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Is It Possible to Eliminate Sutures in Open (Lichtenstein Technique) and Laparoscopic (Totally Extraperitoneal Endoscopic) Inguinal Hernia Repair? A Randomized Controlled Trial With Tissue Adhesive (*n*-Hexyl-α-Cyanoacrylate)

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Abstract

Background. The morbidity linked to the use of sutures in inguinal hernioplasty is well known. Tissue adhesives may be an alternative, so as to be able to improve levels of postoperative comfort, but clinical experience using them is limited. The aim of this study is to evaluate the efficiency of cyanoacrylate as a substitute for sutures in the treatment of inguinal hernias. *Patients*. Randomized clinical trial in abdominal wall unit. A total of 208 patients were operated upon for inguinal hernias of which 102 were unilateral hernias via open surgery using the Lichtenstein technique, randomized to receive prolene sutures (n = 52) or *n*-hexyl-α-cyanoacrylate glue (n = 50) and 106 were patients with bilateral inguinal hernias operated upon via totally extraperitoneal laparoscopy and randomized to receive either tackers (n = 54) or glue (n = 52). *Main Outcome Measures*. The primary endpoints were pain and recurrence. Secondary endpoints were operating time, postoperative morbidity, pain, and analgesic consumption. *Results*. No morbidity associated with the use of the glue existed. The use of glue significantly reduced the mean of surgical time (12 minutes in open surgery, 13 minutes in laparoscopic surgery), pain, and analgesics consumption, both via the open and laparoscopic approaches ($P < .001$). After 1 year the adhesive did not change the recurrence rate in either of the approaches. The economic analysis shows potential yearly savings of 123 916.3 Euros. *Conclusions*. Substituting sutures with glue (*n*-hexyl-α-cyanoacrylate) in open or laparoscopic inguinal hernioplasty is safe with less postoperative pain and the same possibilities of recurrence.

Keywords

tissue adhesive, glue, inguinal hernia, pain, recurrence, morbidity

Introduction

Abdominal wall surgery is continually being updated, and the use of meshes and the laparoscopic approach have been 2 significant innovations. At present we may be witnessing a new change with the introduction of synthetic tissue adhesives (TA), substances that could substitute sutures in hernia surgery because of their adhesive, hemostatic, and bactericidal properties. The adhesives have already shown their effectiveness in numerous medical–surgical procedures.[1-12]

The treatment of hernias has a great social and economic impact, as it is one of the most frequent surgical procedures. Lichtenstein hernioplasty has become the most common method to repair inguinal hernias as it is easy to reproduce, effective, and gives good results for most surgeons. In spite of this, this procedure still presents a not insignificant level of morbidity.[13,14] The totally extraperitoneal endoscopic (TEP) approach should be the reference technique to correct bilateral hernias.[15] For both approaches, open and laparoscopic, the complications have been related to the use of sutures or tackers, which can cause local compression (tissue ischemia), strangulation of muscular fibers, nerve lesions, or reaction to foreign bodies. The use of glues has been proposed as a

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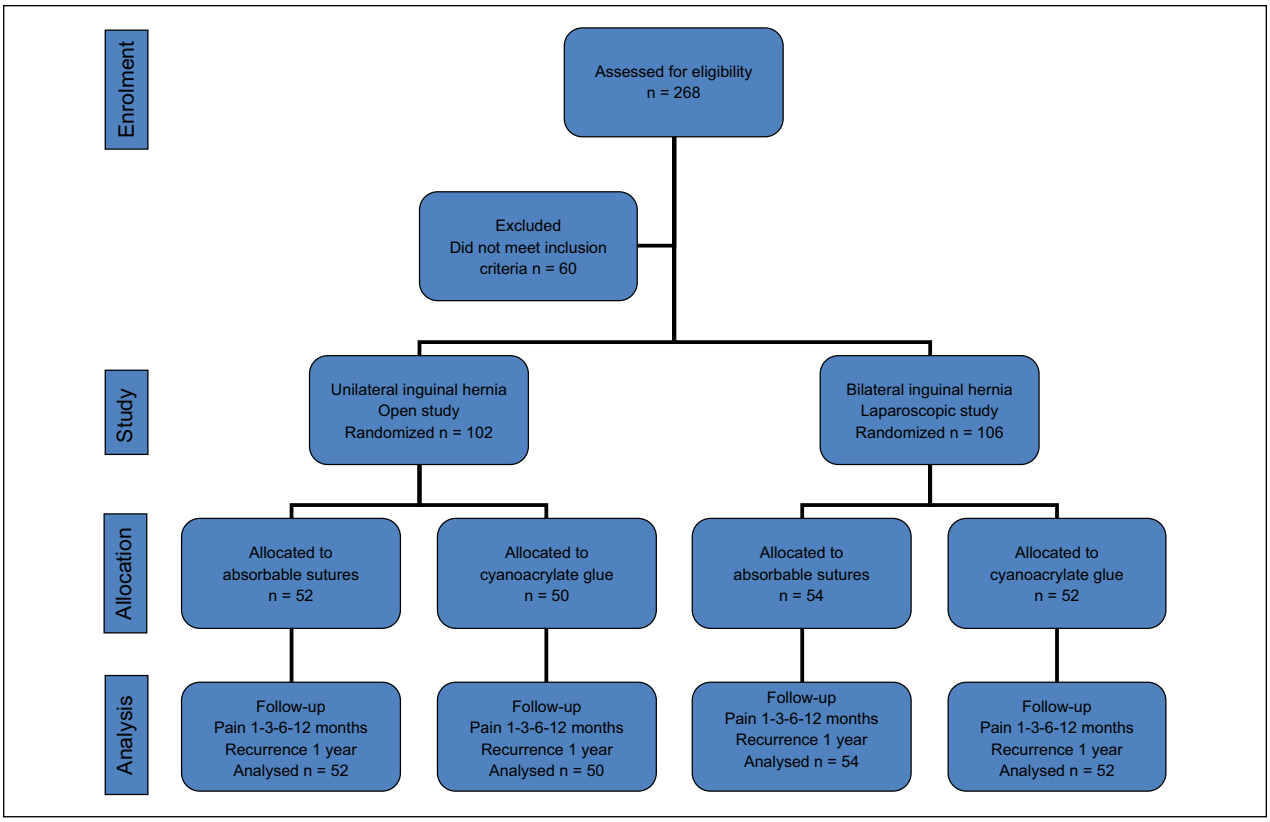

Figure 1. Diagram of the study design.

possible alternative to the classical fixation mechanism to avoid the above-mentioned complications, but as yet there is little information available on these substances and nothing on the new long chain derivative *n*-hexyl-α-cyanoacrylate.[16] The purpose of this study is to evaluate the effectiveness of this new adhesive to treat inguinal hernias, both via open and laparoscopic approaches, as a substitute for sutures.

Methods

Study Design

This randomized, single-blind trial was conducted in the Ambulatory Abdominal Wall Unit of Morales Meseguer University Hospital in Murcia, Spain. The study enrolment took place between January 2008 and January 2011. The study protocol was approved by the ethical committee at the hospital, and gall procedures were performed in accordance with good clinical practice guidelines. All patients signed an informed consent form.

Patients were randomized intraoperatively to receive either sutures (control group) or glue (experimental group) for the repair of the inguinal hernia. Randomization was achieved by a computer program, and all patients were blinded to the allocation. The study was performed without any grants; all costs were covered by the national health care system (Figure 1).

Inclusion and Exclusion Criteria

Patients were enrolled if they met the following inclusion criteria: age >18 years old; clinical diagnosis of primary inguinal hernia, and no comorbidity (no significant cardiopulmonary, hepatic, or renal impairment). The unilateral inguinal hernias were selected for open repair (Open study), and the bilateral ones for totally extraperitoneal laparoscopic repair (TEP study).

Exclusion criteria were patients with incarcerated or strangulated hernia; known femoral hernia; scrotal hernia; those receiving corticosteroid therapy, radiotherapy, or chemotherapy; concurrent neoplasms; proven mental illness or other circumstances that might compromise the patient's cooperation; and those who refused to give informed consent.

Operative Technique

A standardized surgical technique was used by a single senior surgeon specialized in abdominal wall surgery (open and laparoscopic hernia repair; AME. All patients received thromboembolic prophylaxis with a

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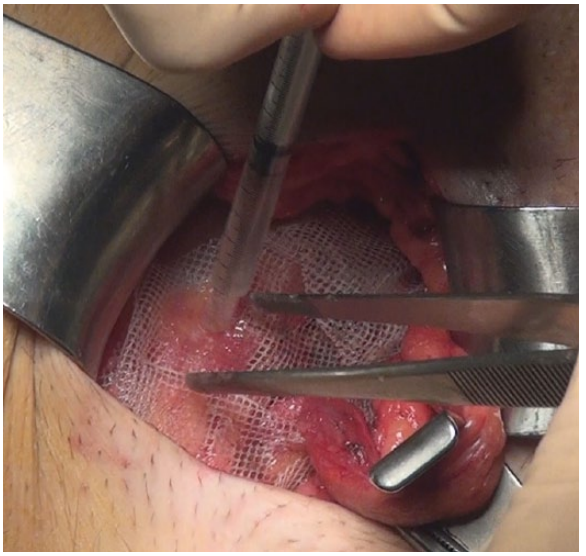

Figure 2. Use of synthetic tissue adhesive on an anterior Lichtenstein hernioplasty.

low-molecular-weight heparin and a 1-shot antibiotic prophylaxis immediately before surgery.

Open Repair. Under local anesthetic, a standard Lichtenstein technique was performed with a lightweight polypropylene-coated titanium mesh, 35 g/m^2 (Pfm, Cologne, Germany). In the control group, the mesh was fixed with interrupted two 2/0 prolene sutures (Ethicon; Johnson & Johnson, New Brunswick, NJ), the aponeurosis of the external oblique muscle with 0 prolene sutures, and the skin with staples. In the experimental group, the surgical management of the site, hernia, sac, and the position of the mesh were the same, but this was fixed to the pubis, inguinal ligament, and internal oblique muscle with 8 well-spaced drops of glue (Ifabond, Fimed, France). The iliohypogastric, genitofemoral, and ilioinguinal nerves were identified and protected. The rest of the planes (aponeurosis of the external oblique, Scarpa, and skin) were also closed with adhesive (Figure 2).

Laparoscopic Repair. Under general anesthetic an infraumbilical incision was performed, the aponeurosis of the anterior homolateral rectus muscle was opened, and a preperitoneal space was created using a distension balloon trocar. A Hasson-type trocar was inserted, and under direct vision two 5-mm trocars were placed on the midline, equidistant between the umbilicus and pubis. The reference structures, including Bogros' space, were located and the sac was parietalized. A 10 × 15 cm polypropylene mesh covered in titanium (35 g/m^2, Tilene, Pfm, Cologne, Germany) was fixed to the Cooper ligament using 2 tacks (AbsorbaTack, Covidien, EU) in the control group or 4 drops of glue in the experimental group (Figure 3).

Tissue Adhesive

The cyanoacrylate monomer, *n*-hexyl-α-cyanoacrylate (Ifabond, Fimed, France) is used. It has 98% purity and low viscosity, and when applied to live tissue in a wet basic environment rapidly polymerizes forming a flexible adhesive polymer in seconds. After 30 seconds it offers great adhesion, and it is progressively reabsorbed, a process that is complete 9 months after application (Table 1).[16]

Follow-Up

Patients were clinically reevaluated 7 days, 1 month, 3 months, 6 months, and 24 months after surgery at which times the primary and secondary outcomes were documented. All the patients included in the study were asked about the existence of pain before surgery, verifying they were not undergoing any analgesic treatment. Patients were given a card and instructions to note every time they needed to take analgesics, the day this corresponded to with respect to surgery, and the day on which the pain disappeared.

The primary endpoints were pain and recurrence. Acute pain was defined as pain reported by a patient in the first 3 months after operation, and chronic pain was defined as pain that persisted for more than 6 months. Pain scores on a 10-cm visual analogue scale (VAS) were measured from 0 (*no pain*) to 10 (*unbearable pain*). Hematoma was defined as the accumulation or drainage of blood, with ecchymosis of the adjacent tissues or of the scrotum with local discomfort. Wound infection was defined as the presence of any sign of infection in the wound (pain, fluctuation, reddening, etc) whether or not it was associated with fever, or pus drainage via the wound, and always confirmed using bacterial culture. The frequency of infections was recorded 1 month after surgery. Recurrence was confirmed by clinical examination and when necessary by ultrasound. Secondary endpoints were morbidity, operating time (minutes), need for oral analgesia (days), and the time required to return to normal activities (days). This period was defined as the time needed to be able to perform household activities, drive, or walk without pain. All patients were given standardized postoperative instructions that did not limit their normal activities.

Economic Analysis

The cost to the hospital was analyzed for each procedure according to the treatment. Data provided by the hospital's 2011 report was used, checking all the costs generated for each patient during the performance of the procedure at the Day Hospital.

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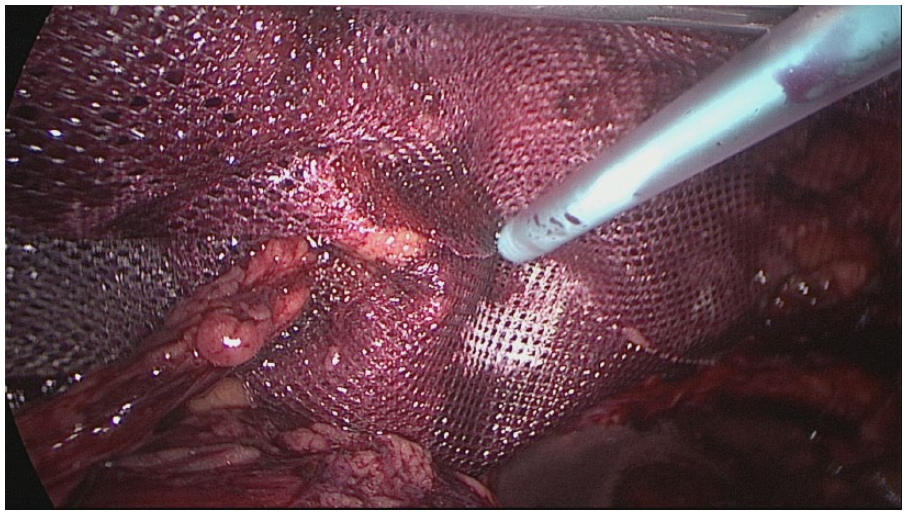
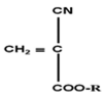


Figure 3. Mesh fixation using glue in a laparoscopic hernioplasty (TEP) through an applicator-dispenser.

Table 1. Properties of the Synthetic Tissue Adhesive Used.

Property	Description
Chemical name	*n*-Hexyl-α-cyanoacrylate
Synonyms	2-Propenoic acid, 2-cyano-, hexyl ester; Acrylicacid, 2-cyano-, hexyl ester
Chemical formula	$C_{10}H_{15}NO_2$
Structural and molecular formula	 R = $C_{10}H_{15}$
Boiling point	270°C at 760 mm Hg
Flash point	121°C
Degradation	Hydrolyze
Degradation products	Alcohol; Acido polycyanoacrylique (minima cantidad de formaldehydo)
Removal or disposal	Urine and feces

Statistical Analysis

To detect the differences between the control and experimental groups, a sample size of 36 patients per group was required. This was determined using the *Z*-test for population proportion with an α value of 5% and power defined as 80%. According to the power calculation, 100 subjects were needed for the study. Descriptive statistics were used to characterize patient groups, presented as mean (standard deviation) or median (range) depending on the type of data and distribution. The data were compared using Student's *t* test or the Mann–Whitney *U* test and variance analysis. Comparisons of dichotomous outcomes were made using Pearson's χ^2 test, and an analysis of smaller groups within the study was permitted, using Fisher's exact test. $P < .05$ was considered significant. Data were analyzed using SPSS software package for Windows (SPSS Inc, v18.0, Chicago, IL).

Results

Patient Characteristics

The patient characteristics and hernia types included in the study are shown in Tables 2 and 3. There were no significant differences in patient characteristics between the 2 treatment groups, in the 2 studies, except that more obese patients were included in the experimental laparoscopic group. All the patients were discharged according to the ambulatory protocol, and there was no need for admission or posterior readmission during the monitoring period. There has been no toxicity associated with the use of the synthetic adhesive tissue (allergy, infection, or cutaneous necrosis).

Open Study

Surgical time was significantly lower for the group using glue, being 12 minutes quicker than for the group using sutures ($P = .001$). The postoperative morbidity was similar from a statistical viewpoint, although in the adhesive group we did not find any cases with infection or chronic pain and the hematoma rate was 2%, whereas in the suture group the percentages for these complications were higher (infection 1.9%, chronic pain 5.7%, and hematoma 9.6%). The pain variable and the use of analgesics have been statistically different during the complete monitoring period, in favor of the adhesive group

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Table 2. Characteristics of the Patients Diagnosed With Unilateral Inguinal Hernia and Operated Upon With Lichtenstein Hernioplasty[a,b].

	Group		
	Control (n = 52)	Experimental (n = 50)	*P* Value
Age (years)	55 ± 14	57 ± 16	.25
Gender			.36
Female	15 (28.8)	16 (32)	
Male	37 (71.2)	34 (68)	
BMI (kg/m^2)	29.8 ± 4.2	29.3 ± 3.7	.26
Comorbidity			
Diabetes	4 (7.7)	3 (6)	.52
COLD	5 (9.6)	6 (12)	.34
Type of hernia			.36
Indirect	43 (82.7)	40 (80)	
Direct	9 (17.3)	10 (20)	
Preoperative pain (VAS)	1.3 ± 0.6	1.2 ± 0.5	.18

Abbreviations: BMI, body mass index; COLD, chronic obstructive lung disease; VAS, visual analog scale (0-5).
[a]Values expressed as mean ± SD for continuous variables and number (%) for categorical variables.
[b]NS: $p > .05$, with 95% confidence interval.

Table 3. Characteristics of the Patients Diagnosed With Bilateral Inguinal Hernia and Operated Upon With Totally Extraperitoneal Laparoscopic Hernioplasty[a,b].

	Group		
	Control (n = 52)	Experimental (n = 50)	*P* Value
Mean operating time (minutes)	48.4 ± 19.7	36.6 ± 15.4	.001
Postoperative morbidity			
Hematoma	5 (9.6)	1 (2)	.11
Infection	1 (1.9)	0	.50
Chronic pain (>3 months)	3 (5.7)	0	.12
Pain score (VAS)			
7 days	4.7 ± 2	2.6 ± 1	.001
1 month	2.8 ± 1.7	1.1 ± 1.3	<.0001
3 months	2.5 ± 1.4	0	.001
6 months	1.4 ± 1.9	0	<.0001
1 year	1.1 ± 1	0	<.0001
Analgesic consumption (days)	14 ± 5.1	8 ± 3.6	<.0001
Recurrence (follow-up) (months)	0 (14 ± 2)	0 (16 ± 1)	

Abbreviation: VAS, visual analog scale.
[a]Values expressed as mean ± SD for continuous variables and number (%) for categorical variables.
[b]NS: $p > .05$, with 95% confidence interval.

($P < .001$). No patient from the group treated with glue needed painkillers after postoperative day 10 nor recorded pain after the third postoperative month. There were no recurrences in either of the 2 treatment groups (Table 4).

Laparoscopic Study

The study of the bilateral inguinal hernia procedure via the totally extraperitoneal laparoscopic approach is shown in Table 5. Results are similar to those for the open approach. The surgical time for the group treated with glue was significantly lower than that treated with tacks (35 minutes vs 48 minutes, $P < .001$). We did not find any significant differences in morbidity, although from a descriptive point of view the hematoma or pain percentages were higher in the group where the mesh was fixed with a mechanical stapler (hematoma rate 3.7% and chronic pain 5.6%, *ns*). Significant differences between both forms of mesh fixation can be seen in the pain and analgesic consumption variable ($P < .001$), where they are lower in the group with the synthetic TA. The laparoscopic approach did not require analgesic treatment after

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Table 4. Postoperative and Monitoring Data for Patients Operated Upon for Inguinal Hernias via the Anterior Approach Using the Lichtenstein Technique With Sutures or Adhesive[a,b].

	Group		
	Control (n = 54)	Experimental (n = 52)	*P* Value
Age (years)	54.9 ± 15.6	55.8 ± 13.8	.37
Gender			.36
Female	15 (27.7)	16 (30.7)	
Male	39 (72.3)	36 (69.3)	
BMI (kg/m^2)	27.6 ± 4.1	29.3 ± 3.7	.01
Comorbidity			
Diabetes	3 (5.6)	2 (3.8)	.51
COLD	4 (7.4)	2 (3.8)	.35
Type of hernia			.36
Indirect	47 (87)	44 (85)	
Direct	7 (13)	8 (15)	
Preoperative pain (VAS)	1.8 ± 0.6	1.7 ± 0.5	.17

Abbreviations: BMI, body mass index; COLD, chronic obstructive lung disease; VAS, visual analog scale (0-5).
[a]Values expressed as mean ± SD for continuous variables and number (%) for categorical variables.
[b]NS: $p > .05$, with 95% confidence interval.

Table 5. Postoperative and Monitoring Data for Patients Operated Upon Laparoscopically for a Bilateral Inguinal Hernia Using the Totally Extraperitoneal Technique[a,b].

	Group		
	Control (n = 54)	Experimental (n = 52)	*P* Value
Mean operating time (minutes)	48.4 ± 13.1	35.6 ± 16.5	.0001
Postoperative morbidity			
Hematoma	2 (3.7)	0	.25
Chronic pain (>3 months)	3 (5.6)	0	.12
Pain score (VAS)			
7 days	3.2 ± 1.9	1.3 ± 1.6	<.0001
1 month	2.4 ± 2.1	1.1 ± 1.5	.0001
3 months	1.8 ± 1.8	0	.001
6 months	1.6 ± 1.4	0	.001
1 year	1.1 ± 1	0	.001
Analgesic consumption (days)	15 ± 3.6	5 ± 4.6	.001
Recurrence (follow-up) (months)	0 (13 ± 1)	0 (15 ± 2)	

Abbreviation: VAS, visual analog scale.
[a]Values expressed as mean ± SD for continuous variables and number (%) for categorical variables.
[b]NS: $p > .05$, with 95% confidence interval.

the first postoperative week in any of the cases. After 2 years no recurrences have been detected in either of the 2 groups (Table 5).

Economic Analysis

In our hospital, the total cost for an anterior hernioplasty using sutures is 609.36 Euros, compared to 359.36 when the adhesive is used (difference of 250 Euros). The difference in cost in the laparoscopic repair of the bilateral hernias only depended on the fixation system, with a saving of 291 Euros per patient. With an annual number of 420 unilateral hernias and 65 bilateral hernias (hospital data from 2011), the possible savings for just this procedure in an Abdominal Wall Unit would be of 123 916.3 Euros (Table 6).

Discussion

The results of this study show that sutures and tackers are not necessary and can be substituted by glue (*n*-hexyl-α-cyanoacrylate) in the treatment of inguinal hernias, both

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Table 6. Cost Analysis for the Repair of an Inguinal Hernia Over a Year.

	Inguinal Hernioplasty	
	Glue	Suture
Open surgery		
Sutures	0	12.87
Tissue adhesive	105.98	0
Skin stapler	0	5.26
Cost (operating room)	253.38	591.23
Laparoscopic surgery		
Stapler	0	397.00
Tissue adhesive	105.98	0
Annual cost (n= 420+65)	157 819.9	281 736.2
Annual savings	123 916.3	

for open and laparoscopic approaches, on any plane of the abdominal wall and with the same degree of safety and lower morbidity rates. In hernia surgery, it is considered that the ideal fixation should fix well, avoid recurrences, should not present complications owing to its use, and should be easy to use at an acceptable cost. TAs could be an alternative to more traumatic and expensive mechanical fixation methods but as yet we know little about these products. Cyanoacrylate-derived TAs have a common chemical structure and their properties vary depending on the length of their alkyl chain, which controls their degradation speed. The short chain derivatives (methyl and ethyl) have been abandoned for medical use because of their histotoxicity, a consequence of their quick biodegradation.[17,18] For surgical use, the ideal TA should be biocompatible, quick acting, easy to handle, and inexpensive. The long chain derivatives (butyl, octyl, and hexyl) fulfill these requisites and do not present any adverse effects as they degrade more slowly (minimum local inflammatory response), which means they are currently used in general surgery, traumatology, otolaryngology, ophthalmology, maxillofacial and odontology, vascular surgery, urology, plastic surgery, gynecology, and so on.[1-12]

n-Hexyl-α-cyanoacrylate was first synthesized by Dr Valérie Vidal-Sailham in 2004 and reformulated in 2006 to achieve longer duration under the name *Microbond.* In 2007, it got its CE mark, and in 2009 its name was changed to *Ifabond*, and it received a new license for unlimited use in internal and external surgical procedures. This adhesive is extremely pure and has a low polymerization temperature, which helps prevent its toxicity, while at the same time, because of its almost complete lack of impurities, does not affect its effectiveness as an adhesive. Before starting this study, we performed a pilot experiment during 6 months to learn how to use the glue and to develop a standard technique. No patients in the pilot group presented technical problems related to the glue (inflammation, infection, hematoma, dehiscence, allergy, or pain), and we learnt the following: (*a*) that the surfaces to be joined should be dry, with good initial hemostasis; (*b*) to apply the drops with a good view of the spermatic cord and nerves to avoid their damage during polymerization; (*c*) not to touch the tissue or mesh with the cannula in order to avoid it becoming obstructed (this problem is more difficult in laparoscopic surgery where the adhesive is applied through a long cannula); (*d*) to use the lowest possible dose, 6 to 8 drops is enough to fix a 10 × 15 cm mesh; (*e*) the fixation points are the same as for sutures (especially the pubis and inguinal ligament); (*f*) the mesh should be macroporous to ensure correct diffusion of the adhesive; and (*g*) the aponeurosis of the external oblique muscle and fascias (Scarpa and Camper) in the open approach and the anterior aponeurosis of the anterior rectus abdominis muscle in the laparoscopic approach can be glued once they have been drawn together using pean forceps. In our experience, this complete closure of the incisions with the rest of the glue means less surgical time, avoids adding tissue traumatism and hemorrhages by injuring small vessels, reduces the dead spaces and possibilities of hematomas (sealing and bactericide effect), and lowers the costs of the procedure.[16,19-22]

The first publication to use a synthetic TA as an alternative mesh fixation method in an inguinal hernioplasty was by Farouk et al[23] in 1996, using an anterior approach, and by Jourdan and Bailey,[24] in 1998 via the laparoscopic approach, both using butyl derivatives. Since then other authors have published favorable results with both the approaches,[25,26] but our study is the first to use *n*-hexyl-α-cyanoacrylate, with the longer alkyl chain, as a substitute for sutures in all the planes of the abdominal wall and using both approaches, by the same surgeon. Although hernioplasty morbidity is low, the formation of local hematomas is the most frequent complication, and this is due to poor hemostasis or vessel traumatism caused by the suture. This complication is particularly important in the laparoscopic approach as extremely large retroperitoneal hematomas can form, which require secondary

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surgery if the patient exhibits hemodynamic instability. Two facts make this point more serious: first, the average patient age is getting older, thus many have anticoagulant treatments that have to be reverted, and second, the presence of frequent vascular anomalies at a preperitoneal retropubic level.[27] The TA offers clinical benefits in these cases as it is a sealant and is hemostatic, as well as being a bactericide, a fact that may also contribute to the reduction in the risk of local infection.[28,29] In this study, for both forms of approaches, the percentage of hematomas in the hernioplasties using adhesives was small, although it was not statistically significant, a fact that may be explained by the small size of the sample.

The pain score after an inguinal hernioplasty can vary between 10% and 30%.[13] Some authors have published lower postoperative pain scores when using TA as an alternative to sutures.[30-32] This study confirms the hypothesis that suture-free surgery improves postoperative pain as it avoids possible periostic inflammation of the pubis, tension of muscular fibers, trapped or injured nerves, reaction to foreign bodies, or the formation of granulomas. The use of an adhesive, by eliminating these phenomena, offers more physiological support for the concept of a *tension-free technique* than when a mechanical form of fixation is used. The totally extraperitoneal laparoscopic approach is recommended as an alternative treatment for recurrent and bilateral inguinal hernias.[33-35] Some meta-analyses have shown that fixation of the mesh on the extraperitoneal plane may be unnecessary as a routine treatment, but is advisable in medium-large hernias and in direct-type hernias.[36,37] The complications associated with the use of tackers are well known: neuralgias, hemorrhages, and hematomas in the space of Retzius. Our experiment shows that the substitution of tackers for an adhesive in the laparoscopic approach, as in the open approach, offers various advantages for the patient in terms of morbidity and for the institution in terms of lower costs.

For a new treatment method for inguinal hernias to be validated, it is necessary to confirm its advantages, ensure that there is no toxicity, and ensure that the recurrence rate is the same, as this variable should be the ultimate measurement of this surgical technique's success. The glues are slowly degraded from 3 months after surgery, by which time the mesh has been incorporated into the tissue by fibroblast infiltration and collagen deposits. Moreover, after the first month resistance depends more on the host than on the fixation mechanism. Experimental studies confirm that long chain glues do not alter the mesh's incorporation process, and clinical studies confirm that the recurrence rate is the same as that when sutures are used.[38-41]

Sanitary resources are limited and hospital spending is one of the pillars of the clinical management of a surgical service. Fibrin glues, prepared from human plasma and classified as drugs by the World Medicines Agency, are much more expensive, require prior preparation of the product, may imply important risks (disease transmission), and are not comparable to the cyanoacrylates, which are proposed as an easy and quick alternative to the use of manual or mechanical sutures. This study shows that glues reduce surgical time, which can mean an improvement in the efficiency of the surgical program, and reduce morbidity, which favors an early return to work for the patients. These facts should have an economic impact and annual saving that cannot be ignored given the current economic climate.

We recognize that the design of this study has some limitations, but it also has its strong points. We see the limitations as being the small sample size and a relatively short monitoring period, although it is sufficient to evaluate recurrence related to the surgical method. Among the strong points are the fact that the study has been performed in one center using operations by just one surgeon, which significantly reduces the factors related to dispersion (technique, capacity and training, resources and instruments, etc), the lack of patients lost during monitoring, and it being the first study to include the 2 possible approaches for inguinal hernia treatment.

Conclusion

n-Hexyl-α-cyanoacrylate tissue adhesive is safe as an alternative to traditional suture methods, both as means of mesh fixation and for the closure of the surgical wound, in the treatment of inguinal hernias, be it via the laparoscopic or via the open approach. The use of glue offers significant advantages during the first year of monitoring without altering the recurrence rate. Studies with a greater number of patients and a longer time period are necessary to be able to confirm these results.

Declaration of Conflicting Interests

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