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Adverse effects of intraperitoneal onlay mesh used for incisional hernia repair

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Complications liées à la pose de filets intrapéritonéaux lors de cures de hernie incisionnelle

Introduction

In the past 50 years, the use of prosthetic mesh in surgery has dramatically changed the management of primary, as well as incisional hernias. In contrast with suture repair, prosthetic mesh reparation permits a tension-free repair. The recurrence rate decreased from 43% to 24% after a first hernia and from 58% to 20% after a first incisional hernia with this method[1-3]. Currently, there are a large number of different mesh brands and no consensus on the best material, nor the best mesh implantation technique to use[4].

Two things play a role in mesh implantation: the technique used (open versus laparoscopic approach) and the localisation of the mesh (onlay, inlay, sublay).
Currently, two mesh implantation techniques are most frequently used: the laparoscopic approach with intra-peritoneal onlay mesh (*IPOM* technique) and the open approach with insertion of a retro-muscular extra-peritoneal mesh (sublay) following Rives-Stoppa. Many studies compare *IPOM* and *sublay* techniques, but there is currently no consensus about the best technique to use from the point of view of morbidity and cost-benefit ratio.
Many studies compare laparoscopic approach and open approach. A low recurrence rate is achieved by both techniques with no significant difference between them[5,6].
The risk factors for recurrence are suture repair, infection, prostatism and previous history of abdominal surgery for aortic aneurysm. The size of the hernia, however, does not affect the rate of recurrence[1,7]. Recurrence leads to discomfort and possible complications such as bowel incarceration resulting in ischemia, necrosis and perforation with high morbidity.
Laparoscopy or laparotomy with mesh implantation may result in various complications such as infection, abscess, seroma formation, adhesion, fistula and nerve entrapment[5,8]. Infections appear after colic perforation or with parietal necrosis. The average interval between operation and complications is about two years[9].

An intra-abdominal foreign body, as a mesh, induces an inflammatory response with activation of phagocytosis[10]. This leads to the formation of adhesions between the mesh and the abdominal wall. Adhesions are part of the normal healing process and allows good incorporation of the mesh but it can also induce a weakening of the wall and an increased hernia recurrence rate. Adhesions of the mesh are also associated with bowel obstruction, bowel erosion, infertility, fistula and chronic pain and make reoperation technically difficult[3,5,10,11]. Intra-abdominal adhesion is not specifically related to mesh placement, but is an inevitable consequence of surgery of any kind (laparotomy and laparoscopy) and appear in about 90% of all patients after abdominal surgery[11].

Many studies show better results with laparoscopy compared to laparotomy in terms of length of hospital admission and number of complications such as infections and seroma, even if complications such as bowel injury tend to be more severe[5,12,13]. Also, this technique requires more experience and more expensive equipment as laparotomy[5,12,13]. In addition, there is a higher risk of bowel perforation with a laparoscopy.

Currently the Department of the Visceral Surgery of CHUV uses a modified Rives-Stoppa technique. It consists in an anatomical repair of the abdominal wall with placing of a retromuscular non-resorbable mesh. This mesh is placed behind the rectus muscle over the posterior fascia superior, or fascia transversalis inferior to the umbilicus[4,14]. This technique encourages mesh incorporation because the mesh remains in direct contact with well vascularized muscle. This produces strengthening of the abdominal wall and an improved recovery with tension-free closure[7]. This technique is associated with low rates of recurrence, infection, pain and seroma[4].

Polypropylene mesh, for example Ultrapro® and Proceed®, are widely used[3,7]. Some surgeons have observed that the structure and the chemical composition of the mesh both influences host tissue reaction equally[7].
However owing to commercial pressure a large variety of non-resorbable and composite mesh types have appeared on the market, without sufficient transparent studies of complications using actual experience of patients. Indeed, most studies of

the effectiveness of mesh have been performed on experimental animal models[3,10,15].

The type of mesh fixation may also play an important role in the development of complications. Mesh may be secured by spiral tackers, staples, or transfascial sutures[5]. The cut edges of the mesh and spiral tack anchoring devices were associated directly with severe adhesions or even bowel perforation, especially where mesh migration had occurred. Moreover, the use of mesh fixation devices like tackers or transfascial sutures have sometimes resulted in severe chronic neuropathic pain due to nerve entrapment[4]. The type of mesh fixation also determines the degree of tissue contraction (mesh shrinkage) and potentially affects the incidence of recurrent hernia[16,17]. In a randomized clinical trial comparing suture versus tack mesh fixation, shows that transfacial anchoring sutures were associated with less mesh shrinkage after 6 months when compared with mesh fixation using tacks[16].

Few studies have been carried out to examine the morbidity and long-term consequences of intraperitoneal prosthetic mesh placement.

The purpose of this study is to illustrate the ***adverse effects of intraperitoneal onlay mesh used for incisional hernia repair*** encountered in patients treated at CHUV for complications after incisional hernia repair. The type of operation, type of mesh and duration between the first operation and appearance of complications were recorded.

Materials and Methods

Study design and protocol

This report was prepared by permission of the Medical Director of the CHUV and by approval of the Vaud Cantonal Ethics Committee for Human Research.

This work is an observational retrospective study. A PubMed search and a systematic review of literature were performed with the following key words: mesh; intra-peritoneal mesh; incisional hernia repair; laparotomy incisional hernia repair; laparoscopic incisional hernia repair; adhesions.

The medical records of 22 patients, who presented with pain, abdominal discomfort, ileus, fistula, abscess, seroma, mesh infection or recurrent incisional hernia after a laparoscopic or open repair with intra-abdominal mesh, were reviewed.

Inclusion criteria

All patients older than 18 years, who had between 2000 and 2011 complications such as pain, abdominal discomfort, ileus, fistula, abscess, seroma or infection, after incisional hernia with an intra-peritoneal mesh. Reoperations of complications or recurrences were performed in the Department of Visceral Surgery, CHUV, Lausanne, Switzerland. Complications found at surgery were recorded prospectively and photo documentation performed in every case during the procedure.

Data record

Sex, age, type of complication (pain, abdominal discomfort, ileus, fistula, abscess, seroma, infection), hernia recurrence, type of mesh used, type of mesh fixation, surgical approach (open approach versus laparoscopic approach), time from implantation in months, type of surgery (planned surgery versus emergency surgery), observation during the second operation (mesh migration, mesh adhesion, mesh shrinkage, nerve entrapment, seroma, abscess, fistula) and ASA score (American Society of Anesthesiology) were on recorded.

Exclusion criteria:

No complication found intraoperatively, no medical records concerning a first operation in another hospital or country, reoperation before year 2000.

Data analysis

All judgment criteria were analyzed from the medical records and were included in an Excel® table, version 14.1.3 and divided in Word® table 1 and table 2, version 14.1.3. Numeric variables are expressed as median.

Results

Patient characteristics

Patients #	Sex	Median age (ys)	Associated diagnosis and symptoms	Surgical approach: OA vs LS	Time from implantation (months)	Setting of surgery: PS vs ES	Risk classification: ASA score
1	M	41	Seroma	OA	8	PS	2
2	M	29	Rectal fistula	OA	1	ES	2
3	M	63	Pain, bloating	LS	13	ES	3
4	M	79	Pain	LS	15	PS	2
5	M	63	Discomfort, biliary colic	LS	14	PS	2
6	F	73	Fistula, abscess	OA	147	ES	2
7	M	60	Infection, dehiscence	OA	1	ES	2
8	F	73	Seroma	OA	21-32	PS	3
9	F	82	Seroma	LS	17	PS	2
10	F	73	Pain, acute cholecystitis	LS	48	ES	2
11	F	69	Discomfort	OA	7	PS	3
12	F	75	Pain	OA	50	PS	2
13	F	73	Pain, chronic cholecystitis	LS	12	PS	2
14	F	46	Ileus	LS	1-12	ES	2
15	F	30	Pain	OA	29-41	PS	1
16	M	43	Pain	LS	123-134	ES	2
17	M	24	Ileus	OA	3	ES	4
18	F	55	Pain	OA	5	PS	3
19	M	67	Ileus, abdominal pain	OA	47	PS	2
20	F	48	Abdominal pain, infection	LS	11	ES	3
21	F	63	Infection, fistula	OA	66	PS	2
22	M	59	Discomfort, pain	OA	31	PS	2

Table 1: Patient characteristics.

M: Male, F: Female, YS: years, OA: Open approach, LS: Laparoscopic approach, PS: Planned surgery, ES: Emergency surgery, ASA: American Society of Anesthesiologists

Twenty-two persons were reoperated for complications after incisional hernia repair with a prosthetic mesh. Ten were male and twelve female, with a median age of 58,6 years (range 24-82).

Presentation

Associated diagnosis and symptoms resulting in reoperation are:

- abdominal discomfort
- abdominal pain
- infection
- seroma
- fistula
- ileus

These were considered to be directly associated with intra-peritoneal mesh or with hernia recurrence. During an emergency procedure for unrelated pathology to a previous incisional hernia repair in one patient it was possible to visualize results associated with intraperitoneal mesh repair.

Management

Mesh placement was performed by a laparoscopic approach in nine patients and by open approach in thirteen others. The majority underwent elective operation for reoperation but nine underwent an emergency surgery. The setting of surgery (planned surgery versus emergency surgery) depended on the severity of symptoms. All patients had an ASA score between 1 and 4 and 15/22 (68%) had an ASA score of 2.

Physical status	ASA Score
A normal healthy patient	1
A patient with mild systemic disease	2
A patient with severe systemic disease	3
A patient with severe systemic disease that is a constant threat to life	4
A moribund patient who is not expected to survive without the operation	5
A declared brain-dead patient whose organs are being removed for donor purposes	6

Table 2 : ASA Physical Status Classification System from the American Society of Anesthesiology.

These definitions appear in each annual edition of the ASA Relative Value Guide®. (http://www.asahq.org/clinical/physicalstatus.htm)

Outcome of patients following their previous cure of incisional hernia

Patients #	Hernia recurrence	Mesh brand	Mesh position	Mesh fixation	Mesh migration	Mesh shrinkage	Mesh adhesion	Intraoperative findings: S, F, A, NE, O
1	yes	Ultrapro®	Onlay	Prolene™	no	yes	yes	S
2	yes	Mersilene®, Titanium Metals UK Ltd®	Sublay	Prolene™	yes	no	no	F
3	yes	Parietex Composite®	IPOM	AbsobaTack™	no	no	yes	NE
4	yes	Proceed®	IPOM	ProTack™	no	no	yes	O
5	yes	Proceed®	IPOM	EasyTack™	yes	no	yes	O
6	no	Mersilene®	IPOM	Prolene™	no	no	yes	F, A
7	yes	Proceed®, DynaMesh®	IPOM	Prolene™	no	yes	yes	O
8	yes	DynaMesh®	Sublay	Prolene™	no	yes	yes	S
9	yes	Proceed®	Onlay	ProTack™	yes	yes	yes	S
10	no	Ultrapro®	IPOM	ProTack™	no	no	yes	O
11	yes	Parietex Composite®	IPOM	ProTack™	no	no	yes	O
12	no	Ultrapro®, Parietex Composite®	IPOM	Prolene™	no	no	yes	O
13	no	Proceed®	IPOM	ProTack™	no	no	yes	NE
14	no	Parietex Composite®	IPOM	ProTack™	no	no	yes	O
15	no	Ultrapro®	Sublay	ProTack™	no	no	yes	NE
16	no	Parietex Composite®	IPOM	Prolene™	no	no	yes	NE
17	yes	Gore® DualMesh®	IPOM	Prolene™	no	no	yes	O
18	yes	Permacol®	IPOM	Prolene™	no	yes	yes	O
19	yes	Proceed®	IPOM	ProTack™	yes	no	yes	O
20	yes	Parietex Composite®	IPOM	AbsorbaTack™	no	no	yes	F, A
21	yes	Parietex Composite®, Mersilene®	IPOM	Prolene™	no	no	yes	F, A
22	yes	Permacol®	IPOM	Prolene™	yes	yes	yes	O

Table 3: Patients after cure of incisional hernia.

S: Seroma, F: Fistula, A: Abscess, NE: Nerve entrapment, O: Other

Mesh brand

Eight different mesh brands were found in patients in this study. The most frequently found was Parietex Composite®, followed by Proceed®. Titanium Metals UK Ltd® and Gore® DualMesh® were each found in one patient.

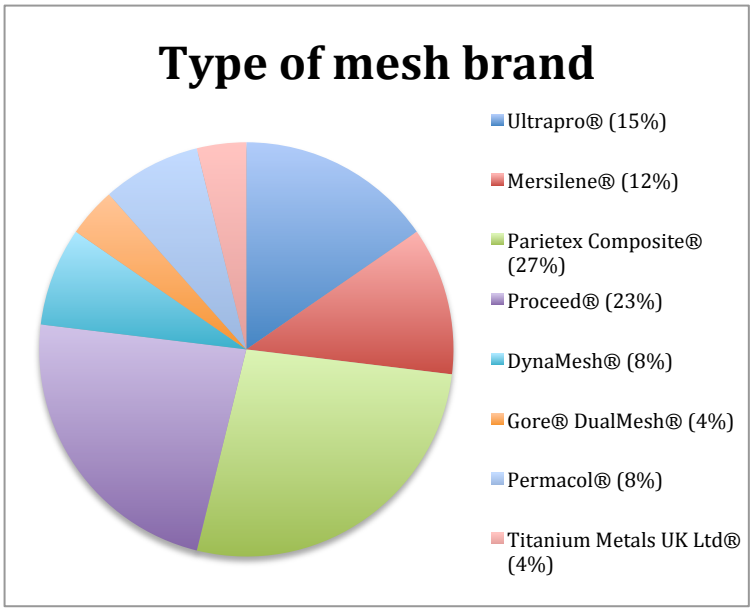

Figure 1 : Distribution of the different mesh brands.

Complications

In our sample of 22 patients, 15 (68%) presented with hernia recurrence. Hernia recurrence was seen with every type of mesh brand. Mesh adhesions is present in 21/22 patients (96%). No complication as bowel strangulation, ischemia or necrosis was observed.

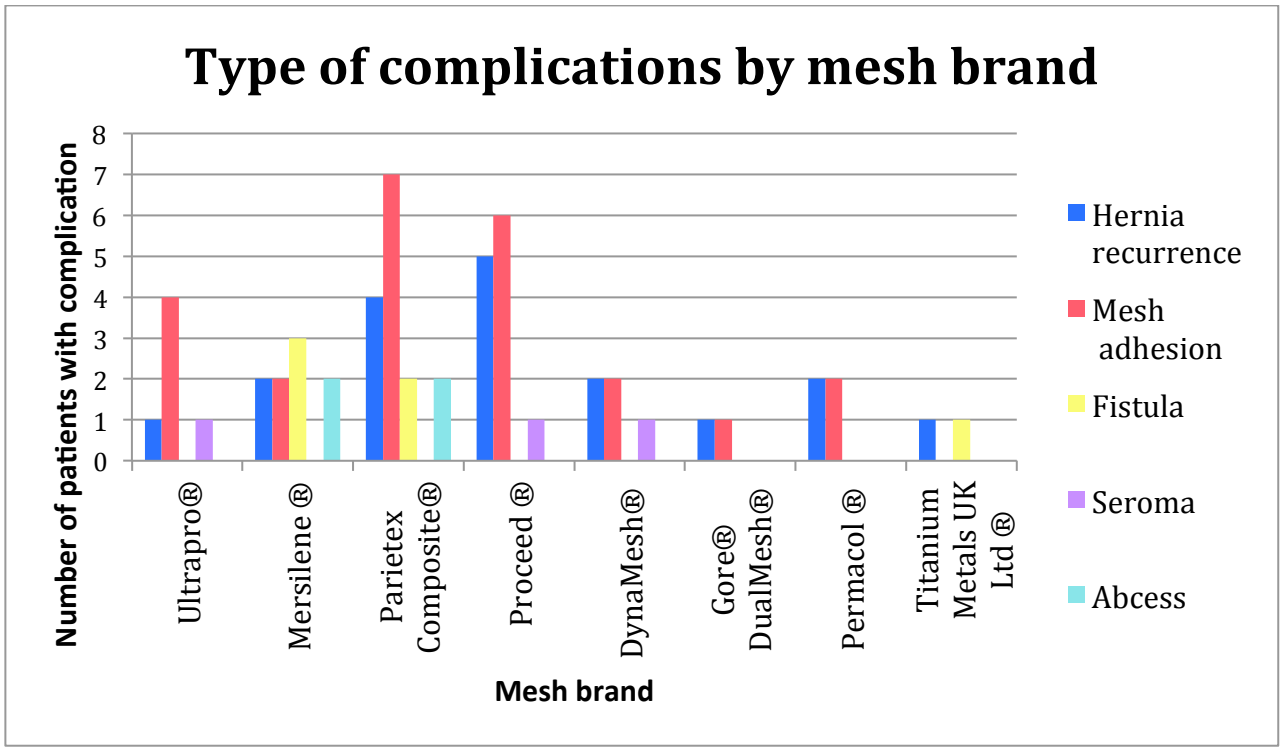

Figure 2: Type of complication by mesh brand.

The median time from initial mesh implantation to reoperation was 34.2 months (range 1-147). Table number 4 summaries the percentage distribution of recurrent hernias and the median time interval between intraperitoneal mesh placement and reoperation for complication. Ultrapro® mesh was associated with the lowest hernia recurrence rate. Hernia recurrences always appeared with Titanium Metals UK Ltd®, DynaMesh®, Gore® DualMesh® and Permacol® meshes. A link between brand of mesh and frequency of hernia recurrence cannot, however, be made in this small study. Time from implantation was a larger time interval between mesh implantation and re-intervention for complications with Mersilene®, Parietex Composite® and Ultrapro® mesh.

Mesh brand	Mesh composition	Hernia recurrence	Time from implantation (Months)
Ultrapro®	polypropylene & poliglecaprone 25	1/4 (25%)	35,2
Parietex Composite®	polyester & collagen	4/7 (57%)	46,3
Proceed®	oxidized regenerated cellulose & Prolene	5/6 (83,3%)	17,7
Mersilene®	polyester	2/3 (67%)	71,3
Titanium Metals UK Ltd®	polypropylene & titanium	1/1 (100%)	1
DynaMesh®	polyvinylidene fluoride & polypropylene	2/2 (100%)	18
Gore® DualMesh®	ePTFE	1/1 (100%)	3
Permacol®	porcin collagen	2/2 (100%)	18

Table 4 : Percentage of recurrent hernias and time interval between intraperitoneal mesh placement

Prolene = polypropylene & polydioxanone polymer

polytetrafluoroethylene (PTFE)

Various consequences were associated with intraperitoneal mesh placement like mesh migration, mesh shrinkage, mesh adhesion, fistula, abscess, seroma and nerve entrapment. (Table 3)

Mesh adhesion was most frequently seen, it was present in 21/22 (96%) of patients in this study. Of note, any abdominal surgical intervention was associated with the formation of adhesion and particularly when reoperation for complication was necessary. The only mesh that was not associated with adhesions is the Titanium Metals UK Ltd®. However, this mesh was found in only one person in this study (4,6%).

Abscesses were observed with Mersilene® and Parietex Composite®. Fistulas were observed with Mersilene®, Parietex Composite® and Titanium Metals UK Ltd®.

Seroma was observed with Ultrapro®, Proceed® and DynaMesh®. Nerve entrapment was observed with Ultrapro®, Parietex Composite® and Proceed®. Nerve entrapment was associeted with chronic pain and is really difficult to objectified during surgical intervention. Mesh migration was present in 5/22 of our patients (23%). Mesh shrinkage was present in 6/22 of patients (27%) even if the mesh was fixed with a non resorbable thread (Prolene®) in 5/6 cases (83%).

Illustration

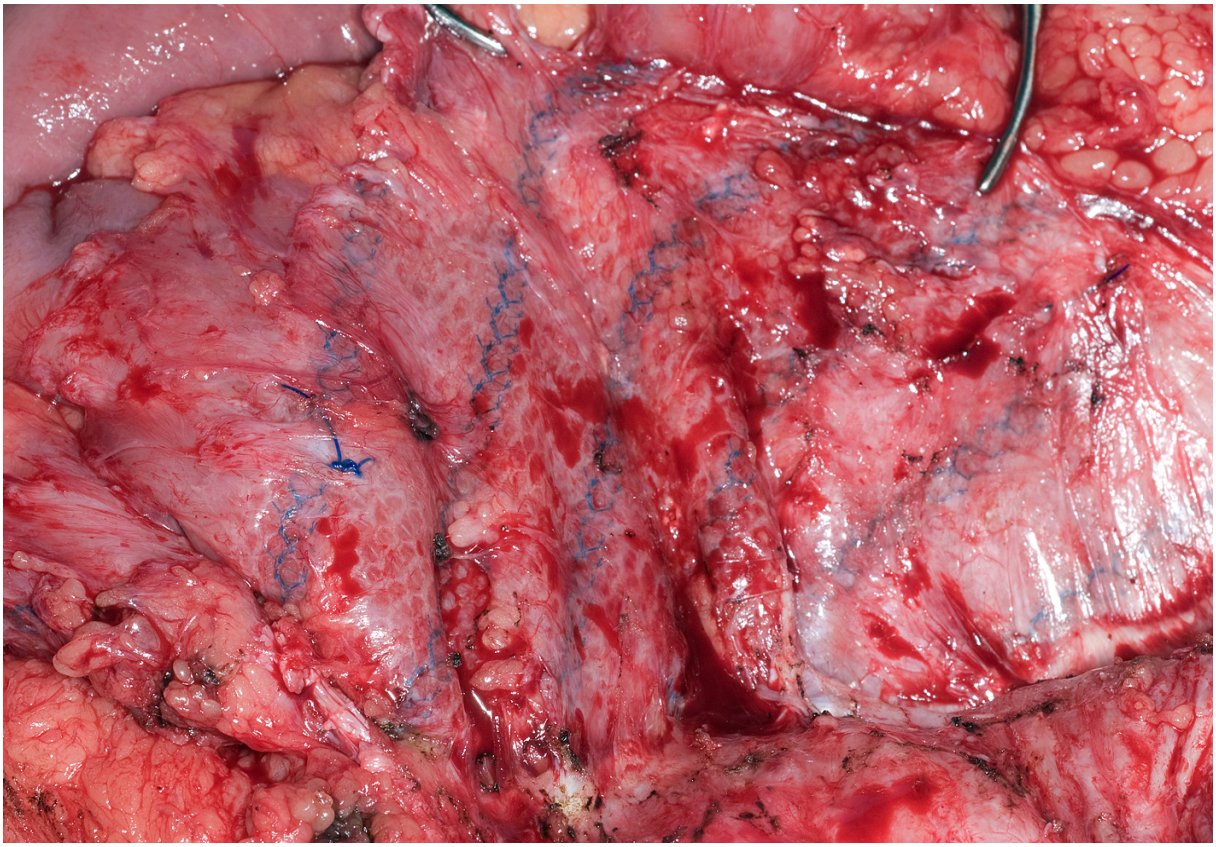

Figure 3: mesh adhesions.

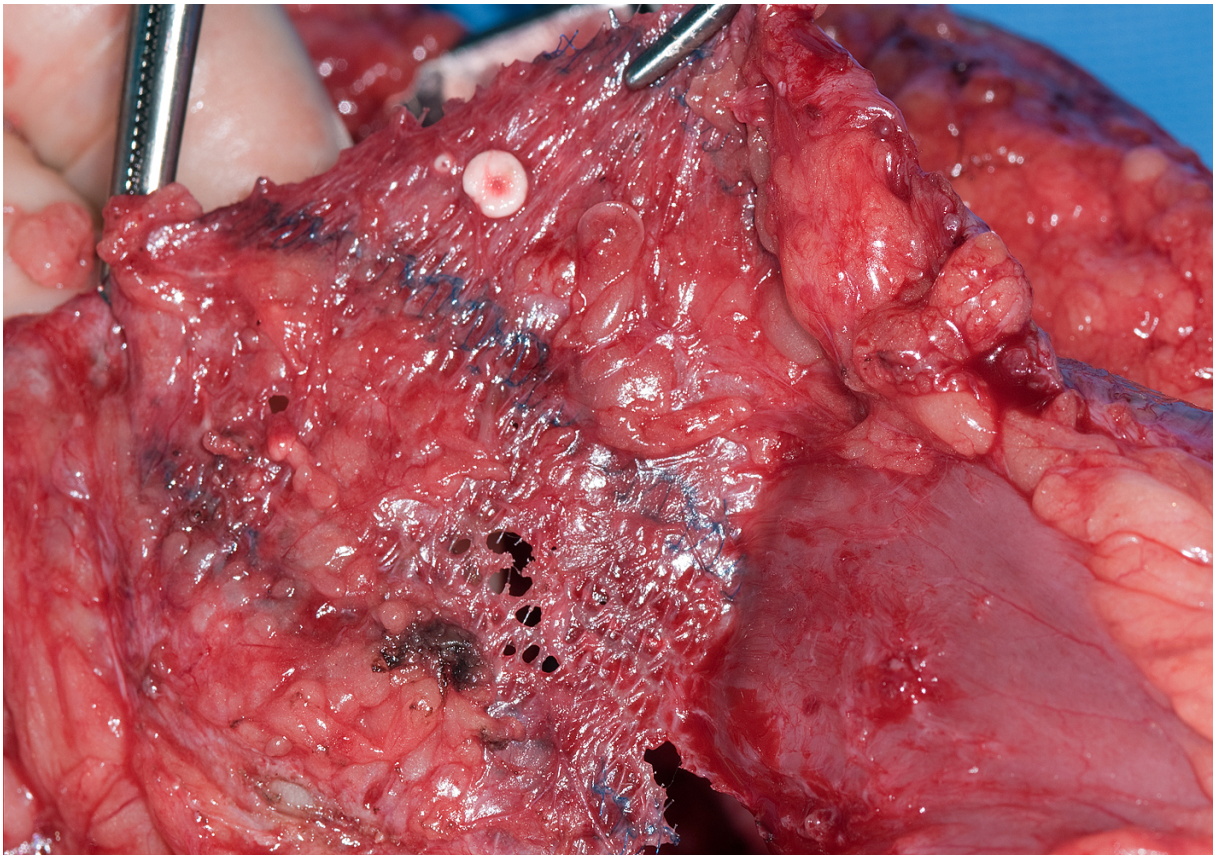

Figure 4: severe mesh adhesions and presence of 2 resorbable spiral fixation (tacks).

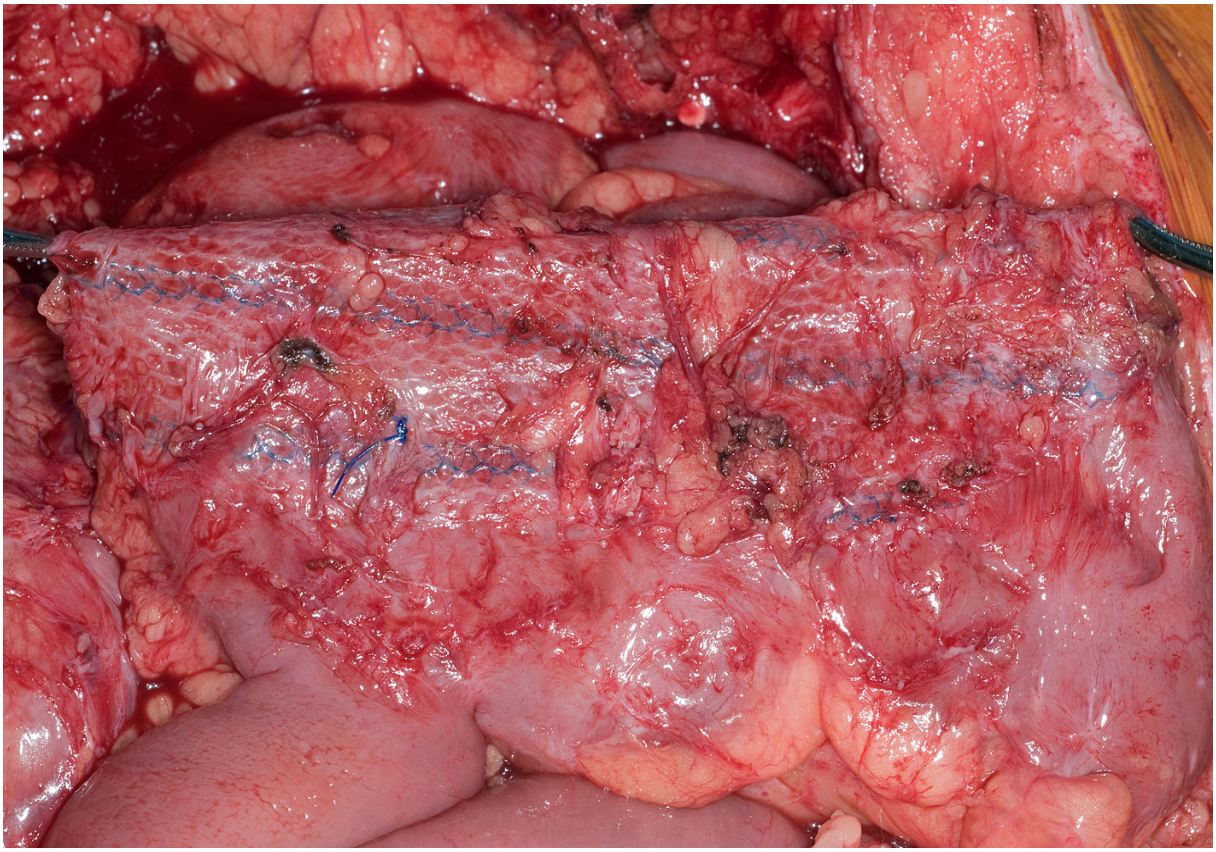

Figure 5: mesh adhesions and firm adhesions to small bowel.

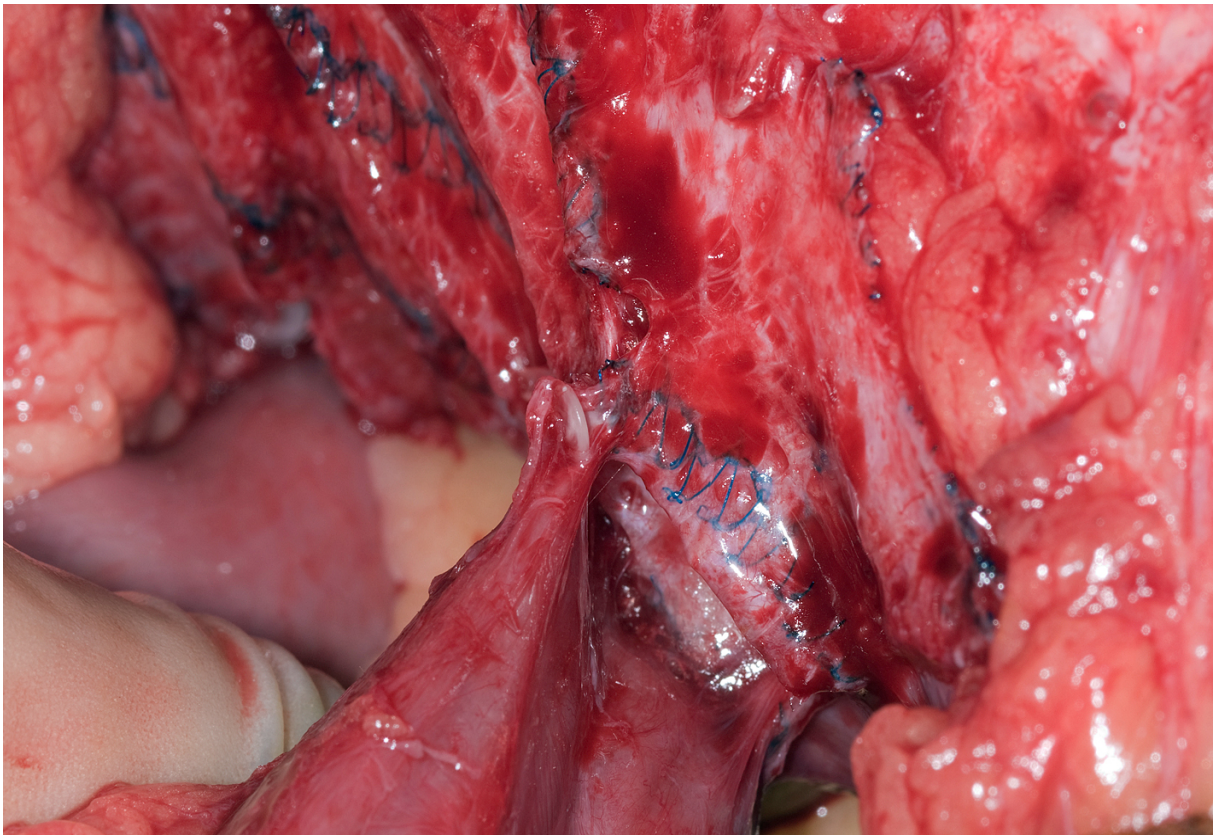

Figure 6: adhesions to small bowel and fistula formation. Adhesions are maximal at anchoring sites.

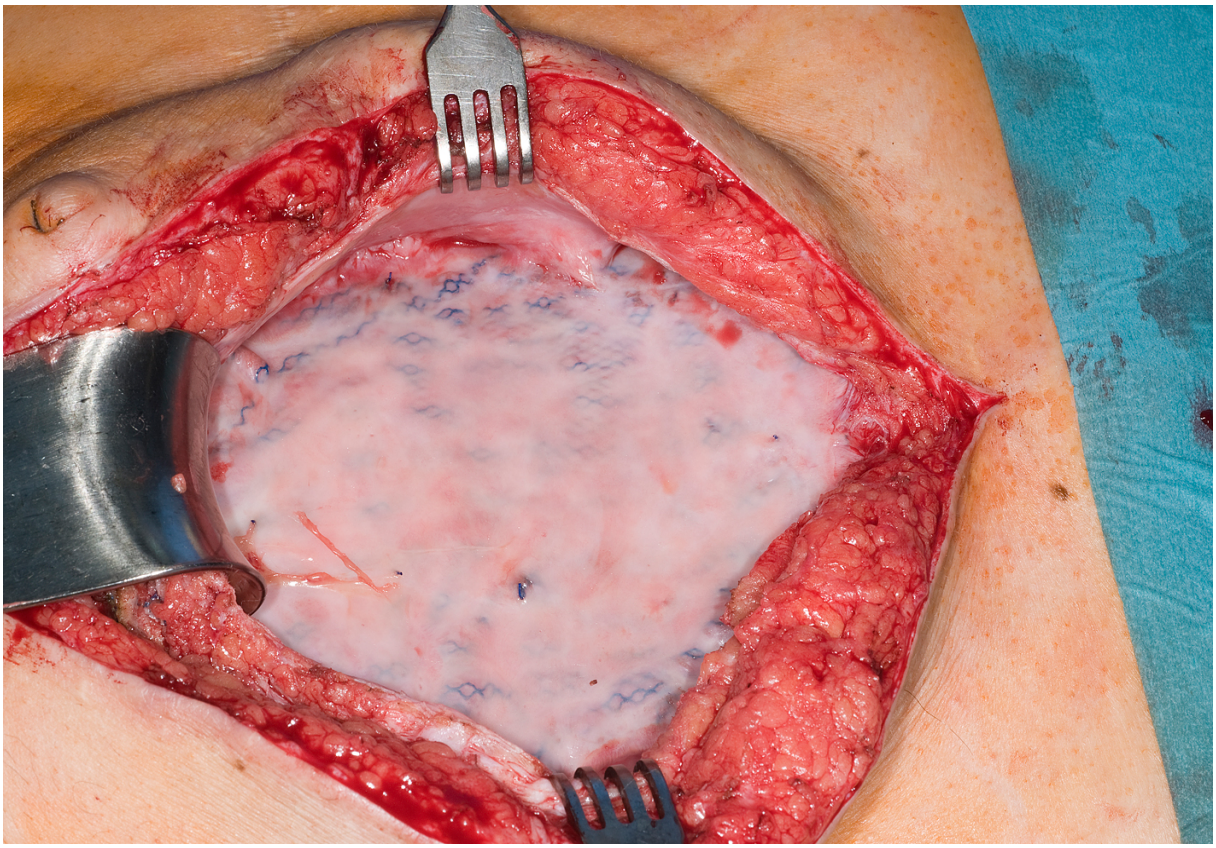

Figure 7: seroma formation above the mesh with a thickened chronic inflammatory shell-like formation.

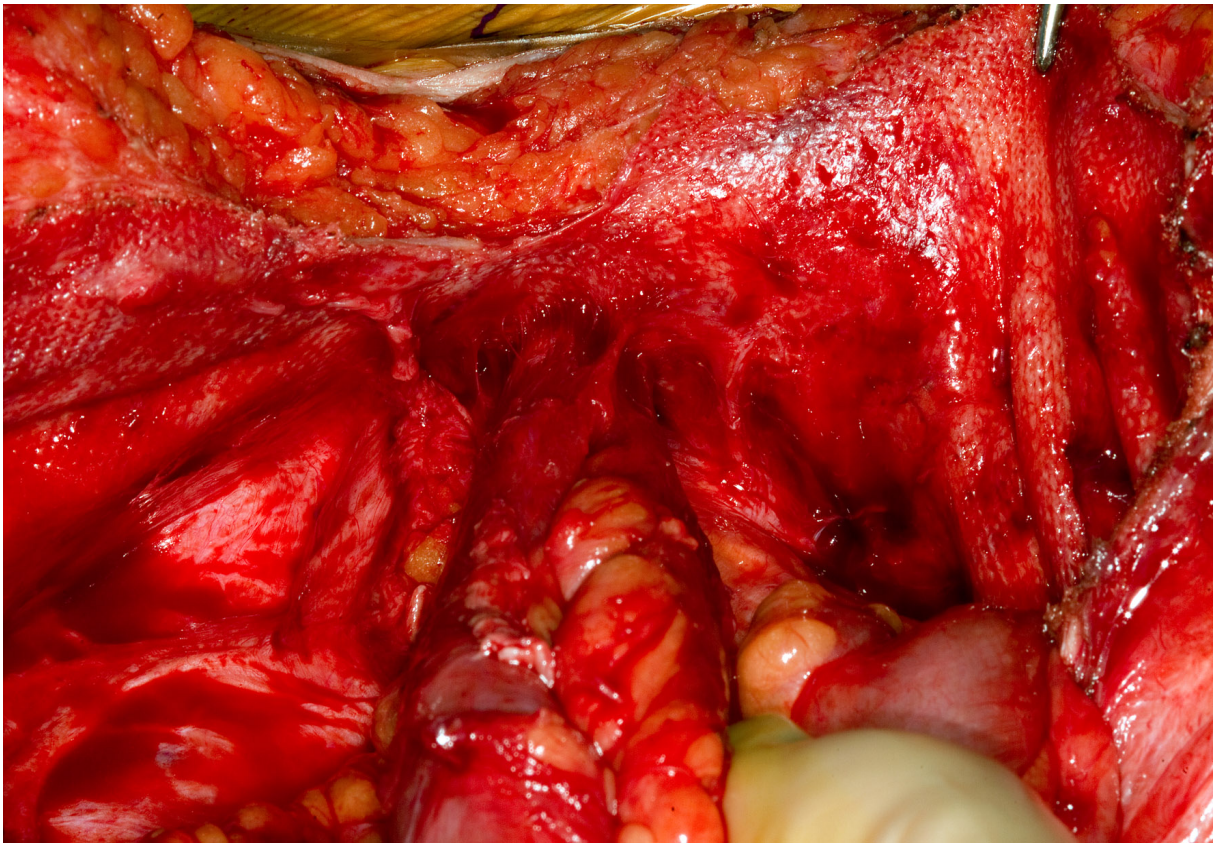

Figure 8: severe adhesions with the mesh embedded into the small bowel, fistula formation and hernia recurrence.

Discussion

This retrospective study shows that placement of an intraperitoneal mesh was associated with complications which are numerous, various, frequent and severe. The most common was mesh adhesion, present in 21/22 (96%) of patients reoperated in this study. The problem of adhesion and related effects is a high morbidity with increase of medical costs[11]. The second common complication was hernia recurrence, present in 15/22 (68%) of patients. This complication strongly correlates with the presence of adhesions except with the Ultrapro® mesh brand. Hernia recurrence is a major problem after a primary incisional hernia repair. This carries a high morbidity and high risk of resulting severe complications such as bowel incarceration leading to ischemia, necrosis and perforation. Mesh shrinkage was present in 6/22 (27%). Mesh migration was present in 5/22 (23%). This problem can lead to further complications such as intestinal perforation and more severe adhesions[4]. There was less migration if the incorporation of the mesh is considerable[3] . Abscess and seroma were each observed in 3/22 (14%), fistula and nerve entrapment were each observed in 4/22 (18%).

Limitations of the study

This work is an observational study with a small sample of individuals. Only patients with objectifiable complications during surgical reoperation were recruited, giving a selection bias. Thus no assumption concerning the frequency of complications, symptomatic or asymptomatic, associated with intraperitoneal mesh, can be made in this study.

Data were recorded in medical records written by different persons and some information have been may forgotten or interpreted differently. However, operations and data collections were always achieved by the same surgical team.

Conclusion

The majority of articles deal with complications induced by intraperitoneal prosthetic mesh, but the effectiveness of mesh has been studied mostly on experimental models. Actually and as shown in the present study, intraperitoneal mesh placement was associated with severe complications witch may potentially be life threatening. Therefore the Department of the Visceral Surgery of CHUV avoids the IPOM technique.

Randomized controlled trials comparing effectiveness of different meshes, placed intraperitoneally or beneath the muscle would be the best way to answer these questions but may be difficult or impossible to conduct. Above all, the follow up of patients for such a study would generate terrible costs.

The most important thing to remember is to be extremely careful with the use of prosthetic mesh and to inform patients about the risks of adhesions and other complications with the use of onlay mesh.

In our opinion, intraperitoneal mesh placement should only be reserved in exceptional situations, when the modified Rives-Stoppa could not be achieved and when tissues covering the mesh are insufficient.

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