

## A COMPARISON OF SUTURE REPAIR WITH MESH REPAIR FOR INCISIONAL HERNIA

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### ABSTRACT

**Background** Incisional hernia is an important complication of abdominal surgery. Procedures for the repair of these hernias with sutures and with mesh have been reported, but there is no consensus about which type of procedure is best.

**Methods** Between March 1992 and February 1998, we performed a multicenter trial in which we randomly assigned to suture repair or mesh repair 200 patients who were scheduled to undergo repair of a primary hernia or a first recurrence of hernia at the site of a vertical midline incision of the abdomen of less than 6 cm in length or width. The patients were followed up by physical examination at 1, 6, 12, 18, 24, and 36 months. Recurrence rates and potential risk factors for recurrent incisional hernia were analyzed with the use of life-table methods.

**Results** Among the 154 patients with primary hernias and the 27 patients with first-time recurrent hernias who were eligible for the study, 56 had recurrences during the follow-up period. The three-year cumulative rates of recurrence among patients who had suture repair and those who had mesh repair were 43 percent and 24 percent, respectively, with repair of a primary hernia ( $P=0.02$ ; difference, 19 percentage points; 95 percent confidence interval, 3 to 35 percentage points). The recurrence rates were 58 percent and 20 percent with repair of a first recurrence of hernia ( $P=0.10$ ; difference, 38 percentage points; 95 percent confidence interval, -1 to 78 percentage points). The risk factors for recurrence were suture repair, infection, prostatism (in men), and previous surgery for abdominal aortic aneurysm. The size of the hernia did not affect the rate of recurrence.

**Conclusions** Among patients with midline abdominal incisional hernias, mesh repair is superior to suture repair with regard to the recurrence of hernia, regardless of the size of the hernia. (N Engl J Med 2000;343:392-8.)

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**I**NCISIONAL hernia is a frequent complication of abdominal surgery. In prospective studies with sufficient follow-up, primary incisional hernia occurred in 11 to 20 percent of patients who had undergone laparotomy.<sup>1-3</sup> Such hernias can cause serious morbidity, such as incarceration (in 6 to 15 percent of cases)<sup>4,5</sup> and strangulation (in 2 percent).<sup>4</sup> If the hernia is not reduced promptly, small bowel that is strangulated in the hernia may become ische-

mic and necrotic and perforation may ultimately occur. Although many techniques of repair have been described, the results are often disappointing. After primary repair, rates of recurrence range from 24 percent to 54 percent.<sup>4,6-9</sup> Repairs that include the use of mesh to close the defect have better but still high recurrence rates, up to 34 percent.<sup>8,10</sup> After repair of recurrent incisional hernias, recurrence rates of up to 48 percent have been reported.<sup>5</sup> These studies of suture repairs and mesh repairs, however, were either uncontrolled or nonrandomized, and it remains uncertain whether mesh repair is superior to suture repair. To define the indications for the use of mesh materials, we undertook a randomized, multicenter study of patients with midline abdominal incisional hernias.

### METHODS

#### Study Design

Between March 1992 and February 1998, we randomly assigned 200 adult patients who were scheduled to undergo repair of a primary hernia or a first recurrence of hernia at the site of a vertical midline incision to suture repair or mesh repair, after stratification according to the type of hernia and the hospital. The preoperative length or width of the fascial defect was not to exceed 6 cm, and patients could be enrolled only once. Exclusion criteria were the presence of more than one hernia, signs of infection, prior hernia repair with mesh, and plans to repair the hernia as part of another intraabdominal procedure. The study was approved by the ethics committees of the participating hospitals, and all the patients gave informed consent after a physician told them about the details of the trial.

The patient-related factors of sex; age; presence or absence of obesity, cough, constipation, prostatism, diabetes mellitus, glucocorticoid therapy; smoking status; and abdominal surgical history were recorded. Obesity was defined as a body-mass index (the weight in kilograms divided by the square of the height in meters) of at least 30. Factors related to the operation, including the surgical technique and the presence or absence of hematoma, dehiscence, and infection, were also analyzed. Wound infection was defined by the discharge of pus from the wound, evaluated up to the

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one-month visit. We also recorded factors related to the hernia, such as whether the hernia was primary or a first recurrence, the preoperative and intraoperative size of the hernia, and the exact location of the hernia (the upper median, 3 cm or less proximal or distal to the umbilicus, or the lower median).

At the onset of anesthesia, a cephalosporin was administered intravenously. In the patients assigned to undergo repair with sutures, the two edges of the fascia were approximated in the midline, usually with a continuous polypropylene suture (Prolene no. 1, Ethicon, Amersfoort, the Netherlands) with stitch widths (tissue bites) and intervals of approximately 1 cm. In the patients assigned to undergo repair with use of mesh, the dorsal side of the fascia adjacent to the hernia was freed from the underlying tissue by at least 4 cm. A polypropylene mesh (Marlex [Bard Benelux, Nieuwegein, the Netherlands] or Prolene) was tailored to the defect so that at least 2 to 4 cm of the mesh overlapped the edges of the fascia, and the mesh was sutured to the back of the abdominal wall 2 to 4 cm from the edge of the defect with a continuous suture (Prolene no. 1). To minimize contact between the mesh and the underlying organs, any peritoneal defect was closed or the omentum was sutured in between. When this could not be done, a polyglactin 910 (Vicryl, Ethicon) mesh was fixed in between. The fascial edges were not closed over the prosthesis unless a completely tension-free repair could be performed. Drainage and closure of the subcutis and closure of the cutis were optional. The duration of surgery and the hospital stay was noted.

The patients were evaluated by physicians 1, 6, 12, 18, 24, and 36 months after surgery. Patients' awareness of any recurrence of the hernia and concern about the scar were noted. When patients were asked whether they had pain, their responses were recorded as simply "yes" or "no." The scar was examined for recurrence of hernia, which was defined as any fascial defect that was palpable or detected by ultrasound examination and was located within 7 cm of the site of hernia repair. The examination included palpation while the patient was in the supine position with legs extended and raised. Ultrasound examinations were performed only when physical examinations were not definitive.

**Statistical Analysis**

Percentages and continuous variables were compared with the use of Fisher's exact test and the Mann-Whitney test, respectively. The cumulative percentages of patients with recurrences over time were calculated and compared with use of Kaplan-Meier curves and log-rank tests. Multivariate analysis of various factors was performed with Cox regression analysis. Through the use of appropriate interaction terms, we investigated whether the effect of treatment depended on the size of the repaired hernia. All statistical tests were two-sided. The primary analysis was performed on an intention-to-treat basis; that is, patients remained in their assigned group even if during the procedure the surgeon judged the patient not to be suitable for the technique assigned. A per-protocol analysis, which excluded patients with major protocol violations, was also performed.

**RESULTS**

Among the 200 patients enrolled in the study, 171 had a primary incisional hernia, and 29 had a first recurrence of incisional hernia. Seventeen patients in the former group and two in the latter group were found to be ineligible for the study, for the following reasons: no incisional hernia was evident intraoperatively (nine patients), the operation was canceled (five patients), no follow-up data were obtained (three patients), hernia repair was part of another procedure (one patient), or herniation was too close to an enterostomy for the specified procedure to be performed (one patient). At base line, the patients as-

signed to the mesh-repair group were slightly younger and had a higher frequency of past surgery for abdominal aortic aneurysm, whereas there were more patients with prostatism in the suture-repair group (Table 1).

The recurrence rates for the two groups, subdivided according to whether the patients had a primary hernia or a first recurrence, are shown in Table 2. Among the patients with primary hernias, 80 were assigned to suture repair and 74 to mesh repair (8 with an additional polyglactin 910 [Vicryl] mesh). The mean duration of follow-up was 26 months (range, 1 to 36) for patients without recurrence and was similar for both treatment groups. Thirty-two patients (16 in each group) were lost to follow-up: 7 patients died (none within 1 month after surgery); 5 underwent further surgery through the repair at a later date; 1 moved abroad; and 19 did not appear at their next appointment for various reasons, such as work or immobility (mean follow-up, 10 months). These 32 patients were included in the analysis, but follow-up data were censored at the time of their last contact with the investigators or at the time of reoperation.

Seven patients assigned to the suture-repair group

**TABLE 1. BASE-LINE CHARACTERISTICS OF THE PATIENTS WITH INCISIONAL HERNIA, ACCORDING TO STUDY GROUP.\***

VARIABLE	SUTURE REPAIR (N=97)	MESH REPAIR (N=84)
Sex ratio — M:F	1.0:1	1.5:1
Age — yr		
Median	63	57
Range	25–82	23–85
Body-mass index†		
Median	26.0	26.2
Range	20.0–41.5	19.7–41.5
Prostatism — no./total no. (%‡)	6/47 (13)	1/49 (2)
Smoking — no./total no. (%)	27/92 (29)	32/82 (39)
Infection — no./total no. (%)	2/92 (2)	3/82 (4)
Hematoma — no./total no. (%)	8/96 (8)	9/83 (11)
Intraoperative size of the hernia — cm <sup>2</sup>		
Median	20	24
Range	1–225	1–160
Main reason for laparotomy before repair — no.§		
Gastrointestinal operation	48	38
Gynecologic operation	16	15
Cholecystectomy	9	5
Abdominal aortic aneurysm	6	12
Other	28	30

\*For some variables, data were not available for all the patients in the group.

†The body-mass index was calculated as the weight in kilograms divided by the square of the height in meters.

‡Percentages are of male subjects.

§Some patients had undergone more than one previous laparotomy.

**TABLE 2.** RATES OF RECURRENCE ACCORDING TO WHETHER THE REPAIRED INCISIONAL HERNIA WAS PRIMARY OR A FIRST RECURRENCE.

TYPE OF HERNIA	NO. OF PATIENTS	NO. OF RECURRENCES	3-Yr CUMULATIVE RATE OF RECURRENCE	DIFFERENCE IN RISK (95% CI)*	P VALUE
			%	percentage points	
Primary					
Suture repair	80	30	43	19 (3 to 35)	0.02
Mesh repair	74	15	24		
Total	154	45			
First recurrence					
Suture repair	17	9	58	38 (-1 to 78)	0.10
Mesh repair	10	2	20		
Total	27	11			
Both					
Suture repair	97	39	46	23 (8 to 38)	0.005†
Mesh repair	84	17	23		
Total	181	56			

\*CI denotes confidence interval.

†The P value was obtained by the stratified log-rank test.

underwent mesh repair, and five patients assigned to the mesh-repair group underwent suture repair; one patient in each group had a recurrence. In all patients who had been assigned to the suture-repair group but underwent mesh repair, the surgeon judged that the defect was too large (all were more than 36 cm<sup>2</sup>) to be repaired without adding a prosthesis for strength. Of the patients assigned to the mesh-repair group who underwent suture repair, two represented violations of the protocol and two underwent suture repair because the surgeon deemed the defect too small for mesh repair. In one case the risk of infection of the planned mesh repair was judged to be high because of an inadvertent enterotomy. Among patients with primary hernias, the three-year cumulative rates of recurrence were 43 percent for those who underwent suture repair and 24 percent for those who underwent mesh repair (P=0.02) (Table 2).

Of the patients with first recurrences, 17 were assigned to suture repair and 10 were assigned to mesh repair. Two patients assigned to the suture-repair group underwent mesh repair because the surgeon judged the defect to be too large (more than 36 cm<sup>2</sup>) for repair without a prosthesis (one patient had a recurrence). The mean duration of follow-up was 30 months (range, 1 to 36) for patients without recurrence and was similar for both treatment groups. The three-year cumulative rates of recurrence in the suture-repair and mesh-repair groups were 58 percent and 20 percent, respectively (P=0.10) (Table 2).

When both hernia groups were combined, the mean duration of follow-up was 26 months (range, 1 to 36) for patients without recurrence and was similar for both treatment groups (P=0.005) (Table 2 and Fig. 1). The three-year cumulative rates of recurrence were 46 percent with suture repair and 23 percent with mesh repair. In the subgroup of 50 pa-

tients with small hernias (10 cm<sup>2</sup> or smaller), the three-year cumulative rate of recurrence after suture repair was 44 percent, as compared with 6 percent in the mesh-repair group (P=0.01).

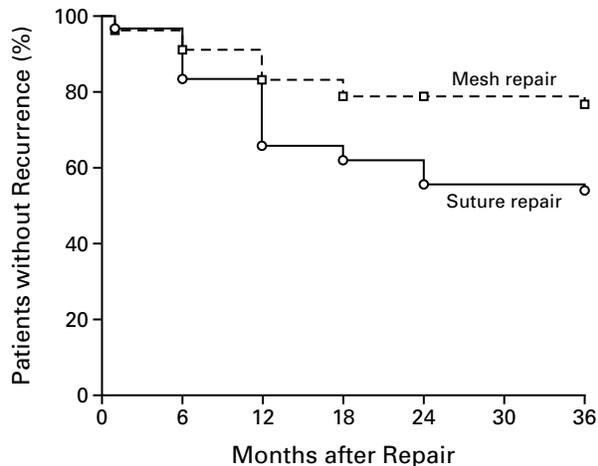
The median duration of the operation was 45 minutes (range, 15 to 135) for suture repair and 58 minutes (range, 15 to 150) for mesh repair (P=0.09). The median length of the hospital stay was 6 days (range, 1 to 37) for suture repair and 5 days (range, 1 to 15) for mesh repair (P=0.44).

#### Per-Protocol Analysis

In the total group of 181 patients, major violations of the protocol occurred in the repairs of 5 patients. In one patient, the most proximal of four hernias found intraoperatively was repaired with use of a prosthesis and the other three hernias were repaired with sutures. In another patient, the fascial defect was sutured under a subcutaneous mesh repair. In the third patient, several intraoperatively discovered weak spots were not completely covered by subcutaneous mesh repair (for unknown reasons), making recurrence inevitable. The other two patients were switched to suture repair despite the fact that a mesh repair could have been performed with ease, according to the operative notes (one patient had a recurrence). With data on these five patients removed from the analysis, the three-year cumulative rates of recurrence in the suture-repair group (95 patients) and mesh-repair group (81 patients) were similar to those in the intention-to-treat analysis — namely, 46 percent and 23 percent, respectively (P=0.005).

#### Recurrences after Mesh Repair

We attempted to determine the reasons for recurrence in all patients who underwent mesh repair, regardless of treatment assignment (excluding repairs



NO. AT RISK

Mesh repair	76	69	56	47	37
Suture repair	87	71	53	48	34

**Figure 1.** Kaplan–Meier Curves for Recurrence of Hernia after Repair of a Primary or First Recurrent Incisional Hernia, According to Whether the Patient Was Assigned to Mesh Repair (N=84) or Suture Repair (N=97).

There were significantly fewer recurrences in patients who were assigned to mesh repair (P=0.005).

that were deemed to reflect major trial violations). Possible explanations were that the mesh was attached with 2 cm or less of overlap (five patients), that interrupted sutures were placed 2 cm apart (one patient), that marked abdominal distention occurred during the first week after surgery (one patient), that recurrence resulted from glucocorticoid therapy (one patient), that it resulted from infection of a large hematoma (one patient), and that the repair was inadequate because the patient had pain during the procedure as a result of inadequate epidural anesthesia (one patient). No explanation for recurrence was found in the cases of seven patients who had undergone mesh repair.

**Analysis of Prognostic Factors**

In the univariate analysis, prostatism (in men), a history of surgery for abdominal aortic aneurysm, and infection were identified as risk factors for recurrence (data not shown). The results of the multivariate analysis of these factors together with the type of repair, age, size of hernia, and primary hernia or first recurrence of hernia are shown in Table 3. In this analysis, suture repair, infection, prostatism (in men), and history of surgery for abdominal aortic aneurysm were all identified as independent risk factors for recurrence. After adjustment for the other factors, mesh repair was found to result in a 57 percent lower rate of recurrence (95 percent confidence interval, 19 to

77 percent; P=0.009) than suture repair. The difference in rates of recurrence between the suture-repair group and the mesh-repair group was not affected by the size of the hernia.

**Complications**

One of the 97 patients in the suture-repair group had complete wound dehiscence after marked abdominal distention that resulted from an ileus on the fifth day after surgery. One of the 84 patients in the mesh-repair group had a recurrence associated with intestinal strangulation 18 months after surgery. In another patient who underwent mesh repair, contact with the intestines was not adequately prevented, so one month later, at laparotomy performed because of a persisting ileus, two loops of small intestine appeared to be fixed to the mesh, prohibiting fecal flow. Three of the 84 patients (4 percent) had postoperative infections but did not require removal of the mesh, 5 patients (6 percent) had postoperative abdominal bulging, and 1 patient (1 percent) had postoperative bleeding.

The frequency of pain one month after surgery was similar in the two treatment groups (suture-repair group, 19 patients [20 percent]; mesh-repair group, 15 patients [18 percent]). The pain usually disappeared after the first month. Seven of the patients had hematomas, and five had recurrent hernias. Postoperative serosanguineous leakage occurred in three patients in the suture-repair group and in four patients in the mesh-repair group. An inadvertent enterotomy occurred in four patients (2 percent), without later complications. Other complications were suture-thread sinus (one patient), pneumonia (four patients), urinary tract infection (three patients), and myocardial infarction (one patient).

**Awareness of Recurrences on the Part of Patients**

All patients were asked before each follow-up physical examination whether they had noticed a recurrence of hernia. Of the 139 patients who believed they had no recurrence, 14 (10 percent) had a recurrence, as evidenced by physical examination. The 42 patients who believed they had a recurrence indeed had one, as shown by examination. When only these self-reported recurrences were counted, the three-year cumulative rates of recurrence were 35 percent for the suture-repair group and 17 percent for the mesh-repair group (P=0.02).

**DISCUSSION**

The techniques used for repairing incisional hernias have generally developed in a practical, experiential way. Several authors have reported favorable results with mesh repair,<sup>3,8,10-19</sup> but to date this technique has not been studied systematically. We now report the results of a prospective, randomized, multicenter trial in which suture repair was compared

**TABLE 3.** RESULTS OF MULTIVARIATE ANALYSIS OF FACTORS AFFECTING THE RATES OF RECURRENCE AFTER REPAIR OF INCISIONAL HERNIA.\*

FACTOR	NO. OF PATIENTS	NO. OF RECURRENCES	3-YR CUMULATIVE RATE OF RECURRENCE† %	RR (95% CI)	P VALUE OF RR
Type of repair					
Suture‡	97	39	46	1.0	
Mesh	84	17	23	0.4 (0.2–0.8)	0.009
Type of hernia					
Primary‡	154	45	34	1.0	
First recurrence	27	11	43	1.7 (0.8–3.5)	0.14
Prior surgery for abdominal aortic aneurysm					
No‡	162	46	32	1.0	
Yes	18	9	67	3.8 (1.7–8.5)	0.001
Infection					
No‡	169	50	34	1.0	
Yes	5	4	≥80	4.3 (1.5–12.6)	0.007
Prostatism					
No‡	89	26	35	1.0	
Yes	7	3	49	6.3 (1.7–23.4)	0.006
NA§	82	26	35	1.0 (0.6–1.8)	0.98
Age					
<65 yr‡	117	34	32	1.0	
≥65 yr	64	22	42	1.0 (0.6–1.8)	0.97
Intraoperative size of hernia >10 cm <sup>2</sup>					
No‡	50	13	31	1.0	
Yes	128	43	38	1.5 (0.7–2.9)	0.30

\*RR denotes relative risk, CI confidence interval, and NA not applicable. For some variables, data were not available for all patients.

†The rates are from the univariate analysis.

‡The patients in this category served as the reference group.

§The data are for female patients.

with mesh repair; the latter was determined to be more effective.

In techniques for the repair of incisional hernias in which sutures are used, the edges of the defect are brought together, which may lead to excessive tension and subsequent wound dehiscence or incisional herniation as a result of tissue ischemia and the cutting of sutures through the tissues.<sup>20</sup> With prosthetic mesh, defects of any size can be repaired without tension. In addition, polypropylene mesh, by inducing an inflammatory response, sets up a scaffolding that, in turn, induces the synthesis of collagen. Our study establishes the superiority of mesh repair over suture repair with regard to the recurrence of hernia.

We took no measures to prevent the evaluating clinicians and patients from knowing the type of repair used in each case; this might be considered a limitation of the study. The forms used to record the findings of the postoperative examinations did not include information on the type of repair used, but in 17 percent of the cases, only the surgeon who performed the operation evaluated the patient at follow-up. Furthermore, in a thorough examination, the technique performed may be detected, because after

mesh repair, a fascial rim can be palpated in some patients with a large fascial defect. Therefore, the examining physicians may have known which technique was used, and bias on their part may have affected the outcome. However, the rate of recurrence after suture repair was similar to that predicted on the basis of our previous work.<sup>6,21,22</sup> Also, when only the self-reported recurrences, which are likely to be less susceptible to biased ascertainment, were counted, the difference remained significant ( $P=0.02$ ).

The size of the hernia was an independent risk factor for recurrence in two retrospective studies by our group, in which “approximating” (edge-to-edge) fascial repairs<sup>6,21</sup> and “overlapping” repairs<sup>22</sup> were evaluated, but not in another study.<sup>5</sup> In medical records, however, the size of the defect is often described insufficiently, so analyses of retrospective data are less reliable. Also, the extent of the decrease in laxity of the tissue surrounding the hernia, which is influenced by retraction of muscle and scarification of tissues, may be more important than the actual size of the fascial defect. In this prospective study, the size of the defect was not a risk factor for recurrence.

Patients with hernias who had undergone surgery

for an abdominal aortic aneurysm had significantly higher recurrence rates than patients without such a history. An increased frequency of primary or recurrent inguinal and incisional hernia in patients who have had an aneurysm has been previously reported in some retrospective studies but not in others.<sup>23-29</sup> Whether an inherent defect in healing exists in patients with aortic aneurysms or hernial disease is not known, but possible defects in healing may be explained by defects in collagen and elastin cross-linkages,<sup>30</sup> increased activity of elastase with reduced content of elastin,<sup>31</sup> and different relative proportions of collagen subtypes.<sup>32-34</sup> Smoking may also be a factor,<sup>35</sup> but it was not a factor in this study (data not shown).

Infection did not lead to the removal of mesh in this and most other series,<sup>6,12,13,15,19</sup> but it was a risk factor for recurrence. Therefore, the administration of broad-spectrum antibiotics at the induction of anesthesia is recommended.<sup>36</sup>

On the basis of our results, we recommend attachment of the prosthesis to the dorsal side of the defect with an overlap as large as possible, and we recommend that the mesh be sutured to the surrounding fascia with intervals of no more than 1 to 2 cm between stitches. Bulging must be prevented, but the mesh should not be implanted under tension. Contact between the polypropylene mesh and the viscera must be avoided because of the risk of adhesions, intestinal obstruction, and fistulas.<sup>19</sup> When the peritoneum cannot be closed or when omentum cannot be interposed, polyglactin 910 (Vicryl) mesh may be interposed to protect the viscera,<sup>17,37,38</sup> but experimental and clinical studies are not conclusive with respect to the efficacy of the interposition of the polyglactin mesh in preventing these complications.<sup>38-40</sup>

In conclusion, in patients with incisional hernias, retrofascial preperitoneal repair with polypropylene mesh is superior to suture repair with regard to the recurrence of hernia, even in patients with small defects.

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