

Laparoscopic incisional hernia repair by lightweight polypropylene mesh with resorbable coating. Technical notes, preliminary results

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Rezumat

Cura laparoscopică a eventrației postoperatorii cu plasă de polipropilenă cu greutate mică și înveliș resorbabil.

Date tehnice, rezultate preliminare

Cura laparoscopică a herniilor abdominale a câștigat popularitate după ce mai multe studii au raportat rezultate încurajatoare. Alegerea plasei și a metodei de fixare sunt elemente cruciale în prevenirea complicațiilor și a recidivelor. Am evaluat prospectiv 30 de cure laparoscopice ale herniilor abdominale efectuate consecutiv la 28 de pacienți (11 bărbați și 17 femei) pentru diferite tipuri de eventrații postoperatorii în perioada februarie 2011 - iunie 2012. Toți pacienții au beneficiat de cura exclusiv laparoscopică a eventrației postoperatorii cu noua plasă de polipropilenă cu greutate mică și înveliș resorbabil (Physiomesh™, Ethicon Endo-Surgery, Johnson & Johnson, Inc.). Nu au fost raportate complicații postoperatorii majore. Au fost diagnosticate două recidive la 5 luni de la prima cură. Ambii pacienți au fost operați laparoscopic cu același tip de plasă. Plasa de polipropilenă cu greutate mică și înveliș resorbabil, prin proprietățile sale de poziționare facilă și biocompatibilitate, reprezintă o inovație în cura laparoscopică

a eventrațiilor și ar trebui luată în considerare pentru evaluare clinică intraoperatorie și pe termen lung.

Cuvinte cheie: eventrație postoperatorie, laparoscopie, plasă de polipropilenă

Abstract

Laparoscopic repair of ventral hernias has gained popularity, since many studies have reported encouraging results. The choice of the mesh and fixation methods are crucial issues in preventing complications and recurrence. 30 laparoscopic ventral hernia repair performed consecutively in 28 patients (11 males, 17 females) for different kinds of incisional hernias from February 2011 to June 2012 were prospectively evaluated. All patients received total laparoscopic incisional hernia repair by the use of the new lightweight polypropylene mesh with resorbable coating (Physiomesh™, Ethicon Endo-Surgery, Johnson & Johnson, Inc.). No major postoperative complications were reported. Two recurrences were diagnosed after 5 months from the first repair. Both patients received laparoscopic repair by the same kind of mesh. Lightweight polypropylene mesh with resorbable coating, with its properties of easy positioning and bio-compatibility, represents an innovation in laparoscopic incisional hernia repair, and should be considered for clinical intra-operative as well as long term evaluations.

Key words: incisional hernia, laparoscopy, polypropylene mesh

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Introduction

Incisional hernia is still a challenging complication of major abdominal surgery, with a reported incidence of about 25% in laparotomic incisions, with unsatisfactory outcomes in terms of patient readmission and major complications (1-3).

Laparoscopic repair of incisional and ventral hernias has gained increasing popularity, since many studies have reported encouraging results, in terms of operative time, wound morbidity, hospital stay and postoperative pain (2-3), even if, to date, no superiority of laparoscopic repair versus open repair has been demonstrated in terms of recurrence rates and cost-effectiveness (3-5). The main reasons for hernia recurrence after laparoscopic repair seems to be migration, protrusion or shrinkage of the mesh due to excessive inflammatory reaction and/or technical operative pitfalls (6).

Patient selection (site, size of the defect), choice of the mesh (in terms of bio-materials and size) and fixation methods

are considered crucial points in preventing mid and long-term recurrences (4-7).

The Authors report a series of 30 consecutive laparoscopic incisional hernia repairs using a new lightweight polypropylene mesh with double-face resorbable coating, focusing on technical details and short-term results.

To our knowledge, this is the first published series of laparoscopic ventral hernia repair using this specific mesh

Materials and Methods

A series of 30 laparoscopic ventral hernia repairs performed consecutively on 28 patients (11 males, 17 females) in two Centers with large experience in advanced laparoscopic surgery, from February 2011 to June 2012, were prospectively evaluated.

Patients characteristics are reported in Table 1. Hernias were classified according to EHS incisional hernia classification (8).

Table 1. Patients demographics and preoperative characteristics

Patient	Age	Sex	Comorbidities	Hernia Classification*	Preop Evaluation
1	59	F	OBESITY, HYPERTENSION	M3, W2,R-	CT SCAN
2	59	F		M3,W2,R+	CT SCAN
3	54	M		L3,W2,R1	CT SCAN
4	46	F	HYPERTENSION	M3,W2,R-	CT SCAN
5	63	M	TYPE II DIABETES	M1,W3,R-	CT SCAN
6	65	M	HYPERTENSION	M3,W2,R-	CT SCAN
7	54	F	OBESITY	L3,W2,R-M2,W2,R-	CT SCAN
8	77	F	OBESITY	M3,W2,R-	US SCAN
9	68	F		M2,W2,R-	CT SCAN
10	47	M	HYPERTENSION	L1,W3,R-	CT SCAN
11	45	M	OBESITY	M1,W3,R+	CT SCAN
12	72	F	COPD	L1,W3,R-	CT SCAN
13	60	F	HYPERTENSION, TYPE II DIABETES	L1,W2,R-L3,W2,R-	CT SCAN
14	74	F		M1,W2,R-	CT SCAN
15	59	F	OBESITY, HYPERTENSION	M4,W1,R+	CT SCAN
16	38	M		M2,W1,R-	US SCAN
17	45	M		M4,W3,R-	CT SCAN
18	43	F	HYPERTENSION	L3,W1,R-	US SCAN
19	56	F	COPD	M3,W1,R-	US SCAN
20	58	F	HYPERTENSION	M3,W2,R-	CT SCAN
21	78	F	HYPERTENSION	M4,W1,R-M2,W2,R-	CT SCAN
22	73	F		M3,W2,R-	CT SCAN
23	70	M		M2,W2,R-	US SCAN
24	48	M	NON-FUNCTIONING ADRENAL ADENOMA (1.8 CM)	M4,W3,R-	CT SCAN
25	54	F		MR,W2,R-	CT SCAN
26	77	F	OBESITY	M3,W1,R+	CT SCAN
27	46	F	HYPERTENSION	M5,W2,R+	US SCAN
28	45	M	TYPE II DIABETES	M2,W1,R-	US SCAN
29	38	M		L3,W2,R-	CT SCAN
30	81	F	HYPERTENSION	M2,W1,R-	US SCAN

Caso 26: laparocele periombelicale, diametro 4x3 cm.

Caso 27: laparocele sovrapubico recidivo, su taglio di pfannesteil, diametro 3.8x4 cm (calcolato alla TC durante ponzamento): protesi 10 x 15 posizionata trasversalmente

Caso 28: laparocele mediano, due porte del diametro max di 1.5 e 2 cm. In questo caso ho sbagliato inserendo le due porte come ernia singola. Comunque abbiamo usato una protesi 10x15

Caso 29: Laparocele su ferita xifo-ombelicale, diametro trasverso max 3.5 cm (quindi W1) calcolato durante l'intervento

Caso 30: laparocele iliaco dopo ferita arma da fuoco, diametro 4 x2 cm



Figure 1. CT scan shows left iliac incisional hernia secondary to gunfire shot

In 12 cases there were multiple defects caused by one incision: they were reported as one single hernia whose width is calculated between the most laterally located margins of the most lateral defect on each side, according to the adopted classification (8).

Hernia defect size was calculated preoperatively by US or multi-slice CT scan (in case of larger or multiple defects) (Fig. 1,2); defect size ranged from 3.4 to 14.5 cm, and four patients were affected by recurrent incisional hernia (all with first recurrence, with previous on-lay open repair).

No patient was submitted to surgery in an emergency setting and no case of contamination was reported in this series.

Mesh characteristics

The mesh used in this prospective study (Physiomesh™, Ethicon Endo-Surgery, Johnson & Johnson, Inc.) is a low-profile composite mesh composed of a non-absorbable macro-porous polypropylene mesh laminated between two polyglecaprone-25 films. An undyed polydioxanone film provides the bond between the polyglecaprone-25 film and the polypropylene structure, constructed of knitted filaments of extruded polypropylene. An additional dyed (purple) polydioxanone film marker is added for mesh orientation during surgery. Since the absorbable polyglecaprone-25 film is present on both sides of the mesh, the implant can be applied on either side on the peritoneal surface (9).

Polydioxanone (PDS) is a polyester absorbable material obtained by ring-opening polymerization of p-dioxanone along with heat and the addition of a catalyst (10). PDS is expected to be completely resorbed in 180 days, by degradation of its ether and ester linkages via hydrolysis ending up into carbon dioxide and water. The polyglecaprone-25 layer is a copolymer of ϵ -caprolactone and glycolide, which is going to be reabsorbed within 240 days, also by hydrolysis (11-12). This slow degradation of the absorbable component, together with the inflammatory response caused by the mesh itself and by



Figure 2. (A) CT scan shows midline recurrent incisional hernia (B) Same patient, 5 months after hernia repair. The mesh appears undetectable on CT-scan, but you can see the titanium tacks in double crown

polypropylene allow the creation of a neo-peritoneum surrounding and covering the mesh with minimal formation of adhesion with intra-abdominal structures.

Several characteristics of this mesh allow an easy positioning into the abdominal cavity: light weight (30 gr/m²), transparency, presence of an orientation marker, possibility to shape the mesh to better fit the hernia defect and to implant the mesh on both sides.

Furthermore, the macropore (3 x3 mm) polypropylene construction, as reported in literature (13), allows a rapid tissue ingrowth in the mesh, so that the mesh itself becomes quickly integrated within the abdominal wall tissue, such integration is the main step to achieve a permanent abdominal

wall reinforcement and avoid intra-abdominal adhesions.

Other characteristics, such as an elasticity (25% at 16 N/cm tension) very similar to the normal abdominal wall (14), tensile strength and pressure resistance (up to 672 mmHg), which is much more than the normal intra-abdominal pressure in healthy adults (calculated as up to 252 mmHg) (15), make the mesh suitable for a “physiologic” hernia repair.

Surgical technique

Pneumoperitoneum (10-12 mmHg) is achieved by Veress needle introduced in left subcostal (or right subcostal in case of left subcostal hernia). After pneumoperitoneum establishment, two 5 mm and one 10-12 mm dilating trocars are placed as far as possible from the hernia site, at least 6 cm far from each other. In case of midline hernia, trocars are placed on the right (or left) flank, between midclavicular and anterior axillary line; in case of subcostal hernia, trocars are placed in the lower controlateral quadrant. We use the 10-12 mm trocar to place the 10 mm, 30 degrees laparoscope, while the other trocars are used to introduce the instruments for adhesiolysis and mesh fixation. The mesh is always inserted into the abdominal cavity through the 10-12 mm trocar.

After a complete lysis of adhesions the defect is measured from the inside of the abdominal cavity (after having reduced the intrabdominal pressure to 7-8 mmHg) and the proper size mesh is positioned (temporarily securing it to the cardinal points of the defect either using four transfixated sutures or four Quincke 22G needles inserted through the abdominal wall into the abdominal cavity at a distance of 3-4 cm from the margin of the defect). The violet marker is very helpful during these maneuvers, to correctly orientate the mesh (Fig. 3). Then

a double crown of tacks is placed to fix the mesh. Tacks are placed at a distance of 1.5-2 cm from each other, with an overlapping of the mesh of at least 4 cm on every side. At the beginning of our experience titanium spiral tacks (ProTac Tyco Healthcare, Mansfield, MA, USA) were used, later resorbable PDS tacks (Securestrap®, Ethicon Endosurgery, Johnson Johnson Inc.) were preferred.

In 9 cases, 2 or 4 ml (depending on hernia size) of fibrin glue (Tisseel®, Baxter International, Inc.) was placed between the mesh and the abdominal wall, in order to achieve a better fixation, and to prevent seroma. Tacks and fibrin glue are placed after reduction of intra-abdominal pressure to 7-8 mmHg.

After hemostasis control, the trocars were removed under direct vision, and compressive dressing was placed above the hernia site.

Results

Surgical outcomes are reported on Table 2. Mean operative time was 75.9 minutes (range 38-145). Only one self-limiting postoperative intra-abdominal bleeding was reported, with moderate decreasing in hemoglobin levels (from 12.4 to 9.6 gr/dl), and no need for transfusion. Mean postoperative stay was 2.5 days (range 1-13), and all patients had compressive dressing left 4 weeks postoperatively. Return to normal life activities was achieved within 1 month after surgery.

Postoperative pain was evaluated at 24 and 48 hours after surgery, at one week and one month after surgery, using the Visual Numeric Scale (VNS) (16). Only one patient did not achieve a satisfactory pain control in the first week and was kept in the hospital until resolution of pain was obtained.

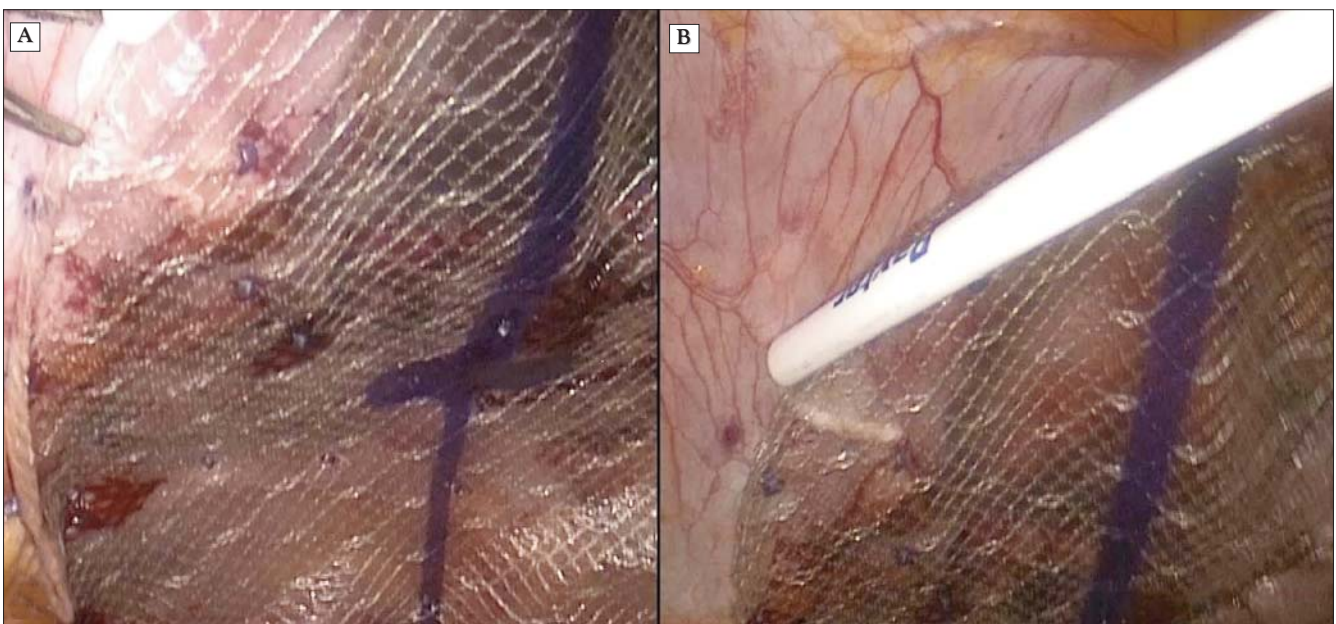


Figure 3. (A) The mesh has been placed and fixed to the abdominal wall by double crown of resorbable tacks (B) after fixing the mesh to the abdominal wall, fibrin glue is placed between the mesh and the wall. Mesh transparency becomes very helpful during these maneuvers

Table 2. Intraoperative and postoperative results

PATIENT	MESH SIZE (CM)	SEALANTS	PROCEDURE LENGTH (MIN)	P.O. STAY (DAYS)	P.O. COMPLICATIONS	FOLLOW-UP (MONTHS)
1	20X25	NO	95	2		18 (recurrence at 5 months)
2	20X25	NO	95	3		14
3	10X15	NO	48	1		8
4	10X15	NO	36	1		8 (recurrence at 5 months)
5	15X20	YES	72	2		8
6	15X15	NO	60	4		8
7	20X30	NO	90	5		8
8	15X15	NO	40	3		8
9	10X15	NO	70	3		8
10	20X25	YES	134	2		7
11	15X20	NO	100	2		7
12	15X20	NO	92	2		6
13	15X20+15X20 (2 MESHES USED)	YES	98	3		6
14	15X20	NO	61	2		6
15	15X20	NO	90	3		6
16	10X15	NO	40	1		5
17	20X25	YES	52	1		5
18	10X10	NO	38	2	Moderate bleeding	3
19	10X15	NO	43	1		3
20	15X20	NO	70	3		3
21	15X20	NO	60	13		3
22	15X20	NO	145	4		3
23	10X10	NO	46	1		2
24	15X20	YES	88	1		2
25	20X20	NO	80	2		2
26	10X15	YES	90	2		2
27	10X15	YES	130	2		2
28	10X15	YES	80	1		2
29	10X15	NO	75	1		2
30	10X15	YES	60	2		1

The remaining patients achieved good pain control using i.v. paracetamol (1000 mg x 3 administrations/die) within the first 24-48 hours after surgery, and then with oral paracetamol (1000 mg) only if necessary. No patients showed more than 6 score according to VNS within the first 48 hours, and only the previously mentioned patient showed more than 4 after one week. The remaining patients had no need to continuous paracetamol assumption at one week. No patient needed any analgesic assumption at 1 month after hernia repair.

After a follow-up time ranging from 2 to 18 months no case of infection and only one case of seroma that required needle drainage one month after surgery were reported. We observed an hernia recurrence in two patients, both 5 months after surgery; one patient was obese (BMI 32), and had midline incisional hernia with 7x5 cm defect, the other patient had sovrappubic incisional hernia, with 5x6 cm defect. After clinical evaluation the patient repeated abdominal CT-scan, demonstrating hernia recurrence (Fig. 4), and then they were submitted to laparoscopic re-do hernia repair (6 and 12 months after first laparoscopic repair). During laparoscopy we observed

a good mesh integration into the abdominal wall (upper portion of the mesh), with neo-peritoneum coverage and only few filmy adhesions in both cases (Fig. 5). Hernia recurrence was due to inadequate overlapping of the defect in one patient (sovrappubic hernia), while in our midline hernia recurrence, an adequate overlap was shown by the position of the tacks found at 4 cm from the margin of the defect. The recurrence was ascribed to the dislodgement of the tack from the large size macropore of the mesh.

In the first patient (midline hernia) a new mesh was placed above the previous implant, and in the second case (sovrappubic hernia) we decided to cut the mesh, freeing the hernia defect and then a new mesh was correctly placed, partially covering the prior implant.

Discussion

The treatment of incisional hernia has become a current problem in modern surgery, even in the era of mini-invasive approaches. During the past 50 years, ventral hernia repair surgery has evolved from direct suture repair to the use of

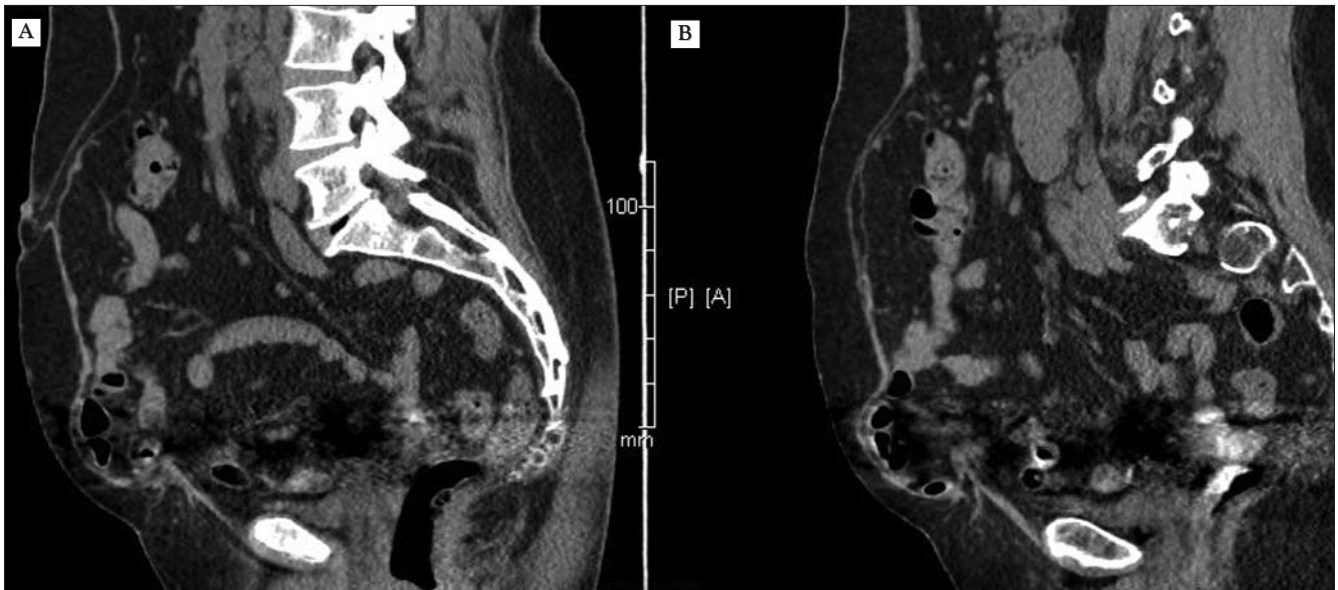


Figure 4. (A) Recurrent supraumbilical incisional hernia after laparoscopic repair: CT scan features; (B) Same patient, during Valsalva

synthetic mesh in order to obtain a tension-free repair, and finally the tension-free concepts have been applied to laparoscopic surgery. Laparoscopic approach, in selected patients, showed recurrence rates similar to open techniques, but reduced length of hospital stay and complication rates (3-5,17). However, even in laparoscopic hernia repair several complications have been reported. Overall complication rate is reported as ranging from 2 to 31% (18-20). Mesh positioning related complications include: seroma formation, from 0 to 7.1% (2,18-20); mesh and/or wound infection in up to 5.6% of patients (18,21); mesh dislocation or shrinkage, chronic pain, and, of course, hernia recurrence, ranging from 0 to 17.6% (18,22). Obesity and COPD have been shown to increase complications, as well as hernia site (supraumbilical and subcostal hernias are related to higher recurrence rates) and hernia size.

Incorrect mesh fixation or defect overlap, and lack of mesh integration within the abdominal wall have been addressed as the commonest causes of recurrence.

The choice of the mesh to implant is of paramount importance, both in open as well as in laparoscopic approaches.

During the last decade, many devices and meshes have been proposed and tested as a tool to better repair primary and incisional ventral hernias. To reduce the problems related to the intra-peritoneal placement of the mesh and to mesh fixation to the abdominal wall, "light weight" meshes have been proposed. Reducing the density of non-absorbable material theoretically induces less foreign-body response, results in improved abdominal wall compliance, and causes less shrinkage of the mesh, with better tissue incorporation.

A light-weight mesh is also easier introduced, handled and positioned to the abdominal wall. It needs to have special features to prevent, on the one side, the formation of adhesions between the mesh itself and the bowel, and on the other side, to achieve perfect integration within the abdominal wall.

The lightweight approach is also based upon studies about the biomechanics of the abdominal wall (14,15,23,24) suggesting the importance of obtaining meshes with characteristics (elasticity, tensile strength and pressure resistance) similar to the normal abdominal wall; so, the mesh should be sufficiently elastic and compliant to cope with the movements and elongation of the different areas of the abdominal wall, but rigid enough to avoid the herniation of the mesh itself, and strong to resist in its position, without degradation, deformation (shrinkage) or creation of defects, for many and many years after its placement.

Among the great amount of meshes and materials utilized for laparoscopic repair of incisional hernias, lightweight polypropylene with macropore construction has been demonstrated

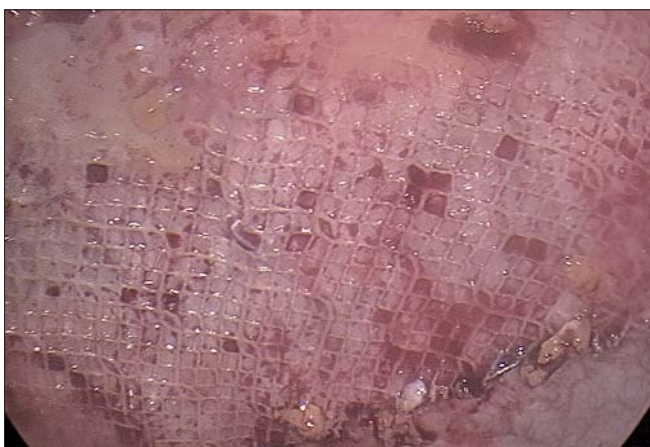


Figure 5. Second-look laparoscopy for recurrent hernia: the previously implanted mesh is well integrated into the abdominal wall

to be more efficient than other materials (included heavy weight polypropylene) in terms of inflammatory response and mesh integration on host tissues (13,25-27).

Better tissue integration means less pain, physiologic mesh deformation during abdominal muscles contraction, no space between mesh and abdominal wall, less shrinkage, and, possibly, less risk of hernia recurrence.

Furthermore, lightweight polypropylene mesh has other construction features (transparency, rigidity and the light weight itself) that are useful to ease the introduction into the abdominal cavity and the fixation to the abdominal wall.

When compared to other prosthetic materials available in clinical practice (10, 28) this mesh shows better physical and biochemical characteristics and, costs are similar to the most used meshes (about 750-800 Euros for 10 x15cm mesh).

In our experience of 30 consecutive laparoscopic repairs of different kinds of ventral hernias, we found this mesh very easy to introduce within the abdomen through the 10-12 mm trocar, to handle and orientate, and to fix, even when a large size prosthesis is necessary.

At the beginning of our experience with this mesh we fixed it to the abdominal wall with the titanium spiral tacks we had been using with other biomaterials; as soon as the resorbable Securestrap® become available, we adopted it as the preferred fixation method with or without transfixated sutures, avoiding the use of non-absorbable fixation devices which are possibly related to instances of prolonged postoperative pain. After we experienced a recurrence likely related to the dislodgement of three spiral tacks from the large pores of the mesh, we no longer use spiral tacks for this prosthesis because we believe that, in addition to the aforementioned disadvantage, its design is not fit to secure a wide knitted mesh. The Securestrap® device has been constructed just to fix the mesh we used in this series and titanium tacks, important in case of non-integrating meshes, are not necessary when the bio-compatible mesh are early integrated within the host tissues, and do not show excessive shrinkage or dislocation risks (10,13,29).

In the present series we showed no intra-operative or post-operative mesh-related complication, and, in the patients that showed hernia recurrence and were submitted to new laparoscopic surgery after hernia repair, we found only scattered filmy adhesions easily separated by light blunt dissection. The mesh was well integrated within the abdominal wall, with neoperitoneum coverage. These patients were re-operated 6 and 12 months after mesh positioning, showing an adequate anti-adhesive effect of the the absorbable coating of the device with tissue ingrowth and integration early in the postoperative period, protecting from mesh-related complications.

To our knowledge, this is the first paper published in literature dealing with clinical evaluation and results of the use of this mesh, and, even if we acknowledge the limits relative to the small size of the series and the short follow-up period, we can state that this mesh, with its aforementioned properties of easy positioning and bio-compatibility, represents an innovation in laparoscopic incisional hernia repair, and

should be considered for clinical intra-operative as well as long term evaluations.

Conflicts of interest

Authors declare that there hasn't been any fund received for the presented study.

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