Surg Endosc (2008) 22:668–673
DOI 10.1007/s00464-007-9458-7

Comparing fibrin sealant with staples for mesh fixation in laparoscopic transabdominal hernia repair: a case control-study

Graziano Ceccarelli · Luciano Casciola · Massimo Codacci Pisanelli · Alberto Bartoli · Lelio Di zitti · Alessandro Spaziani · Alessia Biancafarina · Massimo Stefanoni · Alberto Patriti

Published online: 11 July 2007

Abstract
Background Laparoscopic hernia repair is not as popular as cholecystectomy. We have performed more than 3,000 laparoscopic herniorrhaphies using the trans-abdominal (TAPP) technique. To prevent recurrences we fix the polypropylene mesh with staples. The use of fibrin glue for graft fixation is a possible alternative.
Methods We have performed 3,130 laparoscopic hernia repairs over 14 years. For mesh fixation we used titanium clips and observed a small number of complications. In July 2003 we started using fibrin glue (Tissucol®). The purpose of this retrospective longitudinal study was to evaluate if the use of fibrin sealant was as safe and effective as conventional stapling and if there were differences in post-operative pain, complications and recurrences.
Results From July 2003 to June 2006 we performed 823 laparoscopic herniorrhaphies. Fibrin glue (Tissucol®) was used in 88 cases. Two homogeneous groups of 68 patients (83 cases) treated with fibrin glue and 68 patients (87 cases) where the mesh was fixed with staples, were compared. Patients with relevant associated diseases or large inguino-scrotal hernias were excluded. Operative times were longer in the group treated with fibrin glue with a mean of 35 minutes (range 22–65 mins) compared to the group treated with staples (25 minutes, range 14–50 mins). The time of hospital stay was the same (24 hours). Post-operative complications, that were more frequent in the stapled group, included trocar site pain, hematomas, intra-operative bleedings and incisional hernias. No significant difference was observed concerning seromas, chronic pain and recurrence rate.
Conclusions Less post-operative pain, and a faster return to usual activities are the main advantages of laparoscopic repair compared to the traditional approach. The use of fibrin sealant reduces in our experience the risk of post- and intra-operative complications such as bleeding and incisional hernia; recurrence rates are similar, but the operative time is longer.

Keywords Fibrin sealant · Tissucol · Inguinal hernia · Laparaoscopic herniorrhaphy · TAPP · Mesh fixation

The diffusion of laparoscopic cholecystectomy and the increasing use of the mesh for inguinal hernia repair have led to a laparoscopic approach in hernia repair since 1991 [1–4]. During the last 15 years laparoscopic hernia repair, however, has not become as common as cholecystectomy, although there is a good evidence of better results than with the conventional technique: earlier return to normal activities and reduced short-term pain [5, 6]. The reasons for this slow diffusion probably are: a long learning curve, the possibility of important complications, the costs, and anesthesiological problems. Today laparoscopic hernia repair represents only 5% of cases treated in Italy, and is only performed in reference centres. In these centres the use of this technique in recent years has actually increased and it has been introduced in the teaching curriculum for young surgeons.

G. Ceccarelli (✉) · L. Casciola · A. Bartoli · L. Di zitti · A. Spaziani · A. Biancafarina · M. Stefanoni · A. Patriti
Department of General, Vascular and Mininvasive Surgery, Spoleto Hospital, Spoleto, PG, Italy
e-mail: g.cecca2003@libero.it

M. Codacci Pisanelli
Surgical Department "Pietro Valdoni", University of Rome "La Sapienza", Rome, Italy

The correct fixation of the mesh, as well as the right size of the graft, are considered the most important surgical steps in the laparoscopic hernia repair to prevent the risk of recurrence. The use of 10 mm titanium staples to fix the mesh is the conventional approach. Some studies of laparoscopic hernia repair have shown that recurrences are caused by the rolling up of the mesh, incorrect stretching of the mesh, or by incomplete covering of the hernia defect. A correct method of securing the mesh has been recommended by several authors [7, 8]. Anyway, some complications of laparoscopic hernia repair, such as nerve injury (chronic post-operative pain, neuralgias, pubalgias) and hematomas in the Retzius space (bleeding from vascular lesions) are inherent to the use of the staples [9–15].

Some studies have evaluated the possibility of performing laparoscopic herniorrhaphy without mesh fixation with good results in terms of neuropathic complications and recurrence [16–18].

In recent years, different, less-traumatic mesh fixation procedures have been proposed: tacks, anchor-shaped devices, and glues. The fibrin sealant (Tissucol® Baxter) is a biodegradable adhesive obtained by the combination of human-derived fibrinogen and thrombin activated by calcium chloride, leading to the formation of polymerized fibrin chains, duplicating the last step of the coagulation cascade. the fibrinogen component gives tensile strength, thrombin stimulates fibroblast proliferation and aprotinin, an antifibrinolytic agent, enhances the life span of the sealant [19]. The product has been used as hemostatic agent in cardiothoracic, general, and trauma surgery [20, 21].

The use of fibrin sealant to fix the mesh in open hernia repair was first described in 1999 by Canonico et al. [22]. Many authors have since confirmed these results in the laparoscopic technique as well, albeit in limited series [23–26].

Methods

In our experience of 3,130 cases of laparoscopic hernia repairs from 1992 to June 2006 we have always performed the transabdominal preperitoneal repair (TAPP) technique. Our laparoscopic inclusion criteria were: age 18 or more, bilateral hernia, recurrent hernia, associated abdominal diseases (incisional hernia, uncomplicated cholecystolithiasis), young patients, sportsmen, patient preference. From July 2003 to June 2006 we have used the human fibrin glue (Tissucol® Baxter) in 88 of 823 laparoscopic herniorrhaphies for mesh securing. We have compared in a longitudinal retrospective analysis the results of two homogeneous groups of patients: a group of 68 consecutive patients (83 hernias) treated with fibrin glue, with a second case control group of 68 patients (87 hernias) where the mesh was fixed with conventional staples. The second series of patients were operated by the same surgical team of two surgeons with a large amount of experience in laparoscopic hernia repair, using the same surgical technique. Patients in the standard-technique group were randomly chosen from our files, selecting those operated in the same period and with baseline characteristics similar to those of the study group.

Table 1 Comparisons of patients and hernia characteristics

Group	Fibrin glue	Staples
Patients/hernias	68/83	68/87
Bilateral/monolateral	30/53	38/49
Males/females	62/6	64/4
Age	45 (26–78)	48 (21–79)
Recurrent hernia treated	8 (9.6%)	13 (14.9%)
Hernia type:		
Indirect	*67%*	*71%*
Direct	*28.20%*	*22.20%*
Direct+ indirect	*3.60%*	*4.6*
Femoral	*1.20%*	*2.20%*

Patients had comparable age, medical conditions and relevant comorbidities. Bilateral hernia was found in 30 patients (36%) in the first group, and in 38 (43%) in the second group. In the first group there were 62 males and six females, while in the second there were 64 males and 4 females. The average age in the two groups was 45 (range 26–78) and 48 years (range 21–79), respectively. The data for the two groups are reported in Table 1.

We excluded from the study the first five cases treated with Tissucol, as we considered this part of the learning curve period. We also excluded cases with associated diseases, very large scrotal and incarcerated hernias, and steroid treatment. The aim of this study was to evaluate the feasibility and efficacy of the Tissucol-technique, short- and long-term postoperative pain (by visual analogical scale), surgical complications (bleeding, seroma, hematoma, wound infection, incisional hernia, testicular complications). and recurrence rate. The mean follow-up period was 19 months (range 4–40 months). Data for the two treatment groups were obtained from a systematic review of all medical records. We had used a standardized protocol for follow-up: clinical examination and interview at one week, one month, and every year after surgery. Also patients were seen when they spontaneously requested a clinical visit.

Laparoscopic TAPP hernia repair: our surgical procedure

Before surgery all patients received antibiotic prophylaxis and in selected cases antithrombotic prophylaxis. The patient was placed in the supine and Trendelemburg position, with upper limbs abducted, under general anesthesia; the

table was rotated to the side opposite the hernia. The surgeon was placed opposite to the hernia and the assistant on the right side of the patient. Pneumoperitoneum of 10–12 mmHg was created with a Veress needle and the first trocar was inserted into the umbilical 1 cm scar; two other trocars (one of 5 mm and one of 10 mm) were placed under direct vision. With fibrin glue it is possible to use two 5 mm trocars, but the surgical steps are the same in both procedures. The following anatomical landmarks are identified: epigastric vessels, iliac vessels, spermatic cord or round ligament, Cooper's ligament, and rectus muscle. The peritoneum is incised and opened, the entire pre-peritoneal inguinal area is completely prepared, the hernia sac dissected and reduced into the abdomen, a lipoma, if present, was excised. An hernia sac of very large size (inguinoscrotal hernia) may be sectioned at the neck. Extreme care has to be given to control bleeding. A rectangle of polypropylene mesh of about 15 x 10 cm was used and tailored to each patient, shaped as shown in Fig. 1. The mesh was rolled and introduced into the abdomen trough a 10 mm cannula, positioned to cover the hernia defect and the entire inguino-femoral region (potential hernia spaces). It is important to ensure that the inferior border of the mesh stays in place when the peritoneum is lifted. Incorrect positioning of the mesh is an important cause of recurrence. The mesh was fixed in place in the conventional way using a stapling device introduced in a 10 mm trocar and the metal staples placed paying attention to avoid epigatstric vessels, iliac vessels, and the nerve area; the clips are positioned at the Cooper ligament, on the rectus muscle, and laterally to epigastric vessels in the area of transversal sheath. The aim of mesh fixation is to prevent graft displacement and consequent recurrence. When fibrin glue is used, a special 5 mm laparoscopic applicator (Duplocath, Baxter HC) is required, and 2 ml of Tissucol

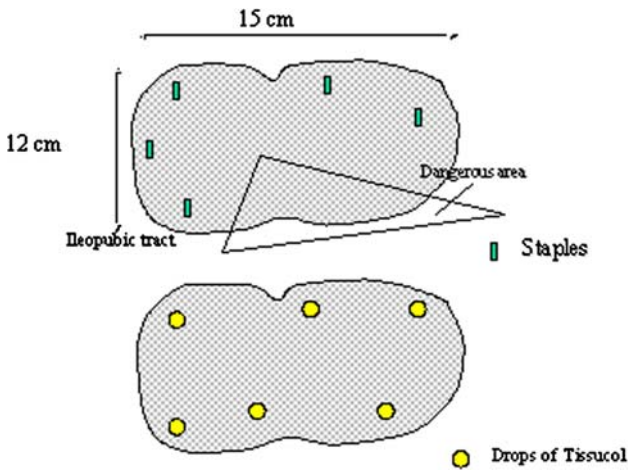

Fig. 1 Polypropylene mesh shape in male right-side inguinal hernia, comparing staples and fibrin glue drops positioning

was placed after heating at 37°C, with small drops around the mesh border; there is no need to look for vessels or nerve location. In female patients the round ligament is surrounded by the two tails of the mesh, fixed together by a clip or a stitch (if we use fibrin glue). Peritoneum closure using staples is faster; with the fibrin glue we need a running suture, and more laparoscopic experience is required. The laparoscopic cannulas are then removed under visual control because of the risk of bleeding. All 10 mm trocar sites need of a fascial suture because of the risks of bleeding and incisional hernia. Skin incisions are closed by stitches. No drains into the abdomen are required.

Statistical analysis

Categorical variables were compared by χ^2 test. Continuous variables were compared by Student's *t*-test. Data were expressed as mean ± standard deviation (SD). To assess the congruity of the Student's *t*-test we first used the Kolmogorow-Smirnow test for the normality on each sample data.

All *p* values were two-sided. A *p* value of less than 0.05 indicated a significant difference. Statistical analysis was performed using the SPSS software.

Results

A total of 170 hernia repairs were performed on 136 patients, with a mean follow up of 19 months (range 4–40 months); the characteristics of the patients and hernias are described in Table 1. The two groups were similar for age, gender, hernia types and follow-up. No serious intraoperative complications occurred in both groups, but three trocars site bleeding at the end of operation (10 mm lateral trocar extraction) were observed and treated.

The operative times were longer in the group where glue was used with a mean duration of 35 minutes (range 22–65 mins) versus the group with staples (lower) with a mean time of 25 minutes (range 14–50 mins). The hospital stay was the same: all patients were discharged after 24 hours (one night of observation). The postoperative complications of the two groups are reported in Table 2. We underline a significant difference only in terms of 10 mm trocar site post-operative pain, evaluated with VAS (1–10). We considered positive a VAS > 4; all four cases observed were in the stapled group and in the right lateral 10 mm site, but the pain disappeared after 30 days. This pain may be associated to fascial suture to secure the site port for the prevention of post-operative complications.

No significant difference were observed with respect to seromas, chronic pain in the groin site, and recurrence rate. Our total recurrence rate for laparoscopic TAPP hernia repair was 0.4%, during the period of follow-up in the two

Table 2 Results and complications

	Fibrin glue use	Staples use	*p*
Operative time	35′(22–65)	25′(14′–50′)	<0.05
Discharge (hours)	24 h	24 h	*n.s.*
Complication:			
Groin chronic pain	*0*	*0*	*n.s.*
Hematoma of scrotum	*0 (0%)*	*1(1.14%)*	*n.s.*
Seroma	*2 (2,4%)*	*2 (2.29)*	*n.s.*
Trocar hernia	*0 (0%)*	*1 (1.14)*	*n.s*
Trocar site bleeding	*0 (0%)*	*3 (4.41%)*	*p < 0,05*
10 mm trocar site pain	*0 (0%)*	*4 (5.88%)*	*p < 0,05*
Recurrence rate	0	0	n.s.

groups observed we had no recurrences; we have observed that generally the period in which laparoscopic recurrence is observed is about 4–8 months after operation.

Discussion

Use of laparoscopic hernia repair in Italy today does not exceed 3–5% of all procedures. The reasons for this are common but not all are correct: the long learning curve, expensive, important complications, the necessity for general anesthesia, and longer hospitalization times. Laparoscopic hernia repair is a technique that cannot be learned as quickly as the conventional open technique by young surgeons or by surgeons who are not expert in minimal-invasive surgery. Some surgeons consider a good learning curve of about 250 operations for laparoscopic hernia repair [27] to reach a recurrence rate similar to that of the Lichtenstein technique. This is not correct in our opinion, as a young surgeon who works in a mininvasive surgical department can easily learn the minimal-invasive technique working with an expert senior surgeon. The operative cost of laparoscopy is higher, but it is important in our opinion to consider the results and patient satisfaction. The costs depend on the operative time, use of disposable instruments, type of mesh and method of fixation, hospital stay, and time to return to normal activity [28, 29]. In many cases however, the laparoscopic approach is adopted at the request of the patient during their first visit.

Complications in laparoscopic approach may be important but are related to the surgeon's laparoscopic experience and to a good knowledge of laparoscopic anatomy which can avoid the risks of vascular or nerve injury during dissection or clips positioning. Others complications are typical of laparoscopy (trocar lesions, electrocautery lesions, and so on).

We use a laparoscopic or conventional open approach to repair inguinal hernia depending on the characteristics of the patient and hernia type, but when possible a minimal-invasive approach gives the patients more benefits and better results.

The possibility of using different methods to fix the mesh, during recent years, may be an interesting possibility to reduce the complication rate and to obtain better postoperative recovery. The first experience in the use of human fibrin glue (Tissucol®) for mesh fixation was in open hernia repair [26]. For laparoscopic hernia repair the possibility of nerve injury (pain or parasthesia) caused by entrapment from incorrect placement of staples (above all lateral cutaneus femoral nerve, but ilioinguinal, and genitofemoral are also at risk) [13, 30] and epigastric vessels lesion by clips application may be avoided using fibrin glue either in the TAPP technique [25] or in the TEP [24, 31]. It seems that not only entrapment but also postoperative fibrous scar around the staples can lead to nerve injury [16]. Various studies report from 0 to 6% of postoperative nouropathic complications [13, 32, 33]. In our total laparoscopic experience the incidence is very low (0.09%) as we tend to avoid staples placement in nerve areas and to use the minimum number of staples. Chronic pain is not always due to staples, but may be caused by inflammatory reaction around the mesh with scarring around the nerve, which may induce neurologic pain as in open technique. Bleeding and incisional hernia from the 10 mm trocar site may be reduced using 5 mm ports. Another important aspect is recurrence after hernia repair; in the laparoscopic technique the possible causes are: insufficient extent of dissection, inadequate size of the prosthesis, and incorrect kind of fixation of the mesh. In our opinion it is important to reach on overlap of at least 2–3 cm from the hernia edge; if this is not possible the possibility of migration of the prosthesis is too high. In our retrospective observational study, the use of fibrin glue to fix the mesh was not associated with an increased recurrence rate, but no significant difference were observed in terms of neuropathic complications or seroma. It is the use of a 5 mm trocar rather than 10 mm that reduces intra-operative bleeding, and postoperative trocar site pain, as well as incisional hernias. The use of Tissucol reduces epigastric vessels incidental lesions, and has a hemostatic effect, reducing hematomas. However operative time is longer by about 10 minutes compared with the use of staples; this is due primarily to the peritoneum closure using a running laparoscopic suture. The operative costs of the two techniques compared are in our experience similar if we use 2 ml of Tissucol for each hernia. In some studies the use of fibrin glue was less expensive than stapling [24].

Concerning chronic pain after laparoscopic hernia repair, we include in this definition the persistence of pain for more than three months after surgery. In our experience of 3,130 laparoscopic hernia repairs performed before 2006

using the TAPP technique, chronic pain was only observed in four cases (0.13%). In the cases randomly selected for comparison with patients treated using Tissucol there were no cases of chronic pain. We therefore did not include the evaluation of chronic pain as an end-point in our analysis since it did not appear relevant, even if some authors are concerned by this aspect. We did observe a statistically significant difference concerning post-operative pain 30 days after surgery on the right flank in the area of the 10 mm trocar (Table 2). Other differences that are worth mentioning, even if we are aware of the limited sample analyzed, are those related to some post-operative complications due to the 10 mm trocar on the right flank: reduced bleeding, reduced post-operative discomfort and the lower risk of incisional hernias.

This is a pilot study; it of course needs confirmation in a larger randomized trial.

Conclusions

Our study shows that it is possible to fix hernia mesh using different and non-traumatic devices such as fibrin glue (Tissucol®) with the same results in terms of recurrence rate, hospital stay, and costs; but with better results in terms of post-operative pain, seromas, and trocar-related trauma. The incidence of neuropathic problems (acute and chronic pain) were in our experience low in both techniques, with no significant difference. However the use of fibrin glue, in our opinion, needs extensive experience in laparoscopic techniques, as the anatomical dissection and inguinal region preparation have to be carefully performed, and the mesh size has to be adequate; peritoneum closure with a running suture is more time consuming. Ours is a retrospective study, comparing two groups of selected cases (recurrences, inguino-scrotal hernias and large direct hernias were excluded). Large randomized trials and longer follow-up are required to demonstrate the advantages of either technique [17].

References

1. Corbitt JD (1991) Laparoscopic herniorrhaphy. Surg Laparosc Endosc 1:23–25
2. Ger R (1991) The laparoscopic management of groin hernias. Contemp Surg 63:15–19
3. Arregui ME, Davis CJ, Yucel O, Nagan RF (1992) Laparoscopic mesh repair of inguinal hernia using a preperitoneal approach: a preliminary report. Surg Laparosc Endosc 2:53–58
4. Filipi CJ, Fitzgibbon RJ, Salerno GM, Hart RO (1992) Laparoscopic herniorrhaphy. Surg Clin North Am 72:1109–1123
5. Barkun JS, Wexler MJ, Hinchey EJ, Thibeault D, Meakins JL (1995) Laparoscopic versus open inguinal herniorrhaphy: preliminary results of a randomized controlled trial. Surgery 118:703–710
6. Tanphiphat C, Tanprayoon T, Sangsubhan C, Chatamura K (1998) Laparoscopic versus open inguinal hernia repair. Surg Endosc 12:846–851
7. Deans GT, Wilson MS, Royston CMS, Brough WA (1995) Recurrent inguinal hernia after laparoscopic repair: a possible cause and prevention. Br J Surg 82:539–541
8. Felix E, Scott S, Crafton B, Geis P, Duncan T, Sewell R, McKernan B (1998) Causes of recurrence after laparoscopic hernioplasty: a multicenter study. Surg Endosc 9:135–139
9. Phillips EH, Arregui ME, Carroll BJ, Corbitt J, Crafton WB, Fallas MJ, Filipi C, Fitzgibbons J, Franklin MJ, McKernan B, et al. (1995) Incidence of complications following laparoscopic hernioplasty. Surg Endosc 9:16–21
10. Sayad P, Hallak A, Ferzli G (1998) Laparoscopic herniorrhaphy: review of complications and recurrence. J Laparoendosc Adv Surg Tech 8:3–10
11. Andrew DR, Gregory RP, Richardson DR (1994) Meralgia paraesthetica following laparoscopic inguinal herniorrhaphy. Br J Surg 81(5):715
12. Chevallier JM, Wind P, Lassau JP (1996) Damage to the inguinofemoral nerves in the treatment of hernias: an anatomical hazard of traditional and laaproscopc techniques. Ann Chir 50:767–775
13. Stark E, Oestreich K, Wendl K, Rumstradt B, Hagmuller E (1999) Nerve irritation after laparoscopic hernia repair. Surg Endosc 13:878–881
14. Kraus MA (1993) Nerve injury during laparoscopic inguinal hernia repair. Surg Laparosc Endosc 3:342–345
15. Rosen A, Halevy A (1997) Anatomical basis for nerve injury during laparoscopic hernia repair. Surg Laparosc Endosc 7:469–471
16. Khajanchee YS, Urbach DR, Swanstrom LL, Hansen PD (2001) Outcomes of laparoscopic herniorrhaphy without fixation of mesh to the abdominal wall. Surg Endosc 15:1102–1107
17. Ferzli GS, Frezza EE, Pecoraro AM Jr, Ahern KD (1999) Prospective randomized study of stapled versus unstapled mesh in laparoscopic preperitoneal inguinal hernia repair. J Am Coll Surg 188:461–465
18. Smith AI, Royston CM, Sedman PC (1999) Stapled and nonstapled laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair. A prospective randomized trial. Surg Endosc 13:804–806
19. Byrne DJ, Hardy J, Wood RA, McIntosh R, Cuschieri A (1991) Effect of fibrin glues on the mechanical properties of healing wounds. Br J Surg 78:841–843
20. Spotnitz WD, Falstrom JK, Rodeheaver GT (1997) The role of sutures and fibrin sealant in wound healing. Surg Clin North Am 77:651–699
21. Fernandez LF, Tejero E, Tieso A (1996) Randomized trial of fibrin glue to seal mechanical oesophagojejunal anastomosis. Br J Surg 83:40–41
22. Canonico S, Sciaudone G, Pacifico F, Santoriello A (1999) Inguinal hernia repair in patients with coagulation problems: prevention of postoperative bleeding with human fibrin glue. Surgery 125:315–317
23. Katkhouda N, Mavor E, Friedlander MH, Mason RJ, Kiyabu M, Grant SW, Achanta K, Kirkman EL, Narayan K, Essani R (2001) Use of fibrin sealant for prosthetic mesh fixation in laparoscopic extraperitoneal inguinal hernia repair. Ann Surg 233:18–25
24. Novik B, Hagedorn S, Mork UB, Dahlin K, Skullman S, Dalenback J (2006) Fibrin glue for securing the mesh in laparoscopic totally extraperitoneal inguinal hernia repair: a study with a 40-month prospective follow-up period. Surg Endosc 20(3):462–467

25. Olmi S, Erba L, Bertolini A, Scaini A, Mastropasqua E, Conti M, Croce E (2005) Use of fibrin glue (Tissucol) for mesh fixation in laparoscopic transabdominal hernia repair. Chir Ital 57(6):753–759
26. Canonico S, Santoriello A, Campitiello F, Fattopace A, Corte AD, Sordelli I, Benevento R (2005) Mesh fixation with human fibrin glue (Tissucol) in open tension-free inguinal hernia repair: a preliminary report. Hernia 9(4):330–333
27. Neumayer L, Giobbie-Hurder A, Jonasson O, Fitzgibbons R Jr, Dunlop D, Gibbs J, Reda D, Henderson W (2004) Veterans Affairs Cooperative Studies Program 456 Investigators: Open mesh versus laparoscopic mesh repair of inguinal hernia. N Engl J Med 350:1819–1827
28. Heikkinen TJ, Haukipuro K, Koivukangas P, Hulkko A (1998) A prospective randomized outcome and cost comparison of totally extraperitoneal endoscopic hernioplasty versus Lichtenstein hernia operation among employed patients. Surg Laparosc Endosc 8:338–344
29. Stylopulos N, Gazzelle GS, Rattner DW (2003) A cost-utility analysis of treatment options for inguinal hernia in 1,513,008 adult patients. Surg Endosc 17:180–189
30. Kraus MA (1993) Nerve injury during laparoscopic inguinal hernia repair. Surg Laparosc Endosc 3:342–345
31. Schwab R, Willims A, Kroger A, Becker HP (2006) Less chronic pain following mesh fixation using a fibrin sealant in TEP inguinal hernia repair. Hernia 10:272–277
32. Felix EL, Harbertson N, Vartanian S (1999) Laparoscopic hernioplasty: significant complications. Surg Endosc 13:328–331
33. Knook MTT, Weidema WF, Stassen LPS, van Steensel CJ (1999) Endoscopic total extraperitoneal repair of primary and recurrent inguinal hernias. Surg Endosc 13:507–511