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Three-month results of the effect of Ultrapro or Prolene mesh on post-operative pain and well-being following endoscopic totally extraperitoneal hernia repair (TULP trial)

J. P. J. Burgmans · C. E. H. Voorbrood · N. Schouten · N. Smakman · S. Elias · G. J. Clevers · P. H. P. Davids · E. J. M. M. Verleisdonk · M. E. Hamaker · R. K. J. Simmermacher · T. van Dalen

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Abstract
Background Recurrence rates after inguinal hernia repair have been reduced to a few per cent, since mesh repair has become standard of care. Lightweight meshes reduce post-operative pain and stiffness in open anterior repair, but for endoscopic repair, the discussion about this benefit is ongoing. This study was done to analyse the effects of lightweight mesh versus heavyweight mesh following endoscopic totally extraperitoneal (TEP) hernia repair.
Methods In a single-centre double-blindly randomized clinical trial, 950 patients with unilateral primary inguinal hernia were randomized to undergo endoscopic TEP using either an Ultrapro® or a Prolene® mesh. Data were collected by validated questionnaires at day 1, day 7, after 6 weeks and after 3 months, and clinical assessment was performed after 3 months. The presence of groin pain after 3 months, defined as an NRS score >3, was evaluated as the primary outcome measure. Secondary outcomes were foreign body feeling and the impact of pain and foreign body feeling on daily activities.
Results At 3-month follow-up, the incidence of pain (NRS 4–10) was 2 versus 0.9 % in the lightweight and heavyweight mesh group, respectively ($p = 0.17$). Pain interfered with daily activities in 1.7 % of the lightweight and 1.5 % of heavyweight group. In the lightweight group, 20 % of patients reported a foreign body feeling versus 18 % in the heavyweight group ($p = 0.62$). No differences between the groups were observed regarding time to return to work, interference with sports and sexual activities, testicular pain and ejaculatory pain. Severe preoperative pain (OR 2.01, 95 % CI 1.21–3.35, $p = 0.01$) was the only independent predictor of any post-operative pain after 3 months.
Conclusion Three months after TEP inguinal repair, there were no significant differences between lightweight and heavyweight mesh use regarding the incidence of pain, foreign body feeling or any other endpoint.

Keywords TEP repair · Lightweight mesh · Heavyweight mesh · Chronic groin pain · Mesh awareness · Quality of life

Trial registration: The TULP study is registered in the Dutch Trial Register (NTR2131).

J. P. J. Burgmans (✉) · C. E. H. Voorbrood · N. Smakman · G. J. Clevers · P. H. P. Davids · E. J. M. M. Verleisdonk · T. van Dalen
Department of Surgery, Hernia Clinic, Diakonessenhuis Utrecht/Zeist, Room: Secretariaat Heelkunde, Professor Lorentzlaan 76, 3707 HL Zeist, The Netherlands
e-mail: iburgmans@diakhuis.nl

N. Schouten
Department of Surgery, Atrium Medical Centre Parkstad, Heerlen, The Netherlands

S. Elias
Julius Centre for Health Sciences and Primary Care, Utrecht, The Netherlands

M. E. Hamaker
Department of Geriatric Medicine, Diakonessenhuis Utrecht/Zeist, Zeist, The Netherlands

R. K. J. Simmermacher
Department of Surgery, UMCU, Utrecht, The Netherlands

Since the introduction of mesh repair for patients with inguinal hernias, low recurrence rates of 2–4 % are observed and the use of mesh irrespective its application has become standard practice [1]. While mesh placement prevents recurrences, the mesh itself might be a source of

mechanical impairment of the patient's moving abilities or generate a phenomenon called foreign body feeling. The subsequent inflammatory reaction after placement may cause chronic pain [2]. The incidence of post-operative pain after inguinal hernia repair is reported in up to 43 % of the patients, but the rate varies significantly due to heterogeneity in the definition of chronic pain, the methods to assess pain and the times of assessment [3].

Persistent pain after groin operations affects daily activities in about 2–20 % of patients [4]. There is ample evidence that endoscopic hernia repair is associated with less post-operative pain and earlier return to daily activities [5–7]. Assuming that the mesh characteristics are responsible for the long-term functional hindrance, lightweight meshes were introduced. These lightweight meshes have larger pores and contain less prosthetic material, and they assumedly produce less post-operative scarring of the abdominal wall [8–10].

A number of studies have compared heavyweight with lightweight meshes in open anterior hernia repair and revealed a significant reduction in foreign body feeling and overall post-operative pain [11–14]. Lightweight meshes are, therefore, recommended as the material of choice in primary open inguinal hernioplasty [15]. In a recent meta-analysis of eight randomized controlled trials comparing lightweight versus heavyweight mesh in laparoscopic hernia repair [16], the benefit of lightweight meshes was not reproduced, although the quality of several studies was hampered by small sample size [8, 17, 18] or missing data regarding the endpoint of interest, i.e. chronic pain after 3 months [9, 19]. Two large RCT's showed a slight improvement in patient comfort and less foreign body feeling after lightweight mesh [20, 21]. However, there is still no consensus which type of mesh should be used in laparoscopic hernia repair.

A randomized controlled trial was conducted in a high-volume hernia centre to address the effect of different meshes on post-operative pain and mesh awareness following the first 3 months after endoscopic totally extraperitoneal (TEP) hernia repair using validated questionnaires for pain, mesh awareness and quality of life.

Materials and methods

A prospective double-blind randomized controlled trial (RCT) study was conducted in a high-volume hospital specialized in the TEP technique for inguinal hernia repair between March 2010 and October 2012. Male patients ≥18 years of age with a primary, reducible, unilateral inguinal hernia and no contraindications for endoscopic TEP repair were eligible for inclusion. Patients with collagen or connective tissue disorders as well as patients who were unlikely to complete the follow-up regimen since they had no fixed address or their comprehension of the language was insufficient were excluded. After screening for eligibility, informed consent was obtained. The study was approved by the regional Medical Ethics Committee (VCMO, Nieuwegein, the Netherlands) and the local ethics board of the hospital. The study is registered in the Dutch Trial Register (NTR2131) [22].

In addition to standardized history and physical examination items, information regarding the preoperative presence of pain and data regarding quality of life was obtained. Pain was measured using the numeric rating scale (NRS, 0 = no pain, 10 = extremely painful, Dutch version). The Inguinal Pain Questionnaire (IPQ, Dutch version [23]) and the Carolinas Comfort Scale (CCS, Dutch version [24]) were used to assess the impact of pain on daily life activities. Pain related to sexual function and ejaculatory was measured using the pain related to sexual function questionnaire (PSF, a Dutch translation of the questionnaire described by Aasvang et al. [25]).

Patients were randomly assigned to the intraoperative use of either a lightweight mesh or a heavyweight mesh. Randomization was done in the operating room after administration of general anaesthesia by computerized block randomization of eight. For the lightweight mesh a 10 × 15 cm, polypropylene–poliglecaprone monofilament mesh was used with large pores (3–4 mm), weighing 55 g/m^2 (after absorption of the poliglecaprone 28 g/m^2) (Ultrapro, Ethicon, Johnson & Johnson company, Amersfoort, the Netherlands). The heavyweight mesh was a 10 × 15 cm polypropylene monofilament mesh with small pores (0.8–1.2 mm), weighing 80 g/m^2 (Prolene, Ethicon, Johnson & Johnson Company, Amersfoort, the Netherlands). Lightweight meshes have a disadvantage because handling and mesh positioning are impaired, especially in endoscopic repair. We choose Ultrapro® with a monocryl component lacking this disadvantage. The monocryl component poliglecaprone is completely absorbed by hydrolysis without increased cellularity, inflammatory and fibrotic reaction [26] and even a decreased foreign body reaction compared to heavyweight polypropylene meshes is described [27].

All patients were operated by one of four surgeons with vast experience (>500 TEP procedures/surgeon), and all procedures were performed under general anaesthesia. The peroperative care and surgical technique were standardized and the same in all patients. The operative details of the TEP technique have been described previously [28, 29]. In particular, the mesh graft was not fixated since staples may induce specific complaints that can be ascribed to nerve entrapment and haematoma. Hernia types were classified intraoperatively according to the Nyhus classification, and the presence of a lipoma was recorded. Intraoperative

complications and operative time were registered. The used mesh type was not mentioned in the operating chart.

Patients were discharged on the day of surgery, unless complications occurred. Post-operative complications were registered. At discharge, patients were advised to take analgesics during the first 2 days (1 g paracetamol every 6 h) and to avoid strenuous physical activity (lifting, sports) during the first post-operative week. There were no other restrictions.

Follow-up of patients took place in a standardized manner according to a fixed schedule. The patient, coordinating investigator and the surgeon involved in the follow-up of enroled patients were blinded for the allocated mesh. NRS scores were measured daily during the first week in a patient diary and after 6 weeks and 3 months by questionnaires. IPQ, CCS and PSF questionnaires were filled in at 6 weeks and 3 months. All patients were examined physically after 3 months in the outpatient department by one of the four hernia surgeons (not being the surgeon having performed the operation). Post-operative complications and recurrences were registered. In case of unclear inguinal pain or complaints suggestive of a recurrent hernia, ultrasound of the groin or MRI scan was performed. For the registration of pain symptoms, a standardized clinical evaluation form was used (Inguinal Pain Form by Loos [30] translated in Dutch).

The primary endpoint of the study was the presence of pain (NRS $>$ 3) 3 months after a TEP hernia repair, as measured by the NRS. The definition of the International Association for the Study of Pain (IASP) was used, and chronic post-operative pain was defined as persistent pain at the site of the operation 3 months after the primary surgery that differed from the pain before the operation [30]. In accordance with the literature, pain intensity was categorized as follows: NRS 1–3 = mild pain; NRS 4–6 = moderate pain; and NRS 7–10 = severe pain. Moderate to severe pain (NRS 4–10) was considered clinically relevant and therefore used as the definition of pain in the present study [30].

Power calculation and statistical analysis

The hypothesis used in the design of the study was that the incidence of pain 3 months after operation was lower after implantation of a lightweight mesh compared to a heavyweight mesh. According to the literature at the time of the initiation of our study and based on a pilot study in our hospital, a reduction of 7.5 % in the incidence of pain was expected. With a two-sided alpha of 0.05 and a power of 0.80, a total of 429 patients were required in each allocation group. Secondary outcome measures were foreign body feeling, impact of pain and foreign body feeling on daily activities and sexual activities, ejaculatory pain and testicular pain and time to return to normal daily activities and work. Operation time, complications and recurrences were registered as well.

Data were prospectively collected on indigenously developed software and converted to SPSS software (SPSS, Chicago, IL, USA) for analysis. All data were analysed on an intention-to-treat basis. Descriptive statistics were used for baseline data. The incidence of pain was compared between lightweight and heavyweight by means of Chi-square analysis. To determine the effect of mesh type on chronic pain, a multivariable logistic regression analysis was performed. First, a univariate logistic regression analysis was performed for potential risk factors for pain at 3 months [32], including mesh type, age, body mass index (BMI), surgeon, type of hernia, the presence of severe preoperative pain, operation time and the presence of severe pain on day 1 of post-operative period. Subsequently, factors with a p value <0.20 in the univariate analysis were entered in the multivariable analysis in addition to mesh type.

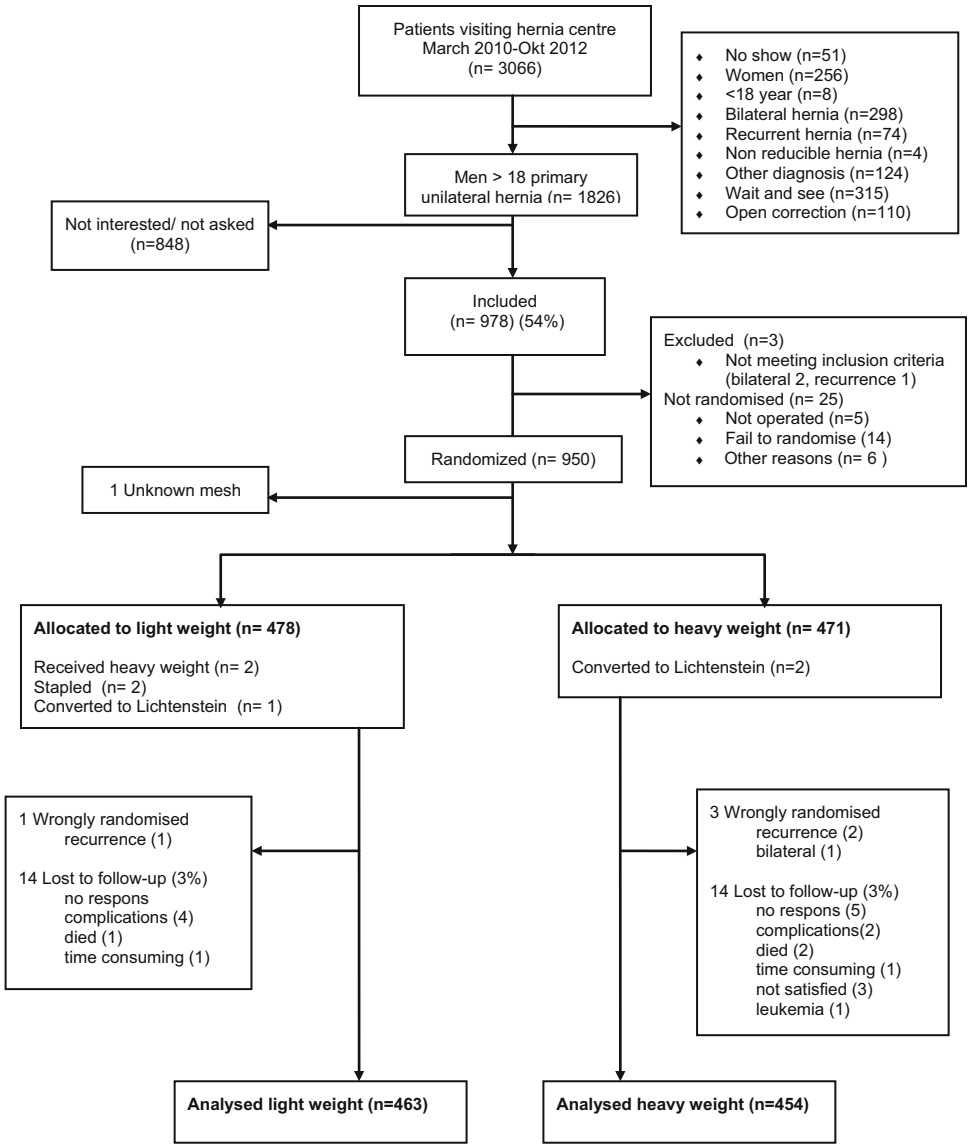
Secondary endpoints were analysed by using a Student's t test (normally distributed continuous), Mann–Whitney analysis (not normally distributed continuous) or Chi-square analysis (categorical variables). Effect estimators were described with 95 % confidence intervals. Significance is set at a level of $p \leq 0.05$.

Results

From March 2010 to October 2012, 3,066 patients visited the hernia centre, 1,826 patients were eligible to include and 978 male patients with a unilateral primary reducible hernia planned for TEP repair were enroled in the study (Fig. 1). After inclusion, 28 patients were not randomized because they did not meet the criteria, cancelled their operation or failed to be randomized. The study population comprised 950 patients, 478 patients randomized for lightweight mesh and 471 for heavyweight mesh. After randomization, one patient was excluded because the allocated mesh type was unknown. The three-month follow-up was completed in 463 (97 %) patients of the lightweight group and 454 (96 %) patients of the heavyweight group. Both groups were statistically comparable regarding patient and hernia characteristics and peroperative details (Table 1).

Median operation time for lightweight mesh was 20 min (range 10–50) compared to 19 min (range 7–60) for heavyweight mesh ($p = 0.12$). Three procedures were converted to open repair, two in the heavyweight group and one patient in the lightweight group. In the lightweight group, two meshes were stapled and two patients received a heavyweight mesh instead of the randomized lightweight

Fig. 1 Flow chart



mesh because of a very large hernia defect. There were no statistical differences in peroperative and post-operative complications in both groups: peroperative bleeding in five (1.1 %) patients of the lightweight group and seven (1.5 %) patients of the heavyweight group ($p = 0.83$), post-operative bleeding in four (0.9 %) and five (1.1 %) patients ($p = 0.96$), haematoma in 12.7 and 12.1 % ($p = 0.92$), infection in 1.1 and 1.1 % ($p = 0.98$) and other complications in 1.3 and 0.9 % ($p = 0.91$) of patients in lightweight and heavyweight, respectively.

Chronic relevant pain (NRS 4–10) at 3 months was present in four (0.9 %) patients in the heavyweight group as compared with nine (2 %) patients in the lightweight group ($p = 0.17$). No significant differences were observed regarding the intensity of pain in the two groups ($p = 0.48$). In the heavyweight group, 19.6 % of the patients experienced any pain (18.7 % mild pain, 0.7 % moderate pain and 0.2 % severe pain) as compared with 18.6 % of the patients in the lightweight group (16.7 % mild pain, 1.3 % moderate pain and 0.7 % severe pain, $p = 0.65$; Table 2).

The feeling of a foreign body at 3-month follow-up was mentioned by 20.0 % of patients with lightweight meshes and 17.6 % in the heavyweight group ($p = 0.56$). In four patients, a recurrent hernia was diagnosed after 2–3 months: two (0.4 %) patients in each group. The median time to return to work was equal in the groups: 7 days (range 1–45) ($p = 0.50$).

No difference in pain intensity at any post-operative time point was observed between the patients treated with lightweight mesh and heavyweight mesh (Table 3). No significant differences were demonstrated on any aspect

regarding quality of life using IPQ and PSF questionnaires (data not shown).

Table 4 shows the univariate and multivariable analysis for possible risk factors for post-operative pain (mesh type, age, body mass index, hernia type, surgeon, severe pre-operative pain, operation time, severe pain day 1 post-operative). Preoperative NRS pain scores of 8–10 and severe post-operative pain at day one (NRS 8–10) significantly prospect the risk of any pain after 3 months. After correction for potential cofounders, no difference in any pain after 3 months was seen between the lightweight and heavyweight mesh groups. Severe preoperative pain (OR 2.01, 95 % CI 1.21–3.35, $p = 0.01$) was the only independent predictor of any post-operative pain after 3 months. Subgroup analysis of patients with or without relevant preoperative pain and influence of mesh on post-operative pain and mesh awareness was performed, but no significant differences were found during the post-operative period and at 3 months.

Table 1 Baseline characteristics

	Lightweight	Heavyweight
n	478	471
Age (years), median (range)	55 (19–88)	55 (18–94)
Paid work (%)	70	67
BMI (kg/m^2), mean (SD)	25 (2.7)	25 (2.5)
Side (%)		
Left	45	41
Right	55	59
Previous operations (%)		
Lower abdomen midline	7	8
Lower abdomen same side	7	10
Preoperative pain NRS (%)		
NRS 0	29	29
NRS 1–3	43	46
NRS 4–7	19	16
NRS 8–10	9	9
Preoperative testicular pain (%)	28	26
Preoperative ejaculatory pain (%)	2.6	2.2
Preoperative pain during sex (%)	38	38
Hernia type (%)		
Lateral	73	75
Medial	27	24
Femoral	0.6	0.4
Surgeon (%)		
1	30	29
2	31	27
3	11	14
4	26	28
5 resident	2	2
Lipoma (%)	36	34

BMI body mass index, *NRS* numeric rating scale (NRS 0 = no pain, NRS 1–3 = mild pain, NRS 4–7 = moderate pain, NRS 8–10 = severe pain)

Discussion

Despite numerous publications and one meta-analysis, there is still no consensus which type of mesh is optimal for endoscopic hernia repair regarding post-operative pain and foreign body feeling. There are only two RCT's comparing lightweight and heavyweight meshes in endoscopic repair with large sample sizes and at least a follow-up of 3 months [20, 21]. Both studies showed slight benefits with lightweight meshes during the early post-operative period, regarding chronic pain and impairment of physical activities. However, in our large, randomized controlled trial comparing lightweight mesh with heavyweight mesh for TEP inguinal repair, there was no difference regarding the incidence and intensity of pain, foreign body feeling or any other endpoint at 3 months after surgery. In addition, no differences were found at other time moments throughout the early post-operative period until 3 months.

The strength of this study is its volume: it is the largest double-blind RCT studying different types of mesh used in TEP herniorrhaphy. The study is sufficiently powered and used validated questionnaires to assess pain, mesh awareness and quality of life preoperatively and post-operatively. However, a weakness of this study is the limited follow-up of 3 months. We chose this period while writing the study protocol according to the definition of chronic pain [31]. Recently, some suggested to adjust the definition of chronic post-operative groin pain to its presence at least 6 months

Table 2 Comparison of pain after 3 months in both groups

Chronic pain (at 3 months)	Lightweight ($n = 463$)	Heavyweight ($n = 454$)	p value
Relevant pain (NRS 4–10) %	2.0	0.9	0.17
Any pain (NRS > 0) %	18.6	19.6	0.65
No pain (NRS 0) %	81.3	80.4	0.48
Mild pain (NRS 1–3) %	16.7	18.7	
Moderate pain (NRS 4–7) % (n)	1.3 (6)	0.7 (3)	
Severe pain (NRS 8–10) % (n)	0.7 (3)	0.2 (1)	

NRS numeric rating scale (NRS 0 = no pain, NRS 1–3 = mild pain, NRS 4–7 = moderate pain, NRS 8–10 = severe pain)

Table 3 Comparison of pain after 1 day, 1 week and 6 weeks

	1 day			1 week			6 weeks		
	Light	Heavy	*p* value	Light	Heavy	*p* value	Light	Heavy	*p* value
No pain	5.2	6.3	0.23	27.2	26.8	0.81	70.2	73.9	0.50
Mild pain	49.0	44.2		58.4	59.2		26.1	23.5	
Moderate pain	35.9	41.5		13.1	13.3		3.1	2.4	
Severe pain	9.8	7.9		1.3	0.7		0.7	0.2	

Table 4 Univariate and multivariate analysis for any pain after 3 months

	Univariate analysis			Multivariate analysis		
	OR	95 % confidence interval	*p* value	OR	95 % confidence interval	*p* value
Mesh	0.93	0.67–1.29	0.65	0.91	0.65–1.28	0.60
Age (<25)	1.86	0.65–5.33	0.25			
BMI (>25)	1.20	0.86–1.67	0.28			
Surgeon	1.14	1.00–1.30	0.06	1.07	0.96–1.20	0.25
Hernia type	1.15	0.50–2.63	0.75			
Severe preoperative pain	2.03	1.22–3.39	0.01	2.01	1.21–3.35	0.01
Severe pain day 1	1.85	1.11–3.12	0.02	1.64	0.96–2.79	0.07
Operation time > 35 min	0.67	0.23–1.96	0.47			

post-operatively as this allows the mesh-related inflammatory response to subside as a causative factor of pain [33]. However, the study population will be followed for 3 years and data regarding pain and quality of life issues at 1, 2 and 3 years after surgery are expected.

In the present study, chronic relevant pain, according to the classification published by Loos et al. [30] present 3 months post-operatively, was reported by 2.0 % of patients after lightweight mesh and 0.9 % of patients after heavyweight mesh use. A comparable study of Chowbey et al. [21] showed similar results, reporting moderate to severe pain in 2.1 % patients after lightweight mesh and 1.9 % after heavyweight mesh.

The incidence of chronic pain in our study is low compared to previously data reporting an overall incidence of 6 % (range 1–16 %) after endoscopic repair [34]. This could potentially be due to the positive effect of experience and high volume and is confirmed by other groups with an abundant experience in performing endoscopic repair [20, 35].

Another relevant aspect of chronic pain is its impact on daily activity and work. Severe pain assumedly results in inability to work or to perform daily activities. Severe pain after 3 months (NRS 7–10) was mentioned by 0.7 and 0.2 % of patients treated with lightweight and heavyweight meshes in the present study, compared to 0 and 0.5 %, respectively, in the study of Chowbey, whereas Bittner did not report pain severity after 3 months [20, 21]. The impact of pain on daily activities in our study was 1.7 and 1.5 % and also comparable with the result of Chowbey et al. [21]. The impact of pain on the days needed to return to work was 7 days in both groups and low comparable with the literature, reporting 7.2–38.1 days [9, 21, 36].

In our study, we found a relatively high percentage of patients with any pain (NRS 1–10) after 3 months (18.6 % lightweight and 19.6 % heavyweight) which was higher when measured after 6 weeks (29.8 % lightweight and 26.1 % heavyweight). This was not statistically different between the two groups. The study of Bittner reported any pain in only 10 and 8.0 % of patients after 4 weeks. However, pain was measured by VAS scores and it has previously been described that a higher failure rate is present using VAS compared to NRS [37].

When considering the endpoint any pain after 3 months, Chowbey et al. reported lower frequencies and better results for lightweight mesh: 3.7 % compared with 7.1 % for heavyweight mesh. The difference was not statistically significant ($p = 0.164$). In their study, pain was not measured by VAS or NRS, but only assessed for severity (mild, moderate or severe) in the selection of patients who reported having pain. Thus, these data probably underestimate the true frequency. Other studies with small sample sizes used mean VAS scores to compare differences [9, 19, 37]. As the majority of patients report very low VAS scores, the mean VAS scores were very low. In the present study, mean pain (measured by NRS) was also only 0.5 and 0.4 after 6 weeks and 0.4 and 0.3 % after 3 months. Therefore, mean VAS scores are not useful to assess pain and discomfort. As previously emphasized in 2002 by

Kehlet et al. [38], this underscores the importance of uniform assessment, the use of validated questionnaires and valid methods to measure pain to enable comparison of study results.

Lastly, we observed no significant difference with respect to foreign body sensation, neither after 6 weeks nor after 3 months. At 3 months, 20 % of patients with lightweight meshes and 17.6 % with heavyweight meshes reported awareness of a foreign body in the groin. Other studies only reported foreign body feeling after 1 year, and reported differences were not statistically different between lightweight and heavyweight meshes.

This study did not show any difference in pain and comfort between the two mesh types. Other studies reporting on mesh types in endoscopic repair showed absent or slight differences in comfort [16]. Then again, in open repair, evidence is available that lightweight meshes provide better results. While all foreign bodies induce an inflammatory response, lightweight meshes with larger pores are associated with a reduced inflammatory response and less scar tissue [39]. This theoretical advantage of a reduced inflammatory response of lightweight meshes, as evident in open repair, does not translate into a clinical benefit after TEP hernia repair. The preperitoneal position of the mesh is the likely explanation, and this position offers two potential benefits. First, there is a reduced risk of direct nerve damage when working in the preperitoneal space in comparison with open anterior repair. Second, the preperitoneal as a barrier consists of two layers (parietal and visceral) separated by a thin fascia [40]. The large sensory nerves are located behind this fascia in the parietal space. Direct contact between the mesh and the nerves is usually avoided. The extent of the inflammatory response and its resulting swelling and fibrosis has limited influence in this space because of the protecting fascia. Longer follow-up (1–2 years) is warranted to confirm this theory and to know whether the effect of less fibrosis results in less comfort after 3 months and later and in a higher recurrence rate or not.

In conclusion, no beneficial effect regarding post-operative pain, mesh awareness and impact on daily life was observed of a lightweight over a heavyweight mesh 3 months after TEP hernia repair.

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References

1. Bay-Nielsen M, Kehlet H, Strand L, Malmstrøm J, Andersen FH, Wara P, Juul P, Callesen T, Danish Hernia Database Collaboration (2001) Quality assessment of 26,304 herniorrhaphies in Denmark: a prospective nationwide study. Lancet 358:1124–1128
2. Klinge U, Klosterhalfen B, Müller M, Schumpelick V (1999) Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg 165:665–673
3. Simons MP, Aufenacker T, Bay-Nielsen M, Bouillot JL, Campanelli G, Conze J, de Lange D, Fortelny R, Heikkinen T, Kingsnorth A, Kukleta J, Morales-Conde S, Nordin P, Schumpelick V, Smedberg S, Smietanski M, Weber G, Miserez M (2009) European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. Hernia 13:343–403
4. Bay-Nielsen M, Perkins FM, Kehlet H (2001) Pain and functional impairment 1 year after inguinal herniorrhaphy: a nationwide questionnaire study. Ann Surg 233:1–7
5. Kehlet H (2008) Chronic pain after groin hernia repair. Br J Surg 95:135–136
6. Kuhry E, van Veen RN, Langeveld HR, Steyerberg EW, Jeekel J, Bonjer HJ (2007) Open or endoscopic total extraperitoneal inguinal hernia repair? A systematic review. Surg Endosc 21:161–166
7. O'Reilly EA, Burke JP, O'Connell PR (2012) A meta-analysis of surgical morbidity and recurrence after laparoscopic and open repair of primary unilateral inguinal hernia. Ann Surg 255:846–853
8. Agarwal BB, Agarwal KA, Mahajan KC (2009) Prospective double-blind randomized controlled study comparing heavy- and lightweight polypropylene mesh in totally extraperitoneal repair of inguinal hernia: early results. Surg Endosc 23:242–247
9. Bringman S, Wollert S, Osterberg J, Heikkinen TJ (2005) Early results of a randomized multicenter trial comparing Prolene and Vypro II mesh in bilateral endoscopic extraperitoneal hernioplasty (TEP). Surg Endosc 19:536–540
10. Bringman S, Wollert S, Osterberg J, Smedberg S, Granlund H, Heikkinen TJ (2006) Three-year results of a randomized clinical trial of lightweight or standard polypropylene mesh in lichtenstein repair of primary inguinal hernia. Br J Surg 93:1056–1059
11. Li J, Ji Z, Cheng T (2012) Lightweight versus heavyweight in inguinal hernia repair: a meta-analysis. Hernia 16:529–539
12. Sajid MS, Leaver C, Biag MK, Sains P (2012) Systematic review and meta-analysis of the use of lightweight *versus* heavyweight mesh in open inguinal hernia repair. Br J Surg 99:29–37
13. Smietanski M, Smiemanski IA, Modrzejewski A (2012) Systematic review and meta-analysis on heavy and lightweight polypropylene mesh in Lichtenstein inguinal hernioplasty. Hernia 16:519–528
14. Uzzaman MM, Ratnasingham K, Ashraf N (2012) Meta-analysis of randomized controlled trials comparing lightweight and heavyweight mesh for Lichtenstein inguinal hernia repair. Hernia 16:505–518

15. Miserez M, Peeters E, Aufenacker T, Bouillot JL, Campanelli G, Conze J, Fortelny R, Heikkinen T, Jorgensen LN, Kukleta J, Morales-Conde S, Nordin P, Schumpelick V, Smedberg S, Smietanski M, Weber G, Simons MP (2014) Update with level 1 studies of the European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. Hernia 18:151–163
16. Currie A, Andrew H, Tonsi A, Hurley PR, Taribagil S (2012) Lightweight versus heavyweight mesh in laparoscopic inguinal hernia repair: a meta-analysis. Surg Endosc 26:2126–2133
17. Chui LB, Ng WT, Sze YS, Yuen KS, Wong YT, Kong CK (2010) Prospective, randomized, controlled trial comparing lightweight versus heavyweight mesh in chronic pain incidence after TEP repair of bilateral inguinal hernia. Surg Endosc 24:2735–2738
18. Peeters E, Spiessens C, Oyen R, De Wever L, Vanderschueren D, Penninckx F, Miserez M (2010) Laparoscopic Inguinal hernia repair in men with lightweight meshes may significantly impair sperm motility: a randomised controlled trial. Ann Surg 252:240–246
19. Heikkinen T, Wollert S, Osterberg J, Smedberg S, Bringman S (2006) Early results of a randomised trial comparing Prolene and Vyproll-mesh in endoscopic extraperitoneal inguinal hernia repair (TEP) of recurrent unilateral hernias. Hernia 10:34–40
20. Bittner R, Schmedt CG, Leibl BJ, Schwarz J (2011) Early postoperative and one year results of a randomized controlled trial comparing the impact of extralight titanized polypropylene mesh and traditional heavyweight polypropylene mesh on pain and seroma production in laparoscopic hernia repair (TAPP). World J Surg 35:1791–1797
21. Chowbey PK, Garg N, Sharma A, Khullar R, Soni V, Baijal M, Mittal T (2010) Prospective randomized clinical trial comparing lightweight mesh and heavyweight polypropylene mesh in endoscopic totally extraperitoneal groin hernia repair. Surg Endosc 24:3073–3079
22. Schouten N, van Dalen T, Smakman N, Elias SG, Clevers GJ, Verleisdonk EJ, Davids PH, Burgmans IP (2012) The effect of ultrapro or prolene mesh on postoperative pain and well-being following endoscopic totally extraperitoneal (TEP) hernia repair (TULP): study protocol for a randomized controlled trial. Trials 13:76
23. Fränneby U, Gunnarsson U, Andersson M, Heuman R, Nordin P, Nyrén O, Sandblom G (2008) Validation of an Inguinal Pain Questionnaire for assessment of chronic pain after groin hernia repair. Br J Surg 95:488–493
24. Heniford BT, Walters AL, Lincourt AE, Novitsky YW, Hope WW, Kercher KW (2008) Comparison of generic versus specific quality-of-life scales for mesh hernia repairs. J Am Coll Surg 206:638–644
25. Aasvang EK, Mohl B, Bay-Nielsen M, Kehlet H (2006) Pain related sexual dysfunction after inguinal herniorrhaphy. Pain 122:258–263
26. Schug-pas C, Tamme C, Sommerer F, Tannapfel A, Lippert H, Kockerling F (2008) A lightweight, partially absorbable mesh (Ultrapro) for endoscopic hernia repair: experimental biocompatibility results obtained with a porcine model. Surg Endosc 22:1100–1106
27. Klosterhalfen B, Junge K, Klinge U (2005) The lightweight and large porous mesh concept for hernia repair. Expert Rev Med Devices 2:103–117
28. Langeveld HR, van,t Riet M, Weidema WF, Stassen LP, Steyerberg EW, Lange J, Bonjer HJ, Jeekel J (2010) Total extraperitoneal inguinal hernia repair compared with Lichtenstein (the LEVEL-Trial): a randomized controlled trial. Ann Surg 251:819–824
29. Lau H, Patil NG, Yuen WK (2006) Day-case endoscopic totally extraperitoneal inguinal hernioplasty versus open Lichtenstein hernioplasty for unilateral primary inguinal hernia in males: a randomised trial. Surg Endosc 20:76–81
30. Loos MJA, Roumen RMH, Scheltinga MRM (2007) Classifying postherniorrhaphy pain syndromes following elective inguinal hernia repair. World J Surg 31:1760–1765
31. Classification of chronic pain (1986) Description of chronic pain syndromes and definitions of pain terms. Prepared by the International Association for the study of pain Subcommittee on Taxonomy. Pain Suppl 3:S1–S226
32. Kalliomaki ML, Meyerson J, Gunnarsson U, Gordh T, Sandblom G (2008) Long-term pain after inguinal hernia repair in a population-based cohort; risk factors and interference with daily activities. Eur J Pain 12:214–225
33. Kehlet H, Roumen RM, Reinpold W, Miserez M (2013) Invited commentary: persistent pain after inguinal hernia repair: what do we know and what do we need to know? Hernia 17:293–297
34. Aasvang E, Kehlet H (2005) Chronic postoperative pain: the case of inguinal herniorrhaphy. BJA 95:69–76
35. Dulucq JL, Wintringer P, Mahajna A (2009) Laparoscopic totally extraperitoneal inguinal hernia repair: lessons learned from 3,100 hernia repairs over 15 years. Surg Endosc 23:482–486
36. Langenbach MR, Schmidt J, Zirngibl H (2006) Comparison of biomaterials: three meshes and TAPP for inguinal hernia. Surg Endosc 20:1511–1517
37. Loos MJA, Houterman S, Scheltinga MRM, Roumen RMH (2008) Evaluating postherniorrhaphy groin pain: visual analogue or verbal rating scale? Hernia 12:147–151
38. Kehlet H, Bay-Nielsen M, Kingsnorth A (2002) Chronis postherniorrhaphy pain—a call for uniform assessment. Hernia 4:178–181
39. Hollinsky C, Sandberg S, Koch T, Seidler S (2008) Biomechanical properties of lightweight versus heavyweight meshes for laparoscopic inguinal hernia repair and their impact on recurrence rates. Surg Endosc Surg Endosc 22:2679–2685
40. Amid PK, Hiatt JR (2007) New understanding of the causes and surgical treatment of postherniorrhaphy inguinodynia and orchialgia. J Am Coll Surg 205:381–385