Postoperative Pain After Laparoscopic Repair of Primary Umbilical Hernia: Titanium Tacks Versus Absorbable Tacks: A Prospective Comparative Cohort Analysis of 80 Patients With a Long-term Follow-up

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Abstract: We investigated if a novel fixation device with absorbable tacks (Securestrap) causes less early and chronic postoperative pain after laparoscopic repair with a double-crown mesh fixation of ventral abdominal wall hernia when compared with the standard fixation device with nonabsorbable titanium tacks (Protack). The primary outcome measure was early postoperative pain at 2, 6, and 12 weeks postoperatively. The secondary outcome measure was chronic postoperative pain measured ≥ 18 months after surgery. Pain levels were assessed using a visual analog scale ranging from 0 (no pain) to 100 mm (excruciating pain). Early postoperative pain was significantly lower in group 2 (absorbable tacks) at 6 (2 vs. 5; $P = 0.008$) and 12 weeks (1 vs. 2; $P = 0.008$) but not at follow-up (6 vs. 11; $P = 0.21$). Given the very low visual analog scale scores in both groups, the clinical significance of these finding remains open to discussion.

Key Words: absorbable, securestrap, protack, tacks, pain, mesh fixation

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Postoperative pain after laparoscopic repair of ventral or incisional hernia (LRVIH) seems to be primarily caused by the fixation of the implanted mesh. Nearly all commonly used mesh fixation techniques involve the use of tacks and their role in genesis of this pain is undoubtedly important.[1–4] Because of their easy use and consistent efficacy, nonabsorbable titanium tacks have gained wide popularity and are considered the current standard.[5–8]

Increasing interest in the genesis of postoperative pain has led to recent developments such as absorbable tacks. In this prospective comparative cohort study, we investigated whether a novel device with absorbable tacks—differing in material, shape, and mechanism of insertion—causes less early and chronic postoperative pain when compared with nonabsorbable titanium tacks.

MATERIALS AND METHODS

All adults with a symptomatic primary umbilical hernia no larger than 2 cm in diameter were included in this study. They underwent laparoscopic repair (LR) with a mesh and were divided into 2 groups. The surgical technique differed only in the choice of tacking device. The first group was extracted from a previous prospective comparative cohort study and included 40 consecutive patients who underwent LR with nonabsorbable titanium tacks (Protack, TycoUSS, Norwalk, CT).[1] The second group was a prospective cohort of 40 consecutive new patients who were enrolled between August 2013 and July 2015 and underwent LR with absorbable tacks (Securestrap, Ethicon, Somerville, NJ). All patients gave their informed consent before surgery. Patients with any form of chronic pain syndrome were excluded from this study.

The primary endpoint of this study was early postoperative pain measured with a visual analog scale [VAS; 0 (pain absent) to 100 mm (excruciating pain)] obtained preoperatively (baseline) and at outpatient visits at 2, 6, and 12 weeks after LR.

The secondary endpoint was chronic postoperative pain. We attempted a follow-up of all patients in January 2017 and measured their VAS scores. All patients were at least 18 months after surgery: group 1 (nonabsorbable tacks) mean 93.6 ± 5.1 months (range: 72 to 100 mo) and group 2 (absorbable tacks) mean 27.3 ± 6.2 months (range: 18 to 40 mo).

All procedures were performed under general anesthesia and by either of 2 senior surgeons (S.R. and J.T.F.R.) who already had extensive experience with LRVIH before the enrolment of the first group. A completely standardized and identical technique was used in both groups. Pneumoperitoneum was acquired with the use of a Veress needle inserted at the left subcostal margin (Palmer's point). The intra-abdominal pressure was set to a standard 12 mm Hg throughout the whole procedure. In all procedures we used a 2-trocar technique. The first trocar (11 mm) was inserted at the left subcostal margin through which a 30 degrees laparoscope was used. The second trocar (5 mm) was inserted on the left side at the level of the umbilicus and as lateral as possible. Preparation of the landing zone routinely included desinsertion of the round ligament. No attempt was made to approximate the edges of the hernia opening. A 1 mm thick microporous expanded polytetrafluoroethylene mesh (DualMesh, WL Gore & Associates, Flagstaff, AZ) of either 12×10 cm or 15×10 cm was tailored to overlap the hernia by at least 4 cm in all directions. The cranial and caudal apexes of the mesh were affixed with an absorbable positioning suture with one end cutoff. They were retrieved with a suture passer after the mesh had been introduced intra-abdominally through the 11 mm trocar. The mesh could then be positioned by tightening of the sutures. The

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positioning sutures were clamped outside the abdomen once the mesh was positioned as desired. The mesh was then fixated with a double crown of tacks. The method of fixation was identical in both groups. Typically 16 tacks were placed at 15 to 20 mm intervals in the outer ring and 4 tacks in the middle ring with an option to place more as deemed necessary. No transabdominal sutures were used. The temporary absorbable positioning sutures were cut under tension so that they retract into the subcutaneous tissue. Patients from both groups were prescribed with the same nonopioid analgesics at discharge. No local infiltration was applied.

Data were collected in an Excel database, and statistical analyses were performed on an intention to treat analysis using the Statistical Package for Social Sciences (SPSS) for Windows version 20.0 (SPSS Inc., Chicago, IL). Categorical variables were compared using the χ^2 test, and continuous variables were compared using the independent-samples t test. A P-value <0.05 was considered statistically significant.

RESULTS

Demographic data and perioperative characteristics are presented in Table 1. VAS scores at 2, 6, and 12 weeks were obtained for all patients. A total of 13 (16%) patients were lost to follow-up in January 2017. In group 1 (nonabsorbable tacks) 5 patients had deceased. In both groups 4 patients had moved and could not be contacted even after consultation with their former general practitioner.

Early and chronic postoperative pain scores are presented in Table 2.

Three complications occurred in the early postoperative phase but none required surgery or invasive radiologic intervention. One patient from group 1 was readmitted within 1 week because of a paralytic ileus and was successfully treated using conservative measures. One patient from group 1 developed a hospital-acquired pneumonia that was successfully treated with antibiotic medication. Another patient from group 2 developed a symptomatic seroma at the umbilicus. Complaints resolved spontaneously within several weeks.

TABLE 1. Demographic Data and Peroperative Characteristics

	Nonabsorbable Tacks* (N = 40)	Absorbable Tacks† (N = 40)	*P*
Age (mean ± SD) (y)	53.13 ± 13.82	50.25 ± 13.99	0.91
Sex [n (%)]			
Male	28 (70)	29 (72)	0.81
Female	12 (30)	11 (28)	—
ASA classification			0.66
1 [n (%)]	17 (43)	21 (52)	0.95
2 [n (%)]	19 (47)	16 (40)	
3 [n (%)]	4 (10)	3 (8)	
4 [n (%)]	0	0	
Mean ± SD	1.68 ± 0.66	1.55 ± 0.64	
BMI ± SD	28.75 ± 4.33	28.54 ± 4.25	0.76
No. tacks ± SD	20.43 ± 1.43	21.80 ± 1.74	0.03
Hernia size ± SD (cm^2)	1.29 ± 0.82	1.58 ± 0.95	0.40
Mesh size ± SD (cm^2)	136.90 ± 15.48	131.95 ± 19.09	0.03

*Group 1 Protack.
†Group 2 Securestrap.
ASA indicates American Society of Anaesthesiologists; BMI, body mass index (kg/m^2).

TABLE 2. Preoperative and Postoperative VAS Scores

	Nonabsorbable Tacks* (n = 40)	Absorbable Tacks† (n = 40)	*P*
Preoperative (mean ± SD)	21 ± 26	14 ± 23	0.23
2 wk (mean ± SD)	12 ± 14	13 ± 19	0.23
6 wk (mean ± SD)	5 ± 9	2 ± 5	0.008
12 wk (mean ± SD)	2 ± 4	1 ± 3	0.008
Follow-up‡	6 ± 18	11 ± 21	0.21

*Group 1 Protack.
†Group 2 Securestrap.
‡Follow-up group 1, 94 ± 5 months (range: 72 to 100 mo) and group 2, 27 ± 7 months (range: 18 to 40 mo) ($P = 0.08$).
VAS indicates visual analog scale on a scale of 0 to 100 points.

At follow-up we reported mean VAS scores with relatively high SD as compared with the other time points in this study. In group 1 (nonabsorbable tacks), 2 patients reported VAS scores of 80 and 70. The first patient had developed a primary epigastric hernia and underwent another LR with a mesh and became pain free thereafter. During this second laparoscopy no complications of the previous repair were observed. The second patient experienced abdominal pain not located at a particular tack fixation point. She underwent an abdominal computed tomography scan and subsequent diagnostic laparoscopy that excluded a recurrence or a complication related to the LR with a mesh. No explanation was found for her complaints. In the second group (absorbable tacks), 3 patients reported VAS scores of 90, 70, and 50. The first patient had developed an anterior cutaneous nerve entrapment syndrome not located at any of the tack fixation points. She underwent an anterior neurectomy and became pain free thereafter. The other 2 patients initially reported high VAS scores at follow-up that spontaneously declined to below 10/100. An explanation for their pain was not detected.

There were no recurrences detected during the study period.

DISCUSSION

In our vision, ideal tacks should be easy to correctly apply, provide reliable fixation of the mesh, disappear after incorporation of the mesh has been completed while causing as little postoperative pain as possible and be reasonably priced. User-friendly and reliable titanium tacks definitely possess some of these qualities and are considered the standard in LRVIH.[7–10] But, titanium tacks remain in the body indefinitely and involved in the most frequent adverse outcome of LRVIH—postoperative pain. In rare instances they have been associated with complications such as dense adhesion formation, erosion of tacks into hollow viscera and tack hernias.[2,4,6,11–17] Efforts at further improvements have recently resulted in the development of absorbable tacks, which differ from titanium tacks in several important ways such as material, shape, and mode of penetration.

In this study we investigated whether absorbable tacks cause a different level of early and chronic postoperative pain when compared with nonabsorbable titanium tacks. We aimed to create a maximally homogenous model with identical groups of patients with the same hernia type and

size, one type of prosthetic mesh, a standardized technique performed by either of 2 experienced surgeons, and identical postoperative care. The groups differed only in the choice of tacking device. To minimize systematic and random errors, we analyzed only one outcome: postoperative pain. This protocol made performance bias unlikely and we assumed that this might compensate for the fact that the 2 groups were not contemporaneous.

The absorbable feature of the tacks cannot explain our findings that they cause significantly less pain at 6 and 12 weeks postoperatively as absorption of the polymer (polydioxanone) by hydrolysis is complete within 12 to 18 months after implantation. We hypothesize that less early pain is explained by its different shape (forked instead of spiral) and different mechanism of insertion (arrow-like instead of rotation) causing less impingement of tissue. Regarding chronic pain, the absorbable feature did not seem to be of any relevance for pain scores were low and similar in both groups.

Two factors arguably confound postoperative pain scores in this study. First, one strap more was used in group 2, which was in concordance with study protocol. On the basis of our previous study,[1] it seems unlikely that this affected the postoperative VAS scores. Second, we observed a slightly different mesh size between both groups because we trim a standard mesh to accommodate different hernia sizes. So far, there exists no data indicating that mesh size by itself can influence postoperative pain and we considered the observed difference of 4 cm^2 unlikely to influence postoperative pain.

Compared with the available literature, VAS scores (0 to 100) in this study seemed lower. In group 1 (nonabsorbable tacks) scores were lower at 2 weeks (12 vs. 16[2]), 6 weeks (5 vs. 9[2] and 25[3]) and 12 weeks (2 vs. 6[2] and 6[9]). In group 2 scores were lower at 12 weeks (1 vs. 11[10]). However, comparison is limited by the heterogenous design of the reported studies that used pooled data of mostly incisional hernia of larger sizes.

From a clinical point of view, the pain scores in both groups were very low in absolute terms. We did not have to prescribe any of the study subjects with oral analgesics at follow-up. The guidelines of the Dutch Society of Anesthesiologists indicate administration of analgesics for moderate pain (VAS >40) and upwards.[11] This cutoff point is far greater than any of the mean postoperative VAS score measured in this study. This put the clinical significance of our findings into question.

From a technical point of view, absorbable tacks require 2 sharp prongs to guide a forked tack through the mesh and into the tissue. At 90 degree angles, fixation is readily achieved but the tack regularly fails to penetrate at more acute angles. This finding is in concordance with several in vitro studies that conclude that titanium tacks fired from perpendicular as well as acute angles provide significantly stronger fixation (tensile strength) than absorbable tacks.[12–16]

Strength of this study was that we did not pool data with incisional hernia—these are separate entities that should be investigated separately.[17,18] We chose primary umbilical hernia because this type of hernia can easily be compared between groups. It allowed us to create a model in which a uniform technique could be used differing only in the choice of tacking device therewith reducing the possibility of bias to a minimum. We focused only on this difference and its relation to postoperative pain.

We did not use "a larger hole" to treat "a smaller one." Only 2 trocars were used during LR (11 and 5 mm) with a sum of 16 mm in diameter. The average diameter of the hernias was 17 mm in group 1 and 20 mm in group 2 (nonsignificant).

The limitations of this study need mentioning. A selection bias could not be fully excluded given that it was not randomized and that the data of the first group were extracted from a previous study.[1] Even though the 2 groups were not contemporaneous, a performance bias is unlikely because the technique used in both groups was identical. Besides, we already had extensive experience with LRVIH of more than 6 years before the collection of group 1. The traditional disadvantages of retrospective data collection do not seem applicable because data from groups 1 and 2 were collected prospectively. Because of the study design, other complications than postoperative pain remained beyond the scope of this study. An on-going randomized controlled trial comparing absorbable tacks with titanium tacks (TACS trial) may provide additional information on this issue.[19]

To the best of our knowledge, we are reporting the first prospective study comparing a relatively novel fixation device with absorbable tacks (Securestrap) with the standard fixation device with nonabsorbable titanium tacks (Protack). According to these results, the absorbable tacks seem to cause less early postoperative pain at 6 and 12 weeks when compared with nonabsorbable titanium tacks. At follow-up chronic pain was not different between both groups. Given the very low VAS scores in both groups, the clinical significance of these finding remains questionable.

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