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ORIGINAL ARTICLE

# Open inguinal hernia repair by plug and patch: the value of fibrin sealant fixation

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**Abstract**
*Background* Prosthetic meshes give excellent results in groin hernia repair. However, although recurrence rates are very low, chronic pain remains frequent and mesh fixation may play a role in the occurrence of this complication. The use of fibrin sealant to secure the mesh may represent a useful alternative for the prevention of chronic pain. The aim of this study is to confirm that the mesh may be secured by spraying fibrin sealant and to assess the reduction in the incidence of chronic pain.
*Methods* Seventy hernias were operated on in 57 patients and were evaluated on a prospective basis. The procedure involved placement of a plug and patch mesh which was secured with fibrin sealant alone. These patients were compared to a matched retrospective series of 57 patients who underwent the same procedure, except that conventional non-absorbable suture was used to secure the mesh.
*Results* The two groups were equivalent for inclusion criteria and preoperative data. The complication rate was similar in the two groups. The operative time was shorter in the fibrin sealant group: 7 min for unilateral hernia ($p = 0.0017$) and 16 min for bilateral hernia ($p = 0.0008$). The length of hospital stay was also shorter in the fibrin sealant group (1.8 days vs. 2.5 days: $p < 0.0001$). There was no recurrence in the fibrin sealant group after a minimum follow-up of 12 months and no recurrence in the suture group after a minimum follow-up of 25 months. Finally, a significant reduction in chronic pain was observed in the fibrin sealant group (3.5% vs. 22.8%: $p = 0.042$).
*Conclusion* This study confirms the effectiveness of fibrin glue in securing prosthetic meshes and reducing chronic inguinal pain.

**Keywords** Fibrin sealant · Groin hernia · Prosthetic mesh · Chronic pain

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## Introduction

Groin hernia is a particularly frequent surgical disease, as nearly 800,000 patients are operated on every year in the United States [1], making this disease a major public health issue.

Moreover, surgical techniques have continued to evolve. Bassini in 1889 then Shouldice in 1945 first codified hernia repair [2]. During the last 20 years, there has been considerable debate about the value of using mesh prostheses for wall reinforcement. Meta-analysis finally showed that the incidence of recurrence was lower after mesh repair [3]. These simple and rapid techniques have become very widely used and today account for 80–90% of groin hernia operations [1].

The prosthetic material used is secured by either using a conventional suture or with staples, in particular, in laparoscopic surgery. Despite the "tension-free" nature of these hernioplasties, sutures may cause strangulation of muscle fibres or even a lesion or compression of the regional nerves, leading to invalidating pain or dysesthesia. The incidence of these chronic

complications was underestimated for a long time and is currently estimated to be between 0% and 75.5% [4, 5].

With the reduction or even disappearance of recurrences, this morbidity is now of primordial importance and we therefore decided to modify the method used to anchor prostheses. After a preliminary feasibility study in animals [6], we chose a fixation method with the application of biological glue.

The objective of this study is to assess the value of biological glue for mesh fixation and to determine if it induces a reduction in chronic postoperative pain.

## Patients and methods

### Study period and population

Fifty-seven consenting patients who had been followed up for more than 12 months were included in this study and were evaluated prospectively. A total of 70 hernias were operated on (44 unilateral and 13 bilateral hernias).

The diagnosis was confirmed by the anamnesis and clinical examination. Apart from the preoperative assessment required for anaesthesia, no additional examination was carried out.

The inclusion and exclusion criteria are summarised in Table 1.

The data were compared to a retrospective series of 57 patients operated on between January 2001 and January 2004 using the conventional repair procedure with suture for mesh fixation according to Robbins and Rutkow [7]. The inclusion criteria of this group were identical and the preoperative data of the patients were matched to obtain two homogeneous groups.

All patients of each group were contacted to be interviewed and examined at the point of statistical analysis of this study. The objective of the clinical examination was to detect a recurrence. For the postoperative pain sequelae, a standardised questionnaire was given out and analysed for all patients of the two groups. The criteria defined by Cunningham et al. [8] were used to establish this questionnaire and to characterise the chronic pain as follows:

- Mild: occasional pain or discomfort that did not limit activity, with a return to pre-hernia lifestyle
- Moderate: pain preventing return to normal preoperative activities (inability to continue any sports or to lift objects without pain)
- Severe: pain constantly or intermittently present but so severe as to impair normal activities, such as walking

**Table 1** Inclusion and exclusion criteria

| Inclusion | Exclusion |
|---|---|
| Age > 18 years | Age > 80 years |
| Elective surgery | Emergency (incarceration, strangulation) |
| "Primary" hernia | Recurrence |
| Inguinal hernia | Crural hernia |
| Follow-up > 12 months | Follow-up < 12 months |
| | Recent infection (operative site or general sepsis) |

### Surgical and anaesthetic technique

General or spinal anaesthesia was used.

Antibiotic prophylaxis with cephazolin (single dose of 2 g) was administered on induction.

Identical surgical procedures were used for the fibrin sealant group and suture group, apart from the method used to secure the prostheses. They were all carried out by the same operator.

An inguinal incision of 5–6 cm was made to expose the external oblique aponeurosis. The genital branches of the abdominogenital nerves were separated from the aponeurosis and then reclined. The upper and lower leaves of the external oblique muscle were largely separated from the underlying tissues in order to establish a space to allow the subsequent placing of the mesh.

The spermatic cord was then dissected and separated from the posterior wall. The cremaster muscle was incised longitudinally. Two flaps were therefore isolated and resected. In the case of external oblique hernia, the sac was separated from the cord, resected and then closed with a suture of absorbable suture material. In the case of direct hernia, the transversalis fascia was opened and partially resected. The sac was either excised or reduced, depending on its volume.

The plug (Bard PerFix Plug) was then inserted through the deep inguinal ring. In the glue group, it was secured with fibrin sealant at four points (Tissucol, Baxter, Deerfield, IL, USA) on the deep face of the conjoined tendon. In the suture group, fixation was ensured by four non-absorbable sutures.

The split oval-shaped mesh (Bard PerFix Plug) was then slipped behind the cord and spread on the external oblique aponeurosis.

In the fibrin sealant group, a single point was required to close the slit of the prosthesis and, thereby, encircle the spermatic cord. This point is only supported by the sides of the mesh and never by the tissues. Two millilitres of Tissucol was then sprayed on the anterior side of the mesh. In the suture group, the

prosthesis was fixed to the crural arcade and conjoined tendon by interrupted non-absorbable sutures.

The aponeurosis was then closed posterior to the cord structures by a suture.

The operation was terminated by suture of the subcutaneous tissue and skin by an absorbable suture. No drainage system was necessary.

### Postoperative period and follow-up

Patients were monitored in a recovery room for a minimum of 2 h. Systematic analgesia by class 1 analgesics was instituted. Depending on the pain evaluated by the patient using a visual scale, it was possible to combine non-steroidal anti-inflammatory drugs, class 2 analgesics or even opioids.

Anticoagulant therapy with low molecular weight heparins was prescribed throughout the hospital stay.

Intake of liquid food was resumed in the evening after the operation and a normal diet as from the following day.

Patient discharge to home was authorised from D1 after surgery, depending on the patient's age and autonomy.

### Statistical analysis

Categorical variables were compared according to surgical technique (suture or glue) with the $\chi^2$ law or hypergeometric law (exact Fisher test) when at least one of the expected sample sizes was lower than 5; for continuous variables, the means were compared by Student's $t$ test for unpaired series. The same methods were used to compare patients with or without pain after the operation.

The relationship between the operative time and the surgical technique was assessed after adjusting the data according to the unilateral or bilateral nature of the hernia.

Type I risk was fixed at 5%. The Data were analysed with Statview F-5.0 (SAS Institute Inc.).

## Results

### Preoperative data

Nearly all of the 57 patients operated in the two groups were males: 54 men, 3 women.

The average age in the fibrin sealant group was 60.8 ± 12.6 years (range: 35–80); 45.6% (26/57) were active workers or sportsmen. The average age was 59.2 ± 13 years (range: 33–79) in the suture group; 42.1% (24/57) of the patients were active.

A risk factor was found in 35.1% (20/57) of the patients in the glue group vs. 42.1% (24/57) in the suture group.

The mean body mass index was 24.7 ± 3.2 (range: 17.3–40.5) in the glue group vs. 24.8 ± 3.4 (range: 17.8–33.1) in the suture group.

In the fibrin sealant group, the hernia was on the right in 34 cases, on the left in 10 cases and bilateral in 13 cases. In the suture group, the hernia was on the right in 30 cases, on the left in 14 cases and bilateral in 13 cases.

Overall, there was no statistical difference observed between the preoperative data validating the matching of the two groups. All of the data are summarised in Table 2.

**Table 2** Preoperative data

| | "Fibrin sealant" group | "Suture" group | $p$ |
|---|---|---|---|
| Age | 60.8 ± 12.6<br>Range: 35–80 | 59.2 ± 13<br>Range: 33–79 | NS; $p = 0.5122$ |
| Gender | 54 men<br>3 women | 54 men<br>3 women | NS; $p > 0.9999$ |
| BMI | 24.7 ± 3.2<br>Range: 17.3–40.5 | 24.8 ± 3.4<br>Range: 17.8–33.1 | NS; $p = 0.9781$ |
| Lifestyle | Active: 26/57 (45.6%)<br>Sedentary: 31/57 (54.4%) | Active: 24/57 (42.1%)<br>Sedentary: 33/57 (57.9%) | NS; $p = 0.8503$ |
| Laterality | | | |
| Bilateral | 13/57 | 13/57 | NS; $p = 0.6323$ |
| Right | 34/57 | 30/57 | |
| Left | 10/57 | 14/57 | |
| Risk factors | | | |
| Smoking | 10 | 11 | NS; $p = 0.5975$ |
| Prostatism | 6 | 5 | |
| BPCO | 4 | 6 | |
| Constipation | 0 | 2 | |
| Total | 20/57 (35.1%) | 24/57 (42.1%) | |

### Intraoperative data

Forty-nine operations (86%) were carried out under general anaesthesia in the glue group vs. 45 (78.9%) in the suture group. Spinal anaesthesia was performed in all of the other cases.

No intraoperative complication was noted in the two groups.

After adjusting the data according to the unilateral or bilateral nature of the hernia, we observed a reduction of 7 min in the operative time in the cases of unilateral hernia ($p = 0.0017$) and 16 min in the cases of bilateral hernia ($p = 0.00018$) in favour of the fibrin sealant group. The median operative times are given in Table 3.

### Immediate surgical outcome

At day 1, for the fibrin sealant group, the average post-operative VAS pain score was 2.1/10 ± 1.5 (range: 0–7). The results are summarised in Fig. 1

The pain score at day 2 has not been analysed, since a majority of patients had left the hospital.

In the suture group, these data were absent because of the retrospective database.

The overall complication rate was 8.8% (5/57) in the fibrin sealant group vs. 12.3% (7/57) in the suture group. Surgery had to be resumed in one patient in the suture group presenting with a post-operative haematoma. The occurrence of a haematoma was more frequent in the suture group, though this difference was not significant.

All of the complications are summarised in Table 4.

In addition, the hospital stay was significantly shorter in the glue group (1.8 ± 0.9 vs. 2.4 ± 0.7 days: $p < 0.0001$).

### Complications during follow-up

As the control group comprised a historical series, the average follow-up was longer in the suture group (40 ± 9.2 vs. 25.2 ± 8.8 months; $p < 0.0001$).

There was no early recurrence either in the fibrin sealant group after a follow-up of at least 12 months or in the suture group with a minimum follow-up of 25 months.

Moreover, two patients in the fibrin sealant group suffered chronic inguinal pain assessed as mild in one case and moderate in another. Pain was reported by 13 patients in the suture group. The severity of the pain was distributed as follows in this group:

- Mild: 8/57 (15.8%)
- Moderate: 3/57 (5.3%)
- Severe: 2/57 (3.5%)

The incidence of this chronic inguinal pain was, therefore, significantly lower in the fibrin sealant group (3.5% vs. 22.8%: $p = 0.042$).

Although the sample size was small, comparison of the patient characteristics failed to show any other factors affecting the occurrence of chronic pain.

**Table 3** Mean operative times

| Operative time | "Fibrin sealant" group | "Suture" group | $p$ |
|---|---|---|---|
| Unilateral hernia | 44 ± 9<br>Range: 28–70 | 54 ± 11<br>Range: 30–75 | $p = 0.0017$ |
| Bilateral hernia | 82 ± 10<br>Range: 65–95 | 98 ± 10<br>Range: 70–110 | $p = 0.0008$ |

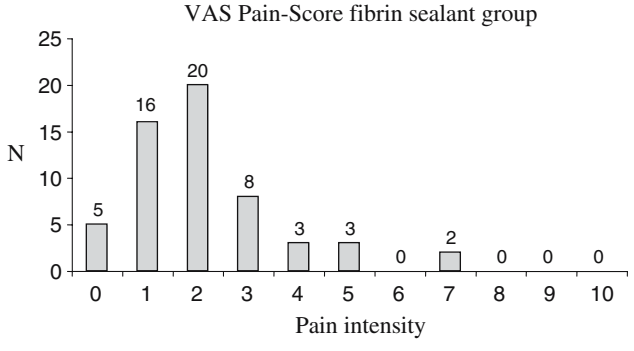


**Fig. 1** Postoperative VAS analyses in the fibrin sealant group

## Discussion

The main end-point for the evaluation of the treatment of inguinal hernia is the recurrence rate. In this respect, wall reinforcement with prosthetic meshes is clearly superior to simple herniorrhaphy [3]. The evaluation of secondary variables such as post-operative morbidity or hospital stay therefore provides useful decisional criteria. In this study, we chose the occurrence of chronic inguinal pain as an efficacy variable. Although "tension-

**Table 4** Postoperative complications

| Complications | "Fibrin sealant" group | "Suture" group | $p$ |
|---|---|---|---|
| Thromboembolism | 1/57 | 1/57 | |
| Haematoma | 1/57 | 4/57 | |
| Urinary retention | 3/57 | 2/57 | |
| Total | 5/57 (8.8%) | 7/57 (12.3%) | NS; $p = 0.7602$ |

free" hernia repair is reputed for its simplicity, it may lead to neurological complications, such as neuralgia, dysesthesia or hypoesthesia [4, 5, 8–10]. Lesions mainly involve the iliohypogastric, ilioinguinal or genitofemoral nerves and may be due to severing of the nerve, trapping in a suture, stretching or even electro-coagulation, which usually occurs during the dissection of the hernia or securing of the mesh. These lesions are all the more frequent as there are numerous anatomical variations in the neurological parts of the region [11, 12].

These painful sequelae are so frequent that we sought an alternative means of securing the prostheses in order to reduce them. Katkhouda et al. was the first to demonstrate the feasibility of a technique of laparoscopic repair using fibrin sealant in animals with promising results [6].

A recent randomised trial [13] showed the reliability and reproducibility of the results of open surgery, whereas they largely depend on the operator by laparoscopy. In this trial, although the inguinal pain rate was lower than by laparoscopy (14% vs. 10%), the recurrence risk (10% vs. 4.9%) and the complication rate (39% vs. 33%) was higher in this group.

The open route is, therefore, fully valid for hernia repair so that research to find a means of preventing chronic inguinal pain is justified.

We chose to use the mesh plug because of its facility of use [14] and the immediate post-operative comfort [15] procured by this technique. Moreover, it gave similar results after long term follow-up as other prosthetic techniques in terms of recurrence and quality of life [16].

The first part of our study consisted of standardising the technique. We started the current series after operating, following up and establishing the feasibility in 18 patients.

Although the sample size was small, the results in terms of immediate and late post-operative pain are encouraging, with a reduction in both the incidence and severity of the pain. The reduction in the length of hospital stay in the fibrin sealant group is probably due to this reduction in the pain and the more rapid recovery of autonomy. Moreover, this technique is very simple and reproducible, as shown by the significant reduction in operative time.

These results support other studies evaluating repair by mesh fixation with fibrin sealant [17, 18] for feasibility and technical facility. Our study goes further by demonstrating a reduction in pain sequelae.

In addition, the fibrin sealant, which is recognised for its haemostatic, adhesive and healing properties, was also found to be useful for wall repair surgery, as it reduced certain local complications, such as haematomas, seromas or abscesses [19, 20]. In our series, haematomas were less common in the fibrin sealant group, though this trend was not significant. Otherwise, total morbidity was similar in the two groups.

Although follow-up is short, no recurrence has been observed in the fibrin sealant group. It is difficult to predict the long-term efficacy of this type of repair, though it seems that the application of sealant is sufficient to secure the mesh and prevent its forceful erosion into the surrounding tissues, which may cause early recurrence. Besides, most recurrences occur during the first 3 months. After 3 months, peri-prosthetic fibrosis should keep the mesh in place and consolidate wall reinforcement.

In addition, fibrin sealant is a blood derivative and, therefore, presents a potential risk of infection. To date, no case of hepatitis or HIV seropositivity has been described after the use of this type of product [21, 22]. This is probably because of a rigorous selection of donors and the processes used to inactivate and eliminate viruses. Nevertheless, patients must be informed and their consent obtained.

Lastly, the excess costs due to spraying the fibrin sealant (2 ml are sufficient for a hernia repair) should be compared with the cost of sutures or staples required for conventional fixation, the reduced operative time, hospital stay and the cost of the chronic pain.

To conclude, mesh fixation with fibrin sealant in open hernia repair surgery is a simple, original and reproducible technique. It is accompanied by a reduction in chronic inguinal pain, with no increase in the early recurrence rate, justifying a large-scale randomised prospective study to confirm these results.

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