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Comparison of two different concepts of mesh and fixation technique in laparoscopic ventral hernia repair: a randomized controlled trial

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Abstract

Background Patients' need to improve outcomes and to reduce the number of complications triggers the development of new materials and surgery concepts. Currently, there are many implants and fixation systems dedicated for intraperitoneal onlay mesh procedure. The aim of this study was to compare two different mesh/fixation system concepts (PH: Physiomesh/Securestrap and VS: Ventralight ST/SorbaFix) for laparoscopic ventral hernia repair with respect to pain.

Methods A single-center, prospective, randomized study was designed to include 50 patients per group with a planned interim analysis for safety after 25 patients. The endpoints were pain occurrences and intensity, which was measured with the visual analogue scale 7 days, 30 days, 3 months and 6 months after surgery. The safety parameters included the number of recurrences and postoperative complications.

Results During the interim analysis, the study was stopped due to safety reasons. We observed five (20 %) recurrences in the PH group in first 6 months and none in the VS group. We observed a significantly higher pain rate in the PH group after 3 months ($p < 0.0001$) and no difference after 7 days ($p = 0.7019$). The pain intensity decreased significantly over time ($p < 0.0001$) and was significantly higher in the PH group ($p < 0.0001$).

Conclusions Although this clinical trial was terminated prior to the preplanned recruitment goal, the obtained results from the enrolled patients indicate that the PH system associated with significantly greater hernia recurrences and postoperative pain compared with the VS system. This confirms the superiority of the elastic mesh concept, which may be a safer and more efficacious option for laparoscopic ventral hernia repairs.

Keywords Laparoscopic abdominal wall hernia repair · Ventral hernia · Incisional hernia · Intraperitoneal onlay mesh

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Background

Many recently published articles consistently report good laparoscopic ventral and incisional hernia repair (LVIHR) outcomes [1–4]. LVIHR continues to demonstrate low rates of wound complications and short hospital stays [5]. However, the optimal fixation techniques, mesh design, and other issues, such as the hernia recurrence mechanism and pain pathophysiology, require additional appraisal. Until now, many publications have observed high postoperative pain in patients undergoing LVIHR [1, 6–8]. In search of possible factors that induce pain, authors have tried to demonstrate that various

fixation methods can be the most influential [8–13]. Secondly, inappropriate mesh selection can also contribute to complication development.

In the mathematical model that described forces acting on implants anchored to the front abdominal wall, our team found that one of the most important factors affecting the tearing process of the tackers is mesh elasticity [14, 15]. Moreover, our studies proved that the mesh, fixation and fascia are functional systems that should not be treated and described separately [14, 16–18]. To further explore and validate this in clinical settings, authors have decided to compare two mesh implants, with different elastic properties, dedicated for the intraperitoneal onlay mesh (IPOM) procedures: first mesh initially stiff and a second one presenting high elasticity prior to incorporation.

Objective

The aim of this study was to show the superiority of an elastic mesh concept (VS) versus a control, rigid mesh concept (PH) to confirm theoretical findings from the biomathematical model [14, 16, 19, 20].

Methods

Trial design

The study was designed as a prospective, randomized, single-center clinical study to directly compare mesh and dedicated fixation systems for LVIHR in a parallel group design. The trial was conducted within the Ceynowa Hospital General Surgery Department in Wejherowo, Poland. The trial was reviewed and approved by the local bioethics committee (KB-24/12) and registered on ClinicalTrials.gov (identifier: NCT02233569).

Participants

All patients with confirmed informed consent, a primary or secondary ventral hernia <20 cm in length and <11 cm in width that required elective surgical repair, recurrences after a former mesh repair or recurrences after a suture repair were eligible to participate in the study. Patients under 18 years of age or that required emergency surgery (such as an incarcerated hernia), body mass index (BMI) exceeding 40.0 kg/m^2, contaminated surgical field, or patients with immunosuppression, steroid therapy, constant pain therapy, or a life expectancy shorter than 1 year (i.e., due to a generalized malignancy) were excluded.

Interventions

Theoretical background

Failure of the LVIHR due to insufficient fixation, small overlap together with pain at the operation site and chronic pain are the most common problems associated with the IPOM repair [7]. Moreover, various authors have suggested that the elastic properties of the human fascia must be better described to assess the potential elongation profile of an implanted prosthesis, as well as the junction forces that affect the fascia–mesh connection [21–23]. The optimal number of tacks and trans-abdominal sutures (TAS) used to fix the mesh is not known. Commonly, tackers should be placed in a double-crown configuration every 2 cm on the mesh to avoid slippage of the bowels between the mesh and the peritoneum. On the other hand, using too many fixators can cause neuralgia at the application site.

Therefore, analyzing the factors that influence the aforementioned problems is very important. In previous publications [14–18], the physiomechanical properties of available meshes and the tissue–implant link along with the junction forces were examined. To achieve that goal, we investigated the in vivo elasticity of the front abdominal wall and distinguished the strain zones [18]. Subsequently, the forces applied to the fascia–mesh system with the division of the crucial elements, such as the implant elasticity and size, tackers and sutures maintenance forces, hernia ring localization and size as well as the intra-abdominal pressure were highlighted and examined [14–17]. As a result, it was possible to construct computer software that supports the decision-making process when performing IPOM surgeries [14, 19, 20]. Hal2010 allows for biomechanical modeling, which takes into account all of the factors important to maintain the connection between the fascia and the implant. This software was used in this study to determine the mesh dimension, the tacker quantity and localization and also to determine the TAS use necessity.

Mesh type and fixation

To date, the ideal mesh suited for intraperitoneal placement has not been discovered. In theory, such a mash should be strong enough to withstand physiologic stresses over a long period of time, conform to the abdominal wall, promote strong host tissue ingrowth, which mimics normal tissue healing, and resist the formation of bowel adhesions and erosions into visceral structures [24]. We have focused our research on implants with a similar core structure and distinctive initial elastic properties. For that, we have chosen two meshes newly introduced to the market, both rigorously

tested in our biomechanical laboratory. The physiome-chanical properties of implants were identified on the basis of uniaxial tensile tests on the Zwick Roell Z020 strength machine as discussed by Szymczak and Śmietański [17, 20]. To evaluate the junction forces of implant connection to the tissue, the same type of tests as described by Tomaszewska was used [14]. Both tackers have exhibited similar forces needed to rip the junction between mesh and fascia, were as high as for other products available on the market and therefore could not influence the outcome of the study. Moreover, those rapture forces were corresponding only when using dedicated stapler with dedicated mesh, as delivered by the producer. When cross-checked SorbaFix passed through the macroporous structure of the Physiomesh (due to the diameter of the pores and the elasticity of the polypropylene fibers correct mounting of SorbaFix tackers was not possible) and destroyed the structure of the mesh. When SecureStrap was applied to Ventralight, the trigger mechanism in combination with the dense weaves and mesh thickness did not allow proper anchoring in the tissue. Those introductory technical findings influenced the decision of the study design to compare both meshes with dedicated mounting kits in two parallel groups instead of four. What is the most important laboratory test confirmed the technical information on the physiomechanical properties of both meshes and the differences in the values of the elastic modulus E and limit stress (stress–strain relations) on the moment of implantation. Therefore, the data obtained in vitro, in particular, the comparable limit tearing forces of joints for both examined fascia–mesh fixation schemes enabled us to separate mesh elasticity as an independent factor influencing the outcome of the planned prospective study in vivo.

The Ventralight™ ST Mesh with SorbaFix™ Absorbable Fixation System represents elastic features (VS group), and the Physiomesh™ with SecureStrap™ system represents rigid features when implanted (PH group).

The Ventralight™ ST Mesh (Davol Inc, Subsidiary of C. R. Bard, Inc., Warwick, RI, USA) is a medium-weight monofilament polypropylene (PP) mesh that is co-knitted with an absorbable polyglycolic acid (PGA) fiber. The visceral side is coated with chemically modified sodium hyaluronate (HA) and carboxymethylcellulose (CMC), which are the two key components of the Sepra® technology as its anti-adhesive barrier.

Physiomesh™ (Ethicon, Somerville, NJ, USA) is comprised of a monofilament polypropylene (PP) mesh coated with a monocryl (polyglecaprone 25) absorbable barrier layers, one to each side of the polypropylene mesh. A polydioxanone film (PDO) binds the polyglecaprone 25 to the PP mesh.

Considering the construction of the meshes, Physiomesh, despite its lightweight macroporous structure presented lest elastic properties due to the monocryl (polyglecaprone 25) absorbable barrier layers. In contrast, Ventralight mesh despite the relatively dense weave in the tests performed demonstrated higher elasticity values and thus fulfilled the requirements of the study design.

Preoperative evaluation

All patients received a complete physical examination and standard laboratory workup prior to surgery. Anesthesiological risk was classified according to the American Society of Anesthesiologists' (ASA) classification.

Operative technique

Venous thromboembolism (VTE) was prevented with low molecular weight heparin (LMWH). Preoperative single-dose antibiotic prophylaxis with 1 g of cefazoline was administered at the time of anesthesia induction. In all cases, LVIHR was conducted or supervised by a surgeon with experience of at least 100 LVIHR surgeries, who was also a study director. After creation of a pneumoperitoneum with a Veress needle at the left hypochondrium (Palmer's point), a 11-mm laparoscopic port for a 10-mm 30° telescope was introduced in the left flank at the umbilicus level. Additionally, two 5-mm ports were placed under direct visualization depending upon the hernia defect location. In cases when Ventralight ST mesh with ECHO PS Positioning System greater than 15 cm × 20 cm was used, we changed the 11-mm trocar to 13 mm. When necessary, adhesiolysis was cautiously performed with scissors and cautery, the hernia was then exposed, and the surrounding area was prepared for mesh placement with a minimum of 7 cm overlap in the cranio-caudal direction and 5 cm laterally. Hernia defect closure was not attempted.

The randomly selected mesh tailored to overlap the hernia defect by at least 5 cm was placed intraperitoneally and anchored with the assigned fixation device using the "double-crown" technique. The tack number was determined by computer software, which was based on the HAL2010 biomathematical model [20]. The distance between the fasteners ranged from 1.5 to 2 cm. If necessary, PDS (Ethicon, Inc., Somerville, NJ, USA) size 0 sutures (TAS) were utilized, in a vertical line only. No drains were allowed in the peritoneal cavity, except under bleeding circumstances. The abdominal cavity was exsufflated and the fascia was sutured at port sites exceeding 5 mm, followed by skin closure.

Postoperative management

All patients received standard postoperative care, including mobilization and return to normal diet as quickly as

possible. A truss was ordained and worn for 3 weeks (day and night) and for a subsequent 3 weeks (day only). Analgesia that was given during the postoperative period consisted of metamizolum natricum (1 g) or paracetamol (1 g) and was administered intravenously (every 6 h) within the first 24 h. The study protocol allowed for administration of additional opioid and non-opioid analgesic agents for consecutive 3-day periods after the operation (if necessary).

Outcomes

The primary endpoints were the presence of pain at 7 days and 3 months postoperatively. The secondary parameters were: (1) pain intensity, which was measured on a visual analogue scale at 7days, 30 days, 3 months and 6 months postoperatively, (2) operation and (3) hospital stay duration. Additionally, short-term safety parameters, including the complication rate and hernia recurrences, were evaluated. After discharge, the patients were followed up in the outpatient clinic by a blinded investigator during their checkup visits. Overall pain was assessed at rest and during physical activity using a 0–10 visual analogue scale (VAS): 0 = no pain and 10 = most severe pain. Additionally, a descriptive evaluation of pain was performed and grouped into four categories:

1. No pain.
2. Mild pain (periodically, does not interfere with daily functioning).
3. Moderate pain (interferes in certain situations, such as running).
4. Severe pain (interferes with daily life).

An abdominal wall examination was conducted, and late postoperative complications, such as seroma formation, wound infection, recurrence or any other problems, were noted.

Sample size

The assumption was made that a total sample size of 90 patients had to be enrolled to detect a difference of 20 % in pain occurrence including a 10 % dropout rate. This number was then rounded up to 100 (50 per group). To be more specific, a hierarchical test procedure by means of testing the 3-month difference first and the 7-day difference later was applied maintaining the overall and experiment-wise 5 % significance level. Assuming a clinically relevant rate difference of 20 % after 7 days and 50 % after 3 months, we were able to detect a 20 % rate difference after 7 days with a two-sided Fisher exact test at the 5 % level change from a 99 % (95 %) pain rate in the VS group with a power of 85 % (73 %) with a sample size of 50 per

group (nQUERY Advisor 7.0). This seemed to be a reasonable approach taking into account that the power was much higher for the test at the third month.

Randomization

A randomization list was generated using sealedenvelope.com. The list consists of permutated blocks of size 50. According to the randomization list, sealed opaque envelopes were prepared by the Study Secretary. Randomization took place within the operation theater by a scrub nurse after the surgeon confirmed the patient eligibility.

Blinding

The type of utilized mesh/fixation system was blinded within the patient record and a discharged letter until the end of the study. A blinded Medical Secretary together with blinded medical investigator conducted the follow-up measurements.

Statistical methods

Data were documented by a study secretary and entered into the EuraHS database. The primary endpoints (the presence of pain at 7 days and 3 months) were tested with Fisher's exact test. We fitted a linear mixed effects model (two-level model) to the pain intensity data using random intercepts of the subject and treatment group and time as a fixed effects. We further evaluated the time until recurrence with a log-rank test. The (two-sided) significance level was set to 5 %. All computations were performed with the Windows 7 SAS® 9.3 (TS1M2) software.

Results

Participant flow

Enrollment started on November 01, 2012, and lasted up until August 31, 2013. Figure 1 illustrates the patients' flow. Within this study, there were 135 patients screened for eligibility at the time of the scheduled interim analysis (25 patients were officially recruited into each group).

Baseline data

The patient baseline data, preoperative hernia characteristics and the intraoperative variables are given in Table 1. The two groups (VS and PH) were similar in terms of their demographic profiles. There were no cases of conversion to an open operation. All patients were included in the 6-month follow-up, and no mortality occurred within the
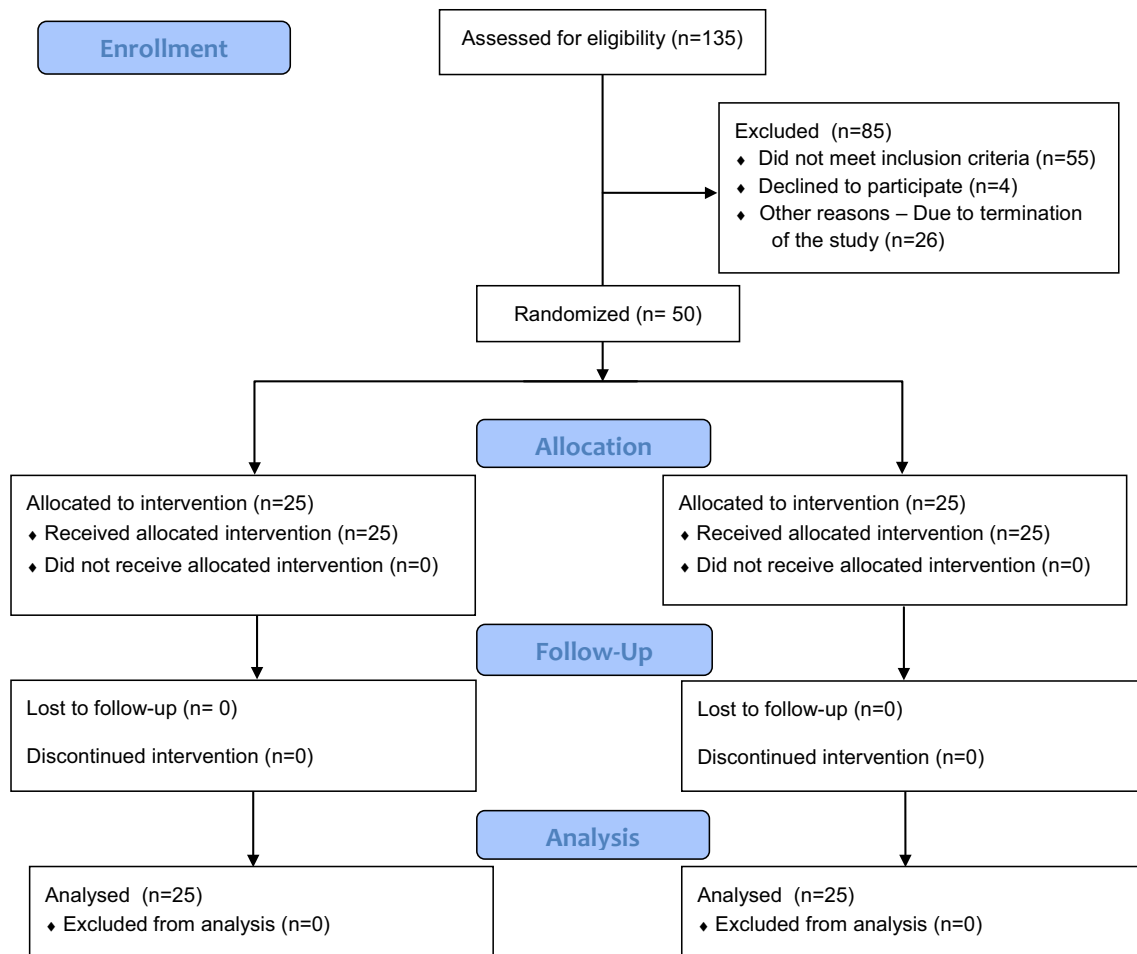
Fig. 1 CONSORT flow diagram of the study. The target sample size was 100 patients. The recruitment was stopped for safety reasons at the preplanned interim analysis time due to safety reasons. At this point, five (20 %) recurrences were observed in the control group and zero in the intervention group

patient population. The groups were heterogenic in terms of hernia size, with larger defects and corresponding mesh sizes noted within the VS group [mesh area: PH: 305.4 (SD 106.47); VS: 393.0 (SD 122.49)].

Numbers analyzed

After the enrollment of 25 patients in both groups, five recurrences (one at 3 months and four at 6 months) in the PH group and zero recurrences in the VS group were observed. These rates were significantly different (log-rank test; $p = 0.0197$); thus, the Polish Hernia Study Group (PolishHSG) data safety and monitoring committee had concerns about safety and consequently terminated the trial. The primary endpoints were evaluated in all 50 patients.

Outcomes and estimation

At 3 months, the PH group demonstrated a significantly greater presence of pain. Specifically, 14 PH group patients experienced pain versus zero in the VS group (Fisher's exact test, $p < 0.0001$). At 7 days, we observed no difference in the pain occurrences, which included 22 in the PH group and 20 in the VS group (Fisher's exact test, $p = 0.7019$).

Pain intensity (VAS) was evaluated with a linear mixed effects model, as described in "Statistical methods" section. The model fit was acceptable while noting that the residuals demonstrated a fairly normal distribution, and no marked effect could be detected with the influence diagnostic. The two-way interaction between time and treatment was not significant ($F = 1.52$, ddf 191, ndf 3, $p = 0.2104$), meaning that the patients within the two groups demonstrated a similar trend in pain intensity over time (Fig. 2). However, the pain intensity decreased significantly over time ($F = 41.50$, ddf 191, ndf 3, $p < 0.0001$) and was significantly higher in the PH group versus the VS group ($F = 42.29$, ddf 191, ndf 3, $p < 0.0001$) across time. Moreover, when considering the descriptive evaluation of pain, patients in the PH group

Table 1 Baseline characteristics

Characteristics	PH group $n = 25$	VS group $n = 25$
Gender (male/female)	12/13	13/12
Age (mean, SD, min, max)	58.1 (SD 13.3) 37–86	61.6 (SD 11.5) 28–79
BMI (mean, SD)	31.80 (SD 4.80)	30.70 (SD 6.50)
Cigarettes (y/n)	5/20	8/17
Cigarette quantity (0/5/10/15/20/30)	20/0/2/1/1/1	14/2/1/1/4/0
Work (no/light/heavy)	10/11/4	18/4/3
Hernia type single/multifocal	20/5	22/3
Hernia diameter (mean, SD)	3.38 (SD 2.03)	4.24 (2.48)
Hernia length (mean, SD)	4.30 (SD 2.4)	7.32 (3.89)
Hernia width (mean, SD)	3.92 (SD 2.7)	7.34 (3.95)
Mesh area (mean, SD)	305.4 (SD 106.47)	393.0 (SD 122.49)
EHS hernia classification: I./II./III./IV.[a]	19/3/2/1	17/7/1/0
Hernia incisional/primary	11/14	18/7
Recurrent hernia yes/no	4/21	4/21
ASA 1/2/3[b]	14/11/0	10/14/1
Pain before surgery yes/no	7/18	7/18
Number of TAS 0/2[c]	6/19	6/19
Intraoperative complications	22/3/0	25/0/0
No/vessel injury/bowels injury		
Analgesics yes/no	25/0	25/0

[a] EHS classification for primary and incisional abdominal wall hernias. (I) Middle line hernia (subxiphoidal—M1; epigastric—M2; umbilical—M3). (II) Middle line hernia (infraumbilical—M4; suprapubic—M5). (III) Right lateral hernia (subcostal—L1; flank—L2; iliac—L3; lumbar—L4). (IV) Left lateral hernia (subcostal—L1; flank—L2; iliac—L3; lumbar—L4)

[b] ASA—American Society of Anesthesiologists' classification

[c] TAS—trans-abdominal sutures

complained of more severe symptoms influencing daily activity also 3 months after operation (Fig. 3).

Ancillary analyses

At 1 month, the presence of pain was significantly higher in the PH group with 20 patients experiencing pain versus five patients in the VS group (Fisher's exact test, $p < 0.0001$). At 6 months, the presence of pain was still significantly higher in the PH group with eight patients experiencing pain versus zero in the VS group (Fisher's exact test, $p = 0.0016$).

The operative time was also found to differ significantly between the groups, with a shorter mean operative time of 34.6 min (SD 12.74) for the PH group versus 51.0 min (SD 20.92) for the VS group (t test -3.35, df 39.66, $p = 0.0018$). Prolonged operation in the event of Ventralight ST mesh was caused by the need to perform additional activities related to the installation of ECHO system used for positioning of the implant.

The hospital stay durations did not differ significantly between the groups (Fisher's exact test, $p = 0.1654$). There were 23 patients in the PH group and 18 in the VS

group with 3-day hospital stays, two in the PH group and five in the VS group with 4-day hospital stays, and zero in the PH group and two in the VS group with 5-day hospital stays.

We have observed only one type I seroma in the PH group, whereas in the VS group there were one type I seroma and two type II seroma cases (1—IIa and 1 IIb) according to Salvador Morales-Conde seroma clinical classification [25].

Harms

There were three non-severe complication cases in the PH group, which included minor bleeding from the trocar site due to vessel injuries. The patients received treatment intraoperatively. There was no need for blood transfusions. No other complications were noted during the implantations.

We observed five hernia recurrence cases (20 %) in the PH group within the first 6 months of observation. The diagnosis was based on clinical and ultrasonographical examination. All of the patients were admitted to the hospital and were re-operated on. The re-operations
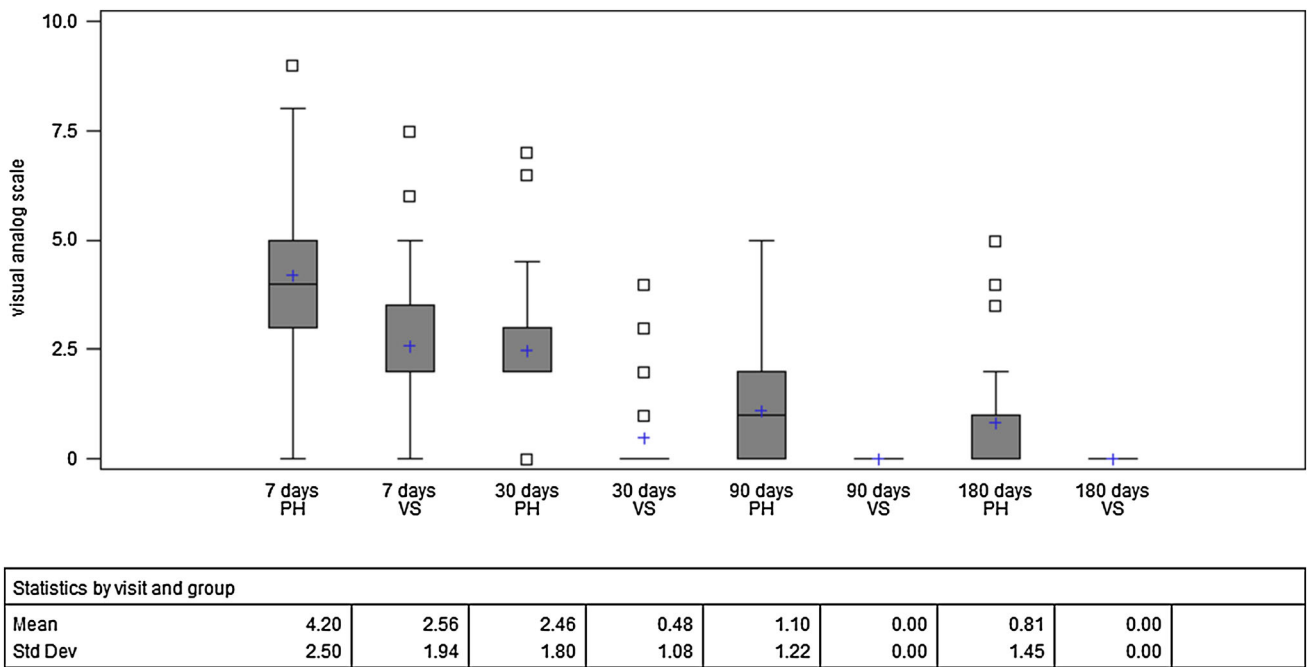
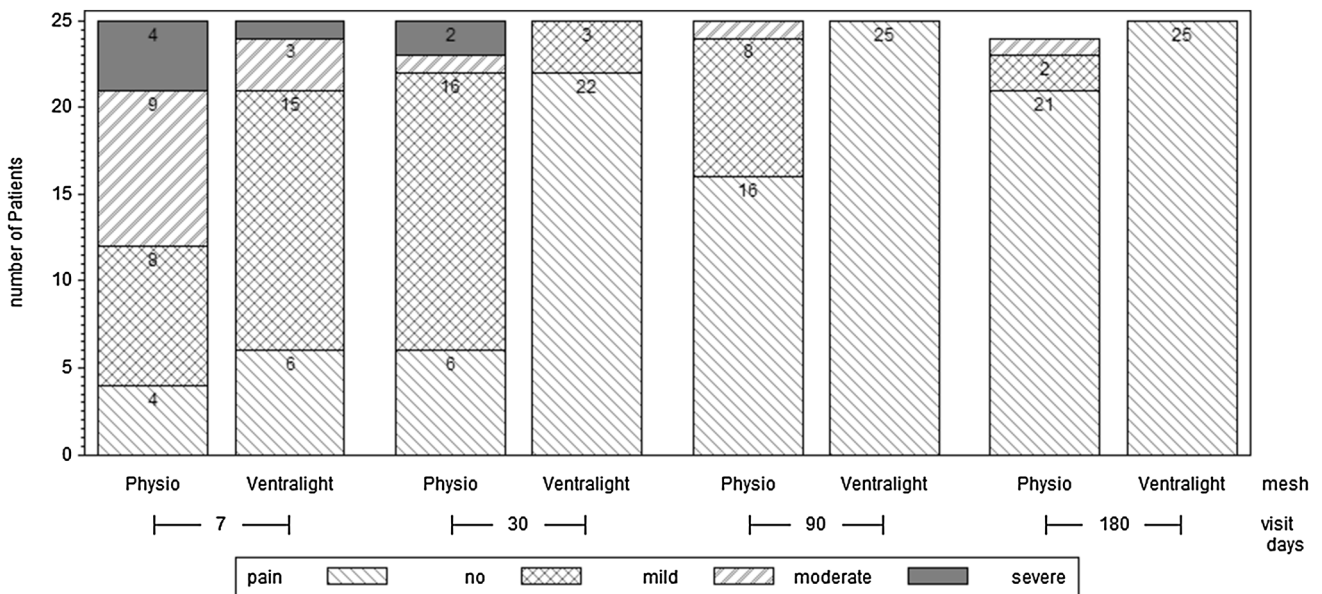**Fig. 2** Box plot of pain intensity by visit and group, including the descriptive statistics

Fig. 3 Severity of pain in descriptive terms by visits and groups

revealed hernia recurrences with dense adhesions, including omentum and intestines that were adhered directly to the PH system. Incorporation of the mesh into the abdominal wall was poor, and the mesh was easily detached. The video documentation has been made for each intervention. The high recurrence rate and the aforementioned intra-operative findings during re-operation were considered serious adverse events and were the primary reason for the early study termination.

Discussion

Limitations

Blinding in surgical trials is almost always difficult to confirm. We are convinced that the primary endpoint measurement was only weakly influenced by the potential knowledge of the treatment specification because we concealed the surgical procedure in the medical records, and

the patients' pain assessment was independently measured by the study secretary.

Premature stoppage of the trial might be a source for criticism due to the loss in power (at the predefined level), and thus, the proteus phenomenon might underlie our findings [26]. However, in our opinion, the higher recurrence rate in one group conflicts the patients' welfare. The findings are impressive in two ways. On the one hand, the pain assessment significantly favored the elastic mesh concept. On the other hand, we observed differences in the covariables (hernia size) in favor of the rigid mesh concept. Thus, we are convinced that the observed difference in pain toward the elastic concept describes a true patient benefit, although the magnitude of the effect might be smaller.

Generalizability

Our study assumption has a twofold nature. First, we wanted to check, in vivo, the mesh fixation algorithm for LVIHR operations that were created by our team (HAL2010) [20] and the influence of the elasticity of the mesh on the occurrence and intensity of pain. At the same time, we wanted to compare two implant and fixation device systems that had been recently introduced onto the market. At present, there are no long-term data concerning applied meshes and tackers. Therefore, this allowed us to present, for the first time, outcomes regarding the implementation of the Physiomesh and Ventralight ST meshes with dedicated tackers in humans.

These findings not only refer to implants used in the study, but also, in a broader sense, include meshes that have similar properties. To date, this comparison was made between different fixation devices or different operation techniques and their influence on pain, patients' satisfaction and functional status. Our study also extended on other high value aspects, such as the mesh mechanical properties, forces applied to the fixing system and the reasonableness of the application of hernia repair sets.

Interpretation

There are no randomized control trials (RCTs) available in the literature comparing new meshes with anti-adhesive absorbable barriers and new absorbable fixation devices for LVIHR. Searching the PubMed database, we found only few experimental and comparative studies, which were mainly in animal models. Most of the articles show similar results in terms of mechanical properties, adhesion characteristics and histological testing [27–29]. The main disadvantage of those studies was the short observation time periods after the mesh implementations, which went from the 14th to the 28th day. This time period is when the inflammation and tissue incorporation processes are still ongoing, and the absorbable barrier is in the process of being resorbed. Within the current study, we observed that most of the recurrences were discovered between the 3rd and 6th months after implantation, a timeframe in which mesh incorporation and peritonealization should be completed.

There is one article available that compared Ventralight ST and SorbaFix with Physiomesh and SecureStrap in a Porcine Model [28]. The authors evaluated mesh contracture, adhesion characteristics, tissue ingrowth strength and the resulting host tissue response after a 14-day implantation period. The results were in favor of the Ventalight ST mesh whereby adhesion formation (50 vs. 30 %) and coverage were greater (1.2 ± 0.7 vs. 6.0 ± 3.5 %), significantly less inflammation ($p = 0.0001$), fibrosis ($p = 0.0017$), hemorrhage ($p = 0.0001$) and angiogenesis ($p = 0.0032$) occurred, and significantly greater tissue ingrowth strength was observed ($p = 0.0003$). Other findings were similar for both mesh fixation device combinations and were comparable to the results of other absorbable barrier mesh studies that took place in animal models.

The issue of high pain intensity after laparoscopic hernia repair is a growing subject as the number of procedures performed yearly increases. The laparoscopic approach for incisional and primary ventral hernia has gained popularity because of its low recurrence, short hospital stay and low complication rates compared with the open repair approach [2, 4, 5, 30]. However, it was observed that as many as one-fourth of patients have poor outcome following laparoscopic ventral hernia repair [1]. Eriksen observed that his participants complained about pain that was stronger (median VAS 78 mm) than the pain experienced after laparoscopic cholecystectomy (median 40 mm) immediately after the procedures.

Postoperative pain produced by fixation techniques could play an important role in deciding between sutures and tacks for mesh fixation. The attention of many researchers is focused on exploring the nature of the problem. Sutures running through a whole abdominal wall (TAS) are regarded as the main pain source. Bellows and Berger proved that injecting topical anesthetic around the sutures led to decreased pain [12]. Yet, a randomized study conducted by Wassenaar did not confirm those observations [10]. On the other hand, Chelala, followed by Bensal, made observations that when decreasing intra-abdominal pressure, loose knot tying can significantly reduce pain symptoms [7, 9]. However, Sharma, in his study of 1223 patients, did not observe the relation between pain symptoms and the implant–abdominal wall fixation method over a 6-month postoperative period [3]. In contrast, Beldi, in a randomized clinical trial, compared suture versus tack fixation and found that transfascial sutures were associated

with more pain within the first 6 weeks postoperatively. Another question would be whether the number of tacks influenced the pain intensity. This issue was a subject of research conducted by Schoenmaeckers. He concluded that fewer tacks do not create less pain, nor do more tacks [31]. The data obtained from previously published studies led us to the concept that there are a number of factors responsible for the increased perception of pain after LVIHR, and they appear to be associated with the forces applied to the fasteners. Therefore, the adequate tack number and mesh elasticity could reduce the pain. In the current study, we demonstrate that mesh/fixation device properties can significantly influence the pain level.

The recurrence rate for LVHIR varies among the available literature. The recurrence number is usually attributed to the fixation type. The lowest recurrence rate is usually found for the mesh fixated with transfascial sutures and the highest when a single row of tacks is utilized. The gold standard, tacker fixation with the double-crown (DC) technique (with or without TAS), has a hernia recurrence rate of approximately 5 %. In the largest study by Heniford, the rate for DC with TAS was 4.7 % [32]. Similar outcomes were presented in the Cochrane meta-analysis. The total recurrence number for the laparoscopic control group was 5 %, but authors state that this figure is clearly lower than can be reasonably expected [5]. In the recently published RCT by Hasan Eker, the cumulative recurrence rate for the group receiving laparoscopic treatment was 18 %, and the majority of the recurrences were observed in the first year of follow-ups [30].

In the current study, the VS group presented no hernia recurrences in the first 6 months. We believe that this result was achieved by selecting adequate mesh with a proper fixation method, based upon employing simple algorithms (HAL2010) into surgical practice.

Conclusions

In summary, the data indicated that five (20 % of the patients) hernia recurrences occurred in the PH group within the first 6 months compared with zero (0 %) hernia recurrences in the VS group. Furthermore, PH group was associated with significantly greater pain intensity (VAS) compared with VS group. This confirms the superiority of the elastic mesh concept, which may be a safer and more efficacious option for LVIHR procedures, and clinically validates the biomathematical algorithm derived from the HAL 2010 study.

References

1. Liang MK, Clapp M, Li LT, Berger RL, Hicks SC, Awad S (2013) Patient satisfaction, chronic pain, and functional status following laparoscopic ventral hernia repair. World J Surg 37:530–537. doi:10.1007/s00268-012-1873-9
2. Kapischke M, Schulz T, Schipper T, Tensfeldt J, Caliebe A (2008) Open versus laparoscopic incisional hernia repair: something different from a meta-analysis. Surg Endosc 22:2251–2260. doi:10.1007/s00464-008-9773-7
3. Sharma A, Mehrotra M, Khullar R, Soni V, Baijal M, Chowbey PK (2011) Laparoscopic ventral/incisional hernia repair: a single centre experience of 1,242 patients over a period of 13 years. Hernia 15:131–139. doi:10.1007/s10029-010-0747-z
4. Rogmark P, Petersson U, Bringman S, Eklund A, Ezra E, Sevonius D, Smedberg S, Osterberg J, Montgomery A (2013) Short-term outcomes for open and laparoscopic midline incisional hernia repair: a randomized multicenter controlled trial: the ProLOVE (prospective randomized trial on open versus laparoscopic operation of ventral eventrations) trial. Ann Surg 258: 37–45. doi:10.1097/SLA.0b013e31828fe1b2
5. Sauerland S, Walgenbach M, Habermalz B, Seiler CM, Miserez M (2011) Laparoscopic versus open surgical techniques for ventral or incisional hernia repair. Cochrane Database Syst Rev (3):CD007781. doi:10.1002/14651858.CD007781.pub2
6. Eriksen JR, Poornoroozy P, Jørgensen LN, Jacobsen B, Friis-Andersen HU, Rosenberg J (2009) Pain, quality of life and recovery after laparoscopic ventral hernia repair. Hernia 13:13–21. doi:10.1007/s10029-008-0414-9
7. Chelala E, Debardemaeker Y, Elias B, Charara F, Dessily M, Allé J-L (2010) Eighty-five redo surgeries after 733 laparoscopic treatments for ventral and incisional hernia: adhesion and recurrence analysis. Hernia 14:123–129. doi:10.1007/s10029-010-0637-4
8. Beldi G, Wagner M, Bruegger LE, Kurmann A, Candinas D (2011) Mesh shrinkage and pain in laparoscopic ventral hernia repair: a randomized clinical trial comparing suture versus tack mesh fixation. Surg Endosc 25:749–755. doi:10.1007/s00464-010-1246-0
9. Bansal VK, Misra MC, Kumar S, Rao YK, Singhal P, Goswami A, Guleria S, Arora MK, Chabra A (2011) A prospective randomized study comparing suture mesh fixation versus tacker mesh fixation for laparoscopic repair of incisional and ventral hernias. Surg Endosc 25:1431–1438. doi:10.1007/s00464-010-1410-6
10. Wassenaar E, Schoenmaeckers E, Raymakers J, van der Palen J, Rakic S (2010) Mesh-fixation method and pain and quality of life after laparoscopic ventral or incisional hernia repair: a randomized trial of three fixation techniques. Surg Endosc 24:1296–1302. doi:10.1007/s00464-009-0763-1

11. Nguyen SQ, Divino CM, Buch KE, Schnur J, Weber KJ, Katz LB, Reiner MA, Aldoroty RA, Herron DM (2008) Postoperative pain after laparoscopic ventral hernia repair: a prospective comparison of sutures versus tacks. JSLS 12:113–116

12. Bellows CF, Berger DH (2006) Infiltration of suture sites with local anesthesia for management of pain following laparoscopic ventral hernia repairs: a prospective randomized trial. JSLS 10:345–350

13. LeBlanc KA (2007) Laparoscopic incisional hernia repair: are transfascial sutures necessary? A review of the literature. Surg Endosc 21:508–513. doi:10.1007/s00464-006-9032-8

14. Tomaszewska A, Lubowiecka I, Szymczak C, Śmietański M, Meronk B, Kłosowski P, Bury K (2013) Physical and mathematical modelling of implant-fascia system in order to improve laparoscopic repair of ventral hernia. Clin Biomech 28:743–751. doi:10.1016/j.clinbiomech.2013.06.009

15. Lubowiecka I (2013) Behaviour of orthotropic surgical implant in hernia repair due to the material orientation and abdomen surface deformation. Comput Methods Biomech Biomed Eng. doi:10.1080/10255842.2013.789102

16. Śmietański M, Bury K, Tomaszewska A, Lubowiecka I, Szymczak C (2012) Biomechanics of the front abdominal wall as a potential factor leading to recurrence with laparoscopic ventral hernia repair. Surg Endosc 26:1461–1467

17. Szymczak C, Lubowiecka I (2010) Modeling of the fascia-mesh system and sensitivity analysis of a junction force after a laparoscopic ventral hernia repair. J Theor 48:933–950

18. Szymczak C, Lubowiecka I, Tomaszewska A, Smietański M (2012) Investigation of abdomen surface deformation due to life excitation: implications for implant selection and orientation in laparoscopic ventral hernia repair. Clin Biomech (Bristol, Avon) 27:105–110. doi:10.1016/j.clinbiomech.2011.08.008

19. Lubowiecka I (2013) Mathematical modelling of implant in an operated hernia for estimation of the repair persistence. Comput Methods Biomech Biomed Eng. doi:10.1080/10255842.2013.807506

20. Szymczak C, Śmietański M (2012) Selected problems of laparoscopic ventral hernia repair—modeling and simulation. Alfa-Medica Press, Gdańsk

21. Cobb WS, Peindl RM, Zerey M, Carbonell AM, Heniford BT (2009) Mesh terminology 101. Hernia 13:1–6. doi:10.1007/s10029-008-0428-3

22. Carter SA, Hicks SC, Brahmbhatt R, Liang MK (2014) Recurrence and pseudorecurrence after laparoscopic ventral hernia repair: predictors and patient-focused outcomes. Am Surg 80:138–148

23. Hernández-Gascón B, Peña E, Melero H, Pascual G, Doblaré M, Ginebra MP, Bellón JM, Calvo B (2011) Mechanical behaviour of synthetic surgical meshes: finite element simulation of the herniated abdominal wall. Acta Biomater 7:3905–3913

24. Robinson TN, Clarke JH, Schoen J, Walsh MD (2005) Major mesh-related complications following hernia repair: events reported to the Food and Drug Administration. Surg Endosc 19:1556–1560. doi:10.1007/s00464-005-0120-y

25. Morales-Conde S (2012) A new classification for seroma after laparoscopic ventral hernia repair. Hernia 16:261–267. doi:10.1007/s10029-012-0911-8

26. Button KS, Ioannidis JPA, Mokrysz C, Nosek BA, Flint J, Robinson ESJ, Munafò MR (2013) Power failure: why small sample size undermines the reliability of neuroscience. Nat Rev Neurosci 14:365–376. doi:10.1038/nrn3475

27. Pascual G, Sotomayor S, Rodríguez M, Bayon Y, Bellón JM (2013) Behaviour of a new composite mesh for the repair of full-thickness abdominal wall defects in a rabbit model. PLoS ONE 8:e80647. doi:10.1371/journal.pone.0080647

28. Deeken CR, Matthews BD (2013) Ventralight ST and SorbaFix versus Physiomesh and Securestrap in a porcine model. JSLS 17:549–559. doi:10.4293/108680813X13693422520125

29. Winslow ER, Diaz S, Desai K, Meininger T, Soper NJ, Klingensmith ME (2004) Laparoscopic incisional hernia repair in a porcine model: what do transfixion sutures add? Surg Endosc 18:529–535. doi:10.1007/s00464-003-8519-9

30. Eker H, Hansson B (2013) Laparoscopic vs open incisional hernia repair a randomized clinical trial. JAMA 148:259

31. Schoenmaeckers EJP, de Haas RJ, Stirler V, Raymakers JTFJ, Rakic S (2012) Impact of the number of tacks on postoperative pain in laparoscopic repair of ventral hernias: do more tacks cause more pain? Surg Endosc 26:357–360. doi:10.1007/s00464-011-1876-x

32. Heniford BT, Park A, Ramshaw BJ, Voeller G (2003) Laparoscopic repair of ventral hernias: nine years' experience with 850 consecutive hernias. Ann Surg 238:391–399. doi:10.1097/01.sla.0000086662.49499.ab **(discussion 399–400)**