Hernia (2008) 12:177–183
DOI 10.1007/s10029-007-0317-1

ORIGINAL ARTICLE

Laparoscopic resorbable mesh fixation. Assessment of an innovative disposable instrument delivering resorbable fixation devices: I-Clip^{TM}. Final results of a prospective multicentre clinical trial

M. Lepere · S. Benchetrit · J. C. Bertrand · J. Y. Chalbet · J. P. Combier · B. Detruit · G. Herbault · P. Jarsaillon · J. Lagoutte · H. Levard · P. Rignier

Received: 24 August 2006 / Accepted: 13 November 2007 / Published online: 18 December 2007

Abstract
Background The aim of this study was to assess the performance and tolerance of an innovative disposable instrument delivering resorbable clips (I-Clip^{TM}, Sofradim, France) intended for mesh fixation in inguinal, incisional and umbilical hernias of the abdominal wall. The fixation device was designed to be resorbable in 1 year, with reduced trauma to the underlying tissues or the mesh, and with initial mechanical properties equivalent to those of conventional metal staples.
Methods The study involved 105 patients with inguinal, umbilical or incisional hernias enrolled from 11 centres. Inguinal totally extra peritoneal (TEP) or trans abdomino pre-peritoneal (TAPP) repair was performed with Parietex® mesh, incisional or umbilical hernias were treated via the intraperitoneal route with Parietex® composite. I-Clips^{TM} were used for mesh fixation in both indications according to the surgeon's habits. Efficacy was the principal assessment criteria evaluated by two parameters: quality of fixation evaluated subjectively at the time of procedure and recurrence rate according to the follow up at 1, 6 and 12 months. Pain evaluated by the patients using a visual analogue scale (VAS) was the principal secondary assessment criteria. Other tolerance criteria were also evaluated during surgery and follow up.
Results The surgeons' evaluation of the fixation quality was assessed as good to very good in 100% of ventral hernias and good to very good in 85–92% of inguinal

M. Lepere (✉)
Clinique St. Charles, 11 bd René Levesque,
BP 669, 85016 La Roche sur Yon Cedex, France
e-mail: lepere.marc@wanadoo.fr

S. Benchetrit
Clinique Jeanne d'Arc, 32–34 cours Albert Thomas,
69371 Lyon Cedex 08, France

J. C. Bertrand
Institut Arnault Tzanck, avenue Maurice Donat,
06721 Saint Laurent du Var, France

J. Y. Chalbet
Polyclinique de Montélimar, 56 avenue du Teil,
26200 Montelimar, France

J. P. Combier
Fondation Hôtel Dieu, 175 rue Maréchal Foch,
71206 Le Creusot Cedex, France

B. Detruit
CMC de Parly II, 21 rue Maxouris, 78150 Le Chesnay, France

G. Herbault
Clinique de l'Espérance, 14 bis avenue Victoria,
83400 Hyeres, France

P. Jarsaillon
Clinique du Renaison, 75 cours Général Giraud,
BP 273, 42308 Roanne, France

J. Lagoutte
Polyclinique du Beaujolais,
120 ancienne route de Beaujeu, 69400 Arnas, France

H. Levard
Institut Mutualiste Montsouris, 42 bd Jourdan,
75674 Paris Cedex 14, France

P. Rignier
Polyclinique Les Bleuets,
24–44 rue du Colonel Fabien, 51100 Reims, France

hernias. At 1 month, 90% of patients (94/104) were totally pain-free (VAS score: 0) and only ten patients reported low pain (VAS scores: 0.3–3.1). At 1 year, the pain described by those ten patients finally disappeared, 98% of patients (102/104) were totally pain-free. The rate of minor complications not related to the device concerned 5% of the patients at 1 month, which was reduced to 2% at one year and no recurrence or mesh sepsis was observed.

Conclusions The ease of use of this device, combined with the absence of recurrence related to the investigated device and the good pain-free outcome in this group of patients confirmed the effectiveness and tolerance of the resorbable fixation concept of I-Clip™.

Keywords Resorbable fixation · I-Clip · Laparoscopic · Ventral hernia · Inguinal hernia

Introduction

Primary musculo fascial repair leads to a high rate of recurrences, particularly in obese patients [1–3]. These arguments encourage surgeons to use synthetic textile devices for wall defect repair. In ventral hernia repair, the techniques using a retromuscular mesh are correlated with complications due to the wideness of the required dissection [4].

The appearance of new materials, intraperitoneally implanted and, therefore, feasible via a laparoscopic approach, has been widely accepted by the surgical community [5–7].

One of the success factors of this procedure is the quality of the mesh fixation that enables the surgeon to obtain accurate positioning of the mesh, while preventing early migration with its associated complications.

Concerning inguinal hernias, mesh fixation during a laparoscopic procedure is a frequently chosen option allowing a precise positioning of the mesh and, thus, avoiding also an early migration and its correlated drawbacks [8]. This technical point is often preferred to the absence of mesh fixation, even if the results obtained after laparoscopic procedure with fixed and non-fixed mesh does not demonstrate statistical difference between the two groups [9, 10]. Recently, the gluing of mesh has been successfully experienced by some authors [11, 12].

In those laparoscopic parietal repairs, conventional metallic stapling may, however, be itself the source of other complications, such as chronic pain due to local nerve injury, haemorrhage, osteitis and intraperitoneal adhesions [13, 14]. These neuropathic pains are more frequent and persistent than generally estimated and they usually interfere with patients' daily lives [15, 16]. Their treatment may require surgery [17]. The purpose of this study was to assess the effectiveness and the tolerance of a new resorbable mesh fixation device, I-Clip™ by Sofradim, France. The concept of I-Clip™ is to have a disposable instrument delivering a slow resorption anchor via a hollow needle (Figs. 1, 2, 3). The composition of the anchor is polylactic acid. This concept has been validated for over 10 years in osteosynthesis and ligament anchoring [18, 19]. Its mechanical anchoring resistance data are comparable to current stapling devices using metal, with a high resistance to the peeling test. Polylactic acid is well known for its excellent tolerance and it degrades in 12 months by hydrolysis. In the case of improper positioning of the clip, it can be easily cut with laparoscopic scissors and removed.

Patients and methods

Tested device

The I-Clip™ device, a 10-mm disposable instrument delivering resorbable fixation clips, is intended for mesh fixation

Fig. 1 Positioning the needle

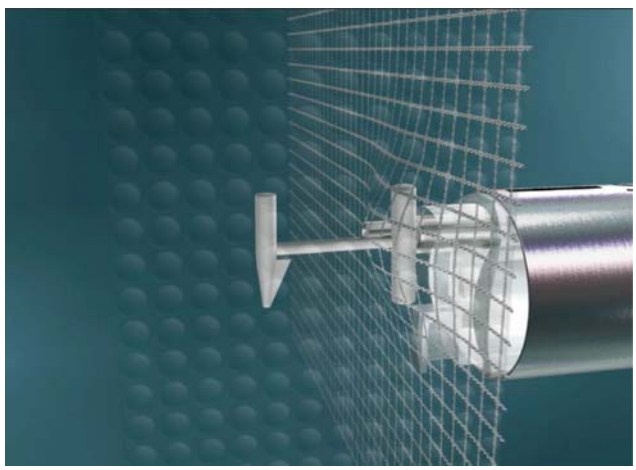

Fig. 2 Inserting the I-Clip™ staple

Fig. 3 Laparoscopic view of the staple in situ

via a laparoscopic approach. The cartridge contains ten slow-resorption fixation I-Clips™.

The delivered resorbable I-Clip™ fixation device is made of polylactic acid and it ensures fixation of the mesh during the necessary duration of tissular ingrowth within the mesh. The mechanical resistance of the clip is equivalent to conventional stapling during 6 weeks and then degrades in about 12 months (Figs. 1, 2, 3).

General method

This study has been conducted in accordance with the European standards on clinical studies (EN540) and good clinical practices. The investigation plan was submitted and approved by the Ethics Committee (CCPPRB) of Nantes. All of the patients gave informed consent prior to surgery.

Inclusion criteria

The inclusion criteria were: agreement and signature of informed consent, first or recurrent inguinal hernia (size <4 cm), incisional or umbilical hernias (size ≤10 cm), laparoscopic treatment of the defect.

Non-inclusion criteria

The non-inclusion criteria were: major obesity (body mass index [BMI] exceeding 40), concomitant surgical steps on the digestive tract or septic risk, psychiatric disease affecting pain perception, patients who were mentally incompetent or not able to give an informed consent signature, inguino-scrotal hernia over 4 cm, bilateral hernia, residual intraperitoneal mesh.

Baseline study

The history of the patients was obtained especially for preoperative pain, localisation and consequences on patients' activity and previous surgeries (recurrence, surgical route etc.). Professional and sporting activities were collected with the aim to objectivise the return to normal activity.

Surgical technique

A total of 105 patients were included from 11 centres between October 2001 and March 2003. According to the protocol, all of the inguinal hernias (n=76 [72.4%]) were treated via a laparoscopic approach by preperitoneal polyester mesh (Parietex®, Sofradim Trévoux, France) and umbilical and incisional hernias (n=29 [27.6%]) were treated by laparoscopic intraperitoneal placement of a polyester composite mesh (Parietex® composite, Sofradim, France).

The operative technique used for inguinal hernia repair was kept to the surgeons' preference, either TAPP (n=48 [63%]) or TEP (n=28 [37%]). The size of the defects was measured during the surgical procedure, comparing the edges of the wall defect with the tips of the dissection instruments. The number of anchors used for any mesh fixation has been left free to the surgeons' habits. The only recommendation was to respect a mesh overlap of 4–5 cm over the defect for umbilical and incisional hernias. The mean surgery duration was 30±10 min for inguinal and umbilical hernias and 40±25 min for incisional hernias. The mean number of I-Clips™ used ranged from 5.5±1.5 for inguinal hernias to 16±5 for incisional hernias.

End points

The primary efficacy end point of the study was the perioperative and long-term quality of mesh fixation.

The quality of mesh fixation was assessed by surgeons during the procedure. Different situations were checked: fixation on the upper part of Cooper's ligament (inguinal hernia) and in the abdominal wall (inguinal hernia and incisional and umbilical hernias).

The long-term quality of fixation was assessed by the recurrence rate at the end of the study.

The secondary end points were:

- Post-operative pain at fixation area (principal secondary parameter)
- Complications (inflammatory granuloma or haematoma)
- Device use assessment: preciseness of fixation, ergonomics of the stapler

Data collection and follow up

The data collection was performed on standardised clinical report forms during the clinical follow up of the patient organised at 1, 6 and 12 months. Surgeons' perioperative assessment of the quality of fixation and manipulability parameters (preciseness and ergonomics) were collected using an analogical scale. Post-operative pain was reported for each time point (evaluated by the patient using a 10-cm visual analogue scale [VAS]: scores ranged from 0 for no pain to 10 for unbearable pain).

Complications were monitored, especially any recurrence symptoms.

Results

The results reported here are based on a follow up of 1 year.

Characteristics of the patients

The patient demographics of the 105 patients enrolled in this multicentre study are shown in Table 1.

The following potential risk factors were identified: obesity (BMI>30) in 19 patients (18.1%), diabetes in seven patients (6.7%), chronic bronchitis in three patients (2.9%).

Pre-procedure observations and discharge

The perioperative evaluation of the fixation quality to the abdominal wall was assessed by the surgeons as good to very good in 100% of umbilical and incisional hernias and in 92% of inguinal hernias, and into Cooper's ligament it was good to very good in 85% of cases. The accuracy of stapling was assessed as good to very good in 91% of inguinal hernias and in 83% of umbilical and incisional hernias. The ergonomics of the stapler was judged to be good to very good in 74% for inguinal and 69% for incisional hernias.

No incident or difficulty of mesh fixation was reported during surgery (Table 2).

Table 1 Patient demographics

Demographic	*n*=105
Mean age (years)	54±13
Body mass index (BMI, weight/height^2)	25.9±4.2
Hernia type	
Umbilical/incisional	29 (28%)
Inguinal	76 (72%)
Procedure	
TEP	28 (37%)
TAPP	48 (63%)

Table 2 Surgeons' assessment and discharge summary

		Inguinal hernia	Umbilical hernia
Fixation quality			
Coopers' ligament	Good to very good	85%	NA
Abdominal wall	Good to very good	92%	100%
Preciseness of fixation	Good to very good	91%	83%
Ergonomics of stapler	Good to very good	74%	69%
Discharge summary			
Hospital stay (days)		1.6±0.8	2.9±1.6
Complications		0	0

NA=non-applicable

Patient follow up

The post-operative pain assessment is shown in Table 3.

One can note that the mean post-operative pain at discharge is low and is at the same level as that of preoperative pain, whatever the indication is. During follow up, the decrease in post-operative pain is comparable in the two indications.

In ten patients who reported pain at 1 month (five in each indication), the pain decreased during follow up in all cases and had disappeared at 1 year. At the end of the study, no patient was lost to follow up (Table 4) and only two patients reported pain inferior to 3/10, even though they reported no pain at the 1-month visit. Analgesic treatment was taken by three patients at the 1-month visit, and at the end of the 1-year follow up, no patients took analgesic treatment. Complications were few: one patient was operated with a clinical diagnosis of umbilical recurrence but surgical findings showed this to be a lipoma and, therefore, not related to a clip fixation failure. This has been confirmed by scanner results in favour of an absence of mesh migration. No recurrence was reported in the inguinal group. In both groups, no sepsis was noted (Table 4).

Discussion

This prospective multicentre study demonstrates the effectiveness of the I-Clip^{TM} innovative mesh fixation system using slow resorbable polylactic acid clips in laparoscopic mesh fixation in inguinal and incisional hernia treatment.

The objectives were for the mesh-fixation procedure to be as similar as possible in terms of efficacy to standard procedures using metal staples, adding the advantage of reducing chronic pain and other complications associated with metal staples.

Although our study was based on a limited number of patients, the clinical follow up was long enough to study

Table 3 Pain assessment

Pain (EVA scale 0–10)	Inguinal hernia			Umbilical/incisional hernias		
	Mean	Median	Range	Mean	Median	Range
Before surgery	2.0	1.0	0–7.8	2.3	2.0	0–9.0
At discharge	1.7	1.5	0–8.5	2.6	3.0	0–6.0
At 1 month	0.1	0	0–2.0	0.3	0	0–3.1
At 12 months	0.1	0	0–3.0	0	0	0–0.3

Table 4 Clinical results

	Inguinal hernia, *n*=76	Umbilical/incisional hernias, *n*=29
Complications		
1 month	3[a]	3[b]
12 months	0	2[c]
Recurrence		
1 month	0	0
12 months	0	0[d]

[a] 2 seroma, 1 scrotal oedema

[b] 2 seroma, 1 repair

[c] 1 seroma, 1 death

[d] Excision of a lipoma, scan results in favour of a non-slipped mesh

pain evolution during the degradation time of the polylactic staples. The results are in accordance with the suspected clinical advantages of using this innovative fixation device.

The surgeons' evaluation of the fixation quality to the abdominal wall, and to Cooper's ligament when appropriate, was assessed as good to very good in 100% of umbilical and incisional hernias and in 85–92% of inguinal hernias (Table 2). The ergonomics of the first generation of stapler used in this study was not optimum and has been improved since that time.

The accurate and precise placement of a fixation device is one of the key factors to preventing perioperative complications like haematomas and nerve injuries, especially during the initial surgeons' experience of a new device [20, 21].

The long-term post-operative quality of fixation can be judged by the rate of recurrence, which is null in this study: only one suspected recurrence, operated under local anaesthesia (for poor general condition) was found to be an umbilical lipoma. A later computed tomography (CT) scan suggested that the mesh had not slipped. The use of a 10-mm device did not induce any complication, such as trocar site hernia. It is unusual to observe no recurrence in a study, as this complication is multifactorial: quality of mesh fixation, morbid obesity or previous surgery, especially when complicated. However, this rate is in accordance with the published results of larges series on umbilical and incisional hernias in which mechanical tension is increased. Previous animal studies had assessed that the tensile strength of this resorbable clip is comparable to metallic tacks [22]. In addition, the use of a macroporous (large pore size) mesh—Parietex® composite—is known to be correlated with a fast tissue ingrowth and effective mechanical properties. Moreover, it makes sense to use a resorbable fixation mean with the hydrophilic resorbable film on the visceral side of this composite mesh in order to obtain a best neoperitoneum surface and, therefore, less visceral adhesions [22].

Concerning inguinal hernias, our recurrence rate compares favourably to laparoscopic series [23, 24], showing that polylactic acid clips used alone seem to be as efficient as conventional staples or sutures in mesh fixation.

In inguinal hernia repair, randomised studies comparing stapled to non-stapled laparoscopic inguinal hernia repair reported promising results when the mesh was not fixed [9, 25]. However, it has been recently demonstrated that an absorbable fixation device can provide equivalent tensile strength to metallic staples in groin hernia repair [11]. In this animal study, the tissular mesh ingrowth was significantly improved when the mesh was fixed either by staples or glue compared to non-fixed meshes, thus, concluding that mesh fixation should always be performed at least during some months.

Another end point of our study was to give an answer to the difficult point of avoiding post-operative chronic pain that can impair the patient's quality of life and their psychological implications when enduring pain for more than 3 months and quoted a pain score of more than 3/10. Indeed, at this level, the pain syndrome can affect daily activity, including work, walking or sleeping [16]. At 1-year follow up, none of the 105 patients experienced this severe complication and its complex therapeutic requirements. One may note that the patients' evaluation of pain was low at discharge and can explain the hospital stay being reduced to 1.6 days for inguinal surgery and 2.9 days for incisional hernia treatment.

At 1 month, only ten patients reported weak pain (scores: 0.3–3.1) and one patient had pain >3/10.This low rate of mid-turn post-operative pain could be linked to the atraumatic shape of the I-Clip™: the reduced tissular trauma during the clip penetration seems to be a favourable property.

At 1-year follow up, all of the reported pain at 1 month (ten patients) had disappeared. This is clearly a benefit of the resorbable fixation concept of the I-Clips™ that could be one answer to pain related to nerve entrapment concern in laparoscopic surgery [20, 21, 26, 27].

Finally, at 1 year, 98% of patients (102/104) were pain-free. There was no severe chronic pain, even for ventral hernia, which often characterises other systems of fixation [14]. Only two patients who had no previous pain reported moderate pain inferior to 3/10 (with no analgesic treatment).

The pain measured in our study compared favourably with the literature. Indeed, the authors usually described chronic pain as post-operative pain persisting more than 3 months after surgery [16]. According to this criteria, chronic pain ranged from 0.4% to 22% of cases [28, 29]. Topart [12] recently reported 14.7% with tacks and a reduced rate of 4.5% with an absorbable device. Similar results have been published in a retrospective study using the same devices [30]. Our results are comparable, reinforcing the interest for a long-term resorbable fixation device and encouraging us to postulate that the resorption of the clips is correlated with a more comfortable outcome.

Only minor complications not related to the device (seroma and oedema) occurred in 5% of patients during perioperative follow up. At the end of the study, this rate of minor complications had fallen to 2%. One death occurred in the inguinal hernia group not related to the tested device.

The overall final assessment at 1 year was for no recurrence categorically related to the resorbable device, no chronic pain and no infection.

Conclusion

The reported ease of use by the surgeons, the absence of recurrence categorically related to the device and the low rate of post-operative pain reported by patients confirmed the tolerance and the effectiveness of the resorbable fixation concept I-Clip™. Further studies are in progress to confirm these initial good results.

References

1. Burger JW, Luijendijk RW, Hop WC, Halm JA, Verdaasdonk EG, Jeekel J (2004) Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg 240(4):578–583
2. Vidović D, Jurisić D, Franjić BD, Glavan E, Ledinsky M, Bekavac-Beslin M (2006) Factors affecting recurrence after incisional hernia repair. Hernia 10:322–325
3. van der Linden FT, van Vroonhoven TJ (1988) Long-term results after surgical correction of incisional hernia. Neth J Surg 40(5):127–129
4. McLanahan D, King LT, Weems C, Novotney M, Gibson K (1997) Retrorectus prosthetic mesh repair of midline abdominal hernia. Am J Surg 173(5):445–449
5. Henniford BT, Ramshaw BJ (2000) Laparoscopic ventral hernia repair: a report of 100 consecutive cases. Surg Endosc 14(5):419–423
6. Balique JG, Alexandre JH, Arnaud JP, Benchetrit S, Bouillot JL, Fagniez PL, Flament JB, Gouillat C, Jarsaillon P, Lepère M, Magne E, Mantion G (2000) Intraperitoneal treatment of incisional and umbilical hernias: intermediate results of a multicenter prospective clinical trial using an innovative composite mesh. Hernia 4(Suppl 1):S10–S16
7. Chelala E, Gaede F, Douillez V, Dessily M, Alle JL (2003) The suturing concept for laparoscopic mesh fixation in ventral and incisional hernias: preliminary results. Hernia 7(4):191–196
8. Knook MTT, Weidema WF, Stassen LP, van Steensel CJ (1999) Endoscopic total extraperitoneal repair of primary and recurrent inguinal hernias. Surg Endosc 7(5):507–511
9. Smith AI, Royston CM, Sedman PC (1999) Stapled and nonstapled laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair. A prospective randomized trial. Surg Endosc 13(8):804–806
10. Khajanchee YS, Urbach DR, Swanstrom LL, Hansen PD (2001) Outcomes of laparoscopic herniorrhaphy without fixation of mesh to the abdominal wall. Surg Endosc 15(10):1102–1107
11. Katkouda N, Mavor E, Friedlander MH, Mason RJ, Kiyabu M, Grant SW, Achanta K, Kirkman EL, Narayanan K, Essani R (2001) Use of fibrin sealant for prosthetic mesh fixation in laparoscopic extraperitoneal inguinal hernia repair. Ann Surg 233(1):18–25
12. Topart PA, Vandenbroucke F, Lozac'h P (2005) Tisseel versus tack staples as mesh fixation in totally extraperitoneal laparoscopic repair of groin hernias: a retrospective analysis. Surg Endosc 19(5):724–727
13. Lau H, Patil NG (2004) Acute pain after endoscopic totally extraperitoneal (TEP) inguinal hernioplasty: multivariate analysis of predictive factors. Surg Endosc 18(1):92–96
14. Vermeulen J, Alwayn I, Stassen LPS (2003) Prolonged abdominal wall pain caused by transfascial sutures used in the laparoscopic repair of incisional hernia. Surg Endosc 17(9):1497
15. Gillion JF, Fagniez PL (1999) Chronic pain and cutaneous sensory changes after inguinal hernia repair: comparison between open and laparoscopic techniques. Hernia 3:75–80
16. Courtney CA, Duffy K, Serpell MG, O'Dwyer PJ (2002) Outcome of patients with severe chronic pain following repair of groin hernia. Br J Surg 89(10):1310–1314
17. Amid PK (2004) Causes, prevention, and surgical treatment of postherniorrhaphy neuropathic inguinodynia: triple neurectomy with proximal end implantation. Hernia 8(4):343–349
18. Schwach G, Vert M (1999) In vitro and in vivo degradation of lactic acid-based interference screws used in cruciate ligament reconstruction. Int J Biol Macromol 25:283–291
19. Boileau P, Krishnan SG, Coste JS, Walch G (2001) Arthroscopic biceps tenodesis: a new technique using bioabsorbable interference screw fixation. Tech Shoulder Elbow Surg 2(3):153–165
20. Rosen A, Halevy A (1997) Anatomical basis for nerve injury during laparoscopic hernia repair. Surg Laparosc Endosc 7(6):469–471
21. Sayad P, Hallak A, Ferzli G (1998) Laparoscopic herniorrhaphy: review of complications and recurrence. J Laparoendosc Adv Tech A 8(1):3–10
22. Duffy AJ, Hogle NJ, LaPerle KM, Fowler DL (2004) Comparison of two composite meshes using two fixation devices in a porcine laparoscopic ventral hernia repair model. Hernia 8:358–364
23. EU Hernia Trialists Collaboration (2000) Laparoscopic compared with open methods of groin hernia repair: systematic review of randomized controlled trials. Br J Surg 87:860–867

24. Tamme C, Scheidbach H, Hampe C, Schneider C, Köckerling F (2003) Totally extraperitoneal endoscopic inguinal hernia repair (TEP). Surg Endosc 17(2):190–195
25. Ferzli GS, Frezza EE, Pecoraro AM Jr, Ahern KD (1999) Prospective randomized study of stapled versus unstapled mesh in a laparoscopic preperitoneal inguinal hernia repair. J Am Coll Surg 188(5):461–465
26. Heniford BT, Park A, Ramshaw BJ, Voeller G (2003) Laparoscopic repair of ventral hernias: nine years' experience with 850 consecutive hernias. Ann Surg 238(3):391–399, Discussion 399–400
27. LeBlanc KE, LeBlanc KA (2003) Groin pain in athletes. Hernia 7(2):68–71
28. Kumar S, Wilson RG, Nixon SJ, Macintyre IM (2002) Chronic pain after laparoscopic and open mesh repair of groin hernia. Br J Surg 89(11):1476–1479
29. Quilici PJ, Greaney EM Jr, Quilici J, Anderson S (2000) Laparoscopic inguinal hernia repair: optimal technical variations and results in 1700 cases. Am Surg 66(9):848–852
30. Schwab R, Willms A, Kröger A, Becker HP (2006) Less chronic pain following mesh fixation using a fibrin sealant in TEP inguinal hernia repair. Hernia 10:272–277