



## Long-term Results of Polyglactin Mesh for the Prevention of Incisional Hernias in Obese Patients

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**Abstract.** The aim of this study was to compare prospectively the incidence of incisional hernia in two groups of patients operated on for morbid obesity, with or without intraperitoneal polyglactin mesh. From October 1990 to September 1993, a total of 288 patients were randomly assigned to the two groups. There were 144 patients in the mesh group and 144 in the no-mesh group. Altogether 240 patients (83%) were reviewed personally, 45 (16%) were interviewed by phone ( $n = 39$ ) or mail ( $n = 6$ ), and 3 (1%) were inaccessible for follow-up since discharge from the hospital. The mean follow-up period was 29.8 months (range 0–67 months). A total of 33 incisional hernias were observed in the mesh group and 41 in the no-mesh group. There was no significant difference in the distribution of herniation time between the two groups ( $p = 0.43$ ). The two main predictive factors of herniation were age and weight. In conclusion, the use of an intraperitoneal polyglactin mesh does not prevent postoperative incisional hernias in obese patients.

Incisional hernia remains one of the most common complications of abdominal surgery and a significant source of morbidity with considerable economic impact. The usual predisposing factors are related to the condition of the patient, type of incision, and method of closure of the abdominal wall [1–3]. A number of incisional hernias occur with no known etiologic factor, and most develop a year or more after laparotomy in an apparently well healed wound. Urschel et al. [4] hypothesized that mechanical stress plays an important part in the development of late incisional hernia. Coughing, heavy physical exercise, straining during defecation, or vomiting after gastroplasty increases intraabdominal pressure and abdominal muscle tension; accordingly, these factors represent major mechanical forces.

These findings led us to the idea that an intraperitoneal absorbable mesh, placed just under the wound and spread far from it, might decrease the exerted tension and promote better healing during the 4 weeks preceding absorption of the mesh. The use of an absorbable polyglactin mesh is already well known for protecting a laparotomy, treating and preventing postoperative fascial disruption, strengthening a parietoplasty, and treating incisional hernia [5–7].

Hence we decided to conduct a prospective randomized study (to our knowledge, the first) using a polyglactin mesh to prevent the occurrence of incisional hernia in a group of patients at high risk of developing this kind of complication. We performed a preliminary study in 1994, dealing with only 112 patients [8]. The present paper reports the final results of the whole study.

### Patients and Methods

The study comprised 288 patients operated on for morbid obesity by a midline supraumbilical laparotomy from October 1990 to September 1993. Patients who had had a previous midline laparotomy were excluded from the randomization. A previous right subcostal incision for cholecystectomy was not an exclusion criterion. The patients had been informed and were randomly assigned at surgery to the mesh or the no-mesh group.

The gastroplasty performed was either a vertical silicone ring gastroplasty (VSRG) [9] or an adjustable silicone gastric banding (ASGB) [10] in accordance with the preoperative patient's choice. The associated procedures are listed in Table 1. The abdominal incision was closed by means of interrupted polyglactin 910 sutures (Vicryl; Ethicon, Somerville, NJ, USA), with or without an intraperitoneal polyglactin mesh (Vicryl mesh),  $21.5 \times 26.5$  cm, placed above the omentum. The mesh was not fixed in any way, but care was taken to spread it as far as possible into the flanks. All patients received prophylactic antibiotic therapy, consisting of cefazolin, for 48 hours. Postoperative morbidity was recorded. Incisional hernia was defined as a protrusion in the abdominal wound, revealed on careful examination when the patient lifted the legs upward while lying in the supine position.

Follow-up was done by physical examination at the outpatient clinic. This examination was performed by two of the authors (A.P. and C.D.). The patients who were not followed up after 2 years postsurgery were contacted by phone or mail. The follow-up was stopped for the study when the patients underwent a further abdominal operation.

Group differences were assessed by *t*-tests for quantitative variables and chi-square tests for clinical findings. Stepwise logistic regression was used to predict the incidence of incisional hernia. Herniation time was studied by the Kaplan-Meier survival

**Table 1.** Associated procedures with the gastroplasty.

Associated procedure	With mesh	Without mesh
Tubal ligation	1	1
Gastric polyp resection	0	1
Vagotomy + suture of crura	7	11
Vagotomy + suture of crura + cholecystectomy	1	3
Cholecystectomy	21	25
Partial hepatectomy	1	0
Carpal tunnel	0	1
Thyroidectomy	1	1
Total	32	43

**Table 2.** Preoperative data.

Parameter	Patients with mesh	Patients without mesh	<i>p</i>
Age (years)	36.6 ± 0.9	36.4 ± 0.9	0.86
Sex (F/M)	103/41	114/30	0.13
Weight (kg)	125.4 ± 1.8	122.4 ± 1.8	0.25
BMI (kg/m <sup>2</sup> )	43.8 ± 0.5	43.7 ± 0.6	0.95
Diabetes	18	18	1.00
Type of gastroplasty			
ASGB	29	36	0.32
VSRG	115	108	

Results are expressed as means ± SEM and as number of cases.

BMI: body mass index; ASGB: adjustable silicone gastric banding; VSRG: vertical silicone ring gastroplasty.

curve, and the log-rank test was used to compare the two groups. All results were considered to be significant at the 5% critical level ( $p < 0.05$ ). Statistical calculations were carried out using SAS (SAS Institute, Cary, NC, USA) and S-Plus (Stat. Sci. Europe; Oxford, UK) software packages.

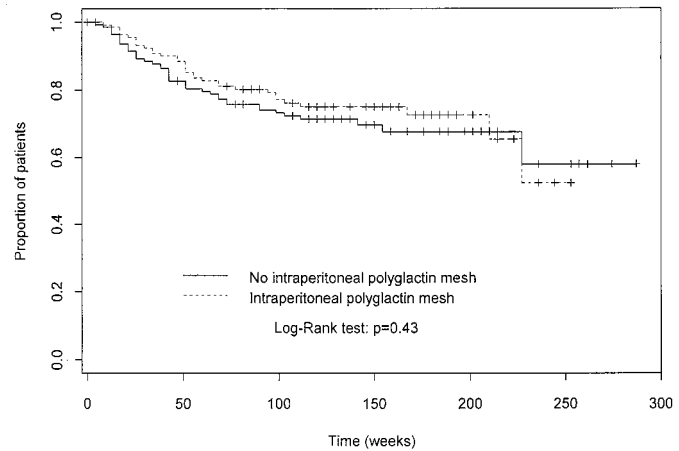
## Results

There were 144 patients in the mesh group and 144 in the no-mesh group; 240 patients (83%) were reviewed personally, 45 (16%) were interviewed by phone ( $n = 39$ ) or mail ( $n = 6$ ), and 3 (1%) were inaccessible for follow-up after discharge from the hospital. The follow-up was stopped for 23 patients who underwent a further abdominal operation (censored cases). The mean (range) follow-up period for the whole population was 29.8 months (0–67 months). It was similar in the mesh group [28.7 months (0–64 months)] and the no-mesh group [30.8 months (0–67 months)]. No significant difference was observed between the two groups as regards age, sex, weight, body mass index (BMI), diabetes, type of gastroplasty, or associated surgical procedures ( $p = 0.14$ ) (Tables 1, 2). No preoperative use of steroid therapy was reported by the patients.

Postoperative complications observed in the two groups are presented in Table 3. The early postoperative obstruction recorded was due to adhesion between intestinal loops, requiring a laparotomy: the mesh was removed without difficulty to allow

**Table 3.** Postoperative complications.

Complication	Patients with mesh (no.)	Patients without mesh (no.)
Wound infection	5	4
Acute respiratory distress syndrome	2	0
Bronchitis	1	0
Pneumonia	1	1
Pulmonary embolism	2	0
Obstruction	1	0
Acute pancreatitis	1	0
Peritonitis	1	0

**Fig. 1.** Comparison of herniation time in the two groups by Kaplan-Meier survival curves.

abdominal exploration. The case of peritonitis was due to a gastric perforation of the small curvature near the Silastic ring and required laparotomy and removal of the ring. There were 74 incisional hernias (26%): 33 in the mesh group and 41 in the no-mesh group. The difference between the Kaplan-Meier curves was not statistically significant ( $p = 0.43$ ), indicating that herniation time was comparable in the two groups (Fig. 1).

Among the 21 patients with a previous subcostal incision, four incisional hernias were observed. Two were in the mesh group ( $n = 12$ ) and two in the no-mesh group ( $n = 9$ ) ( $p = 0.7$ ).

As for the time elapsed between the operation and the occurrence of incisional hernia, 87% of the hernias were observed during the first 18 months. Seven patients could not specify the time elapsed. There was no significant difference between the two groups regarding incisional hernias (Table 4).

To detect risk factors of incisional hernia independently of the presence of a mesh, we compared subgroups with and without hernia among the 179 patients assessed by personal examination and for whom the follow-up period without hernia was at least 2 years. Only in this group was it considered that the number of cases of incisional hernia diagnosed accurately reflected the incidence of this condition. Male sex, old age, high weight, and body mass index (BMI) appeared as significant risk factors for the development of an incisional hernia, whereas diabetes, the associated procedures, and wound infection had no detectable influence (Table 5). Stepwise logistic regression was used to predict

**Table 4.** Comparison of patients with an incisional hernia.

Parameter	With mesh (n = 33)	Without mesh (n = 41)	p
Age (years)	41.5 ± 2.0	40.1 ± 1.6	0.61
Sex (F/M)	20/13	28/13	0.49
Weight (kg)	131 ± 3.8	130 ± 3.7	0.92
BMI (kg/m <sup>2</sup> )	45 ± 1.1	46 ± 1.3	0.49
Wound infection	2	1	0.43
Diabetes	7	4	0.17
Associated procedures	10	11	0.74

Results are expressed as means ± SEM and as number of cases.  
BMI: body mass index.

**Table 5.** Risk factors for incisional hernia.

Parameter	With hernia (n = 72)	Without hernia (n = 107)	p
Age (years)	40.7 ± 1.3	33.8 ± 0.9	0
Sex (F/M)	48/24	86/21	0.038
Weight (kg)	130.0 ± 2.7	121.0 ± 1.9	0.005
BMI (kg/m <sup>2</sup> )	45.5 ± 0.9	42.9 ± 0.6	0.012
Diabetes	10	14	0.88
Associated procedures	20	26	0.60
Wound infection	3	3	0.62

Results are expressed as means ± SEM and as number of cases.  
BMI: body mass index.

the incidence of incisional hernia from age, sex, weight, BMI, diabetes, wound infection, type of gastroplasty, and associated cholecystectomy as covariates. Age and weight were the only covariates selected by the regression related to the incidence of incisional hernia (73% agreement between observed and predicted values), thereby confirming the results of the univariate analysis.

## Discussion

The four main strategies surgeons usually use to reduce the incidence of incisional hernia are the type of incision, suture material, method of suturing, and antibiotic prophylaxis. Despite numerous studies, the prevention of incisional hernia remains a significant problem, especially in patients who are at high risk for wound complications. We tried a new method—placement of an intraperitoneal polyglactin mesh—in a population at high risk of developing an incisional hernia: patients suffering from morbid obesity. Excessive fat in the abdomen and subcutaneous tissue results in increased strain on the wound with body movement during the early postoperative period. Associated poor muscle tone and lack of muscle mass are also causative factors in the development of incisional hernias [11].

Most incisional hernias occur within the first postoperative year [3], but it seems that a 1-year follow-up is too short, causing the incidence of incisional hernias to be underestimated. Mudge and Hughes [12] found that only 44% of hernias occur during the first postoperative year. In another reported study, 80% of the recorded hernias occurred during the first 24 months [2]. Therefore a follow-up period of at least 2 years was recommended for studies focusing on incisional hernias. In the present study the

mean follow-up period was 29.8 months, and 87% of the hernias were observed during the first 18 months.

Several authors have stressed the importance of a physical examination in determining the presence of incisional hernia [13, 14]. We were unable to review personally the whole population, a fact liable to bias the analysis. Among the 240 patients examined personally, 32 incisional hernias were observed in the mesh group and 40 in the no-mesh group. Among the 45 patients interviewed by phone or mail, two hernias were reported (one patient with and one without a mesh). We cannot assess the extent to which this number is an underestimation, as a patient may be unaware of the presence of a small incisional hernia.

The use of polyglactin mesh did not reduce the incidence of incisional hernia (26%). However, the mesh was not tacked into place. This absence of fixation, allowing theoretically subsequent displacement, could play a role in the inefficiency of the mesh to prevent incisional hernias, but in the two patients who were reoperated for acute complications (obstruction and peritonitis) the mesh was in good place. In our opinion, the large size of the mesh, associated with the pressure of the omentum and abdominal organs, reduces the risk of subsequent displacement. In the literature it is difficult to appreciate the incidence of incisional hernia in bariatric surgery because most of the series are not comparable in terms of the type of surgery and length of follow-up. Often the incidence recorded equals only the number of cases operated on for incisional hernia. Incidences of incisional hernia from 10% to 65% have been reported in obese patients [15–18]. In the present study the relevant risk factors of incisional hernia were old age, male gender, large weight, and high BMI. The stepwise logistic regression demonstrated that age and weight were the best variables to predict the risk of herniation.

## Conclusions

The use of an intraperitoneal polyglactin mesh does not prevent incisional hernia in obese patients. At the present time we usually perform gastroplasty by laparoscopy, which is the best method for reducing the incidence of incisional hernia. When a gastroplasty must be carried out by laparotomy, significant weight loss before the operation is advised for the patients with the highest weights.

## Résumé

Le but de cette étude a été de comparer prospectivement l'incidence d'événement chez deux groupes de patients ayant été opérés pour obésité morbide, avec ou sans l'utilisation d'une treillis intrapéritonéale de polyglactine. Entre Octobre 1990 et Septembre 1993, 288 patients ont été randomisés en deux groupes. Il y avait 144 patients dans chaque groupe. 240 patients (83%) ont été revus en consultation, 45 (16%) ont été interviewés par téléphone (n = 39) ou par courrier (n = 6) et 3 (1%) ont été perdus de vue après leur sortie d'hôpital. La durée moyenne de suivi a été de 29.8 (0–67) mois. On a observé 33 évènements dans le groupe treillis comparé à 41 dans le groupe sans treillis. On n'a pas observé de différence significative dans le délai d'apparition de l'événement dans les deux groupes (p = 0.43). Les deux facteurs prédictifs principaux d'événement ont été l'âge et le poids. En conclusion, l'utilisation d'une plaque intrapéritonéale en polyglactine ne prévient pas l'événement postopératoire chez l'obèse.

## Resumen

El propósito del presente estudio fue comparar en forma prospectiva la incidencia de hernia incisional en dos grupos de pacientes operados por obesidad mórbida, con o sin malla de poliglactina intraperitoneal. Doscientos veintiocho pacientes fueron randomizados en dos grupos, en el período entre octubre de 1990 y septiembre de 1993. El grupo en que se colocó malla comprendió 144 pacientes, contra 144 del grupo en que no se colocó. Para seguimiento a partir de su egreso del hospital, 240 pacientes fueron revisados personalmente, 45 (16%) fueron entrevistados por teléfono (n = 39) o por correo (n = 6) y 3 (1%) resultaron inaccesibles. El promedio del seguimiento fue de 29.8% (rango 0–67) meses. Se encontraron 33 hernias incisionales en el grupo con malla y 41 en el grupo sin malla, diferencia que no es estadísticamente significativa (p = 0.43). Los dos factores principales de predicción en cuanto al desarrollo de hernia ventral fueron la edad y el peso. En conclusión, el uso de una malla intraperitoneal de poliglactina no previene el desarrollo de hernias incisionales postoperatorias en pacientes obesos.

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## Invited Commentary

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This study was a worthwhile effort that, unfortunately, failed to yield a positive result. The incidence of incisional hernia in obese patients is high. In this study of incisional hernia following gastric surgery for obesity, the frequency was 23% in the group in whom absorbable polyglactin mesh was placed underneath the fascial closure and 28% in those in whom it was not used, a difference that is neither clinically nor statistically significant. Perhaps there might have been a difference had they stapled the mesh in place; however, as mentioned in the paper, in the two patients operated on for acute complications the mesh was where it had been placed at the time of surgery. In a previous report from our experience [1], the frequency of incisional hernia following gastric bypass was 20% (198/968). Additional risk factors in our study included diabetes, sleep apnea, and obesity hypoventilation. We believe that the primary cause of the increased risk of incisional hernia in

obese patients is related to chronically increased intraabdominal pressure [2], which leads to preoperative fascial thinning and increased postoperative wound tension. Our frequency of incisional hernia in a group of ulcerative colitis patients [1] who underwent total abdominal colectomy and ileoanal pouch anastomosis through a much larger lower midline incision (which is supposed to carry a higher risk of hernia than an upper midline incision)—and in whom 60% were taking prednisone (which is thought to interfere with wound healing)—was only 4% (7/171), and five of these seven patients were quite obese (body mass index  $\geq 30$  kg/m<sup>2</sup>). Thus anything that would lower this high incidence of incisional hernias would be welcomed by both patients and surgeons (although some patients are delighted when they get an incisional hernia, as plastic surgeons are inclined to perform abdominoplasty with the hernia repair, a procedure for which it is difficult to obtain insurance coverage in the United States). We have found that, presumably a result of the thinned fascia, repair of these hernias requires nonabsorbable polypropylene mesh, placed in a prefascial position [1]. We have been reluctant to do this at the time of the gastric bypass procedure when the bowel is opened. More recently we have been placing Gore-Tex Dual Mesh laparoscopically for incisional hernias when the adhesions are not too dense. It is probable, as suggested by the authors, that

the laparoscopic adjustable silicone gastric banding (LAGB) procedure is associated with an almost negligible incidence of incisional hernia; what remains to be determined with the LAGB is its effectiveness for weight loss and risk of other complications that may be more devastating, such as band erosion, slippage, and infection. The current Food and Drug Administration (FDA) trial in the United States should help answer these questions.

In summary, it is unfortunate that placement of polyglactin mesh underneath the fascia at the time of surgery in obese patients was not effective for lowering the frequency of incisional hernia. The authors are to be commended for undertaking this

study and the *World Journal of Surgery* for publishing it; negative studies are often as important as positive ones.

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