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Primary incisional hernia repair with or without polypropylene mesh: a report on 384 patients with 5-year follow-up

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Abstract *Background and aim:*
Several studies have claimed that
mesh repair of incisional hernia low-
ers recurrence rates when compared
to suture repair. We investigated the
relative effectiveness of mesh and
suture repair in a large homogeneous
cohort of patients with primary
incisional hernia. *Patients and
methods:* In a retrospective single-
centre cohort study, a total of 446
consecutive patients were identified,
of whom 86% could be followed up.
Mean length of follow-up was 5
years. In 79 patients (22%), we
implanted a mesh, usually polypro-
pylene (Prolene). *Results:* Compared
to suture repair, mesh repair pro-
longed operating time by over 30 min
and caused seroma in 12.7% of the
patients ($p<0.001$). Only 4 of the 79
patients with mesh repair developed
recurrence, compared to 55 of the 305
patients with suture repair (5 vs 18%,
$p=0.02$ by log-rank test). In multi-
variate Cox regression, recurrence
rates were fourfold higher after suture
than after mesh repair ($p=0.02$).
Interestingly, old age was associated
with a decreased susceptibility for
recurrence ($p=0.01$). *Conclusion:*
Our data confirms the long-term
effectiveness of mesh repair under
routine conditions. Suture repair
should be restricted to small hernias
in patients free of known risk factors.

Keywords Incisional hernia ·
Prosthetic mesh · Hernia recurrence ·
Multivariate model

Introduction

At least 10% of midline laparotomies are complicated by
the development of hernia. As there is no consensus about
the best technique for repairing incisional hernia, a variety
of different procedures are currently being used [7, 13].
Many surgeons have stopped to perform simple suture re-
pairs [15, 21] because additional implantation of a pros-
thetic mesh has been reported to yield lower recurrence
rates in various cohort studies [2, 19]. Whereas open sur-
gery for mesh placement has been a common technique for
many decades, laparoscopic mesh repair is quite a new
procedure, also requiring new mesh materials [3, 6, 12, 16].

However, to date, only four randomised controlled trials
have compared traditional suture repair vs open or laparo-
scopic mesh repair [5, 14, 18, 26]. Furthermore, these four
trials did not include patients with either a very large or a
very small hernia defect, thus suggesting that suture repair
still may be the standard technique in certain subgroups
of patients. Since prosthetic repair is associated with a high-
er incidence of haematoma, seroma and infection [11, 14,
16, 25], the decision between mesh or suture repair re-
quires a detailed assessment of the individual patient's risks
and benefits [7, 20]. Several studies therefore have looked
at patient-related factors that might portend an increased
likelihood of recurrence after incisional hernia repair.

The purpose of this study was to compare the recurrence
rates of open incisional hernia repair either with or without
mesh placement. In addition, we sought to identify patient-
related factors that were associated with a higher proba-
bility of recurrence.

Patients and methods

Study cohort

This retrospective study reviewed a consecutive series of patients treated within a single institution. Patients operated on between 1990 and 1999 were identified from the hospital's database of surgical procedures. All patients had been diagnosed to have an incisional hernia of the midline or any other place of the anterior abdominal wall. To make the patient sample more homogeneous, we excluded all patients who had been operated for a recurrent hernia (n=168 cases). This was also necessary to prevent multiple inclusion of the same patient in the database.

Surgical techniques and variables

The choice of surgical technique was left to the operating surgeon. During the last years of the study, however, mesh repair was gaining more and more popularity among study surgeons. If mesh repair was deemed necessary, the mesh was placed anterior to the posterior rectus sheath in most cases (i.e. sublay technique). In one third of the patients, onlay repair was performed. If reapproximation and apposition of hernia edges were impossible, the mesh was placed in between the edges (i.e. inlay technique, n=3). The standard prosthetic material used in mesh repair was monofilament double-fibre polypropylene (Prolene, Ethicon, Norderstedt, Germany). Three patients, however, received Goretex (W.L. Gore and Associates, Flagstaff, AZ, USA) and two received polyethylene. Mesh fixation was achieved by the use of non-resorbable 2–0 polypropylene sutures with additional tacks in a few patients. Suture repair consisted of Mayo duplication in 82% of patients, whereas the remaining patients received a simple reapproximation of fascia edges with either single stitch or continuous sutures. Non-resorbable sewing material was used.

The incidence of complications was determined by using homogeneous definitions. As seroma, we counted only those fluid collections that required puncturing due to symptoms. The definition of wound infection was based on microbiologic culture together and clinical signs of infection. Primarily, follow-up evaluation consisted of a detailed review of hospital records. This was followed by a mail survey, where patients were asked to provide information on their clinical course and the occurrence of a recurrence. For those patients who did not reply, we obtained information directly from their general practitioners or other physicians. Only patients with complaints suggestive of recurrence were invited for a hospital visit.

Recurrence was defined as any palpable protrusion at the site of the prior repair. The time lapse to recurrence was determined from the patient's symptoms. In cases where only the date of reoperation was known (n=28), we assumed recurrence to have taken place 1 month prior to surgery.

Statistical analysis

Possible associations between therapeutic and prognostic variables and hernia recurrence were first examined univariately by means of Student's t test and Fisher's exact test. For variables with more than two categories, we employed the chi-square test, including trend analysis, where appropriate. Since different lengths of follow-up can possibly lead to different absolute recurrence rates, we used life-table analyses to adjust for these group differences. For multivariate analysis, we used the Cox regression model. The full Cox model included age, gender, body mass index (BMI), hernia size, hernia localization and mesh use. Age and BMI were used as continuous variables. By backward selection of variables with the threshold at p=0.1 by Wald's test, a simplified model was developed. The fit of the model was assessed by the −2 log-likelihood ratio. For all risk ratios (RRs), 95% confidence intervals (95% CIs) were calculated. Our data is reported as means with standard deviations (SDs).

Table 1 Demographic characteristics of the study population

	Patients with follow-up	Patients without follow-up	p Value
n	384	61	–
Age (mean, SD)	62.7 (12, 6)	58.9 (15, 2)	0.07[a]
Gender (female/male)	218/166	35/26	>0.99[b]
BMI			0.15[c]
Less than 20 kg/m²	11 (3%)	1 (2%)	
20 to <25 kg/m²	101 (28%)	10 (17%)	
25 to <30 kg/m²	160 (44%)	25 (43%)	
30 kg/m² or more	92 (25%)	22 (28%)	
Weight data missing	20	3	
Hernia orifice diameter			0.74[c]
Less than 2 cm	86 (22%)	12 (20%)	
2 to <4 cm	130 (34%)	24 (39%)	
4 cm or more	126 (33%)	17 (28%)	
Complete dehiscence	42 (11%)	8 (13%)	
Midline hernia	211 (59%)	37 (61%)	0.90[b]
Mesh implantation	79 (21%)	7 (11%)	0.15[b]

[a]Student's t test
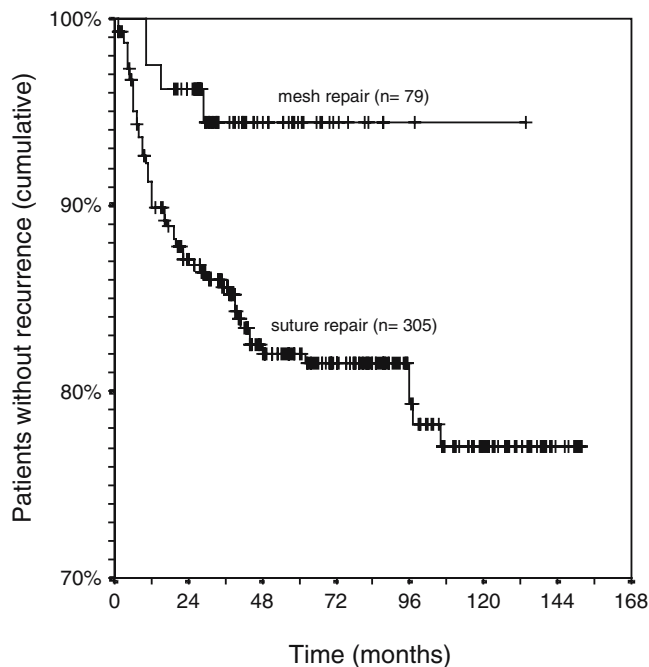[b]Fisher's exact test
[c]Chi-square test

Fig. 1 Kaplan–Meier analysis of recurrence after mesh or suture repair. (The numbers of patients at risk after 24, 36, 48 and 60 months are 70, 38, 24 and 15 in the mesh repair group and 244, 212, 170 and 145 in the suture repair group, respectively)

Results

In 89 patients, follow-up was not possible, thus leaving 384 patients with primary incisional hernia for analysis. This represents 86.3% of all 446 cases. Patients who were lost to follow-up did not differ from those included in the study, although they tended to be younger, heavier and less likely of having received suture repair (Table 1). The mean duration of follow-up was 60 months (SD 40, median 48). There was a strong association between hernia size and surgeon preference for implanting a mesh ($p<0.001$ by chi-square test).

Mesh repair took significantly longer to perform, with a mean operating time of 78.3 min (SD 38.9, $n=79$), whereas suture repair was accomplished within a mean time of only 52.9 min (SD 36.5; $n=305$). In both groups, about every fourth patient underwent an additional procedure (e.g. cholecystectomy) during the same anaesthesia (20 of 79 vs 88 of 305 cases). After exclusion of these cases with other simultaneous operations, operation times were shorter, but still significantly different with a mean difference of 31.8 min (95% CI 21.5 to 42.2) in favour of suture repair. Seroma developed in 12.7% of mesh repair patients, but only in 1.6% of suture repair patients ($p<0.001$). Wound infection occurred in two patients (2%) after mesh repair and nine patients (3%) after suture repair. Two of 11 infected cases also developed recurrence ($p=0.68$). Postoperative hospital stay did not differ between mesh and suture repair with 11.5 days (SD 8.4) vs 10.2 days (SD 5.6).

In total, there were 59 recurrences among the 384 patients (15.4%). Of all recurrences, 28 (48%) developed within the first year, 14 (24%) between the first and the second year, whereas 17 (29%) hernias recurred after more than 2 years. Only 4 of the 79 patients with mesh repair developed recurrence as compared to 55 of 305 patients with suture repair (5 vs 18%). Three of these recurrences were seen after sublay repair. In survival curve analysis (Fig. 1), the proportion of recurrence-free patients was significantly higher in the mesh than in the suture repair group ($p=0.015$ by log-rank test). Also in multivariate analysis, suture repair as opposed to mesh repair resulted in a fourfold higher risk of recurrence ($p=0.017$; Table 2). Results did not essentially alter when excluding three patients who had received inlay mesh repair or five patients, in whom a mesh other than Prolene was used. None of these eight patients experienced recurrence. Similarly, recurrences were not more frequent after simple suture as compared to Mayo duplication.

With regard to patient characteristics, we noted that patients with recurrence were significantly younger (mean 58.1 years, SD 11.1) when compared to those without recurrence (63.5, 12.7). Furthermore, only 18 of the patients (11%) in the age group over 65 years suffered a recurrence as opposed to 41 (19%) of a younger age ($p=0.03$). Nineteen of the 57 recurrent cases (33%) were obese (defined as a BMI over 30), whereas obesity was present in only 73 (24%) of the non-recurrent cases ($p=0.28$). The distribution of recurrence was not associated with gender ($p>0.99$) or hernia size ($p=0.48$). In full multivariate Cox regression (Table 2), only age was significantly associated with recurrence. In the reduced regression model, three variables were selected as predictors of recurrence: age [odds ratio (OR) 0.97, 95% CI 0.95 to 0.99], hernia size (OR 1.28, 95% CI 0.96 to 1.69) and non-mesh repair (OR 4.4, 95% CI 1.4 to 14.2).

Table 2 Results of multivariate analysis (full Cox regression model; −2 log-likelihood ratio 619.5)

Risk factor	Coding of variable	RR (95% CI)	p Value (Wald's test)
Gender	Women vs men	1.02 (0.60–1.78)	0.920
Age	Per each life–year increase	0.97 (0.95–0.99)	0.013
Weight	Per one unit BMI (kg/m^2) increase	1.29 (0.93–1.81)	0.133
Hernia size	Per one degree of size (1 to 4 scale)	1.12 (0.90–1.40)	0.328
Hernia localization	Midline hernia vs other sites	1.30 (0.75–2.24)	0.363
Mesh implantation	Without vs with mesh	4.18 (1.29–13.57)	0.017

Discussion

In this study, incisional hernia had excellent long-term results, with minimal morbidity. Our data is in good concordance with the randomised evidence on mesh implantation for incisional hernia repair. In the trial by Burger et al. [4] and Luijendijk et al. [18], recurrence rates for primary incisional hernia repairs with and without mesh were quite high (24 and 43% after 5 years and 32 vs 63% after 10 years). Our data confirm that mesh techniques can at least halve recurrence rates. Low recurrence rate in our study is partly due to the exclusion of cases with recurrent incisional hernia. As we were partly reliant on the patients themselves reporting non-recurrence, absolute recurrence rates were probably understimated in the present study. On the other hand, our findings are important for surgeons because the generalizability of randomised trials in surgery is considered to be low due to many differences in case of mix, surgical skill and healthcare settings [9].

A possible weakness of the present study lies in its retrospective design. We tried to standardise surgery, perioperative care and data collection so that the long time span of the study does not interfere with results. The grouping of onlay and sublay repair into one single group remains disputable, but major differences between the two techniques were not detectable. Furthermore, multivariate techniques were used to account for baseline differences between the different groups. As a result of which, shorter duration of follow-up in the mesh repair group was accounted for. Another great strength of the present study, other than its huge data intake, is the high percentage of follow-up examinations and their long duration, which suggests that our results are valid with regard to overall representativeness. External validity was additionally tested by analysing those patients who were lost to follow-up. Finally, the homogeneity of the patient sample was high, since this was a monocentric study focussing on primary incisional hernia exclusively.

When looking at the clinical variables, an expected finding of this study was the (non-significant here) relationship between the width of the hernia defect and the rate of recurrence. Similarly, obesity was confirmed as a prognostic variable [23]. Contrary to common belief [1], however, this study also found that young age is independently associated with incisional hernia recurrence. No experimental or clinical trial has yet shown that young or old age strongly interfere with wound healing. We suggest that the higher incidence of recurrence in younger patients may probably reflect inherent defects of collagen metabolism [22] rather than higher levels of physical activity during work or leisure.

The decision of incisional hernia repair technique is commonly made on an individual basis, although the reasons for this are not clear and may include reimbursement problems with a uniform policy of mesh repair for all cases. Therefore, the importance of prognostic variables is increasing. Still, we believe that the majority of incisional hernias are best being treated with mesh implantation. Nevertheless, mesh repair also induces other problems. Although we found a clearly increased risk of seroma formation after mesh repair, the clinical importance of this complication should not be overrated. Furthermore, the rate of infection was just as low after mesh as with suture repair.

During the last years, newer mesh products have begun to decrease the amount of biomaterial that is implanted. In this regard, Prolene (which was used in this trial) represents the second generation of materials. It is medium weight but slightly softer than previous monofilamented products. We did not specifically assess mesh-related complications, such as stiffness and pain of the abdominal wall or adhesions, but we are not aware of any patients with such problems. In Germany, Prolene has been the leading mesh product in incisional hernia repair over many years [15]. Still, it may be argued that the ideal mesh has yet to be developed [10]. In this regard, slowly resorbable meshes represent a new and promising alternative, which we are starting to test now [24].

Of particular importance is the technique of mesh implantation and fixation. We agree that mesh inlay is not a good option and should be restricted to large defects in which the peritoneum cannot be closed over the viscera. When comparing onlay and sublay mesh repair, we were unable to detect major differences. In other studies, implanting the mesh in an onlay position (as described by Chevrel [8]) was found to frequently cause seroma [17, 27], but the more important effect on recurrence needs to be determined in randomised trials. We know of two such trials, the results of which will be available soon.

The obvious conclusion of this study is that one should refrain from suture repair techniques in most patients with incisional hernia. Only those hernias with a narrow gap can be simply resutured if the patient is free of known risk factors. Younger patients should not generally be denied mesh repair, since young age was independently associated with recurrency.

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