

Efficacy and safety of a resorbable collagen membrane COVA+TM for the prevention of postoperative adhesions in abdominal surgery

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Abstract

Background This clinical study was designed to assess the efficacy and safety of $COVA+^{TM}$, a collagen membrane (CM), for the prevention of postoperative adhesions in abdominal surgery.

Methods This prospective multicenter study concerned one hundred and thirteen patients undergoing two-stage abdominal surgeries between 2011 and 2014: either bariatric surgery (BS) or reversal of a diverting stoma (DS). They were divided into two groups, according to whether a CM was placed at the end of the first procedure or not. The primary endpoint was the evaluation of adhesions (incidence, severity, and extent) on the operative site during the second surgery using standard grading scales and a combined adhesion score. Secondary endpoints were the duration of reoperation and the overall postoperative morbidity.

Results Sixty-five patients were included in the BS group, and forty-eight patients in the DS group. Mean time interval between surgeries was 33.2 ± 51.1 weeks for BS and 14.1 ± 10 weeks for DS. In both indications, results in the CM group were better compared to the control group regarding incidence, severity, and extent of adhesions. Mean combined adhesion scores were lower in the CM

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group: respectively, 2.1 ± 1.6 versus 3.6 ± 1.7 (p < 0.001) for BS and 1.1 ± 1.7 versus 3.1 ± 2.2 (p < 0.005) for DS. In BS group, the operative duration at reoperation was significantly shorter if a CM was used: 56 ± 34 versus 77 ± 47 min (p < 0.03). No adverse events related to the use of the CM were observed. Overall complication rate was 13.5 % in the CM group versus 27.9 % in the control group. Ease of handling and application of the CM were rated as satisfying or very satisfying in the great majority of cases.

Conclusions In abdominal surgery, $COVA+^{TM}$ acts efficiently on the prevention of postoperative adhesions with lower incidence, severity, and extent levels. The CM can be used safely and might render reoperations less difficult.

Keywords $COVA+^{TM} \cdot Postoperative adhesions \cdot Two$ $stage abdominal surgery \cdot Adhesion prevention \cdot Bariatric$ $surgery \cdot Diverting stoma$

Following surgical interventions with peritoneal trauma, abnormal scar tissue may form between two contiguous peritoneal surfaces that are normally unattached, resulting in definitive adhesion formation [1, 2]. After abdominal and pelvic surgeries, adhesions develop over 90 % of the time [3, 4]. Adhesions are commonly reported after upper and lower abdominal surgeries. For the patients, complications such as bowel obstruction or women infertility may appear overtime and may require reoperations [2, 5–9]. Indirect complications of peritoneal adhesions (such as difficult reoperations, prolonged operative time, pre- and postoperative complications) are also often encountered at surgical reoperations [2]. For example, lysis of adhesions may prolong the operative duration and increase the risk of intraoperative complications such as bleedings [6]. During

bariatric surgery procedures, the presence of extensive and/ or severe adhesions is responsible for surgical conversion or aborted surgery [10–14]. Adhesion prevention strategy is important in abdominal surgery, especially for planned two-stage operations to facilitate the access to the operative site [15], reduce the incidence of complications related to adhesiolysis, and finally reduce hospitalizations costs [15– 17]. Thus, the presence of tissue attachments after gastrointestinal surgery is responsible for significant morbidity and constitutes an important public health problem [2]. Underestimating the burden of adhesions seems to be an important explanation for the lack of use of adhesions barriers [18, 19].

COVA+TM is a resorbable collagen membrane intended for the prevention of postoperative adhesions. Preclinical and clinical studies have shown its usefulness and good tolerance profile in cardiac and abdominal surgeries [20– 23]. The aim of this prospective multicenter study was to assess the efficacy and safety of COVA+TM during twostage abdominal surgeries.

Materials and methods

Study protocol

Fifteen surgeon members of the Club Coelio, a group of French and Belgian surgeons specialized in abdominal surgery, participated in this prospective multicenter trial (twelve investigational sites). Inclusion criteria were (1) patients with a planned two-stage abdominal surgery and (2) patients older than 18 years. The two-stage abdominal surgeries considered for that study were either a removal of a gastric band to be followed by a new bariatric surgery (sleeve gastrectomy or gastric bypass) or a low anterior rectal resection with protective stoma to be followed by reversal of the diverting stoma. Exclusion criteria included (1) concomitant anti-adhesion treatment at the first surgery, (2) pregnant or lactating women, and (3) participation to another clinical study in the abdominal area. There was no sample size calculation prior to inclusion, but all consecutive patients operated on between 2011 and 2014 and who fulfilled the criteria were included in the study. They were divided in two groups, according to whether a COVA+TM membrane (CM) was placed at the end of the first procedure or not. The choice for the application of a CM was left free to each individual surgeon. In total, five surgeons included patients exclusively in the CM group, four exclusively in the control group, and six in both groups. The study protocol obtained all the required approvals from the French consultative committees on data processing for biomedical observational research, and practitioners informed patients about the study (CCTIRS and CNIL).

Surgical techniques

Whatever the surgery, practitioners followed conventional surgical procedures by either laparotomy or laparoscopy. In the CM group, the adhesion barrier was applied on the adhesiogenic site at the end of the initial surgery according to its instructions for use. In patients undergoing gastric band removal, the CM was placed between the posterior side of the left liver lobe and the anterior side of the stomach, covering the dissected area left by the removed perigastric device. For stoma procedures, a hole of approximately 2 cm in diameter was made in the center of the CM to allow the passage of the bowel limbs and the membrane was then placed intraperitoneally on the posterior side of the abdominal wall.

As described in the instructions for use, COVA+TM (Biom'Up, Saint-Priest-France) is a resorbable and suturable membrane, composed of reticulated collagen [21]. COVA+TM is CE marked and indicated in the prevention of postoperative adhesions in abdominal or pelvic surgery. It acts as a natural barrier between the organs and the adjacent tissues. COVA+TM is supplied in dry form in several sizes for different surgical procedures. It is recommended by the manufacturer that the membrane is moistened for 10-15 min prior to use by immersing it in sterile water or sterile physiological saline. The membrane can be cut and sutured if needed. In laparoscopy, the membrane may be rolled and introduced in the abdominal cavity through a 10- to 12-mm trocar. As indicated in the instructions for use, surgeons took care not to use the membrane on staple lines or on intestinal anastomotic sutures.

Data collection and endpoints

Data were prospectively recorded on a secure electronic case report form. Surgeons participating at the study recorded their own clinical data without any access to the clinical data of the other participants. At the end of the study period, the available data were analyzed independently by the scientific coordinator of the Club Coelio. Patient's data were collected until their discharge visit following the second surgery. Age, gender, body mass index (BMI), abdominal surgical history, and indication for surgery were recorded at hospital admission. Intraoperative data during the first- and second-stage surgeries included at least operative duration, surgical approach, conversion, complications, evaluation of adhesions, and surgeon's satisfaction relating the use of the CM during the first surgery. Postoperatively, the presence and type of complications were also recorded.

The primary endpoint of this study was to evaluate the incidence, severity, and extent of adhesions on the initial operated site during the second intervention. The severity and extent of adhesions were assessed according to standardized and commonly used four-point grading scales [24-27] described in Table 1. In order to characterize incidence, extent, and severity by a single value, a combined adhesion score was used by summing the score for extent and severity of the scoring system previously described [28]. Thus, for no adhesions the combined adhesion score was 0, whereas in cohesive adhesions involving the whole area, the score was 6. In the bariatric group (BS), the evaluation of adhesions was determined at the site of the removed gastric band between the left lobe of the liver and the stomach (hepatogastric adhesions). In the diverting stoma group (DS), adhesions were graded on the abdominal wall around the stoma. The operative duration of the second surgery, overall complications regarding the relationship with the surgical procedure, and the use of the CM were evaluated as secondary endpoints. Finally, ease of handling and ease of application of the CM were also assessed as secondary endpoints by the practitioners using a five-point satisfaction's grading scale [from score 1 (very satisfactory) to score 5 (very unsatisfactory)].

Statistical analysis

All calculations were made with the SigmaStat 3.5 program (Systat Software, San Jose, CA, USA). Results were expressed as mean/standard deviation for continuous values with normal distribution and as median/range for values with skewed distribution. Comparisons between groups were made, respectively, with the Student *t* test or the Mann–Whitney *U* test as appropriate. Fisher's exact test or Chi-square tests were used for comparison of categorical values. Adhesion score and operative duration during the second surgery were subjected to univariate and multivariable analyses. All variables with *p* value <0.2 on univariate analysis were entered into multivariable linear regression analysis. A *p* value <0.05 was considered statistically significant.

Results

Between 2011 and 2014, one hundred and thirteen consecutive patients who fulfilled the inclusion criteria were included in the study. Sixty-five patients had removal of a gastric band followed by a second bariatric surgery (sleeve gastrectomy or gastric bypass), and forty-eight patients had a low anterior rectal resection with protective stoma followed by reversal of the diverting stoma.

Efficacy in the bariatric group (BS)

The BS group included four men and sixty-one women with a mean age of 40 ± 11 years and a BMI of 39 ± 6 kg/m². Sixty-four patients had removal of the gastric band by laparoscopy, and one patient was operated on by laparotomy. A CM was placed in thirty-four patients. The compared data of the patients in the CM group and in the control group are reported in Table 2. All the variables were comparable between groups with the exception of mean age. The mean time interval between band removal and second bariatric surgery was 33.2 ± 51.1 weeks. The second surgery was a gastric bypass for nineteen patients and a sleeve gastrectomy for forty-six patients. Intraoperative data at reoperation are reported in Table 3.

Prior to performing a sleeve gastrectomy or a bypass, surgeons need to have access to the whole stomach. During reoperation, practitioners assessed hepatogastric adhesions. Results are presented in Fig. 1 and Table 4. Results in the CM group were better compared to the control group regarding incidence, severity, and extent of adhesions. CM significantly reduced the severity of postoperative adhesions between the stomach and the liver. No hepatogastric adhesions were observed in 23.5 % of the patients in the CM group versus 9.7 % in the control group. Rate of severe adhesions (Grade 3) in the CM group was significantly lower in comparison with the control group with a decrease of 89.9 % (Fig. 2). Extent of postoperative adhesions was significantly improved as well. The adhesion score, combining severity and extent, is summarized in Table 4. Results demonstrated a significant lower mean combined adhesion score in the CM group $(2.1 \pm 1.6 \text{ vs.})$ 3.6 ± 1.7 in the control group) with a decrease of 41.1 %

 Table 1 Severity and extent grading scales

Severity	Extent
Grade 0: no adhesion	Grade 0: no adhesion
Grade 1: mild adhesion, smooth dissection with the finger	Grade 1: located ($<1/3$ of the site is covered)
Grade 2: moderate adhesion, separated by blunt and sharp dissection	Grade 2: moderate (between 1/3 and 2/3 of the site is covered)
Grade 3: severe adhesion, separated only by sharp dissection	Grade 3: extent (> $2/3$ of the site is covered)

 Table 2 BS group—

 comparability of the groups:

 patients' characteristics and

 intraoperative data (first

 operation)

	CM $(n = 34)$	Control $(n = 31)$	p value
Gender male/female—n (%)	3 (8.8)/31 (91.2)	1 (3.2)/30 (96.7)	0.614
Mean age—years (±SD)	37.2 (±10.3)	44.0 (±10.2)	0.010
Mean BMI—Kg/m ² (\pm SD)	38.4 (±5.5)	40.6 (±6.6)	0.144
History of abdominal surgery—n (%)	34 (100)	31 (100)	1.000
Gastric band removal reason—n (%)			
Not efficient	26 (76.5)	21 (67.7)	0.514
Banding complication	6 (17.6)	9 (29.0)	
Other ^a	2 (5.9)	1 (3.2)	
Mean initial operative duration-min (±SD)	39.8 (±16.6)	47.1 (±23.9)	0.186
Surgical approach—n (%)			
Laparoscopy	34 (100)	30 (96.8)	0.476
Open	0 (0)	1 (3.2)	
Conversion—n (%)	0 (0)	0 (0)	1.000
Associate gesture—n (%)	0 (0)	1 (3.2)	0.476
Mean hospitalization stay-days (±SD)	1.4 (±0.9)	1.8 (±1.1)	0.121
Hepatogastric adhesions—n (%)	18 (52.9)	21 (67.7)	0.322

BMI indicates body mass index

n number, SD standard deviation

^a Intolerance or gastroesophageal reflux disease (GERD)

Table 3 BS group—comparability of the groups:intraoperative data (secondoperation)

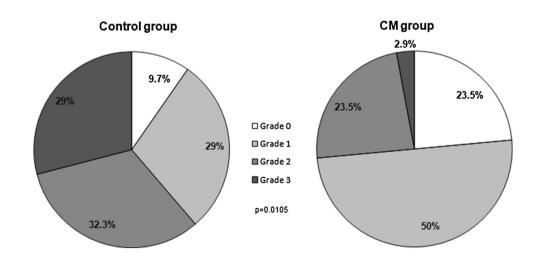
Fig. 1 Adhesion severity-

(BS)

second-stage bariatric surgery

	CM $(n = 34)$	Control $(n = 31)$	p value
Laparoscopic approach—n (%)	34 (100)	31 (100)	1.000
Type of redo-bariatric surgery-n (%)			
Sleeve gastrectomy	26 (76.5)	20 (64.5)	0.414
Gastric bypass	8 (23.5)	11 (35.5)	
Mean operative duration—minutes $(\pm SD)$	56 (± 34)	77 (± 47)	0.048

n: number, SD standard deviation



(Fig. 3). Multivariate linear regression analysis demonstrated that the use of a CM (coefficient $\beta = 1.13$, p = 0.012) and the age (coefficient $\beta = 0.77$, p = 0.020)

were the only independent predictive factors of developing less adhesions. At reoperation, a significant shorter operative duration was noted in the CM group (56 ± 34 vs.

 Table 4 BS group—extent of adhesions and mean combined adhesion score

	CM $(n = 34)$	Control $(n = 31)$	p value
Extent—n (%)			
Grade 0	8 (23.5)	2 (6.5)	0.0144
Grade 1	18 (52.9)	10 (32.3)	
Grade 2	6 (17.6)	12 (38.7)	
Grade 3	2 (5.9)	7 (22.6)	
Combined adhesi	on score		
Mean (±SD)	2.1 (± 1.6)	3.6 (± 1.7)	0.0007

n number, SD standard deviation

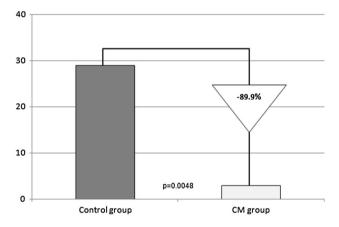


Fig. 2 Rate of severe adhesions (Grade 3)—second-stage bariatric surgery (BS)

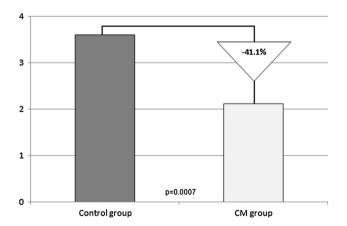


Fig. 3 Combined adhesion scores (BS)

 77 ± 47 min). Multivariate linear regression analyses were performed to determine predictive factors for a shorter operative duration at reoperation. The type of surgery (sleeve vs. bypass; coefficient $\beta = 72$, p = 0.001) and the use of a CM (coefficient $\beta = 16$, p = 0.007) appeared as the only independent predictive factors for shorter operative duration at reoperation.

Efficacy in the diverting stoma group (DS)

The group included thirty-four men and fourteen women with a mean age of 66 ± 12 years and a BMI of 26 ± 4 kg/m². All the patients had a low anterior rectal resection either by laparoscopy (n = 40) or by laparotomy (n = 8) with creation of a protective stoma. A diverting ileostomy was used in forty-one patients and a colostomy in seven patients. A CM was placed at the stoma site in eighteen patients. The demographic characteristics of the patients and the intraoperative data were comparable between the CM group and the control group (Table 5). The mean time interval between the first surgery and stoma reversal was 14.1 ± 10.0 weeks. All the patients had restoration of continuity by an open approach centered on the stoma site.

Evaluation of peristomal adhesions was performed during the second-stage surgery. Results in the CM group were also better compared to the control group regarding incidence, severity, and extent of adhesions. The CM group compared favorably with the control group in terms of adhesions incidence and severity with a significant difference between the groups (p < 0.05). No peristomal adhesions were reported in 61.1 % (CM group) versus 26.7 % (control group) of the patients (Fig. 4). Analyses of the extent of adhesions as well as mean combined adhesion score were also performed (Table 6). The presence of CM significantly decreases the extent as well as the mean combined adhesion score of peristomal adhesions. The mean combined adhesion score was significantly lower in the CM group $(1.1 \pm 1.7 \text{ vs. } 3.1 \pm 2.2 \text{ in the control})$ group) with a difference of 64.5 % between the two groups (Fig. 5). Multivariate linear regression analysis results demonstrated that the use of a CM (coefficient $\beta = 1.85$, p = 0.008) was the only independent predictive factors for developing less adhesions. Mean operative duration of stoma closure was comparable between the two groups: respectively, 36 ± 14 in the CM group versus 35 ± 13 min in the control group (not significant).

Satisfaction and safety

Practitioners who used the CM reported their satisfaction regarding the ease of handling and application of the CM (satisfied or very satisfied in 86.5 % of the cases, moderately satisfied in all the other cases).

Intraoperative and postoperative complications were recorded during the study period in both indications. No complications reported were related to the use of the CM. No deaths were recorded. Overall complication rate was Table 5 DS group—comparability of the groups:patients' characteristics andintraoperative data (firstoperation)

	CM $(n = 18)$	Control $(n = 30)$	p value
Gender male/female—n (%)	13 (72.2)/5 (27.8)	21 (70.0)/9 (30.0)	1.000
Mean age—years (±SD)	62.6 (± 15.5)	68.0 (± 9.5)	0.141
Mean BMI—Kg/m ² (±SD)	25.7 (± 4.7)	25.4 (± 3.3)	0.817
History of abdominal surgery—n (%)	9 (50.0)	16 (53.3)	1.000
Type of stoma procedure— n (%)			
Ileostomy	13 (72.2)	28 (93.3)	0.086
Colostomy	5 (27.8)	2 (6.7)	
Mean initial operative duration-minutes (±SD)	150.7 (± 49.4)	178.0 (± 46.7)	0.062
Surgical approach—n (%)			
Laparoscopy	14 (77.8)	26 (86.7)	0.451
Open	4 (22.2)	4 (13.3)	
Conversion—n (%)	4 (22.2)	3 (10.0)	0.400
Associate gesture—n (%)	4 (22.2)	3 (10.0)	0.658
Mean hospitalization stay-days (±SD)	10.0 (± 4.7)	12.1 (± 9.8)	0.394
Intestinal adhesions—n (%)	5 (27.8)	8 (26.7)	1.000

n number, SD standard deviation

Fig. 4 Adhesion severity of second-stage diverting stoma surgery (DS)

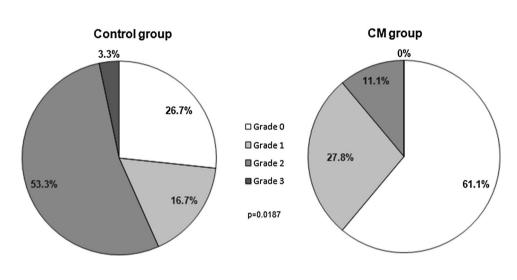


Table 6 DS group—extent of adhesions and mean combined adhesion score

	CM $(n = 18)$	Control $(n = 30)$	<i>p</i> value
	$\operatorname{CM}(n=10)$	Control (n = 50)	<i>p</i> value
Extent—n (%)			
Grade 0	11 (61.1)	8 (26.7)	0.0171
Grade 1	5 (27.8)	5 (16.7)	
Grade 2	0 (0.0)	4 (13.3)	
Grade 3	2 (11.1)	13 (43.3)	
Combined adhesi	on score		
Mean (±SD)	1.1 (± 1.7)	3.1 (± 2.2)	0.002

n number, SD standard deviation

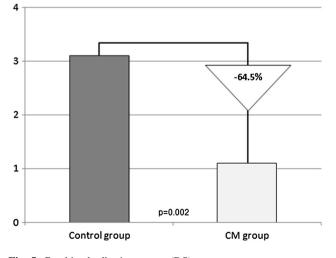


Fig. 5 Combined adhesion scores (DS)

Table 7 Intraoperative and postoperative complications

n (%)	CM $(n = 52)$	Control $(n = 61)$
Overall complications	7 (13.5)	17 (27.9)
Intraoperative complications		
Organ injury	1 (1.9)	1 (1.6)
Postoperative complications	6 (11.5)	16 (26.2)
DS		
Fever-infection	1 (1.9)	2 (3.3)
Ileus	-	2 (3.3)
Bowel obstruction	1 (1.9)	2 (3.3)
Fistula	-	3 (4.9)
Edema	-	1 (1.6)
Inflammatory reaction	1 (1.9)	1 (1.6)
Pulmonary embolism	-	1 (1.6)
Peristomal hernia	1 (1.9)	1 (1.6)
Anastomotic stenosis	1 (1.9)	_
Pouching system leakage	1 (1.9)	_
BS		
Hemoperitoneum	-	1 (1.6)
Bowel obstruction	-	1 (1.6)
Dressing allergy	_	1 (1.6)

n number

13.5 % in the CM group versus 27.9 % in the control group (Table 7). In the BS group, one intraoperative complication occurred in each group (organ injury). In the CM group, no postoperative complications were observed, whereas in the control group, one serious postoperative complication occurred (hemoperitoneum graded as IIIb according to Clavien–Dindo classification [29]). For five patients (16.1 %), aborted second-stage sleeve gastrectomy procedures were reported in the control group: During the reoperations, postoperative adhesions between liver and stomach were assessed as severe and extended. For four patients, an adhesiolysis was performed and a CM was placed. In the CM group, no second-stage surgery was aborted.

In DS indication, one complication required a revision surgery in the CM group (anastomotic stenosis scored as IIIb according to Clavien–Dindo classification). In the control group, four events were classified as serious with a Clavien–Dindo score of IIIb or IVa (two fistulas, one bowel obstruction, and one pulmonary embolism). The occurrence of bowel obstruction was comparable between groups (one in the CM group and two in the control group). The other complications were easily solved. For each type of complications reported, rates were equivalent between groups and no specific adverse events related to the use of the CM were observed.

Discussion

Undesirable intraperitoneal adhesions are the most frequent cause of late complications following abdominal surgeries: They have been known to reach an occurrence rate as high as 90 % [3–5, 8] and can have serious impacts on health [2] and quality of life. Adhesions are also responsible for 50 % of bowel obstructions [2, 5, 6, 30], 15–20 % of female secondary infertility [7, 31], and a large amount of long-term abdominal pain [6, 32] related to intraperitoneal tissue attachment. Moreover, postoperative adhesions increase surgical task and risks, therefore leading to increased risk of reoperations, prolonged hospital stays, and excess costs [4, 16, 17].

Revisional surgery of adjustable gastric bands in order to perform a gastric bypass or a sleeve gastrectomy was widely studied, and the presence of adhesions was regularly reported [10–14] but not quantified. In this multicenter prospective study, we observed that gastric band removal without using an anti-adhesion product correlated with a high rate of postoperative adhesions (90.3 % including 29 % of severe adhesions), whereas we observed a highly significant reduction (89.9 %) in severe adhesions when a CM is used (<3% of severe adhesions were described in the CM group). Furthermore, neither conversion to laparotomy nor aborted surgeries were reported in the CM group, whereas fives cases occurred in the control group: These aborted surgeries and/or conversion events due to adhesions were already described in the literature [10-14]. This appears to be a strong argument for the use of CM, which significantly minimizes the tissue attachment, increases the success of further reoperation, and diminishes the risk associated with the final procedure. The operative duration was significantly lower in the CM group during the second stage (21 min on average). Statistical multivariate analyses showed that the use of CM was a predictive factor for a shorter operative duration at reoperation: In correlation with data describing potential cost savings associated with the use of anti-adhesion agents [33–35], the use of the CM could consequently decrease hospital costs.

To the best of our knowledge, in the case of two-stage bariatric surgery, the use of an adhesion prevention product has not yet been described in the literature. In such surgical indications, application of the CM revealed advantageous properties.

In diverting stoma surgery (DS), numerous papers assessed the efficacy of anti-adhesion barriers [15, 25, 36, 37]. Kusunoki et al. [15] and Salum et al. [36] using Seprafilm[®] (hyaluronic acid–carboxymethylcellulose membrane) in randomized controlled trials (RCT) reported, respectively, 13.3 and 17.7 % of patients with no adhesions around the stoma in the treated groups. In

another RCT using the same membrane, Tang et al. [37] found no significant difference in time and difficulty for ileostomy closure between the two groups. At 3 weeks closure, all evaluated patients presented mild to severe adhesions. A hydrogel adhesion barrier was assessed by Tjandra and Chan [25] in a RCT in a similar indication with poor results: 89 % of patients with mild to moderate and 11 % of patients with severe adhesions were observed in the treated group. The results of this current study favorably compare with these trials: We observed a significant 61.1 % of adhesion-free patients at the time of the closure of the ostomy. These data were confirmed by the assessment of the mean combined adhesion score and highlighted the fact that the CM might facilitate the surgical reoperation.

In terms of safety, no complications or adverse events related to the use of the CM were observed in this trial. The overall rate of nonspecific adverse events in both groups (CM and control) is lower than in series using another product [26]. Let us emphasize that five bariatric revision procedures aborted due to severe adhesions (control group) did not benefit of a prior CM placement.

Surgeon's opinions about the use of the CM are favorable in terms of easiness of use—including laparoscopically—ability to handle, and to be cut, thus ensuring an adequate and accurate placement, first factor of adhesion prevention [2]. This was obvious in laparoscopic procedures, where the introduction and placement of CM were much easier than other products [2, 38].

This study has some limitations due to its observational and nonrandomized design. Nevertheless, the number of participating study sites (twelve centers, fifteen surgeons), the inclusion of all consecutive patients, and the significant results obtained still validated the clinical benefits of the CM in bariatric and colorectal surgeries. The results of this multicenter, prospective clinical study confirmed the observed advantageous properties of the CM previously described in cardiopediatric [22] and hepatic [23] surgeries. The CM is easy to use in laparoscopy or open surgery and is safe. By preventing the formation of postoperative adhesions in the abdominal cavity, the CM might render reoperations less difficult.

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Villeurbanne, France), E. Magne (Clinique Tivoli, Bordeaux, France), P. Ledaguenel (Clinique Tivoli, Bordeaux, France).

Compliance with ethical standards

Disclosures As president of the Club Coelio and organizer of the Club Coelio Congress, Constantin ZARANIS has financial partnerships with a number of companies. However, he received no personal funding for this study. The Club Coelio is an independent scientific institution whose objective is to assess the use of different procedures and prostheses for laparoscopic procedure. It therefore has relationships with a number of companies with an interest in independent evaluation of their products. Drs. Dabrowski, Lepère, Zaranis, and Hauters have no conflicts of interest or financial ties to disclose.

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