

Fibrin Sealant versus Use of Tackers for Fixation of Mesh in Laparoscopic Inguinal Hernia Repair

Pramod T Shinde

Consultant Laparoscopic Surgeon, Bhagwati Hospital, Mumbai, Maharashtra, India

Abstract

Background: Laparoscopic fixation of meshes prior to their fibrous incorporation should be reliable to minimize recurrences following transabdominal preperitoneal hernia repair (TAPP) and totally extraperitoneal repair (TEP) repair of inguinal hernias. However, suture, tack and staple-based fixation systems are associated with postoperative chronic inguinal pain. Initial fixation with fibrin sealant offers an atraumatic alternative, but there is little data showing that fibrin-based mesh adhesion provides adequate biomechanical stability for repair of inguinal hernia by TAPP and TEP.

Methods: A literature search was performed using medline and the search Google, Springer link and Highwire press. The following search terms were used: *Laparoscopic hernia mesh, Fibrin glue, and Tackers*. 2293 citations were found in total. Selected papers were screened for further references. Criteria for selection of literature were the number of cases (excluded if less than 80), methods of analysis (statistical or nonstatistical), operative procedure (only universally accepted procedures were selected) and the institution where the study was done (specialized institution for laparoscopic surgery).

Results: Mesh fixation has always invited lots of interest amongst surgeons and instrument companies due to the wide range of post-operative complications each of them caused. TAPP and TEP usually involves fixation of mesh, however many studies challenging the mesh fixation in TEP are being published. There are two most common methods of fixing mesh using fibrin glue (Tissucol) and tackers. Fibrin sealant possesses both mechanical strength and elasticity. Overall, data from previous studies, shows that mesh stability with fibrin sealant fixation is at least equivalent to suture fixation, indicating that fibrin sealant could be considered the fixation method of choice in inguinal hernia repair. This new method of mesh fixation is obviously potentially less harmful than stapling the mesh and can help reduce the risk of chronic postoperative pain at a comparative or even lower cost than a stapling device.

Conclusions: Fibrin glue gives an adequate mesh fixation with a less chance of chronic postoperative pain. It appears to be an alternative to staples and may help reduce the postoperative pain problems after hernia repair. All methods give 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. However the use of fibrin glue needs extensive study, 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. Large randomized trials and longer follow-up are required to demonstrate the advantages of either technique.

Keywords: Laparoscopic hernia mesh repair, fibrin sealant and tackers, mesh fixation.

INTRODUCTION

Laparoscopic repair of inguinal hernias can be accomplished by totally extraperitoneal (TEP) or transabdominal preperitoneal (TAPP) techniques. It involves mesh fixation to avoid displacement and recurrence. Fixation usually uses staples that can lead to nerve injury and chronic postoperative pain.¹⁻⁴

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.⁷ 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. Anyhow, some complications of laparoscopic hernia repair, such as nerve injury (chronic postoperative pain, neuralgias, pubalgias) and hematomas in the Retzius space (bleeding from vascular lesions) are inherent to the use of the staples.¹⁰

Fibrin glue (Tissucol/Tisseel, Baxter health care, Deerfield, IL, USA) offers an atraumatic alternative, but there is insufficient data giving direct evidence whether fibrin-based mesh adhesion provides adequate biomechanical stability.^{9,11}

Tackers are associated with a certain amount of surgical trauma and complications such as neuralgia or paresthesia because of nerve entrapment. Pubalgia is caused by stapling of the prosthesis to Cooper's ligament. Bleeding or hematomas in Retzius space (muscular, corona mortis) also can occur. In terms of tensile strength and mesh dislocation, fibrin glue is equivalent to stapling and better than no fixation of the mesh.

Some data suggest that mesh fixation is not needed for preserving satisfactory long-term results, stapling of the mesh

to avoid displacement and reduce the risk of recurrence prevails among surgeons. The chronic pain that may persist in the groin area postoperatively is one of the most serious problems that may affect the results of hernia surgery.

Postoperative chronic pain is defined as pain persisting more than 3 months after the operation. The prevalence of chronic postoperative pain after hernia surgery ranges from 3% to 54%.¹² Although laparoscopic repair appears to be significantly less likely to induce postoperative chronic pain this type of complication is still reported up to 22.5% of patients.¹⁴ Stapling of the mesh, which may lead to nerve injury and osteitis pubis, has been identified as one of the possible causes of the persistence or development of pain after hernia surgery.^{15,17}

AIMS AND OBJECTIVES

The aim of this study was to compare the effectiveness and safety of using fibrin sealant and tackers for mesh fixation in laparoscopic inguinal hernia repair based on:

- Operative time
- Discharge period
- Complications
 - Groin chronic pain
 - Hematoma of scrotum
 - Seroma
 - Trocar hernia
 - Trocar site bleeding
 - 10 mm trocar site pain
- Recurrence rate

MATERIAL AND METHODS

A literature search was performed using medline and the search Google, Springer link and Highwire press. The following search terms were used: *Laparoscopic hernia mesh, Fibrin glue, and Tackers*. 2293 citations were found in total. Selected papers were screened for further references. Criteria for selection of literature were the number of cases (excluded if less than 80), methods of analysis (statistical), operative procedure (only universally accepted procedures were selected) and the Institution where the study was done (specialized institution for laparoscopic surgery).

Content

Mesh fixation has always invited lots of interest amongst surgeons and instrument companies due to the wide range of postoperative complications each of them caused.¹⁹ TAPP and TEP usually involves fixation of mesh, however many studies challenging the mesh fixation in TEP are being published.²² There are two most common methods of fixing mesh using fibrin glue (Tissucol) and tackers.

Ideal Mesh

Ideally, modern hernia mesh fixation methods should be compatible with the mechanical properties of the mesh. A

breaking strength of 16-32 N is the minimum required. Also, the fixation aid should tolerate elasticity in the range of 20-30% in new meshes, without provoking rigid shear forces. Fibrin sealant possesses both of these mechanical properties. Overall, data from previous studies, shows that mesh stability with fibrin sealant fixation is at least equivalent to suture fixation, indicate that fibrin sealant could be considered the fixation method of choice in inguinal hernia repair. Tissucol_/Tisseel_ fibrin sealant has been approved in Germany for the indication of mesh fixation in hernia surgery.

Fixation of the Prosthesis

Mesh is fixed with 1 ml of Tissucol for unilateral hernias and 2 ml for bilateral hernias. The prosthesis is fixed along its upper margin, from Coopers ligament to the *triangle of disaster* and to the *triangle of pain*, using a 3 mm catheter (Duplotip; Baxter health care), which fits the Tissucol syringe. The mesh also may be fixed wherever necessary to increase its stability. Tissucol may be applied in two different ways: by resting the tip of the Duplotip catheter where the mesh is to be fixed and by squeezing out a few drops of glue. With the latter method, the glue seeps across the mesh and fixes it. One also can separate the mesh slightly from the inguinal wall, spray the glue directly on it, and then place the mesh to the wall. The two methods appear to be comparable.

Postoperative Complications

After a 23.7 months follow-up regarding postoperative pain, hospital stay, complications and recurrence, together with short term resumption of regular physical activity show the efficacy and safety of this technique. The results are better considering there is no dissection of peritoneal structures that mesh fixation is completely nontraumatic and the procedure is easily reproducible.

With the use of Tissucol as the means of fixation (in both TAPP and TEP techniques) there is decreased neuralgia, caused mainly by staples placed in proximity to one of the several nerves that course below the ileo-pubic tract with a percentage varying from 0 to 19.6%.^{18,20,21,24,27,31} Stapling Cooper's ligament may cause pain through osteitis, as stated by Toy.³¹ Regarding long-term results in terms of seroma and recurrence, the former are avoided by the porous structure of the mesh and by the no structural dissection procedure. There is an argument going on as to how long follow-up has to last to assess recurrences correctly.

Stoppa et al, showed that recurrences usually occur during the first postoperative year.³⁰ It's important for the mesh to overlap the defect by 3 or 4 cm and to properly fix it with Tissucol. Pascal's hydrostatic law states that pressure applied within a limited space is transmitted equally in all direction. If the mesh lies well over the defect, it will be kept in place by the abdominal pressure.³⁰ There are two kind of meshes for these procedures,

paramount and parietex (Sofradim) which seems ideal because it is easily glued and the polyester structure is rapidly integrated into the peritoneum. This is also helped by fixing with Tissucol.

Polyester is a reticular knit able to promote genesis of new vessels, whilst polytetrafluoroethylene (PTFE) is of laminar structure, and enhances cellular infiltration of the outer third of the structure. Newly formed vessels do not penetrate PTFE because the laminar interface is not as good as the reticular one. Polyester is also better because it causes a milder inflammatory reaction and a great fibroblastic proliferation. For these reasons we believe polyester and fibrin glue to be the biomaterials of choice for peritoneal only laparoscopic hernioplasty.

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 repair²⁷ to reach a recurrence rate similar to that of the Lichtenstein's technique. This is not correct, as a young surgeon who works in a minimally invasive 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 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).

A laparoscopic or conventional open approach to repair inguinal hernia is used 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 paresthesia) caused by entrapment from incorrect placement of staples (above all lateral cutaneous 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 technique²⁵ 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 neuropathic complications.^{13,32,33} In our total review, the incidence is very low (0.09%) as surgeons 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. It is important to reach an 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. 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 intraoperative 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.

The 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 is 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

Results and complications (832 Patients)

	<i>Fibrin glue use</i>	<i>Staples use</i>
Operative time (minutes)	35	25
Discharge (hours)	24	24
Complications:		
• Groin chronic pain	0%	0%
• Hematoma of scrotum	0%	1.14%
• Seroma	2.4%	2.29%
• Trocar hernia	0%	1.14%
• Trocar site bleeding	0%	4.41%
• 10 mm trocar site pain	0%	5.88%
Recurrence rate	0	0

Using the TAPP technique, chronic pain was only observed in 0.13%. A statistically significant difference was found concerning postoperative pain 30 days after surgery on the right flank in the area of the 10 mm trocar. Other differences that are worth mentioning are those related to some postoperative complications due to the 10 mm trocar on the right flank: reduced bleeding, reduced postoperative discomfort and the lower risk of incisional hernias. This was a pilot study; it of course needs confirmation in a larger randomized trial.

In some studies, TAPP hernia repair with Tissucol resulted in a low rate of postoperative pain and rapid resumption of normal activities. Postoperative complications affected only 2.2% (7/320) of the hernias and were readily treated without the

need to extend the hospital stay. Importantly, no recurrences have been observed in this study. These results compare favorably with those reported by other studies of laparoscopic hernia repair. A multicenter study of 9,955 laparoscopic hernia repairs reported postoperative complication rates of 4.6% for hematomas, 2% for neuralgias, and 0.4% for chronic pain.⁴⁶ Reports of persistent neuralgia with inguinal pain attributable to stapling vary in the literature from 0.5 to 14%.^{37,41,46}

In a study by Stark et al,⁴⁹ the rate of nerve entrapment in laparoscopic patients was 4.2% (19/448). The genitofemoral nerve was affected with a high frequency (2%), and the ilioinguinal or lateral cutaneous nerve of the thigh was affected in 1.1% of the cases.

Some studies have investigated the use of mesh without any fixation. Like the application of fibrin glue, this method is nontraumatic because it avoids all stapling problems.²³ Ferzli et al³⁹ reported a 1.8% recurrence rate for patients without fixation of their prosthesis. Other studies comparing stapling without fixation of the mesh found no difference.^{41,47,48} However, these studies have been criticized as having too few patients, too short a follow-up period (range, 1-32 months), or too great a loss to follow-up evaluation (8-12% of patients).^{5,6} The size of the prosthesis is an important factor.

In few experience, fixation of a 14.13 cm mesh ensures better prosthesis stability, and consequently less dislocation and recurrence. The use of smaller stapled prostheses (11.6 cm) is associated with recurrence rates of up to 5%, whereas patients treated using TAPP with no mesh fixation have recurrence rates as low as 0.16%.^{41,47} Inadequate lateral fixation is a main cause of recurrence after both TAPP (36%) and TEP (22%).³⁸ The reason for this is that most of the nerves run laterally where no staples can be applied.

Gluing a large mesh on the triangles of disaster and pain is likely to stop the prosthesis from lifting and dislocating, thereby avoiding inferomedial and inferolateral recurrence,³⁸ as seen in 0.4% (3/715) of the hernias treated with staples.⁴⁵ Fibrin glue is reported to have hemostatic properties, thus reducing seroma and hematoma formation.⁴⁴

In other study, the incidence of postoperative seromas was 1.8% (6/320), whereas the incidence reported in the literature varies from 3.8 to 10.5%.^{40,41,47} Tissucol also is cheaper than any other means of mesh fixation. For example, 1 ml of Tissucol costs e80, as compared with e300 for Endoanchor (Ethicon Endo-Surgery) and e250 for Protak (Tyco, Norwalk, CT, USA). The use of fibrin glue instead of stapling means that the TAPP procedure is nontraumatic and minimally invasive, as evidenced by the absence of inguinofemoral pain in this study.³⁶

In an animal study in which TEP groin hernia repairs were performed, Katkhouda et al.⁴³ demonstrated that graft motion and tensile strength were similar in the staples and fibrin glue groups, and both were significantly superior compared to those

of the nonfixed mesh group. In addition, histological examinations revealed that the fibrin glue triggered a stronger fibrous reaction and inflammatory response with more fibroblastic mesh ingrowth in comparison to the other two groups. This again suggests that mesh fixation is preferable and that the fibrin glue meets the requirements for both efficiency and security of fixation.

It applies particularly to unilateral TEP repairs but more so to bilateral repairs in which the dissected space for the mesh implantation is the same as the working space, making it larger than needed for mesh placement as opposed to the space in which mesh is placed in TAPP repairs. The recurrence rate in the fibrin glue group was slightly lower than in the tack staples group but did not differ significantly, and the case of recurrence reported in the fibrin glue group is probably related to an inadequate mesh size in a large direct hernia. Overall, the recurrence rate in the fibrin glue group remains within the value range of most of the reports on TEP repairs irrespective of mesh fixation.^{39,49,52}

DISCUSSION

During the past few years, there has been more focus on the pain that may arise after groin hernia surgery. Chronic pain after hernia surgery is a complex and controversial problem that affects not only open but also laparoscopic procedures. Three pain syndromes have been identified: somatic, neuropathic, and visceral pain.⁴² Besides nerve damage during dissection, thermal injury due to electrocautery, and inflammatory and/or mechanical reaction to the mesh, stapling of the mesh is the most frequent evocated mechanism.^{34,45,48}

Among other potential factors causing postoperative pain is the repair of recurrent hernias. There is a great variation in the rate of postoperative chronic pain, ranging from 0.1 to 0.4% and 22.5%^{41,45,49} in laparoscopic repairs for which staples are used to attach the mesh. Among the explanations for such a wide discrepancy are the range of pain evaluation methods used, which include clinical examination of the patients, phone calls, and mailed questionnaires and tools to score the severity of the pain. Some studies have reported only cases of pain clinic attendance, possibly underestimating the problem.⁸

The rate of chronic postoperative pain observed in the tack staples group (14.7%) is among the highest reported in the literature,^{45,49} but it included all patients who reported even transient or mild pain in the long-term. To date, the series reporting the lowest postoperative chronic pain rates have not used any means of mesh fixation.^{34,35,52}

Tamme et al.⁵² and Beattie et al.³⁴ observed 2.55 and 0% chronic pain problems, respectively, after TEP repair, with a recurrence rate of less than 0.6%. However, the largest of these two series did not specify the length of follow-up and the other one was a rather small series (n = 89). Although two randomized studies with a short follow-up of nonfixed mesh in laparoscopic

repairs (one in TEP and the other in TAPP) did show promising results in terms of recurrence,^{40,51} justification for routine nonstapling of the mesh in TEP is not yet substantiated.¹³ The low rate of chronic pain complications was similarly observed in many studies by avoiding stapling. This confirms that mesh stapling does play a key role in generating postoperative pain after laparoscopic hernia repair.⁵⁰ The compared studies had a relatively short follow-up with a small number of patients and different evaluation periods, the procedures compared were identical except for the fixation means in two similar groups of patients.

It is not known if the enhanced inflammatory response induced by fibrin glue,⁴⁴ may explain the slightly higher-rate of seromas in the fibrin glue group (12 vs 9.8%). This minor complication is generally associated with direct hernias. In addition, there is no report of any other complications (fever or local inflammation) that could be related to an enhanced inflammatory process. Among the explanations for the increased inflammatory reaction in the animal study is the use of human fibrin glue in pigs.⁴⁴

There was no significant difference in the development of postoperative hematomas, although the rate was slightly lower in the fibrin glue group, in which one of the three patients with hematoma had to be operated on while on calciparin. In this study, it is impossible to attribute the lower risk of hematoma to the effect of Tisseel on local hemostasis.³⁷ Although no comparison is available between the tack staples group and the fibrin glue group in terms of operation duration, the use of Tisseel and its application device did not seem to change the mean operative time of 54 minutes, which is comparable to that of other series using stapling or not,^{46,52} as long as the fibrin glue is prepared during the hernia sac dissection. The only difference in terms of operating costs between the two series was in the fixation devices. Two milliliters of Tisseel is available for 149 USD, whereas the single-use tacker stapler is 287 USD.

In conclusion, there is no evidence in the literature to support nonfixation of the mesh in TEP repair of groin hernias, whereas the use of staples has been identified as one of the factors for postoperative chronic pain. Although prospective randomized trials should be performed. Tisseel fibrin glue for mesh fixation is secure as the tack staples, ensuring an adequate fixation and a low recurrence rate. This new method of mesh fixation is obviously potentially less harmful than stapling the mesh and can help reduce the risk of chronic postoperative pain at a comparative or even lower cost than a stapling device.

CONCLUSION

Fibrin glue gives an adequate mesh fixation with a less chance of chronic postoperative pain. It appears to be an alternative to staples and may help reduce the postoperative pain problems after hernia repair. All methods give the same results in terms of recurrence rate, hospital stay, and costs; but with better results

in terms of postoperative pain, seromas, and trocar-related trauma. However the use of fibrin glue needs extensive study, 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. Large randomized trials and longer follow-up are required to demonstrate the advantages of either technique.

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