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Less chronic pain following mesh fixation using a fibrin sealant in TEP inguinal hernia repair

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Abstract Endoscopic hernia repair methods have become increasingly popular over the past 15 years. The postulated main advantages of the endoscopic technique are less postoperative pain, early recovery and lower recurrence rates. Fixation of the endoscopic mesh seems to be necessary to minimize the risk of recurrence. Stapling has been implicated to cause chronic inguinal pain syndromes. We performed a retrospective study on male patients who were endoscopically operated on primary inguinal hernias. Our aim was to clarify whether mesh fixation using a fibrin sealant is as safe and reliable as conventional stapling. Additionally, we compared the prevalence of chronic inguinal pain. A standardized population of 133 male patients (mean age 55.9 years) with 186 (80 unilateral; 53 bilateral) consecutive primary laparoscopic total extraperitoneal inguinal hernia repairs was assigned to two groups, depending on whether stapling or a fibrin sealant had been used for mesh fixation. A retrospective case control study was performed to conduct statistical analysis based on the following parameters: recurrence, complications, chronic inguinal pain, foreign body sensation and numbness. Hernia repairs numbering 173 (staples $n=87$; fibrin $n=86$) were followed up for a mean duration of 23.7 (11–47) months. The prevalence of chronic inguinal pain was significantly ($P=0.002$; Fisher exact test) higher in the stapled group—20.7% than in the fibrin sealant group with a prevalence of 4.7%. In terms of recurrence rate, complications and foreign body sensation, fewer patients were affected in the fibrin group than in the reference population, although the differences were not statistically significant. There were no major complications in either of the groups. The mean postoperative stay in hospital was 1.4 days. Fibrin sealing is as effective as stapling in providing secure mesh fixation.

The fibrin group displayed a statistically significant lower prevalence of chronic pain syndromes. Mesh sealing provides adequate fixation and reduces the risk of chronic inguinal pain as a complication of the intervention.

Keywords Hernia · TEP · Mesh fixation · Staples · Fibrin glue · Tissucol

Introduction

Hernia surgery has basically changed over the past 15 years as a result of thorough scientific investigation of the origins and treatment of inguinal hernias. Improved surgical techniques and a wide use of mesh are responsible for this. Whereas synthetic meshes were used in less than 10% of patients in 1995, they are now implanted in approximately one out of two German patients undergoing conventional or endoscopic interventions. In England, Scotland and the USA, the percentage of patients undergoing mesh repair today is about 70–85% [1, 2]. Endoscopic surgical techniques such as total extraperitoneal (TEP) and TAPP repair are believed to be associated with lower recurrence rates, shorter postoperative pain and improved recovery [3]. Long-term studies now suggest a recurrence rate of well below 5–10%. Therefore, patient comfort has become a higher priority for hernia surgeons and their patients. Secure fixation of the endoscopically applied mesh helps to reduce recurrence owing to implant dislocation by improving the intended overlap of the hernia orifices. However, fixation sutures and staples have been accused of causing irritation to nerves and intractable pain syndromes [4–6]. In the literature, the overall prevalence of pain syndromes after open and laparoscopic operations is about 15–54%, with 11–14% of patients saying that pain impairs their daily activities [6–8]. Analysis of larger series after TAPP and TEP repair shows that 9.8% [9] to 22.5% [10, 11] of patients still report intractable pain for as long as 2 years after the

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intervention. This indicates that chronic inguinal pain is the main factor causing poor patient satisfaction after laparoscopic hernia repair [12]. A possible solution would be to forego initial fixation of the mesh [13–16]. But especially in subjects with larger hernia orifices, the risk of mesh dislocation is increased and excessively narrow overlap results in a higher risk of recurrence. A concept was therefore sought for initial atraumatic mesh fixation until fibrous incorporation of the implant into the abdominal wall. The principle of mesh fixation by sealing was first described in 1997 by Chevrel and Rath [17]. Katkhouda et al. [18] demonstrated the feasibility of fibrin sealing for TEP repair in an animal model. The first clinical trials with promising results followed [19, 20]. The aim of conducting our own case control study in a standardized patient population with primary inguinal hernias was to answer the following questions:

Is mesh fixation using Tissucol® sealant for TEP inguinal hernia repair safe and reliable enough in comparison with ProTack® staples in terms of the recurrence rate? Are there differences in the severity or prevalence of chronic groin pain in subjects undergoing TEP inguinal hernia repair?

Patients and methods

All patients who underwent inguinal hernia repair in our department from 2002 to 2004 were investigated retrospectively. Approximately, 1,000 inguinal hernia procedures were performed during this period. Endoscopic TEP repair by a standardized technique was performed in 359 of these hernias. Differences applied with regard to the technique used to fix the mesh implant. In the period from 1999 to 2003, the mesh was fixed in place with three to four spiral tacks in all cases of defects measuring larger than 2 cm. Adhesion with fibrin sealant started to become established in early 2003 and completely replaced staple fixation in 2004.

After excluding operations due to recurrent hernias and all patients with hernia orifices measuring less than 2 cm, who did not undergo fixation of any kind, there was left a patient population of 133, who underwent surgery for 186 primary inguinal hernias (80 unilateral; 53 bilateral). All the patients investigated were operated by the same surgeon and re-examined by a different investigator using a standardized questionnaire. For subsequent analysis, the study patients were divided into two groups, one who had undergone mesh fixation with spiral staples and another with fibrin sealant.

Surgical technique

For endoscopic hernia repair, a standardized TEP approach was used and always carried out under general anesthesia. An infraumbilical skin incision was made and the posterior rectus sheath was identified. Following

blunt dissection, a distension balloon was inserted and inflated to create the extraperitoneal space, which extended to the symphysis. After the balloon had been removed, the peritoneal space was insufflated with carbon dioxide until a maximum pressure of 15 mmHg was reached. A laparoscope was then inserted through the umbilical incision and two 5-mm trocars were placed through two midline incisions. Following the endoscopic identification of the anatomical structures of the inguinal region and the separation of the hernia sac, the hernia defect was closed with a 10 by 15 cm sheet of a large porous polypropylene composite mesh.

For the stapled group, the mesh was fixed in position by four titanium tacks (Auto Suture® ProTack®-5 mm, Tyco Healthcare, Norwalk, USA) anchored in the region of the pubic ramus, the medial, lateral and the upper edge of the mesh. No staples were placed below the iliopectic tract lateral to the Cooper's ligament.

Patients in the fibrin sealant group underwent mesh fixation using a 1 ml package of sealant (Tissucol® Duo S Immuno 1 ml, Baxter, Vienna, Austria). The glue was prepared by the scrub nurse during preparation of the hernia sac. The Tissucol® dual syringe was connected to a Duplotip® 6 laparoscopic applicator (Baxter, Vienna, Austria) and the sealant was applied on several locations at the edges of the mesh and in between the mesh and the abdominal wall (Fig. 1).

Following the removal of the carbon dioxide gas and the endoscopic instruments, the three small skin incisions were closed in anatomic layers. The use of drains or urinary catheters was not necessary.

Follow up

The usual postoperative stay was for 1 day (mean 1.4 days). Wound monitoring and follow up of findings were performed before discharge. The second scheduled



Fig. 1 Fibrin sealing of the mesh to the abdominal wall (1 ml Tissucol® applied using a Duplotip 6® laparoscopic instrument)

evaluation took place on days 5–7 for wound assessment and removal of suture material, and to identify possible hematomas or seromas. All follow ups for the study took place in October 2005, corresponding to not earlier than 11 and not later than 47 months after the intervention.

The questionnaire contained the following study parameters and qualitative characteristics: recurrence, complications, chronic inguinal pain, foreign body sensation and numbness. Chronic pain was defined as an intractable postoperative pain lasting for more than 3 months, in accordance with International Association for the Study of Pain recommendations [21]. The study variables were taken and evaluated on a binary basis without using a scale. If any of the questions elicited the mention of a pain syndrome, extensive clinical and sonographic examinations were performed.

Statistical analysis

The data generated were analyzed using SPSS® 12.0 software (Software Package for Social Science, SPSS Inc., Chicago, USA). The population was divided into two groups depending on the fixation technique. The mesh fixation method, ProTack®-Staples versus Tissucol®-Sealant, was tested on a univariate basis for a significant correlation with the endpoints of recurrence, perioperative complications, chronic pain, foreign body sensation and any numbness. Fisher's exact test was used. The Kruskal–Wallis test was used as a non-parametric test. A *P*-value lower than 0.05 was defined as significant in accordance with the biostatistical design.

Results

Follow up

Mesh fixation by spiral tacks or fibrin sealant was performed in 133 of the enrolled patients with 186 primary inguinal hernias and a hernia orifice measuring more than 2 cm. During follow up (follow-up rate of 94%), 125 patients with 173 hernias were evaluated in person. All patients were male. Seventy-seven unilateral and 48 bilateral hernias were followed up. The average age at the time of surgery was 55.9 years, range 20–80. Among the 173 hernias analyzed, the implanted mesh had been fixed by spiral tacks in 87 cases (50.3%) and by fibrin sealant in 86 patients (49.7%). The mean follow-up interval was 23.7 months (range 11–47 months) or almost 2 years. The fact that staple mesh fixation was gradually replaced by fibrin sealant in our department gave rise to significant differences in the follow-up interval. The staple group was followed up after an average of 32.1 (17–47) months and the fibrin sealant group after an average of 15.3 (11–21) months (Table 1).

Table 1 Patient details and procedures

		No.
Hernia	Total	186
	Re-examined	173
	Unilateral	77 (61.6%)
Fixation	Bilateral	48 (38.4%)
	Staples	87 (50.3%)
	Fibrin	86 (49.7%)
Follow-up rate		94%
Mean follow up (months)	Total	23.7 [11–47]
	Staples	32.1 [17–47]
	Fibrin	15.3 [11–21]
Mean age (years)	Total	55.9 [20–80]
	Staples	57.0 [20–79]
	Fibrin	54.7 [27–80]
Gender		All male

Complications

Complications occurred in four patients during the perioperative period (Table 2). One case of wound infection was noted both in the stapled group and in the fibrin group. There was one case of relevant hematoma and one case of postoperative pneumonia in the stapled group. No clinically conspicuous seromas were documented. The mean hospitalization period for both groups was 1.4 postoperative days. None of the complications observed during hospitalization or at the first follow up on postoperative day 5–7 required surgical revision. Univariate statistical analysis indicated no significant differences with regard to postoperative complications (Table 3).

Recurrences

A 2-year recurrence rate of 4.0% was determined for all patients, with seven cases of recurrent hernia. There were two recurrences in the fibrin sealant group corresponding to a recurrence rate of 2.3% at a mean follow-up interval of 15.3 months. There were five recurrences in the stapled group after an average of 32.1 months, corresponding to a rate of 5.7% (Table 3). Four of the five recurrences in the stapled group occurred within the first 15 months after surgery.

Chronic pain and foreign body sensation

Chronic inguinal pain was defined as any postoperative pain persisting for longer than 3 months after the

Table 2 Postoperative complications

Fixation	Complication	No.	Percentage
Staples	Wound infection	1	3.5
	Hematoma	1	
	Pneumonia	1	
Fibrin sealant	Wound infection	1	1.2

Table 3 Statistical analysis (Fisher exact test)

	Total <i>n</i> = 173	Staples <i>n</i> = 87	Fibrin <i>n</i> = 86	Staples versus fibrin <i>P</i> = (Fisher exact test)
Recurrence rate	7 (4.0%)	5 (5.7%)	2 (2.3%)	0.443 (n.s.)
Complications	4 (2.3%)	3 (3.5%)	1 (1.2%)	0.621 (n.s.)
Chronic pain	22 (12.7%)	18 (20.7%)	4 (4.7%)	0.002 (n.s.)
Foreign body sensation	6 (3.5%)	5 (5.7%)	1 (1.2%)	0.211 (n.s.)
Numbness	0 (0%)	0 (0%)	0 (0%)	1 (n.s.)

surgical intervention [21]. At follow up, 21 patients with 22 (12.7%) of the 173 hernias from the total population reported chronic inguinal pain (Table 3). These patients included 17 cases with unilateral pain and unilateral repair (3 fibrin; 14 stapler), three patients with bilateral surgery and unilateral pain (1 fibrin; 2 stapler) and one patient with bilateral surgery and bilateral pain after stapler fixation. Hence, a pain prevalence of 20.7% was established for the stapler group, corresponding to 18 out of 87 TEP repairs. In the fibrin group, the chronic inguinal pain prevalence was only 4.7%; corresponding to four out of 86 hernia repairs. Univariate analysis using Fisher's exact test shows that, at $P=0.002$, fixation by stapler is associated with a significantly higher prevalence of postoperative pain (Fig. 2). Due to the types of pain no reoperation was needed, but 10 of the 18 cases of the stapled group and none of the fibrin group required local infiltrations of anesthetics.

With regard to analysis of the other parameters, six post-hernia repair patients (3.5%) reported a persistent foreign body sensation in the groin. The prevalence was 5.7% in the stapler group and 1.2% in the fibrin group. The differences disclosed by univariate analysis were not significant, at a level of significance of $P>0.05$. Persistent numbness did not occur in any of the patients studied.

In summary, stapler fixation is associated with a significantly higher prevalence of postoperative pain.

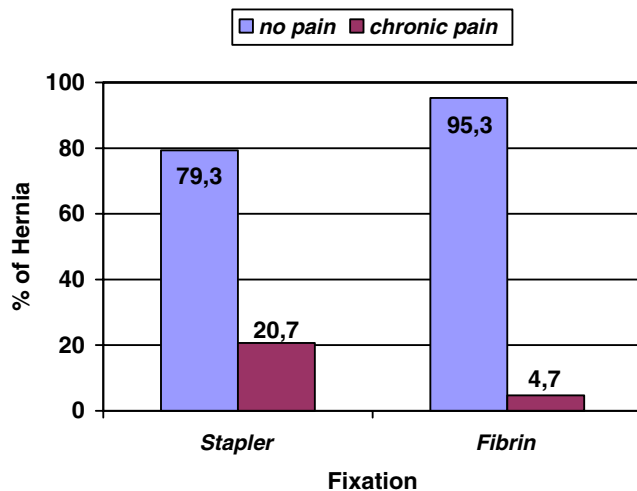


Fig. 2 Chronic inguinal pain: stapler versus fibrin sealant ($P=0.002$)*, *Fisher exact test

The two groups did not differ significantly with regard to any of the other parameters investigated (Table 3).

Discussion

The establishment of new methods and the modification of known surgical techniques have significantly reduced the incidence of recurrence after inguinal repairs, with the result that patient comfort is now assuming a higher priority for hernia surgeons and patients. The main arguments for widespread use of endoscopic techniques include less postoperative pain and early recovery. The issue of chronic inguinal pain following open and laparoscopic techniques is frequently discussed. Reports of intractable pain syndromes vary considerably with regard to the prevalence of pain. Whereas a large-scale study by Tamme et al. [22] disclosed a prevalence of only 0.3% after TEP repair, the literature contains numerous studies documenting chronic pain prevalence rates of 9.2–22.5% [8–11, 19, 23] after laparoscopic hernia repair. Comparison of published papers shows that studies focusing on pain syndromes invariably report pain prevalence rates from 5% to more than 25%. Callesen et al. [12] are therefore right in describing chronic inguinal pain as “the most serious problem that may affect the results of hernia surgery.”

Mesh fixation is intended to prevent the risk of recurrence due to implant dislocation. It was common in the past to recommend fixation with various stapling devices, but these surgical tacks and clips have been implicated in promoting the development of chronic inguinal pain [4, 13, 24]. Stark et al. [6] demonstrated that reducing the number of clips employed significantly reduces nerve irritation and chronic pain syndromes. The logical conclusion might be to abandon the practice of local fixation of laparoscopically implanted mesh. Although some clinical [4, 13, 15, 24] and animal [16] studies postulate that the mesh fixation is not absolutely necessary, this has not been universally adopted to date.

Selective non-stapling of the mesh has been proposed as a possible alternative to non-fixation in subjects with small abdominal wall defects [14, 24]. This is a standard practice in our department, where we have dispensed with mesh fixation in TEP repair since 2000 in patients with hernia orifices measuring less than 2 cm. Clinical follow ups for quality assurance purposes disclosed no disadvantage of this practice in terms of recurrence rates. However, we do not dispute the need for implant

fixation in large medial hernia defects after laparoscopic mesh augmentation, at least in the initial stages until scarring and tissue integration is complete.

The more atraumatic practice of gluing appears to be a suitable alternative to stapling meshes to the abdominal wall. As early as 1998, Jourdan and Bailey [25] published the first clinical data on the use of *n*-butyl-2-cyanoacrylate glue for laparoscopic mesh fixation. Outcomes with cyanoacrylate in open sutureless Lichtenstein repair were first reported by Helbling and Schlumpf in 1993 [26]. However, routine intracorporeal use of cyanoacrylate glues never became established in routine surgical practice. A major reason was its proven cytotoxicity. Montanaro et al. [27] demonstrated that the fluid released by polymerized cyanoacrylate glues is cytotoxic to L929 cells at dilutions of up to 1:10. Another disadvantage of these adhesives is their significant hardening properties, precluding extensive and planar application to the mesh.

Fibrin sealant is more suitable for intracorporeal application because it permits initial local fixation but later on disintegrates completely following fibroblastic infiltration of scar tissue. In 1997, Chevrel [17] published his experience with the use of fibrin glues in 110 incisional hernia repairs carried out since 1989. Katkhouda et al. [18] studied the laparoscopic fixation of hernia meshes with fibrin sealant versus staples in a porcine model and demonstrated that this technique produces mechanically effective and biocompatible mesh fixation. Our department started using Tissucol® for implant fixation in TEP repair in December 2003 in response to the results of the first clinical case reports.

The first clinical data on fibrin sealing versus stapler mesh fixation in laparoscopic hernia surgery was published in mid-2005 by Topart et al. [20]. Lau [19] published his Hong Kong data in November 2005. Both these studies demonstrated significantly lower chronic pain rates in the fibrin sealant group than in the stapled group: 4.5% versus 14.7% in Topart's study and 13.2% versus 20% in Lau's study. These findings are similar to the study outcomes presented by us (4.7% vs. 20.7%).

Whereas gender distribution and surgical history differed between the two groups investigated in Topart's study [20] (more women and interventions due to hernia recurrence in the stapled group), it was important to us to compare two homogeneous standardized cohorts. The stapled and fibrin groups in the present study were matched in terms of age and size and all the patients were male. We also excluded recurrent hernia repairs in order to rule out any confounding effects of prior scarring or previously implanted mesh material on the study endpoint, i.e., chronic inguinal pain.

Lau's study [19] involved subjects with bilateral hernia only. The effect of the significantly higher quantity of implanted foreign material (heavyweight, small-pore polypropylene meshes in particular) on the development of chronic inguinal pain ultimately remains unclear, but this might help to explain the fairly high 13.2% prevalence of pain in the fibrin group.

Another issue worth discussing is the recurrence rate in our cohort, which, at 4.0%, was fairly high in comparison with other TEP populations [22]. These findings however agree with the results of recently published large randomized series [9, 28] showing that hernia recurrence is observed in 6.6–10.1% of cases within 2–5 years after endoscopic hernia repair. A conclusive statistical comparison of the two groups is not yet possible because of the differences in the follow-up period; although four out of five recurrences after stapler fixation occurred within 15 months after surgery, which is within the follow-up interval for the fibrin group. Continued observation will show whether the recurrence rate in the fibrin group remains lower than in the stapler group. If this is confirmed, the benefits of adhesion fixation might be an explanation: fibrin sealing also enables fixation in the pelvic floor, the perineural sheath and below the iliopubic tract lateral to the Cooper's ligament, i.e. in regions where stapling would not be feasible.

Both Topart [20] and Lau [19] observed a higher prevalence of postoperative seroma in the fibrin group. No relevant seromas were observed or reported during follow up of our patients on the day of discharge, 5–7 days after discharge, and during the study. A possible explanation was provided by Chevrel [17]. In response to a higher incidence of seromas after the application of fibrin sealing for additional mesh fixation in large meshes for incisional hernia repair, the amount of glue was reduced by half and the phenomenon disappeared. This was attributed to the fact that high local fibrin sealant concentrations result in the formation of depots which tend to form a kind of pseudobursa and then need to be re-absorbed by the body through the production of a seroma. In contrast [19, 20], our interventions were performed using only 1 ml Tissucol. We made sure to create no depots during adhesion and spread the fibrin glue as thinly and planar as possible. An endoscopic spraying device, comparable to open surgery, would be useful in the future.

Conclusions

Fibrin sealing for fixation of laparoscopically implanted meshes is associated with less long-term pain than in stapling but is equally reliable. The method deserves to be established on the basis of recent data from animal experiments and clinical studies. Additional therapeutic indications such as fibrin sealing for open mesh repair are currently being studied [29]. Additional prospective randomized studies in large populations must follow. Long-term follow-up studies will show whether the method lives up to its current promise.

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