.

Conclusions

All the evaluated mesh techniques are suitable for execution under local anaesthesia. The Prolene Hernia System and plug-and-patch techniques can be performed with shorter operation times than the Lichtenstein method. Early and late outcomes are, however, comparable, with few and insignificant differences concerning complication rates, return to full functional ability and/or pain response.

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References

1. Rutkow IM (2003) Demographic and socioeconomic aspects of hernia repair in the United States in 2003. Surg Clin North Am 83(5):1045–1051, v–vi
2. Nordin P (2006) Swedish Hernia Register Annual Report. Available online at: http://www.svensktbrackregister.se/pdf/red06.pdf
3. Kingsnorth AN, Porter CS, Bennett DH, Walker AJ, Hyland ME, Sodergren S (2000) Lichtenstein patch or Perfix plug-and-patch in inguinal hernia: a prospective double-blind randomized controlled trial of short-term outcome. Surgery 127(3):276–283
4. Kingsnorth AN, Wright D, Porter CS, Robertson G (2002) Prolene Hernia System compared with Lichtenstein patch: a randomised double blind study of short-term and medium-term outcomes in primary inguinal hernia repair. Hernia 6(3):113–119
5. Bringman S, Ramel S, Heikkinen TJ, Englund T, Westman B, Anderberg B (2003) Tension-free inguinal hernia repair: TEP versus mesh-plug versus Lichtenstein: a prospective randomized controlled trial. Ann Surg 237(1):142–147
6. Nienhuijs S, Kortmann B, Boerma M, Strobbe L, Rosman C (2004) Preferred mesh-based inguinal hernia repair in a teaching setting: results of a randomized study. Arch Surg 139(10):1097–1100

7. Sanjay P, Harris D, Jones P, Woodward A (2006) Randomized controlled trial comparing prolene hernia system and Lichtenstein method for inguinal hernia repair. ANZ J Surg 76(7):548–552
8. Frey DM, Wildisen A, Hamel CT, Zuber M, Oertli D, Metzger J (2007) Randomized clinical trial of Lichtenstein's operation versus mesh plug for inguinal hernia repair. Br J Surg 94(1):36–41
9. Gilbert AI, Graham MF, Voigt WJ (1999) A bilayer patch device for inguinal hernia repair. Hernia 3:161–166
10. Gilbert AI, Young J, Graham MF, Divilio LT, Patel B (2004) Combined anterior and posterior inguinal hernia repair: intermediate recurrence rates with three groups of surgeons. Hernia 8(3):203–207
11. Amid PK (2004) Lichtenstein tension-free hernioplasty: its inception, evolution, and principles. Hernia 8(1):1–7
12. Rutkow IM (2003) The PerFix plug repair for groin hernias. Surg Clin North Am 83(5):1079–1098, vi
13. Robbins AW, Rutkow IM (1998) Mesh plug repair and groin hernia surgery. Surg Clin North Am 78(6):1007–1023, vi–vii
14. Amid PK, Shulman AG, Lichtenstein IL (1996) Open "tension-free" repair of inguinal hernias: the Lichtenstein technique. Eur J Surg 162(6):447–453
15. Vironen J, Nieminen J, Eklund A, Paavolainen P (2006) Randomized clinical trial of Lichtenstein patch or Prolene Hernia System for inguinal hernia repair. Br J Surg 93(1):33–39
16. Nordin P, Zetterström H, Gunnarsson U, Nilsson E (2003) Local, regional, or general anaesthesia in groin hernia repair: multicentre randomised trial. Lancet 362(9387):853–858
17. Nordin P, Hernell H, Unosson M, Gunnarsson U, Nilsson E (2004) Type of anaesthesia and patient acceptance in groin hernia repair: a multicentre randomised trial. Hernia 8(3):220–225
18. Bay-Nielsen M, Perkins FM, Kehlet H; Danish Hernia Database (2001) Pain and functional impairment 1 year after inguinal herniorrhaphy: a nationwide questionnaire study. Ann Surg 233(1):1–7
19. Fränneby U, Sandblom G, Nordin P, Nyrén O, Gunnarsson U (2006) Risk factors for long-term pain after hernia surgery. Ann Surg 244(2):212–219
20. Bay-Nielsen M, Nilsson E, Nordin P, Kehlet H; Swedish Hernia Data Base the Danish Hernia Data Base (2004) Chronic pain after open mesh and sutured repair of indirect inguinal hernia in young males. Br J Surg 91(10):1372–1376