Acta Chirurgica Belgica

ISSN: 0001-5458 (Print) (Online) Journal homepage: http://www.tandfonline.com/loi/tacb20

Laparoscopic ventral hernia repair using a composite mesh with polypropylene and expanded polytetrafluoroethylene: a prospective, multicentre registry

Wen Wen, Bernard Majerus, Marijke Van De Moortel, Salvatore Lobue, Didier Fobe, Patrick Philippart, Luc Berwouts, Joris Coteur, Karen Gabriels & Kurt Van der Speeten

To cite this article: Wen Wen, Bernard Majerus, Marijke Van De Moortel, Salvatore Lobue, Didier Fobe, Patrick Philippart, Luc Berwouts, Joris Coteur, Karen Gabriels & Kurt Van der Speeten (2017): Laparoscopic ventral hernia repair using a composite mesh with polypropylene and expanded polytetrafluoroethylene: a prospective, multicentre registry, Acta Chirurgica Belgica, DOI: 10.1080/00015458.2017.1313526

To link to this article: http://dx.doi.org/10.1080/00015458.2017.1313526

Published online: 25 Apr 2017.

ACTA CHIRURGICA BELGICA, 2017
http://dx.doi.org/10.1080/00015458.2017.1313526

ORIGINAL PAPER

Laparoscopic ventral hernia repair using a composite mesh with polypropylene and expanded polytetrafluoroethylene: a prospective, multicentre registry

Wen Wen[a], Bernard Majerus[b], Marijke Van De Moortel[c], Salvatore Lobue[d], Didier Fobe[e], Patrick Philippart[f], Luc Berwouts[g], Joris Coteur[h], Karen Gabriels[h] and Kurt Van der Speeten[a]

[a]Hospital East Limburg, Genk, Belgium; [b]Hospital Saint-Pierre, Ottignies, Belgium; [c]Hospital Jan Palfijn, Antwerp, Belgium; [d]Hospital of Tubize-Nivelles, Tubize, Belgium; [e]Hospital of CHR of Namur, Namur, Belgium; [f]Hospital Epicura, Ath, Belgium; [g]Hospital Sint-Vincentius, Deinze, Belgium; [h]Archer Research, Agoralaan Abis, Diepenbeek, Belgium

ABSTRACT

Background: Abdominal wall hernias are a common problem. Composite meshes placed intraperitoneally for abdominal wall hernia repair are widely used. This registry evaluated the safety and efficacy of one specific composite mesh with polypropylene and expanded polytetrafluoroethylene (Intramesh® T1) in laparoscopic ventral hernia repair.

Methods: A prospective multicentre registry with data from seven centres was collected between January 2013 and September 2014. Primary endpoint was recurrence rate at 12 months determined by clinical examination. Secondary outcome measures included intraoperative complications, complications during hospitalisation and at 1-month and 12-months follow-up.

Results: The registry included 90 patients (30 female and 60 male). Fifty-five patients (61.1%) presented with primary ventral hernias and 35 patients (38.9%) with incisional ventral hernias. Median hernia size was 4 cm^2. Intraoperative complications were reported in two patients (2.2%). Complications during hospitalisation were reported in four (4.4%) patients. At 1-month follow-up, 17 (18.9%) patients had postoperative complications, of which 5 complications were major and 19 were minor. Late complications at 12-months were observed in 10 patients (11.1%), of which 2 were major and 8 minor complications.

Conclusion: Intramesh® T1 is a safe and effective composite mesh with favourable short and midterm outcome and morbidity. (NCT01816867)

Abbreviations: ASA: American Society of Anaesthesiology; BMI: body mass index; ePTFE: expanded polytetrafluoroethylene; PPL: polypropylene

ARTICLE HISTORY
Received 11 May 2016
Accepted 27 March 2017

KEYWORDS
Ventral hernia; recurrence; abdominal wall

Introduction

Abdominal wall hernias still remain a challenging problem for physicians and patients. Often, high recurrence rates are associated with high costs and increased morbidity [1].

Different techniques of ventral hernia repair have been described [2]. The traditional open suture technique results in unacceptably high recurrence rates of up to 63%. The open mesh technique has lowered the recurrence rate to 10–32% [3–5].

Currently, there are more than 250 meshes available in the market for hernia repair. These meshes can be classified into different categories according to the type of material, composition, weight and pore size. The most commonly used mesh is made of polypropylene (PPL), which cannot be used intraperitoneally because of significant adhesions and fistula formation [6]. Meshes made of expanded polytetrafluoroethylene (ePTFE) are biologically inert, with less in-growth of host tissues and limited adhesion formation. This mesh can be used intraperitoneally, but infection and mesh shrinkage are the major problems [7,8]. The commonly-used, so-called composite meshes are dual-sided meshes. These meshes are designed to supplement the shortcomings of the single-sides meshes. One surface, mostly made of polypropylene or polyester, is in contact with the abdominal wall to promote tissue in-growth. The other surface acts as a long-term anti-adhesive barrier for the viscera. Since 2000, many experimental and clinical studies have been done on composite meshes which demonstrated that these meshes are effective and safe [9].

The aim of this prospective multicentre registry is to evaluate the safety and efficacy of one specific composite mesh, the Intramesh® T1, for

CONTACT Kurt Van der Speeten kurt.vanderspeeten@zol.be Hospital East Limburg, Schiepse Bos 6, 3600 Genk, Belgium

intraperitoneal use in both primary and incisional ventral hernia repair.

Materials and methods

Patients

A total of 90 patients from seven centres were included in a prospective multicentre registry between January 2013 and September 2013 (NCT01816867). Ethics committee approval was obtained at all investigational sites. Only patients with a minimal age of 18 years were included. For older or high-risk patients, watchful waiting was defendable if asymptomatic. Indication for surgery was symptomatic ventral hernias. Both primary and incisional abdominal wall hernias were included. Inguinal hernias and recurrent abdominal wall hernias were excluded.

The following patient demographics at baseline were documented in the medical records: age, gender, body mass index (BMI), American Society of Anaesthesiology (ASA), diabetes status, smoking status, and use of corticosteroids. The ASA classification was used for operative risk stratification [10].

Mesh type

The composite mesh (Intramesh® T1, Cousin Biotech, France) was used in all cases. This dual-sided mesh has a pore size of >75 µm and is available in different sizes. One side is knitted and made of polypropylene (PPL) monofilament, which integrates into the peritoneum. The other side is smooth and made of expanded polytetrafluoroethylene (ePTFE), which prevents and limits adhesions to the viscera during intraperitoneal use.

Surgical technique

The laparoscopic repair technique was used. The mesh was placed intraperitoneally in all patients. Choice of fixation was left at the discretion of the operating surgeon. Several types of fixation were used: tacks, sutures or surgical tissue glue. The surgeon chose the appropriate size of the Intramesh® T1 after evaluation of the hernia diameter. In all cases there was a minimal overlap of 3 cm with the size of the hernia port.

Follow-up

Patients returned to hospital for a clinical examination after 1 month and after 12 months. Indications for further technical investigations depended on the result of the clinical examination. Time window for the first follow-up visit at 1 month was 21 days. Time window for the 12-month follow-up was 30 days.

Efficacy and safety assessment

The primary objective of the study was to evaluate the efficacy of the Intramesh® T1 in terms of the recurrence rate at 12 months determined by clinical examination. Secondary outcome measures included intraoperative complications, defined as complications occurring during index-procedure from 'skin-into-skin'; postoperative complications occurring during hospitalisation; complications occurring between discharge and 30 days (assessed at 1-month follow-up after index-procedure) and late complications occurring between 1-month and 12-month follow-up after index-procedure.

The severity of complications was divided into minor and major complications. Minor complications consisted of those not requiring further treatment and being without further consequences for the patient, or requiring minor therapy including unplanned extension of hospital admission (≤24h). Major complications consisted of those requiring surgical or radiological re-intervention, an unplanned increase in the level of care with prolonged hospitalization (>48h), return to the ICU, or death.

Statistics

R software version 3.1.1 (Vienna, Austria) was used to conduct statistical analyses. Descriptive statistics of all study parameters were provided. Continuous data were summarized by their mean, standard deviation, median, minimum and maximum. Categorical data were summarized by their frequency and proportion.

Results

Patient characteristics

The data of 90 patients were included in the efficacy and safety analysis. Follow-up data were collected from 88 patients at 1 month and from 86 patients at 12 months. Of note, 18 of the 86 patients did not undergo a clinical examination after 12 months but were questioned by telephone. The mean age of patients was 56.4 years

ranging in age from 25 to 80 years, with 30 (33.3%) females and 60 (66.7%) males. Mean BMI was 29.8 (SD 5.5) and 42 patients (46.7%) were obese (BMI $\geq$30 kg/m^2), 20 patients (22.2%) were current smokers, and 14 patients (15.6%) had diabetes. Only two patients (2.2%) used corticosteroids. Fifty-five patients (61.1%) had a primary ventral hernia and 35 patients (38.9%) had an incisional ventral hernia. According to the ASA classification, used for operative risk stratification, 36 patients (40.0%) were healthy and 54 patients (60.0%) had coexisting medical problems (53.3% mild and 6.7% severe systemic disease).

Surgery

Ninety patients had a laparoscopic repair. There were no complications during laparoscopic repair necessitating conversion to open surgery. The hernia sac was resected in 40 patients (44.4%). Seventy-four patients (82.2%) received prophylactic antibiotics.

Median operating time was 45 minutes (range 20–105 minutes). Median hernia size was 4 cm^2 (range 0.4–195 cm^2). In order to repair the defect, different sizes of Intramesh® T1 (15 × 15 cm, 20 × 20 cm, 30 × 30 cm, 30 × 50 cm, 10 × 15 cm, 15 × 20 cm, 20 × 25 cm, diameter of 12 cm) were used. The mesh size most frequently used was a square (15 × 15 cm, $n = 49$), followed by circle (12 cm diameter, $n = 19$), and by a large rectangle (15 × 20 cm, $n = 10$). In the majority of the patients, the meshes were fixed with tacks only (4 cm^2 median hernia size). Furthermore, only surgical tissue glue for the smaller defects (1.5 cm^2 median hernia size) or for the larger defects tacks in combination with sutures (24 cm^2 median hernia size), trans-umbilical stich (3.5 cm^2 median hernia size) or surgical tissue glue (4 cm^2 median hernia size) was used (Table 1). Intraoperative complications were reported in two patients (Table 2). The first patient had a serosa tear on transverse colon, which was resolved by placing one suture. The second patient had a skin breach at the umbilicus while dissecting the hernia sac. Both complications were minor and both were resolved.

Table 1. Type of mesh fixation used in 90 patients and median hernia size.

Fixation type	*n* (%)	Median hernia size (cm^2)
Tacks only	41 (45.5)	4
Surgical tissue glue only	19 (21.1)	1.5
Tacks and sutures	15 (16.7)	24
Tacks and surgical tissue glue	1 (1.1)	4
Tacks and transumbilical stich	14 (15.6)	3.5

Hospitalisation

Median length of stay was 2 days, with a range of 0 and 10 days. Four patients had five postoperative complications before discharge (Table 2). The first patient needed a nasogastric tube for ileus and analgesic medication use. The second patient developed pneumonia. Intravenous antibiotics and physiotherapy were necessary. The third patient also suffered from a paralytic ileus, which responded to nil per os and intravenous fluids. The fourth patient reported pain due to fixation with tacks before discharge. The severity was considered major for the first three patients, and minor for the fourth patient.

1-Month follow-up

Between discharge and 1-month follow-up, 17 patients reported 24 postoperative complications (Table 2). The most frequent complication was seroma formation, followed by local numbness, pain, wound infection, hematoma, small bowel obstruction and ileus due to faecal impaction confirmed with a CT-scan. There were five major complications, all were resolved. One patient suffered from local numbness, which required two days of hospitalization and analgesic medication use. One patient needed a resection of the umbilical hernia sac with refixation of the umbilicus, because of an esthetical problem due to seroma formation. Another patient had a small bowel obstruction with need of a nasogastric tube and rehydration. The same patient also had an umbilical wound dehiscence with drainage of serous fluid. This was surgical drained and secondary closed. Then, this patient developed a wound infection (minor complication) at the umbilicus, which was resolved with daily wound care. The other complications were minor in severity. There were 3 patients who reported pain at the fixation site. Fixation method was surgical tissue glue for one patient and tacks only for the other two.

12-Months follow-up

The median follow-up period was 408.5 days (range 262–615 days). Of note, 68 patients were clinically evaluated, 33 of them were evaluated outside the given time window (more than 395 days after the index procedure). Between 1-month and 12-month follow-up, 10 patients reported 10 late complications (Table 2). There were two major complications, both were resolved. One patient

Table 2. Intraoperative and postoperative complications.

Variable	Intraoperative ($n = 90$)	Hospitalisation[a] ($n = 90$)	1-month[b] ($n = 88$)	12-month[c] ($n = 86$)
Major Complications, *n* (%)		4 (4.4)	5 (5.7)	2 (2.3)
Serosa tear	–	–	–	–
Opening umbilicus	–	–	1 (1.1)	–
Seroma	–	–	1 (1.1)	–
Local numbness	–	–	1 (1.1)	–
Hematoma	–	–	–	–
Wound infection	–	–	–	–
Pain	–	1 (1.1)	1 (1.1)	–
Bowel obstruction	–		1 (1.1)	1 (1.2)
Ileus		2 (2.2)	–	–
Swelling	–	–	–	–
Pneumonia	–	1 (1.1)	–	–
Re-laparoscopy				1 (1.2)
Minor complications, *n* (%)	2 (2.2)	1 (1.1)	19 (21.6)	8 (9.3)
Serosa tear	1 (1.1)	–	–	–
Opening umbilicus	1 (1.1)	–	–	–
Seroma	–	–	8 (9.1)	2 (2.3)
Local numbness	–	–	3 (3.4)	2 (2.3)
Hematoma	–	–	1 (1.1)	–
Wound infection	–	–	3 (3.4)	–
Pain	–	1 (1.1)	3 (3.4)	3 (3.5)[d]
Ileus	–	–	1 (1.1)	–
Swelling	–	–	–	1 (1.2)
Pneumonia	–		–	–

Major complications consisted of those requiring surgical or radiological re-intervention, an unplanned increase in the level of care with prolonged hospitalization (>48 h), return to the ICU, or death.
Minor complications consisted of those not requiring further treatment and being without further consequences for the patient, or requiring minor therapy including unplanned extend of hospital admission (≤24 h).
[a]Between index-procedure and date of discharge.
[b]Between discharge and 30 days.
[c]Between 1-month and 12-month follow-up.
[d]Prolonged pain for more than 8 weeks.

had a pseudo-obstruction of the small bowel with need of a nasogastric tube and rehydration. There was presumably one recurrence suspect on ultrasonography. This patient was contacted for re-laparoscopy, which showed no recurrence. Recurrence rate was 0.0%. Three patients had prolonged pain at 12 months, tacks were used in one patient and the other two patients had the combination of tacks and trans-umbilical stitch.

Discussion

In the literature, recurrence rates are comparable for the laparoscopic (2.9–15%, mean 4.8%) and the open (1–10%, mean 4.5%) approach. In most trials the median follow-up is one year, which is too short. In the first-year follow-up, recurrences are often the result of technical errors, such as the use of small meshes with inadequate overlap of the defect, inadequate fixation or unnoticed parietal defects. Moreno-Egea et al. found for the laparoscopic approach a recurrence rate of 6.2%, with a median follow-up of 6 years [11]. Burger et al. [5] did a prospective long-term follow-up study of incisional hernia repair. Although mesh repair is superior to suture repair, the recurrence rate of incisional hernias even with mesh repair is still as high as approximately 32% over a 10-year follow-up period. According to the Danish Hernia Database, the real recurrence rate is 5 times higher than the reoperation rate. That is because true recurrences are not always symptomatic [12]. Longer follow-up is necessary to appreciate the true rate of hernia recurrence. Le Blanc et al. [13] suggest a follow-up period of at least 3 years. Table 3 compares results of our trial with 4 other larger trials with longer follow-up periods [11,13–15]. Beside the technical errors, there are also other factors that influence the recurrence rate. A significant relationship is found between recurrence and obesity, hernia size and multiple Swiss-cheese defects [16]. Also, previous repair and postoperative complications are factors related to recurrence [14]. Given the limited number of patients in our study and the short follow-up period of 12 months, the recurrence rate (0.0%) of our study is probably underestimated. Furthermore, in 20.9% (18/86) of the patients, only a telephone conversation took place without a clinical examination. An asymptomatic recurrence could be missed. However, Eisenberg et al. [17] recently published a study examining the feasibility and outcomes of implementation of a telephone follow-up program for laparoscopic inguinal hernia repair. A trained certified physician assistant called the patients ∼2 weeks postoperatively to assess the need for a clinic visit. Hwa et al. [18] did the same for elective open hernia repair and laparoscopic cholecystectomy. There were no complications that resulted from the substitution of a

Table 3. Comparison of this study with other large studies with long follow-up periods.

Study	Heniford et al. [14]	Franklin et al. [15]	LeBlanc et al. [13]	Moreno-Egea et al. [11]	This study
No.of patients	819	348	100	200	90
Incisional hernia	278	114	90	200	35
Centres	4	1	1	1	7
Follow-up (month)	20	47	51	60	12
Examination	Physical	Physical	Physical	Physical	Physical
Lost patients	75 (9%)	23 (6%)	12 (12%)	24 (12%)	4 (4.4%)
Operation					
Mesh	ePTFE	PPL	ePTFE	Parietex	Intramesh T1
Overlap (cm)	3–4	3–5	–	>5	>3
Fixation	Suture Tacks	Suture Tacks	Varied	Tacks only	Varied
Results					
Operating time (min)	120	68	86	51	45
Converted to open surgery	3.80%	4.70%	4.0%	2.50%	0%
Hospital stay (days)	2.3	2.9	1	2.6	2
Intestinal injury *n* (%)	14 (1.8)	5 (1.4)	1 (1)	5 (2.5)	1 (1.1)
Ileus/obstruction *n* (%)	25 (3)	5 (1.3)	5 (5)	2 (1)	5 (5.8)
Prolonged pain *n* (%)	13 (1.6)	12 (5)	7 (7)	0 (0)	6 (7.0)
Mesh infection *n* (%)	6 (0.7)	1 (0.3)	2 (2)	0 (0)	0 (0)
Seroma early *n* (%)	–	15–20%	–	6 (3)	9 (10.2)
Seroma late *n* (%)	21 (2.6)	12 (3.1)	7 (7)	0 (0)	2 (2.3)
Recurrence *n* (%)	35 (4.7)	11 (3.2)	9 (9)	11 (6.2)	0 (0)[a]

PPL: polypropylene; ePTFE: expanded polytetrafluoroethylene; Parietex: composite mesh with resorbable collagen barrier on one side to limit visceral attachments, and a three-dimensional polyester knit structure on the other site to promote differentiated tissue ingrowth.
[a]68 patients with clinical examination.

telephone call for a 'gold standard' clinic visit. Implementation of telephone follow-up seemed not to compromise patient care in these studies, but the follow-up call was only 2 weeks after surgery. No conclusions can be made for the efficacy of telephone calls for longer follow-up periods.

Seroma formation is one of the most common reported problems in hernia surgery, especially in laparoscopic repair. The real incidence is difficult to find in the literature, since it has been described following different parameters. It varies between 0.7 and 93%, which is primarily due to heterogeneous definitions, different methods of measuring seromas and the different time of measurement after the operation. Almost every patient has seroma formation after hernia repair in radiological examinations [19,20]. Most of these patients do not have any or very few symptoms. Seroma formation could lead to potential complications, which include pain, discomfort, cellulites and infection. There are several methods proposed to avoid seroma formation, such as resection of the hernia sac, closing the fascia defect and using antibiotics to prevent infection [19]. But, it is difficult to evaluate the effectiveness of these techniques because of the different definitions. Morales-Conde et al. [20] published a classification in order to establish the real incidence of seromas. The intention is to distinguish the incidents from the complications. This classification can be useful to compare trials on the real seroma rate based on similar criteria. In our study, the seroma rate at 1-month and 12-months follow-up was 10.2%, and 2.3%, with an overall seroma rate of 12.2%. After using the classification of Morales-Conde et al. [20] there were 5 (4.5%) incidents, which include type I (0.9%) and type II (3.8%) seroma, and 6 (5.6%) complications, which include type III (2.8%) and type IV (2.8%) seroma. The real seroma rate of our study would be 5.6% based on this classification. Only one patient had a seroma related infection. Table 3 gives an overview of the seroma rate in other trials. A higher seroma rate is generally found with the use of ePTFE meshes, which is also associated with higher infection rates.

Infection is considered one of the most challenging complications since it might lead to mesh removal and recurrence. Although widely used, there is no evidence about the prophylactic use of antibiotics. There is some evidence about impregnating meshes with antiseptics [21]. A recent study found that steroid or immunosuppressive drugs use, urgent repair, and development of a postoperative surgical site infection are predictive of mesh infection. Risk factors of mesh removal are ePTFE mesh, onlay mesh position and associated enterotomy in the same procedure [22]. Microporous meshes, such as ePTFE, have the highest risk of infection. Macrophages and neutrophils are unable to penetrate the small pores ($<10\,\mu m$), which allows the bacteria ($<1\,\mu m$) to survive within the pores and formation of a bacterial biofilm.

Acute postoperative pain is usually due to nerve damage at the time of operation, there is little difference in the type of mesh used. In contrast, pain due to foreign body reaction typically presents after 1 year. Chronic pain following hernia repair has a quoted risk of over 50%. Prolonged postoperative pain is often described as a result of mesh fixation with transabdominal sutures, metal

fixation devices (tacks) or both together. A recent prospective study investigated the outcome between three different fixation methods: non-absorbable sutures, absorbable sutures, and double crown technique. Postoperative pain was not significantly different between these groups [23]. Also Wassenaar et al. [24] and Nguyen et al. [25] found no difference in postoperative pain and quality of life. Beldi et al. [26] compared tacks and sutures, and found more postoperative pain for sutures: after 6 weeks (28% vs 61%) and after 6 months (38% vs 50%). Surgical glue was used in 21.1% of our patients, but the median hernia size was only 1.5 cm^2. No conclusions could be made in our study, because of lack of protocol in fixation methods and heterogeneous data. However, this might not be relevant, as the literature states no consensus.

Mesh shrinkage has been related to hernia recurrence rate. Substantial decrease in mesh size is a known consequence after intraperitoneal implantation. There is a general consensus that a mesh should overlap the hernia defect by 3–5 cm [27]. Transabdominal sutures seem to have the best results because the tensile strength of suture fixation is significantly higher compared with tack fixation. van't Riet et al. found a 2.5 times greater tensile strength for transabdominal sutures [28]. Beldi et al. [26] found an equal effect for tacks and sutures in preventing mesh shrinkage following repair for hernia smaller than 8 cm. For bigger hernias, there is lower mesh shrinkage after suture fixation compared with tack fixation. But, an increased infection rate is found after suture fixation according to Brill et al. [29]. The degree of shrinkage varies also between different mesh materials. Higher rates of hernia recurrence were observed at the interface of ePTFE and the fascia. This has been attributed to the decreased inflammatory response elicited by ePTFE. The tendency towards most shrinkage occurs after ePTFE implantation. A bigger overlap is recommended when using only ePTFE meshes [19,27].

In the management of ventral hernias, the use of intraperitoneal meshes is generally accepted. Direct contact between mesh material and abdominal organs forms a major problem. Composite meshes are developed to prevent adhesion formation and at the same time to enhance mesh incorporation. Both the chemical composition and the morphology of these meshes have been studied in several experimental and clinical trials. Burger et al. [30] compared 8 different meshes, placed intraperitoneally and in direct contact with abdominal viscera of 200 rats: polypropylene (Prolene®), e-PTFE (DualMesh®), polypropylene–polyglecaprone composite (Ultrapro®), titanium–polypropylene composite (Timesh®), polypropylene with carboxymethylcellulose–sodium hyaluronate coating (Sepramesh®), polyester with collagen-polyethylene glycol–glycerol coating (Parietex Composite®), polypropylene–polydioxanone composite with oxidized cellulose coating (Proceed®), and bovine pericardium (Tutomesh®). They found the best results in Parietex Composite® and Sepramesh®, because they have the combination of minimal adhesion formation with maximum mesh incorporation and tensile strength. Composite meshes may be classified into two categories: coated mesh with a temporary barrier coating, or dual-sided mesh with a permanent barrier layer. Examples of coated mesh are Proceed® (degenerates over 28 days), Sepramesh® (degenerates over 7 days), Physiomesh® (degrades over 240 days). Dual-sided meshes are Composix® (PPL-ePTFE), and DualMesh® (double-sided ePTFE), and Timesh® (PPL-titanium). The Intramesh® T1, used in our study, belongs to the group of dual-sided meshes with a non-absorbable barrier. The physical presence of a layered coating between the intraperitoneal content and the abdominal wall seems to be more important than the chemical properties of the coating [30]. Schreinemacher et al. found that absorbable coatings only reduce adhesions in short term, but the effect diminishes and phagocytosis of absorbable coatings may contribute to adhesion formation [31]. Proceed® mesh, in particular, demonstrated a prolonged active inflammatory response and fibroblast influx, thereby promoting adhesion formation; several studies have shown that this mesh is more likely to generate adhesions than are other types of composite mesh [32].

There are no general recommendations for the choice of mesh based on randomized controlled trials. No difference seems to exist in relevant outcome parameters from clinical series between different mesh materials. The final choice of mesh will be based on surgeons' preference and cost [11].

The purpose of this trial was to evaluate the practical use of Intramesh® T1 in a wide spectrum of patients with different risk factors and ASA-scores, with different surgeons and their own surgical techniques and different fixation techniques. In conclusion, Intramesh® T1 is a safe and effective composite mesh with favourable short and mid-term outcome and morbidity.

Acknowledgements

This study was funded by Be Medical, Zutendaal, Belgium.

Disclosure statement

W.W. declares no conflict of interest; B.M., M.V.D.M, S.L., D.F., P.P. and L.B. declare conflict of interest directly related to the submitted work (investigator fee from sponsor); J.C. and K.G. declare having received funds from the study sponsor in relation to this study and for activities outside of this work; K.V.D.S. declares having received funds in relation to this study.

Funding

This study was funded by Be Medical, Londerzeel, Belgium.

ORCID

Wen Wen http://orcid.org/0000-0002-3394-5620
Marijke Van De Moortel http://orcid.org/0000-0002-4627-9452
Didier Fobe http://orcid.org/0000-0002-0561-9502

References

[1] Poulose BK, Shelton J, Phillips S, et al. Epidemiology and cost of ventral hernia repair: making the case for hernia research. Hernia. 2012;16:179–183.
[2] Cassar K, Munro A. Surgical treatment of incisional hernia. Br J Surg. 2002;89:534–545.
[3] Luijendijk RW, Hop WC, van den Tol P, et al. A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med. 2000;343:392–398.
[4] Den Hartog D, Dur AHM, Tuinebreijer WE, Kreis RW. Open surgical procedures for incisional hernias. Cochrane Database of Syst Rev. 2008;3:1–33.
[5] Burger JW, Luijendijk RW, Hop WC, et al. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg. 2004;240:578–585.
[6] Draus JM Jr, Huss SA, Harty NJ, et al. Enterocutaneous Fistula: are treatments improving? Surgery. 2006;140:570–576.
[7] Harrell AG, Novitsky YW, Peindl RD, et al. Prospective evaluation of adhesion formation and shrinkage of intra-abdominal prosthetics in a rabbit model. Am Surg. 2006;72:808–813.
[8] Johnson EK, Hoyt CH, Dinsmore RC. Abdominal wall hernia repair: a long-term comparison of Sepramesh and Dualmesh in a rabbit hernia model. Am Surg. 2004;70:657–661.
[9] Aguayo-Albasini JL, Moreno-Egea A, Torralba-Martinez JA. The labyrinth of composite prostheses in ventral hernias. Cir Esp. 2009;86:139–146.
[10] Wolters U, Wolf T, Stützer H, et al. ASA classification and perioperative variables as predictors of postoperative outcome. Br J Anaesth. 1996;77:217–222.
[11] Moreno-Egea A, Bustos JAC, Girela E, et al. Long-term results of laparoscopic repair of incisional hernias using an intraperitoneal composite mesh. Surg Endosc. 2010;24:359–365.
[12] Helgstrand F, Rosenberg J, Kehlet H, et al. Reoperation versus clinical recurrence rate after ventral hernia repair. Ann Surg. 2012;256:955–958.
[13] LeBlanc KA, Booth WV, Whitaker JM, et al. Laparoscopic incisional and ventral herniorrhaphy in 100 patients. Am J Surg. 2000;180:193–197.
[14] Heniford BT, Park A, Ramshaw BJ, et al. Laparoscopic repair of ventral hernias: nine years' experience with 850 consecutive hernias. Ann Surg. 2003;238: 391–400.
[15] Franklin ME Jr, Gonzalez JJ Jr, Glass JL, et al. Laparoscopic ventral and incisional hernia repair: an 11-year experience. Hernia. 2004;8:23–27.
[16] Nguyen DH, Nguyen MT, Askenasy EP, et al. Primary Fascial Closure With Laparoscopic Ventral Hernia Repair: Systematic Review. World J Surg. 2014;38:3097–3104.
[17] Eisenberg D, Hwa K, Wren SM. Telephone follow-up by a midlevel provider after laparoscopic inguinal hernia repair instead of face- to-face clinic visit. JSLS. 2015;19:e2014.00205.
[18] Hwa K, Wren SM. Telehealth Follow-up in Lieu of Postoperative Clinic Visit for Ambulatory surgery: results of a pilot program. JAMA Surg. 2013;148: 823–827.
[19] Susmallian S, Gewurtz G, Ezri T, et al. Seroma after laparoscopic repair of hernia with PTFE patch: is it really a complication? Hernia. 2001;5:139–141.
[20] Morales-Conde S. A new classification for seroma after laparoscopic ventral hernia repair. Hernia. 2012;16:261–267.
[21] Carbonell AM, Mathews BD, Dreau D, et al. The susceptibility of prosthetic biomaterials to infection. Surg Endosc. 2005;19:430–435.
[22] Lledo JB, Gallud AT, Hernandez AS, et al. Predictors of mesh infection and explantation after abdominal wall hernia repair. Am J Surg. 2017;213:50–57.
[23] Bansal VK, Misra MC, Kumar S, et al. A prospective randomized study comparing suture mesh fixation versus tacker mesh fixation for laparoscopic repair of incisional and ventral hernias. Surg Endosc. 2011;25:1431–1438.
[24] Wassenaar E, Schoenmaeckers E, Raymakers J, et al. Mesh-fixation method and pain and quality of life after laparoscopic ventral or incisional hernia repair: a randomized trial of three fixation techniques. Surg Endosc. 2010;24:1296–1302.
[25] Nguyen SQ, Divino CM, Buch KE, et al. Postoperative pain after laparoscopic ventral hernia repair: a prospective comparison of sutures versus tacks. JSLS. 2008;12:113–116.
[26] Beldi G, Wagner M, Bruegger LE, et al. Mesh shrinkage and pain in laparoscopic ventral hernia repair: a randomized clinical trial comparing suture versus tack mesh fixation. Surg Endosc. 2011;25:749–755.
[27] Zinther NB, Wara P, Friis-Andersen H. Shrinkage of intraperitoneal onlay mesh in sheep: coated polyester mesh versus covered polypropylene mesh. Hernia. 2010;14:611–615.
[28] van't Riet M, de Vos van Steenwijk PJ, Kleinrensink GJ, et al. Tensile strength of mesh fixation methods

in laparoscopic incisional hernia repair. Surg Endosc. 2002;16:1713–1716.

[29] Brill JB, Turner PL. Long-term outcomes with transfascial sutures versus tacks in laparoscopic ventral hernia repair: a review. Am Surg. 2011;77:458–465.

[30] Burger JWA, Halm JA, Wijsmuller AR, et al. Evaluation of new prosthetic meshes for ventral hernia repair. Surg Endosc. 2006;20:1320–1325.

[31] Schreinemacher MH, van Barneveld KW, Gijbels MJ, et al. Coated meshes for hernia repair provide comparable intraperitoneal adhesion prevention. Surg Endosc. 2013;27:4202–4209.

[32] Jacob BP, Hogle NJ, Durak E, et al. Tissue ingrowth and bowel adhesion formation in an animal comparative study: polypropylene versus Proceed versus Parietex composite. Surg Endosc. 2007;21:629–633.