

TEP With Long-Term Resorbable Mesh in Patients With Indirect Inguinal Hernia

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ABSTRACT

Background and Objectives: The role of long-term degradable implants in reducing the risk of chronic postoperative pain after inguinal hernia repair is still unclear. A pilot study using a synthetic long-term resorbable mesh in Lichtenstein repair showed good results regarding pain and discomfort in patients with indirect inguinal hernia (IH) without recurrences, but higher recurrence rate in patients with direct inguinal hernia (DH). The purpose of this study was to assess the incidence of pain and early recurrence in patients with LIH surgically treated with the TEP technique using a long-term degradable mesh. This is the first human study to use long-term degradable mesh with the TEP approach.

Methods: This study was prospective, including 35 primary IHs surgically treated with TEP repair using TIGR Mesh (Novus Scientific Pte, Ltd, Singapore). At the 1-year follow-up recurrence was assessed by clinical examination and the incidence of pain or discomfort was assessed before and after surgery by Visual Analog Scale (VAS) and Inguinal Pain Questionnaire (IPQ).

Results: After 12 months, no patients had chronic pain. Only 1 (2.8%) patient reported pain using the VAS (score = 2), and 4 patients reported pain that could easily be ignored. All 4 patients reported less pain 1 year after the operation using both IPQ and VAS, compared with the preoperative assessment. One patient (2.8%) developed a recurrence 20 months after the primary operation.

Conclusion: TEP repair using a synthetic long-term resorbable mesh was found to be safe and promising regarding pain and discomfort at 1-year follow-up in pa-

tients with IH. Longer follow-up is necessary to establish the risk of recurrence.

Key Words: Hernia, Absorbable implant, Indirect inguinal hernia, Chronic pain and recurrence.

INTRODUCTION

Chronic postoperative pain is a well-known complication after groin hernia surgery. The causes of chronic pain are possibly multifactorial. Implants, surgical technique, and preconditions surely play major roles in the development of chronic postoperative pain.¹

Theoretically, surgeons could select a surgical technique and mesh that have demonstrated lower risk for chronic postoperative pain in patients with higher risk of developing such pain.

It has been suggested in diverse studies that so-called lightweight meshes reduce the risk of chronic pain.^{2,3} Biological and synthetic resorbable meshes hypothetically could reduce the risk of chronic postoperative pain, given that the reconstructive tissue formed by the patient replaces the implant and that foreign material is absent after resorption of the mesh. Nevertheless, uncertainty has been pointed out because of the risk of recurrence over time if the new connecting tissue is not robust enough to resist the abdominal pressure.⁴

A pilot study recently published by our group showed no recurrences and promising results with low risk for chronic pain in patients with indirect inguinal hernia (IH) surgically treated with the Lichtenstein technique with a long-term resorbable mesh, TIGR Matrix Surgical Mesh (Novus Scientific Pte Ltd, Singapore). On the other hand, patients with direct inguinal hernia (DH) have a near 45% recurrence.⁴

Both the totally preperitoneal (TEP) and transabdominal preperitoneal (TAPP) techniques for repair of inguinal hernia have shown a lower risk of postoperative chronic pain compared with the Lichtenstein approach in earlier studies.^{5,6}

The purpose of this first human prospective study using a long-term resorbable mesh with TEP technique was to

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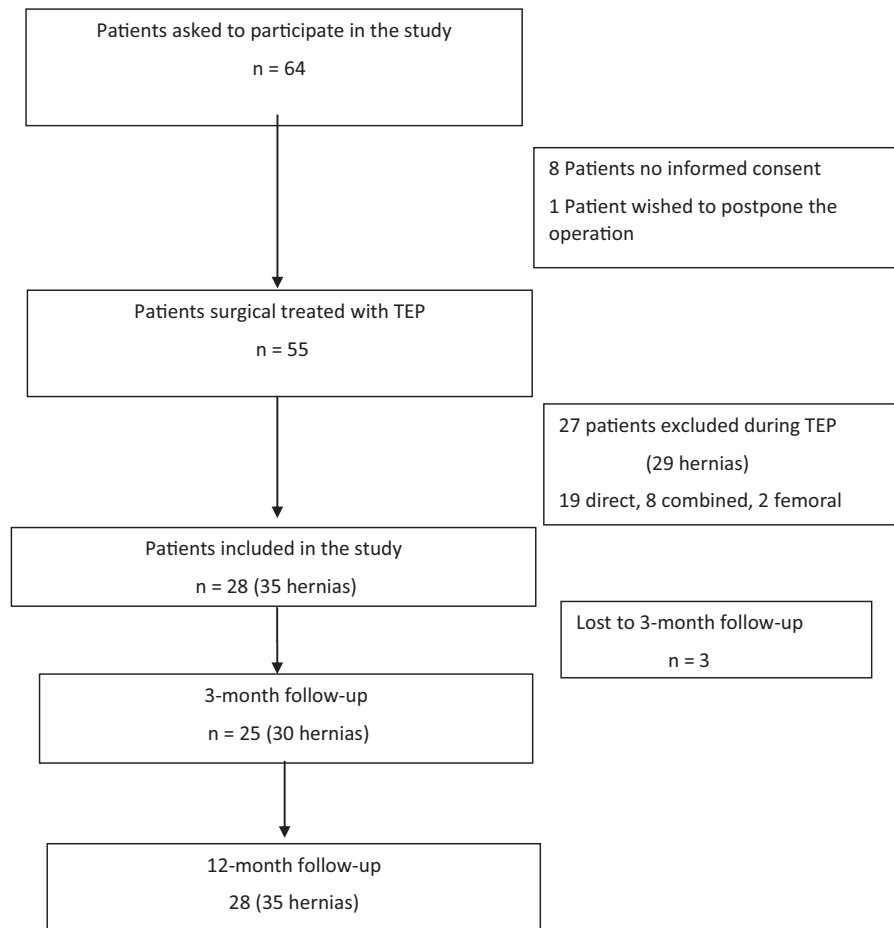


Figure 1. Enrollment and follow-up of patients in the study.

evaluate the incidence of chronic postoperative pain and hernia recurrence in patients with IH. If the results with respect to hernia recurrence are satisfying, this approach could be a means of reducing chronic postoperative pain.

This publication focuses on chronic postoperative pain and early recurrence of hernia until the 1-year follow-up. Our intention in the future is to publish data on recurrence at the 3- and 5-year follow-ups.

METHODS

This prospective study was approved by the regional ethics committee in January 2014. From June 2014 to February 2015, 28 adult patients who were assessed for primary IH and were considered suitable for a TEP procedure in the Department of Surgery at Halland's Hospital (Kungsbacka, Sweden), were included in the study. Patients with BMI >35, irreducible hernias, unwillingness or inability to give in-

formed consent to participate in the study and pre-existing inguinal pain conditions unrelated to the hernia were excluded.

Mesh

A 10 × 15 cm TIGR Matrix Surgical Mesh (Novus Scientific Pte Ltd) was used in the study; This macroporous mesh has 2 types of resorbable fibers, one of the fibers resorbs within 4 months and the second fiber within ~3 years after implantation, degradation occurs by hydrolysis.⁷

TIGR Matrix Surgical Mesh has an initial burst strength of 300 N, comparable to existing commercially available products. More than 50% of the initial mechanical strength of the mesh is maintained during the first 26 weeks, after which the mechanical strength of the mesh is gradually lost.⁷

Surgery

Patients who had given informed consent underwent a TEP procedure while under general anesthesia performed any of the staff surgeons with experience of more than 100 TEP procedures. The TEP technique comprises inversion without resection of the lateral inguinal sac and dissection of the peritoneum from the level of the anterior iliac spine to the retropubic space, including exposure of the vas deference, the testicular blood vessels, and the distal part of the external iliac artery. The implant was centered on the internal ring.

During the operation, patients with DH were excluded from the study and received a nondegradable mesh. Patient with IH received a TIGR Matrix Surgical Mesh without any permanent fixation.

Data Recording and Follow-up

Patient data, intraoperative details, and perioperative and postoperative complications, among other things, were recorded in the Swedish Hernia Register.⁸

Early postoperative complications were monitored by a visit to a nurse at the surgical outpatient clinic 7–10 days after surgery. In case of a complication, a surgeon was consulted. Late complications and recurrences were assessed by physical examination by a surgeon at the 1 year follow-up.

Pre- and postoperative pain was registered by 2 validated methods: Visual Analog Scale (VAS) 0–10 during different physical activities,⁹ and the Inguinal Pain Questionnaire (IPQ).¹⁰ The IPQ included questions about inguinal pain and pain medication, among others. The pain experienced during rest, sitting, coughing, rising from lying to sitting, climbing one step in a flight of stairs, and taking a 30 m indoor walk was measured by VAS.

The VAS and IPQ questionnaire were completed before surgery and patients with inguinal pain not associated with the hernia were excluded from the study. The VAS and IPQ were also completed at 3 and 12 months after surgery (**Figure 1**).

RESULTS

Twenty-eight male patients with 35 hernias were included in the study, and all patients were followed up at least 1 year after surgery. Three patients didn't return the pain questionnaires at the 3-month follow-up. Pre- and intraoperative data are shown in **Table 1**.

Table 1.
Pre- and Intraoperative Data

Variable	Data
Patients, (n)	35
Age (years)	55.7 (26–75)*
Body mass index (kg/m ²)	26.3 (20–33)*
Operating time (minutes)	54.9 (33–100)*
Site of hernia	
Left	18 (51.4)
Right	17 (48.6)
Unilateral	19 (54.3)
Bilateral	16 (45.7)
Size of hernia defect	
<1.5 cm	5 (14.3)
1.5–3 cm	28 (80.0)
>3 cm	2 (5.7)

Data are number of patients (percentage of patients in total group). *Mean (min–max).

Examination at 7–10-day follow up showed that nearly all the patients had followed a normal initial postoperative course. Complications that did not need any treatment were local hematoma 5 (18%) and seroma 2 (7.4%). One patient developed urinary retention immediately after surgery that was resolved promptly with a single urinary drainage.

In almost all patients, the intensity of pain in any activity was reduced 1 year after surgery, when measured with the VAS, compared with the preoperative level (**Figure 2**).

The number of patients with pain >1 (VAS) diminished over time versus that recorded before the operation. No one complained about pain at rest and the maximum reported pain in any activity was 2 at the 1-year follow-up (**Table 2**).

In the IPQ questionnaire, the number of patients who declared pain that could not be ignored or interfered with daily activities dropped from 24 (69%) before surgery to 4 (13%) at 3 months after the surgery and then to 0 (0%) at 12 months (**Table 3**). Before surgery, 1 patient was taking medication for pain related to the hernia, but no patient need it 1 y after surgery.

At the 1-year follow-up, no patient had chronic postoperative pain, as defined in the World Guidelines for Groin Hernia Management¹¹: equal or higher pain intensity than moderate and affecting daily activities.

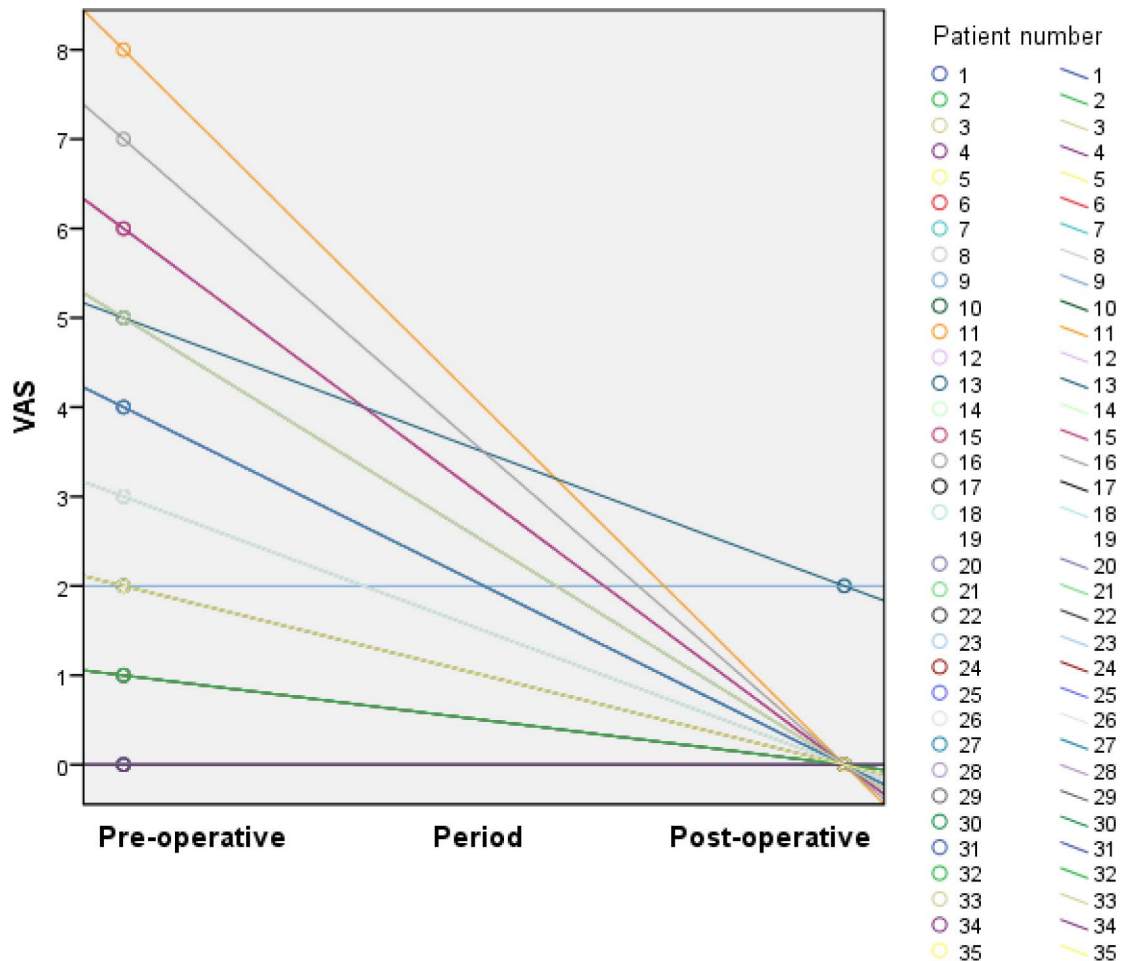


Figure 2. Plot of patients' pain, registered on the VAS before surgery and at the 12-month follow-up. Patients reporting the same results have been combined.

Table 2.
Number of Patients With Inguinal Pain ≥ 2 (VAS 0–10)

	Before Surgery (n = 35)	3 Months After Surgery (n = 30)	12 Months After Surgery
Patients, n	35	30	35
At rest	7 (20)	2 (6.6)	0 (0.0)
On coughing	18 (51.4)	1 (3.3)	1 (2.9)
While sitting	15 (42.9)	2 (6.6)	1 (2.9)
When climbing one step in a flight of stairs	8 (22.9)	1 (3.3)	1 (2.9)
When taking a 30-m indoor walk	12 (34.3)	1 (3.3)	1 (2.9)
When rising from lying to sitting	12 (34.3)	2 (6.6)	1 (2.9)

Data are number (percentage of patients in the total group). Patients with bilateral hernias counts double because they had answered a pain questionnaire for each side.

Table 3.
Summary of Results of the IPQ Questionnaire “Worst Pain Past Week”

Pain Estimation	Before Operation	3 Months After Surgery	12 Months After Surgery
Patients	35	30	35
No pain	10 (28.6)	21 (70.0)	30 (85.7)
Can easily be ignored	1 (2.9)	5 (16.7)	5 (14.7)
Cannot be ignored, no interferences with daily activities	9 (25.7)	3 (10.0)	0 (0.0)
Interferences with concentration on chores and daily activities	14 (40.0)	1 (3.3)	0 (0.0)
Need bed rest because of pain	1 (2.9)	0 (0.0)	0 (0.0)

Data are number (percentage of total patients in the group).

Recurrence was found in just 1 patient (2.8%). This patient had no recurrence by palpation at the 1-year follow-up but became symptomatic 20 months after surgery. Because the absence of a recurrence was physically confirmed by a surgeon participating in the study, no further radiographic investigation was necessary.

DISCUSSION

This is the first study in humans with IH treated with TEP, using a synthetic implant with slow resorption. Slow, or long-term, resorption is not clearly defined in the literature, but we mean a mesh that resists the theoretical highest abdominal pressure for at least 6 months after implantation.

Four earlier studies involving a biological mesh of purified porcine small intestinal submucosa^{12,13} in hernia repair have found satisfactory recurrence rates in patients with IH. This mesh has 90% degradation 3 months after surgery.

At the same time, synthetic mesh (GoreBio-A; W. L. Gore, Flagstaff, AZ, USA), with resorption time similar to the biological mesh mentioned above, shows higher rates of recurrence in patients with IH treated with an open surgical technique.¹⁴

Our study using TIGR Mesh in open hernia surgery did not show recurrences in patients with IH at the 3-year follow-up,⁴ but most recurrences in patients with DH were found between 1 and 3 years. The present study applying the same mesh in a TEP approach showed a low rate of recurrence at the 1-year follow-up. A follow-up of at least 3 years is necessary to determine a more realistic rate of recurrence as mentioned above.

A possible explanation of the differences in recurrences between these synthetic meshes could be that GoreBio-A mesh loses more than 50% of its initial mechanical strength after 6 weeks, compared with 6–9 months for the TIGR Mesh; 6 weeks may be a very short time for the formation of a new collagen tissue capable of supporting the abdominal pressure once the mesh is degraded.

The frequency of persistent pain after laparoendoscopic hernia surgery is not uniform in the literature (1.6–9.7%),¹ but this study showed a 0% incidence of chronic pain, as defined in the literature,¹¹ with the use of a long-term resorbable mesh in selected patients. Those patients had just an IH and no history of inguinal pain unrelated to the hernia.

Even when taking into account the selection criteria and the small number of patients included in the study, these results showed a good effect of TEP with degradable mesh on preoperative pain, because 65% of the patients had hernia-related pain that could not be ignored before the surgery.

The difference in the percentage of patients with pain that cannot be ignored 3 and 12 months after surgery in the IPQ questionnaire—13.3% and 0%, respectively—indicates that perhaps a follow-up of 3 months is too short a time in which to determine the real incidence of chronic pain after hernia repair. Pain reports at 3 months may represent more the frequency of natural short-term postoperative pain, as other authors have suggested.^{14,15}

Our results are very hopeful and indicate that endoscopic hernia surgery, together with slowly absorbable implants, could reduce the risk of chronic postoperative pain in

selected patients with IH, but longer follow-up is necessary to establish the risk of recurrence.

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