Randomized clinical trial comparing lightweight composite mesh with polyester or polypropylene mesh for incisional hernia repair

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Background: Polymer mesh has been used to repair incisional hernias with lower recurrence rates than suture repair. A new generation of mesh has been developed with reduced polypropylene mass and increased pore size. The aim of this study was to compare standard mesh with new lightweight mesh in patients undergoing incisional hernia repair.

Methods: Patients were randomized to receive lightweight composite mesh, or standard polyester or polypropylene mesh. Outcomes were evaluated at 21 days, 4, 12 and 24 months from patient responses to the Short Form 36 (SF-36) and daily activity questionnaires. Complications and recurrence rates were recorded.

Results: A total of 165 patients were included in an intention-to-treat analysis (83 lightweight mesh, 82 standard mesh). Postoperative complication rates were similar. The overall hernia recurrence rate was 17 per cent with the lightweight mesh versus 7 per cent with the standard mesh (P = 0.052). There were no differences in SF-36 physical function scores or daily activities between 21 days and 24 months after surgery.

Conclusion: The use of the lightweight composite mesh for incisional hernia repair had similar outcomes to polypropylene or polyester mesh with the exception of a non-significant trend towards increased hernia recurrence. The latter may be related to technical factors with regard to the specific placement and fixation requirements of lightweight composite mesh.

Introduction

Incisional hernia is a complication in 11–20 per cent of patients after laparotomy¹,² and can lead to bowel strangulation, requiring emergency surgery³. In most cases elective repair is the preferred option. The rate of recurrence remains high¹, although it has been reduced to less than 10 per cent by the use of prosthetic mesh⁴. The only randomized controlled trial of recurrence following repair of incisional hernia reported a recurrence rate of 23 per cent for mesh repair compared with 46 per cent for suture repair⁵.

Complications of mesh include local wound infection⁷ and seroma, patient discomfort and restriction of abdominal wall mobility⁸,⁹. Standard flat mesh made from polypropylene or polyester has a tensile strength that is far greater than that required physiologically¹⁰. Reducing the amount of polypropylene by increasing pore size produces a lighter weight mesh that may improve the functional properties and diminish local complications¹¹. Lightweight composite mesh is the result of incorporating an absorbable component into a reduced polypropylene mass¹².

To evaluate the potential of lightweight composite mesh, a prospective randomized multicentre trial was...
undertaken in patients undergoing incisional hernia repair.

**Patients and methods**

Eight surgical centres participated in the trial: four from Germany, two from the UK, one from France and one from the Netherlands. Local ethics committee approval was obtained for each surgical centre to enrol patients with an incisional hernia into a randomized trial comparing repair with lightweight composite mesh to repair using one of three standard meshes. Randomization was achieved by computer-generated random numbers in sealed envelopes with block sizes to ensure balanced recruitment within each centre.

All patients gave written informed consent. Patients had to be more than 18 years old. Patients were excluded if the hernia was less than 4 cm in diameter, or acute and incarcerated, or if the hernia was not derived from a vertical midline incision. The study was observer and patient blinded, such that the study personnel performing the postoperative assessments and the patients were unaware of treatment allocation.

**Meshes**

Three meshes, two polypropylene and one polyester (Atrium™, Atrium Medical, Mijdrecht, The Netherlands; Marlex™, C.R. Bard, Inc, Murray Hill, NJ, USA; and Mersilene™, Ethicon GmbH, Norderstedt, Germany), were used for standard mesh repair. The decision to use a particular mesh was based on the standard treatment in each centre, and individual centres used the same standard mesh throughout the study.

The lightweight composite mesh was constructed from multifilaments of polypropylene with additional absorbable polyglactin (Vypro™; Ethicon GmbH). Absorption of the polyglactin component usually takes up to 84 days.

Characteristics of all the meshes employed are summarized in Table 1.

**Baseline characteristics**

Details of patient demography, medical history and occupation were recorded. Before surgery, all patients completed Short Form 36 (SF-36) and daily activity questionnaires.

**Operative details**

The type, size and dimensions of the hernia defect were recorded, in addition to operating time and type of anaesthesia. The mesh was implanted using the modified preperitoneal sublay procedure described by Rives et al. The different layers of the abdominal wall were reconstructed with mesh placed behind the rectus muscle. The posterior rectus sheath and the peritoneum were closed to prevent direct contact between mesh and intestine. The mesh was sized to give an overlap of at least 5 cm in all directions from the aponeurotic edges. Fixation of the mesh was performed according to each centre’s standard procedure; some used absorbable and others non-absorbable sutures, employing interrupted or continuous suture techniques. The anterior fascia of the rectus sheath was then closed to reconstruct the linea alba. Drainage and wound closure was performed according to each centre’s standard procedure.

**Clinical follow-up**

Patients attended for clinical follow-up at 21 days, 4, 12 and 24 months after surgery. At each visit, a SF-36 and daily activity questionnaire was completed. Times for return to normal activities and work were recorded. Wound assessments were completed to determine the presence of wound infection, seroma, haematoma, chronic wound pain and recurrence.

**Statistical analysis**

Owing to lower than expected patient recruitment, the power of the study was reduced to 80 per cent, requiring 126 patients. Consequently, enrolment was stopped once...
sufficient patients had been recruited for testing with reduced power.

The primary endpoint was the SF-36 physical function score at 21 days after surgery. Before testing for any treatment difference, the standard mesh group was tested for homogeneity with regard to the three polypropylene and polyester meshes. If there was no evidence of a significant difference ($P < 0.050$) between results from the standard meshes, homogeneity was assumed and the standard mesh results were combined.

Analysis of variance was used to examine the effect of treatment, centre, pretreatment score, age and sex. The analysis was based on an intention-to-treat population that included all randomized patients who had incisional hernia repair within the study. For the primary analysis, patients with 21-day data were included. For physical function scores and daily activity questionnaire variables at 4, 12 and 24 months, patients with missing data for an assessment were analysed using the last valid observation carried forward. Times for return to work and normal activities were analysed using survival techniques (Kaplan–Meier plots). For wound complications, a $\chi^2$ test that allowed for centre differences was used (Cochran–Mantel–Haenszel test) to determine any treatment differences. Other data were not analysed statistically but were summarized as mean(s.d.) (range) values.

### Results

#### Baseline

Between June 1999 and December 2000, 171 patients agreed to take part in the study. A total of 165 patients met the criteria for analysis: 83 received the lightweight composite mesh and 82 a standard mesh. Some 136 patients (80.5 per cent) completed the study after a follow-up of 2 years (Fig. 1). Twelve patients (7 per cent) withdrew consent, ten (6 per cent) were lost to follow-up, one patient in the composite mesh group died from pulmonary embolism 4 days after surgery, and ten (6 per cent) withdrew for other reasons (five from each group). In each group there were two patients who did not wish to attend as they were in good health, and three who were in hospital or care for other reasons.

Patient and hernia characteristics in the treatment groups were similar at trial entry (Table 2), although a greater proportion of men had standard mesh repair (56 versus 47 per cent for lightweight mesh). Baseline SF-36 dimension scores were comparable, although emotional problems scored higher in the standard mesh group.

#### Surgical details

All procedures were performed under general anaesthesia. The mean(s.d.) operating time was 1.8(0.7) h for both standard and composite mesh repair. Three centres used non-absorbable sutures to fix the mesh (40 patients), and absorbable sutures were used in five centres (125 patients).

There was no difference in the mean(s.d.) number of days spent in hospital after surgery (14(0.8-2) days for composite mesh versus 13(2) days for standard mesh).
Short Form 36 physical function dimension

Homogeneity testing across the three standard mesh repairs confirmed that there was no significant treatment effect, enabling the data to be combined for comparison with composite mesh.

Some 130 patients completed the SF-36 physical function scoring at baseline and at 21 days, and were thus included in the analysis. There was no difference between the two mesh groups at day 21, with a mean value of 50·4 for composite mesh and 48·4 for standard mesh. By 4 months after surgery, physical function scores were higher than baseline and day 21 values, and remained unchanged between 4 and 24 months (Fig. 2).

Other Short Form 36 dimension scores

There were no differences in the scores of other SF-36 dimensions (physical problems, emotional problems, social functioning, mental health, energy/vitality, pain, general health perception and change in health) at any time point.

Daily activities

As expected, there were marked reductions in the ability to perform strenuous daily activities (stretching, arising from bed in the morning, arising from a sitting position and heavy lifting) 21 days after surgery compared with baseline. Heavy lifting was severely limited in more than 60 per cent of patients at 21 days, compared with around 40 per cent at baseline. At 4, 12 and 24 months, the number of patients without limited daily activities was largely unchanged from baseline. Improvements from baseline were observed for heavy lifting, tying laces, coughing and sneezing. Both treatment groups followed the same pattern over time.

Wound complications

Although fewer seromas were observed at 21 days after standard mesh repair, between 4 and 24 months there were more seromas than with the composite mesh. Overall, there was no difference in the number of seromas during the 24-month follow-up; about one-third of patients developed a seroma (Table 3).

Five patients had a postoperative haematoma that required surgery (four with composite mesh versus one with standard mesh). The rates of other wound complications were similar, and no patient required mesh removal for infection (Table 3).

Chronic wound pain was recorded only at 12 and 24 months. Three patients with composite mesh were affected at 24 months, and five with standard mesh (three at 12 months and two at 24 months).

Recurrence

Overall, 20 recurrent hernias were identified during follow-up: 14 (17 per cent) in the composite mesh group and six (7 per cent) in the standard mesh group.

Table 3 Wound assessment after repair of incisional hernia with mesh

<table>
<thead>
<tr>
<th></th>
<th>Composite mesh (n = 83)</th>
<th>Mersilene™ (n = 34)</th>
<th>Marlex™ (n = 29)</th>
<th>Atrium™ (n = 28)</th>
<th>Overall standard mesh (n = 82)</th>
<th><em>p</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Seroma</td>
<td>28 (34)</td>
<td>3 (9)</td>
<td>4 (20)</td>
<td>17 (61)</td>
<td>24 (29)</td>
<td>0·270</td>
</tr>
<tr>
<td>Haematoma requiring surgery</td>
<td>4 (5)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td>1 (1)</td>
<td>0·187</td>
</tr>
<tr>
<td>Minor haematoma</td>
<td>13 (16)</td>
<td>4 (12)</td>
<td>3 (15)</td>
<td>6 (21)</td>
<td>13 (16)</td>
<td>0·790</td>
</tr>
<tr>
<td>Wound infection requiring surgery</td>
<td>5 (6)</td>
<td>1 (3)</td>
<td>1 (5)</td>
<td>3 (11)</td>
<td>5 (6)</td>
<td>0·916</td>
</tr>
<tr>
<td>Minor wound infection</td>
<td>10 (12)</td>
<td>2 (6)</td>
<td>3 (15)</td>
<td>3 (11)</td>
<td>8 (10)</td>
<td>0·580</td>
</tr>
<tr>
<td>Bruising</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td>1 (1)</td>
<td>0·914</td>
</tr>
<tr>
<td>Hernia recurrence</td>
<td>14 (17)</td>
<td>5 (15)</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td>6 (7)</td>
<td>0·052</td>
</tr>
<tr>
<td>Neuralgia</td>
<td>3 (4)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>5 (18)</td>
<td>5 (6)</td>
<td>0·488</td>
</tr>
</tbody>
</table>

Values in parentheses are percentages. *Composite versus standard mesh (Cochran–Mantel–Haenszel test).
Time to recurrence ranged from 131 to 742 days for composite mesh and from 164 to 833 days for standard mesh. Statistical analysis indicated a non-significant difference in favour of standard mesh ($P = 0.052$, Cochran–Mantel–Haenszel test).

**Discussion**

The use of mesh for repair of incisional hernia has been shown to halve the rate of recurrence compared with standard suture repair\(^6\). However, reports of complications following the use of standard polypropylene mesh have ranged from minor complaints, such as discomfort and increased wound infection rate, to more serious but rare complications, such as perforation and fistula formation\(^7\). Modifications to limit foreign body material by reducing polypropylene mass and increasing pore size have led to the development of a more physiologically compatible mesh\(^12\). In experimental studies this material-reduced mesh had a significantly decreased foreign body reaction in comparison with standard mesh. Investigation of abdominal wall mobility by three-dimensional stereography revealed a pronounced restriction after incisional hernia repair with standard mesh\(^9\).

This prospective randomized multicentre trial compared standard polypropylene and polyester mesh with lightweight composite mesh for incisional hernia repair. The primary endpoint was SF-36 function after 21 days. There were no treatment differences between the two groups in the SF-36 domains or daily activity questionnaire findings at 21 days, or at any of the later time points. After a decrease in SF-36 scores between baseline and 21 days after surgery, both groups showed a noticeable improvement between 21 days and 4 months. Between 4 and 24 months, the SF-36 values showed no further improvement. Noticeably, the SF-36 function scores at 4 months were above baseline and remained at this higher level for the rest of the follow-up, confirming the benefit of the operation, irrespective of type of mesh. Analogous results were published recently by Post et al.\(^{15}\) for Lichtenstein groin hernia repair with lightweight composite mesh.

There were two shortcomings to this study. First, the textile parameters of the polyester mesh (Mersilene\(^\text{®}\)) resembled those of the composite mesh. Second, most of the patients with chronic postoperative pain had one type of standard polypropylene mesh (Atrium\(^\text{®}\)), which was used in only three of the study centres. A subanalysis of data from these three centres revealed that 5 of 28 patients with Atrium\(^\text{®}\) mesh had chronic pain, compared with 3 of 83 patients who had lightweight mesh. Although not statistically significant, this trend was consistent with the reduction in pain observed following the use of lightweight mesh for Lichtenstein hernia repair\(^{15,16}\). In addition, previous studies used specific questions related to hernia repair as primary endpoints, whereas in the present study the physical function domain of the SF-36 was not sufficiently specific to detect differences in groin pain.

Secondary endpoints were mesh-related complication and recurrence. About one-third of the patients had seroma formation, independent of the type of mesh implanted. Schachtrupp et al.\(^{17}\) have shown that there is an individual response to biomaterials. The size of seroma varied greatly, ranging from less than 1 cm\(^3\) to more than 2000 cm\(^3\). In previous reports\(^{18,19}\), the rate of seroma formation varied between 0 and 41 per cent, probably depending on the diagnostic effort for detection.

In the present trial there was also a high rate of reoperation for haematoma. Whether this was due to ultrasonographic findings with, or without, clinical relevance cannot be differentiated retrospectively. The rate of infection after mesh repair was similar for the two types of mesh, and accords with the literature in which variations between 4 and 16 per cent have been described.\(^6,20\). The infections were mostly subcutaneous and it was never necessary to remove the mesh.

The overall hernia recurrence rate (12.1 per cent) in this trial was higher than that in personal series, but lower than in the other prospective randomized trial\(^6\). Although not statistically significant, the recurrence rate after lightweight composite mesh repair was higher than with standard polypropylene or polyester mesh (17 versus 7 per cent). Most recurrences occurred at the cranial edge of the wound in the midline, revealing a possible technical problem in achieving sufficient mesh coverage\(^{21–23}\). The surgical steps of the operation, such as suture technique and material for mesh fixation, and closure of the anterior fascia were performed according to each centre’s standard procedure. Examination of the surgical details showed that in 19 of the 20 patients with recurrence absorbable sutures were used for both mesh fixation and closure of the anterior fascia. The importance of surgical technique in preventing recurrence was underlined by the fact that only three of the eight centres were responsible for all recurrences.

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Lightweight versus standard mesh for incisional hernia repair

References