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The impact of atraumatic fibrin sealant vs. staple mesh fixation in TAPP hernia repair on chronic pain and quality of life: results of a randomized controlled study

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Abstract
Background Mesh reinforcement has become the standard of care in the open and laparoscopic repair of inguinal hernia. Chronic pain after inguinal hernia repair is often due to nerve injury by penetrating mesh fixation devices such as staples (ST), tacks, or sutures. In several studies on hernioplasty, atraumatic mesh fixation with fibrin sealant (FS) proved to be efficient in terms of fixation strength and elasticity. Unfortunately, most of these studies did not provide a standardized follow-up and assessment of the development of chronic pain (CP) and the quality of life (QoL). Therefore, a randomized controlled trial comparing CP and QoL after FS fixation of mesh with ST in transabdominal preperitoneal hernioplasty (TAPP) was performed at our department. The primary end point of our study was to assess the patient outcome by using a visual analog scale (VAS) and the short form 36 (SF-36). The evaluation of recurrence rates was the secondary aim.

Methods According to the randomization, a macroporous mesh (TiMESH®) was fixed in group A (44 patients with 54 inguinal hernias) with FS (TISSEEL) or in group B (45 patients with 56 inguinal hernias) with ST (EMS® Stapler). The observation period was 1 year with regular clinical check ups and assessment of VAS and SF-36.
Results Patient characteristics expressed by BMI, ASA scores, and Schumpelick hernia classification were similar in both treatment groups. In each group there was one recurrence within 8 (FS) and 9 months (ST) postsurgery. The mean preoperative pain values scored by VAS were 1.7 (range = 0–7.5) in the FS group and 2.2 (range = 0–6) in the ST group. Postoperative mean VAS scores measured at 1 year postsurgery were 0.4 (range = 0–3) in the FS group and 0.9 (range = 0–7.5) in the ST group. One year postsurgery there was no significant difference between the two groups with respect to the parameter pain in the SF-36 and VAS.
Conclusion Fibrin sealant fixation leads to a low rate of hernia recurrence and avoids tissue trauma. ST provide similar results in the hand of the expert but bear inherent risks of complications due to tissue perforation.

Keywords TAPP · Mesh fixation · Staples · Fibrin sealant · QoL · Chronic pain · Safety

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Mesh reinforcement has become the standard of care in the open and laparoscopic repair of inguinal hernia. One of the most severe postoperative (postOP) drawbacks of transabdominal preperitoneal hernioplasty (TAPP) is the incidence of chronic pain (CP) in at least 4% of the patients [1]. This pain is often due to dissection and nerve injury by penetrating mesh fixation devices such as staples (ST), tacks, or sutures. The commonly used locations for fixation

are the pubic tubercle, Cooper's ligament, posterior sheet of the rectus muscle, and the abdominal wall bilateral to the epigastric vessels. Placing fixation devices at the pubic tubercle and Cooper's ligament often induces local inflammation leading to chronic pain (CP) [2]. Another dangerous location for fixation is above the ilioinguinal ligament, to the external inguinal ring, because of variations in the course of the iliohypogastric nerve [3]. In particular, the use of spiral tacker leads to a high risk of injury to the iliohypogastric nerve due to the penetration depth into the muscle. Taking these facts into account, the atraumatic fixation technique of using biologic glue, e.g. fibrin sealant (FS), seems to be a good alternative. In several studies on hernioplasty via open and endoscopic repair, atraumatic mesh fixation with FS proved to be efficient in terms of fixation strength, elasticity, and quality of life (QoL) [4–15]. The learning curve seems to play an important role in TAPP repair [16] and demands clarification if mesh fixation via ST in experienced hands leads to equally good results in terms of patient safety and satisfaction.

The aim of this study was to assess recurrences and the preoperative and postoperative (preOP and postOP) pain QoL using the visual analog scale (VAS) and the short form 36 (SF-36).

Methods

Study design

The study was registered (ISRCTN41994541 at www.controlled-trials.com) and approved by the local ethics committee. It was designed as a prospective randomized controlled trial comparing two cohorts of patients undergoing TAPP in primary unilateral and bilateral hernias. After informed written consent, the randomization was performed using a web-based program provided by the Department of Statistics of the Vienna Medical School. Patients were randomized into group A or group B. According to the study protocol, the mesh fixation in group A was achieved by FS and in group B by ST. Exclusion criteria included recurrent and incarcerated inguinal hernias, patients younger than 18 or older than 70 years, pregnancy, previous surgery in the pelvic region (except appendectomy), and deficient language skills.

Eighty-nine consecutive male patients were recruited in the outpatient ward of our department. These patients underwent a standard TAPP procedure [17] by a single surgeon (RHF). A macroporous mesh (TiMESH®, pfm medical ag, Köln, Germany) was fixed in group A (44 patients with 54 inguinal hernias) with FS (TISSEEL, Baxter Healthcare Corporation, Deerfield, IL) or with ST (ENDOPATH® endoscopic multifeed stapler, Ethicon Endo-Surgery, Cincinnati, OH) in group B (45 patients with 56 inguinal hernias). The group sizes were based on a statistical power analysis to assess the primary aims (quality of life and CP) of the study. The hernias were classified according to Schumpelick classification [18]. The observation period was 1 year with regular clinical checkups and assessment of VAS and SF-36.

Surgical procedure and anesthesia

After implantation of an open umbilical port, pneumoperitoneum of 12 mmHg was established and two additional atraumatic bladeless trocars (XCEL®, Ethicon Endo-Surgery) were inserted bilaterally. After incision of the peritoneum, careful attention was paid to accurate preparation of the affected groin and precise hemostasis as well as identification and preservation of all relevant anatomical structures, e.g., the spermatic sheet. In the case of a medial hernia, the hernia sac was dissected, and after inversion of the overstretched transversal fascia, the defect was closed with a single suture (PDS 2/0, Ethicon, Norderstedt, Germany) to create a counterbearing for the FS. We used TiMESH extra light (TMxl, 16 g/m^2) for lateral hernias and TiMESH light (TML, 35 g/m^2) for medial hernias. All meshes were 10 cm × 15 cm and were not tailored. For bilateral repair, the meshes were positioned with an overlap of at least 3 cm in the midline. TMxl was applied for the reinforcement of lateral hernias, and TML was chosen for medial defects because it was stiffer. The meshes were fixed with 2 ml FS per side in group A and with 4–5 ST in defined locations, preserving the pubic tubercle and the area of the course of the iliohypogastric nerve [3], minimizing the risk of lesion to nerves and inducing periostitis in group B. Finally, the peritoneum was closed with a running suture (PDS 2/0). Trocar sites were closed in anatomical layers. No antibiotic prophylaxis was administered perioperatively. The operation was performed under standardized general anesthesia, excluding nitrous oxide, remifentanil, and ketamine. Postoperative analgesic therapy was conducted by a specialized anesthesiologist (WJ) in terms of postoperative pain management according to a standardized protocol. On the day of surgery and the first postoperative day, the patients received intravenous acetaminophen regularly as a basic analgesic therapy starting at the end of surgery. In the post anesthetic care unit, piritramid, a strong opioid, was administered intravenously until a pain score of $\leq$3 was reached using a 10-cm VAS. On the surgical ward, tramadol was used as a rescue medication. No NSAID or COX-2 inhibitor was allowed throughout this period.

Statistics

To analyze the variables observed in a 1-year time span, we used ANOVA with repeated measurements with fixed factor group. A P value <0.05 was considered to indicate statistical significance. A sample size of 44 hernias per group gave as an 80% ($\alpha = 0.5$) to detect an effect in the primary aim (0.6 × standard deviation). Metric variables are reported as mean ± SD. We used the SAS statistical software system ver. 8.2 (SAS Institute Inc., Cary, NC) to carry out the calculations.

Results

Of 93 patients, 89 male patients were included in the study; 44 were randomized into the FS group and 45 received staple (ST) fixation. Four patients were excluded from analysis: one due to a reoperation for sigmoid carcinoma and three failed to show up for follow-up appointments. The mean age of the FS group was 45.5 ± 11.3 years and that of the ST group was 45.0 ± 14.0 years. The FS group included 33 unilateral and 11 bilateral hernias and the ST group was composed of 35 unilateral and 10 bilateral hernias.

Patient characteristics of BMI [26 ± 7.2 (FS) vs. 25.6 ± 3.4 (ST)], ASA scores [1.25 ± 0.5 (FS) vs. 1.3 ± 0.5 (ST)] [19], and Schumpelick hernia classification were similar in both treatment groups.

The mean operation time was 70 ± 19 min for the FS group and 69 ± 23 min for the ST group. The mean total duration of hospitalization was 4.5 ± 0.8 days for the FS group and 4.2 ± 0.9 days for the ST group.

The follow-up of the study patients was fully performed and included regular clinical checkups and postoperative pain assessments.

Recurrences

In each group we detected one recurrence within 8 (FS) and 9 (ST) months postOP. Both recurrences appeared as indirect hernias, each with a diameter of about 1.5 cm, and were treated with a re-TAPP using additional TMxl.

QoL outcome

The mean preoperative VAS pain values were 1.7 (range = 0–7.5) in the FS group and 2.2 (range = 0–6) in the ST group. VAS scores measured after surgery in the recovery room were 2.2 (range = 0–5) in the FS group and 3.1 (range = 0–6) in the ST group; and at the time of discharge, 1.8 (range = 0–6) in the FS group and 2.3 (range = 0–7) in the ST group (Fig. 1). Mean VAS scores

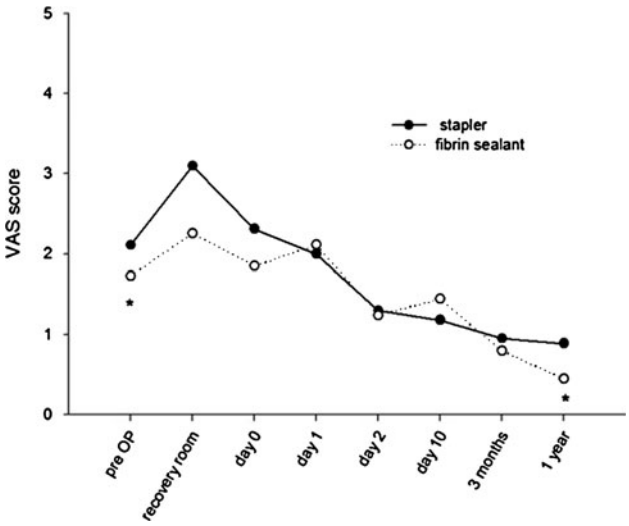

Fig. 1 VAS pain scores of FS versus ST patients at specific time points. * indicates statistical significance ($P < 0.05$)

measured at 10 days postOP were 1.4 (range = 0–5) in the FS group and 1.2 (range = 0–5) in the ST group; at 3 months postOP, 0.8 (range = 0–6) in the FS group and 0.95 (range = 0–3.5) in the ST group; at 1 year postOP, 0.4 (range = 0–3) in the FS group and 0.9 (range = 0–7.5) in the ST group (Fig. 1). The reduction of VAS scores in the FS group (preOP vs. postOP) proved to be significant ($P < 0.05$, paired t-test).

Analyzing the SF-36, the physical health summary scores, there is a significant increase in the FS group after 3 months, whereas the scores of the ST group reaches significance only after 1 year compared to preoperative values (Fig. 2). Similarly, the mental health summary scores show a significant improvement in the FS group after 3 months, but there is no significant change of the subscores in the ST group (Fig. 3). Concerning the pain subscores, there is an improvement in both groups after 3 months and 1 year compared to preoperative values (Fig. 4). However no statistical significance could be observed.

Discussion

This study demonstrates that mesh fixation with FS leads to results equally good as stapling in the hands of an experienced surgeon. This might be surprising given the great enthusiasm that accompanied the increasing popularity of mesh sealing. The fixation of mesh with FS has sharpened the awareness for the development of CP and quality of life. It has indirectly led to the introduction of new approaches to fixation and mesh design by enhancing the competition. Several experimental publications demonstrated its efficacy

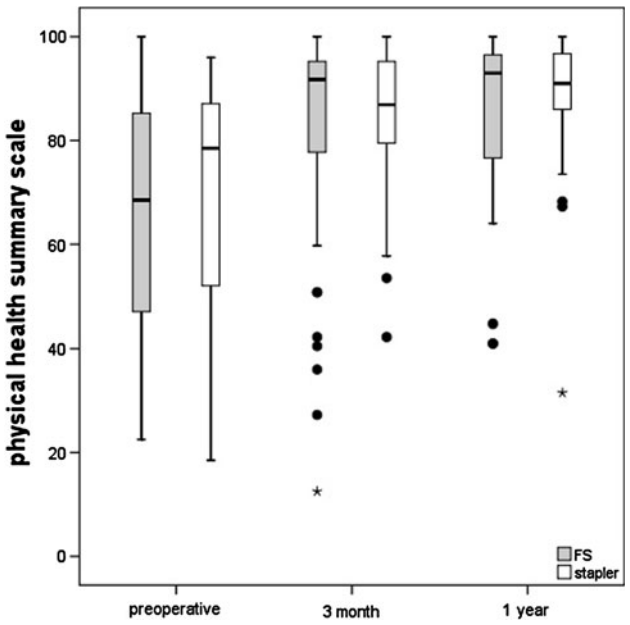

Fig. 2 Analysis of SF-36 questionnaire showing the physical health summary scale of FS versus ST patients at specific time points. * indicates statistical significance ($P < 0.05$)

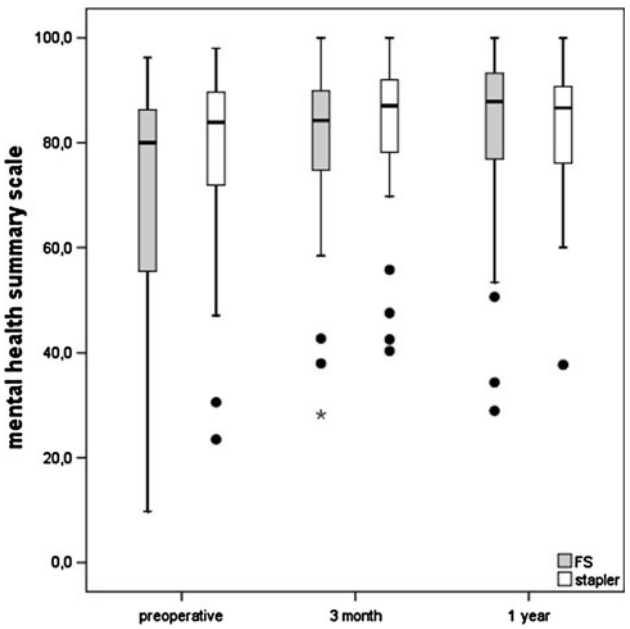

Fig. 3 Analysis of SF-36 questionnaire showing the mental health summary scale of FS versus ST patients at specific time points. * indicates statistical significance ($P < 0.05$)

and safety [7, 10, 11]. Clinical trials postulated distinct advantages of FS over ST and sutures in terms of pain and quality of life in open and laparoscopic techniques. Interestingly, no randomized controlled multicenter trial on this topic has been conducted so far for laparoscopic inguinal hernia repair, and single-center trials have lacked

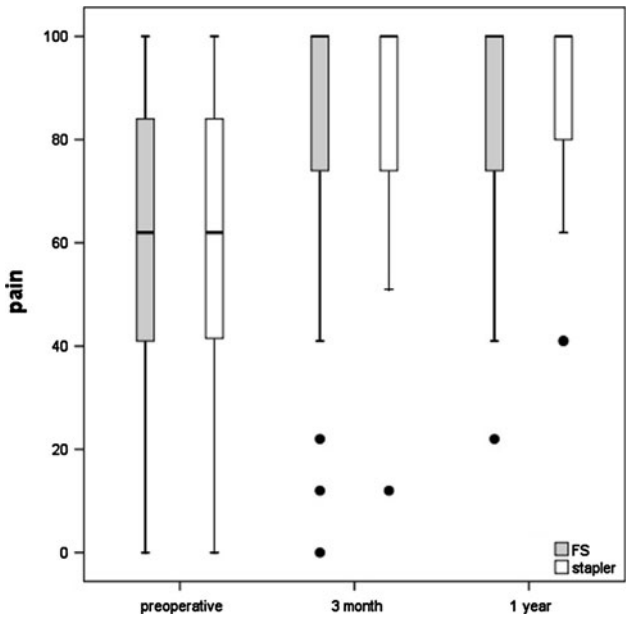

Fig. 4 Analysis of SF-36 questionnaire showing the pain scale of FS versus ST patients at specific time points

comparative preoperative data. The presented clinical trial was designed to provide the missing data of pre- and postoperative assessment of pain and QoL after TAPP operations performed by a single surgeon. Bearing in mind the controversial evidence concerning the impact of untrained surgeons on the recurrence rate brought forward by authors like Neumayr et al. [16], this study demonstrates that a highly trained expert can achieve results with ST similar to those with FS.

In our hands, FS mesh fixation was not superior to ST when assessed with the standard SF-36 or with the VAS score, and the rates of recurrence were comparable.

Do we think that our findings contradict the results presented by other study groups? This question cannot easily be answered. We believe that our results are in accordance with those of other studies because the QoL improved significantly within groups when pre- and postoperative data were analyzed. Unfortunately, preoperative data and the SF 36 are not disclosed in the work published by Lovisetto et al. [6], impairing any valid comparison. In our study, patients in both groups returned to age- and sex-corrected normal values for physical and mental well-being 1 year after TAPP. Bittner et al. [21] reported better short-term pain results in a cohort of 276 patients (not randomized) who underwent TAPP repair with FS versus staple fixation. However, there was no significant difference after the 7th postoperative day, supporting the results of the randomized controlled trial performed at our department. The incidence of CP in the staple group of this study was lower than could have been expected from the literature and from our previous findings [5]. This aspect is most interesting and deserves critical

discussion. The anatomical " no go" regions for staple placement, i.e., the triangle of doom and the triangle of pain, have been defined a long time ago. Maybe less known is the observation that placing a staple or tack in the pubic tubercle will invariably lead to a high percentage of postoperative pain. This observation was published by Hindmarsh et al. [2] in an excellent study. Unfortunately, it still seems to be common practice of many laparoscopic surgeons to (mis)use the pubic tubercle as an anchor and pivot point for staple mesh fixation. The avoidance of these hot spots of pain development and the resulting reduction in the number of ST used per patient (4 max) can partly explain the outstanding results. However, it is not justified to blame perforating fixation devices alone for the onset of postoperative pain. If this truly were the case, no pain should have occurred in the sealant group. The meticulous preparation of the groin with preservation of the spermatic sheet is, in our opinion, necessary to provide effective pain reduction in the TAPP operation. The neglect of any of these principles leads to results that do not reflect the real potential and limitation of the fixation method per se.

It is evident that staple mesh fixation is safe in the hands of an expert laparoscopic hernia repair surgeon. However, the possible trauma to nerves and vessels bears an inherent risk of morbidity and even mortality, regardless of whether resorbable or nonresorbable devices are used.

Concerning no mesh fixation in TAPP repair, there is certain evidence for its use for small indirect inguinal hernias [20]. The precondition for the use of this technique is a sufficient parietalization and the correct position of the mesh, i.e., sufficient overlap.

The FS is easy to apply, leads to efficient mesh fixation, and causes no tissue trauma. For a variety of users these properties and hemostatic effects may present a clinical advantage. We emphasize that these aspects are hard to assess in a single-center RCT and deserve further elucidation. Finally, costs are a decisive factor in most health-care systems. In this context we report that at our department the costs are neutral for both fixation methods for unilateral hernias and favor FS for bilateral hernias.

Conclusion

The results of our study show that both ST and FS are safe mesh fixation techniques in TAPP repair in terms of hernia recurrence and patient safety. FS does not markedly improve QoL or reduce CP over ST when the latter is used by an expert surgeon. The avoidance of tissue trauma is an a priori advantage which should be taken into account.

Disclosure Prof. Redl works as senior consultant for Baxter Biosciences. Drs. Fortelny, Petter-Puchner, May, Jaksch, and Benesch, Mr. Kkakpour, and Prof. Glaser have no conflicts of interest or financial ties to disclose.

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