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Open Mesh versus Laparoscopic Mesh Repair of Inguinal Hernia

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ABSTRACT

BACKGROUND

Repair of inguinal hernias in men is a common surgical procedure, but the most effective surgical technique is unknown.

METHODS

We randomly assigned men with inguinal hernias at 14 Veterans Affairs (VA) medical centers to either open mesh or laparoscopic mesh repair. The primary outcome was recurrence of hernias at two years. Secondary outcomes included complications and patient-centered outcomes.

RESULTS

Of the 2164 patients who were randomly assigned to one of the two procedures, 1983 underwent an operation; two-year follow-up was completed in 1696 (85.5 percent). Recurrences were more common in the laparoscopic group (87 of 862 patients [10.1 percent]) than in the open group (41 of 834 patients [4.9 percent]; odds ratio, 2.2; 95 percent confidence interval, 1.5 to 3.2). The rate of complications was higher in the laparoscopic-surgery group than in the open-surgery group (39.0 percent vs. 33.4 percent; adjusted odds ratio, 1.3; 95 percent confidence interval, 1.1 to 1.6). The laparoscopic-surgery group had less pain initially than the open-surgery group on the day of surgery (difference in mean score on a visual-analogue scale, 10.2 mm; 95 percent confidence interval, 4.8 to 15.6) and at two weeks (6.1 mm; 95 percent confidence interval, 1.7 to 10.5) and returned to normal activities one day earlier (adjusted hazard ratio for a shorter time to return to normal activities, 1.2; 95 percent confidence interval, 1.1 to 1.3). In prespecified analyses, there was a significant interaction between the surgical approach (open or laparoscopic) and the type of hernia (primary or recurrent) ($P=0.012$). Recurrence was significantly more common after laparoscopic repair than after open repair of primary hernias (10.1 percent vs. 4.0 percent), but rates of recurrence after repair of recurrent hernias were similar in the two groups (10.0 percent and 14.1 percent, respectively).

CONCLUSIONS

The open technique is superior to the laparoscopic technique for mesh repair of primary hernias.

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SURGICAL REPAIR OF INGUINAL HERNIAS is a common procedure in adult men. However, recurrence of hernias has been reported to occur after repair in 15 percent or more cases, and postoperative pain and disability are frequent.¹⁻⁵ When traditional surgical methods are used, outcomes after repair of recurrent hernias have been worse than after primary repair.^{6,7} After the introduction of tension-free surgical repair with the use of prosthetic mesh, recurrence rates were reported to be less than 5 percent, and patients' comfort was reported to be substantially improved over that obtained by the traditional, tension-producing techniques.^{8,9} Local anesthesia is used, and patients are discharged within a few hours. A laparoscopic method of performing a tension-free repair has subsequently been reported to result in low recurrence rates and to be associated with substantially less pain in the immediate postoperative period and earlier return to normal activities than the open-repair technique.^{10,11} The laparoscopic technique, however, requires general anesthesia, and it is more often associated with serious intraoperative complications than is open repair,¹¹⁻¹³ although such complications are infrequent.

We conducted a multicenter, randomized trial to compare recurrence rates and other outcomes after either of two standardized tension-free herniorrhaphies: open repair and laparoscopic repair.

METHODS

STUDY POPULATION, RECRUITMENT, STUDY INTERVENTIONS, AND FOLLOW-UP

Men presenting to general-surgery clinics at 14 Veterans Affairs (VA) medical centers who were 18 years of age or older, had a diagnosis of inguinal hernia, and gave written informed consent were eligible for random assignment to open tension-free repair or laparoscopic tension-free repair. Patients in American Society of Anesthesiologists (ASA) class IV (i.e., those who had systemic disease that is a constant threat to life) or class V (i.e., those who were unlikely to survive for 24 hours, with or without an operation)¹⁴ were excluded, as were those who had contraindications to general anesthesia, bowel obstruction, bowel strangulation, peritonitis, bowel perforation, local or systemic infection, contraindications to pelvic laparoscopy, a history of repair with mesh, or a life expectancy of less than two years. Patients who were participating in another trial were also excluded. Randomization was carried

out by a computer-generated, permuted-block sequence and was stratified according to the type of hernia (primary or recurrent), whether the hernia was unilateral or bilateral, and the study site (the VA medical center). In patients with bilateral hernias, both sides were repaired simultaneously; one side was chosen randomly by the coordinating center to be the "study" hernia to be included in the intention-to-treat analysis. The protocol was approved by the human-rights committee of the Hines VA Cooperative Studies Program and by the institutional review board at each site. Details of the study design can be found in a previous report.¹⁵

All the patients underwent standardized repairs by attending surgeons who had performed (and documented) 25 open or 25 laparoscopic repairs in order to qualify to perform the open or the laparoscopic procedure, respectively.^{16,17} The participating surgeons' self-reported experience was recorded at the beginning of each operation. The surgeons agreed to follow a precise protocol, including pre-trial submission of a videotaped laparoscopic procedure that was reviewed by a surgeon member of the study's executive committee. The presence of the attending surgeon at the operating table throughout the procedure was required. The open procedure was performed according to the Lichtenstein method, as described by Amid.¹⁸ Laparoscopic repairs were performed either by a transabdominal preperitoneal approach or by a totally extraperitoneal approach.¹⁹⁻²² All repairs involved the use of mesh. Recurrent hernias were repaired by the same standardized procedures as were primary hernias. All the patients were given standardized postoperative instructions that did not restrict their activities unless the activities caused pain.

DETERMINATION OF THE PRIMARY OUTCOME

The primary outcome of the trial was recurrence of a hernia within two years after the repair. The patients were followed for a minimum of two years. Postoperatively, each patient was examined at two weeks, at three months, and yearly thereafter to determine the presence or absence of recurrence by a surgeon who had not been involved in that patient's operation. Recurrences were confirmed by examination by an independent surgeon, by ultrasound examination, or during a second operation. A patient with bilateral hernias who had a recurrence on the side opposite the side of the study hernia was considered not to have had a recurrence in the intention-to-treat analysis.

DETERMINATION OF SECONDARY OUTCOMES

Secondary outcomes were complications, death, and patient-centered outcomes. Complications were assessed intraoperatively and at specified intervals postoperatively. Long-term complications were assessed at the three-month and annual visits. Life-threatening complications were defined before the start of the study and were assessed for 30 days after the procedure. All deaths and life-threatening complications were reviewed by an independent end-points committee to determine whether the event was related to the operation.

Patient-centered outcomes (pain, functional status, and activity levels) were assessed at baseline, two weeks, three months, six months, and yearly thereafter. Pain was assessed with the use of a visual-analogue scale on the day of the operation and daily until the first postoperative visit (at two weeks).²³ Functional status was assessed with the Medical Outcomes Study 36-item Short-Form General Health Survey (SF-36) questionnaire, version 2.²⁴

ORGANIZATION AND MONITORING

Each site was visited by the principal investigator or coprincipal investigator during the first few months of the study to ensure compliance with study protocols. Deaths and life-threatening complications were determined to be related or unrelated to the treatment by an independent committee consisting of a surgeon, an anesthesiologist, and a pathologist.

STATISTICAL ANALYSIS

The study was designed to detect a 3 percent difference in recurrence rates between the groups with a sample of 2200 patients and a power of 80 percent.¹⁵ The members of the data and safety monitoring board terminated enrollment one month early because they determined that the study had sufficient power to detect a difference in the rate of recurrence within two years. The study included 1983 patients who underwent surgery, and thus it had more than 88 percent power to distinguish a difference of 4 percentage points in recurrence rates, allowing a two-sided type I error rate of 5 percent and six interim analyses of the primary end point.

In the primary analysis, the two-year rates of recurrence were compared between the two groups according to the intention to treat. The two-year rates of recurrence were compared with the use of O'Brien–Fleming boundaries to account for sequential monitoring of the primary outcome.²⁵ All 95

percent confidence intervals for the two-year recurrence rates were adjusted for sequential monitoring, as were the 95 percent confidence intervals for the rates or mean values of each secondary outcome. Subgroup analyses of the primary outcome are presented as adjusted odds ratios calculated from logistic-regression analyses after adjustment for stratification factors (primary or recurrent hernia, unilateral or bilateral hernia, and study site). Proportions were compared on the basis of adjusted odds ratios obtained by logistic-regression analysis to control for stratification factors. Differences in outcomes related to pain and functional status were compared by multiple linear-regression analysis, with generalized estimating equations used to control for stratification factors and to account for repeated assessments. Differences in the times to return to normal activity, after adjustment for stratification factors, were assessed by Cox regression analysis. Statistical tests were not adjusted for comparisons related to multiple secondary end points or subgroup analyses. Analyses controlling for stratification factors were prespecified.

RESULTS**BASELINE CHARACTERISTICS OF THE PATIENTS**

Between January 1999 and November 2001, 3518 eligible patients were screened (Fig. 1). Of these patients, 2164 (61.5 percent) with inguinal hernias met the entry criteria and were randomly assigned to either open or laparoscopic hernia repair. The two-year follow-up period ended in November 2003 and was completed in 85.5 percent (1696) of the 1983 patients who underwent surgery (85.0 percent of the open group and 87.4 percent of the laparoscopic group). Ninety-seven of the 989 patients assigned to laparoscopic repair (9.8 percent) instead underwent open repair, and 16 of the 994 patients assigned to open repair (1.6 percent) instead underwent laparoscopic repair. Intraoperative conversion to open herniorrhaphy accounted for approximately half the patients in the laparoscopic group who did not undergo the assigned repair; the others were switched to open repair for technical reasons discovered at the time of surgery or the patient's preference.

Table 1 shows the baseline characteristics of the patients according to treatment group. Demographic characteristics, the characteristics of the hernia, coexisting conditions, and ASA classifications were similar in the two groups.

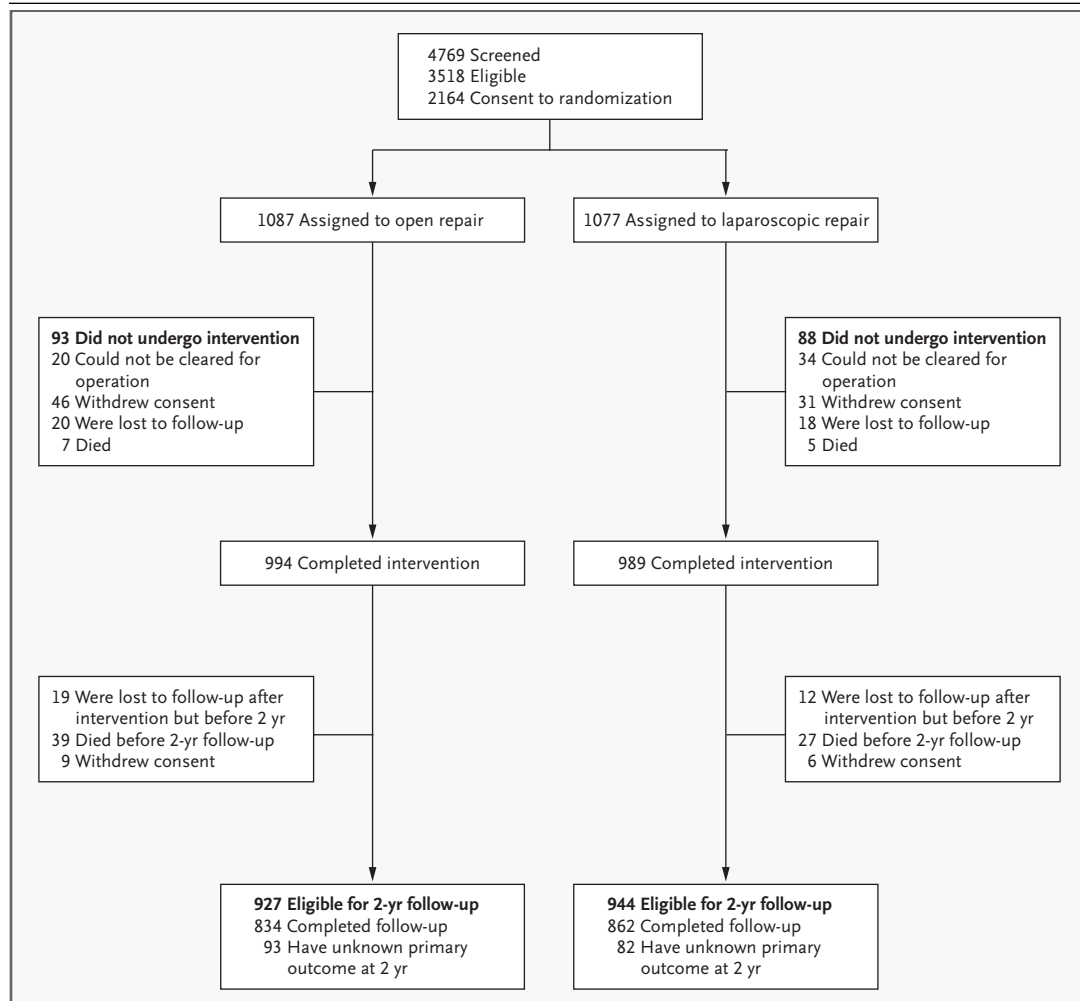


Figure 1. Flow Chart of Patients Screened for Participation in the Study.

RECURRENCE

The intention-to-treat analysis showed that at two years, recurrences were more common in the laparoscopic group (in which there were 87 recurrences among 862 patients [10.1 percent]) than in the open group (in which there were 41 recurrences among 834 patients [4.9 percent]; odds ratio, 2.2; 95 percent confidence interval, 1.5 to 3.2) (Table 2). The difference remained significant in logistic-regression analysis that controlled for stratification factors (primary or recurrent hernia, unilateral or bilateral hernia, and study site). Rates of recurrence were statistically similar when analyzed in cohorts enrolled in the first, second, or third year of the study.

Similar results were obtained in an analysis in which patients were classified as treated, with the 113 patients who crossed over from their assigned

procedure classified according to the procedure actually performed. In patients with bilateral hernias who had a recurrence on the nonstudy side (five patients in the open group and eight in the laparoscopic group), inclusion of these recurrences did not materially affect the results (data not shown).

In additional prespecified analyses, we found a significant interaction between treatment group and the type of hernia (primary or recurrent) (P=0.012) but not between treatment group and whether the hernia was unilateral or bilateral (P=0.29). With respect to the repair of primary hernias, the recurrence rate was significantly higher among patients who underwent the laparoscopic procedure (79 recurrences among 781 patients [10.1 percent]) than among those who underwent the open procedure (30 recurrences among 756 patients [4.0 percent];

adjusted odds ratio, 2.9; 95 percent confidence interval, 1.8 to 4.5). The same was not true with respect to the repair of recurrent hernias; the number of recurrences was similar: 8 of 81 patients in the laparoscopic group had a recurrence (10.0 percent), as compared with 11 of 78 such patients in the open group (14.1 percent; adjusted odds ratio, 0.7; 95 percent confidence interval, 0.3 to 2.0).

COMPLICATIONS AND DEATH

Overall, 718 of the 1983 patients who underwent a repair procedure (36.2 percent) had at least one complication; there were 386 complications among the 989 patients in the laparoscopic group (39.0 percent) and 332 among the 994 patients in the open group (33.4 percent) (adjusted odds ratio, 1.3; 95 percent confidence interval, 1.1 to 1.6) (Table 2). Intraoperative, immediate postoperative, and life-threatening complications occurred significantly more frequently in the laparoscopic group than in the open group. The rate of long-term complications (those assessed at three months and at yearly visits) were similar in the two groups (Table 2).

Within 30 days after the operation there were two deaths in the laparoscopic group (both considered to be related to the surgery) and none in the open group. The two-year mortality rates were not different between the groups: over the two-year follow-up period there were 32 deaths in the laparoscopic group (3.2 percent) and 34 deaths in the open group (3.4 percent) (adjusted odds ratio, 1.0; 95 percent confidence interval, 0.6 to 1.6). Four deaths were determined by the end-points committee to be related to the operation. The causes of death in these patients were a pulmonary embolus on postoperative day 3 (in the laparoscopic group); an intestinal injury during laparoscopic repair (in the laparoscopic group); a perioperative myocardial infarction, which led to coronary-artery bypass surgery and death 60 days after the repair (in the laparoscopic group); and, 2 years after the repair, complications from a bowel obstruction in a femoral hernia (which presumably was missed at the time of the study operation) (in the open group).

PATIENT-CENTERED OUTCOMES

Patients in the open-repair group had significantly greater levels of pain (at rest, at work or during exercise, and during normal activities) than did those in the laparoscopic group during the two-week postoperative assessment period. On the day of surgery, the difference in the mean score on the visual-

Table 1. Baseline Characteristics of the Patients, According to Treatment Group.*

Characteristic	Open Repair (N=994)	Laparoscopic Repair (N=989)
Age (yr)	58.4±12.7	58.6±12.8
Race (%)†		
White	75.3	73.9
Black	20.3	22.1
Asian	0.2	0.1
Multiracial	3.0	2.6
No response	1.2	1.3
Duration of hernia (%)		
<6 wk	9.8	9.0
6 wk to 1 yr	46.6	49.3
>1 yr	36.0	35.2
Unknown	7.6	6.5
Hernia (%)		
Unilateral	82.1	82.3
Bilateral	17.9	17.7
Primary	91.1	90.3
Recurrent	8.9	9.7
Coexisting conditions (%)‡		
Congestive heart failure	0.1	0.5
Prior myocardial infarction	0.3	0.2
Hypertension	35.6	34.3
Severe chronic obstructive pulmonary disease	5.0	4.9
Chronic cough	7.9	9.1
Prostatism	17.0	17.9
Diabetes	4.6	6.2
Smoking	42.9	40.4
Alcohol consumption >2 drinks/day	16.0	13.8
ASA class (%)§		
I	33.6	34.7
II	47.7	46.8
III	18.7	18.5

* Plus-minus values are means ±SD.

† Race was self-reported.

‡ Coexisting conditions were determined to be present or absent by the examining physician according to defined criteria on the basis of current medications and problem lists in their charts (for congestive heart failure, prior myocardial infarction, and diabetes)¹⁵ or on the basis of the patients' own report (for symptoms of prostatism, chronic cough, smoking, and alcohol consumption).

§ American Society of Anesthesiologists (ASA) class I denotes healthy status, class II mild systemic disease, and class III severe systemic disease.

analogue scale was greatest (10.2 mm [95 percent confidence interval, 4.8 to 15.6]), but the score decreased to 6.1 mm (95 percent confidence interval, 1.7 to 10.5) by the time of the two-week assessment. The two treatment groups were similar with

Table 2. Characteristics of the Repair Procedures, Postoperative Complications, and Recurrences at Two Years.*

Variable	Open Repair (N=994)	Laparoscopic Repair (N=989)	Adjusted Odds Ratio (95% CI)
<i>% of patients</i>			
Type of anesthesia			NA
General	61.0	99.1	
Regional	27.5	0.7	
Local, with or without sedation	11.5	0.2	
Type of laparoscopic repair			NA
Totally extraperitoneal	NA	90.0	
Transabdominal preperitoneal	NA	10.0	
Intraoperative complications	1.9	4.8	2.6 (1.5–4.7)
Problems related to anesthesia†	0.8	1.3	
Injury to spermatic-cord structure	0.8	0.1	
Injury to vessel	0.1	1.0	
Peritoneal defect over mesh at closure	0	1.5	
Other	0.2	1.0	
Immediate postoperative complications	19.4	24.6	1.4 (1.1–1.7)
Urinary retention	2.2	2.8	
Urinary tract infection	0.4	1.0	
Hematoma or seroma	13.6	16.4	
Orchitis	1.1	1.4	
Wound infection	1.4	1.0	
Neuralgia or other pain	3.6	4.2	
Other	0.6	2.2	
Life-threatening complications‡	0.1	1.1	11.2 (1.3–95.3)
Long-term complications	17.4	18.0	1.1 (0.8–1.5)
Hematoma or seroma	3.0	9.0	
Orchitis or other testicular problems	2.2	1.9	
Infection	0.6	0.4	
Neuralgia or other pain	14.3	9.8	
Other	1.8	1.8	
Recurrence at two yr	4.9	10.1	2.2 (1.5–3.2)

* Some patients had more than one complication. Some long-term complications, notably hematoma and seroma, began in the immediate postoperative period and persisted. Neuralgia or other pain and orchitis were persistent in some patients but in other patients were newly observed at a long-term follow-up visit. CI denotes confidence interval, and NA not applicable.

† Problems related to anesthesia include difficulty with intubation or extubation, hypertension before or after intubation, arrhythmias, a chipped tooth, and ineffective local or spinal anesthesia, requiring conversion to general anesthesia.

‡ Life-threatening complications included myocardial infarction, ischemia, or arrhythmia (in three patients in the laparoscopic group and one in the open-repair group), port-site hernia (in two patients in the laparoscopic group), hemorrhage requiring reoperation (in two patients in the laparoscopic group), anaphylactic drug reaction (in one patient in the laparoscopic group), and postoperative respiratory insufficiency (in one patient in the laparoscopic group).

respect to all pain assessments by the time the three-month visit took place (Fig. 2).

The time to the resumption of daily activities was significantly shorter among those undergoing laparoscopic repair (median time, four days) than among those undergoing open repair (five days) (adjusted hazard ratio for a shorter time to return

to normal activities, 1.2; 95 percent confidence interval, 1.1 to 1.3). Approximately half the patients (859) were sexually active before the operation; the time to the resumption of sexual activity was similar in the two groups (median time, 14 days in the laparoscopic group and 14 days in the open group). More patients in the laparoscopic group than in the

open group were able to perform specific activities (e.g., climbing stairs and engaging in vigorous activities, such as shoveling or weight lifting) at two weeks. At three months of follow-up, however, differences in activity level between the groups were not apparent.

Both groups had improved function at three months relative to preoperative levels of function, according to physical-component scores and mental-component scores on the SF-36. There were no differences between the groups in the improvement in these scores at two years (data not shown).

SURGEONS' EXPERIENCE

We also performed a post hoc evaluation of the association between surgeons' self-reported experience (the number of procedures previously performed that involved use of the same technique [open or laparoscopic] as that for the planned operation, categorized as 0 to 25, 26 to 50, 51 to 75, 76 to 150, 151 to 250, and more than 250) and rates of hernia recurrence. The recurrence rate associated with laparoscopic repair was greater than 10 percent for the 58 surgeons who reported having performed 250 or fewer laparoscopic repairs in any category, whereas the recurrence rate was less than 5 percent for the 20 surgeons who reported having performed more than 250 laparoscopic repairs ($P < 0.001$ for the comparison of this category to all other categories). For open repairs, there was no significant difference in the rate of recurrence between the most experienced group of surgeons (those who had performed more than 250 repairs) and surgeons with less experience ($P = 0.12$). On the basis of the finding in the laparoscopic group, we defined "highly experienced" surgeons as those who reported having performed more than 250 repairs that involved use of the same technique as that for the planned operation. During the study period, 15 of 117 surgeons in the open group (12.8 percent) and 5 of 69 in the laparoscopic group (7.2 percent) gained enough experience to move into that category. The interaction between surgeons' experience and the treatment group was significant ($P = 0.013$).

Among primary-hernia repairs performed by highly experienced surgeons, recurrence rates did not vary significantly according to the type of procedure: of 253 such procedures in the laparoscopic group, recurrences occurred after 13 (5.1 percent), and of 635 such procedures in the open group, recurrences occurred after 26 (4.1 percent; adjusted odds ratio, 1.3; 95 percent confidence interval, 0.6

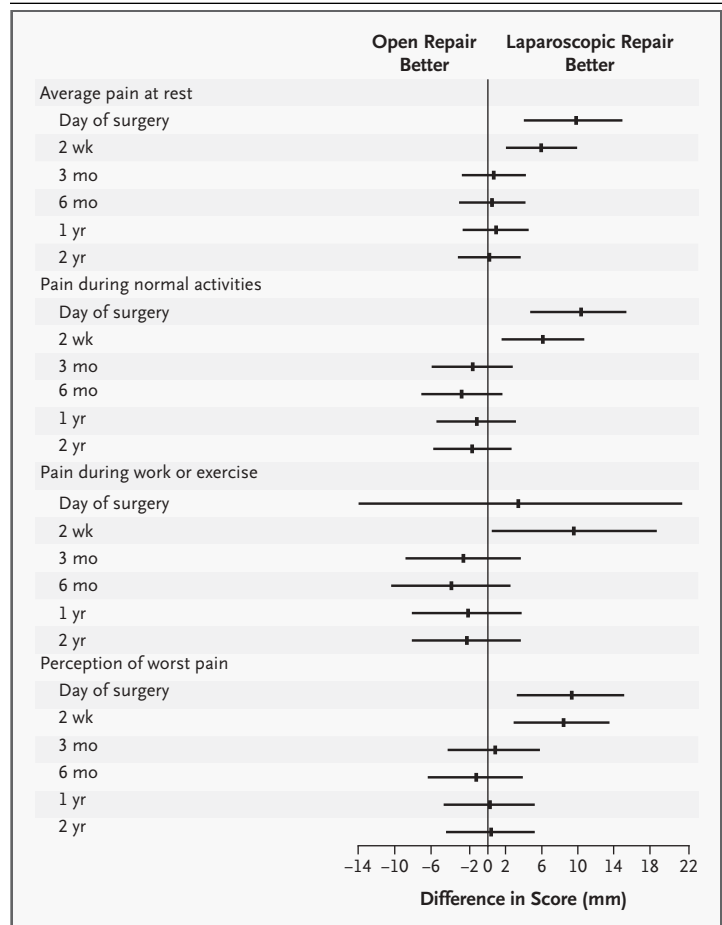


Figure 2. Difference between the Open-Repair and Laparoscopic-Repair Groups in Pain Scores on a Visual-Analogue Scale over Time, after Adjustment for Stratification Factors.

The visual-analogue scale was a 150-mm line with 0 (representing no pain) and 150 (representing the worst pain imaginable). In the graph shown, a value above 0 indicates more pain in the open-repair group than in the laparoscopic-repair group, and a score below 0 indicates more pain in the laparoscopic-repair group than in the open-repair group. The horizontal lines represent the 95 percent confidence intervals.

to 2.7). For less experienced surgeons performing primary repairs, the recurrence rate was greater after laparoscopic procedures (65 recurrences after 528 such repairs [12.3 percent]) than after open procedures (3 recurrences after 121 such repairs [2.5 percent]; adjusted odds ratio, 7.4; 95 percent confidence interval, 2.1 to 26.6). Among repairs of recurrent hernias performed by highly experienced surgeons, fewer recurrences were recorded after laparoscopic repair (1 recurrence after 28 such repairs [3.6 percent]) than after open repair (11 recur-

rences after 64 such repairs [17.2 percent]; adjusted odds ratio, 0.3; 95 percent confidence interval, 0.1 to 1.0), but the numbers were small. The number of recurrent hernia repairs performed by less experienced surgeons was insufficient to analyze (with a power below 25 percent to detect a difference of 15 percent).

DISCUSSION

This multicenter, randomized trial compared two tension-free, mesh-based hernia-repair techniques: the Lichtenstein open procedure and the laparoscopic procedure. Overall, recurrence rates were higher among patients whose hernias were repaired by the laparoscopic technique. There was significant interaction between the surgical approach and the type of hernia (primary or recurrent). Recurrence rates were significantly higher after laparoscopic repair of primary hernias than after open repair of primary hernias, but recurrence rates associated with the two techniques were similar for the repair of recurrent hernias. The presence of bilateral hernias did not alter the rate of recurrence after either procedure.

Intraoperative, immediate postoperative, and life-threatening complications were more frequent in the laparoscopic-repair group than in the open-repair group, although rates of long-term complications and mortality rates were similar in the two groups. These results are consistent with others' findings.^{11,12}

As other studies have reported, patients who underwent a laparoscopic repair returned to their usual activities one day sooner than those who underwent an open repair.^{11,12} Differences in activity levels were not apparent three months after the procedure and thereafter. Patients who underwent an open repair experienced significantly higher levels of pain than those who underwent a laparoscopic repair, both on the day of operation and at two weeks, but no significant differences were apparent after two weeks. Though statistically significant, the magnitude of the differences in pain may not be clinically meaningful.^{26,27} Results of sequential SF-36 assessments showed no significant differences between the two groups at any time. Because of the large number of secondary end points considered over several periods, some statistically significant findings could have occurred by chance alone.

In contrast to other findings published before this study was initiated, indicating that surgeons'

learning curve for laparoscopic hernia repair plateaued after as few as 30 cases,^{16,17} post hoc analyses in our study showed a decrease in the rate of recurrence only among surgeons who reported having previously performed more than 250 procedures. Recurrence rates among surgeons who had performed 250 or fewer laparoscopic hernia repairs were consistently above 10 percent. Among primary repairs performed by highly experienced surgeons (those who had performed more than 250 procedures), recurrence rates appeared to be similar for hernias repaired by the laparoscopic approach and those repaired by the open approach. These findings should be interpreted cautiously.

The rates of recurrence after repair of a recurrent hernia did not differ significantly between the groups. The high rate of recurrences after the repair of recurrent hernias by the open technique may be due to the presence of scarring, making further surgery difficult.

The overall increased rate of recurrence after laparoscopic repair in our study could be due to several factors. The high rate of retention in the study allowed us to assess recurrences thoroughly during the two-year follow-up period. In addition, objective assessment of recurrence was performed by an independent surgeon. The results of our large, multicenter, randomized trial may be a good indicator of the results that can be expected in the general population when hernia repair is performed by surgeons who are practicing outside of specialized centers.

This study has several limitations. The average age of the men enrolled was high, and their health-related quality of life was below that of the general population.¹⁵ Information on surgeons' experience was self-reported and may not have been precise. We excluded patients who had previously undergone a hernia repair with the use of mesh, and thus the data cannot be generalized to second repair procedures in these difficult cases. We conclude that for primary hernias, the open technique of tension-free repair is superior to the laparoscopic technique, both in terms of recurrence rates and in terms of safety.

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Dr. Fitzgibbons reports holding patents for an articulating stapler and a trocar site-closing device. He also reports serving as an expert consultant in matters involving a laparoscopic clip applier and hernia-repair mesh.

We are indebted to the American College of Surgeons for its support and to Margaret Ring Gillock for her editorial contributions. This study would not have been possible without the vision of James Carrico, M.D., who died before its completion.

APPENDIX

Members of VA Cooperative Study 456 were as follows (asterisks denote former participants): Chair — L. Neumayer (VA Medical Center, Salt Lake City); Biostatistician — A. Giobbie-Hurder; Health Scientist — J.O. Gibbs; Lead Health Economist — D.M. Hynes; Health Economist — K. Stroupe; Patient-Centered Outcomes Consultant — M. McCarthy; National Study Coordinator — R. Denwood*; Clinical Nurse Coordinator — S. Hatton-Ward; Data and Safety Monitoring Board — R. Bell (Northwestern University Medical School, Chicago), H. Buchwald (Chair) (University of Minnesota School of Medicine, Minneapolis), K.S. Ephgrave (VA Medical Center, Iowa City, Iowa), and R. Woolson (Medical University of South Carolina, Charleston); Executive Committee — C.J. Carrico (deceased) (University of Texas Southwestern Medical Center, Dallas), D. Dunlop and J.O. Gibbs (Northwestern University, Chicago), R.J. Fitzgibbons, Jr. (Creighton University, Omaha, Nebr.), W.G. Henderson (University of Colorado Health Outcomes Program, Aurora), A. Giobbie-Hurder, D.M. Hynes, and D. Reda (Acting Director) (Cooperative Studies Program Coordinating Center, Hines, Ill.), K. Itani (VA Medical Center, Houston), O. Jonasson (University of Illinois College of Medicine, Chicago), L. Kim (VA Medical Center, Dallas), M.J. London (VA Medical Center, San Francisco), L. Neumayer (Chair) (VA Medical Center, Salt Lake City), and T.N. Pappas (VA Medical Center, Durham, N.C.); End Points Committee — M.E. Arregui (Surgery, St. Vincent's Hospital and Healthcare Service, Indianapolis), M.J. Bishop (Anesthesiology, VA Medical Center, Seattle), and E. Jensen (Pathology, VA Medical Center, Salt Lake City); VA Central Office (Washington, D.C.) — J. Feussner (Chief Research and Development Officer), S. Berkowitz (Assistant Director, Cooperative Studies Program), and J. Gough (Program Assistant, Cooperative Studies Program); Site personnel — B. Bass, G. Bochicchio, C. Alvarez,* and K.B. Stem (Baltimore); J.J. Gleysteen, K. Mitchell, and R. Ragoza* (Birmingham, Ala.); G. Rodkey, R. Dennis, D. Soybel,* J. Gordon,* M. Campasano, B. Dionian,* and J. Moriuchi* (Boston); B. Miedema and K. Crews (Columbia, Mo.); T. Anthony, C. Willis, and C. Rowder* (Dallas); S. Tennenberg, R. Kozol,* and C. Yales (Detroit); N. Lee (Durham, N.C.); S. Brown (Houston); R. Muldoon,* D. Johnson,* and K. Marchant (Little Rock, Ark.); E. Mangiante, K. Phillips, K. VanFrank, F. Hatmaker,* and A. Collins* (Memphis, Tenn.); D.M. Hinson and B. Salabsky (Salt Lake City); Q.Y. Duh and M. Marovich (San Francisco); C. Mendez, T. Durrant, and B. Wright* (Tampa, Fla.); G. Glantz, E.H. Livingston,* and W. Murphy (West Los Angeles, Calif.); S. Hatton-Ward and B. Redfield (Chair's Office, Salt Lake City); K. Tir, S. Heard, J. Motyka, and C. Sullivan* (Cooperative Studies Program Coordinating Center, Hines, Ill.).

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