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Randomized clinical trial of laparoscopic hernia repair comparing titanium-coated lightweight mesh and medium-weight composite mesh

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Abstract
Background The use of lightweight meshes in incisional hernia repair could have beneficial effects on quality of life. This study aimed to compare a new titanium-coated lightweight mesh with a standard composite mesh after laparoscopic incisional hernia repair.
Methods A randomized controlled single-center clinical trial was designed using the basic principle of one unit, one surgeon, one technique (midline incisional hernia with a laparoscopic approach), and two meshes: a lightweight titanium-coated mesh (group 1) and a medium-weight collagen-polyester composite mesh (group 2) used in 102 patients. The primary end points were pain and recurrence. The secondary end points were morbidity and patient outcomes (analgesic consumption, return to everyday activities).
Results The postoperative complication rates were similar for the two meshes. Pain was significantly less common in group 1 than in group 2 at 1 month ($P = 0.029$) but was similar for the two groups at 6 months and 1 year. There was a significant difference between the two groups in the average use of analgesics: 6.1 days in group 1 versus 1.6 days in group 2 ($P < 0.001$). The lightweight group returned to everyday activities after 6.9 days versus 9.7 days for the composite group ($P < 0.001$). The rate of recurrence did not differ between the two groups at the 2-year follow-up evaluation.
Conclusions The light titanium-covered polypropylene mesh was associated with less postoperative pain in the short term, lower analgesic consumption, and a quicker return to everyday activities than the Parietex composite medium-weight mesh. The recurrence rates at 2 years showed no difference between the two groups.

Keywords Laparoscopy · Morbidity · Pain · Parietex composite medium-weight mesh · Recurrence · Titanium-coated lightweight mesh

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Prosthesis use in hernia surgery has become standard practice. In recent years, a new generation of meshes has been developed with larger pores and a lower weight or density. These meshes are classified as heavyweight (>80 g/m^2), medium weight (50–80 g/m^2), or lightweight (<35 g/m^2) [1]. This technological development also has helped clinicians focus on a new phase that lays greater stress on patients' postoperative quality of life. Patients' pain and the convalescence period are of growing interest in the choice of the surgical technique to be used.

It is suggested that the inflammatory reaction to foreign material correlates with the pore size and the amount of material inserted. Clinical trials have already shown minor benefits with the use of lightweight meshes in terms of reducing long-term postoperative discomfort after inguinal hernia surgery [2–7]. However, the clinical behavior of these lightweight meshes when used intraabdominally still is unknown.

A new type of compound material, titanium-covered polypropylene, seems to have shown certain advantages both experimentally and clinically because it provokes a less pronounced foreign body reaction than identical meshes lacking a titanium coating. However, no studies are

available on its behavior intraabdominally in incisional hernias [8–13].

The current randomized, prospective clinical trial aimed to compare postoperative pain and recurrences in patients up to 2 years after laparoscopic incisional hernia repair with a lightweight mesh (TiMesh) or a standard intraabdominal medium-weight mesh (Parietex).

Patients and methods

Study design

The study was set up as a single-blind, randomized controlled trial. To minimize the lack of blinding, the researchers who collected the evolutive variables and results and those who analyzed them were different from the surgeon who performed the interventions.

Patients at least 18 years old who had an incisional hernia diagnosed at the Abdominal Wall Unit of Morales Meseguer University Hospital of Murcia were eligible to participate in the study. In this study, incisional hernia was defined as any midline abdominal wall gap with a bulge in the area of a postoperative scar perceptible or palpable by clinical examination and imaging (located between the xiphoid and the pubic bone) [14].

Patients with non-midline hernias and a fascial defect larger than 10 cm were excluded from the study [15]. Other exclusion criteria specified patients who had incisional hernias repaired with a synthetic mesh; those receiving corticosteroid therapy, radiotherapy, or chemotherapy; patients with concurrent neoplasms, proven mental illness, or other circumstances that might compromise their cooperation; and those who refused to give informed consent. All the patients signed an informed consent form. The study was approved by our institution's ethics committee.

The patients were randomized intraoperatively to receive either a 35 g/m^2 mesh (group 1) or a 75 g/m^2 mesh (group 2) for repair of the incisional hernia. The simple randomization sequence was performed by a computer, which generated a table of random numbers, with patients assigned to the groups via closed opaque envelopes using identification numbers. The study was performed without any grants, and all costs were covered by the national health care system.

Meshes

In the study group, a 20 × 25-cm lightweight mesh made of polypropylene (35 g/m^2) and coated with titanium (Timesh Light, GfE, Nuremberg, Germany) was used. In the control group, a 20 × 25-cm, double-layer, medium-weight mesh was used. One layer was a hexagonal-structure, three-dimensional multifiber polypropylene (75 g/m^2), and the other layer was a hydrophilous re-absorbable nonstick membrane of collagen (Parietex composite; Sofradim, Villefranche sur Saone, France) (Table 1).

Table 1 Characteristics of mesh used for incisional hernioplasty

Material	TiMesh light (lightweight) Titanium PP	Parietex (medium weight) Polyester-Co
Distribution of components	Monofilament	Multifilament
Weight (g)	0.50	1.49
Weight (g/m^2)	35	75
Thickness (mm)	0.30	0.53
Pore size (mm)	>1.24	3.00
Ultimate tensile strength (N/cm)	21	109
Modulus of elasticity (N/mm^2)	23	57
Price at our hospital (€)	490	1,141

Parietex (Covidien): polyester/collagen; TiMesh: polypropylene/titanium (GfE); The ultimate tensile strength and the modulus of elasticity are shown as maximum values (Hollinsky et al. [39])

Operative technique

A standardized surgical technique was used by a single senior surgeon specialized in laparoscopic hernia repair (A.M.-E). All the patients received thromboembolic prophylaxis with a low-molecular-weight heparin and a one-shot antibiotic prophylaxis (cefuroxime 750 mg) immediately before surgery. The complete analgesic protocol (pre-, intra- and postsurgery) used in our Abdominal Wall Unit has been published previously [16].

Each patient was prepped from the xiphoid to the pubis and as far laterally as possible, and the patient's skin was covered with a protective skin drape to avoid any contact between skin flora and the prosthetic mesh. Repair was performed with the patient under general anesthesia, and pneumoperitoneum was achieved using a Veress needle, usually in the left subcostal area. The position of the three trocars depended on the size, site, and number of existing wall defects (two 5-mm trocars and one 10-mm trocar for the scope), and the access points to the intraabdominal cavity were infiltrated with local anesthetic (bupivacaine 0.25 %).

After complete lysis of adhesions, the hernia contents were reduced. A mesh large enough to overlap all the margins by 5 cm was used, and the four ends were referenced with a guidance suture, leaving a long thread inserted via the 10-mm trocar and extended close to the defect. A Gore suture-passer instrument (Gore-Tex; Flagstaff, AZ, USA) was used to puncture the abdominal wall at the four predetermined sites, grasp the threads, and pull

them out through the abdominal wall. Once the mesh was placed over the defect, it was fixed with staples no more than 1 cm apart (Absorbtack; Covidien, MA, EEUU) No sutures fixation was used. Then, after further inspection, all ports were removed under direct visualization, and the abdominal entry sites were closed.

All the patients received standardized postoperative oral pain medication consisting of diclofenac 2×50 mg, novaminsulfone 4×500 mg, and omeprazole 1×20 mg. Pain was documented and managed with paracetamol or ibuprofen as needed.

Study outcome measures

Patients were clinically re-evaluated 7 days after surgery, then in 1, 6, 12, and 24 months, at which point the primary and secondary outcomes were documented. The patients were given a card and instructions to mark when they needed to take an analgesic, which day it was after surgery, and the day when the pain disappeared.

The primary end points of the study were pain and recurrence. Acute pain was defined as pain reported by a patient during the first 6 months after surgery, and chronic pain was defined as pain that persisted for more than 12 months [17, 18]. Pain scores on a 10-cm visual analog scale (VAS) were measured from 0 (no pain) to 10 (unbearable pain). Recurrence was confirmed by clinical examination and computed tomography (CT). The secondary end points were morbidity, operating time (min), hospital stay (days), need for oral analgesia (days), and the time required for a return to everyday activities (days). This period was defined as the time the patient needed to be able to perform household activities, drive, or walk painlessly. An increased analgesic requirement was defined as an analgesic intake that lasted for more than 1 day. All the patients were given standardized postoperative instructions that did not limit their everyday activities.

Statistical analysis

The sample size of the study was designed to detect a reduction in the treatment time with analgesics during the first month after surgery, assuming a standard deviation of 5.5 days in the group with Parietex, which was reduced to 3.1 days in the TiMesh group. With an α error of 0.05 and a β error of 0.2 and with about a 3 % tracking loss after a month, the minimum sample size was calculated to be 51 patients per group ($n = 102$ patients). Patient analysis was performed on an intention-to-treat basis.

Descriptive statistics were used to characterize the patient groups. They are presented as mean $\pm$ standard deviation or median (range) depending on the type of data and distribution. These data were compared using Student's t test or the Mann–Whitney U test and variance analysis. Comparisons of dichotomous outcomes were made using Pearson's Chi-square test.

Analysis of smaller groups within the study was permitted using Fisher's exact test, with a P value lower than 0.05 considered significant. Kaplan–Meier survival curves with log-rank analysis were created for the postoperative pain and the analgesic consumption of each group. All tests were two sided, and the data were analyzed using the SPSS software package for Windows (SPSS Inc., v13.0, Chicago, IL, USA).

Results

Between January 2005 and December 2008, 215 consecutive patients with a diagnosis of a midline incisional hernia underwent laparoscopic incisional hernia repair at our University Hospital (Fig. 1). The 2-year follow-up period for the last patient ended in December 2010.

Table 2 shows the characteristics of the patients according to the two treatment groups. The two groups were comparable in terms of patient and hernia characteristics as well as operative details. There were no differences in intra- or postoperative surgical complications, either early or late (30-day morbidity), and no conversions, re-interventions, or wound complications were noted in either group. The only variable that showed any statistical differences between the two groups was the surgical time (74.7 min for lightweight mesh vs 58.7 min for standard heavyweight mesh; $P < 0.001$).

Postoperative pain

All the patients in the study were asked about the presence of pain before surgery as a check on the absence of pain (VAS 0) and of analgesic treatment. No differences were found between the two study groups at 1 week ($P = 0.356$) or at 6 months ($P = 0.730$). Acute pain measured at 1 month did though show any significant differences between the two groups ($P = 0.029$), with the lightweight group giving better results. Lower points were scored in the lightweight mesh group, with no patients at VAS level 2, whereas in the medium-weight mesh group, 5.8 % of the patients marked the VAS level 2 pain score. In our trial, no patients with chronic pain evaluated at 1 year after surgery were found (Table 3) (Fig. 2).

Analgesic consumption

During the early postoperative period, 26 % of the patients in the TiMesh group needed no analgesics compared with

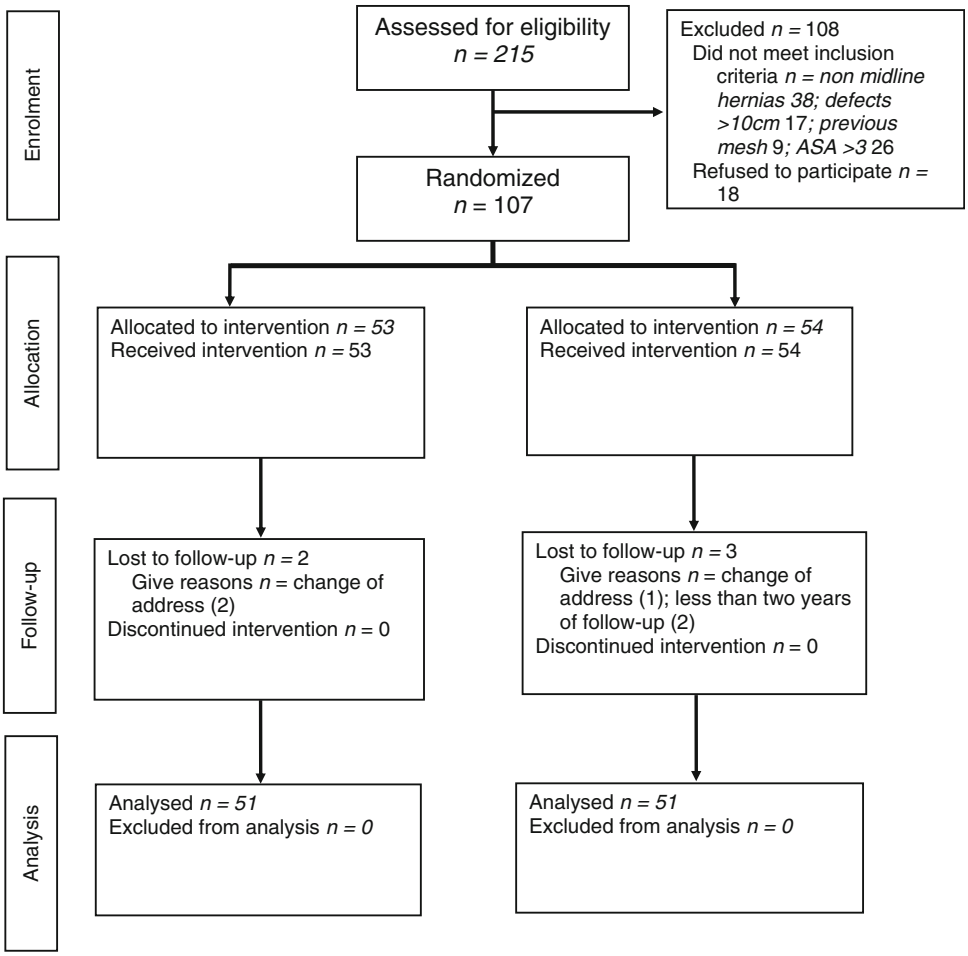

Fig. 1 Randomized controlled trial of medium-weight parietex mesh and lightweight titanium-coated mesh in patients undergoing laparoscopic incisional hernia repair

3.8 % in the Parietex group ($P = 0.002$). At 1 year after surgery, no patients received pain medication.

The average consumption time for analgesics also differed significantly between the two treatment groups. The patients with medium-weight mesh received analgesics an average of 6.1 days versus 1.6 days for those with the lightweight mesh ($P < 0.001$) (Table 3). At 6 months and at 1 year after surgery, three patients in the Parietex group (5.8 %) and none in the TiMesh group received analgesic medication. The probabilities of not presenting with pain or not needing analgesic medication are shown using survival curves in Figs. 2, 3.

Return to everyday activities

The return to everyday activities (e.g., going for a walk, driving, making family visits, attending social meetings) was significantly faster for the TiMesh patients than for the patients who had surgery with a Parietex composite mesh (6.9 days for lightweight mesh *vs.* 9.7 days for medium-weight mesh; $P < 0.001$) (Table 3).

Recurrence

For the type of hernias included in this study (midline and <10 cm), no recurrences were reported during a 2-year follow-up period in either group.

Discussion

The laparoscopic approach has improved results for many surgical interventions. However, its application in the treatment of abdominal wall hernias remains controversial because it does not mimic open surgery techniques but rather repairs the hernia by bridging the defect with the placement of an intraabdominal mesh [19–24]. With this new approach, the mesh is a central pillar of the technique and one on which the results may depend.

The introduction of new lightweight meshes (<35 g/m^2) with larger pores could improve the postoperative process for hernia patients. This fact could be associated with two

Table 2 Patients and operative data

	MW group ($n = 51$)	LW group ($n = 51$)	P value
Age (years)	55.9 ± 13.4	55.8 ± 13.7	0.952
Gender			0.729
Male	14 (27.4)	16 (31.3)	
Female	37 (72.5)	35 (68.6)	
BMI (kg/m^2)	27.8 ± 4.2	27.3 ± 3.7	0.514
Comorbidity			
Diabetes	3 (5.8)	1 (1.9)	0.618
COLD	3 (5.8)	3 (5.8)	1.000
Location of the hernia[a]			0.331
M2	11 (21.5)	13 (25.4)	
M3	13 (25.4)	7 (13.7)	
M4	27 (52.9)	31 (60.7)	
Defect			0.127
Single	44 (86.2)	47 (92.1)	
Multiple	7 (13.7)	4 (7.8)	
Size of defect (cm)	7.2 ± 1.6	7.6 ± 1.5	0.243
Area (cm^2)	32.1 ± 11.8	33.5 ± 10	0.542
Mean operating time (min)	58.4 ± 19.7	74.6 ± 17.4	<0.001
Intraoperative morbidity[b]	2 (3.9)	0	0.495
Hospital stay (days)	2.3 ± 0.7	2 ± 0.8	0.188
Postoperative morbidity[c]	4 (7.8)	0	0.118

MW group 2 with medium-weight Parietex composite mesh, *LW* group 1 with lightweight TiMesh, *BMI* body mass index, *COLD* chronic obstructive lung disease

[a] Values are expressed as mean ± standard deviation for continuous variables, and the distributions of dichotomous data are given in absolute values (%)

[b] Muysoms et al. [14] European Hernia Society (EHS) classification for incisional abdominal wall hernia: M2, epigastric; M3, periumbilical; M4, infraumbilical

[c] Intense intestinal adhesions

[d] Seroma

Table 3 Mesh study in laparoscopic technique

	MW group ($n = 51$)	LW group ($n = 51$)	P value
Analgesics at 7 days			0.002
Yes	50 (98)	37 (72.5)	
Analgesic consumption (days)	6.1 ± 6.3	1.6 ± 2.5	<0.001
Return to normal activities (days)	9.7 ± 5.6	6.9 ± 2	<0.001
Pain at 7 days (VAS)			0.356
0	33 (64.7)	33 (64.7)	
1	11 (21.5)	15 (29.4)	
2	6 (11.7)	3 (5.8)	
3	1 (1.9)	0	
Pain at 1 month (VAS)			0.029
0	41 (80.3)	48 (94.1)	
1	7 (13.7)	3 (5.8)	
2	3 (5.8)	0	
Pain at 6 month (VAS)			0.730
0	49 (96)	49 (96)	
1	1 (1.9)	2 (3.9)	
2	1 (1.9)	0	
Pain at 1 year (VAS)	51	51	
None (0)			1.000
Recurrence	0	0	1.000

MW medium-weight group with Parietex composite; *LW* lightweight with TiMesh, *VAS* visual analog scale (0–10)

Values are expressed as mean ± standard deviation for continuous variables, and the distributions of dichotomous data are given in absolute values (%)

factors: (1) a reduction in the quantity of alien material placed in the host, thus causing less reaction to the alien body as well as less inflammation and fibrosis, and (2) induction of less fibrosis in the receptive tissue and thus less restriction of abdominal wall compliance [25–29].

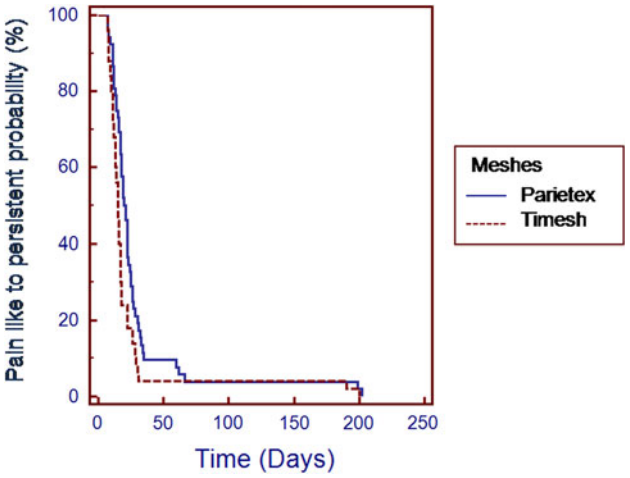

Fig. 2 Kaplan–Meir curves showing the probability of pain persisting after surgical intervention with the two types of mesh (test log rank, 6.1191; p:0.013)

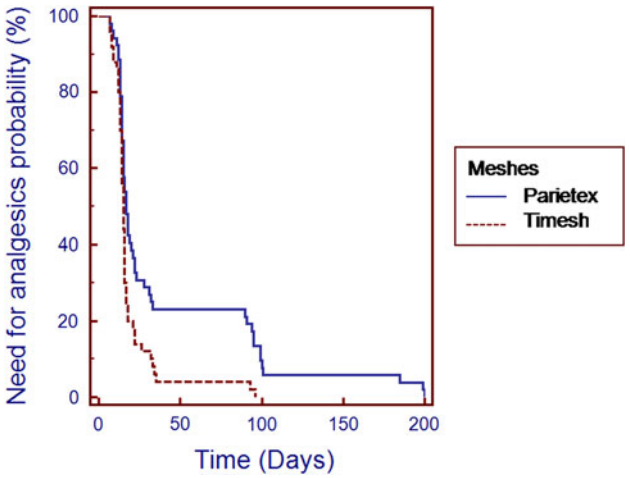

Fig. 3 Kaplan–Meir curves showing the probability of the need for analgesics after surgical intervention depending on the type of mesh (test log rank, 8.7578; p:0.003)

In clinical practice, mesh placed inguinally results in considerable musculoaponeurotic contact and a large integration surface, but when placed intraabdominally, the mesh bridges the defect and less musculofascial contact occurs, which could reduce its final integration into the posterior abdominal wall. In theory, the results of the laparoscopic operation could depend on the type of mesh and on the implant's suitable incorporation. Therefore, this new generation of lightweight prostheses could potentially have a detrimental effect on the long-term recurrence rate because they also reduce the fibrosis.

Experimental studies have shown that the integration and biomechanical resistance of the lightweight prosthesis is similar to that of the heavyweight mesh prosthesis [30, 31]. The clinical data in the literature differ greatly, however, because authors such as O'Dwyer et al. [3], Chowbey et al. [5], and Akolekar et al. [32] have published a higher recurrence rate with lightweight meshes, whereas others such as Schopf et al. [9], Koch et al. [12], and Bringman et al. [33] have found no differences between the types of mesh.

Our study supports the second group and confirms that the type of mesh (medium or lightweight) does not seem to affect the recurrence rate. This may be due to technical aspects of the procedure, which is supported by the fact that most of the published recurrences with laparoscopic procedures occur shortly after surgery (1–3 years). Therefore, in the future, we may be able to offer more accurate instructions with regard to the type of procedure for each abdominal wall hernia and to individualize this technique depending on a personalized balance between different variables that can be modified, namely, the type of mesh, the fixation method, and the size of the overlap [34].

The ideal structure for a mesh with maximum biocompatibility in the intraabdominal region has yet to be found, although the Parietex mesh has given good results, both experimentally and clinically, over the last decade, as is supported by our lengthy experience with the material [15, 16, 35–38]. The mesh coated with titanium was introduced in 2001, and since then, experiments have shown that it induces a less pronounced foreign body reaction (less inflammatory infiltrate, surface induration, scar formation, and shrinkage) than identical meshes lacking a titanium coating [8, 10, 11, 39].

The studies by Schug-Pass et al. [11], Hollinsky et al. [39], and other authors [40] establish that the titanium-coated mesh is clearly superior to the DualMesh and Parietex in terms of biocompatibility, and Bittner et al. [1], Koch et al. [12], and Horstmann et al. [41] have shown its clinical benefits when used inguinally. To date, however, no clinical studies have investigated its use with intraabdominal incisional hernias. Our study showed that in this position, the titanium-coated mesh provides advantages in the early postoperative period for patients undergoing surgery for incisional hernias without affecting the long-term results.

Concerning quality of life, the type of material also seems to influence postoperative pain, analgesic consumption, and return to everyday activities. In our randomized clinical trial, the surgery for all the patients was performed using the same technique. Thus, pain caused by fixation of the mesh with tacks can be excluded completely. The only difference between the two groups was the type of mesh used. The surgeries using lightweight mesh had a higher percentage of patients free of pain, needing no treatment, and returning to everyday activities than the surgeries using medium- or heavyweight mesh.

Koch et al. [12] showed a significant reduction of 3 days in the time until return to everyday activities and of

Table 4 Clinical experience with titanium-coated mesh

References	Study	Region	Surgery	Compared	Results
Scheidbach et al. [8]	E (pigs)	Inguinal	TEP	Light vs PP-T	Less foreign body reaction
Junge et al. [10]	E (rats)	Subc	Open	Light vs PP-T	No differences in Bioc
Tamme et al. [40]	PS	Inguinal	TEP	Light vs ExtraL	No differences in the RR
Schug-Pass et al. [11]	E (pigs)	Intraabd.	IPOM	Light vs DualMesh	Superior biocompatibility
Horstmann et al. [41]	RCT	Inguinal	TAPP	Light vs Prolene and Vipro II	No differences in the RR
					Less seromas
					Less FBS
					Less sensitivity changes
Koch et al. [12]	RCT	Inguinal	Licht	Light vs Prolene	Less return to work and normal activity
					No difference in pain or RR
Bittner et al. [2]	RCT	Inguinal	TAPP	ExtraL vs Prolene	Less seroma
					<1 month: less pain, AC, IPA
					No chronic pain or FBS
Schopf et al. [9]	RCT	Inguinal	TAPP	Light vs ExtraL	Less chronic pain (3 years)
					No differences in RR
Moreno-Egea et al. (this study)	RCT	Intraabd	IPOM	Light vs PC	Less pain, consume analgesics and return to work
					No differences in the RR

E: animal experimental model, *TEP* total extraperitoneal, *Subc* subcutaneous position, *PP-T* pure polypropylene mesh without titanium, *Bioc* biocompatibility, *PS* prospective study, *ExtraL* extralight, *RR* recurrence rate, *Intraabd* intraabdominal mesh, *IPOM* intraperitoneal inlay mesh, *RCT* randomized clinical trial, *TAPP* transabdominal preperitoneal polypropylene, *FBS* foreign body sensations, *Licht* Lichtenstein technique, *AC* analgesics consumption, *IPA* impairment of physical activities

2.5 days in the time until return to work for patients with the lightweight mesh versus heavyweight mesh. Our study showed slightly less difference in the return to everyday activities (2.8 days) and a longer time of analgesics consumption (4.5 days), with a curve showing that the greatest benefits were obtained during the first month after surgery, which then disappeared at 1 year. This study seems finally to confirm what other authors have confirmed on an inguinal level (Table 4) [2, 9, 12, 41, 42], that the percentage of material can modify the early postoperative period for patients who undergo laparoscopic surgery for incisional hernias.

Laparoscopic techniques have low levels of morbidity, both intra- and postoperatively. Although the mesh is inserted blindly through a 10-mm trocar, we have never observed intestinal injuries because of this, although the use of a 5-mm auxiliary scope to introduce the mesh under visual control is recommended to reduce the risk of inadvertent injury. The use of a lower-density mesh, which induces less fibrosis, means that its initial fixation to prevent early relapses is a high priority. This may explain why the group with the low-density meshes have had a significantly longer surgical time. Findings have shown that mechanical fixation with re-absorbable material is as effective as the permanent tacks and that it is always advisable because findings also have shown that it reduces the formation of bowel adhesions and the chronic pain that may be associated with the use of permanent tacks.

We realize that this study had certain limitations. First, because it was conducted in a single center and by only one surgeon who had considerable experience with this type of pathology, the results can be extrapolated only with caution to other centers that have no specialized laparoscopic hernia treatment unit. Second, despite of the large number of patients, the results should be confirmed in future studies that include a greater number of patients. Finally, the open nature of this study may have conditioned the appearance of bias, which could have altered the results. Because of this, we believe that analysis of the results by researchers other than the surgeon who performed the technique minimized the risk.

In conclusion, the use of light titanium-covered polypropylene mesh was associated with less postoperative pain in the short term and with shorter convalescence than experienced by the patients with Parietex composite medium-weight mesh. The recurrence rates during the 2-year follow-up period did not differ between the two groups.

Disclosures Alfredo Moreno-Egea, Andrés Carrillo-Alcaraz, and Víctor Soria-Aledo have no conflicts of interest or financial ties to disclose.

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