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### Original article

# Use of adhesive mesh in hernioplasty compared to the conventional technique. Results of a randomised prospective study

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#### ARTICLE INFORMATION

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#### ABSTRACT

Introduction: The use of meshes made with reabsorbable materials and structures that allow them to be fixed to the tissue without sutures, is considered as a therapeutic possibility in inguinal hernioplasty, reducing surgical times and supposedly improving pain and post-operative recovery.

Material and methods: A prospective randomised study of patients intervened for inguinal hernia between March 2009 and March 2010. Those patients chosen for hernia repair with a self-adhesive mesh (Parietene Progrip®) were placed in the in the SA (self-adhesive) group, and those chosen for hernia repair with a polypropylene mesh fixed with a monofilament suture in the CL (Classic Lichenstein) group. Complications and pain, using the visual analogue scale, were evaluated over 7 days.

Results: A total of 90 patients were divided into 2 groups of 45. The mean age was 60 and 49 years, respectively, with the mean size of the hernia defect being 3 cm, and approximately 60% were indirect hernias. The time of fixing the mesh and the overall surgery time was lower in the SA group than in the CL group: 56 s vs 3 min and 52 s, and 17 min and 45 s versus 20 min and 10 s, respectively. There were no differences in hospital stay, complications or post-operative pain.

Conclusion: The use of this type of mesh reduces the time of fixing the prosthesis and the total surgical time, with no effect on early post-operative pain or surgical complications compared to hernioplasty with a polypropylene mesh fixed with a monofilament suture.

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Utilización de mallas autoadhesivas en la hernioplastia frente a la técnica convencional. Resultados de un estudio prospectivo y aleatorizado

RESUMEN

Palabras clave: Hernioplastia inguinal Mallas autoadhesivas Dolor postoperatorio Introducción: El empleo de mallas confeccionadas con materiales reabsorbibles y estructuras que les permiten fijarse al tejido sin suturas se plantea como posibilidad terapéutica en la hernioplastia inguinal, disminuyendo tiempos quirúrgicos y mejorando supuestamente dolor y recuperación postoperatoria.

Material y métodos: Estudio prospectivo y aleatorizado de pacientes intervenidos de hernia inguinal unilateral entre marzo de 2009 y marzo de 2010. En el grupo AutoAdhesiva (AA) se incluyeron los sometidos a hernioplastia inguinal con malla autoadhesiva (Parietene Progrip®) y en el grupo Lichtenstein clásico (LC) aquellos sometidos a hernioplastia con malla de polipropileno fijada con sutura monofilar. Durante 7 días postoperatorios se evaluaron las complicaciones y el dolor mediante la escala visual analógica.

Resultados: Un total de 90 pacientes fueron divididos en 2 grupos de 45. La edad media fue de 60 y 49 años, siendo, en ambos, el tamaño medio del defecto herniario de 3 cm y aproximadamente un 60% hernias indirectas. El tiempo de colocación de la malla y el quirúrgico global fue menor en el grupo AA frente al LC: 56 segundos frente a 3 minutos y 52 segundos y 17 minutos y 45 segundos frente a los 20 minutos con 10 segundos respectivamente. No hubo diferencias en estancia hospitalaria, analgesia, complicaciones ni dolor postoperatorio.

Conclusión: El empleo de este tipo de mallas disminuye el tiempo de colocación de la prótesis y el quirúrgico total, sin efecto en el dolor y complicaciones postoperatorias precoces frente a la hernioplastia con malla de polipropileno fijada con sutura monofilar.

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#### Introduction

Inguinal hernia is one of the surgical entities of greatest incidence these days, representing a great number of interventions and involving a significant healthcare cost. Advances in both the prosthetic materials used and the various wall reconstruction and mesh placement techniques have delineated the evolution of surgical management of this disease.

At present, the recent emergence of mesh made from absorbable materials and techniques that use items such as fibrin glues for fixing prostheses, along with the use of self-adhesive or low density mesh are issues under development and whose short- and long-term clinical outcomes remain to be assessed.

The objective of this study is to determine whether inguinal hernioplasty using the Lichtenstein technique, and the use of adhesive and partially absorbable mesh provides benefits over traditionally employed mesh in terms of surgical technique, pain and complications in the early postoperative period.

#### Material and method

We conducted a prospective, randomised and comparative study of patients undergoing inguinal hernioplasties between March 2009 and March 2010 in our department. Our department has extensive experience in this technique, having performed more than 2000 Lichtenstein hernioplasty procedures in the last 15 years.

Patients were randomly divided into 2 groups of 45 individuals by blindly selecting a piece of paper marked with letters self-adhesive (SA) or Classic Lichtenstein (CL) from a bag, moments before the surgery. The SA group included individuals who underwent inguinal hernia repair with preformed self-adhesive polypropylene and polylactic acid mesh (Parietene ProGrip®). The CL group underwent a Lichtenstein hernioplasty with polypropylene mesh fixed with a monofilament suture.

Patients with femoral, recurrent or bilateral hernias or those who underwent emergency procedure for any acute complication were not included in the study.

For the preoperative study we collected various epidemiological and comorbidity variables of the patients, cataloguing the anatomical classification of the hernia as proposed by Gilbert. The same preoperative antibiotic prophylaxis dosage was used for all cases 30 minutes before skin incision (750 mg intravenous cefuroxime and 200 mg intravenous ciprofloxacin for allergic patients). All patients were under spinal anaesthesia during the procedure. The surgical wound was not infiltrated under local anaesthetics during the procedure for any of the cases.

The same surgical team operated on both SA and CL patient groups, performing the same steps. The only technical difference was the method used to attach the mesh. In the SA group, the mesh was placed over the posterior wall of the inguinal canal beyond the limits of the pubis symphysis and

reaching the iliopubic eminence without any attachment point, while in the CL group, the mesh was attached with a continuous 3-0 monofilament suture to the inguinal ligament and discontinuous stitches to the conjoint tendon using the technique proposed by Lichtenstein. In both groups, if there was evidence of weakness of the posterior wall of the inguinal canal, we used a continuous 3-0 monofilament suture joining the conjoint tendon to the iliopubic eminence.

Common analgesics (paracetamol and ibuprofen, and tramadol as rescue analgesia) were administered postoperatively with both groups receiving the same dosage, and all patients received identical recommendations on hospital discharge. Patients were discharged after assessing their degree of pain, ability to start walking, and checking that their oral tolerance and was correct and that there were no complications. For seven days after discharge, pain was evaluated daily by the visual analogue scale (VAS), which quantifies the degree of pain between 0 (no pain) to 10 (maximum pain tolerable). We removed the stitches 8 days after surgery and then ensured there were no complications by carefully examining the surgical site.

We developed a comprehensive database in which we stored the various parameters on the patient, type of hernia, surgical procedure and postoperative complications, in order to perform the descriptive, comparative and analytical statistical analysis using SPSS 15.0 for Windows.

#### **Results**

A total of 90 patients between March 2009 and March 2010 were included in this study, and each of the comparative groups included 45 individuals.

The average age in the SA group was 60 (26-80) years vs 49 (19-83) in the CL group. Most patients were male (91% and 84.4%, respectively), and there were no significant differences in comorbidities in both groups (Table 1). Some 44% in the SA group and 39.6% in the CL group were smokers. Some 11% and 8% of the patients in each group had been operated on previously for other hernias (Table 1).

The average hernia evolution time was 6 months in the 2 groups, with left-side hernias (57.7%) being more frequent in the SA group and right-side hernias more frequent (53.3%) in the CL group. In both groups, the average size of the hernia defect was 3 cm in diameter, showing indirect hernias in 66.6% of patients in the SA group and 60% of the CL group. The most prevalent types of hernia, according to the Gilbert anatomical classification, were type II and IV in both groups (Table 2). When dissected, 66.7% and 86.7% of hernia sacs were empty in the SA and CL groups, respectively, and 9 patients (20%) of the first group and 3 (6.7%) in the CL group contained omentum. In 3 SA group patients, the large intestine had slipped into the inguino-scrotal hernia sac (Table 2). Posterior reinforcement was performed with a 3-0 monofilament suture joining the conjoint tendon to the iliopubic eminence in 52.2% and 57.1% of patients in the SA and CL groups, respectively (Table 2).

The average intraoperative time for mesh placement was 56 seconds in the SA group compared to 3 minutes and 52 seconds in the CL group (P<.001). The overall surgical time was also statistically significantly lower in the SA group, with 17 minutes and 45 seconds versus 20 minutes and 10 seconds in the CL group (P=.007) (Figure 1).

As for the cost of the materials, the self-adhesive mesh cost  $\in$ 178.69, compared with  $\in$ 114.48 for the polypropylene mesh ( $\in$ 111.78) and the two 3-0 monofilament sutures ( $\in$ 1.35 each) used for attachment.

All patients were operated on in the afternoon and discharged the morning after the first pain assessment. The average hospital stay was 15h in throughout the series, without significant differences between groups. No patient in our series remained in hospital for more than 24 hours and no reintervention or hospital readmission was necessary.

Postoperative pain and analgesic requirements were studied in both groups using the VAS during the first 7 days after surgery, and the statistical analysis of data showed no significant differences, as shown in Figure 2. Average pain gradually decreased: 67.4% of patients in the CL group had no pain (VAS 0-1) 7 days after surgery, compared to 70.4% in the SA group.

	SA group		CL group	
	Median/n	Range%	Median/n	Range%
Age, years	60	26-80	49	19-83
Sex				
Male	41	91.1%	38	84.4%
Female	4	8.9%	7	15.6%
Patient history				
Arterial hypertension	19	41.8%	17	37.4%
Diabetes mellitus	8	17.6%	6	13.2%
Bronchial diseases	5	11%	4	8.8%
Smoker	20	44%	18	39.6%
Time of evolution (months)	6	3-36	6	3-24
Operated on for other hernia	5	11%	4	8.8%

	SA group		CL group	
	Median/n	Range%	Median/n	Range%
Hernia location				
Left	26	57.7%	21	46.7%
Right	19	42.3%	24	53.3%
Hernia type				
Indirect	30	66.6%	27	60%
Direct	14	31.1%	18	40%
Mixed	1	2.2%	0	0%
Size of opening, cm	3	1-6	3	1-5
Gilbert Classification				
I. Small indirect	5	11.4%	3	6.7%
II. Indirect less than 4 cm	17	38.6%	21	46.7%
III. Indirect greater than 4 cm	7	15.9%	3	6.7%
IV. Direct with total wall involvement	10	22.7%	13	28.9%
V. Direct 1-2 cm	4	9.1%	5	11.1%
VI. Mixed	1	2.3%	0	0%
Hernia volume				
Small	10	22.2%	8	17.8%
Medium	24	53.3%	28	62.2%
Large	11	24.4%	9	20%
Content of hernia sac				
Omentum	9	19.8%	3	6.6%
Small intestine	2	4.4%	3	6.6%
Colon	3	6.6%	0	0%
Empty	31	68.2%	39	86.8%
Posterior reinforcement				
No	22	52.2%	19	42.9%
Yes	23	48.8%	26	57.1%

 Total surgical time, (s)
 SA group Median
 LC group Median
 Range

 1065
 710-1240
 1210
 760-1250

 Time for mesh placement (s)
 56
 33-118
 232
 179-302

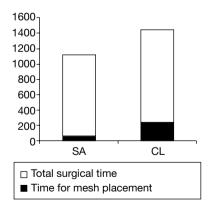


Figure 1 – Global surgical time and time for placement of the mesh in the groups. CL indicates Classic Lichenstein; SA, self-adhesive.

The overall morbidity of the series amounted to 15.4% (7 cases) in the SA group and 11% (5 cases) in the CL group with no significant differences (P=.38). The main complications were acute urinary retention in 2 patients in each group and 2

patients in the SA group had scrotal oedema, the large intestine was discovered to have slipped into inguinal-scrotal hernia at the time of the intervention. The percentage of seroma and infection was 2.2% in both groups (Table 3). No deaths were recorded in our series during the follow-up period.

#### Discussion

Since 1887 when Bassini<sup>2</sup> published their knowledge and technique for inguinal hernioplasty, many procedures and other materials and prostheses have been developed to try to improve this type of surgery's results. It seems clear that hernioplasty techniques using mesh are better than anatomic repair in terms of recurrence rates and better postoperative patient recovery,<sup>3</sup> and the Lichtenstein hernioplasty technique is the most commonly used throughout the world.<sup>4</sup> With technological developments, meshes of different compounds, structures and dimensions have been designed to try to encourage better integration of the material in the tissue, thus reducing the number of complications.

In this respect, adhesive and partially absorbable meshes provide another alternative for inguinal hernia repair, with benefits such as reduced surgical time<sup>5</sup> and decreased pain,<sup>6</sup> without increasing the number of complications or recurrences.

In our study we have prospectively compiled a successive series of cases, evaluating intraoperative parameters

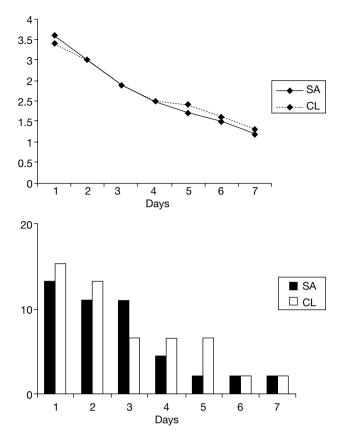


Figure 2 – Postoperative pain according to a visual analogue scale and percentage of cases that needed rescue analgesia in the first 7 postoperative days. CL indicates Classic Lichenstein; SA, self-adhesive.

Table 3 – Morbidity of our series divided by groups								
Morbidity	SA group (15.4%)		CL group (11%)					
Haematoma	1	2.2%	1	2.2%				
Seroma	1	2.2%	1	2.2%				
Infection	0	0%	0	0%				
Scrotal oedema	2	4.4%	0	0%				
Urine retention	2	4.4%	2	4.4%				
Fever+diarrhoea	0	0%	1	2.2%				
Fever	1	2.2%	0	0%				
CL indicates Classic Lichenstein; SA, self-adhesive.								

and short-term results of two techniques for inguinal hernioplasty. We compared a classic technique in which the polypropylene mesh is attached with a monofilament suture, with another technique that uses a self-adhesive mesh made of polypropylene and polylactic acid, which needs no attachment points due to the microhooks that hold the tissue on which it rests. We found no significant differences in pain and immediate postoperative complications.

The risk of entrapment or regional nerve injury is reduced in the self-adhesive mesh procedure, supposedly because no sutures are used. Consequently, a reduction in pain is also thought to be linked with this.5 Similarly, less postoperative pain could also be related to the fact that mesh is not attached to the pubis. However, we have not found significant differences in early postoperative pain in either patient groups. There are conflicting data in literature about which surgical approach should be used to reduce immediate and chronic pain associated with the nerve branches of the inguinal region during hernioplasty. While some studies advocate identifying different nerves and preserving them.<sup>7,8</sup> others champion removing them so that chronic pain associated with these procedures is reduced.9 We are in favour of preserving the nerve fibres identified and handling them as little as possible during surgery, but we do not systematically search for or identify them. We do however pay special attention to cases in which we attach the mesh with sutures to be sure that none of the stitches cover any nerve branches in the area.

Given that time is not needed for suturing, to attach the prosthesis in self-adhesive mesh procedures, the surgical duration is reduced. In our study, both the overall surgical time as well as that for mesh attachment was significantly lower in the group with the self-adhesive prosthesis, and was similar to that provided by other authors.<sup>6</sup> This technique reduces the exposure time of the mesh, which could presumably decrease the number of infectious complications. This is not proven in our series, and would require a larger number of cases to really assess this effect.

In general, self-adhesive mesh is comfortable to handle, providing subjectively good quality and accuracy of attachment.<sup>6</sup> However, they are sometimes difficult to attach in obese patients, because the absorbable microhooks which facilitate the grip of the mesh adhere to other tissues to which they are exposed. This necessitates adequate exposure of the inguinal canal and the posterior wall as well as correct skeletonisation of the inguinal cord to the deep inguinal opening, as in the classical technique. Perhaps using this type of self-adhesive mesh could reduce dissection of the anatomical structures involved and provoke incorrect prosthesis placement, with the risk of increasing the number of relapses. This therefore emphasises the importance of correct dissection.

The cost of the techniques compared in this study shows that self-adhesive mesh is more expensive than the conventional technique, although the time saved in surgery related with their use could match the overall costs of the procedures. Similarly, long-term study of results and complications of both groups would enable us to make a fuller assessment of the real cost-effectiveness of these techniques.

In terms of immediate postoperative complications, both groups had the same percentage, and there were no cases of recurrence, which is comparable to most published series.<sup>6</sup>

Currently, we are continuing the postoperative clinical monitoring of the patients included in this study, to re-evaluate the differences in pain, recurrences and other complications a year after surgery.

Therefore, we can conclude that prosthesis placement time and overall surgical duration are reduced when using self-adhesive mesh in hernioplasty in accordance with the Lichtenstein technique. Furthermore, pain or early postoperative complications are not affected.

#### **Conflict of interest**

The authors affirm that they have no conflicts of interest.

#### REFERENCES

- Amid PK, Shulman AG, Lichtenstein IL. Open 'tension-free' repair of inguinal hernias: the Lichtenstein technique. Eur J Surg. 1996;162:447-53.
- Bassini E. Sulla cura radicale dell'èrnia inguinale. Arch Soc Ital Chir. 1887;4:380-6.
- E.U. Hernia Trialist Collaboration. Mesh compared with nonmesh methods of open groin hernia repair: systematic review of randomized controlled trials. Br J Surg. 2000;87:854-9.

- Kingsnorth AN, Porter CHS, Bennett DH, Walker AJ, Hyland ME, Sodergren S. Lichtenstein pacth or Perfix plug and patch in inguinal hernia: a prospective double-blind randomized controlled trial of short-term outcome. Surgery. 2000;127:276-83.
- Chastan P. Tension-free open hernia repair using an innovative self-gripping semi-resorbable mesh. Hernia. 2009;13:137-42.
- Chastan P. Tension free open inguinal hernia repair using an innovative self-gripping semi-resorbable Mesh. J Min Access Surg. 2006;3:139-43.
- 7. Wijsmuller AR, Van Veen RN, Bosch JL, Lange JF, Kleinrensink GJ, Jeekel J, et al. Nerve management during open hernia repair. Br J Surg. 2007;94:17-22.
- 8. Alfieri S, Rotondi F, Di Giorgio A, Fumagalli U, Salzano A, Di Miceli D, et al. Influence of preservation versus division of ilioinguinal, iliohypogastric, and genital nerves during open mesh herniorrhaphy: prospective multicentric study of chronic pain. Ann Surg. 2006;243:553-8.
- Smeds S, Löfström L, Eriksson O. Influence of nerve identification and the resection of nerves 'at risk' on postoperative pain in open inguinal hernia repair. Hernia. 2010. [Epub ahead of print].