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ORIGINAL ARTICLE

A self-adhering mesh for inguinal hernia repair: preliminary results of a prospective, multicenter study

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Abstract
Background Prosthetic reinforcement is the gold standard treatment for inguinal hernia and reduces the risk of recurrence. Yet up to one-third of patients complain of post-surgical pain due to irritation and inflammation caused by the mesh and the fixation materials. Of these patients, 3–4% will experience severe and disabling chronic pain. We performed a prospective multicenter clinical study of a self-adhering prosthesis, consisting of a lightweight polypropylene mesh (40 g/m²) coated on each side with synthetic glue, to evaluate early postoperative complications and patient outcomes.
Patients and methods Between August 2008 and June 2010, 186 patients underwent hernia repair using the Lichtenstein technique and the self-adhering prosthesis. Primary endpoints were the frequency of disabling complications and quality of life (QoL) at 3-month follow-up. Pain, numbness, and groin discomfort were evaluated pre- and postoperatively (1 week, 1 and 3 months) using a visual analogue scale (VAS). Patients' pre- and postoperative QoL were measured using the SF12 questionnaire. Secondary endpoints were number of complications and recurrence rate, use of analgesic drugs, length of hospital stay, delay to return to normal activities, and patient satisfaction. The quality of the self-adhering mesh and its clinical utility were also evaluated by the participating surgeons.
Results A total of 186 patients were enrolled and followed for at least 3 months after inguinal hernia repair. A total of 174 (95%) primary hernias and 12 (5%) recurrent hernias were treated. There were no intraoperative complications, no recurrences, and no repeat interventions performed during the study. The post-surgical complication rate was 4.5%. The mean delay to recover normal physical activity was 4 days. For the primary endpoint of pain, a VAS of zero was reported by 93/184 (50.5%) patients at 1 week, 130/171 (76.0%) patients at 1 month and 119/132 (90.2%) patients at 3 months' follow-up ($P < 0.0001$). The postoperative SF12 scores showed a significant improvement in patient QoL following surgery ($P < 0.0001$).
Conclusions Adhesix® self-adhering mesh for prosthetic reinforcement following inguinal hernia repair is atraumatic and associated with infrequent post-surgical complications or pain, a rapid recovery rate, and a high patient-reported QoL. A longer follow-up is underway to assess the frequency of post-surgical recurrence.

Keywords Inguinal hernia repair · Lichtenstein technique · Self-adhering mesh · Prosthetic reinforcement

Introduction

The use of prosthetic reinforcement is considered to be the standard of care in the surgical management of inguinal hernia, and it significantly reduces the risk of recurrence. Today, the risk of chronic post-surgical pain may be the most important variable to consider in groin hernia repair. Estimated rates of chronic pain vary considerably from 0 to 53% [1].

A self-adhering mesh: Adhésix®—Laboratoires Cousin Biotech—59117 Wervicq Sud (France).

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Up to one-third of patients will complain of some degree of pain 1 year after surgery, and in 3–4% of patients, this pain will be severe and disabling [2]. The causes of pain following inguinal hernia repair are poorly understood, but factors such as nerve and tissue injury may be involved.

The characteristics of the mesh used for prosthetic reinforcement have evolved over the last 15 years. Polypropylene is material used with the greatest frequency. Several studies have examined the potential role of the mesh as a cause of post-surgical pain. Possible etiologies include irritation or damage of inguinal nerves by sutures or the mesh, inflammatory reactions against the mesh, or the development of scar tissue. As an alternative to traditional polypropylene mesh, lightweight polypropylene mesh has been developed to reduce pain, reduce the inflammatory response, and improve outcomes, while reducing the risk of recurrence [3].

Prostheses are usually fixed in order to avoid migration, which can lead to hernia recurrence. There are numerous techniques for fixation, ranging from simple stitches to various stapling systems. Fixation devices are time consuming, costly, and may contribute to postoperative pain by causing nerve or tissue injury [4]. Some investigators have proposed the use of biological adhesives, such as fibrin, to reduce or avoid the use of staples [5].

We recently reported the results of an experimental study in pigs in which a new self-adhering prosthesis, coated with a synthetic glue, demonstrated excellent results in terms of handling, adhesiveness, and wound integration [6]. Here, we report the results of a prospective, multicenter clinical study of this new prosthesis used with the Lichtenstein technique for inguinal hernia repair.

Patients and methods

Study design and patients

The objective of this prospective, multicenter, observational study was to evaluate the frequency of disabling complications and to assess various measures of patient QoL after undergoing open inguinal hernia repair using the Lichtenstein technique and a self-adhering mesh prosthetic reinforcement device (Adhesix®, Laboratoires Cousin Biotech, Wervicq Sud, France).

A total of 217 consecutive patients between the ages of 18 and 80 years with primary or recurrent unilateral inguinal hernia were enrolled from August 2008 to June 2010. After informed written consent was obtained, the patients underwent sutureless Lichtenstein hernia repair. Exclusion criteria included pregnancy, bilateral and femoral hernia, EHS hernia classification L3H3 [7], emergency cases, associated surgery, body mass index (BMI) >35 kg/m², insulin-dependent diabetes mellitus, hepatocellular disease, drug or alcohol addiction, psychiatric pathologies, regular use of pain-killers, steroids, immunosuppressants, or anticoagulation therapy. Preoperative data were collected, including management history, physical and professional activity level, European Hernia Society (EHS) and American Society of Anaesthesiologists (ASA) hernia classification, and the presence of co-morbidities and risk factors (e.g, arterial hypertension, prostatitis, smoking).

Surgical technique

The type of anesthesia and antithrombotic and antibiotic prophylaxis were left to the investigators' discretion at each study site. Intraoperative local anesthetic (Naropeine® 40 mg, Astra Zeneca, France) could be used. Lichtenstein repair was performed as described previously [7]. After a 5–8-cm skin incision was made, the external oblique aponeurosis was divided. Surgeons measured the size of the hernia after dissection and assessed it according EHS classification. The necessary space for placement of the mesh was then created laterally along the inguinal ligament from the pubic tubercle towards the anterior superior iliac spine, and then between the external oblique aponeurosis and the conjoint tendon to expose the rectus muscle aponeurosis. The pubic bone was cleared, allowing an easy dissection of the cord. The cremaster muscle was resected if necessary, and the three nerves were localized and preserved, if possible. The hernia sac was isolated (and in some cases opened) and repositioned along its course without any suturing. The collar diameter was measured (internal ring). The dimensions of the operating field were then precisely noted in cm, as follows: from the inguinal ligament to the upper limit; laterally from the pubic tubercle to the internal ring; and from the internal ring to the lateral (external) limit of the muscle dissection. The mesh was then cut exactly to the same dimension. Local hemostasis was controlled, and the cord was retracted vertically. The flaps of the mesh were released and loosely closed around the cord away from the deeper part of the wound. The mesh was placed in the axis of the cord and carefully oriented to the definitive position. The fixation to the muscle plan was achieved by applying pressure on the mesh with dry forceps, starting caudally on the pubic bone, then medially to the internal oblique structures. The cranial part of the mesh was placed, without any digital manipulation, under the external oblique aponevrosis. Finally, the mesh was positioned in a single application with no additional fixation. The external oblique aponevrosis and the skin were then closed with a running resorbable suture.

Study endpoints

The primary endpoint was the frequency and severity of disabling complications (chronic pain, numbness, and

groin discomfort) and changes in patient-reported QoL within 3 months after inguinal hernia surgery using the self-adhering mesh prosthesis. Pain was evaluated by patient self-assessment preoperatively and 1 week (W1), 1 month (M1), and 3 months (M3) after surgery using a visual analogue scale (VAS). The VAS, with 0 equaling no pain and 100 equaling the worst conceivable pain, was presented to the patient, who selected the number on the scale that corresponded to the worst level of pain experienced during the period since the previous evaluation. Pain was classified according to the VAS into mild (1–30 mm), moderate (31–60 mm), and severe (>60 mm). Absence of pain was defined as VAS = 0.

Numbness was defined as paresthesia in a defined part of the body, and was assessed preoperatively and at W1, M1, and M3 after surgery, using the same VAS as described for pain. Groin discomfort was a more general term used to describe a less severe nociception. Discomfort is often used to describe a non-continuous sensation in the groin or upper thigh that does not require analgesics. It was assessed preoperatively and at W1, M1, and M3, using a VAS.

QoL was measured using the SF12 questionnaire, which was administered before the operation and at 1 and 3 months after surgery. Results were compared with those of the normal American healthy population [8].

Secondary endpoints were evaluated as follows:

- Mesh quality: handling, adhesiveness, and utility during the operation were rated by the surgeon on a scale from 0 (poor) to 5 (excellent);
- Intraoperative, immediate, and mid-term (3 months) postoperative complications were separately assessed, in particular hematoma, seroma, bruising, ecchymosis, wound infection, and mesh infection.
- Use of WHO class I–III analgesic drugs during the entire follow-up period;
- Duration of initial hospital stay (and need for readmission) and time to return to normal activity (physical, sport, and professional);
- Frequency of recurrence as confirmed by an independent blinded surgeon during a medical examination or during other examinations such as ultrasound;
- Incidence of adverse events assessed at each follow-up visit;
- Patient satisfaction at 3 months, as determined by the answer to the question, "Would you be willing to undergo the same type of operation again?"

Statistical analysis

Variables were described as mean ± standard deviation or number and percentages. Percentages were calculated using the number of documented data as the denominator. When relevant, the 95% confidence interval (95% CI) was added assuming a binomial distribution. For binary variables between groups, comparisons used the chi-squared test. For SF-12 scores, comparisons between the study population and the normal values of the US population used the Student's t-test for unpaired samples. Evaluation of SF-12 scores at baseline and after 3 months used the Student's t-test for paired samples.

Table 1 Comparison of the 8 SF12 QoL domain measurements between the study patients and a healthy American control population (mean ± standard deviation)

SF12 domain	Patients $N = 186$	Control group	P value*
Physical functioning	61.53 ± 35.33	81.18 ± 29.11	<0.0001
Role limitations due to physical health	63.64 ± 21.24	80.53 ± 27.13	<0.0001
Bodily pain	63.47 ± 24.96	81.74 ± 24.53	<0.0001
General health	65.86 ± 19.23	72.20 ± 23.19	<0.0001
Vitality	46.95 ± 19.93	55.59 ± 24.84	<0.0001
Social functioning	75.15 ± 24.16	83.74 ± 24.76	<0.0001
Role limitations due to emotional problems	71.31 ± 23.16	86.41 ± 22.36	<0.0001
Mental health	66.46 ± 18.82	70.18 ± 20.51	0.01
Physical component[a]	−0.66 ± 0.81		
Mental component[a]	−0.24 ± 0.91		

* Comparison between patients and control population [8] using Student's t test

[a] Z-score

Results

Overall, 186 patients were included in the study. As expected for inguinal hernia repair, there were 175 males (94%) and the median age was 53 ± 15 years. Mean BMI was 24.6 ± 3.1 kg/m². At entry, 103 patients (58%) had an ASA score of I, 80 patients (41%) had a score of II, and the remaining 2% had a score of III. The preoperative co-morbidity prevalence rate was 4.2%. Seventy-one patients (38%) reported no professional activity (34% retired, 4% unemployed); 67 (36%) were manual workers, and 48 (26%) engaged in sedentary professional activity. Sixty-four patients (36%) reported active participation in sports. The mean preoperative pain score, measured by VAS, was 17 ± 19 mm. Fifty-two patients (28.6%) reported no pain; 130 patients (71.4%) had a score between 0 and 30; and 35 (19%) had a score >30. The results of the preoperative SF12 QoL questionnaire compared with those of a healthy American control population are reported in Table 1.

Of the hernias treated (55% right side, 44% left side), 174 (95%) were primary and 12 (5%) were recurrences.

Table 2 Type of hernia according to the European hernia society (EHS)

Type	*n*	%
LP1	31	16.9
LP2	31	16.9
MP1	53	28.8
MP2	53	28.8
LR1	1	0.5
LR2	4	2.2
MR1	1	0.5
MR2	5	2.7

LP lateral/indirect primary hernia, *MP* medial/direct primary hernia, *LR* lateral/indirect recurrent hernia, *MR* medial/direct recurrent hernia

Table 3 Resumption of normal activities after surgery

Activity	*n*	At discharge (%)	M1 (%)	M3 (%)	Mean time to resumption (days)
Daily (physical)	186	66.9	96.3	98.4	4
Sport	64	8.8	35.9	73.3	32
Professional	115	11.4	70.5	93.2	19
Active	67	8.6	69.1	92.1	21
Sedentary	48	15.6	72.5[a]	93.8	15[a]

[a] Difference between active and sedentary professional activity was not statistically significant

The recurrent hernias had previously been treated with mesh ($n = 8$) and non-mesh repairs ($n = 4$). The mean duration of the hernia was 1.5 ± 3.9 years. The types of hernias treated, by EHS classification, are reported in Table 2. The hernias were indirect in 87 patients (47%), direct in 86 patients (46%) and combined in 13 patients.

General anesthesia was used in 97% of the cases. The median size of incision was 6.3 ± 1.37 cm, and the mean "skin-into-skin" operating time was 40.6 ± 16.8 min. The majority of hernias were small to mid size, consistent with protocol entry criteria. The mean collar diameter of the hernia was 2.8 ± 1.2 mm.

During the surgical procedure, the following nerves were observed by the surgeon in 145 patients (78%): ilio-inguinal (94%), ilio-hypogastric (66%), and femoral branch (63%). Nerves were preserved in 152 cases (82%) and cut in 34 cases. When cut, nerves were either ligated (4 cases) and/or buried (30 cases). Intraoperative local infiltration of Naropeine was performed in 126 patients (63%). A total of 143 patients (77%) received prophylactic antibiotics, and 180 (97%) received intraoperative analgesics. Six patients (3.2%) required a drain at the end of the procedure. There were no intraoperative complications. One hundred fourteen patients were discharged 3 h after the operation, and no patients required readmission to the hospital. The overall wound healing complication rate was low: a total of eight patients (4.3%), of which five (2.6%) developed either hematoma or seroma, and four (1.3%) developed ecchymosis. There were no cases of wound or mesh infection, and no recurrence or reintervention required for any of the patients.

The mean time to recover normal physical activity was 4 days. A total of 126 patients (67.7%) were able to engage in normal activity at the time of hospital discharge; 167 of 173 patients (96.5%) had recovered normal physical activity by the 1-month follow-up, and 135 of 137 patients (98.5%) had done so by the 3-month follow-up (Table 3). Anaglesics were used by 99% of patients in the immediate postoperative period, and by 14% of patients at 1 month and 2% of patients 3 months after surgery.

Evaluation of the primary endpoint (frequency and severity of pain, numbness, and groin discomfort) was performed preoperatively (pain only) and during at the 1-week, 1-month, and 3-month follow-up time points using VAS scales. The results are reported in Tables 4, 5, and 6. Most patients reported mild to no pain preoperatively and at the 1-week follow-up; the proportion of patients reporting no pain, numbness, or discomfort then steadily increased at the 1- and 3-month time points. At 3-month follow-up, the percentage of patients reporting a VAS = 0 for pain, numbness, and discomfort were 90, 97, and 87%, respectively. Compared with preoperative pain, there was a significant improvement in pain by 3 months after surgery ($P < 0.0001$; Table 4).

Table 4 Patient-reported pain using the VAS scale prior to surgery and at each follow-up visit

	Before surgery $n = 182$	W1 $n = 184$	M1 $n = 171$	M3 $n = 132$	*P* value*
None (VAS = 0; no.)	52 (28.6%)	93 (50.5%)	130 (76%)	119 (90.2%) 95% CI [83.7–94.8%]	<0.0001
Mild (VAS 1–30; no.)	99 (54.4%)	80 (43.5%)	36 (21%)	13 (9.9%) 95% CI [5.2–16.3%]	<0.0001
Moderate (VAS 31–60; no.)	27 (14.8%)	10 (5.4%)	5 (3%)	2 (1.5%) 95% CI [0.5–7.0%]	0.0006
Severe (VAS > 60; no.)	4 (2.2%)	1 (0.6%)	0 (0%)	1 (0.6%) 95% CI [0.02–4.5%]	0.32

*Comparison of pre-surgical and M3 rates

Table 5 Patient-reported numbness using the VAS scale at each follow-up visit

	Preoperative $n = 182$	W1 $n = 184$	M1 $n = 171$	M3 $n = 132$
Mean ± SD (VAS/100)		3.8 ± 9.9	1.6 ± 4.6	0.7 ± 4.6
None (VAS = 0; no.)		151 (82.1%)	147 (86.0%)	b 128 (97%)
Mild (VAS 1–30; no.)		27 (14.6%)	24 (14%)	3 (2.2%)
Moderate (VAS 31–60; no.)		6 (3.3%)	0	1 (0.8%)
Severe (VAS > 60; no.)		0	0	0

Table 6 Patient-reported discomfort using the VAS scale at each follow-up visit

	Preoperative $n = 182$	W1 $n = 184$	M1 $n = 171$	M3 $n = 132$
Mean ± SD (VAS/100)		6.5 ± 12.4	2.5 ± 8.5	1.1 ± 5.0
None (VAS = 0; no.)		107 (58.2%)	131 (76.6%)	116 (87.9%)
Mild (VAS 1–30; no.)		66 (35.9%)	38 (22.2%)	15 (11.3%)
Moderate (VAS 31–60; no.)		11 (5.9%)	1 (0.6%)	1 (0.8%)
Severe (VAS > 60; no.)		0	1 (0.6%)	0

Table 7 SF12 QoL domain measurement at the preoperative visit and 1 and 3 months post-surgery (mean ± SD)

	Preoperative $n = 175$	M1 $n = 160$	M3 $n = 125$	*P* value*
Physical functioning	61.5 ± 35.33	68.8 ± 33.0	77.6 ± 32.5	0.0005
Role limitations due to physical health	63.6 ± 21.24	61.3 ± 23.1	78.1 ± 20.4	<0.0001
Bodily pain	63.5 ± 24.96	72.0 ± 24.3	83.0 ± 21.3	<0.0001
General health	65.9 ± 19.23	68.4 ± 16.4	70.0 ± 19.5	0.01
Vitality	46.9 ± 19.93	51.0 ± 19.5	55.0 ± 21.4	<0.0001
Social functioning	75.2 ± 24.16	76.9 ± 26.3	87.1 ± 18.8	<0.0001
Role limitations due to emotional problems	71.3 ± 23.13	75.1 ± 23.1	83.5 ± 18.9	<0.0001
Mental health	66.5 ± 18.82	71.4 ± 18.3	72.9 ± 18.8	0.003

* Compared with preoperative visit using Student's t comparing preoperative and M3

QoL improved from the preoperative visit to the 1- and 3-month postoperative visits in all domains of the SF12 questionniare (Table 7). At 3 months post-surgery, 97.7% of patients reported that they were very satisfied with the procedure and would choose the same operation again.

Discussion

Hernia studies have shifted their focus to adverse events and patient outcomes. Chronic pain following surgery has emerged as a common and sometimes severe problem that can significantly affect a patient's health-related quality of life. In a recent review of the literature, the incidence of chronic pain following hernia repair was reported to range between 25 and 30% for the majority of studies, with 2–9% of patients complaining of severe pain [9]. Risk factors for chronic postoperative pain include younger age, obesity, preoperative pain, and preexisting pain syndromes [12]. Surgical risk factors include use of mesh, open surgery, inadvertent nerve injuries, postoperative infection, and hernia recurrence [10].

Some studies have reported that high-density, microporous (or heavy-weight) polypropylene meshes stimulate inflammatory reactions, which may be responsible for adverse mesh shrinkage, particularly as scar tissue develops [14]. In addition, several studies have examined the role of the mesh as a causal factor in postoperative pain and other complications. Possible factors include irritation or damage of inguinal nerves by sutures or the mesh [11], inflammatory reactions against the mesh [12], or development of scar tissue.

Fixation of the mesh, especially with staples or stitches, is a recognized as a causal factor in postoperative pain, and is correlated with direct injury to nerves. To avoid this complication, the use of glue to affix the mesh has been proposed for some time [13]. Atraumatic mesh fixation with fibrin sealant has proven to be an efficient alternative in terms of feasibility and fixation strength. Fibrin sealant is a biodegradable biological adhesive formed by the combination of human-derived fibrinogen and human-derived thrombin. A randomized experimental study in a laparoscopic pig model of inguinal hernia was performed to compare the efficacy of mesh fixation with Tissucol®-Tisseel® (Baxter, Austria) using staples or no fixation [14]. Furthermore, fibrin glue fixation of the entire mesh avoided the creation of "dead space," thereby limiting fluid collection [13], and improving postoperative outcomes by reducing hematomas and other wound healing complications. Several centers have reported the use of fibrin sealant for mesh fixation in both laparoscopic (TAPP/TEP) [15] and open (Lichtenstein) hernia repair techniques [28], and have described less frequent postoperative pain, significant reduction of wound edema, and fewer hematomas [16].

Here, we performed a similar evaluation of the Adhesix® mesh using the same population, open Lichtenstein technique, and study endpoints: the frequency and severity of disabling complications (pain, numbness, and discomfort) and measures of QoL by the SF12 questionnaire. Compared with the Timeli® study, the Adhesix® mesh is a macroporous light-weight (40 g/m²) mesh that uses a synthetic resorbable glue (polyvinylpyrolidone and polyethylene glycol based) that has proven safety and efficiency [6].

There are significant differences between the synthetic and the fibrin mesh sealants. Adhesix® is pre-coated on both faces with the synthetic glue in a regular pattern and is ready to use. Fibrin glue must be prepared and applied to only one face of the mesh in a spot pattern, a process that delays mesh placement. The fibrin sealant is also relatively costly and can be associated with a biological reaction. These differences may explain the better results in our study compared with the fibrin-sealant study. We observed infrequent wound healing complications (4.2%), no infections, and no recurrences. However, longer term follow-up is needed to assess the recurrence rate.

With regard to patient-reported pain, it is important to note that the number of patients with no pain (VAS = 0) was very high at 3 months (89.3%), and was significantly higher compared with preoperative and immediate postoperative scores. A similar trend was seen for numbness (VAS = 0, 97%) and discomfort (VAS = 0, 85%) at 3 months. As a consequence, patients were able to return to normal activities, both professional and physical, and the rate of patient satisfaction with the procedure was also very high (97%).

Similar to other studies, [17] we used the SF12 questionnaire to evaluate QoL, a method that has been validated for assessment of QoL after hernia repair [18]. In the preoperative evaluation, we found a significant difference between the patients enrolled in the study and a healthy American control population (Table 1) for all eight of the SF12 questionnaire domains. At 3 months, all eight criteria, including overall measures of mental and physical well-being, were significantly improved compared with the preoperative evaluation and at 1 month after surgery. These results suggest that the majority of the patients recovered quickly to achieve a good QoL.

Conclusion

While the ideal mesh and fixation method for prosthetic reinforcement in inguinal hernia repair do not yet exist, the use of mesh in hernia repair is now accepted globally. The self-adhering Adhesix® mesh is a light-weight (40 g/m²) mesh coated with synthetic glue. It avoids aggressive fixation and the biological risks of fibrin sealant, and at a lower cost. It is easy to handle with respect to the specific technique and shows a good integration with the tissue [19]. The clinical results of this study focused on the frequency and severity of disabling complications. The high percentage of patients with "no pain, no numbness, and no discomfort" and the normalization of endpoints at 3 months after surgery on all dimensions of QoL are encouraging. Thorough and extended follow-up is needed. It is significant that there have been no recurrences at 3 months post-surgery. Taken together, the self-adhering (Adhesix®) mesh appears to have promising utility in laparoscopic hernia repair.

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