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ORIGINAL ARTICLE

Open IPOMs for medium/large incisional ventral hernia repairs in the French Hernia Registry: factors associated with their use and mesh-related outcomes

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Abstract

Purpose The use of open intra-peritoneal onlay mesh repairs (O-IPOMs) for treating medium/large incisional ventral hernias has come into question due to the development of minimally invasive and sublay procedures. This study aimed to identify factors that are associated with the use of O-IPOMs in France.

Methods We analysed prospectively collected data from the French Hernia Registry on incisional ventral hernia repairs (IVHR) for hernias ≥ 4 cm in width.

Results We obtained data for 2261 IVHR (from 11/09/2011 to 30/03/2020): 733 O-IPOMs and 1,528 other techniques. We found that the O-IPOMs were performed on patients with more patient-related risk factors compared with the other techniques. Specifically, there was a higher proportion of patients with ASA III/IV (40.47% vs. 28.02%; $p < 0.00001$) and at least one patient-related risk factor (66.17% vs. 58.51%; $p = 0.0005$). Of the 733 O-IPOMs, 195 used Ventrio ST™ (VST), the most commonly used mesh for such IPOMs in our database; the other 538 O-IPOMs used other meshes (OM). The VST subgroup had a higher proportion of patients with ASA III/IV (52.58% vs. 36.07%; $p < 0.0001$) and on anticoagulants (26.04% vs. 18.41%; $p = 0.0229$) compared with the OM subgroup; they also had a lower recurrence rate after 2 years (5.83% vs. 15.41%; $p = 0.008$). However, large (≥ 10 cm) or lateral defects were more common in the OM subgroup, and their mesh/defect area ratio was lower.

Conclusion O-IPOMs were performed on patients with more comorbidities and/or complex incisional hernias compared with other techniques.

Keywords Incisional hernia · Ventral hernia · Open IPOM · Intraperitoneal · Mesh repair · Comorbidities

Introduction

Intraperitoneal onlay mesh repair (IPOM) [1] is widely used to treat incisional ventral hernias. It can be carried out using minimally invasive techniques, either laparoscopy [2], including with robots [3], or open surgery with small hernia patches [4, 5] for very small defects. The use of IPOMs increased following the development of bilayer (or covered) meshes, which are designed to minimise the risk of adhesions and complications related to contact with the viscera. However, there has been recent concern about late complications related to the intraperitoneal meshes [6], increased morbidity during repeat operations (e.g., related to inadvertent enterotomy [7, 8]) and higher rates of recurrence for larger defects [9] than when using preperitoneal (underlay) and/or retro-rectus (sublay) (1) mesh placement. As a result,

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the use of preperitoneal sublay repairs is currently increasing, as in previous years, boosted by advances in minimally invasive surgery (MIS), robotic [10], open and combined surgical techniques [11].

At present, the place of Open-IPOMs (O-IPOMs) in the surgical armamentarium appears questionable, given the advantages of minimally invasive IPOMs and sublay techniques. However, in a recent Expert Consensus, it was stated that '*for open elective incisional hernia repair, sublay mesh location is preferred, but open intraperitoneal onlay mesh may be useful in certain settings*' [12]. As there is little research on this topic [13], we aimed to identify the 'settings' in which O-IPOM is performed. We hypothesised that surgeons favour quick and safe procedures when there are hernia-related or patient-related risk factors, such as patients on anticoagulants. We also aimed to determine whether the Ventrio ST™ (VST) mesh, the most frequently used mesh for medium/large O-IPOMs in our database, presents advantages compared with other O-IPOM meshes.

Materials and methods

Study design

We conducted a descriptive study based on prospectively collected data from the French Hernia Registry [14]. We included data for incisional ventral hernia repairs (IVHR) that were carried out to treat midline or lateral incisional ventral hernias that were ≥ 4 cm in width and classified as W2/W3 according to the European Hernia Society (EHS) classification [15]. Data were included that were collected from 11/09/2011 to 30/03/2020. Data were excluded for repairs that were carried out to treat smaller (W1) incisional hernias, primary ventral hernias, lumbar hernias or parastomal hernias. Data were also excluded for repairs that used biological or slowly absorbable meshes.

The first aim of the study was to determine the prevalence of patient-related and hernia-related risk factors for patients who were treated using O-IPOM compared with other techniques. The second aim was to compare the early/2-year outcomes and risk factors for patients treated using the Ventrio ST mesh (the most commonly used O-IPOM mesh in our database for treating incisional hernias ≥ 4 cm in width) versus other O-IPOM meshes (OM).

French Hernia Registry

The French Hernia Registry is a secure online national database (Club-Hernie.com) for members of the French Hernia Club, which has been running since 11/09/2011. Details concerning the registry have been previously described [16]. The French Hernia Registry platform also hosts a number of prospective cohort studies, including a study run by the French Society of Surgery (AFC) [17], which involved 61 hospitals in several French-speaking countries. Data from this AFC cohort were also included in the present study.

Follow-up

The follow-up of patients in the database is carried out by a self-employed clinical research assistant. This involves structured telephone interviews that are conducted after 1, 2 and 5 years (± 3 months). The interviews are based on a questionnaire that has been administered since 1999 [18]. A patient is considered to be lost to follow-up (LTFU) if they cannot be contacted after five attempts on different days and at different times. If the patients report any symptoms, they are strongly advised to make an appointment to see their surgeon. Data are entered into the Registry concerning the results of physical examination, CT scans, recurrence, reoperation, adverse events and medication changes.

Ethics

This retrospective study used data that was prospectively collected in the French Hernia Registry. The study complies with the General Data Protection Regulation (GDPR), French legal requirements (CNIL MR4: 2,212,908) and local ethical standards (institutional review board approval: IRB00010835).

Data

The data included demographics, patient-related risk factors, hernia-related risk factors (including the Altemeier classification [19]), operative data and postoperative complications, including surgical site occurrences (SSO), surgical site infections (SSI), organ space complications [20] and the Clavien-Dindo classification [21]. The data also included postoperative pain, as assessed using a visual analogic scale (VAS; 1–10) at days 0, 1 and 8 as well as 1-month post-surgery. Data concerning hernia recurrence and late adverse events were collected during the follow-up interviews (at 1 and 2 years). Recurrence was classified as either reoperated or not reoperated but confirmed by CT scan, ultrasound and/or medical examination by a surgeon. Chronic pain was assessed using the VRS-4 (verbal rating scale: no pain, mild pain or discomfort, moderate pain, severe pain)[22].

O-IPOM: surgical techniques

After adhesiolysis, and replacing the hernia contents in the abdominal cavity, the non-absorbable mesh is placed intraperitoneally, secured with sutures and/or tacks, and the wound (midline or lateral defect) is closed (bridging repairs

were excluded) with slowly absorbable sutures. The technical details are displayed on tables and in the result section.

Ventrio ST™ mesh

The Ventrio™ ST mesh (VST; Davol Inc., Subsidiary of C.R. Bard, Inc, Warwick, R.I. 02886, US) is a self-expanding (absorbable memory ring), uncoated, monofilament polypropylene patch. On its visceral side, it is covered with an absorbable hydrogel barrier, based on Sepra™ Technology, and it has a pocket designed to facilitate fixation.

Primary measures of interest Patient- and hernia-related risk factors.

Secondary measures of interest Operation duration and early/late outcomes, including the recurrence rate, late adverse events and chronic pain.

Statistical analysis

Categorical variables were presented using numbers and percentages; comparisons were carried out using Chi^2 tests (or Fisher's exact tests, when necessary). Continuous data were presented as the mean with the standard deviation (SD) or the median with the interquartile range (IQR); comparisons were carried out using Student t-tests. Statistical significance was inferred for $p < 0.05$.

Results

Flow chart (Fig. 1)

Data were obtained for 2,261 IVHR that were carried out between 11/09/2011 and 30/03/2020. The incisional hernias were ≥ 4 cm in width and classified as W2/W3 according to the EHS classification [15]. The IVHR included 482 operations from the AFC study (from 01/10/2015 to 31/03/2016) [17].

There were 733 (32.42%) operations that used O-IPOM; other techniques were used for the remaining 1,528 operations. The latter included 502 (22.20%) laparoscopic IPOM (L-IPOM), 790 (34.94%) open-sublay repairs, 51 (2.26%) robotic-sublay repairs, 51 (2.26%) open-onlay repairs, 102 (4.51%) open-suture repairs, and 32 (1.42%) non-specified procedures.

The O-IPOM used VST meshes for 195 operations and OM for the remaining 538 operations. The patients who received these different meshes (VST or OM) were compared in terms of their risk factors, postoperative outcomes, postoperative pain and follow-up results. The proportion of patients in these two groups remained relatively stable throughout the follow-up period.

Trends in surgical procedures for IVHR (Figs. 2 and 3)

The surgical procedures that are used for IVHR have evolved over the years. Figure 2 shows that the proportion of IPOMs (both open and laparoscopic) in our database steadily decreased over the study period, while the proportion

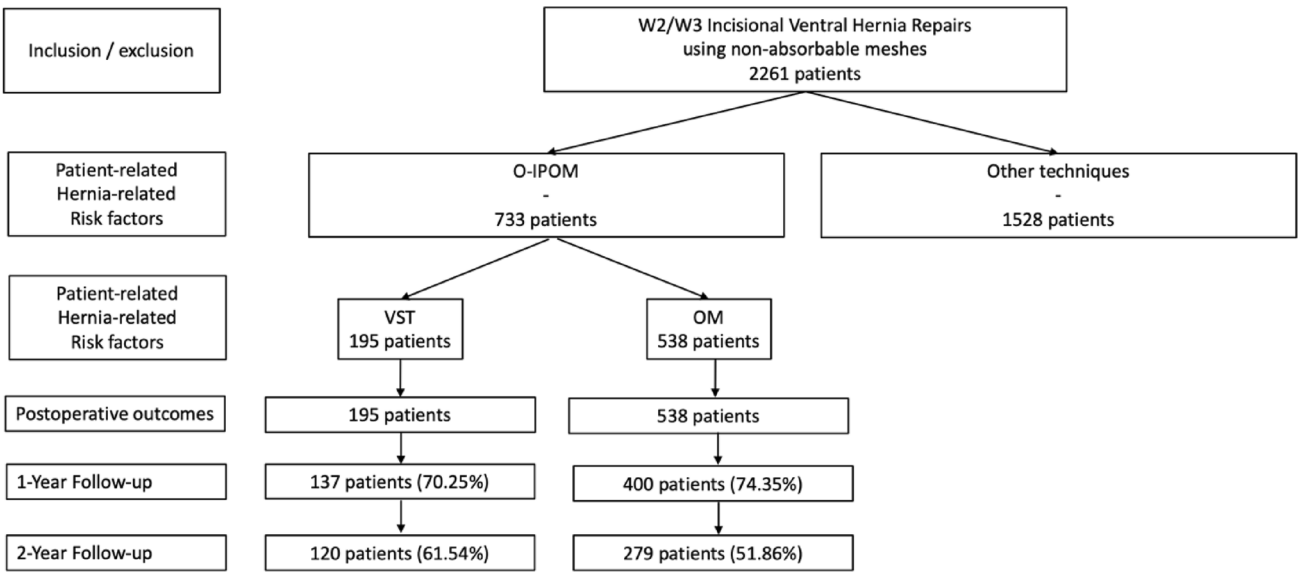

Fig. 1 Flow chart

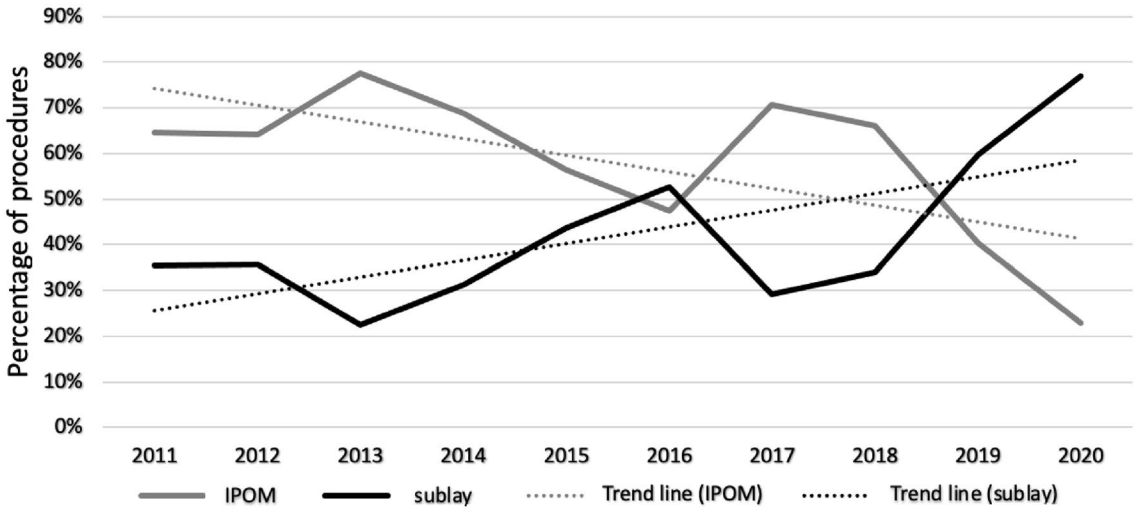

Fig. 2 Trends in the proportion of W2/W3 incisional ventral hernia repairs that use IPOM vs. sublay mesh placement. NB. 2011 and 2020 are not full years (4 months and 3 months, respectively); the W2/W3 classification is according to the European Hernia Society [15]; IPOM: intraperitoneal onlay mesh; sublay: sublay mesh placement

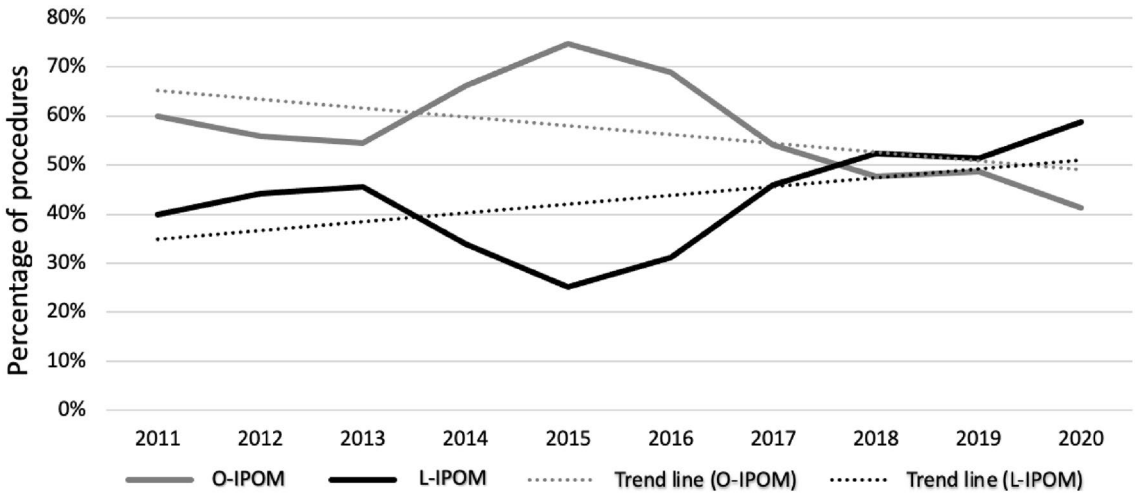

Fig. 3 Trends in the proportion of open vs. laparoscopic IPOM for treating W2/W3 incisional ventral hernias. NB. 2011 and 2020 are not full years (4 months and 3 months, respectively); the W2/W3 classification is according to the European Hernia Society [15]; *IPOM* intraperitoneal onlay mesh, *O-IPOM* open IPOM, *L-IPOM* laparoscopic IPOM

of extraperitoneal (sublay) procedures increased and eventually exceeded the IPOMs. As these were the two main techniques that were used, the two curves can be seen to mirror each other. In Fig. 3, it can be seen that the proportion of O-IPOMs steadily decreased while the proportion of L-IPOMs increased, with a 50:50 ratio by the end of the study period. Marked changes can be seen in the central sections of the curves for both Figs. 2 and 3, which correspond to the inclusion of data from the AFC study from 01/10/2015 to 31/03/2016 [17]. During this period, the proportion of IPOMs decreased (Fig. 2) and the ratio of O-IPOMs/L-IPOMs increased (Fig. 3).

Comparison of O-IPOMs and other techniques

Patient-related risk factors (Table 1)

The patients who had O-IPOMs had significantly more comorbidities than those who had IVHR using other techniques (control group). Specifically, 40.47% of the patients in the O-IPOM group had an American Society of Anaesthesiologists (ASA) physical status classification of III/IV compared with 28.02% in the control group ($p < 0.00001$). In addition, the proportion of patients with at least one risk factor (e.g., current smoker, diabetic)

Table 1 Demographic characteristics and patient-related risk factors for patients who had incisional ventral hernia repairs using open IPOM vs. other techniques

N (%) or median (IQR)	Open IPOM (N = 733)	Other techniques (N = 1528)	p-value
Age, years (median, IQR)	71 (61–80)	70 (60–78)	0.5925
Sex, female	388 (52.93)	818 (53.53)	0.7886
BMI, kg/m^2 (median, IQR)	29 (26–34)	29 (26–33)	0.6832
ASA classification			
ASA I/II	434 (59.53)	1092 (71.98)	
ASA III/IV	295 (40.47)	425 (28.02)	**< 0.00001**
Missing	4 (0.55)	11 (0.73)	
A. Risk factors: abdominal pressure			
Chronic cough (> 3 months; > 2 years)	84 (11.46)	145 (9.49)	0.1491
Chronic constipation (> 3 days)	45 (6.14)	73 (4.78)	0.1730
Nocturia (> 2 per night)	27 (3.68)	45 (2.95)	0.3492
Daily carrying of heavy loads (> 10 kg)	46 (6.28)	86 (5.63)	0.5389
B. Risk factors: wound healing			
Active smoker	108 (14.73)	247 (16.16)	0.3813
Anticoagulant therapies	147 (20.05)	257 (18.41)	0.0601
History of chemo-/radiotherapy	76 (10.37)	136 (8.90)	0.2624
Diabetes mellitus, steroids	131 (17.87)	271 (17.74)	0.9368
Any patient-related risk factor (A/B)	485 (66.17)	894 (58.51)	**0.0005**

Bold values indicate $p < 0.05$ (statistically significant)

IPOM intraperitoneal onlay mesh, *IQR* interquartile range, *ASA* American Society of Anaesthesiologists. *BMI* body mass index, *Chronic cough* more than 3 months for 2 consecutive years, *Constipation* defecation delayed > 3 days

was significantly higher in the O-IPOM group than in the control group (66.17% vs 58.51%; p = 0.0005).

Hernia-related risk factors (Table 2)

There were no statistically significant differences between the O-IPOM and control groups apart from the number of concurrent small bowel resections (0.55% vs. 1.57%; p = 0.0416).

Comparison of O-IPOMs using VST vs. other meshes

Analyses were run to compare the 195 patients who had O-IPOMs using VST with the 538 patients who had O-IPOMs using OM (37 different types). All of the meshes were designed for intraperitoneal placement.

Patient-related risk factors (Table 3)

A higher proportion of patients in the VST subgroup had an ASA classification of III/IV compared with the OM subgroup (52.58% vs. 36.07%; p < 0.0001); there were also more patients on anticoagulants (26.04% vs. 18.41%; p = 0.0229). Of note, the different subcategories of anticoagulants or antiplatelet drugs were not specified in the database and so could not be analysed further. We also found that the proportion of patients with a history of chemotherapy and/or radiotherapy was significantly higher in the OM subgroup (4.17% vs. 12.90%; p = 0.0008). There were no statistically significant differences between the subgroups in terms of the demographic characteristics or other risk factors, including those related to abdominal pressure.

Hernia-related risk factors (Table 4)

There were no statistically significant differences between the VST and OM subgroups in terms of the hernia-related risk factors. However, the proportion of patients with at least one of these risk factors was significantly higher in the OM subgroup (47.03% vs. 34.87%; p = 0.0034). It was also found that there was less antibiotic prophylaxis in the OM subgroup.

Table 2 Hernia-related risk factors for patients treated using open IPOM vs. other techniques

N (%)	Open IPOM (N = 733)	Other techniques (N = 1528)	p-value
No antibiotic prophylaxis (%)	66 (9.00)	179 (11.71)	0.0523
Missing data	7 (0.95)	7 (0.46)	
Altemeier classification			
Clean	678 (92.50)	1424 (93.19)	0.5439
Clean-contaminated	45 (6.14)	73 (4.78)	0.1729
Contaminated or dirty	7 (0.95)	28 (1.83)	0.2646
Missing data	3 (0.41)	3 (0.20)	
Concurrent surgery			
Stomach, small bowel, colon	24 (3.27)	51 (3.34)	0.9371
Gallbladder, urogenital	17 (2.32)	27 (1.77)	0.3736
Groin hernia repair	14 (1.91)	39 (2.55)	0.3446
Repair for recurrent incisional hernia	183 (24.97)	362(23.69)	0.5071
Mesh in place			
Retro-muscular/preperitoneal	35(16.13)	96 (26.52)	0.0564
Intraperitoneal	96 (52.46)	171 (47.24)	0.2495
No mesh	40 (21.86)	85 (23.48)	0.6704
Not specified	12 (6.56)	10 (2.76)	
Emergency surgery	35 (4.77)	60(3.93)	0.3467
Non reducible hernia contents	179 (24.42)	341 (22.32)	0.2659
Small bowel resection	4 (0.55)	24 (1.57)	**0.0416**
Large bowel resection	4 (0.55)	7 (0.46)	0.7549
Any hernia-related risk factor (C)	320 (43.66)	705 (46.14)	0.2670

Bold values indicate $p < 0.05$ (statistically significant)

IPOM Intraperitoneal onlay mesh; Altemeier classification [19]

Table 3 Demographic characteristics and patient-related risk factors for patients treated using open IPOM with Ventrio™ ST vs. other meshes

N (%) or median (IQR)	VST (N = 195)	OM (N = 538)	p-value
Age, years (median, IQR)	69 (62–77)	71 (61–80)	0.1695
Sex, female	110 (56.41)	278 (51.67)	0.2562
BMI, kg/m^2 (median, IQR)	30 (27–35)	29 (26–34)	0.2966
Missing	0	5 (0.93)	
ASA classification			
ASA I/II	92 (47.42)	342 (69.93)	
ASA III/IV	102 (52.58)	193 (36.07)	**< 0.0001**
Missing	1 (0.51)	3 (0.56)	
A. Risk factors: abdominal pressure			
Chronic cough (> 3 months; > 2 years)	15 (7.69)	69 (12.83)	0.0539
Chronic constipation (> 3 days)	7 (3.59)	38 (7.06)	0.0883
Nocturia (> 2 per night)	6 (3.08)	21 (3.90)	0.6054
Daily carrying of heavy loads (> 10 kg)	17 (8.72)	29 (5.39)	0.1007
B. Risk factors: wound healing			
Active smoker	33 (16.92)	75 (13.94)	0.3140
Anticoagulant therapies	50 (26.04)	97 (18.41)	**0.0229**
History of chemo-/radiotherapy	8 (4.17)	68 (12.90)	**0.0008**
Diabetes mellitus, steroids	30 (15.63)	100 (18.98)	0.3866
Any patient-related risk factor (A/B)	118 (60.51)	367 (68.22)	0.0515

Bold values indicate $p < 0.05$ (statistically significant)

IPOM intraperitoneal onlay mesh, *VST* Ventrio™ ST, *OM* other meshes, *IQR* interquartile range, *ASA* American Society of Anaesthesiologists, *BMI* body mass index; chronic cough: > 3 months for 2 consecutive years; constipation: defecation delayed > 3 days

Table 4 Hernia-related risk factors for patients treated using open IPOM with Ventrio™ ST vs. other meshes

N (%)	VST (N = 195)	OM (N = 538)	p-value
No antibiotic prophylaxis	5 (2.56)	61 (11.34)	**0.0002**
Missing	0 (0.0)	7 (1.30)	
Altemeier classification			
Clean	180 (92.31)	498 (92.57)	0.5036
Clean-contaminated	14 (7.18)	31 (6.69)	0.8168
Contaminated or dirty	1 (0.51)	6 (1.12)	
Missing	0	3 (0.56)	
Concurrent surgery			
Stomach, small bowel, colon	9	15	0.1366
Gallbladder, urogenital	6	11	
Groin hernia repair	4	10	
Repair for recurrent incisional hernia	42 (21.54)	141(26.21)	0.1968
Mesh in place			
Retro-muscular/preperitoneal	10 (23.81)	25 (17.73)	0.7871
Intraperitoneal	19 (45.24)	77 (54.61)	
No mesh	10 (23.81)	30 (21.28)	
Not specified	3 (7.14)	9 (6.38)	
Emergency	7 (3.59)	28 (5.20)	0.3649
Non reducible hernia contents	48 (24.62)	131 (24.35)	0.9410
Bowel resection	1 (0.51)	7 (1.30)	
Any hernia-related risk factor (C)	68 (34.87)	253 (47.03)	**0.0034**

Bold values indicate $p < 0.05$ (statistically significant)

IPOM intraperitoneal onlay mesh, *VST* Ventrio™ ST, *OM* other meshes, Altemeier classification [19]

Intra-operative data (Table 5)

The proportion of patients with midline defects was significantly higher in the VST subgroup compared with the OM subgroup (90.59% vs. 82.07%; p = 0.0078), while the proportion of patients with lateral defects was significantly lower (VST: 9.41% vs. OM: 17.93%; p = 0.0078). There was also a higher median mesh/defect surface area ratio (11.01 cm^2 vs. 5.06 cm^2; p < 0.0001) and larger overlap in the VST subgroup (p = 0.0005), which can be attributed to this subgroup having smaller defects and larger meshes (Table 5). The mean defect area was larger than the median area in both subgroups (VST: 56.61 cm^2 vs. 36 cm^2; OM: 89.52 cm^2 vs. 42 cm^2), particularly in the OM subgroup, as this group had some particularly large defects.

The method of mesh fixation differed significantly between the subgroups (p < 0.0001) and was mainly performed using absorbable tacks in the VST subgroup (57.0%) and sutures in the OM subgroup (64.4%).

Operation duration

The median operative time was significantly shorter in the VST subgroup compared with the OM subgroup (50 min vs. 65 min; p < 0.0001), with a difference of around 15 min.

30-day postoperative outcomes (Table 6)

The 30-day postoperative complications were not found to differ significantly between the VST and OM subgroups, neither in terms of their incidence nor their severity. We found that there were 33 patients (16.92%) in the VST subgroup and 98 (18.21%) in the OM subgroup (p = 0.7724) who had at least one complication. For patients with more than one complication, the most severe was used for the Clavien-Dindo grading.

In terms of the specific complications that occurred, there was bowel obstruction (or postoperative ileus) in 20 of the 733 patients (2.73%) who had O-IPOM; all of these resolved without reoperation after a median (IQR) hospital stay of 7 (4–11) days. Intraperitoneal bleeding was found to occur in three patients (VST subgroup: one patient; OM subgroup: two patients), all of whom were reoperated. A mesh infection occurred in eight patients (VST subgroup:

Table 5 Intra-operative data for patients treated using open IPOM with Ventrio™ vs. other meshes

N (%) or median (IQR)	VST (N = 195)	OM (N = 538)	p-value
Incisional hernia location			
Midline	**183 (90.59)**	467 (82.07)	**0.0078**
Lateral	19 (9.41)	102 (17.93)	
Including midline + lateral	*– 8 (4.12)*	*– 34 (6.36)*	
Not specified	1 (0.51)	3 (0.56)	
Hernia size & EHS classification			
W1 (defect width < 4 cm)	0	0	
W2 (defect width > = 4 cm)	173 (88.72)	406 (75.46)	
W3 (defect width > = 10 cm)	22 (11.28)	132 (24.54)	**< 0.0001**
Defect width, cm (median; IQR)	5 (5–7)	6 (4–9)	**0.0006**
Defect area, cm^2 (median; IQR)	36 (25–56)	42 (20–100)	**0.0031**
Mesh size			
Mesh surface, cm^2 (median; IQR)	456 (252–594)	300 (144–500)	**< 0.0001**
Mesh/defect surface area ratio (median; IQR)	11.01 (6.29–16.67)	5.06 (3.00–9.98)	**< 0.0001**
Overlap < 3 cm	1 (0.61)	42 (9.79)	
Overlap ≥ 3 cm, < 5 cm	57 (34.97)	128 (29.84)	**0.0005**
Overlap ≥ 5 cm	105 (64.42)	259 (60.37)	
Missing	32 (16.41)	109 (20.26)	
Mesh fixation			
Sutures (absorbable or not)	86 (43.00)	353 (64.42)	**< 0.0001**
Tacks (absorbable)	114 (57.00)	195 (35.58)	
Including Sutures + tacks	*– 6 (3.09)*	*– 42 (8.30)*	
Not specified	1 (0.51)	32 (5.95)	
Operative time, min (median; IQR)	50 (30–70)	65 (45–95)	**< 0.0001**

Values in italics indicate combined locations. Bold values indicate $p < 0.05$ (statistically significant)

IPOM intraperitoneal onlay mesh, *VST* Ventrio™ ST, *OM* other meshes, *IQR* interquartile range, *EHS* European Hernia Society classification [15]

three patients; OM subgroup: five patients), all of whom required reoperation. The median (IQR) hospital stay for these eight patients was 10 (5–33) days. Of note, three of these patients were on anticoagulants, one had a history of chemotherapy, and all had been given antibiotic prophylaxis.

Other complications that occurred included periprosthetic fluid collection. This was found in one patient (0.5%) in the VST subgroup (which resolved spontaneously) and in seven patients (1.3%) in the OM subgroup, three of whom required treatment (including CT-guided percutaneous drainage). General complications also occurred, which accounted for almost half of all the complications. These affected 17 patients (8.72%) in the VST subgroup and 49 (9.11%) in the OM subgroup (p = 0.8706). However, it is relevant to note that 82% of the postoperative complications were benign (Clavien-Dindo I/II), and more than 80% of the patients did not have any postoperative complications (uneventful postoperative course).

Recurrence and late adverse events (Table 8)

The median (IQR) follow-up duration was 26 (6–61) months for the VST subgroup and 24 (17–29) months for the OM subgroup. For the first follow-up, there were a total of 537 patients: 137 (70.25%) in the VST subgroup and 400 (74.35%) in OM subgroup. For the second follow-up, there were 399 patients: 120 (61.54%) in the VST subgroup and 279 (51.86%) in the OM subgroup (Fig. 1). Over this follow-up period of around 2 years, the recurrence rate was significantly lower in the VST subgroup (5.83% vs. 15.41%; p = 0.008). Two cases of bowel obstruction were noted in the OM subgroup (one operated, one not operated), while there were none in the VST subgroup. There were also two cases of late SSO in the VST subgroup (both reoperated) compared with three cases in the OM subgroup (none reoperated; p = 0.6058).

The PROM included a VRS pain assessment, which was completed by 462 patients: 122 in the VST subgroup and 340 in the OM subgroup. The proportion of patients who reported moderate or severe pain did not differ significantly between the two subgroups (14.75% vs. 14.71%; p = 0.9897).

Table 6 30-day postoperative outcomes for open IPOM using Ventrio™ vs. other meshes

N (%)	VST (N = 195)	OM (N = 538)	p-value
Organ space complications			
Bowel obstruction/Ileus	4 [(0)] (2.05)	16 [(0)] (2.97)	0.4980
Intraperitoneal bleeding	1 [(1)] (0.51)	2 [(1)] (0.37)	
Surgical site infections (SSI)			
Mesh infection	3 [(3)] (1.54)	5 [(5)] (0.93)	0.4445
Superficial infection	0	5 [(2),a] (0.93)	
Hematoma/Seroma			
Periprosthetic seroma	1 [(0)] (0.51)	7 [(3),a] (1.30)	0.6886
Superficial seroma	10 [(0)] (5.13)	17 [(1)] (3.16)	0.2112
Superficial hematoma	1 [(0)] (0.51)	10 [(4)] (1.86)	0.3043
Surgical complications (total)	20 (10.26%)	62 (11.52%)	0.6797
General (non-surgical) complications	17 (8.72%)	49 (9.11%)	0.8706
Patients with at least one complication	33 (16.92%)	98 (18.21%)	0.7724
Clavien-Dindo (one per patient[b])			
I/II	27 (13.85%)	80 (15.06%)	0.6831
III/IV	6 (3.08%)	16 (2.78%)	0.8359
V	0	2[c] (0.4%)	
Hospital stay, days (median; IQR)	5 (4–6)	4 (2–6)	**0.0112**

Bold values indicate $p < 0.05$ (statistically significant)

IPOM intraperitoneal onlay mesh, *IQR* interquartile range, *VST* Ventrio™ ST, *OM* other meshes, Clavien-Dindo classification [21]

[()]Number given in superscript brackets = number of complications requiring further intervention

[a]One of the interventions was CT scan-guided percutaneous drainage

[b]For patients with more than one complication, the most severe one is used for scoring

[c]Two non-surgical deaths: heart failure at day 2; pulmonary embolism at day 7

Discussion

Key results

This multi-centre study on W2/W3 incisional hernia repairs showed that, compared to other techniques, O-IPOMs were carried out more frequently when there were patient-related risk factors. Specifically, we found that patients who had IPOMs were more likely to have an ASA classification of III/IV (40.47% vs. 28.02%; p < 0.00001); they were also more likely to have at least one patient-related risk factor (66.17% vs 58.51%; p = 0.0005). In terms of the meshes, it was found that patients who had VST were more likely to have an ASA classification of III/IV (52.58% vs. 36.07%; p < 0.0001) and to use anticoagulants (26.04% vs. 18.41%; p = 0.0229) than those who had OM. The 2-year recurrence rate was also found to be significantly lower for the patients who had VST compared with those who had OM (5.83% vs. 15.41%; p = 0.008). However, this result should be interpreted with caution because the OM subgroup had more W3 and lateral defects as well as a lower mesh/defect surface area ratio.

As in the Herniamed registry [23], we found that the proportion of IPOMs steadily decreased over time, while the proportion of sublay procedures increased (Fig. 2). Nevertheless, there was still a large number of IPOMs, with 1,235 (54.62%) operations (733 O-IPOMs and 502 L-IPOMs) out of a total of 2,261 W2/W3 incisional ventral hernia repairs. The proportion of L-IPOMs was fairly similar (22.20% vs. 27.25%) to that found in the German Herniamed registry [24] for W2/W3 IVHR, but we found a higher proportion of O-IPOMs (32.42% vs. 13.84%) and a lower proportion of open-sublay procedures (34.94% vs. 49.82%). These differences may relate to different surgical preferences and guidelines for different countries, but also to different types of hospitals. As can be seen in Figs. 2 and 3, the inclusion of patients from the AFC study [17] had a marked effect: during this period the proportion of IPOMs decreased (Fig. 2), while the ratio of O-IPOMs/L-IPOMs increased (Fig. 3). The participating centres in the AFC study were mostly public hospitals (some academic), while most of the Hernia Club founder-members work in private hospitals, where laparoscopic IPOM is frequently used as a rapid procedure that avoids large retro-muscular dissection. However, the inclusion of the AFC data did not modify the global trend lines for the whole cohort.

We found that the rates of reoperation for bowel obstruction were low following the IPOMs, as assessed at the 2-year

follow-up. Specifically, this was found to be 0.4% (2/537; Table 8), which is similar to the 0.3% previously found for primary umbilical hernia (≥ 4 cm) repairs treated using L-IPOMs [25]. In addition, another study from the Danish Hernia Registry [6] found a rate of reoperation for bowel obstruction of 0.8% (9/1119) for open mesh repairs and 1.6% (28/1,757) for laparoscopic repairs.

Although the follow-up of patients in our study was conducted through telephone calls, which are not the best way to detect subclinical recurrence, they are nevertheless effective for detecting adverse events and reoperations. A recent systematic review [26] concluded that the "*short-term risks of intraperitoneal placement for incisional hernia repair are not life-threatening and are comparable to other prosthetic surgical techniques*". The most serious complications that can occur following IPOMs include mesh migration, visceral erosion and enterocutaneous fistulas, and they are all generally late complications. However, fortunately, they are rare and have only been described as case reports. It is difficult to investigate the occurrence of these complications in a study such as ours, as the follow-up of patients over long periods of time (10 years or more) is challenging [27], even when nationwide comprehensive administrative records are available. Such records were used in the Danish Hernia Registry and they showed that coated polypropylene meshes were associated with fewer complications than uncoated polypropylene meshes at the 5-year follow-up (hazard ratio = 1.20; 95% CI 0.04–0.90; p = 0.04) [6].

Many previous studies, systematic reviews and meta-analyses have compared the results of O-IPOM, L-IPOM and open-sublay procedures [28–30]. Each of these techniques has its own advantages and drawbacks, and they may vary in terms of their clinical usefulness. In a recent Expert Consensus, guided by systematic review [12], it was agreed that "*for open elective incisional hernia repair, sublay mesh location is preferred, but open intraperitoneal onlay mesh may be useful in certain settings*".

In our study, we did not primarily aim to compare the results of O-IPOM with other techniques, but rather to identify factors that may have led to O-IPOMs being performed for W2/W3 incisional ventral hernias. We were able to show that open-IPOMs were carried out more often in the presence of patient-related risk factors (Table 1). Specifically, patients who had O-IPOM were more likely to have an ASA classification of III/IV compared with those who were operated using other techniques (40.47% vs. 28.02%; p < 0.00001); in addition, they were more likely to have at least one patient-related risk factor (66.17% vs 58.51%; p = 0.0005). We also analysed hernia-related risks factors (Table 2) and found that there were no statistically significant group differences for the Altemeier classification or the use of antibiotic prophylaxis. Of note, the latter was not recorded for almost 10% of cases; this could have been due to missing data or to misinterpretation of the old French guidelines, which were not as clear as the current version (revised in 2018). We found that concurrent small bowel resection was rarer in patients undergoing O-IPOM compared with other techniques. In general, O-IPOMs are not recommended when there is concurrent enterotomy, although in rare cases an alternative technique may not be possible. For instance, in complex cases, O-IPOMs tend to be used to treat large incisional hernias [31, 32], and they have even been described as "*a desperate solution to solve a complex problem when there is no other alternative due to anatomical conditions after previous surgery*" [13]. However, such cases were not reported in our cohort, probably because biological and slowly absorbable meshes were not included.

The second aim of our study was to compare patients who were treated using the VST mesh with those treated using other meshes. The VST, which was designed to facilitate and shorten the O-IPOM procedure, is the most-frequently used mesh for medium/large O-IPOMs in our registry. We focused on W2/W3 defects because the treatment of smaller defects (W1) can be very different, especially when using small ventral hernia patches [4, 5, 33]. We found that patients in the VST subgroup were more likely to have an ASA classification of III/IV compared with the OM subgroup (52.58% vs. 36.07%; p < 0.0001); this classification concerned over half of the VST patients (Table 3). We also found that around two-thirds of the patients in the VST subgroup had at least one patient-related risk factor, and that more than a quarter suffered from conditions requiring anticoagulants, which is a well-known risk factor [24, 34]; this latter proportion was significantly higher in the VST than in the OM subgroup (26.04% vs. 18.41%; p = 0.0229). Conversely, a history of chemotherapy and/or radiotherapy was more common in the OM subgroup (4.17% vs. 12.90%; p = 0.0008), as was the presence of at least one hernia-related risk factor (47.03% vs. 34.87%; p = 0.0034). There were also more patients with no antibiotic prophylaxis in the OM subgroup, although the reason for this is unclear. Of note, none of the 61 patients in OM subgroup for whom antibiotic prophylaxis was not recorded developed a mesh infection.

Differences were found between the VST and OM subgroups in terms of the mesh/defect surface area ratio (Table 5; 11.01 vs. 5.06; p < 0.0001). The ratio was twice as large in the VST subgroup, which can be attributed to a smaller defect width (5 cm vs. 6 cm; p = 0.0006) and a larger mesh area (456 cm^2 vs. 300 cm^2; p < 0.0001) with more overlap ≥ 5 cm (64.42% vs. 60.37%; p = 0.0005). These findings may relate to the higher proportion of midline repairs for the VST subgroup (90% of the VST procedures), as it is easier to insert a large mesh for midline repairs than for some lateral repairs. In addition, the surrounding pocket of the VST facilitates secure far-lateral stapling, which may

Table 7 30-day postoperative pain after open IPOM using Ventrio™ vs. other meshes

Median (IQR)	VST (N = 195)	OM (N = 538)	p-value
VAS Day 0	5 (3–6)	3 (2–5)	**0.0002**
VAS Day 1	4 (3–5)	3 (2–4)	**< 0.0001**
VAS Day 8	2 (1–3)	2 (0–3)	**0.0388**
VAS M1	0 (0–2)	0 (0–1)	**0.0009**

Bold values indicate $p < 0.05$ (statistically significant)

IPOM intra peritoneal onlay mesh, *VST* Ventrio™ ST, *OM* other meshes, *IQR* interquartile range, *VAS* visual analogue scale (0–10), *M1* one-month visit

have encouraged the surgeons to choose a larger mesh. We also found that there was more variation in the size of the defect in the OM subgroup. This could be attributed to some rare, complex cases that required very large meshes. As a result, the difference between the mean and median defect area was larger in the OM subgroup (89.52 cm^2 vs. 42 cm^2) than in the VST subgroup (56.61 cm^2 vs. 36 cm^2).

We found that mesh fixation was performed using tacks more frequently in the VST subgroup than in the OM subgroup (Table 5). This may relate to the design of the VST mesh, which is equipped with a surrounding pocket to facilitate secure stapling. As the exposed part of the staple is covered by the pocket tissue, it has no direct contact with the bowels, thus reducing the risk of adhesions. The VST also has an antiadhesive layer, based on Seprafilm™ technology (widely studied and reviewed by the Cochrane collaboration) [35], which is reabsorbed within 30 days after having provided visceral protection during the critical postoperative healing period.

Table 8 Recurrence and late adverse events after open IPOM using Ventrio™ vs. other meshes

Fu period	VST (N = 195)			OM (N = 538)			p-value
	1y-Fu	2y-Fu	Cumulative	1y-Fu	2y-Fu	Cumulative	
Fu, months (median; IQR)			26 (6–61)			24 (17–29)	
Patients followed	137 (70.25%)	120 (61.54%)		400 (74.35%)	279 (51.86%)		
Recurrences 1y-Fu							
Reoperated	4	LTFU (4)	4	10	LTFU (6) OK (4)	10	
Not reoperated	2	LTFU (1) Idem (1)	2	20	LTFU (9) Idem (10) REOP (1)	20	
Recurrences 2y-Fu							
Reoperated	–	0		–	3	3	
Not reoperated	–	1	1	–	10	10	
Recurrence (total)			7 (5.83%)			43 (15.41%)	**0.0080**
Bowel obstruction							
Operated	0	0	0	0	2	2	NA
Non operated	0	0	0	1	0	1	
Late SSO/SSI							
Operated	2[a,b]	0	2	0	0	0	0.6058
Non operated	0	0	0	2[c,d]	1[e]	3	
PROM							
PROM completed			122			340	0.8753
Moderate or severe pain			18 (14.75%)			50 (14.71%)	0.9897

Bold values indicate $p < 0.05$ (statistically significant)

IPOM intraperitoneal onlay mesh, *VST* Ventrio™ ST, *OM* other meshes, *PROM* patient-reported outcome measure, *Fu* follow-up, *LTFU* lost to follow-up, *OK* recovered, *REOP* reoperated, *NA* not applicable, *Idem* same status as at 1st follow-up, *SSO* surgical site occurrence, *SSI* surgical site infection

[a]Body mass index: 34; ASA 2; Operation for peritonitis before day 30; Operation at 6 months for indolent sinus; No further infections but bulging noted at the 2-year follow-up

[b]Body mass index: 23; Smoker; Chronic obstructive pulmonary disease; Clean-contaminated preoperative setting; Reoperation at 12 months for partial excision of the mesh; No further issues at the 2- and 5-year follow-ups

[c,d,e]Persistent superficial fluid collection

The median operative time for O-IPOMs using VST was 15 min shorter than for those using OM (50 min. vs. 65 min; Table 5). This difference is statistically highly significant ($p < 0.0001$) and clinically relevant, given the 23% reduction in the operation duration. This finding is likely to relate to the VST mesh design, as described above.

The 30-day postoperative outcomes were analysed for the VST and OM subgroups (Table 6). No statistically significant differences were found between the two groups. The outcomes are in line with the high incidence of patient-related and hernia-related risk factors in both groups (Table 3, Table 4). General complications accounted for almost half of the complications, affecting 17 patients (8.7%) in the VST subgroup and 49 patients (9.11%) in the OM subgroup, including two deaths.

Other complications that occurred within 30 days following surgery included postoperative ileus or early postoperative bowel obstruction, which affected four patients (2.05%) in the VST subgroup and 16 patients (2.97%) in the OM subgroup ($p = 0.4980$). All of these patients recovered without reoperation after a median (IQR) hospital stay of 7 (4–11) days. These percentages are in line with those found after L-IPOM [36] and are much lower than those reported for colorectal surgery [37]. Early mesh infection was also found to occur, affecting three patients (1.54%) in the VST subgroup and five patients (0.93%) in the OM subgroup ($p = 0.4445$), all of whom were reoperated. These rates are lower than the 4% reported in a large recent meta-analysis [38]. Four of the eight patients with mesh infection had patient-related risk factors: anticoagulant therapy for three patients and a history of chemotherapy for one patient. Intraperitoneal bleeding and superficial hematomas were found to be rare following surgery, even though there were patient-related risk factors, particularly anticoagulant therapy. This supports the safety of O-IPOMs even when such risk factors are present. The median hospital stay (Table 6) was one day longer for the VST subgroup than for the OM subgroup, which may relate to higher levels of pain at days 0 and 1 (Table 7), possibly resulting from stapling. Although the differences in pain between the subgroups are statistically significant, they are not clinically significant, with a difference of just one VAS point; and by day 30, the median VAS was zero for both subgroups.

The follow-up rate at 1 year (70.25% vs. 74.35%) and 2 years (61.54% vs. 51.86%) was similar for the two subgroups, as was the timing of the 2-year follow-up (26 vs. 24 months). Over the 2 years, it was found that bowel obstruction was very rare, with no cases occurring in the VST subgroup (0.00%) and just three cases (0.75%) occurring in the OM subgroup, with two requiring reoperation. This incidence is lower than that found in a recent review (ranging from 1.1 to 3.7%), which examined complications that occurred following intraperitoneal mesh repairs for incisional hernias [26]. These results indicate that O-IPOMs can be used to treat incisional hernias without increasing of the risk of small bowel obstruction. However, larger studies of a longer duration are required to more reliably determine the incidence of bowel obstruction as well as the incidence of mesh complications, which can occur very late on [39].

Other complications that were identified in our study include surgical site occurrences, which affected two patients in the VST subgroup (both reoperated) and three patients in the OM subgroup (none reoperated; $p = 0.6058$, Table 8). There was also chronic pain (moderate/severe), which affected a similar proportion of patients in the two subgroups (14.75% vs. 14.71%; $p = 0.9897$). Such pain is common after incisional ventral hernia repairs [40], especially IPOMs [28]. In the Herniamed study, it was found that this pain did not relate to mesh fixation using tacks [28]. While the possibility of chronic pain must be taken into consideration when decision making with the patient, especially when patients have few symptoms [40], there may be little choice when seeking a solution for frail patients with comorbidities.

The recurrence rate was found to be the only significant difference between the two subgroups in terms of the late outcomes. This was significantly lower for the VST subgroup (5.83% vs. 15.41%; $p = 0.008$). This result should be interpreted with caution because, as described above, the OM subgroup had a smaller mesh/defect surface area ratio, more W3 hernias and more lateral defects, which are known to relate to poorer outcomes [28].

Limitations

The main limitation of the present study is that this was a descriptive study, based on prospectively collected, non-randomised data. Although propensity score matching was initially considered, this was not carried out because the study aimed to describe the real-life settings in which O-IPOMs were performed; this would have been hindered by a propensity score based on patient-related or hernia-related risk factors.

Conclusion

This observational study included 733 O-IPOMs that were performed to treat W2/W3 incisional ventral hernias. The results showed that, compared with other techniques, O-IPOMs were used more often to treat frail patients with comorbidities, most probably when the priority was to perform a quick and safe procedure. We also found that, in our registry, the VST was mainly used for regular midline,

medium/large incisional ventral hernia repairs in frail patients, especially those taking anticoagulants, where a quick and safe repair may be considered the wisest option.

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Data availability statement Data was extracted from Club-Hernie registry (club-hernie.com).

Declarations

Conflict of interest JFG has received honoraria as a consultant from BD, Cousin-Surgery, Intuitive, Medtronic, Microval, and Swing THT. GF has received honoraria as a consultant from Medtronic. Other co-authors: No competing interests related to this study.

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