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Factors affecting hernia recurrence after Strattice mesh repair: A retrospective study

Abdulraouf Y. Lamoshi,* Gerry R. Hobbs and Fawad J. Khan

Department of General Surgery, West Virginia University, Morgantown, West Virginia, USA.

Aim: The aim of the present study was to explore the factors that affect hernia recurrence after Strattice mesh repair.

Patients and Methods: The present study is a retrospective study of the medical records of 42 patients who underwent Strattice mesh hernia repair at Ruby Memorial Hospital, West Virginia University. Strattice mesh was employed in a variety of ventral hernia procedures, including primary ventral hernia repair, recurrent ventral incisional hernia repair, component separation (abdominal wall reconstruction), parastomal hernia repair and infected inguinal hernia repair. The main collected variables were body mass index, intraoperative hernia defect size, diabetes, wound events and steroid use.

Results: For 42 patients, the overall recurrence rate was 21.43 per cent. The mean body mass index (BMI) was 36.4. BMI and sex were significant risk factors for recurrence ($P = 0.036$, $P = 0.002$), respectively. The mean defect size was 97 cm^2. The hernia defect size was not significantly associated with the hernia recurrence rate ($P = 0.166$). Of the 10 diabetics, five developed recurrence. However, diabetes was not significantly associated with the hernia recurrence rate ($P = 0.726$). A total of four patients (9.52 per cent) were using steroids; one developed recurrence, which was not significantly associated with the hernia recurrence rate ($P = 0.20$). Wound infection also was not significantly associated with recurrence ($P = 0.323$).

Conclusions: Only sex and an increase in the BMI were significantly associated with the risk of hernia recurrence. In order to decrease the modifiable risk of hernia recurrence, surgeons should counsel obese patients regarding preoperative weight loss.

Key words: hernia recurrence, risk factor, sex, Strattice mesh, weight.

Introduction

In the USA, approximately 250 000 ventral abdominal wall hernias are repaired per year.[1] Prosthetic mesh utilization decreases the recurrence rate of repaired hernias by approximately 50 per cent when compared with the use of sutures only.[1] Many complications with the use of synthetic polypropylene mesh have been reported, such as pain, bowel obstruction, perforation and/or enterocutaneous fistula, as a result of the fibrosis that forms inside and around the mesh, which leads to adhesions with the viscera.[1] However, biological meshes that have the advantage of being used in contaminated cases are exceedingly expensive.[2] The earliest biological mesh, which is derived from porcine intestinal submucosa, showed good outcomes post-Lichtenstein procedure.[2] The aim of this retrospective study was to examine the effect of the body mass index (BMI), defect size, smoking and steroid use on the recurrence rate after Strattice mesh (LifeCell, Bridgewater, NJ, USA) hernia repair.

Surgical mesh is made from either animal tissue or synthetic materials.[3] Synthetic materials have a full range of absorbability (absorbable, non-absorbable or a combination of both). Animal-derived mesh is absorbable and made mainly from animals' intestines or skin, which have been processed and disinfected for humans' needs.[3] The main sources of used tissues are from cow (bovine) or pig (porcine). The Strattice reconstructive tissue matrix is a surgical mesh derived from porcine skin, where a phosphate-buffered aqueous solution is used to preserve the processed tissue and add matrix stabilizers.[4] Its structural characteristics decrease tissue adherence to the mesh.[4] Strattice mesh provides for a strong and biocompatible support that incorporates into the receiver tissue and enhances cell and microvascular growth in that area.[4] Strattice mesh is used to repair hernias or abdominal wall defects that need strengthening, or bridging material to provide closure.[4]

*Author to whom all correspondence should be addressed.
Email: raofdr@yahoo.com
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The repair of hernia defects has many pros; however, the recurrence rate remains the main expected consequence. There are number of factors that have impact on the recurrence rate, such as obesity, steroid use, increased intraabdominal pressure, chronic lung diseases and comorbidities.[5] Prior studies have shown variable recurrence rates (30.3–45 per cent), with a median follow up of 45 months (range: 6–73).[5,6] The main identified factors that have negative impact on the healing process are malnutrition, obesity, type II diabetes, steroids, chronic lung disease, smoking, jaundice, chemotherapy oral anticoagulants, radiotherapy, anaemia, heavy lifting and malignancy.[7]

We herein report the results of an average 12-month follow up of 42 patients who had undergone Strattice mesh repair of ventral hernias in terms of clinical outcome evaluation and the durability of repair.

Methods

We retrospectively studied the medical records of 45 patients who underwent Strattice mesh hernia repair at the West Virginia University, Ruby Memorial Hospital (Morgantown, VA, USA). Six surgeons conducted the procedure. We collected data regarding age, sex, type of repair, BMI, intraoperative hernia size, diabetes and steroid use. The recurrence rate was explored with regards to diabetes and steroid use (as dichotomous variables), and age, BMI and defect size (as both continuous and subcategorized variables, < 65 and ≥ 65 years, < 30 and ≥ 30 and < 55 and ≥ 55 cm^3, respectively). Defect size was calculated using elliptical area formula, with maximum length and maximum width noted on computed tomography (CT) scan. All patients were asked for follow-up examinations. The mean follow-up period was 22.37 months (range: 12–47 months). Additionally, chronic kidney disease, chronic obstructive pulmonary diseases (COPD), benign prostatic hyperplasia, liver disease and serum albumin were included.

Recurrence was defined clinically by the presence of a palpable mass at the site of the previous hernia repair, and confirmed radiologically by conducting a CT scan. Mesh laxity was taken as CT scan evidence of no defect in the abdominal wall, whereas recurrence was taken as a noted defect on radiological imaging. The decision for using Strattice mesh was taken for hernias that included clean, clean-contaminated, contaminated and dirty wounds and patients who underwent medically-indicated open repair of ventral hernia.

Intraoperatively, Strattice mesh was employed in a variety of hernia repairs. These included primary ventral hernia repair, recurrent ventral incisional hernia repair, component separation (abdominal wall reconstruction), parastomal hernia repair and one infected inguinal hernia repair. Strattice mesh was almost always positioned in a 'sublay' (preperitoneal) position, except in one case where it was placed in an 'onlay' (anterior fascial) position. All operative reports described mesh being affixed to surrounding fascia using interrupted horizontal mattress sutures. The fascia was able to be closed entirely over the mesh in approximately half the cases. During surgery, all patients received a single dose of antibiotics and closed suction drainage. The present study included all staff surgeons at our hospital who had performed Strattice mesh repair in their elective general surgery or acute care surgery practice.

For statistical analysis, we used JMP (version 10; SAS Institute, Cary NC, USA) software and *P*-values of less than 0.05 were considered statistically significant. Age, BMI and defect size were analysed as continuous variables; their means and standard deviations (SD) were calculated. Chronic kidney disease, COPD, benign prostatic hyperplasia, liver disease, serum albumin and steroid use were analysed as categorical variables, and summarized with frequencies and percentages. Logistic regression test was used to study the associations between hernia recurrence rate and other factors, and χ^2-test and Fisher's exact test were used to examine the differences between the subcategories independent samples for categorical (nominal) data, such as BMI (< 30 and ≥ 30), defect size (< 55 and ≥ 55 cm^3) and age (< 65 and ≥ 65 years).

Results

The mortality rate was 6.66 per cent (3/45) among the patients who underwent Strattice mesh repair over the past 2 years. Of the remaining 42 patients who were analysed, 23 (54.76 per cent) were women and 19 (45.24 per cent) were men, with an average age of 56 years (range: 25–85 years). The overall recurrence rate was 21.43 per cent (9), according to CT imaging. Demographics, where age was not statistically related to recurrence ($P > 0.05$), are summarized in Table 1. Of the nine patients who developed recurrence, eight (88.89 per cent) were males ($P = 0.002$) (Table 2). Additionally, the mean length of hospital stay mean was 16.3 days (1–62, SD: 15). The types of surgery and the degree of fascial closure are shown in Table 3.

At an average of 22.37 months' postrepair, a total of 23 (54.8 per cent) wound events were experienced by our patients. The infection rate was reported in 13 (30.95 per cent) patients, seroma developed in one patient (2.38 per cent), wound dehiscence in two patients (4.76 per cent), skin necrosis in six patients

Table 1. Population demographics

Participants	*n* (per cent or SD)
Sex	
Male	19 (45.24 per cent)
Female	23 (54.76 per cent)
Age	56 years (range: 25–85 years)
BMI	36.4 (SD: 11.77)
Defect size	97 cm^2 (SD: 1.72)
Steroids use	4 (9.52 per cent)
Diabetes	10 (23.81 per cent)
Wound events	23 (54.80 per cent)
Infection	13 (30.95 per cent)
Dehiscence	2 (4.76 per cent)
Laxity	1 (2.38 per cent)
Seroma	1 (2.38 per cent)
Skin necrosis	6 (14.29 per cent)
Chronic kidney disease	2 (4.80 per cent)
COPD	11 (26.20 per cent)
BPH	0
Serum albumin	2.61 g/dL (SDL 0.641)
Liver disease	3 (7.10 per cent)

BMI, body mass index; BPH, benign prostatic hyperplasia; COPD, chronic obstructive pulmonary diseases; SD, standard deviation.

(14.29 per cent) and mesh laxity in one patient (2.38 per cent).

The mean BMI was 36.4 (16.88–57.24, SD: 11.77). The BMI was found to be the only significant risk factor ($P = 0.035$) for recurrence; however, subcategorizing BMI into two groups (< 30 and ≥ 30) showed no significant difference in terms of risk of recurrence ($P > 0.05$) (Table 2). The mean of the defect size was 97 cm^2 (8.88–530.14, SD: 1.72). The hernia defect size was not significantly associated with the hernia recurrence rate ($P = 0.93$). Also subcategorizing defect size into two groups (< 55 and ≥ 55 cm^3) showed no significant difference in terms of risk of recurrence ($P > 0.05$) (Table 2). Ten patients (23.81 per cent) were diabetic, five (50 per cent) of whom developed recurrence. However, diabetes was not significantly associated with the hernia recurrence rate ($P = 0.726$). A total of four patients (9.52 per cent) were using steroids; only one of them developed recurrence. Steroid use was not significantly associated with the hernia recurrence rate ($P = 0.200$). Wound infection was not significantly associated with recurrence ($P = 0.323$), where of the 13 (30.95 per cent) wound infections detected, only four (30.95 per cent) developed recurrence. The association between the studied risk factors and the recurrence after Strattice mesh repair is summarized in Table 4. Chronic kidney disease,

Table 2. Gender, age, defect size, and BMI sub-grouping impact on recurrence

	Recurrence	No recurrence	*P*-value
Sex			0.002
Male	8/9 (88.89 per cent)	11/33 (33.33 per cent)	
Female	1/9 (11.11 per cent)	22/33 (66.67 per cent)	
Age (years)	59.11 (8.37)	55.15 (14.78)	0.088
< 65	7 (77.78 per cent)	25 (75.76 per cent)	
≥ 65	2 (22.22 per cent)	8 (24.24 per cent)	
Defect size	99.84 (8.32)	96.27 (2.29)	0.066
< 55 cm	7/9 (77.78)	14/33 (42.42 per cent)	
≥ 55 cm	2/9 (22.22 per cent)	19/33 (57.58 per cent)	
BMI	43.62 (12.23)	34.42 (11.02)	0.087
< 30	1/9 (11.11 per cent)	13/33 (39.99 per cent)	
≥ 30	8/9 (88.89 per cent)	20/33 (60.61 per cent)	

BMI, body mass index.

Table 3. Surgery types and the degree of fascial closure

Types of surgery	Frequency (no. cases)	Fascial closure over mesh	Frequency (no. cases)
Primary ventral hernia repair	2	No fascial closure	14
Recurrent ventral incisional hernia repair	26	Partial fascial closure	7
Component separation (abdominal wall reconstruction)	7	Complete fascial closure	21
Parastomal hernia repair	6		
Inguinal hernia repair	1		
Total	42	Total	42

Table 4. Analysis of risk factors for recurrence after Strattice mesh repair

Source	No. parameters	d.f.	Likelihood ratio, χ^2	*P*-value	Odds ratio	95 per cent confidence interval
Sex	1	1	9.55	0.002	0.038	0.003–0.503
Age	1	1	0.60	0.439	1.074	0.964–1.197
BMI	1	1	4.37	0.035	1.134	1.012–1.270
Diabetes	1	1	2.45	0.118	3.6	0.738–17.560
Steroid use	1	1	0.023	0.879	1.208	0.110–13.249
Defect size	1	1	0.007	0.932	1.00	0.994–1.007
Wound infection	1	1	0.934	0.334	7.429	1.473–37.455

BMI, body mass index.

COPD, benign prostatic hyperplasia, liver disease and serum albumin did not show a significant association with hernia recurrence ($P > 0.05$).

Discussion

The recurrence of incisional hernia is a critical issue due to its high rates, even with the number of diverse surgical approaches.[8–10] Repairing contaminated hernia using acellular dermal matrix, Strattice, adds an extra challenge to this kind of surgery. We found the overall recurrence rate among our patient cohort to be high (25 per cent). However, this rate is comparable to those reported by authors, and confirms the recurrence rates found in the literature. One study found that using large-size prostheses to cover the entire hernia defect and using sutures generously to fix the mesh resulted in a lower recurrence rate and less abdominal pain.[11] The ideal mesh should be biocompatible, sterile and nonallergenic, noncarcinogenic, and it should be strong enough to endure mechanical tensions and chemical effects of body fluids.[12] Based on these requirements, there is no ideal prosthetic mesh available.[12] It is worth noting that small defect-sized hernias can be treated by primary suturing with a decent recurrence rate.[13–15]

Our results show a statistically-significant relation between obesity and a high risk of failure after incisional hernia repair that is comparable with the results of similar studies.[16,17] We conclude that obesity was the only independent risk factor for recurrence. So if patients were to follow a preoperative weight-loss programme, it might be possible to decrease both the tension on the repaired incisional hernia and the technical difficulties encountered by the surgeon when operating on a morbidly-obese patient. Some authors even suggest bariatric procedures in an attempt to reduce the impact of morbid obesity on the positive outcome of incisional herniorrhaphy.[5] Kaminski concluded that morbidly-obese patients can be treated with a gastric-restrictive procedure at the same time of hernia repair in order to both reduce body weight and the potential risk of recurrence.[18] Although we did not find an association between hernia defect size and the risk of recurrence, many other studies concluded that large incisional hernias (diameter: > 10 cm) have an increased risk of recurrence, and a mesh prosthesis should be used to treat it in order to decrease the risk of recurrence.[19] That discrepancy could be explained by the different mesh types used in those studies compared with using only Strattice mesh in our study, or it could it be because of the small sample size of our study.

One of the most important issues is recognizing wound infection, dehiscence and necrosis as risk factors associated with hernia recurrence.[5] There are a number of risk factors that increase the likelihood of wound infection, such as the approach for hernia repair, patient comorbidities, immunity status and risk of infection.[5] The present study included a significant number of patients who were diabetic (10, 23.81 per cent), elderly (10, 23.81 per cent) and/or using steroids (4, 9.52 per cent), which can explain the high incidence of wound events (54.8 per cent). It is worth noting that more than one type of wound event had been recorded in the same patients of the more vulnerable group. Clinical examination was the main tool to diagnose those incidents, and standard medical care was provided to those patients.

Furthermore, patients with diabetes mellitus, those using steroids and those with different defect hernia sizes did not appear to have a significantly higher hernia recurrence rate in our study. This observation is supported by the results reported by van der Linden and van Vroonhoven in an earlier study.[20] Other investigators have identified postoperative wound infection as a crucial risk factor for the recurrence of incisional hernias.[21] We found only one prospective study (the Prospective Multicenter Clinical Study of Single-Stage Repair of Infected or Contaminated Abdominal Incisional Hernias Using Strattice™ Reconstructive Tissue Matrix), which explored the factors that can affect hernia recurrence after Strattice mesh repair [22] In that study, of 85 patients followed prospectively,

only 15 (18.8 per cent) developed recurrence.[22] Patients who experienced a recurrence had a significantly larger defect size at initial repair in comparison with those who did not develop recurrence.[22] However, the present study did not show any association between the BMI and recurrence.

Limitation

Our study population was relatively small ($n = 42$), and not all comorbidities were collected, such as chronic constipation, chronic cough and urinary obstructive disease. Many surgeons have performed this procedure, so the individual skill differences in technique could not be excluded. Future studies are needed to explore the impact of all comorbidities on hernia recurrence for longer periods of time on larger scales.

In conclusion, this retrospective study of utilizing Strattice mesh shows that only an increase in the BMI and being male are correlated to the risk recurrence of hernia repair. The present study shows that steroid use, defect size, chronic kidney disease, COPD, benign prostatic hyperplasia, liver disease and serum albumin are not associated with the recurrence rate. In conclusion, it is important to be aware of recurrence following Strattice mesh hernia repair in order to be able to decrease preoperative risk factors that the surgeon can manipulate, such as obesity.

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Declaration of conflict of interest

All authors declare that they have no conflicts of interest.

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