

## Human Fibrin Glue Sealing versus Suture Polypropylene Fixation in Lichtenstein Inguinal Herniorrhaphy: a Prospective Observational Study

G. Damiano<sup>1</sup>, M.C. Gioviale<sup>2</sup>, V.D. Palumbo<sup>1,2,3</sup>, G. Spinelli<sup>1</sup>, S. Buscemi<sup>2,3</sup>, S. Ficarella<sup>1</sup>, A. Bruno<sup>1</sup>, G. Tomasello<sup>1,2</sup>, A.I. Lo Monte<sup>1,2,3</sup>

<sup>1</sup>AOUP Paolo Giaccone, University of Palermo, Italy

<sup>2</sup>Department of Surgical, Oncological and Dentistry Studies, University of Palermo, Italy

<sup>3</sup>PhD in Surgical Biotechnology and Regenerative Medicine in Organ Failure – Coordinator: Prof Attilio Ignazio Lo Monte University of Palermo, Italy

### Rezumat

**Adezivul de fibrină versus fixarea prin sutură cu fir de polipropilenă în herniorafia inghinală Lichtenstein: un studiu prospectiv observațional**

**Introducere:** Pacienții care au suferit rezolvare primară a herniei inghinale raportează o rată mai mare a durerii postoperatorii după operație, din cauza efectului de fixare al plasei de sutură. O alternativă este utilizarea de adeziv de fibrină umană. Am comparat cele două tehnici.

**Metode:** 468 de pacienți au suferit în mod aleatoriu o intervenție pentru rezolvarea primară Lichtenstein a herniei inghinale, cu fixarea protezei prin suturi sau adeziv de fibrină umană; în ambele cazuri plasa fost fixată la peretele posterior al canalului inghinal și la ligamentul inghinal.

**Rezultate:** Nu s-au înregistrat diferențe semnificative între cele două grupuri în ceea ce privește complicațiile, în timp ce tehnica cu adeziv de fibrină reduce timpul operator și durerea postoperatorie.

**Concluzii:** O tehnică utilizată la scară largă în tratamentul herniei inghinale este aplicarea unei plase prin procedura Lichtenstein. Proteza poate fi fixată prin sutură clasică sau

folosind o nouă metodă de fixare sutureless cu materiale adezive, care demonstrează o tolerabilitate locală excelentă și lipsa de efecte adverse și contraindicații.

**Cuvinte cheie:** plasă de polipropilenă, herniorafie inghinală Lichtenstein, adeziv de fibrină umană

### Abstract

**Background:** Patients who underwent primary inguinal hernia repair still report a high rate of postoperative pain after operation due to the effect of mesh fixation by suture. An alternative is the use of human fibrin glue. We compared the two techniques.

**Methods:** 468 patients randomly underwent primary inguinal hernia Lichtenstein repair fixing the mesh by suture or by human fibrin glue (HFG); in both cases the mesh was fixed to the posterior wall of the inguinal canal and to the inguinal ligament.

**Results:** No significant differences were recorded between the two groups in terms of complications, while the sutureless technique reduces the operative time and the postoperative pain.

**Conclusions:** A widespread technique for the treatment of inguinal hernia is the application of a mesh using Lichtenstein procedure. The prosthesis can be fixed by traditional suture or using a new method of sutureless fixation with adhesive materials that shows an excellent local tolerability and lack of adverse effects and contraindications.

### Corresponding author:

Giuseppe Damiano, MD  
Department of Surgical, Oncological and  
Dentistry Studies, University of Palermo, Italy  
Via del Vespro, 129, 90127 Palermo, Italy  
E-mail: giuse.damiano@gmail.com

**Key words:** polypropylene hernia mesh, Lichtenstein inguinal herniorrhaphy, human fibrin glue

## Introduction

Inguinal hernia repair surgery is a continuous evolving field due to the elevated incidence of disease in the population and the difference of satisfaction reported from patients after surgery. Many theories about hernia pathophysiology succeeded over the time, either partially accepted and related each to others (1-3).

The most accepted aetiology made the current repair technique founded upon the principle of "closing the defect" in internal inguinal ring, either by suturing closed under tension, covering with a mesh or obliterating the defect with a plug. Many variants of each method are refined to achieve better clinical outcomes.

Prosthetic repair techniques dramatically improved the outcome of surgical repair of abdominal wall defects. Since their introduction in clinical use, meshes became to be used in more different applications, up to repair of post-incisional hernias following renal transplantation: when prostheses are correctly handled, their safety is confirmed even in transplanted patients (4-6). The shape and composition of prosthesis is object of continuous evolution starting from plane mesh up to new three-dimensional prosthesis (7).

In the last few years, Lichtenstein "tension-free" hernioplasty, described for the first time in 1989 (8), became a widely accepted method due to its safety, easiness of learning and low recurrence rate (9,10).

The crucial point of this technique is securing the mesh to the posterior wall of the inguinal canal. Still today, suturing the mesh with polypropylene remains the standard, but many innovative techniques have been described. The reports concerning application of glues in inguinal hernia repair are growing in number (11). In the first preliminary report, Canonico et al. (12) showed the efficacy of mesh fixation with human fibrin glue (HFG), and indicated the viability of a sutureless Lichtenstein procedure. Similarly Hidalgo et al. (13)

demonstrated that the use of fibrin glue in hernia repair is safe and it is no burdened from early recurrence. We report our experience of HFG mesh fixation compared to tradition fixation in hernia repair surgery.

## Materials and Methods

This prospective observational study was carried out between January 2004 and February 2010.

468 consecutive patients underwent surgical operation for primary unilateral inguinal hernia repair (Table 1). These were randomized either to the control group (A group: mesh fixed with 3/0 polypropylene suture) and the study group (B group: mesh secured with HFG - Tissucol®, Baxter Healthcare, Deerfield, IL, USA). The use of sutures or fibrin glue was dependent on a blind draw of type of fixation at time of operation. Exclusion criteria included recurrent and femoral hernia, urgent cases, metabolic diseases (diabetes and obesity), patients in oral anticoagulant treatment and no more than 2 years of symptomatic hernias.

All surgical procedures were performed under local anaesthesia (mixture of 2% Lidocaine and 1% Ropivacaine) by the same surgical team.

Into the A group hernia repair was performed as described by Lichtenstein. The mesh was secured by a running 3/0 polypropylene and interrupted 3/0 Dexon® (Davis-Geck, Wayne, NJ, USA) to the inguinal ligament and to the internal oblique and transverse muscles, respectively. Into the B group the mesh was fixed to the posterior wall of the inguinal canal and to the inguinal ligament by applying the HFG over the mesh surface. Successively the edges of external aponeurosis were approximated and the HFG was applied to allow the complete closure. After repositioning the Scarpa's fascia, the skin was closed with a subcuticular absorbable suture 3/0 PDS (Ethicon Endosurgical®, Cincinnati, OH, USA).

All the patients were discharged the same day of the surgical procedure and were reviewed at 7 days, 6 and 12 months after surgery. For all the patients the following parameters were recorded: the operative time, the intra-operative and post-operative complications, the first and seventh postoperative days pain according to a 0-10 numeric rate scale (NRS) (14-20), the persistent pain and the recurrences (Fig. 1).

**Table 1.** Demographic characteristics of patients and complications' date

|  | A Group     | B Group      | P  |
|--|-------------|--------------|----|
| Total number of patients                                   | 252         | 216          | -  |
| Age (mean ± SD)  | 55.1 ± 5.35 | 52.94 ± 4.89 | ns |
| Patients with indirect hernia                              | 186         | 160          | -  |
| Patients with direct hernia                                | 50          | 32           | -  |
| Patients with combined hernia                              | 16          | 24           | -  |
| Number of patients with seroma at 7 days following surgery | 10          | 5            | -  |
| Number of patients with mesh infection at 6 months         | 4           | 2            | -  |
| Patients with mesh rejection at 6 months                   | 3           | 0            | -  |

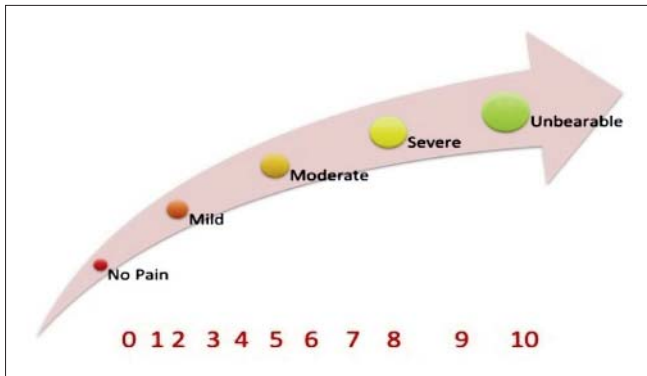


Figure 1. NRS, Numeric Rating Scale pain

The statistical analysis - made by statistical software GraphPad Prism 5 - included the difference of demographic characteristics, the skin-to-skin operative time between the two groups using t Student's test for parametric variable. The NRS score during follow-up was tested by t-Student test for each comparison between groups in the same period and by one-way ANOVA analysis of variance for the whole period of follow up. A p value < 0.05 was considered significant.

## Results

The A group included 252 patients and the B group 216. Indirect hernia were recognized in 186 and 160, direct in 50 and 32 and combined in 16 and 24 patients of the A group and B, respectively. The mean  $\pm$  SD of age was  $55.10 \pm 5.35$  years into the A group, and  $52.94 \pm 4.89$  years into the B group. The skin-to-skin operative time was  $51.6 \pm 6.27$  minutes and  $48.89 \pm 5.71$  minutes into the A group and B, respectively. All patients were discharged 5-6 hours after surgery and none of them required readmission to hospital. Seven days after the surgical procedure 10 patients from the A group and 5 patients from the B group developed a small seroma that was eventually evacuated by percutaneous puncture. Four patients into the A group and 2 patients into the B group developed wound infection, whereas 3 patients of the A group and none of the patients of the B group developed mesh rejection at 6 months from surgery. At 12 months, no recurrence or late complications, such as scar immobility, fibrosis, neuralgia or scrotal hyperesthesia, were observed. The statistical analysis showed no significance in term of age or operative time for both the groups. The NRS score during follow-up resulted lower for the B group at 7 days ( $p < 0.05$ ) and at 12 months compared to the A group ( $p < 0.05$ ) showing instead none differences at 6 months ( $p > 0.05$ ) (Fig. 2).

## Discussions

The prospective, observational, randomized study we present compared the HGF fibrin glue mesh fixation versus conventional sutures for inguinal hernia repair according to Lichtenstein.

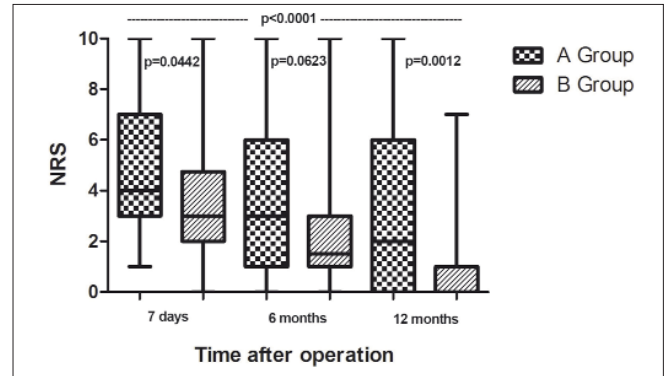


Figure 2. Whisker and box plot of NRS score during follow-up with  $p < 0.001$

The postoperative pain occurrence during the first months following open inguinal hernia surgery shows a high prevalence, causing in some cases, severe limitation to daily activities and/or keep patients away from their work (1).

The method of mesh fixation is currently considered - when surgical technique is well performed - a crucial factor from which it depends the chronic pain syndrome (21).

At initial follow-up assessments, the patients in the fibrin glue study group reported a lower NRS score basing in term of less pain, numbness, and discomfort compared to the patients into the sutures group for the whole period of observation. At 12 months we observed no recurrence or late complications, such as scar immobility, fibrosis, neuralgia or scrotal hyperesthesia for both the groups. Interesting and consistent to other authors' findings in the first month - the period time in which patients experienced the bigger discomforts and reduction of quality of life - we found an advantage in using the HGF compared to the traditional mesh fixation.

Several studies have already demonstrated the effect of HGF for hernia repair surgery. The use of biological glues is safe and they are currently applied in different medical applications (22).

The HGF is an effective biodegradable adhesive combining human-derived fibrinogen and thrombin that replicates the last step of the coagulation; it possesses an excellent local tolerability and lack of adverse effects and contraindications (23).

Some Authors (24) reported a prospective randomized clinical trial comparing the classical procedure with "sutureless Lichtenstein" where the mesh was glued by n-butyl-cyano-Acrylate. During follow-up period, no complications or early recurrences were observed. Furthermore, the Authors underlined better results in the group with glue application, in terms of pain and local numbness. The reason for the lower postoperative pain may be the scarce irritating potential of the adhesive material and a lower tissue tension or nerve compression, as it may be caused by fixing sutures. They observed that the duration and the cost of the surgical procedure were similar in suture and adhesive group. They emphasized the strong tendency to earlier return to daily activities of patients in adhesive group. Our data confirm that HGF is suitable for

use in open tension-free inguinal hernia repairs. However after 7 days follow-up we observed 15 seromas (10 into the A group and 5 into the B group) but probably these were related to a local inflammation. No complications regarding the spermatic cord were observed because, as the genitofemoral nerve, it was lifted in order to avoid any direct contact until the glue was dried. The mean operative time instead not showed significant difference compared to the classic Lichtenstein technique.

## Conclusions

During the follow-up, no difference in terms of hernia reparation result between the sutured and the sutureless groups was detected, but the analysis of our data suggests that using HFG in mesh fixation could substitute the suture fixation in consideration of the reduction of postoperative pain and the efficacy in mesh fixation. The slight increase in costs is balanced by an overall improvement of the quality of life and a early return to daily activity and work, thus reducing the days of sickness from work.

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