



First Year Preliminary Results on the Use of a Monofilament Polyester Mesh With a Collagen Barrier for Primary and Incisional Ventral Hernia Repair

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Aim: The SymCHro study objective is to assess patient outcomes and surgeon satisfaction following ventral hernia repair with a three-dimensional (3D) monofilament polyester mesh (Symbotex composite mesh) that contains an absorbable collagen barrier on 1 side to minimize tissue attachment.

Methods: SymCHro is a multicenter observational study of 100 consecutive patients in the French Club Hernie registry who underwent primary and incisional ventral hernia repair with a Symbotex composite mesh. The primary objective is to assess recurrences and

complications within 2 years of repair. This analysis reports 1-year results from the ongoing study.

Results: A total of 105 hernias (37.1% primary, 62.9% incisional) in 100 patients were repaired by open or laparoscopic surgery. The patient follow-up rate at 1 year was 94%. A total of 6 (6.0%) low-grade seromas; 3 (3.0%) cases of low-grade transitory ileus; and 1 (1.0%) recurrence, which was asymptomatic but was repaired, occurred within 1-year follow-up. No serious adverse events were reported. All surgeons responded as satisfied with mesh flexibility and ease of insertion. Relative to baseline, patient pain reduced significantly at day 1 through month 3 postoperatively. At 1 year, 88.3% (83/94) patients assessed the hernia operation results as “good” or “excellent.”

Conclusion: At this 1-year analysis, 94% of patients were followed up and experienced minimal pain and low complication rates, suggesting that Symbotex composite mesh provides an effective and safe repair for primary and incisional ventral hernias.

Key words: Hernia repair – Ventral hernia – Incisional hernia – Abdominal hernia – Surgical mesh

The wide use of meshes has reduced the incidence of recurrences after ventral hernia repairs, but at long-term follow-up, the benefits attributable to mesh might be offset in part by mesh-related complications either after primary or even incisional repairs.¹ Besides the technique being elected and the way to realize this technique, the choice of the appropriate mesh is obviously of major importance for minimizing complications and pain while improving quality of life. Primary and incisional ventral hernias can be successfully repaired either by open or laparoscopic procedures. Placement of prosthetic mesh in the intraperitoneal space is now a common repair technique, but the mesh must provide a strong, durable repair while minimizing risk of bowel adhesions and complications related to intraperitoneally (IP) positioning of the mesh.² Symbotex composite mesh (hereafter referred to as Symbotex mesh) is an innovative three-dimensional (3D) monofilament macroporous polyester textile protected by an absorbable hydrophilic film on 1 side designed to minimize visceral attachments when placed in the intraperitoneal space for abdominal wall reinforcement.

The aim of this study was to assess short- and mid-term (2-year) clinical outcomes of Symbotex mesh implanted intraperitoneally during open or laparoscopic repairs for primary or incisional ventral hernias. This intermediate analysis reports the 1-year results of this study.

Methods

Study design

SymCHro is an observational study of prospectively and consecutively collected data from the multicenter French Club Hernie Registry.³ Our aims were:

1. to assess the perioperative and postoperative complications, including recurrences, within 2 years following primary and incisional ventral hernia repair with Symbotex mesh by laparoscopic or open approach;
2. to evaluate the postoperative patient satisfaction and quality of life (QOL) compared to baseline; and
3. to study in detail the ease of use and handling of the prosthesis, because they can play a role in accurate positioning of the mesh and thus in the results of the repair.

The trial was conducted according to applicable French regulations and received ethics committee waiver [EC (CPP Sud Est III Lyon) comité de protection des personnes (File QH 15/2014)]. The study was registered on www.clinicaltrials.gov (NCT02206828).

Test device

Symbotex mesh (Medtronic, Trevoux, France) is a three-dimensional (3D) monofilament macroporous polyester textile mesh with an absorbable hydrophilic film on 1 side, composed of porcine-derived

collagen and glycerol to limit tissue attachment. Symbotex mesh is intended for reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

Participants

The first 100 consecutive adult patients who were treated for primary (epigastric, umbilical/supraumbilical, Spigelian, or lumbar) or incisional ventral hernia with Symbotex mesh in the Hernia Club registry were included in the study. Patients were given a written information notice from the surgeon about the nature of the study.

Operative technique

Surgical technique (open or laparoscopic) was based on surgeon preference. Mesh placement was intraperitoneal, except in 1 case where a large part of the mesh had to be inserted in the preperitoneal space.

Outcomes Measures

Patient outcome measures at preoperative, perioperative, and postoperative follow-up (at 1 day, 8 days, 1 month, 1 year, and 2 years) were assessed. This analysis reports the completion of the 1-year follow-up; 2-year follow-up is ongoing. The primary endpoint was incidence of adverse events assessed peri- and postoperatively, within 2 years. Secondary endpoints included operative time and length of hospital stay; QOL; patient satisfaction; and surgeon satisfaction with mesh handling, manipulability, and ease of use. Postoperative pain was measured on a visual analogue scale (VAS; 0–10), and QOL was assessed with a previously qualified questionnaire.⁴ Patient demographic data, comorbidities, and hernia symptoms were recorded preoperatively. Physical health status was assessed based on the American Society of Anesthesiologists (ASA) classification. Hernia defect size was calculated as circular area for primary hernia defects [$\pi * ([\text{Length} + \text{Width}/2]/2)^2$] and as an elliptical area for incisional hernia defects [$\pi * (\text{Length}/2) * (\text{Width}/2)$].

Statistics

Sample size was calculated based on the highest reported recurrence rates following incisional hernia repairs using a 3D multifilament polyester mesh (Parietex PCO) by laparoscopic (5.9%),⁵ and open

(5.6%)⁶ approach. Assuming a 95% confidence interval for a recurrence rate of 5.9% with $\pm 5\%$ precision, $n = 86$ patients are needed for the evaluable population. A total of 100 patients were included, anticipating a 15% loss to follow up at 24 months.

Endpoints were represented by descriptive measures. Data were summarized by counts, means, standard deviations, medians, minimum, and maximum (for continuous variables) or frequencies and percentages (for categorical variables). Mean comparisons between subgroups were run using Student's *t*-test, nonparametric Wilcoxon rank sum test, or the Wilcoxon signed rank test for paired data. All comparisons were performed using two-sided tests with an α level of 5%. Analyses were performed using statistical software (SAS version 9.2 or higher, SAS Inc, Cary, North Carolina).

Results

Subject and procedural characteristics

A total of 100 consecutive patients (51 female, 49 male) registered in the Club Hernie database from July 4, 2014, to May 13, 2015, were included in the study. These 100 patients were treated by 14 surgeons with a mean 7.1 (range 1–27) patients treated per surgeon. Thirty-eight patients had primary hernias and 62 patients had incisional hernias. Of the 62 incisional hernia patients, 2 patients had 2 incisional defects each, 1 patient had 3 defects, and 1 had an incisional and a primary hernia. All other patients had a single hernia defect. Patient and hernia characteristics are listed in Table 1. Median BMI was 29.5 and 28.5 for primary and incisional hernias, respectively, and 75.0% ($n = 75$) of patients had a risk factor related to hernia dissection and/or healing. Most hernias (85.4%) were associated with preoperative discomfort or pain. A total of 32 (31.1%) hernias were incarcerated, where the hernia was not mechanically reducible, but not strangulated; 1 (1.0%) hernia was strangulated with bowel obstruction.

All primary hernias ($n = 37$) were repaired by laparoscopy, whereas 66.1% ($n = 39$) of incisional hernias were repaired by laparoscopy (Table 2). Most primary hernias were umbilical/supraumbilical ($n = 32$, 82.1%), while most incisional hernias were median periumbilical ($n = 27$, 69.2%) or median epigastric ($n = 22$, 56.4%). Patients who were treated by open repair had a higher mean ASA grade than patients treated by laparoscopy (2.3 ± 0.6 versus 1.7 ± 0.8 ; $P = 0.002$).

Table 1 Patient demographics, risk factors, and hernia defect characteristics

	Full analysis set (N = 100 ^a)	Primary hernia (N = 38 ^a)	Incisional hernia (N = 62 ^a)
Sex, male:female	49:51	22: 16	27:35
Age, years (SD)	61.0 (\pm 13.7)	57.1 (\pm 13.8)	63.4 (\pm 13.1)
BMI, median (range)	28.7 (17.8–48.1)	29.5 (17.8–43.1)	28.5 (17.8–48.1)
Smoking, N	98	38	60
Regular smoker, n (%)	14 (14.3)	5 (13.2)	9 (13.2)
Occasional smoker, n (%)	1 (1.0)	0 (0.0)	1 (1.7)
History of smoking ^b , n (%)	30 (30.6)	12 (31.6)	18 (30.0)
Risk factors related to dissection (1 or more), N	99	37	62
Other history of intraperitoneal surgery, n (%)	68 (68.7)	16 (43.2)	52 (83.9)
Mac Burney, n (%)	55 (55.6)	8 (21.6)	47 (75.8)
Other history of extraperitoneal surgery, n (%)	16 (16.2)	8 (21.6)	8 (12.9)
Subperitoneal vascular bypass	7 (7.1)	1 (2.7)	6 (9.7)
Risk factors related to healing (1 or more), n (%)	3 (3.0)	0 (0.0)	3 (4.8)
Anticoagulant treatment or spontaneous coagulation/bleeding disorder, n (%)	N = 97	N = 38	N = 59
Chemotherapy/immunosuppressive treatment, n (%)	32 (33.0)	8 (21.1)	24 (40.7)
Diabetes, n (%)	18 (18.6)	4 (10.5)	14 (23.7)
Hernia Symptoms, (N)	8 (8.2)	1 (2.6)	7 (11.9)
Asymptomatic hernia, n (%)	7 (7.2)	0 (0.0)	7 (11.9)
Discomfort/pain or preoperative dysesthesia, n (%)	103	39	64
Incarcerated hernia, n (%)	8 (7.8)	2 (5.1)	6 (9.4)
Strangulated hernia with obstruction, n (%)	88 (85.4)	34 (87.2)	54 (84.4)
Hernia defect area (cm ²)	32 (31.1)	9 (23.1)	23 (35.1)
N = 104	1 (1.0)	0 (0.0)	1 (1.6)
N = 104	28.0 (\pm 39.0)	5.2 (\pm 5.6)	41.6 (\pm 43.8)
Multisite hernia (\geq 2 sites; N = 104), n (%)	N = 104	N = 38	N = 66
	21 (20.2)	4 (10.5)	17 (25.8)

Data shown as n, n (%), mean (\pm SD), or median (min–max).

^aN = 100 patients and N = 105 hernias (N = 62 patients with incisional hernia, and N = 38 patients with primary hernias; 2 patients had 2 incisional hernias each; 1 patient had 1 incisional and 1 primary hernia; 1 patient had 3 incisional hernias).

^bStopped for >12 months.

All hernias were clean (n = 97) or clean contaminated (n = 1 for primary hernia; n = 2 for incisional hernia) based on Altemeier wound classification.

Incisional procedures took 20.1 minutes longer than primary hernia procedures ($P = 0.0004$, Table 2). Operative time correlated significantly with hernia defect area (Pearson correlation coefficient = 0.517; $P < 0.0001$) and mesh positioning time (Pearson correlation coefficient = 0.474; $P < 0.0001$). Mesh positioning took a mean 9.5 minutes (± 6.3) with no significant difference between incisional and primary procedures. Fascial defect closure rates were recorded for 28 patients. Patients with fascial closure had a 15.6 cm² larger defect area (22.2 ± 13.7 cm²; n = 13) than those without closure (6.6 ± 4.8 cm²; n = 15; $P < 0.001$). Patient hospital stay was longer for those who underwent incisional repair.

Patient complications within 1 year

Median patient follow-up at the time of analysis was 349.5 days (range: 0–579), and 94 patients reached 12 months follow-up. Patient adverse events are reported in Table 3. A total of 6 patients experienced 1 seroma each (4 during primary and 2 during incisional procedures), which were considered by the operative surgeon as being related much more to the technique than to the mesh itself. A total of 3 (3.0%) incisional hernia patients experienced transitory ileus, all Dindo-Clavien⁷ low-grade (grade 1, n = 2 and grade 2, n = 1). One (1.0%) recurrence occurred in an incisional hernia patient between the 6- and 12-month follow-up period. It was asymptomatic; however, the patient eventually underwent reoperation, which was uneventful. No serious adverse events were reported within 12 months.

Table 2 Operative data

S	Full analysis set	Primary hernia	Incisional hernia
Surgical Approach, N	96	37	59
Open (laparotomy), n (%)	20 (20.8)	0 (0.0)	20 (33.9)
Laparoscopy	76 (79.2)	37 (100)	39 (66.1)
Localization of primary hernias			
Epigastric, n (%)		7 (17.9)	
Umbilical/Supraumbilical, n (%)		32 (82.1)	
Spigelian, n (%)		1 (2.6)	
Lumbar, n (%)		0 (0.0)	
Localization for incisional hernias			
Median* (N = 53)			
M1-Supra-xiphoidal, n (%)			3 (7.7%)
M2-Epigastric, n (%)			22 (56.4%)
M3-Periumbilical, n (%)			27 (69.2%)
M4-Subumbilical, n (%)			16 (41.0%)
M5-Suprapubic, n (%)			3 (7.7%)
Lateral* (N = 16)			
L1-Subcostal, n (%)			3 (18.8%)
L2-Flank, n (%)			4 (25.0%)
L3-Iliac, n (%)			7 (43.8%)
L4-Lombar, n (%)			2 (12.5%)
ASA grade, N	99	37	62
Class I, n (%)	39 (39.4%)	24 (64.9%)	15 (24.2%)
Class II, n (%)	37 (37.4%)	8 (21.6%)	29 (46.8%)
Class III, n (%)	23 (23.2%)	5 (13.5%)	18 (29.0%)
Operative time, minutes	N = 95 43.4 (± 27.5)	N = 36 30.9 (± 21.8)**	N = 59 51.0 (± 28.0)**
Overall mesh positioning time, minutes	N = 100 9.5 (± 6.3)	N = 37 8.3 (± 5.6)	N = 62 10.1 (± 6.6)
Fascial closure, N	28	11	17
Yes, n (%)	13 (46.4)	2 (18.2)	11 (64.7)
No, n (%)	15 (53.6)	9 (81.8)	6 (35.3)
Mesh overlap, N	105	39	66
≥ 3 and < 5 cm, n (%)	9 (8.6)	2 (5.1)	7 (10.6)
≥ 5 cm, n (%)	95 (90.5)	37 (94.9)	58 (87.9)
Hospital stay (N = 92), days	2.5 (± 2.3)	0.9 (1.1)***	2.9 (2.1)***

Data shown as N patients, n (%), or mean (\pm SD).

*Three incisional hernias have combined median and lateral localization.

** $P = 0.0004$ for incisional versus primary.

*** $P < 0.0001$ for incisional versus primary.

Surgeon assessment of mesh ease of use

For each repair performed, the operating surgeon answered survey questions on satisfaction or dissatisfaction with mesh ease of use. For mesh flexibility and ease of mesh insertion, 100% ($n = 101$) of surgeons responded as satisfied. For ease of mesh trimming, 19.2% (19/99, 6 primary, 13 incisional) of surgeons were nonrespondents/unknown, and the other 80.8% (80/99) were satisfied. We received 2 (2.1%) unsatisfactory responses during incisional procedures related to mesh memory shape; otherwise, 95.9% of respondents (93/97) were satisfied and 2 incisional procedures were unknown. For mesh properties

that minimize visceral attachment, 92% (92/100) of respondents were satisfied and 8.0% (8/100, 2 primary, 6 incisional) were nonrespondents.

Patient pain, QOL, and satisfaction assessments

Results of the subject quality of life survey are presented in Table 4. Mean patient pain was 4.7 (± 2.5) at baseline and significantly reduced ($P < 0.0001$) by -0.9 (± 1.8), -2.8 (± 2.6), -4.4 (± 2.4), -6.0 (± 2.0) at day 1, day 8, month 1, and month 3, respectively, following the operation and there was no significant difference between pain in primary and incisional patients at any time. At 1 month and

Table 3 Adverse events

Event	Full analysis set, N = 100	Primary hernia, N = 38	Incisional hernia, N = 62	Time of occurrence
Seroma ^a	1 5 6 (6.0%)	1 3 4 (10.5%)^b	0 2 2 (3.2%)^c	Perioperative Post-operative (2–4 weeks) Total within 1 year
Transitory ileus ^d (Clavien 1 or 2) ⁷	2 1 3 (3.0%)	0 0 0 (0.0%)	2 1 3 (4.8%)	Perioperative Postoperative (2–4 weeks) Total within 1 year
Recurrence ^e	1 (1.0%)	0 (0.0%)	1 (1.6%)	Total within 1 year

Data shown as n (%).

^aNo seroma was mesh-related; 5 were minor, requiring no medical treatment; 1 diagnosed at 1 month was punctured at 2 months postsurgery.

^bAll were umbilical/supraumbilical.

^cEpigastric (n = 1) and flank (n = 1).

^dRelation to mesh or procedure is unknown.

^eAsymptomatic (non-reoperated) occurring between 6 and 12 months.

1 year, 76% of patients experienced no pain or discomfort. At 1 year, 1 (1.1%) incisional patient experienced “severe pain” requiring analgesics (Table 4). When asked to “assess the result of your abdominal hernia operation,” 4.3% (4/94) of patients assessed the repair results as “bad” at 1 year. These 4 patients experienced moderate or strong pain at 1 year. On the other hand, 7.4% (7/94) of patients assessed the repair results as “medium” and 88.3% (83/94) of patients assessed the hernia operation results as “good” or “excellent” at 1 year.

Discussion

In this series of 100 consecutive patients operated on with Symbotex mesh, very few postoperative complications occurred, all of which were minor, Clavien⁷ grade ≤ 2. At 1 year, 94% of patients were assessed; only 1 recurrence was reported. No serious adverse events occurred within 1 year (e.g., mesh infection, mesh explant) nor did events related to the intraperitoneal positioning of the mesh (e.g., bowel obstruction, intestinal erosion). One reoperation was required. Except in 3 cases of transient ileus, no bowel obstruction occurred.

Symbotex mesh is a 3D monofilament macroporous polyester (PET) mesh covered with a hydrophilic absorbable film, which minimizes visceral attachments. This film is equivalent to the one designed for Parietex multifilament polyester composite mesh (PCO), the predecessor to Symbotex, which has been used in more than 1 million implantations worldwide and has been assessed for safety by many peer-reviewed publications,

beginning as many as 18 years ago.⁸ Systematic ultrasound examinations⁸ of operated wounds at 12 months follow-up showed that 86% of the patients were adhesion free. A systematic visual assessment of adhesions performed during 85 redo surgeries after 733 laparoscopic treatments for ventral and incisional hernias with PCO⁹ found no adhesions in 47%, minor adhesions of the omentum in 42.3%, and serosal adhesions in only 10.6% of cases.⁹

Despite these excellent results, some concerns—albeit clinically unproven¹⁰—were expressed about the structure of Parietex and its potential impact on some properties (insufficient stiffness/memory for an easy handling in laparoscopy multifilament and relative opacity 3D structure) leading the manufacturer to further research and improve the design. Lightweight meshes were developed to minimize chronic pain and discomfort,¹¹ concerns that were especially raised for Lichtenstein repairs of inguinal hernias,¹² even though the leading cause to that observation was more linked to an increased porosity rather than the reduced weight itself. However, with ventral hernia repairs, especially incisional ones, lightweight meshes could be associated with a higher rate of recurrence¹³ and even central failures with either polypropylene¹⁴ or polyester meshes,¹⁵ as weight and strength are somehow correlated for a given mesh type. This underscores the need for a mesh to remain strong enough to provide a solid repair, even after resorption of the absorbable part of the mesh barrier. This has led to reconsideration of the use of ‘heavier’ meshes in ventral repairs while maintaining macroporous structure for an optimized tissue ingrowth.^{16,17}

Table 4 Patient QOL assessment at 1-month and 1-year follow-up

Assessment	Response at 1-month		Response at 1-year	
	Primary hernia, N = 32	Incisional hernia, N = 50	Primary hernia, N = 37	Incisional hernia, N = 57
Does the abdominal wall seem firm?				
Yes, n (%)			37 (100.0)	53 (94.6)
No, n (%)			0 (0.0)	4 (5.4)
Do you feel a lump?				
No, n (%)			37 (100.0)	51 (89.5)
Yes, on the operated area, n (%)			0 (0.0)	1 (1.7)
Yes, on the midline area, n (%)			0 (0.0)	3 (5.2)
Yes, elsewhere, n (%)			0 (0.0)	1 (1.7)
Do you feel any pain or discomfort?				
No, n (%)	28 (87.5)	34 (68.0)	30 (81.1)	41 (71.9)
Discomfort, n (%)	1 (3.1)	10 (20.0)	6 (16.2)	7 (12.3)
"Pins and needles, n (%)	2 (6.2)	0 (0.0)	0 (0.0)	0 (0.0)
Moderate pain (no analgesic required), n (%)	1 (3.1)	6 (12.0)	1 (2.7)	7 (12.3)
Severe pain (analgesic required), n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)
Loss of sensitivity, n (%)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
Other (description missing), n (%)	0 (0.0)	1 (2.0)	0 (0.0)	1 (1.8)
Hernia type for patients with discomfort or pain (at 1 year)				
Primary (N = 7)				
Umbilical/supraumbilical, n (%)			6 (85.7)	
Epigastric, n (%)			1 (14.3)	
Incisional				
Median* (N = 11)				
Epigastric, n (%)				4 (23.5)
Periumbilical, n (%)				6 (35.3)
Subumbilical, n (%)				4 (23.5)
Suprapubic				1 (5.9)
Lateral* (N = 6)				
Flank, n (%)				1 (5.9)
Iliac, n (%)				3 (17.6)
Lumbar, n (%)				2 (11.8)
Patient assessment of hernia repair (satisfaction rating)				
Excellent, n (%)			6 (16.2)	4 (7.0)
Good, n (%)			28 (75.7)	45 (78.9)
Medium, n (%)			2 (5.4)	5 (8.8)
Bad, n (%)			1 (2.7)	3 (5.3)

Symbotex mesh, which we used in this study, is a macroporous (pore size: 2.1×3.0 mm) monofilament polyester mesh.¹⁸ Taking into account its porosity, its weight is 64 g/m^2 .¹⁸ Therefore, it can be considered as a mid-weight mesh. In a prospective, multi-institutional, surgical and QOL outcomes comparison of heavyweight, midweight, and lightweight mesh in open ventral hernia repair,¹⁹ mid-weight mesh had fewer superficial surgical site infections and shorter length of stay. After controlling for potential confounding variables, lightweight mesh had a worse QOL at 6 and 12 months.

In our series, the mean patient pain was $4.7 (\pm 2.5)$ at day 0 and significantly reduced ($P < 0.0001$) by $-0.9 (\pm 1.8)$, $-2.8 (\pm 2.6)$, $-4.4 (\pm 2.4)$, $-6.0 (\pm 2.0)$ at day 1, day 8, 1 month, and 4 months, respectively,

following the operation. Only 4 of our 94 followed patients mentioned pain at 1 year (mainly moderate, not requiring medication). We observed only 1 recurrence, at the median part of a subcostal incision completed with a median incision made for liver transplantation which has been reoperated on with an uneventful course.

At 1 year 88.3% (83/94) of patients assessed the hernia operation results as "good" or "excellent" (Table 4). In ventral hernias, especially incisional, patient QOL regularly improves after surgery in the literature,²⁰ like in our series. The main events altering the postoperative QOL are recurrences, obstructions, chronic pain, and mesh infection.

Based on case reports, retrospective²¹ and experimental studies²² multifilament polyester knitted

meshes (either microporous: Mersilene or macroporous: Parietex) have been said to favor microorganisms harboring in between the fibers constituting the knitted yarns. On the other hand, the higher hydrophilicity of polyester compared to polypropylene might help the patient cells to win the race for the surface and colonize the mesh before the microorganisms in case of contamination.²³ The 3D structure of the mesh might facilitate an intimate and differentiated connective ingrowth acting as a scaffold.

In contrast with the above-mentioned concerns, the incidence of mesh infection in a clinical series is very low with either flat polyester (0.8%)²⁴ or 3D polyester (1.4%), even in complex patients.²⁵ The Symbotex mesh used in this series is a macroporous monofilament 3D polyester mesh, and even though late infections are always possible, we did not observe any mesh infection during the follow-up period. Moreover, results of macroporous synthetic meshes might be good in clean contaminated settings.²⁶ Cleaning the mesh site with a peroperative gentamicin instillation has been reported to potentially help.¹⁸

The EHS classification²⁷ is different for primary and incisional defects. In this series where primary and incisional hernias were grouped, results are presented by the surface area of the defects. The mean area of the defect in this series (Table 1) was $5.2 (\pm 5.6) \text{ cm}^2$ in primary hernias and $41.6 (\pm 43.8) \text{ cm}^2$ in incisional hernias. Mesh overlap (Table 2) was more than 5 cm in 90% of our cases. Much more than the area of the defect per se, the ratio between the mesh surface and the area of the defect is the most predictive factor for recurrence after laparoscopic ventral hernia repair using a bridging technique.²⁸

As the third aim of this work, we studied in detail the ease of use and handling of the mesh, because these factors can play a role in an accurate positioning of the mesh and therefore help in achieving a perfect repair. Answers from the operating surgeons were close to unanimous: due to its 3D shape, Symbotex mesh remains relatively thin (thickness 0.7 mm) ensuring excellent mesh flexibility and ease of implementation. It is designed for easy mesh deployment and is easy to roll and insert into the trocar. Mesh pliancy and stability facilitated placement against the abdominal wall and was assessed as useful in 96% of cases. Mesh trimming does not alter the mesh structure. Moreover, its transparency and orientation marker help with identification of anatomic structures and to achieve correct centering of the mesh. These features

enable accurate positioning and fixation, which, if performed accurately, ultimately prevents mesh movement after implantation. No recurrence was observed in our 78 laparoscopic repairs. The biggest defects were closed: Patients with fascial closure had a 15.6 cm^2 larger defect area ($22.2 \pm 13.7 \text{ cm}^2$; $n = 13$) than those without closure ($6.6 \pm 4.8 \text{ cm}^2$; $n = 15$; $P < 0.001$).

Finally, this SymCHro study shows an even lower rate of immediate postoperative complications with Symbotex mesh (9%) than the 25% rate with its predecessor, PCO. Nonetheless, Symbotex mesh as a large pore monofilament mesh fulfils the currently accepted mesh recommendations.²⁹

This series, probably the first clinical study on this new mesh, entails some limitations: it is a noncomparative single arm study, and the 1-year follow-up is short. Most hernia recurrences occur within 2 years after surgery for ventral hernias.³⁰ The 2-year-follow-up is ongoing and we will submit our updated results next year.

This study also has several key strengths: prospective and exhaustive data collection (i.e., enrollment of consecutive patients) in a dedicated registry with a very high follow-up rate. The 1-year results described here are promising, but the 2-year results will be used to confirm these results, especially the low recurrence rate.

Conclusion

Primary and incisional ventral hernia repair with Symbotex mesh yielded low rates of adverse events and recurrence, minimal pain, high patient and surgeon satisfaction and within 1-year follow-up. These promising results will be reassessed at 2 years of follow-up.

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