Hernia (2009) 13:505–510
DOI 10.1007/s10029-009-0524-z

ORIGINAL ARTICLE

Fibrin sealant in inguinal hernioplasty: an observational multicentre study in 1,201 patients

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Received: 13 November 2008 / Accepted: 15 June 2009 / Published online: 10 July 2009

Abstract
Purpose A prospective, multicentre, observational study was undertaken to assess Tisseel® fibrin sealant for atraumatic mesh fixation in inguinal hernia repair throughout France.
Methods Surgeons recorded data on patients undergoing tension-free inguinal hernioplasty with mesh fixation with Tisseel®, regardless of the hernioplasty technique used. Assessments were made at 2 days and 1 month after surgery. Data on local complications, operation times and ease of product use were collected.
Results In total, 1,201 patients were recruited (90% men, mean age 57 years), among which 526 procedures were performed using open techniques and 675 using laparoscopic repairs. Local complications occurred in 4.7% of patients: 3.0% haematoma, 1.4% seroma, 0.3% recurrence. The mean visual analogue scale (VAS)-rated pain scores were 3.2 pre-operatively, 2.3 immediately after surgery and 1.8 at 1 month. Surgeons rated the product as very easy to use.
Conclusions Tisseel® fibrin sealant appears to be a well-tolerated and easy-to-use alternative to traditional, tissue-penetrating devices for mesh fixation in hernia repair techniques.

On behalf of the French Tissucol Study Group in Hernia Repair.

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Keywords Fibrin tissue adhesive · Tisseel/Tissucol · Inguinal hernia · Lichtenstein hernioplasty · Laparoscopic surgery

Introduction

Inguinal hernia repair is the most frequently performed procedure in general surgery [1]. Over the last few years, the placement of a prosthetic mesh in front of the hernia orifice has become an increasingly popular strategy to prevent recurrence. Several techniques exist that require permanent fixation of the prosthesis to the abdominal wall, usually using tissue-penetrating devices like staples or sutures. However, such techniques can cause post-operative bleeding as well as pain due to nerve compression [2, 3]. In particular, most reports of chronic pain encountered after tension-free groin hernia repair are related to the use of these tissue-penetrating devices [3–5].

The recognised problem of complications associated with permanent mesh fixation methods in groin hernioplasty prompted the search for other fixation techniques. Tisseel®[1] fibrin sealant (Baxter Healthcare, Deerfield, Illinois, USA) has been proposed as an alternative, atraumatic method for mesh fixation based on its effective, proven adhesive properties, as well as its potential additional wound-healing properties [6–8].

Tisseel® is a biodegradable, biological preparation combining highly concentrated, human plasma-derived fibrinogen (75–115 mg/mL) and thrombin (500 IU/mL). The mixing of these components in the presence of calcium chloride leads to the development of a three-dimensional matrix of polymerised fibrin fibres in a process mimicking

[1] Tisseel® is also known as Tissucol® in some countries.

the last step of biological coagulation. Fibrin sealant can, therefore, be used as an adjuvant to haemostasis in a variety of surgical applications [9, 10].

In 1997, Chevrel and Rath first proposed fibrin sealant as an alternate means of mesh fixation in hernia repair, with the aim of reducing the rate of hernia recurrence [11]. Canonico et al. [9] later reported the benefits of fibrin sealant in reducing bleeding complications following hernia repair in patients with impaired coagulation. Katkhouda et al. [12] have since employed a pig model using a total extraperitoneal (TEP) technique to evaluate the tensile strength of mesh fixation 12 days after the use of Tisseel®, demonstrating equal strength to staples. The results of these studies have encouraged surgeons to use fibrin sealant in daily practice as an atraumatic alternative to mechanical mesh fixation.

In France, an estimated 87,500 tension-free hernioplasty procedures were performed in 2000 [13]. In order to assess the feasibility of a new technique of mesh fixation, we set up an open, multicentre, observational study inviting surgeons across France to report their cases of groin hernia repair involving the fixation of prosthetic meshes with Tisseel®. It was intended that this registry of data would represent real-world surgical practice in France at the time of introduction of a surgical sealant, in the absence of data from large randomised controlled trials. Here, we report data from this study focusing on the rate of recurrence, post-operative pain and complications related to haemostasis, i.e. haematoma and seroma following hernia surgery with Tisseel® as a means of mesh fixation.

Materials and methods

Design

This prospective, multicentre, longitudinal study was initiated in 2003 by Baxter Healthcare under the guidance of a scientific co-ordinator (BD). An independent clinical research organisation was employed to monitor the study and analyse the data collected.

French general surgeons performing at least 100 hernioplasty procedures per year, who were already using fibrin sealant for mesh fixation, were targeted for recruitment. This included surgeons from both private and public healthcare sectors.

Surgeons were asked to record data on adult patients who were scheduled to undergo tension-free hernioplasty, either by the open or laparoscopic approach, with Tisseel® for mesh fixation. No other criteria were stipulated by the study protocol other than that Tisseel® was to be used within its approved indication. Coagulation disorders were not excluded.

The primary outcome of interest in this study of fibrin sealant in hernia repair relates to bleeding complications, i.e. haematoma and seroma. These were seen to be reliable indicators of short-term effectiveness, given that Tisseel®'s core indication is as an adjunct to local haemostasis. Data from the 2003 Cochrane Collaboration systematic review of laparoscopic versus open techniques for hernia repair by McCormack et al. [3] indicate that the combined incidence of haematoma and seroma (excluding bruising) following either method of hernioplasty is approximately 14%. Based on this value, we estimated that we needed to enrol 1,333 cases to demonstrate a 25% reduction in bleeding complications, given a power level of 80% and a 5% two-sided significance level. Other patient-centred outcome measures studied included recurrence, pain, infections and miscellaneous complications. Rigid definitions of each outcome were not provided, as this study was intended to reflect current practice, so classifications were left to the discretion of individual investigators.

Fifty surgeons were targeted for recruitment and each was asked to provide data on 30 cases in order to achieve the target of 1,333 patients, allowing for around 10% drop-out.

Assessments

Approximately 2 weeks prior to surgery, surgeons completed a questionnaire with each patient to collect the following data: demography, hernia risk factors (prostatism, smoking, chronic constipation, chronic obstructive pulmonary disease), type of hernia, haemostasis parameters (prothrombin time, bleeding time, activated partial thromboplastin time), pain assessment (visual analogue scale [VAS], where 0 = no pain and 10 = unbearable pain) and the use of analgesic treatments.

On the day of surgery, surgeons recorded the type of anaesthesia, surgical technique, mesh, means of fixation, and duration of operation. They were also asked to complete a VAS-graded convenience score to describe Tisseel®'s ease of use (where 0 = very easy and 10 = very difficult). Surgeons were briefed to assess and report any post-operative complications occurring during the first 48 h following surgery.

At the one-month follow-up visit, surgeons examined the patients for evidence of recurrence, including careful questioning to evaluate the level of any post-operative pain relative to pre-operative symptoms. Ultrasound imaging was undertaken at the discretion of the surgeon if it was thought to be necessary to confirm recurrence. The duration of sick leave (in non-retired patients) was assessed. Surgeons also completed two additional questionnaires where appropriate: one when sutures had been used in association with fibrin sealant to fix the mesh and the other to describe the previous surgical technique that was used in case of initial recurrent hernia.

Statistical analysis

Descriptive statistics were performed on all of the parameters studied.

Ethical considerations

This study was run in accordance with the principles outlined in the Helsinki Declaration of 1964 and its subsequent amendments and in keeping with the Good Clinical Practice Guide (1988 version) and article L4113-6 of the Public Health Law of France. According to article 78-17 of French law on the freedom of access to computerised data of 06/01/78, the study protocol was approved by the French Advisory Board for the Treatment of Information Related to Research in the Health Sector and the French National Computer Council.

According to article L4113-6 of the Public Health Safety Law, the sponsor submitted the protocol and related documents to the National Medical Council (CNOM), who forwarded a favourable opinion on 27 March 2003.

Each patient was provided with an informed consent form by the operating surgeon.

Results

Collection of data

Forty-five surgeons from 42 public and private institutions of varying sizes completed study questionnaires on 1,201 patients within the allocated recruitment period of 1 year. In addition, 51 'associated sutures' and 29 'initial recurrent hernia' questionnaires were completed.

Pre-operative assessment

Of the 1,201 patients, 90% were male and 47% were sedentary workers or retired. The mean age was 57 years, with a mean height of 1.72 m and mean body weight of 73.8 kg. A total of 38% of patients had at least one hernia risk factor (among them, 39% of patients smoked and 24% had prostatism). In the vast majority of cases, hernias were inguinal (99%) and primary (93%); 79% of hernias were unilateral. The mean pre-operative VAS pain rating was 3.2, indicating moderate pain (Table 1).

Surgical technique

General anaesthesia was performed in 84% of the cases. The techniques used (Table 2) were fairly evenly divided between the open approach (Lichtenstein, 34.1%; plug and patch, 4.4%; various other open techniques such as Stoppa, 5.4%) and laparoscopic repairs (trans-abdominal pre-peritoneal patch repair [TAPP], 28.4%; totally extraperitoneal repair [TEP], 27.8%]. The overall mean duration of surgery was 39 min, with laparoscopic procedures taking slightly longer than open techniques, a result consistent with other trials [3].

In total, 23 different brands of mesh were used; the most frequently used mesh was the composite Parietex (24%). Surgeons used sutures or staples in addition to Tisseel® in 28% of patients, mainly (in 53% of cases) during Lichtenstein repair to fix the prosthesis to the pubic angle or to reduce the hernia orifice in direct hernia. Fixations were located on the pubis or on Cooper's ligament, generally with one suture/staple as per standard practice. The other reason cited for the use of sutures in addition to Tisseel® was in order to reduce the size of the inguinal orifice, and not for mesh fixation to the abdominal wall.

The amount of fibrin glue used was 1 mL in 0.4% of cases, 2 mL in 74.6% of cases and 5 mL in 25% of cases (mostly for bilateral hernia). Application devices were adapted to each kind of surgery (application needle or spray for the open techniques, soft or rigid dual-lumen catheters for laparoscopic techniques). Regardless of the application device used, surgeons found that Tisseel® was easy to apply, with a mean VAS-graded convenience score of 1.6.

Short-term follow-up

Assessed 24–48 h after surgery, patients' mean VAS-graded pain score was 2.3, indicating mild pain (Table 1).

Table 1 Assessment of pain on a visual analogue scale (VAS) pre-operatively, at 1–2 days and at 1 month follow-up

Median time of assessment	Number of answers	Number (%) of patients reporting pain	VAS score Mean (±SD)	VAS score Min–max	Number (%) of patients with VAS score >3[a]
Pre-operative (15 days before surgery)	1,158	1,049 (90.6)	3.2 (±2.1)	0–10	459 (39.6)
Short-term follow-up (2 days)	1,180	1,021 (86.5)	2.3 (±1.7)	0–10	232 (19.7)
Mid-term follow-up (34 days)	1,185	341 (28.8)	1.8 (±1.2)	0–9	25 (2.1)

VAS scale: 0 = no pain, 10 = unbearable pain

[a] Pain >3 on the VAS is considered to be moderate or severe

Table 2 Surgical techniques used, duration of operation and percentage of patients experiencing complications that could be related to fibrin sealant at 34-day follow-up

Patients	Open techniques			Laparoscopic techniques		Total
	Lichtenstein	Plug and patch	Other	TAPP	TEP	
Number (%)	408 (34.1)	53 (4.4)	65 (5.4)	341 (28.4)	334 (27.8)	1,201 (100)
Duration of operation (min), mean [SD]	33.3 [15.9]	30.8 [11.7]	40.0 [17.9]	46.0 [19.1]	39.2 [21.3]	38.8 [19.3]
Patients with haematomas or seromas (%)	5.4	3.8	4.9	3.0	2.7	4.4

TAPP trans-abdominal pre-peritoneal patch repair, *TEP* totally extraperitoneal repair

Analgesics were prescribed to 86.3% of patients reporting pain, mainly paracetamol (63.2% of prescriptions) and dextropropoxyphene (25.3% of prescriptions).

One-month follow-up

Follow-up data were collected at a median of 34 days after surgery (Table 2). Local complications that could be influenced by the use of fibrin sealant were recorded in 4.7% of patients overall: 3.0% of patients had haematoma, 1.4% seroma and 0.3% (four patients) recurrence. No cases of neuralgia at the operating site were recorded; one infection was noted. The mean VAS-graded pain score at that time was 1.8. Only 2.1% of the patients scored pain >3 on the VAS (moderate or severe). No differences in pain intensity were evident between the three most used surgical techniques. The mean (SD) duration of sick leave was 25.2 (13.5) days and was comparable between active and sedentary workers.

Discussion

Initial studies with Tisseel® fibrin sealant as a method of mesh fixation in tension-free hernia repair were promising, prompting further investigation of its utility in large, controlled trials. Such a trial has recently been completed in open inguinal hernia repair (TIMELI trial, Campanelli et al. 2007) [14], with the results expected to be published in 2009.

Tisseel® was introduced to France in 1982 and began to be used in hernia repair from 2002, a time when French surgeons were performing over 87,000 hernia repair operations per year, and quickly became popular as an alternative means of mesh fixation. In the absence of randomised controlled trial data, in 2003, it was decided to set up a registry to collect data on the use of Tisseel® as a means of mesh fixation in hernioplasty, in order to assess its feasibility. This led to the design of this large, multicentre, observational study, which concluded in 2005.

In our study of 1,201 patients, we noted the following low rates of complications at 34 days follow-up: 3.0% haematoma, 1.4% seroma, 0.3% short-term recurrence, with a mean VAS pain score of 1.8. There was one infection noted, and no cases of neuralgia at the site of operation.

Since the completion of our study, many studies that assess the use of fibrin sealant in the most popular forms of inguinal hernia repair have been published (Table 3). For example, in an Italian randomised controlled trial, Lovisetto et al. [15] compared fibrin sealant with staples as a means of mesh fixation in 197 patients undergoing TAPP repair of inguinal or femoral hernia. At 12-month follow-up, the mean VAS pain score (the primary endpoint) was significantly lower in the sealant group (19 vs. 26 mm; $P < 0.05$). One haematoma/seroma was noted in the staples group and one recurrence in the sealant group. In another Italian randomised controlled trial of TAPP hernioplasty, 600 patients received fixation with one of three different tack systems or fibrin sealant [16]. After 1 month, no recurrences were observed in any group, but morbidity was generally lower with Tisseel®, with more rapid return to work noted.

A French study by Topart et al. [17] focused on TEP repair: fibrin sealant was used for mesh fixation in 66 patients, compared with staple fixation in 102 patients. Adequate mesh fixation was achieved with a lower incidence of chronic post-operative pain with fibrin sealant versus staples (4.5 vs. 11.8%, respectively). Lau [18] compared outcomes with fibrin sealant and staple fixation following simultaneous bilateral TEP in 93 patients, demonstrating a significant reduction of analgesic consumption in the fibrin sealant group. There was a small increase in the incidence of post-operative seroma, although this was not considered to be clinically significant. Finally, Olmi et al. [19] performed intra-peritoneal onlay mesh (IPOM) fixation with fibrin sealant in 60 selected patients. After an average of 23.7-months follow-up, one patient experienced trocar-site haematoma, but no other complications were observed.

Table 3 Recently published prospective studies on the use of fibrin sealant in hernia repair, by surgical technique

Technique	Author [references]	Year	Number of patients (hernias) treated	Follow-up (months)	Recurrence	Haematoma	Chronic pain
TAPP	Lovisetto et al. [15][a]	2007	99	12	1.0%	0	1.0%
TAPP	Olmi et al. [16][a]	2007	600 (803)	1	0	–	–
TEP	Topart et al. [17]	2005	66	23.9	1.5%	4.5%	4.5%
TEP	Lau [18][a]	2005	46	14.4	0	–	13.2%
IPOM	Olmi et al. [19]	2007	60 (61)	23.7	0	1 patient	–
Lichtenstein	Canonico et al. [20]	2005	80	12	0	0	2.5%
Lichtenstein	Hidalgo et al. [21]	2005	55	12	0	0.02%	0

TAPP trans-abdominal pre-peritoneal patch repair, *TEP* totally extraperitoneal repair, *IPOM* intra-peritoneal onlay mesh

[a] Randomised controlled trial

Regarding the Lichtenstein technique, Canonico et al. [20] assessed the use of fibrin sealant in 80 patients in an Italian study with 12 months follow-up. No complications were observed, and the use of fibrin sealant was considered to be effective for the prevention of local haemorrhagic complications after herniorrhaphy in patients with coagulation disorders [9]. A Spanish study by Hidalgo et al. [21] assessed mesh fixation using fibrin sealant compared with polypropylene sutures in 55 patients treated for bilateral hernia using the Lichtenstein technique. Fibrin sealant and sutures were used for contralateral hernias in each patient. Similar overall outcomes were reported in both inguinal regions, but there was less post-operative pain and less inflammatory reaction associated with fibrin-fixed hernia repairs. Once again, there were no recurrences after 1 year of follow-up.

The results of our observational study complement the findings of other studies comparing fibrin sealant with standard mesh fixation methods, and suggest that fibrin sealant may yield fewer haematomas, seromas, recurrences and less post-operative pain than mechanical means of mesh fixation. The surgeons in our study found the sealant to be easy to use and operation times appear similar to studies reporting on mechanical forms of mesh in both open and laparoscopic hernia repair fixation [3]. In terms of cost, the price of 2 mL of fibrin sealant (the most commonly used dosage) is similar to that of staples. Clearly, large controlled trials are needed to confirm or disprove these promising indications and we eagerly await the results of the TIMELI trial.

In terms of study limitations, we achieved only 90% of the target patient population before the end of the 1-year recruitment period precluded further enrolment. However, a cohort of 1,201 patients still represents a very large sample.

Given the design of this study, some other limitations deserve mention. In particular, the short-term follow-up is a major shortcoming, and a comprehensive attempt to obtain 12-month follow-up data would have yielded worthwhile information. Perhaps one might have expected to see slightly higher recurrence rates at 12-months follow-up. It is also possible that some small seromas or haematomas may have arisen and resolved between the 2- and 34-day follow-up assessments. The absence of a pre-defined classification system for each complication may also be criticised, as might be the absence of standardised operating procedures, including precise methods for mesh fixation. However, it is important to remember that this study was initiated to collect data reflecting the widespread use of Tisseel® for hernia repair in day-to-day surgical practice in 2003–2004, in the absence of randomised control data. This is the first study of its type in France and remains the largest of its kind in this country. Data from 42 institutions were collected, providing a robust and highly generalisable representation of Tisseel® use in hernia surgery from across the nation.

Conclusion

With a total of 1,201 patients enrolled, this study is the only large-scale French study on the use of fibrin sealant in hernia repair and provides epidemiological support for the use of Tisseel® fibrin sealant in the fixation of prosthetic mesh during groin hernia repair. Fibrin sealant is an appropriate, atraumatic, easy-to-use alternative to the traditional, tissue-penetrating mesh fixation devices used during common hernia repair techniques (Lichtenstein, totally extraperitoneal repair [TEP] and trans-abdominal pre-peritoneal patch repair [TAPP]). In our study, the use of Tisseel® was associated with a very low recurrence rate (0.3%), as well as a low rate of local complications (4.7% overall), and few patients experienced post-operative pain at 1-month follow-up, which has an important impact on the overall patient

satisfaction with surgery. Fibrin sealant appears to be a promising alternative to stapling/suturing for mesh fixation during inguinal hernioplasty. The results of large randomised trials such as the TIMELI trial are keenly anticipated.

Acknowledgments This study was conducted with funding from Baxter BioSurgery, France, to facilitate study monitoring and data management, which was performed by an independent clinical research organisation, Mapi-Naxis, France.

Appendix

Members of the French Tisseel®/Tissucol® study group in hernia repair: Maxime-Boris Alamowitch, Tours; Jean-Gabriel Balique, Saint-Priest-en-Jarez; Pierre Batiste, Cahors; Olivier Baubion, Sarcelles; Marc Bertaux, Gonesse; Jean-Pierre Bobois, Niort; Norbert Boumal, Dax; Roland Boustani, Fleury les Aubrais; Eric Bozon-Verduraz, Toulon; André Caamano, Bastia; Gaétan Capuano, Auxerre; Christian Cave, Tarbes; Philippe Chastan, Lormont; Olivier Czyglik, Sainte-Colombe; André Dabrowski, Seclin; Michel Debaert, Lille; Hervé Delacroix, Marcq-en-Baroeul; Dominique Delarue, Saint Grégoire; Yves Dernier, Sens; François-Charles Desmaizières, Paray le Monial; Didier Dromer, Saint-Quentin; Philippe Espalieu, Saint-Etienne; Florent Gerdil, Valence; Jean-André Gioan, La Valette du Var; Fouzi Lachachi, Limoges; Georges Marachly, Drancy; Frédéric Martin, Bar le Duc; Jean-Christophe Martinot, Lille; Jean-Loup Massard, Châlon-sur-Saône; Franck Maisonnette, Limoges; Pierre Mazarguil, Nice; Philippe Roge, Mainvilliers; Christian Rohr, Strasbourg; Christian Rosburger, Talant; Stéphane Rossi, Rouen; Yves Russier, Carpentras; Michel Sage, Auxerre; Bassam Tantawi, Quincy-sous-Sénart; Philippe Topart, Angers; Jacques Tussiot, Rosny-sous-Bois; Patrick Van Box Som, Lyon; Sorin Vartolomei, Nice; Michel Vazeux, Fontainebleau; Constantin Zaranis, La Rochelle.

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