

# Incisional Hernia: an experimental and clinical study



Martijne van 't Riet



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an experimental and clinical study**

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ISBN: 90-77595-75-9

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Printed by Optima Grafische Communicatie, Rotterdam

**Incisional Hernia:  
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Littekenbreuken:  
een experimentele en klinische studie

**Proefschrift**

ter verkrijging van de graad van doctor  
aan de Erasmus Universiteit Rotterdam  
op gezag van de Rector Magnificus

Prof.dr. S.W.J. Lamberts

en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op  
woensdag 1 september 2004 om 15.45 uur

door

Martijne van 't Riet  
geboren te Utrecht

**Promotiecommissie:**

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Prof.dr. ir. C.J. Snijders  
Prof.dr. O.T. Terpstra

This thesis was financially supported by:  
Johnson & Johnson Medical BV, KCI Medical BV, Rembrandt Medical, Janssen Cilag BV,  
Tyco Healthcare Nederland BV, Bard Benelux NV.

*Aan mijn Ouders,  
aan Jurgen*





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# CHAPTER 1

General introduction

## Introduction

Incisional hernia is one of the most common long-term complications of abdominal surgery. In prospective studies with sufficient follow-up, incidences of incisional hernia after laparotomy up to 20% are reported<sup>1-4</sup>.

Incisional hernia can be defined as an internal abdominal wall defect that develops after a previously closed laparotomy. Intra-abdominal organs such as omentum, bowel or bladder may protrude through the fascial defect, covered by a peritoneal sac and intact skin<sup>5</sup>.

If a rupture of the abdominal wall occurs within the first postoperative days, when the skin has not healed yet, this is defined as a different entity, known as “platzbauch”, “burst abdomen” or “wound dehiscence”.<sup>6,7</sup> In this condition, there is no peritoneal sac and the intra-abdominal organs protrude through the gaping wound. The degree of healing of the skin wound determines whether fascial dehiscence presents as burst abdomen or incisional hernia.

Many incisional hernias are asymptomatic. However, incisional hernias can also be an important source of morbidity. Apart from discomfort and pain, incisional hernia may lead to serious conditions such as incarceration (6-15%) or strangulation of bowel (2%)<sup>8,9</sup>. If not promptly reduced, these conditions can be fatal.

Treatment of incisional hernia following primary nonprosthetic repair has poor results, with recurrence rates of 24 to 54%<sup>10-14</sup>. Prosthetic repairs have better but still high recurrence rates, of 10 to 34%<sup>15-17</sup>. Because of insufficient follow-up, these figures are often underestimated by surgeons who perform incisional hernia repair<sup>18</sup>. For this reason, many surgeons continue to treat incisional hernias with inadequate procedures, thereby contributing to the magnitude of the problem<sup>19</sup>.

In addition to the consequences of the development of an incisional hernia for the individual patient, the high incidence of incisional hernia and poor results of incisional hernia repair have important economic consequences as well. Therefore, prevention of incisional hernia and improvement of incisional hernia repair are mandatory.

## Etiology and risk factors for the development of incisional hernia

### *Wound healing*

With regard to the pathogenesis of incisional hernias, the healing process of the abdominal wound is of special interest. The dynamic process of wound healing can be divided into three phases<sup>20,21</sup>. The first exsudative or inflammatory phase (1st through 4th day) is dominated by vascular, cellular and enzymatic processes and does not provide any holding strength between the edges of the wound. During the second proliferative phase (5th through 20th day), proliferating fibroblasts and macrophages are responsible for the formation of collagen. This results in a rapid increase of tensile strength of the wound, up to 30% of the original tensile strength of the intact tissue. In the third phase, the remodelling phase (21st day up to years), collagen fibers reorganize in a direction that is determined by stress and strain. This phenomenon is called cross-linking, and results in an increase of tensile strength up to 80% of the original tensile strength. The wound however, will never reach the original tensile strength<sup>22,23</sup>.

Disturbance of collagen synthesis may lead to a reduction of tensile strength. Collagen synthesis requires the presence of vitamin C, the elements Zn, Fe, Cu and an adequate oxygen tension. Deficiency of these factors may therefore contribute to the formation of incisional hernias. Further, an altered ratio of collagen types I and III with an increase of collagen type III has been claimed to reduce the mechanical strength of connective tissues, predisposing to the formation of hernias<sup>24-26</sup>.

### *Onset of herniation*

Incisional hernias become apparent over time after surgery. In long term follow-up studies, several authors demonstrated that the incidence may be expected to almost double after the first year<sup>1,8,11,27-29</sup>. The late onset of some hernias has led to the believe that soundly healed laparotomies can weaken over a period of many months due to chronic mechanic stress of immature collagen, allowing the protrusion of a hernial sac<sup>30</sup>. There is, however, an alternative hypothesis regarding the onset of herniation. In this theory, the parting of the sutured aponeurotic edges occurs already within the first few weeks after the operation, and is

not a result of later weakening of a well-healed wound. The gap between the aponeurotic edges is filled by weak fibrous tissue, which gradually stretches to allow later protrusion of a hernia. This theory is supported by two studies<sup>31,32</sup>. In these studies, radio-opaque markers were placed on the edges of the aponeurosis during the closure of laparotomy, in respectively 56 and 149 patients. In 24 patients (6 out of 56 patients and 18 out of 149 patients), early separation of the clips (>12 mm) was visible on postoperative plain radiographs of the abdomen. Twenty-three of these 24 patients with early separation of the clips developed incisional hernias, while none of the patients without early separation of the clips developed incisional hernias. Many of these hernias became clinically apparent after more than one year postoperatively. Thus, an early onset of herniation appears likely.

### *Risk factors*

In the pathogenesis of incisional hernias, numerous factors are believed to play a role. Patient-related (endogenous), as well as operation-related (exogenous) risk factors can be identified. In most cases, more than one risk factor is present.

#### *Patient-related risk factors:*

Impaired wound healing is an important factor in the pathogenesis of incisional hernia. Conditions associated with impaired wound healing are increased age, diabetes mellitus, smoking, obstructive jaundice, collagen diseases, chronic use of corticosteroids, malnutrition, oncologic disease, radiotherapy and chemotherapy. Of these conditions, increased age, diabetes mellitus, smoking, obstructive jaundice and collagen diseases (including aneurysm of the abdominal aorta) were identified as significant risk factors for the development of incisional hernia<sup>33-46</sup>. Further, multiple previous laparotomies have also been shown to weaken the abdominal wall and increase incisional hernia incidence<sup>47</sup>.

Increased intra-abdominal pressure is another important factor for the development of incisional hernia. With increased intra-abdominal pressure, any point of weakness in the abdominal wall may permit the development of an incisional hernia. Conditions that may increase intra-abdominal pressure are obesity, pulmonary diseases, prostatism, obstipation and postoperative abdominal distention. Of these, obesity, pulmonary disease with coughing

and postoperative abdominal distention were identified as significant risk factors for the development of incisional hernia in several studies<sup>33,35,37,38,48</sup>.

Obesity is regarded as one of the most important risk factors for the development of incisional hernia<sup>19</sup>. It is associated with increased intra-abdominal pressure, as well as increased infection rate and impaired wound healing<sup>7,38,49,50</sup>. Because many surgeons consider obesity as a relative contra-indication for incisional hernia repair, they postpone the operation until the patient has lost sufficient weight<sup>19</sup>.

#### *Operation related risk factors*

Of all factors influencing the incidence of incisional hernia, surgical technique is of special interest, since it is the only factor that can be controlled directly by the surgeon. Most important operation-related risk factors are the selected type of incision for laparotomy, and suture material and technique of fascial closure. These factors will be discussed in **chapter II and III** of this thesis.

Other operation-related factors influencing incisional hernia incidence significantly were increased duration of operation and increased peroperative blood loss (also reflected by increased blood transfusion)<sup>51-54</sup>.

Regarding the impact of the surgeon's experience on incisional hernia incidence, two authors reported a significant decrease of incisional hernia incidence with increased experience of the surgeon<sup>33,55</sup>. This was, however, not confirmed in three other studies, which showed no difference in incisional hernia incidences after surgery by either surgical residents or registered surgeons<sup>47,52,56</sup>.

Regarding postoperative complications, wound infection is of special interest. In patients with wound infection, high incidences of incisional hernia ranging from 19% to 64% have been reported<sup>53,57</sup>. Wound infection constitutes an undebatable significant risk factor for the development of incisional hernia, and many authors consider it as the most important risk factor contributing to the development of incisional hernia<sup>5,19,33,35-37,48,51-53,56-61</sup>. In the infected wound, bacteria produce a variety of enzymes, such as collagenases, fibrinolysins, streptokinases and hemolysins, which destroy tissue and may also dissolve suture material<sup>7</sup>. Therefore, infection may affect wound healing seriously with incisional hernias as a result.

## Treatment of incisional hernia

### Conservative treatment

Absence of symptoms and acceptable cosmesis may justify a conservative approach to incisional hernias. If the hernia is not repaired, however, incarceration or strangulation of bowel may occur, especially if the hernial defect is small. For this reason, it is important to inform the patient that a painful, irreducible lump at the site of the hernia requires immediate medical care. Prompt reduction or emergency operation may then forestall the development of visceral gangrene, and have a more favourable outcome than late intervention <sup>7,62-65</sup>.

The patient should be informed that incisional hernias have a natural tendency to progress due to muscular traction and pressure of the viscera. Major incisional hernias, with a diameter greater than 10 cm, are often associated with dystrophic ulceration of the skin or pruriginous intertrigo at the periphery of the protrusion <sup>19,66</sup>. In very large incisional hernias, respiratory function can be disturbed due to inefficient contraction of the diaphragm and abdominal muscles in an open-abdominal cavity where the viscera are no longer retained by the muscular wall. This results in a paradoxical abdominal respiration <sup>19,67,68</sup>.

### Surgical treatment

In 1836, the first report of a successfully repaired incisional hernia was published by Gerdy, followed by the first report of a successfully operated strangulated incisional hernia in 1851 by Henry <sup>7,69</sup>. Since then, many techniques for incisional hernia repair have been described. Most techniques involve dissection and opening of the hernial sac (to expose its contents) and subsequent reduction. Alternatively, the contents of the hernial sac can be reduced without opening the sac. After reduction of the hernial sac, the fascial edges can be approximated by suture repair or rectus sheath technique (e.g. Ramirez technique), or the defect can be repaired using prosthetic mesh.



### ***Suture repairs***

Simple fascial closure can be obtained by edge-to-edge approximation of the fascial edges. Most frequently, a single-layered closure is performed by a continuous or interrupted suture, but two- or three-layered closure is also possible, particularly off the midline.

A variation of this type of repair is the “Keel” technique, which involves an inverting suture, bringing the rectus abdominis muscles together in the midline. In this way, muscle is approximated, rather than the fibroaponeurotic linea alba.

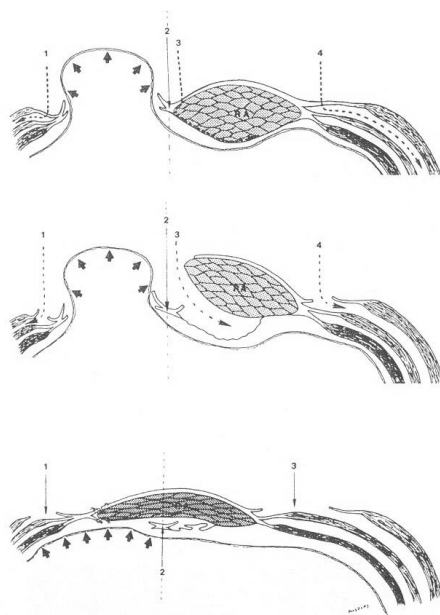
The overlapping repair described by Mayo is an alternative to the edge-to-edge repair<sup>70,71</sup>. With this technique, a transverse closure is performed by positioning the upper layer over the lower layer in a “vest-over-pants” manner. The technique can also be modified to a vertical closure (side to side overlap).

As an adjunct to the techniques mentioned above, tension releasing incisions can be employed. The object of these incisions is to increase mobility of tissues, which avoids undue tension on the repair<sup>19, 72-74</sup>. Tension releasing incisions can be made vertically and bilaterally by a single long incision or by numerous smaller incisions in the anterior or posterior sheath of the rectus abdominis muscle or oblique muscles.

Further, stay sutures can be used as an adjunct to decrease tension to the actual suture line. These sutures are placed through the fascial layers or through the full thickness of the abdominal wall<sup>6,7,75,76</sup>. However, the value of stay sutures has not been clearly established and skin necrosis is a common sequel of stay sutures.

### ***Rectus sheath techniques***

Several authors, such as Chaimoff, Abrahamson, Soliman, Da Silva, Kuzbari, Nuttall and Ramirez, described techniques for incisional hernia repair which include the use of the anterior or posterior rectus sheath. Their object was to obtain a repair without tension<sup>73,77-82</sup>. The most widely used technique has been described by Ramirez<sup>78</sup>. In this method, the external oblique muscle is separated from the internal oblique muscle in a relatively avascular plane, and the rectus muscle is separated partially from the rectus sheath. The rectus muscle and internal oblique and transversus muscle can be displaced medially to allow reconstruction of the abdominal wall.



*Figure: Ramirez technique:*

*Cross-sectional schematic diagram of the dissection of the abdominal wall into its component sections and final flap reconstruction. Note planes of dissection and advancement of muscle layers.*

As an alternative for the repair of very large defects, pedicled and free flaps, like the pedicled fasciomyocutaneous tensor fasciae latae flap can be used<sup>83-85</sup>. However, these techniques often imply extensive operations and, since a transferred free muscle flap is usually denervated, muscle flaps will eventually become atrophic. Therefore, the use of these techniques is often restricted to patients in whom a salvage procedure is warranted after an infected mesh has been removed<sup>86</sup>.

## ***Prosthetic mesh repairs***

### *Mesh materials*

A few decades ago, surgeons started to use prosthetic mesh for the repair of incisional hernias, in order to lessen tension on the repair and provide strength to the weakened abdominal wall.

The first mesh materials were developed at the beginning of the twentieth century and were braided with silver wire or stainless steel wire<sup>7,87</sup>. However, fragmentation and wandering of these wires were encountered. Subsequently nylon and polyvinyl meshes were introduced, but these were difficult to handle and became easily infected.

As an alternative, Ton designed an extractable steel prosthesis in 1967, which was used in combination with primary suture repair. However, a high rate of wound complications was described with this technique<sup>69,88,89</sup>.

In 1963, Usher introduced knitted monofilament polypropylene mesh (Marlex<sup>®</sup>; C.R. Bard, Billerica, Massachusetts, USA) in clinical practice<sup>90</sup>. Since this mesh was easier to handle and less prone to infection than the first mesh materials, it heralded a significant advance in synthetic biomaterials available to the hernia surgeon. Since then, other types of mesh, with different characteristics, have been developed. Currently, most widely used mesh materials are polyester, polypropylene and expanded polytetrafluoroethylene.

*Polyester* meshes are available as monofilament (Dacron<sup>®</sup>; Bard Implants Division, Billerica Massachusetts, USA) or multifilament (Mersilene<sup>®</sup>; Ethicon, Summerville, NJ, USA) prostheses and are mostly used in Europe. Especially in France, they are used in preference to other materials<sup>91</sup>. Polyester prostheses are flexible and are sufficiently reactive to induce rapid fibroblast response to ensure ingrowth of mesh in the surrounding tissue. Several large series reported favorable results after the use of polyester meshes<sup>92-98</sup>. However, Leber reported significantly increased incidence of postoperative infection, enterocutaneous fistula formation and recurrent hernias after the use of polyester meshes in a comparative study<sup>99</sup>. Further, Schumpelick found that the multifilament polyester mesh is subject to natural degradation processes in long-term implantation, which may eventually lead to a complete loss of functionality<sup>100</sup>.

*Polypropylene* meshes are available in several forms: monofilament Marlex<sup>®</sup> (Hill, NJ, USA), double stranded Prolene<sup>®</sup> (Ethicon, Somerville, NJ, USA), multifilament Surgipro<sup>®</sup> (US Surgical Corporation, Inc, USA), Parietene<sup>®</sup> (Sofradim, Villefranche-sur-Saone, France) and Trelex<sup>®</sup> (Meadox Medical Corporation, Oakland, NJ, USA). Polypropylene mesh shows a mild reactivity, good ingrowth in the surrounding tissue and retains its strength for indefinite periods of time<sup>91</sup>. Furthermore, it has a low susceptibility to infection, and if it does get infected, this can generally be treated adequately with drainage and antibiotics, without removal of the mesh<sup>13,27,101-106</sup>. However, concern exists about formation of adhesions between the mesh and the viscera if the mesh is placed intraperitoneally<sup>14,85,107-110</sup>. Some authors suggested that placement of an absorbable polyglactin mesh (Vicryl<sup>®</sup>) on the visceral side of the polypropylene mesh could prevent formation of adhesions to the polypropylene mesh, but this was not confirmed by some experimental studies<sup>111-113</sup>.

*Expanded polytetrafluoroethylene* (ePTFE) is a flexible, woven material that was introduced around 1985. The material is not transparent and is available as Gore-tex<sup>®</sup> (W.L. Gore, Flagstaff, AZ, USA) or Reconix<sup>®</sup> (C.R. Bard). It is relatively inert and has been reported to exhibit a lower rate of adhesion formation than polypropylene<sup>114,115</sup>. However, ingrowth of the patch in the surrounding tissue is relatively poor, which may result in recurrent hernias at the patch-fascia interface<sup>100,116</sup>. For this reason, a double row of sutures with overlap technique is advocated for the fixation of ePTFE patches<sup>116</sup>. Further, if infection of an ePTFE patch occurs, drainage and antibiotic therapy are hardly ever sufficient, and removal of the patch is almost inevitable<sup>117</sup>.

To improve incorporation of the ePTFE patch into the abdominal wall, several companies tried to adjust the ePTFE patch. Bard combined the properties of good ingrowth of polypropylene and lower rate of adhesions of ePTFE in a composite mesh with polypropylene on the visceral side and ePTFE on the side of the abdominal wall (Composix mesh<sup>®</sup>)<sup>118</sup>. In addition, Gore-tex developed the Dual Mesh<sup>®</sup>, with enlarged pore size on the side of the abdominal wall. However, in a prospective randomized trial, the Dual Mesh was associated with significantly higher risk of seroma formation and secondary infection than the component separation technique described by Ramirez, and therefore not advocated<sup>119</sup>.

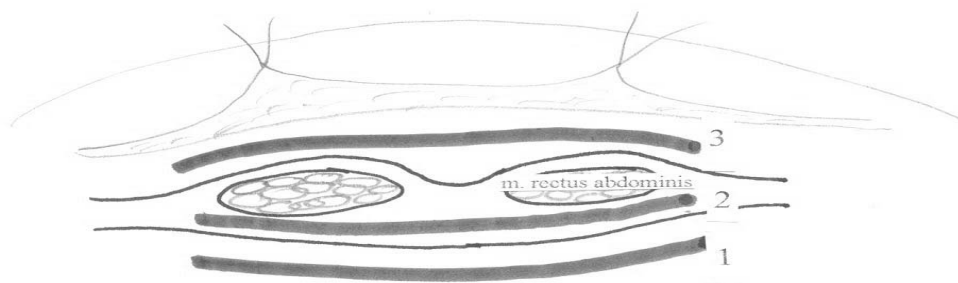
Thus, the ideal mesh still does not exist. Further development of meshes, which provide adequate tissue ingrowth of the mesh, but prevent bowel adhesions to it and prevent mesh infection, is warranted.

### *Technique of mesh placement*

If a mesh is used in incisional hernia repair, antibiotic prophylaxis is useful for the prevention of local septic complications <sup>120</sup>. Fixation of the prosthesis is usually achieved by slowly absorbable or non-absorbable sutures, and there appears to be general agreement about the need to achieve sufficient overlap of the mesh with the healthy tissue of the abdominal wall of at least 3 cm <sup>17,121-125</sup>.

The mesh can be placed either intraperitoneally or extraperitoneally. The disadvantage of an intraperitoneal mesh is that the mesh is in contact with the bowel and may therefore induce visceral adhesions. However, in mesh repair of incisional hernia, it is often not possible to leave the peritoneum intact or close the peritoneum between the bowel and the mesh. Therefore, in situations in which the mesh is placed intraperitoneally, positioning of the omentum between the mesh and the bowel is recommended <sup>126</sup>.

For the position of the mesh with regard to the fascia and rectus abdominus muscle, several anatomical options are possible. From inside to outside these are: subfascial, retromuscular prefascial and suprafascial onlay (subcutaneous).



*Figure: mesh positions: 1: subfascial, 2: retromuscular prefascial, 3: suprafascial onlay*

In the subfascial position, the mesh is placed behind the posterior rectus sheath. This can be done in an intraperitoneal or extraperitoneal position .

In the retromuscular prefascial placement as described by Rives, the mesh is placed anteriorly to the posterior rectus sheath, but posteriorly to the rectus abdominis muscle <sup>127,128</sup>. The space behind the rectus muscle is opened, and the posterior rectus sheath is closed. After that, the mesh is sutured on the anterior surface of the posterior rectus sheath, and covered by the rectus muscle and anterior rectus sheath. In this position, the mesh cannot become adherent to the intestines and the mesh is well incorporated in the abdominal wall <sup>129</sup>. However, extensive tissue dissection is needed.

If the mesh is placed subcutaneously, on the ventral aspect of the anterior rectus sheath (onlay position), patients may experience more tenderness of the abdominal wall, and seroma formation and infection may be increased <sup>7,91</sup>. Furthermore, an onlay repair of incisional hernia may be more susceptible to mesh displacement due to increased abdominal pressure, because the mesh is not held in place by a covering fascia <sup>91,113,130</sup>.

Mesh repair of an incisional hernia can be accomplished in an open procedure, but can also be performed laparoscopically. Laparoscopic incisional hernia repair with a mesh was introduced in the 1990's. The technique for laparoscopic incisional hernia repair is described and discussed further in **chapter VI** of this thesis.

## Results of incisional hernia repair

### *Postoperative complications and mortality*

The most common complications after incisional hernia repair are wound related and include wound infection, haematoma, seroma and suture sinus. If a pedicled or free flap is used, flap necrosis may occur.

After suture repair, reported incidences of wound complications vary from 10 to 44%<sup>73,81,131-133</sup>. After open mesh repair, reported incidence of wound complications varies with the use of different mesh materials, and different mesh positions. In an English review (49 reports), wound infection occurred at a mean of 4.7% after use of polypropylene mesh, 7.2% after use of ePTFE mesh, and 8.3% after use of polyester mesh<sup>91</sup>. After subfascial placement of a polypropylene mesh, a wound infection rate of 4% was reported, whereas suprafascial onlay placement of a polypropylene mesh was associated with an infection rate of 17-33%<sup>17,134</sup>. After laparoscopic incisional hernia repair, reported incidence of wound infection is 0-10%<sup>135-140</sup>. Seroma was found at a mean of 5.5% in patients who had polypropylene or ePTFE mesh repair, and at a mean of 0.8% in patients who had polyester mesh repair<sup>91</sup>. The incidence of this complication, however, may be largely underestimated, since Schumpelick found a seroma rate of 100%, using ultrasonography after mesh placement<sup>19</sup>. Greater pore size of polypropylene mesh decreases incidence of seromas<sup>141</sup>. In most studies, suction drains have been used in an attempt to prevent seroma and haematoma formation. However, suction drains may increase the risk of infection, and Vrijland et al. did not find a relation between insertion of a subcutaneous drain and decrease of seroma formation<sup>126</sup>.

In some cases, enterocutaneous fistulas may develop after placement of an intraperitoneal mesh. The incidence of enterocutaneous fistula appears low (0.3-3.3%), but may be underestimated because of insufficient follow up<sup>14,108,109,126</sup>.

Other complications after incisional hernia repair include urinary or respiratory infection and ileus.

Incisional hernia repair may be complicated by persistent pain. Although only few data on this subject are available, Martin-Duce et al. reported an incidence of prolonged abdominal pain (beyond 6 months postoperatively) in 28% of patients<sup>142</sup>.

Mortality after incisional hernia repair ranges from up to 5.3% after elective repair, to up to 10.4% after emergency repair <sup>128,130</sup>. In most cases, deaths were related to co-morbidity of the patient (cardial-, pulmonary- or oncologic disease), or were due to progressive sepsis.

### Recurrence

Recurrence rates of incisional hernia after suture repair are very disappointing and vary from 10.8 to 53.5 %, depending on technique of repair and length of follow-up (Table 1).

Table 1. Incidence of hernia recurrence rate after *suture repair* (retrospective studies with more than 100 patients).

Reference	No patients	technique	Follow-up	% Recurrence
Fischer <sup>60</sup>	151	Various techniques	3.5 yr	17.2
Pollock <sup>51</sup>	240	Various techniques	>0.5 yr	10.8
Langer <sup>131</sup>	154	Various techniques	> 4 yr	31.2
Vd Linden <sup>133</sup>	151	Various techniques	>1 yr	49.0
Read <sup>8</sup>	169	Prolene, continuous	>1 yr	24.3
Manninen <sup>9</sup>	172	Various techniques	4.5 yr	33.7
Paul <sup>18</sup>	114	Mayo	5.7 yr	53.5

Open mesh repair has lower, but still high recurrence rates, up to 34 % (table 2). Regarding the position of the mesh, no difference in recurrence rate was found between an intraperitoneal sublay position of the mesh, compared to a suprafascial onlay in the review by Morris-Stiff and Hughes <sup>91</sup>. However, since follow up differs widely between studies, it is difficult to compare various techniques of mesh placement.



Table 2. Incidence of hernia recurrence rate after *open mesh repair* in studies with more than 100 patients.

Reference	No patients	Technique	Mesh material	FU	% Recurrence
Usher <sup>90</sup>	156	onlay	PP	>1 yr	10.3
Ponka <sup>7</sup>	219	various	PP	1 yr	3.2
Chevrel <sup>145</sup>	133	onlay	PP	n.r.	9
Leber <sup>14</sup>	151	various	PP polyester	6.7 yr 6.7 yr	13.9 34.4
Gillion <sup>146</sup>	158	subfascial	ePTFE	3 yr	4
Rives <sup>128</sup>	226	prefascial retromuscular	polyester	n.r.	3.2
Adloff <sup>96</sup>	130	subfascial	polyester	1 yr	4.5
Becouarn <sup>47</sup>	160	subfascial	polyester	3 yr	4.3
Stoppa <sup>130</sup>	751	prefascial retromuscular	polyester	2 yr	5.9
Wantz <sup>148</sup>	206	prefascial retromuscular	Polyester	n.r.	1.5
Flament <sup>19</sup>	517	prefascial retromuscular	Polyester	n.r.	5.6
Verhaege <sup>19</sup>	816	prefascial retromuscular	Polyester	n.r.	5.9
Arnaud <sup>149</sup>	250	subfascial	Polyester	8 yr	3.2

FU= follow-up, PP= polypropylene, n.r = not reported

Laparoscopic incisional hernia repair with mesh was introduced in the 1990's. It was expected that recurrence rates might be reduced, with concurrent improvement of recovery time, hospital stay and complication rate. Until now, few studies have been published with hopeful preliminary results, but additional studies with sufficient follow-up by means of physical examination are warranted. (table 3).

Table 3. Incidence of hernia recurrence rate after *laparoscopic mesh repair* in studies with more than 100 patients.

reference	No of patients	Type of mesh	FU	% recurrence
Franklin <sup>150</sup>	176	PP	2.5 yr	1
Toy <sup>151</sup>	144	ePTFE	0.5 yr	4
Carbajo <sup>152</sup>	100	ePTFE	2.5 yr	2
Chowbey <sup>153</sup>	202	PP	3 yr	1
Heniford <sup>154</sup>	100	ePTFE	2 yr	3
Heniford <sup>155</sup>	407	ePTFE	2 yr	3

#### *Comparative studies between suture repair and open mesh repair*

Until now, six studies have compared suture repair and mesh repair for incisional hernia <sup>13,17,134,156-158</sup> (table 4). All comparative studies found a significant reduction of recurrences with mesh repair, except for the study of Korenkov et al., that was aborted early due to high rates of infection after polypropylene onlay mesh repair <sup>13,17, 134,156-158</sup>.

Table 4. Comparison between *suture repair and open mesh repair*

Reference	Study design	No of patients (suture/mesh)	Mesh material	FU	% recurrence suture repair	% recurrence mesh repair
Liakakos <sup>13</sup>	retrospective	102 (53/49)	PP	>7 yr	25	8
Schumpelick <sup>156</sup>	retrospective	272 (190/82)	PP	>5 yr	33	7
Koller <sup>157</sup>	retrospective	96 (70/26)	ePTFE	2 yr	63	13
Clark <sup>158</sup>	retrospective	21 (13/8)	PP	1-2 yr	38	25
Luijendijk <sup>17</sup>	randomized	181 (97/84)	PP	> 2 yr	46	23
Korenkov <sup>134</sup>	randomized	72 (33/39)	PP	9 months	12	8

The only completed prospective randomised trial comparing open suture repair and mesh repair was the study of Luijendijk et al.<sup>17</sup>. In this study, 200 patients were randomised. The three-year cumulative recurrence rates were significantly lower after mesh repair, compared to suture repair. This was found for both repair of primary hernia (23% versus 46%), as well as repair of first time recurrent hernia (20 % versus 58%). Thus, it was concluded that (subfascial) mesh repair is superior to suture repair with regard to hernia recurrence.

*Comparative studies between open mesh repair and laparoscopic mesh repair*

Some comparative studies between laparoscopic and open mesh repair were published recently<sup>135-140</sup>. Their results will be discussed in **chapter VI** of this thesis.

## Outline of the thesis

In this thesis, several experimental and clinical studies have been undertaken, in order to determine the most effective way to prevent and repair incisional hernias.

Regarding *prevention* of incisional hernia, the selected type of incision and selected type of closure for laparotomy are of special interest, since they are the only factors that can be controlled by the surgeon directly.

In **chapter II**, we studied the influence of the selected type of incision used for laparotomy on incisional hernia incidence and other wound complications. For this purpose, a literature study was conducted of all studies comparing midline, paramedian, transverse and oblique incisions.

In **chapter III**, we performed a systematic review and meta-analysis of the literature of all trials randomizing patients with midline laparotomies to different abdominal fascia closure techniques, in order to determine the preferable suture technique and material to reduce incisional hernia incidence.

In **chapter IV** a long-term follow-up study was conducted on 168 patients who underwent wound dehiscence repair, in order to determine the incidence of incisional hernia after wound dehiscence repair. In addition, patient-related- and surgical-technique-related factors increasing the risk for incisional hernia occurrence after wound dehiscence repair were studied. In some of the patients included in this study, wound dehiscence repair was performed by mesh repair, in the presence of intra-abdominal infection. In **chapter V**, the safety of different prosthetic meshes used in these patients, with regard to infectious complications, formation of enterocutaneous fistulas and mortality, was assessed.

Regarding *repair* of incisional hernia, laparoscopic incisional hernia repair is an alternative to open incisional hernia repair. In **chapter VI** results of laparoscopic incisional hernia repair are compared to open mesh repair with a sublay technique, in a cohort study of 101 patients. In addition, an overview of published comparative studies between laparoscopic and open incisional hernia repair is presented.

For successful laparoscopic incisional hernia repair, mesh fixation is crucial. Currently, most frequently used techniques for laparoscopic mesh fixation involve fixation with helical

titanium coils (tackers) or transabdominal sutures. In **chapter VII**, tensile strength of these fixation methods was assessed in a pig model.

In laparoscopic incisional hernia repair, the mesh is always placed intraperitoneally. However, concern exists about development of adhesions between bowel and mesh, predisposing to serious complications as intestinal obstruction and development of enterocutaneous fistulas. In **chapter VIII**, it was assessed whether formation of adhesions to the mesh can be prevented by intraperitoneal administration of anti-adhesive liquids, or the use of meshes with an anti-adhesive coating on the visceral side. For this purpose, an experimental study was performed in an incisional hernia model in 91 rats, in which the anti-adhesive effect of hyaluronic acid solution (Sepracat<sup>®</sup>), Icodextrin<sup>®</sup> solution, Sepramesh<sup>®</sup> (polypropylene mesh with hyaluronic acid and methylcellulose coating) and Parietex Composite mesh<sup>®</sup> (polyester mesh with collagen coating) were tested. In **chapter IX**, the same rat model was used to assess whether addition of a collagen coating on the visceral side of a polypropylene mesh (Parieten mesh<sup>®</sup>) could prevent formation of adhesions to the mesh.

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## CHAPTER 2

### Abdominal incisions: techniques and postoperative complications

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*Scand J of Surg 2002; 91: 315-21*

## Abstract

*Background and aims:* The choice of incision for laparotomy depends on the area that needs to be exposed, the elective or emergency nature of the operation and personal preference. Type of incision may however have its influence on the occurrence of postoperative wound complications. Techniques and features of various incisions are discussed, as well as the incidence of their postoperative complications.

*Method:* A medline search was conducted identifying prospective randomised trials, as well as retrospective studies with sufficient follow-up, comparing midline, paramedian, transverse and oblique incisions.

*Results:* Significant differences in wound infection and wound dehiscence rates were not reported. Transverse, oblique and paramedian incisions caused significantly less incisional hernias than midline incisions. However, trials comparing transverse and midline incisions for larger laparotomies did not show significant differences. All four trials comparing lateral paramedian with midline incisions reported incisional hernia rates of 0% after the lateral paramedian incision. Differences with the midline incision were significant.

*Conclusion:* Transverse or oblique incisions should be preferred for small unilateral operations. The paramedian incision should be used for major elective laparotomies. The use of the midline incision should be restricted to operations in which unlimited access to the abdominal cavity is useful or necessary.

## Introduction

The choice of incision is mainly dependent on the area that needs to be exposed, the elective or emergency nature of the operation and the surgeon's personal preference. However, type of incision may have a profound influence on the occurrence of postoperative wound complications. Considering the number of laparotomies performed (*e.g.* 4.000.000 in the USA annually <sup>[1]</sup>), consequences of the use of a specific type of incision may be substantial.

In the following review the techniques and features of vertical, transverse and oblique abdominal incisions will be discussed, as well as clinical trials and retrospective analysis evaluating these incisions in relation to the severity of postoperative pain and complications like wound infection, wound dehiscence and incisional hernia.

### *Anatomy of the ventral abdominal wall*

The external oblique muscle originates from the 5th to 12th rib and has a medio-caudal direction. The internal oblique muscle originates from the iliac crest and follows a medio-proximal direction. The direction of the fibres of both muscles rarely deviates more than 30<sup>0</sup> from the horizontal <sup>[2]</sup>. The transverse muscle originates from the lower six ribs, the lumbodorsal fascia and the iliac crest. Its fibres are directed horizontally. The aponeuroses of these three muscles form the sturdy rectus sheaths, which enclose the fourth abdominal wall muscle, the rectus abdominis (which inserts on the 5th, 6th and 7th rib superiorly and on the pubic bone inferiorly). Its fibres have a vertical direction and are interrupted by three or four tendinous intersections. The sheaths of the rectus abdominis muscle are continuous with those of its contralateral counterpart. In between both muscles the rectus sheaths join to form the relatively avascular linea alba. The fibre direction within the linea alba is equal to that of the aponeuroses of the oblique and transverse muscles: medio-proximal, medio-caudal and horizontal. The width of the linea alba is approximately 15-20 mm above the umbilicus, 20-25 mm at the level of the umbilicus and 0-5 mm below the umbilicus <sup>[3]</sup>.

Blood supply to the abdominal wall is taken care of by two systems. Firstly, the inferior and superior epigastric arteries form a longitudinal anastomosis, which is called the deep epigastric arcade. The arcade is situated between the rectus abdominis muscle and its

posterior sheath and supplies the muscle by perforating vessels (figure 1). Some of these perforating vessels send small branches across the midline to take care of blood supply to the linea alba. Secondly, blood supply to the oblique and transverse muscles is taken care of by transverse segmental arteries that arise from the aorta and are situated between the internal oblique and transverse muscles. These segmental arteries follow a slightly downward transverse direction.

The innervation of the abdominal wall consists of ventral branches of the 5<sup>th</sup> to 12<sup>th</sup> thoracic nerves and the iliohypogastric and ilioinguinal nerves. These nerves are directed transversely with a course comparable to the course of the segmental arteries. [2, 4, 5]

### *Incisions*

#### *Midline incision*

The *midline incision* implies a vertical incision through skin, subcutaneous fat, linea alba, and peritoneum. Most of the fibres, crossing the linea alba in a medio-caudal and medio-proximal direction, are cut transversely. The incision is easy to perform and results in minimal blood loss, because of the avascular nature of the linea alba. The incision can be made quickly, taking 7 minutes on average [6-9]. Moreover, exposure of the abdomen is excellent. Extensions, when required, can easily be made superiorly or inferiorly, providing access to the whole abdominal cavity, including the retroperitoneum. All these qualities make the midline approach especially suitable for emergency and exploratory surgery.

#### *Paramedian incision*

An alternative for the standard midline incision is the *paramedian incision* (Figure 2). Two variants are known: the *conventional "medial" paramedian incision*, in which the anterior and posterior rectus sheaths are transected close to the linea alba, and the so-called *lateral paramedian* technique. In the latter, a longitudinal incision near the lateral border of the rectus sheath is made. The rectus muscle is freed from the anterior sheath and is then retracted laterally. This lateral retraction prevents dissection of the deep epigastric arcade. After that, the posterior rectus sheath (above the arcuate line) and the peritoneum are opened in the same plane as the anterior rectus sheath. This technique is more complex than the

midline incision, resulting in increased opening time (average 13 minutes [6, 10]) and blood loss. Exposure of the abdomen is better on the side of the incision than on the contralateral side. The possibilities for extending the incision superiorly are limited by the costal margin.

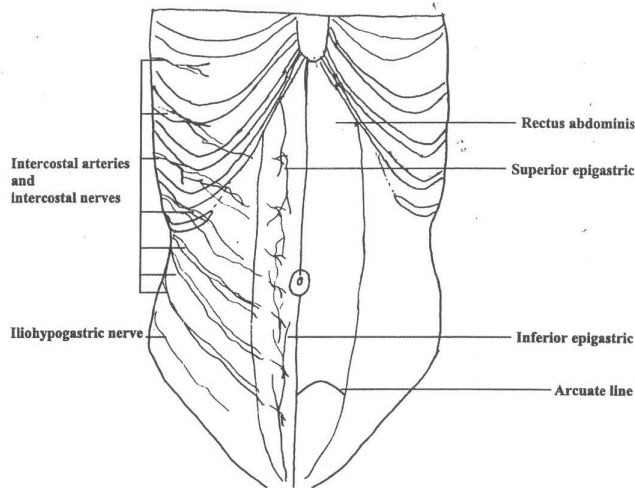


Figure 1: Anatomy of the abdominal wall: vascularisation and innervation

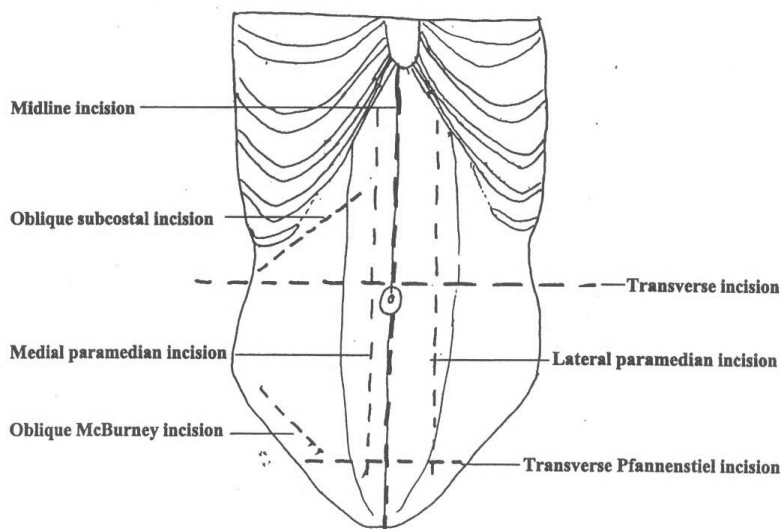


Figure 2: Incisions

### *Transverse incision*

A *supraumbilical transverse* incision offers excellent exposure of the upper abdomen. However, in case the operation area needs to be enlarged, extending the original incision is more difficult than when the midline incision was used and extensions do not always offer the desired view. When a full-length transverse incision is made, the oblique and transverse muscles, as well as the rectus abdominis muscle and linea alba are cut in a horizontal plane. The fibres of the oblique muscles are partly split and partly cut, while the transverse muscle is split along the direction of its fibres. The rectus muscle fibres are cut perpendicular to their direction. The deep epigastric arcade is divided, but as it is supplied from above and below this should not pose a problem. Damage to the segmental arteries and nerves is minor<sup>[4]</sup>. The incision is accompanied by more blood loss than the midline incision<sup>[11]</sup> and is more time-consuming (average 13 minutes<sup>[7, 9]</sup>). Smaller transverse incisions can remain unilateral, take less time to perform and leave the deep epigastric arcade unharmed.

An infraumbilical transverse incision in the lower abdomen is the *Pfannenstiel incision*<sup>[12]</sup>, often used for gynaecological and obstetric procedures. The skin is incised transversely, often with a convexity downward to avoid dissection of blood vessels and nerves. The abdominal wall muscles are often cut in the same plane as the skin incision, but some surgeons open the abdominal cavity in a vertical direction, thus combining a transverse with a vertical technique.

### *Oblique incision*

The *subcostal or Kocher incision* is an oblique incision that follows the profile of the costal margin and is directed in a medio-proximal direction. It provides good exposure for biliary and bariatric surgery and can be extended bilaterally if needed. Many segmental blood vessels and nerves are dissected, as well as the fibres of the external oblique, the transverse and the rectus abdominis muscles<sup>[5]</sup>. The direction of the *gridiron or McBurney* incision is medio-caudal. It follows the direction of the fibres of the external oblique muscle, segmental blood vessels and nerves, damaging as little as possible. Notably, this incision splits all three muscular layers parallel to the direction of their fibres. Time to perform the incision and blood loss are comparable to those of transverse incisions.



## Postoperative complications

### *Postoperative pain*

Randomised trials by Armstrong et al. and Lip et al. showed a significant reduction in postoperative pain in patients that received a transverse incision compared to patients who received a midline incision ( $p < 0,001$ ) (table 1) <sup>[7, 13]</sup>. Halasz et al. reported a significant reduction in the use of postoperative analgesia after oblique incisions, compared to paramedian incisions ( $p < 0,001$ ) <sup>[14]</sup>. Garcia-Valdecasas reported less use of analgesics after oblique than after midline incisions ( $p < 0,001$ ) <sup>[15]</sup>.

	<i>Study design</i>	<i>No of patients</i>	<i>Types of incision</i>	<i>Method</i>	<i>Reduced postoperative pain after</i>
<b>Lacy</b> <sup>[9]</sup>	randomised	50	Midline vs. transverse	Morphine/24h	NS
<b>Armstrong</b> <sup>[13]</sup>	randomised	60	Midline vs. transverse	Total pethidine	Transverse*
<b>Lip</b> <sup>[7]</sup>	randomised	149	Midline vs. transverse	Pain scale	Transverse*
<b>Greenall</b> <sup>[11]</sup>	randomised	557	Midline vs. transverse	Pain scale	NS
<b>Garcia</b> <sup>[15]</sup>	randomised	129	Midline vs. oblique	Meperidine/24h	Oblique*
<b>Ali</b> <sup>[33]</sup>	randomised	19	Midline vs. oblique	Meperidine first 3days	NS
<b>Halasz</b> <sup>[14]</sup>	randomised	100	Paramedian vs. oblique	Total meperidine	Oblique*
<b>Donati</b> <sup>[34]</sup>	retrospective	123	Midline vs. transverse	Time with PCA	NS

Table 1. Postoperative pain, \* =  $p < 0,05$

*Wound infection*

Wound infection is probably an important risk factor for the development of incisional hernia and wound dehiscence [16-18]. Ten randomised clinical trials and four retrospective studies addressed the matter of wound infection and incision technique (table 2). None of these trials reported a significant difference in wound infection rates after the use of different types of incision.

	<i>Study design</i>	<i>No of pts</i>	<i>Midline</i> (%)	<i>Lat para</i> (%)	<i>Med para</i> (%)	<i>Transverse</i> (%)	<i>Oblique</i> (%)
<b>Guillou</b> <sup>[6]</sup>	randomised	116	12	23	11		
<b>Cox</b> <sup>[25]</sup>	randomised	431	8	6			
<b>Kendall</b> <sup>[8]</sup>	randomised	241	11	7			
<b>Stone</b> <sup>[35]</sup>	randomised	551	3			1	
<b>Lip</b> <sup>[7]</sup>	randomised	149	8			2	
<b>Lewis</b> <sup>[36]</sup>	randomised	100	6				2
<b>Garcia</b> <sup>[15]</sup>	randomised	129	3				0
<b>Greenall</b> <sup>[11]</sup>	randomised	557	24			28	see transv.
<b>Brennan</b> <sup>[26]</sup>	randomised	351		8	7		
<b>Halasz</b> <sup>[14]</sup>	randomised	100		14			12
<b>Israelsson</b> <sup>[16]</sup>	prospective	861	9				
<b>Blomstedt</b> <sup>[24]</sup>	retrospective	279	14	13			15
<b>Douzdjan</b> <sup>[37]</sup>	retrospective	56	34			20	
<b>Thompson</b> <sup>[23]</sup>	retrospective	1363	6			3	
<b>Donaldson</b> <sup>[10]</sup>	retrospective	850		15			

Table 2. Wound infection rates (%)

*Wound dehiscence*

None of nine randomised trials was able to show a significant difference in wound dehiscence rates after different types of abdominal incisions (table 3). In a retrospective study, Waldhausen et al found a reduction of wound dehiscence incidence after transverse incision (0,25%), compared to midline incision (1,7%) in a paediatric setting ( $p < 0,001$ )<sup>[19]</sup>.

	<i>Study design</i>	<i>No of pts</i>	<i>Midline (%)</i>	<i>Lat para (%)</i>	<i>Med para (%)</i>	<i>Transverse (%)</i>	<i>Oblique (%)</i>
<b>Guillou</b> <sup>[6]</sup>	randomised	116	0	0	1		
Cox <sup>[25]</sup>	randomised	431	0	1			
<b>Kendall</b> <sup>[8]</sup>	randomised	241	0	0			
<b>Stone</b> <sup>[35]</sup>	randomised	551	4			2	
<b>Greenall</b> <sup>[11]</sup>	randomised	557	0,3			0	
<b>Garcia</b> <sup>[15]</sup>	randomised	129	2				0
<b>Ellis</b> <sup>[27]</sup>	randomised	79	0	2			
<b>Ellis</b> <sup>[27]</sup>	randomised	96		2		0	
<b>Brennan</b> <sup>[26]</sup>	randomised	351		0	0		
<b>Israelsson</b> <sup>[16]</sup>	prospective	861	0,6				
<b>Donaldson</b> <sup>[10]</sup>	retrospective	850		0			
<b>Thompson</b> <sup>[23]</sup>	retrospective	1363	2,5			0,5	
<b>Waldhausen</b> <sup>[19]</sup>	retrospective	2785	1,7*			0,25*	

Table 3. Wound dehiscence rates (%), \* =  $p < 0,05$

*Incisional hernia*

Two randomised trials compared midline with transverse incisions (table 4). Of these, Greenall et al found no statistical difference <sup>[11]</sup>, while Lip et al reported an incisional hernia rate of 14% for midline incisions and 1% for transverse incisions ( $p < 0,05$ ) <sup>[7]</sup>. Two of three retrospective studies showed the same trend but failed to reach significant values <sup>[22, 23]</sup>.

	<i>Study design</i>	<i>No of pts</i>	<i>FU</i> <i>(months)</i>	<i>Midline</i> <i>(%)</i>	<i>Lat para</i> <i>(%)</i>	<i>Med para</i> <i>(%)</i>	<i>Transverse</i> <i>(%)</i>	<i>Oblique</i> <i>(%)</i>
<b>Guillou</b> <sup>[6]</sup>	randomised	116	12	7*	0*	15*		
<b>Ellis</b> <sup>[27]</sup>	randomised	79	12	23		18		
<b>Ellis</b> <sup>[27]</sup>	randomised	96	12			17	14	
<b>Cox</b> <sup>[25]</sup>	randomised	431	12	10*	0*			
<b>Kendall</b> <sup>[8]</sup>	randomised	241	12	7*	0*			
<b>Lip</b> <sup>[7]</sup>	randomised	149	>12	14*			1*	
<b>Garcia</b> <sup>[15]</sup>	randomised	129	4	3				0
<b>Brennan</b> <sup>[26]</sup>	randomised	119	12		0*	4*		
<b>Greenall</b> <sup>[11]</sup>	randomised	557	6	8			6	
<b>Israelsson</b> <sup>[16]</sup>	prospective	861	12	12				
<b>Thompson</b> <sup>[23]</sup>	retrospective	1363	18	3			1	
<b>Johnson</b> <sup>[30]</sup>	retrospective	233	12	5			7	
<b>Lord</b> <sup>[22]</sup>	retrospective	329	12	17			13	
<b>Blomstedt</b> <sup>[24]</sup>	retrospective	279	n.r.	14*		9		4*
<b>Donaldson</b> <sup>[10]</sup>	retrospective	850	12		0,3			
<b>Luijendijk</b> <sup>[38]</sup>	retrospective	272	60				0	

Table 4. Incisional hernia rates (%), \* =  $p < 0,05$

A comparison of midline with oblique incisions was performed in two studies. The randomised trial by Garcia-Valdecasas et al did not show a significant difference <sup>[15]</sup>. A retrospective study by Blomstedt et al. reported a 14% hernia rate after midline and a 4% hernia rate after oblique incisions ( $p < 0,01$ ) <sup>[24]</sup>.

Three prospective randomised clinical trials compared lateral paramedian with midline incisions and found a significant reduction of incisional hernia incidence after the lateral paramedian incision (0 versus 7-10%)<sup>[6, 8, 25]</sup>. A similar low incisional hernia rate of 0,3% after the lateral paramedian incision was reported by Donaldson et al in a large retrospective series<sup>[10]</sup>. In addition, the lateral paramedian incision was associated with a lower incidence of incisional hernia than the medial paramedian incision ( 0 versus 4-15%).<sup>[6, 26]</sup>

## Discussion

The midline incision is generally preferred by surgeons because of its ease, speed and excellent exposure. However, as was shown in the current review, midline incision is associated with increased postoperative pain compared to transverse or oblique incisions. Furthermore, higher incisional hernia rates were found after the use of midline incision than after lateral paramedian, oblique or transverse incisions.

After laparotomy, the incisional hernia incidence lies between 2% and 19%<sup>[5, 17, 18, 20, 21]</sup>. In the Netherlands, a country with 16 million inhabitants, about 125.000 laparotomies are carried out per year, which would mean that every year approximately 12.500 patients will suffer a new incisional hernia. This has both individual and social repercussions. Patients may suffer pain, discomfort and, in the worst case, an incarceration, which is a potentially lethal situation that requires emergency surgery. Furthermore, the loss of productivity, the impact on hospital capacity and financial resources are considerable. The results of hernia repair are disappointing, with recurrence rates up to 43% after suture repair and up to 24% after mesh repair<sup>[28]</sup>. Therefore, prevention of incisional hernia is warranted.

There are possible explanations for the high incisional hernia rate after midline laparotomy. Firstly, contraction of abdominal wall muscles retracts wound edges laterally. Secondly, the avascular nature of the midline incision may impair wound healing. Thirdly, the fibres of the linea alba, which are continuous with abdominal wall muscle aponeuroses, cross the midline mostly in transverse or oblique directions. Therefore, a vertical incision cuts most of them perpendicularly.

The transverse incision gained popularity from the beginning of this century. It was advocated by, amongst others, Maylard, Pfannenstiel, Rees and Thompson [2, 12, 23, 29]. They attributed a reduction of postoperative wound complications to the more sound anatomical and physiological properties of the incision, compared to vertical incisions. When a transverse incision is used, Langer's lines of cleavage are followed, as well as the direction of most oblique and transverse muscle fibres, nerves and segmental blood vessels. Therefore, dissection of segmental blood vessels and nerves is limited. The latter may explain the reduction of postoperative pain [2, 23]. Further, contraction of the abdominal wall muscles (coughing, vomiting, erecting) does not increase tension on the wound as these forces parallel the transverse operation wound. In addition, unlike the midline incision wound, the transverse incision wound is situated in richly vascularised muscular tissue, which may benefit wound healing.

Results of trials comparing midline incision with transverse incision should however be interpreted with care. In those randomised trials finding significant differences between transverse and midline incisions, the transverse incision was always unilateral. No significant differences were found between bilateral transverse incisions and midline incision [11, 22, 30]. Therefore, transverse incisions only seem to have advantages over midline incisions if the operation area is limited to one quadrant of the abdomen. If full exposure of the abdominal cavity is needed, advantages of the transverse incision over the midline incision have not been proven, while exposure of the transverse incision is often less than after a midline incision.

Regarding oblique incisions, only open cholecystectomies were included in the reviewed studies. As the incision has a medio-proximal direction, it tends to cut most nerves, segmental blood vessels and muscle fibres perpendicularly. The partial denervation of the abdominal wall ensues with permanent muscle weakness and numbness [31]. Despite extensive nerve dissection, postoperative pain after oblique incision was less than after midline incision. The incisional hernia rate might be lower than that of the midline incision, although this has not been proven in a randomised clinical trial.

The paramedian incision combines some of the advantages of the midline incision, such as exposure and the possibility of extending the operation, with a richly vascularised wound

bed, which may improve wound healing. When the rectus muscle is retracted, the risk of serious blood vessel dissection is minimal <sup>[4]</sup> and the rectus muscle remains largely intact.

The most noteworthy characteristic of the lateral paramedian incision is the significant reduction of incisional hernia incidence to approximately 0-1%. A possible explanation for the lower hernia rate of the lateral paramedian incision is formed by the so-called shutter mechanism of the rectus muscle, since the rectus muscle is placed in front and medially to the wound of the posterior rectus sheath. Contraction of the abdominal wall muscles will bring the wound edges together, instead of separating them. With the medial paramedian incision, the rectus muscle is still lateral from the wound and therefore not affected by this mechanism. This may explain the less favourable results of the conventional “medial” paramedian incision.

## Conclusion

Although the midline incision is easy and fast, there should be caution with its use, because of the high incidence of incisional hernia. A significant reduction of incisional hernia can be accomplished by the use of a unilateral transverse incision, or by the use of the lateral paramedian incision. Although these incisions take more time to perform, the unilateral transverse incision should be the preferred incision for small unilateral operations. The lateral paramedian incision should be reconsidered as the incision of choice in elective abdominal surgery.

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## CHAPTER 3

### Meta-analysis of techniques for closure of midline abdominal incisions.

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*Br J Surg* 2002; 89: 1350-56

## Abstract

*Background* Various randomised studies have evaluated techniques of abdominal fascia closure but controversy remains, leaving surgeons uncertain about the optimal method of preventing incisional hernia.

*Method* Medline and Embase databases were searched. All trials with a follow-up of at least one year, that randomised patients with midline laparotomies to closure of the fascia by different suture techniques and/or suture materials were subjected to meta-analysis. Primary outcome was incisional hernia, secondary outcomes were wound dehiscence, wound infection, wound pain and suture sinus formation.

*Results* Fifteen randomised prospective studies were included with a total of 6573 patients. Closure by continuous rapidly absorbable suture was followed by significantly more incisional hernias than closure by continuous slowly-absorbable suture ( $p<0.009$ ) or non-absorbable suture ( $p=0.001$ ). No difference in incisional hernia incidence was found between slowly-absorbable and non-absorbable sutures ( $p=0.75$ ), but more wound pain ( $p<0.005$ ) and more suture sinuses ( $p=0.02$ ) occurred after the use of non-absorbable suture. Similar outcomes were observed with continuous and interrupted sutures, but continuous sutures took less time to insert.

*Conclusion* To reduce the incidence of incisional hernia, without increasing wound pain or suture sinus frequency, slowly absorbable continuous sutures appear to be the optimal method of fascial closure.

## Introduction

Incisional hernia is one of the most common long-term complications of open abdominal surgery. In prospective studies, incidences of incisional hernia after median laparotomy vary from 11 to 20%<sup>1-4</sup>. Incisional hernias can cause pain and may lead to serious conditions, such as incarceration (6 - 15 %) or strangulation of bowel (2 %).<sup>5,6</sup> Repair of incisional hernia is associated with recurrence rates up to 45%.<sup>7</sup>

In the pathogenesis of incisional hernia, numerous factors which can impair wound healing, such as diabetes mellitus, malignancy, wound infection, malnutrition, obesity, previous laparotomies and use of corticosteroids, and factors related to surgical technique are believed to play a role.<sup>1,3,8</sup> Of these, surgical technique is of special interest, since it is the only factor that can be controlled directly by the surgeon.

Material and technique for fascial closure are often determined by local custom and surgical tradition. While a substantial number of randomised studies have been conducted to determine the ideal method, these have often been inconclusive or conflicting, and have left many surgeons uncertain about which method should be used.

Two meta-analyses have recently attempted to determine which fascial closure method is best, but neither discriminated between rapidly and slowly absorbing sutures, comparing only absorbable and non-absorbable materials.<sup>9,10</sup> As the characteristics of rapidly absorbable and slowly absorbable sutures differ substantially, discrimination between these groups seems warranted. Furthermore, the above meta-analyses included many studies with a follow-up of less than one year and a variety of abdominal incisions. For these reasons, the authors have conducted a new meta-analysis of the literature, including only midline incisions, with subdivision of suture material into rapidly, slowly and non-absorbing, and with a follow-up of at least one year. The aim of the study was to determine which method of fascial closure should be adopted to prevent incisional hernias and other complications.

## Method

The Embase and Medline databases from 1966 through 2000 were searched by two independent reviewers, using the keywords: "randomised", "randomized", "abdominal", "suture", "technique" and "material" with the boolean operator "or". The search was restricted to titles and abstracts. Criteria for inclusion of studies in this meta-analysis were prospective randomised controlled trials with at least 100 patients, comparing different suture materials and/or suture techniques for midline incision, with a follow-up of at least one year.<sup>11</sup> Trials of children younger than 15 years were excluded. Both independent reviewers extracted data and performed validation of inclusion criteria. Discrepancies were resolved by discussion and consensus.

Twelve prospective randomised trials were excluded because they did not compare midline incisions or lacked sufficient follow-up.<sup>12-23</sup> Fifteen studies were included in the study and analysed.<sup>2,26-39</sup> In the analysis, suture material was categorised as rapidly-, slowly- and non-absorbable (table 1).<sup>25</sup> Suture technique was categorised as continuous or interrupted. Some trials varied both suture material and suture technique within one trial.<sup>2,31-36</sup> For that reason, separate meta-analyses were performed within groups of trials that made the same comparison (e.g. interrupted rapidly-absorbable versus continuous non-absorbable, interrupted rapidly absorbable versus continuous slowly-absorbable), as is pointed out in the tables in the result section.

The primary outcome was postoperative incisional hernia. Secondary outcomes were wound dehiscence, wound infection, prolonged wound pain and suture sinus. Definitions of these outcome parameters were accepted as reported. "Layered closure" was only applied in one study and was defined as separate closure of the peritoneum and the musculoaponeurotic layer.<sup>39</sup>

Analyses were conducted using SPSS (SPSS Inc, Chicago ICC, USA) and EGRET (version 2 Cytel Software Corporation, Cambridge, MA, USA) software. The Mantel-Haenszel method was used to summarise dichotomous outcomes of studies.<sup>24</sup> This method was only used if homogeneity of data was confirmed. Statistical homogeneity was assessed by chi-square tests of heterogeneity. A p-value  $\leq 0.05$  was considered statistically significant.



Table 1. Suture material and duration of total resorption.<sup>25</sup>

Suture material	Total resorption (days)
<i>Rapidly Absorbable:</i>	
Catgut	15
Chromic catgut	90
Polyglycolic acid (Dexon)	20
Polyglactin 910 (Vicryl)	60-90
Monocryl	90-120
<i>Slowly absorbable:</i>	
Polydioxanone (PDS)	180
Polyglyconate (Maxon)	180
<i>Non-absorbable:</i>	
Nylon (Nurulon)	No resorption
Polypropylene (Prolene)	No resorption
Polyethylene (Ethibond)	No resorption
Polyamide (Ethilon)	No resorption

## Results

### *Suture material*

In several studies, suture material was compared with the use of similar suture technique for both groups (either continuous or interrupted), as is shown in table 2 and 3.<sup>2,26-30</sup> One study compared continuous rapidly absorbable suture material with continuous non-absorbable material in 751 patients.<sup>2</sup> In this study, significantly more incisional hernias were seen after the use of rapidly absorbable suture material ( $p=0.001$ ). However, in the patients in whom non-absorbable material was used, significantly more suture sinus ( $p<0.001$ ) and prolonged wound pain ( $p=0.003$ ) were seen. The same study also compared continuous rapidly absorbable sutures to continuous slowly absorbable sutures. Again, they found an increase of incisional hernia incidence after the use of rapidly absorbable sutures ( $p<0.009$ ).<sup>2</sup> Another study, however, compared interrupted rapidly absorbable sutures to interrupted non-absorbable sutures and did not find a difference regarding incisional hernia incidence.<sup>27</sup>

Five studies compared slowly absorbable (Maxon or PDS) with non-absorbable (Prolene or Nylon) continuous sutures in 3413 patients.<sup>2,26,28-30</sup> Meta-analysis of these studies did not identify a significant difference in incisional hernia incidence between slowly-absorbable and non-absorbable suture material ( $p=0.75$ ) However, an increased incidence of prolonged wound pain ( $p<0.005$ ) and suture sinus ( $p=0.02$ ) was found after the use of non-absorbable, compared to slowly-absorbable sutures. No difference was found regarding wound dehiscence or wound infection in the meta-analysis.

### *Suture technique*

In six of the seven trials comparing continuous versus interrupted suture technique, suture material in the interrupted group was different from suture material in the continuous group.<sup>2,31-36</sup> This complicated any comparison between suture techniques. In most of these studies, no significant difference in incisional hernia incidence was found between continuous and interrupted sutures.<sup>31,33-36</sup> All studies favoured continuous suture, because the authors found that this technique was easier and faster than interrupted suture and thus saved operating time.

Separate analyses were performed for different suture materials (rapidly-/slowly-/non-absorbable) as shown in table 4. None of the separate analyses could identify a clear difference in incisional hernia incidence between interrupted and continuous suture technique. Combined analysis of all studies comparing continuous and interrupted suture technique did not identify a significant difference in incisional hernia incidence either with the use of interrupted or continuous suture technique ( $p=0.40$ , OR 0.9, 95% CI 0.61-1.22). In addition no differences were found regarding incidence of wound dehiscence or wound infection. Regarding suture sinus and wound pain, an increased incidence was seen after the use of continuous non-absorbable sutures compared to interrupted rapidly absorbable sutures ( $p=0.001$  and  $p<0.001$  respectively).<sup>2,35</sup>

Table 2. Randomised comparative studies

Reference	No of patients	Follow-up	Suture technique	Material **	Wound dehiscence	Incisional hernia	Wound infection	Prolonged wound pain	Suture sinus	Conclusion on incidence of incisional hernia	Favours
Gys and Hubens <sup>26</sup>	132	1 yr*	Continuous layered	Nylon (N) 67 Maxon (S) 65	3.0% 1.9%	6.0% 6.2%	21% 15.4%			S=N	No preference
Corman et al. <sup>27</sup>	161	1 yr*	Interrupted Mass	Nylon (N) 49	0	8.9%	4.1%		12.2%	F=N	Vicryl (Nylon and Prolene more suture sinus)
				Prolene (N) 53	1.9%	4.4%	9.4%		5.7%		
				Vicryl (F) 59	0	0	10.2%		0		
Israelsson and Jonsson <sup>28</sup>	813	1 yr*	Continuous Mass	Nylon (N) 405	0.7%	15.7%	8.6%	2.7%		S=N	No preference
				PDS (S) 408	0.5%	15.1%	9.4%	2%			
Carlson and Condon <sup>27</sup>	225	2 yr*	Continuous Mass	Nylon (N) 112	2.6%	4%	3.6%	4.5%	1%	S=N	No preference
				Maxon (S) 113	0	7%	1.8%	5.3%	0		
Krukowski et al. <sup>30</sup>	757	1yr	Continuous Mass	PDS (S) 374	0.3%	3.5%	3.2%	3.2%	0	S=N	PDS (Prolene more wound infection)
				Prolene (N) 383	0.3%	4.7%	8%	6.1%	0.3%		
Wissing et al. <sup>2</sup>	1486	1 yr*	Interrupted	Vicryl (F) 365	2.2%	16.9%	6.6%	4.9%	3%	F>N F>S S=N Int F = Cont F Int F = Cont S	PDS (Nylon more suture sinus and wound pain)
			Continuous	Vicryl (F) 379	1.6%	20.6%	9.0%	8.6%	1.4%		
			Continuous	PDS (S) 370	3.5%	13.2%	11.6%	8.2%	3.9%		
			Continuous	Nylon (N) 372	2.1%	10.3%	7.2%	16.7%	7.7%		
Colombo et al. <sup>31</sup>	614 §	3 yr*	Interrupted "Smead-Jones"	Dexon (F) 306	0	10.4%	1.6%		0	Int F = Cont S	Continuous Maxon (faster)
			Continuous	Maxon (S) 308	0.3%	14.7%	1%				
Brolin et al. <sup>32</sup>	229 £	29 months*	Continuous	PDS (S) 120	0%	10%			0	Cont S < Int N	Continuous PDS (faster)
			Interrupted Figure of 8	Ethibond (N) 109	1.9%	18%			5%		
Trimbos et al. <sup>33</sup>	340 ¶	1yr*	Interrupted	Vicryl (F) 172	0%	4%	1%	2%	2%	Int F = Cont S	Continuous Maxon (faster)
			Continuous	Maxon (S) 168	0.6%	3%	3%	1%	0		
Sahlin et al. <sup>34</sup>	301	1yr*	Continuous	Maxon (S) 148	2.7%	13.5%	10%		0	Int F = Cont S	Continuous Maxon (faster)
			Interrupted "Far-and-near"	Vicryl (F) 155	6.5%	7.1%	11%		0		
Richards et al. <sup>35</sup>	473 ¥	1 yr*	Interrupted "Far-and-near"	Dexon (F) 244	0.9%	0.5%				Int F = Cont N	Continuous Prolene (faster)
			Continuous Mass	Prolene (N) 229	2.0%	2%					
McNeil et al. <sup>36</sup>	105 £	1 yr*	Continuous	Dexon (F) 54	0%	10%	4%			Int N = cont F	Continuous Dexon (faster)
			Interrupted "Near-far-far-near"	Stainless steel (N) 51	2%	9%	2%				

\*\*Number of patients is given for each suture material. \* Follow-up by means of physical examination. § Gynaecological cancer. £ Morbidly obese. ¶ Women only. ¥ Only midline incisions included in the present analysis. Incidence of incisional hernia was comparable (=), less (<) or more (>). F: rapidly absorbable, S: slowly absorbable, N: non-absorbable, int: interrupted suture technique, cont: continuous suture technique, vs : versus.

Table 3. Analysis of suture material (for comparable suture technique in both groups).

Suture type	no of patients	incisional hernia	wound dehiscence	wound infection	suture sinus	wound pain
Continuous rapidly- versus non-absorbable <sup>2</sup>	379 vs 372	60 vs 31 p=0.001	6 vs 8 n.s.	34 vs 27 n.s.	4 vs 23 p<0.001	25 vs 50 p=0.003
Continuous slowly- versus non-absorbable <sup>2,26,28-30</sup>	1327 vs 1347	119 vs 117 n.s.	17 vs 17 n.s.	106 vs 107 n.s.	12 vs 28 p=0.02	46 vs 85 p<0.005
Continuous rapidly- versus slowly-absorbable <sup>2</sup>	379 vs 370	60 vs 37 p<0.009	6 vs 13 n.s.	34 vs 43 n.s.	4 vs 11 n.s.	25 vs 23 n.s.
Interrupted rapidly- versus non-absorbable <sup>27</sup>	59 vs 102	0 vs 6 n.s.	0 vs 1 n.s.	6 vs 7 n.s.	0 vs 9 p<0.05	n.r.

n.s. = not significant. n.r. = not reported

Table 4. Analysis of suture technique for different suture materials

suture type	no of patients	incisional hernia	wound dehiscence	wound infection	suture sinus	wound pain
Interrupted versus continuous rapidly-absorbable <sup>2</sup>	365 vs 379	48 vs 60 n.s.	8 vs 6 n.s.	24 vs 34 n.s.	3 vs 4 n.s.	14 vs 25 n.s.
Interrupted rapidly-absorbable versus continuous non-absorbable <sup>2,35</sup>	594 vs 621	49 vs 35 n.s.	10 vs 13 n.s.	47 vs 37 n.s.	3 vs 23 p=0.001	14 vs 50 p<0.001
Interrupted rapidly-absorbable versus continuous slowly-absorbable <sup>2,31,33,34</sup>	991 vs 1001	111 vs 94 n.s.	20 vs 23 n.s.	68 vs 87 n.s.	17 vs 25 n.s.	6 vs 11 n.s.
Interrupted non-absorbable versus continuous rapidly-absorbable <sup>36</sup>	51 vs 54	5 vs 5 n.s.	1 vs 0 n.s.	1 vs 2 n.s.	n.r.	n.r.

n.s. = not significant, n.r. = not reported

*Suture technique: alternative techniques*

In the process of searching for an ideal technique, several technical variations on the interrupted or continuous techniques were developed. Of these, the interrupted "figure of eight"-technique, interrupted "far-and-near" or "near-far-far-near" technique, or the interrupted "Smead-Jones" technique did not reduce incisional hernia incidence compared to continuous sutures.<sup>31,32,34,35</sup> Another technique, the continuous double loop closure method could not reduce wound failure either, although it could resist high intra-abdominal pressures.<sup>40</sup> However, when this continuous double loop closure method was compared to continuous running suture in a randomised trial, it was associated with significantly increased pulmonary complications (5 versus 17%) and postoperative death (8 versus 21%). For this reason the trial was stopped preliminary and not included in the current meta-analysis.<sup>40</sup>

*Suture technique: suture length/wound length ratio*

In order to determine if the use of more suture material, expressed by an increased suture length/wound length ratio would lead to reduction of incisional hernia incidence, three studies measured suture length and compared this to wound length (table 5). Two of these studies concluded that an increased suture length/wound length ratio of 4:1 or even 6:1 would decrease incisional hernia incidence significantly.<sup>37,38</sup> The third study did not find a decrease in incisional hernia incidence, although less wound dehiscence was seen with mass closure with an increased suture length/wound length ratio compared to layered closure.<sup>39</sup>

Table 5. Suture length/wound length ratio: prospective studies

Reference	Nr of patients	Follow-up	Material	suture technique	SL/WL ratio	wound dehiscence	Incisional hernia	Wound infection	remarks	Conclusion on incidence of incisional hernia	favours
Israelsson et al. <sup>37</sup>	363	1 yr* 80%	PDS or nylon	Continuous mass	>4	0	9.0%	4%	SI/WI ratio was similar for both materials	Ratio >4 less incisional hernia than ratio <4	Ratio >4
					<4	0.7%	23.7%	4%			
Varshney et al. <sup>38</sup>	100	1yr* 85%	PDS	Continuous mass	6.2 (6-7)		5%	9%			Ratio >6
Kendall et al. <sup>39</sup>	467	1yr* 78%	PDS	midline layered	Mean 3.7	2.5%	3.5%	6%	lateral para-median incision less incisional hernia than median.	Mass= layered No influence SL/WL ratio	Lateral para-median incision
			PDS	midline mass	Mean 5	0	6.7%	12%			
			PDS	Lateral para-median and catgut layered	Mean 2.6	0	0	7%			

\* : follow-up by means of physical examination, = : comparable incidence of incisional hernia, < : less incisional hernia

## Discussion

The ideal suture method should prevent incisional hernia and wound dehiscence, without increasing wound infection, wound pain and the formation of suture sinus.

In the search for the best technique and ideal suture, meta-analysis can provide high quality level I evidence. However, a valid meta-analysis requires very rigorous patient entry criteria, a series of high quality trials, and qualitative and quantitative homogeneity for all groups that are compared in the analysis. Because many trials varied both suture material and suture technique within one trial, one meta-analysis of all the data did not seem justified. Instead, we performed separate meta-analysis of groups of trials with comparisons of similar suture material and technique.

The type of incision forms an important factor that can influence the occurrence of incisional hernia. Lower incidence of incisional hernia is found after the paramedian incision, compared to the most commonly used vertical midline incision.<sup>39</sup> For this reason, we only included trials which reported incisional hernia incidence after the vertical midline incision. This, in contrast to the recent meta-analyses of Weiland et al. and Hodgson et al., who included trials with a variety of incisions.<sup>9,10</sup>

Another important factor in trials regarding incisional hernia is formed by the duration of follow-up. Since incisional hernia can develop at long term after laparotomy, with up to 40% of incisional hernia occurring more than 1 years after laparotomy, adequate follow up is essential.<sup>1,8</sup> Therefore, we only included studies with follow-up (by means of physical examination) of at least one year, in contrast to the previous meta-analyses, which also included a substantial number of studies (up to 54%) with a mean follow-up of less than one year.<sup>9,10</sup>

The ideal fascial closure should maintain tensile strength throughout the healing process. The dynamic process of wound healing can be divided into three phases.<sup>25,41</sup> The first exudative phase (1st to 4th day) is dominated by vascular, cellular and enzymatic processes, and does not provide any holding strength to the wound. It is followed by the proliferative phase (5th to 20th day), in which epithelialization, wound contraction and connective tissue repair take place.<sup>41</sup> During this phase, the tissue regains approximately 15 to 30 percent of its original tensile strength. The process can be delayed by wound infection or inflammation. As most fast absorbable sutures lose the main part of their tensile strength within this phase (between 14 and 21 days), these sutures are likely to increase incisional hernia incidence, especially if wound infection occurs.<sup>25</sup> This was confirmed by the study on 1486 patients, in which an increase of incisional hernia incidence was found with the use of rapidly absorbable sutures compared to slowly-or non-absorbable sutures.<sup>2</sup>

Slowly-absorbable and non-absorbable sutures retain their tensile strength up to the third phase (21<sup>th</sup> day up to years), in which tissue is remodelled by the rearrangement and cross-linking of collagen fibres. During this phase, tissue regains up to 80 % of the original tensile strength.<sup>41</sup>

In the current review, a discrimination was made between rapidly, slowly- and non-absorbable sutures. We did not identify any difference in incisional hernia incidence between

slowly-absorbable and non-absorbable sutures.<sup>41</sup> Previous meta-analyses identified more incisional hernias after closure with absorbable sutures compared to non-absorbable sutures.<sup>9,10</sup> Weiland et al. did however not discriminate between rapidly and slowly absorbable sutures.<sup>9</sup> Hodgson et al. performed a subgroup analysis of the slowly-resorbable polydioxanone (PDS).<sup>10</sup> In agreement with our meta-analysis, they did not find any difference in incisional hernia incidence either between this slowly-absorbable suture material and non-absorbable sutures. Remarkably, they did not include this finding in their conclusion and still stated that non-absorbable sutures should be used.<sup>10</sup> However, as was shown by the current meta-analysis, non-absorbable sutures are associated with an increased incidence of prolonged wound pain and suture sinus, compared to slowly-absorbable sutures.<sup>2,23,26</sup> Therefore, slowly absorbable sutures should be preferred to non-absorbable sutures.

Regarding suture technique, all studies favoured continuous sutures. Continuous suture technique has the benefit of being easier and faster than interrupted suture technique, without increasing incisional hernia incidence.<sup>31-36</sup> This is consistent with previous meta-analyses.<sup>9,10</sup> Of all alternative suture techniques that were tested, none was able to show a benefit.<sup>31,32,34,35,40</sup> In the study of Niggebrugge et al., the continuous-double-loop-closure method even increased the rate of pulmonary complications and postoperative death significantly.<sup>40</sup> They suggested that the continuous-double-loop-closure method would result in decreased compliance of the abdominal wall, leading to an increase in intra-abdominal pressure, with the possibility for the development of an abdominal compartment syndrome and negative effects on pulmonary function.<sup>40</sup> This is an important finding, because it stresses the fact that the ideal closure method must not only provide adequate tensile strength, but must also guarantee adequate elasticity to accommodate to increased abdominal pressure in the postoperative period.

The question that remains is in what way the continuous suture should be applied. As was shown in the present review, two studies stressed the importance of an adequate suture-length/wound length ratio of at least 4:1.<sup>37,38</sup> This was not confirmed by a third study, in which no difference was found with an increase of suture-length/wound-length ratio of 3.7 to 5.<sup>39</sup> However, this third study varied several parameters between the three study groups at the same time (mass/layered, suture-length/wound/length ratio, median/paramedian incision) and



should therefore be interpreted with care. Regarding mass or layered closure, the meta-analysis of Weiland et al. identified an increase in incisional hernia incidence and wound dehiscence after the use of layered closure compared to mass closure. In addition, because mass closure is easier and faster, it should be preferred.<sup>9</sup> Thus, the ideal suture technique in reducing incisional hernia rates appears continuous mass closure, with an adequate suture-length/wound-length ratio of at least 4:1.

In conclusion, the preferable suture material is slowly-absorbable. Slowly absorbable suture material is associated with a comparable incidence of incisional hernia as non-absorbable suture material, but is associated with a significant reduction of prolonged wound pain and suture sinus formation, compared to non-absorbable sutures.

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## CHAPTER 4

### Incisional hernia after repair of wound dehiscence: incidence and risk factors

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*Am Surg* 2004; 70: 281-6

## Abstract

*Summary background data* The true incidence of incisional hernia after wound dehiscence repair remains unclear, since thorough long-term follow-up studies are not available.

*Method* Medical records of all patients who had undergone wound dehiscence repair between January 1985 and January 1999 were reviewed. Long-term follow-up was performed by physical examination of all patients in February 2001.

*Results* One hundred-sixty-eight patients underwent wound dehiscence repair. Of those, forty-two patients (25%) died within 60 days after surgery. During a median follow-up of 37 months (range 3-146 months), 55 of the remaining 126 patients developed an incisional hernia. The cumulative incidence of incisional hernia was 69% at 10 years. Significant independent risk factors were aneurysm of the abdominal aorta (10-year cumulative incidence of 84%,  $p=0.02$ ), and severe dehiscence with evisceration (10-year cumulative incidence of 78%,  $p=0.01$ ). Wound dehiscence repair by interrupted sutures had no better outcome than repair by continuous sutures. Suture material did not influence incidence of incisional hernia.

*Conclusion* Incisional hernia develops in the majority of patients after wound dehiscence repair, regardless of suture material or technique. Aneurysm of the abdominal aorta and severe dehiscence with evisceration predispose to incisional hernia.

## Introduction

Wound dehiscence, postoperative disruption of all layers of the abdominal wall, occurs in 0.25-3% of all patients after abdominal surgery, and is associated with high morbidity and 10-40% mortality.<sup>1-6</sup>

Repair of wound dehiscence involves suturing the fascial edges together in most patients. Some authors have suggested that this repair is successful and that secondary healing of a fascial wound is better than primary.<sup>7,8</sup> However, long term follow up of wound dehiscence repair is rare, leaving the incidence of incisional hernia unclear.<sup>9-12</sup> Incisional hernia is a serious condition because of pain and the risk of incarceration (6 to 15 %) or strangulation of bowel (2 %).<sup>13,14</sup>

The aim of the present study was to assess the incidence and risk factors for the development of incisional hernia after wound dehiscence repair in a long-term follow-up study.

## Methods

All consecutive patients who had undergone wound dehiscence repair between January 1985 and January 1999 at the Erasmus University Medical Centre Rotterdam were selected for analysis. Data on demographics, medical history, prior surgical procedures, time and severity of wound dehiscence, repair of wound dehiscence and outpatient follow-up were recorded. Dehiscence was defined as moderate when there was only serosanguinous leakage through the abdominal defect without evisceration. Dehiscence was defined as severe when evisceration had occurred. Evisceration was defined as protrusion of bowel beyond the abdominal wall. Surgical repair involved mass closure of the fascia with the rectus muscle in most patients, either with interrupted or continuous suture (depending on the surgeons preference), followed by closure of the skin. Presence of infection, defined as a positive bacterial culture, was recorded. Those patients with large defects of the abdominal wall, requiring great tension to close the abdominal wall with sutures, had mesh repair. The decision to use a mesh was left to the surgeon.

All patients who were alive after 60 days postoperatively were selected for follow-up analysis. At the time of conducting the study (February 2001), all patients had physical

examination of the abdominal wall to detect incisional hernias. For this purpose, the abdomen was examined both while the patient was sitting up and in supine position during Valsalva manoeuvre. Of those patients who had died during follow-up after the 60th postoperative day, follow-up data were obtained from the patients' general practitioner. The follow-up period was defined as the time interval between repair of wound dehiscence and the last physical examination that was performed.

Risk factors for the development of incisional hernia during follow-up were analysed with Kaplan-Meier curves and log-rank tests (univariate analysis). All factors with a p-value of less than 0.15 in the univariate analysis were included in a multivariate analysis by means of a Cox proportional hazard model. The endpoint in these analyses was the detection of incisional hernia, either during regular follow-up or at per-protocol follow-up in February 2001. Patients who died without incisional hernia were considered as censored observations, as well as patients alive at the end of follow-up without incisional hernia. A p-value of less than 0.05 was considered to be statistically significant.

## Results

### *Patient characteristics*

One hundred-sixty-eight patients underwent wound dehiscence repair. Patient characteristics are shown in table 1.

In eighty patients (48%), emergency surgery preceded wound dehiscence. Emergency procedures were performed for gastrointestinal perforation (n=22), peritonitis due to appendicitis, diverticulitis or leakage of a bowel anastomosis (n=27), ileus (n=17), ruptured aneurysm of the abdominal aorta (n=11), liver transplantation (n=2), or oesophageal perforation (n=1).



Table 1. Characteristics of patients with wound dehiscence (n=168).

<b>Patients characteristics</b>	<b>Median (range)</b>
Age	66 years (18-90)
Body Mass Index (BMI; body length/body weight <sup>2</sup> )	25 (17-32)
Number of previous abdominal procedures	2 (1-9)
	<b>Number of patients</b>
Gender	
- Male	125
- Female	43
Indication for surgical procedure preceding wound dehiscence	
- Malignancy	40
- Gastrointestinal perforation/infection	43
- Aneurysm of abdominal aorta	28
- Ileus	17
- Other	40
Suture material surgical procedure preceding wound dehiscence	
- Polyglactin	55
- Polydioxanone	48
- Not recorded	65

### *Wound dehiscence*

Wound dehiscence occurred after a median of 8 days postoperatively (range 0-24). Severity of dehiscence was moderate in 60 patients and severe (with evisceration) in 22 patients. In 86 patients, severity was not recorded. Possible causes of the development of wound dehiscence were insufficient fascial strength with sutures cutting through the tissue (n=34, 20%), breakage of suture material (n=23, 14%) or loosening of the knot (n=8, 5%). Wound- or intra-abdominal infection was found in 67 patients (40%).

Repair was performed within 24 hours after diagnosis of wound dehiscence in the majority of patients. Characteristics of the repair are shown in table 2.

Table 2. Wound dehiscence repair (n=168).

Characteristics of wound dehiscence repair	Number of patients
Suture technique	
- Interrupted	70
- Continuous	62
- Not recorded	36
Suture material	
- Primary suture	130
- Polyglactin	79
- Polydioxanone	42
- Polypropylene	9
- Mesh	26
- Polyglactin	9
- polypropylene	16
- polyester	1
- Not recorded	12

In 22 patients repair was postponed (range 2-28 days). In these patients, initially serosanguinous leakage (which progressed to more severe dehiscence), or poor clinical condition of the patient were underlying causes of postponed surgery.

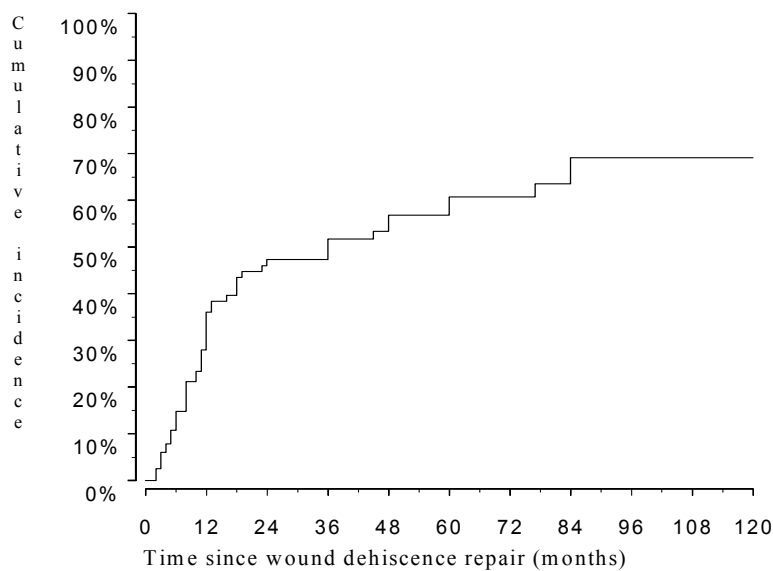
Fourteen patients (8%) had one recurrence after wound dehiscence repair, while 2 patients (1%) had two recurrences. Characteristics of these patients were all comparable to those without recurrence of wound dehiscence. All patients with recurrence underwent another repair. Ten out of these 16 patients had mesh repair.

Before discharge from the hospital, 42 patients (25%) died, all within 60 days after wound dehiscence repair. Main causes of hospital mortality were abdominal sepsis (n=18), cardiac (n=9) or pulmonary (n=5) complications, and malignancy (n=4). Six patients died of other causes.

*Incisional hernia*

All patients who survived more than 60 days postoperatively (n=126) were included in follow-up analysis. During follow-up, 52 of the 126 patients deceased, after a mean interval of 32 months. All patients who were still alive at the time of conducting the study had physical examination of the abdominal wall at the outpatient department, except for five patients who could not be traced (4%).

Mean follow-up was 37 months (range 3-146 months, n=126). In total, 55 patients developed an incisional hernia after wound dehiscence repair. In 17 of these cases (31%) the hernia was diagnosed after more than two years postoperatively, while in ten cases (18%), the patient was even unaware of the presence of an incisional hernia and the hernia was only diagnosed at per protocol analysis. Corrected for survival, the cumulative incidences of incisional hernia rose steeply to 47% in patients who were still alive after 2 years, and more gradually to 69% in patients who were still alive after 10 years (Figure 1).



*Figure 1. Kaplan-Meier curve for the development of incisional hernia after wound dehiscence repair (n=126)*

Incisional hernia repair had only been performed in 14 (25%) patients. In the remaining 41 cases, the incisional hernia was either asymptomatic, or the patient was unfit for surgery.

Analysis of risk factors for development of incisional hernia after wound dehiscence repair is shown in table 3 and 4.

Table 3. Analysis of *patient-related risk factors* for the development of incisional hernia after wound dehiscence repair (n=126)

	N <sup>o</sup> of patients with incisional hernia	10-year cumulative incidence of incisional hernia	P-value in univariate analysis	P-value in multivariate analysis
Gender				
Male	45	73%	0.11	n.s.
Female	10	50%		
Age > 60 years	36	70%	n.s	-
Age < 60 years	19	66%		
BMI > 25	11	60 %		
BMI < 25	44	72%	n.s	-
Number of preceding abdominal surgical procedures:				
1 or 2	33	60%		
> 3	22	100%	0.008	n.s.
Initial surgical procedure				
for abdominal aneurysm	14	84%	0.15	0.02
not for abdominal aneurysm	41	65%		
for abdominal infection	13	73%	n.s	-
not for abdominal infection	42	68%		
in emergency-setting	26	74%	0.12	n.s.
in elective setting	29	66%		

n.s. = not statistically significant

Table 4. Analysis of *risk factors related to wound dehiscence repair* for the development of incisional hernia after wound dehiscence repair (n=126)

	<b>10-year cumulative incidence of incisional hernia</b>	<b>No of patients with incisional hernia</b>	<b>P-value in univariate analysis</b>	<b>P-value in multivariate analysis</b>
Interval between initial procedure and diagnosis of wound dehiscence	64%	30		
< 10 days	76%	25	n.s.	-
> 10 days				
Interval between initial procedure and repair				
< 8 days	29%	3		
> 8 days	74%	52	n.s.	-
Evisceration	78%	14	0.02	0.01
Dehiscence without evisceration	57%	10		
Intra-abdominal- or wound-infection during repair	69%	25	n.s.	-
No intra-abdominal- or wound-infection during repair	62%	23		
technique for repair:				
interrupted	82%	23	n.s.	-
continuous	55%	18		
material for wound dehiscence repair:				
fast resorbable	64%	25		
slowly resorbable	70%	16	0.07	n.s.
non-resorbable	64%	4		
Use of non-absorbable mesh in wound dehiscence repair	59%	6		
No mesh	68%	49	0.12	n.s.
Total	69%	55		

Gender, number of preceding abdominal procedures, initial surgical procedure for abdominal aneurysm, initial emergency procedure, evisceration and the use of non-absorbable mesh were selected for multivariate analysis. In multivariate analysis, statistically significant risk factors were initial diagnosis of aneurysm of the abdominal aorta (10-year cumulative incidence of 84%, p=0.02) and evisceration at the time of wound dehiscence (10-year cumulative incidence of 78%, p=0.01). A history of three or more preceding abdominal procedures was correlated to a 10-year cumulative incidence of incisional hernia of 100%.

However, multivariate analysis did not identify this factor as a statistically significant risk factor, because it was associated with increased incidence of evisceration and therefore not an independent factor.

Male gender, Body Mass Index, initial emergency operation, initial diagnosis of visceral perforation or peritonitis, repair after the eighth day postoperatively and wound-or intra-abdominal infection at the time of repair did not influence incisional hernia incidence significantly. Regarding surgical technique, no significant association was recorded between the incidence of incisional hernia and interrupted versus continuous suture. Further, no influence of suture material was seen. Although non-absorbable mesh repair showed a trend towards less incisional hernia compared to primary suture repair, this difference was not statistically significant in multivariate analysis. As expected, all patients in whom an absorbable mesh was sutured into the defect, who did not die postoperatively, developed incisional hernia (n=4).

## Discussion

Wound dehiscence is a dreaded condition after surgery since it can be a dramatic experience for the patient with significant morbidity and mortality. Advanced age, male gender, poor general condition, malignancy and malnutrition have been associated with increased incidence of wound dehiscence.<sup>1-6,15-20</sup> Further, surgical procedures for colonic disorders or peptic ulcer, emergency laparotomy, mechanical factors that increase intra-abdominal pressure and wound- or intra-abdominal infection were identified as risk factors.<sup>1-6,15-20</sup> In the present study, wound- or intra-abdominal infection was found in 40 per cent of the patients at the time of wound dehiscence repair, consistent with reported incidences in literature of 9 to 44%.<sup>3,5,11,15,16,21</sup>

The high mortality rate in the present study of 25% is comparable to reported rates of 15 to 44% in the literature.<sup>1-6,20,21</sup> It has been suggested that this high mortality rate is due to the poor medical condition which is prevalent in wound dehiscence.

The present study reports a cumulative incidence of incisional hernia after wound dehiscence repair of 69% after 10 years. Reitamo et al. and Madsen et al. recorded incidences of incisional hernia after wound dehiscence repair of respectively 10 and 19 per cent. These

rates only reflected those patients who had repair of their incisional hernia.<sup>9,10</sup> As shown in the present study, the majority of patients with incisional hernia after wound dehiscence does not undergo repair of their incisional hernia, and almost 20% of patients is even unaware of the presence of incisional hernia. Therefore, follow up including physical examination appears essential for identification of the true incidence of incisional hernia. In two other studies, incisional hernias were detected in 43 and 48%.<sup>11,12</sup> However, incomplete and short-term follow-up in these studies suggests that these rates were low estimates. In the present study, 31% of incisional hernias was diagnosed after more than two years postoperatively. Therefore, a follow-up of at least 2 years appears important.

Aneurysm of the abdominal aorta predisposed to incisional hernia in this study. In previous studies that investigated the incidence of incisional hernia after general laparotomy, this condition was also detected as a risk factor for the development of (recurrent) incisional hernia.<sup>22-25</sup> It has been suggested that altered collagen metabolism may play a role in predisposing these patients to hernia formation.<sup>26</sup>

Multiple previous laparotomies render patients at risk for incisional hernia after repair of fascial dehiscence. Repetitive healing of fascial wounds has been shown to be associated with decreasing tensile strength.<sup>27,28</sup> The time of repair of fascial dehiscence varies, and is determined by the degree of the dehiscence and the condition of the patient. Grace et al. reported that late repair, after the eighth postoperative day, was followed by a greater number of incisional hernias.<sup>12</sup> This finding was not confirmed in the present study.

Regarding technique of wound dehiscence repair, Gislason et al. suggested that interrupted suturing technique was preferable. Their hypothesis was that the use of interrupted sutures prevents loosening of the entire wound if sutures cut through the fascia or the knot loosens.<sup>11</sup> This was however not confirmed in the present study, in which interrupted sutures had no better outcome than continuous sutures. Because continuous sutures are less time-consuming they might be preferred.

In addition, no influence of suture material was found. This is a remarkable finding, since polyglactin and polyglycolic acid sutures are already resolved within 30 days and lose their tensile strength much earlier than the slowly resorbable polydioxanone or the non-resorbable polypropylene<sup>29,30</sup>.

An alternative to suture repair is formed by the application of a mesh. Mesh repair offers the opportunity to close the fascial edges, which have already once failed to heal, without tension. In the present study, meshes were only used in a small number of patients, in whom very large or recurrent fascial defects were present. Although not statistically significant, the present study still showed a trend towards decrease of incisional hernia incidence after placement of a non-absorbable mesh. However, in patients with wound dehiscence, intra-abdominal infection is often present and in these patients, use of prosthetic mesh carries the risk of mesh infection and formation of enterocutaneous fistulas.<sup>31,32</sup>

In conclusion, the incidence of incisional hernia after wound dehiscence repair has been largely underestimated. Regardless of suture method or material, incisional hernia develops in the majority of patients who have wound dehiscence repair. In patients without infection, mesh repair might decrease incisional hernia incidence. This must however be determined by further study.

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## CHAPTER 5

Mesh repair of postoperative abdominal wound dehiscence  
in the presence of infection:  
is absorbable mesh safer than non-absorbable mesh?

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*submitted for publication*

## Abstract

*Objective.* In patients with postoperative wound dehiscence in the presence of infection, extensive visceral oedema often necessitates mechanical containment of bowel. For this purpose prosthetic mesh is often used. The aim of the present study was to assess the safety of the use of non-absorbable and absorbable meshes for this purpose.

*Method* All patients who had undergone mesh repair of abdominal wound dehiscence between January 1988 and January 1998 in the presence of intra-abdominal infection were included in a retrospective cohort study. All surviving patients had physical follow-up in February 2001.

*Results* Eighteen patients were included in the study. Meshes consisted of polyglactin (n=6), polypropylene (n=8), polyester (n=1), or a combination of a polypropylene mesh with a polyglactin mesh on the visceral side (n=3). All patients developed complications, mainly consisting of mesh infection (77%), intra-abdominal abscess (17%), enterocutaneous fistula (17%) or mesh migration through the bowel (11%). Mesh removal was necessary in 8 patients (44%). Within 4 months postoperatively, 6 patients (33%) had died because of progressive abdominal sepsis. The incidence of progressive abdominal sepsis was significantly higher in the group with absorbable polyglactin mesh than with non-absorbable mesh (67% versus 11%,  $p=0.02$ ). After a mean follow-up of 49 months, 63% of surviving patients had developed incisional hernia. Compared to non-absorbable meshes, absorbable meshes had no better outcome regarding complications and mortality rate.

*Conclusion* Synthetic graft placement in the presence of intra-abdominal infection has a high risk of complications, regardless of the use of absorbable (polyglactin) or non-absorbable mesh material (polypropylene or polyester), and should be avoided if possible.

## Introduction

Patients with postoperative wound dehiscence in the presence of infection or contamination represent a difficult and challenging problem to the surgeon. In these patients, the bowel is often oedematous and protrudes from the abdominal cavity. Extensive visceral oedema precludes primary closure of the abdominal wall and necessitates other ways for mechanical control.

Currently, one of the most commonly used methods for mechanical containment of abdominal contents in these patients is the use of a prosthetic mesh. However, concern exists about long-term complications after introduction of a foreign body in an infected environment. Particularly if the mesh is non-resorbable, mesh extrusion and enteric fistula formation are feared.<sup>1-4</sup> If the mesh is resorbed within 20 to 90 days, occurrence of mesh-related complications may be lower than with non-absorbable mesh, as was suggested by several authors.<sup>5-8</sup> In order to check this hypothesis, the present study was performed.

The aim of the present study was to assess the safety of the use of non-absorbable and absorbable meshes for wound dehiscence repair in the presence of infection.

## Methods

In a retrospective study, all patients who had undergone mesh repair of acute postoperative wound dehiscence between January 1988 and January 1998 at the Erasmus University Medical Centre Rotterdam were selected for analysis.<sup>9</sup> Wound dehiscence was defined as moderate when there was only serosanguinous leakage through the abdominal defect without evisceration. Dehiscence was defined as severe when evisceration had occurred. Evisceration was defined as protrusion of bowel beyond the abdominal wall.

All patients with signs of intra-abdominal infection (defined as intra-abdominal pus and/or a positive bacterial culture from the abdomen) at the time of mesh placement were included in the study. Data regarding patient characteristics, initial surgical procedures, procedure of mesh placement, postoperative complications, microbiologic findings, antibiotic therapy and late complications were recorded.

Regarding the use of mesh and the choice of mesh material, there were no consistent guidelines. In general, patients with large defects requiring great tension to close primarily were selected for mesh repair. If fascial necrosis was present, necrotomy was performed before graft placement. If possible, the omentum was placed in between the mesh and the viscera.

Postoperative mesh infection was defined as discharge of pus from the mesh, confirmed by positive bacterial culture from the mesh. Postoperative progressive abdominal sepsis was defined as progressive sepsis with positive blood cultures of enteric bacteria.

At the time of conducting the study (February 2001), all surviving patients had physical examination of the abdominal wall at the outpatient department, with special interest for the presence of incisional hernia. For this purpose, the abdomen was examined in both upright and laying position during Valsalva manoeuvre. Follow-up period was defined as the time interval between mesh placement and the last physical examination that was performed.

Statistical analysis was performed using Mann-Whitney U-test for independent samples. A p-value of less than 0.05 was considered to be statistically significant.

## Results

During the study period, a total of 168 patients underwent wound dehiscence repair. Of these, 26 patients had mesh repair of wound dehiscence, of whom 18 patients had repair in the presence of intra-abdominal infection. Thus, eighteen patients (12 male, 6 female) with a median age of 63 years (range 31-89) were included in the study.

The median number of abdominal operations that preceded the procedure of mesh placement was two (range 1-5). In the patients with wound dehiscence, underlying causes of abdominal infection were gastric perforation (n=2), Boerhaave syndrome (n=1), perforated diverticulitis (n=3), pancreatitis (n=1), contaminated initial procedure with bowel surgery for malignancy or gastrointestinal bleeding (n=8), strangulated bowel in a femoral hernia (n=1), inadvertent gallbladder perforation (n=1) and the occurrence of wound infection after surgery for acute aneurysm of the abdominal aorta (n=1). Severity of dehiscence was moderate in 1 patient and severe (with evisceration) in 17 patients.

At the time of mesh placement, clinical signs of infection (pus coming out of the wound, temperature elevation and/or high white blood cell count) had been present for a median of nine days (range 0-22 days). At the time of mesh placement, bacteraemia (confirmed with a positive blood culture) was present in three patients.

At the start of each surgical procedure in which a mesh was placed, broad-spectrum antibiotic therapy was administered. None of the mesh patches was impregnated with antibiotics. Graft materials included polyglactin (n=6), polypropylene (n=8) or polyester (n=1). In another three patients, a polypropylene mesh was combined with a polyglactin mesh on the visceral side. In all patients, the skin was left open.

### *Complications*

Median postoperative hospital stay was 59 days (range 1-142 days). Postoperative complications and comparison of complications for absorbable or non-absorbable mesh material are shown in table 1.

Table 1. Comparison of postoperative complications between absorbable, non-absorbable and a combination of absorbable + non-absorbable mesh material.

<b>Complication</b>	absorbable (polyglactin)  (n=6)	non-absorbable (polypropylene or polyester)  (n=9)	combination (polypropylene + polyglactin)  (n=3)	<i>P</i> -value	Total  (n=18)
<b>Complications:</b>					
- Clinical signs of mesh infection	67%	89%	67%	n.s.	77%
- Enterocutaneous fistula		22%	33%	n.s.	17%
- Bowel perforation due to mesh migration	17%	11%		n.s.	11%
- Intra-abdominal abscess	33%	11%		n.s.	17%
- Ileus		22%		n.s.	11%
- Urinary tract infection	17%	11%		n.s.	11%
- Intra-abdominal bleeding			33%	n.s.	6%
- Pulmonary complications	17%	11%	33%	n.s.	17%
- Gastro-intestinal bleeding		11%		n.s.	6%
- Mesh removed	33%	56%	33%	n.s.	44%
<b>Total mortality</b>	<b>83%</b>	<b>33%</b>	<b>33%</b>		<b>56%</b>
Cause of death:					
- Progressive abdominal sepsis	67%	11%	33%	p=0.02*	33%
- Cardiopulmonary complications	17%	11%		n.s.	11%
- Cerebrovascular accident		11%		n.s.	11%
- Peritonitis carcinomatosa		11%		n.s.	6%
<b>Incisional hernia in surviving patients</b>	<b>100%</b>	<b>67%</b>	<b>0%</b>	<b>n.s.</b>	<b>63%</b>

\* = comparison between absorbable and non-absorbable material



Fifteen patients developed mesh infection (77%), which was bacteriologically confirmed in all cases. A total of 18 different species of pathogens were recovered from the abdominal cavities postoperatively (table 2). There was no difference between the use of absorbable or non-absorbable mesh regarding incidence of mesh infection. Mesh infection was initially treated by broad spectrum antibiotics in all patients. In eight patients, however, this was not successful and the mesh had to be removed. In three patients, mesh infection was associated with intra-abdominal abscesses, which were surgically drained.

Table 2. Pathogens recovered from the abdomen.

	No. of patients with these pathogens
Aerobe pathogens	
Escherichia coli	13
Enterococcus sp	5
Staphylococcus aureus	8
Staphylococcus epidermidis	4
$\beta$ -hemolytic streptococcus	3
Corynebacterium sp	1
Acinobacter sp	2
Proteus sp	4
Pseudomonas sp	12
Streptococcus sp	1
Enterobacter sp	7
Klebsiella sp	4
Bacillus sp	1
Morganella morganii	3
Serratia marcescens	3
Anaerobic pathogens	
Bacteroides sp	1
Mycosis	
Candida sp	7

Three patients developed enterocutaneous fistulas. In the first patient, two enterocutaneous fistulas had developed 5 months postoperatively, after placement of a combined polypropylene with polyglactin mesh. In the second patient, the fistula was diagnosed 18 months postoperatively, after the use of a polyester mesh. In both patients, the mesh was removed and partial bowel resection was performed. In the third patient, a polypropylene mesh had migrated through the bowel and thus perforated the bowel. In this patient, the mesh was removed and a partial bowel resection was performed. A new polypropylene mesh was used to close the abdomen, but the patient developed an enterocutaneous fistula at 9 months after placement of this mesh. In another patient, an absorbable polyglactin mesh had migrated through the bowel and thus caused two bowel perforations. Despite removal of the mesh with partial bowel resection and several relaparotomies with abscess drainage, this patient died at 71 days postoperatively due to progressive abdominal sepsis.

After mesh removal, in four patients a new mesh was placed into the defect, composed of polypropylene (n=3) or ePTFE (ethylpolytetrafluoroethylene, n=1). In the patient who received the ePTFE mesh, the mesh got infected and had to be removed again because of inadequate response to antibiotic therapy.

Postoperatively, two patients developed an ileus. In one patient, the ileus could be treated successfully with conservative therapy. In the other patient reoperation was indicated and adhesiolysis of dense bowel adhesions to a polypropylene mesh was performed.

Six patients died due to progressive abdominal sepsis (at a range of 1-126 days postoperatively). The incidence of this complication was significantly higher in the group with absorbable polyglactin mesh, than with non-absorbable mesh (67% versus 11%,  $p=0.02$ , table 1).

At the time of conducting the study, 10 patients had died (table 1). All patients who were still alive had physical examination at the outpatient department, except for one patient who could not be traced (13%). After a median follow-up of 49 months (range 8-133 months), five of these patients had developed incisional hernia (63%, table 1).

## Discussion

As was shown by the present study, prosthetic mesh placement in patients with wound dehiscence in the presence of intra-abdominal infection has a high risk of complications, regardless of the use of non-absorbable or absorbable mesh.

Polypropylene mesh is not absorbable and is the most widely used material for abdominal wall replacement and reinforcement during hernia repair. Favourable characteristics of polypropylene are its durability, pliability, high tensile strength, and good growth of fibroblasts into the mesh.<sup>10,11</sup> However, as was shown in the present study, the use of polypropylene mesh in contaminated environment is associated with a high incidence of mesh infection and serious long-term complications as mesh migration through the bowel (11%), ileus due to adhesion of bowel to the mesh (11%), and enteric fistulation (22%). This was also found by other authors who noted a fistula rate of 12-50%.<sup>1,12-15</sup>

Polyglactin- and polyglycolic acid meshes are both rapidly absorbable. They can temporarily restore abdominal wall continuity, but when the mesh has been absorbed, all patients will inevitably develop incisional hernia, which was confirmed by the present study.<sup>5,8,16,17</sup>

Several authors suggested that the use of absorbable meshes would reduce the occurrence of mesh-related chronic complications.<sup>5-8</sup> However, as was shown by the present study, the use of absorbable polyglactin mesh was associated with an incidence of mesh migration through the bowel comparable to that of polypropylene mesh (17% versus 11%). Further, enterocutaneous fistulas still developed despite placement of a polyglactin mesh on the visceral side of a polypropylene mesh. In addition, the incidence of mortality due to persistent abdominal sepsis was even higher in the group of patients with absorbable polyglactin meshes compared to non-absorbable polypropylene meshes. Since this is a retrospective study, there may be a bias in patient selection. However, a factor that may contribute to the high incidence of progressive abdominal sepsis with the use of absorbable polyglactin mesh is the multifilament structure of this mesh, compared to the monofilament structure of the polypropylene mesh. As is known, multifilament material is more susceptible to infection than monofilament material and the use of a multifilament foreign body in an infected environment may increase bacterial load on the mesh.<sup>18-20</sup>

Several authors have attempted to develop alternatives for temporary abdominal contents containment in the presence of large contaminated abdominal wall defects, without the use of prosthetic mesh.<sup>21-25</sup> Ghimenton et al. used an empty, sterile, 1- or 3- litre plastic bag, used for intravenous fluid administration or for urological irrigation, which was stitched with a continuous suture to the edges of the rectus sheath or the skin.<sup>22</sup> If no relaparotomies were needed, the plastic bag was removed and split skin grafting was performed. However, all surviving patients developed incisional hernias, which were demanding to repair. Furthermore, massive bowel adherence to the broad midline granulation area with skin graft still posed a small risk of fistula formation, which was seen in 2 out of 75 patients.<sup>22</sup>

Recently, Koniaris et al described the “dynamic retention technique”.<sup>21</sup> With this technique, a bowel bag is used to cover the bowel and omentum. Moistened burn dressings are placed flatly over the bowel bag, and 4 or 5 horizontal retention sutures are placed over this dressing, on top of which a second layer of dressings is added with a drainage catheter. Postoperatively, retention sutures may be tightened and delayed primary fascial closure can be achieved. No fistulas were seen and only one out of 10 patients developed incisional hernia.<sup>21</sup>

In conclusion, as was shown by the present study, synthetic graft placement in the presence of intra-abdominal infection has a high risk of complications, regardless of the use of absorbable polyglactin mesh or non-absorbable polypropylene or polyester mesh. Use of absorbable mesh material was even associated with a significantly increased incidence of progressive abdominal sepsis compared to non-absorbable mesh material. Therefore, use of mesh under contaminated circumstances should be avoided if possible, and alternatives such as the dynamic retention method should be explored.<sup>21</sup> Prospective randomised trials are warranted to determine the best management for large infected abdominal wall defects.

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## CHAPTER 6

### Mesh repair of incisional hernia: comparison of laparoscopic and open repair

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*Eur J Surg* 2002; 168:684-690

## Abstract

*Purpose* Repair of incisional hernias with conventional operative techniques is associated with a considerable risk of postoperative wound complications, pain, long recovery, and high recurrence rates. Laparoscopic incisional hernia repair has the potential to reduce postoperative morbidity. The purpose of this study was to compare open and laparoscopic mesh repairs.

*Method* All patients who had undergone laparoscopic or open mesh repair of a midline incisional hernia, between January 1996 and January 2000, were included in this cohort study. Physical examination was performed in all patients at the time of conducting the study.

*Results* A total of 101 patients, 25 in the laparoscopic group and 76 in the open group, were included. Patient characteristics, operative time and peroperative complications were comparable in both groups. Postoperative infections were found in 14% after open repair and in 4% after laparoscopic repair ( $p=0.29$ ). Median hospital stay was 5 days in the open group and 4 in the laparoscopic group ( $p=0.28$ ). The 2-year cumulative incidence of recurrence was comparable in both groups; 18% after open repair (median follow-up of 17 months) and 15% after laparoscopic repair (median follow-up of 15 months). Recurrences in the laparoscopic group only occurred in the first series of 7 repairs, in which mesh fixation was only accomplished with tackers.

*Conclusion* Although not statistically significant, a trend was seen towards less postoperative wound infection and shorter hospital stay after laparoscopic incisional hernia repair, compared to open repair with mesh. Recurrence rates were comparable in both groups.



## Introduction

Incisional hernia is one of the most frequent long-term complications of abdominal surgery. In prospective studies, the incidence of incisional hernia ranges from 11 to 20% after a laparotomy<sup>1-4</sup>. Although many techniques have been described for incisional hernia repair, results are often disappointing. Following primary suture repair, recurrence rates of 24 to 54% have been reported<sup>5-9</sup>. A tension-free repair using a prosthetic mesh appears associated with lower recurrence rates of 10 to 34%<sup>10-11</sup>. However, open mesh repair requires more tissue-dissection than primary suture repair, predisposing to wound infection and painful recovery<sup>12-15</sup>.

Laparoscopic incisional hernia repair is an alternative to open incisional hernia repair. Because large abdominal incisions and extensive tissue dissection are avoided, less wound infection, and faster recovery with shorter hospital stay are likely. Further, this technique may decrease recurrence rates due to better visual peroperative detection of other subclinical fascial defects.

The purpose of this study was to compare open and laparoscopic mesh repairs, in order to determine if laparoscopic incisional hernia repair is associated with less postoperative wound complications and recurrence rates than open incisional hernia repair.

## Method

All patients who had undergone open or laparoscopic incisional hernia repair between January 1996 and January 2000 at the Erasmus University Medical Center Rotterdam and the Medical Center Rijnmond Zuid in Rotterdam were analysed. Criteria for inclusion in this study were midline incisional hernia and mesh repair. Patients had physical examination at the outpatient department at the time of conducting the study (mid 2000), to detect recurrent incisional hernia.

All surgical procedures were performed under general anesthesia employing antibiotic prophylaxis with a first generation cephalosporin. Regarding patient selection for the open or laparoscopic group, there were no consistent guidelines.

In the open procedure, the dorsal side of the fascia adjacent to the hernia was freed from the underlying tissue by at least 4 cm. The hernial sac was reduced into the abdominal cavity,

without resection of the sac. A polypropylene mesh (Marlex<sup>®</sup> or Prolene<sup>®</sup>) was tailored to the defect in a sublay position with a continuous suture of Prolene no.0 or 1., with an overlap with the fascial edges of at least 3 cm. The hernial defect was not sutured.

In the laparoscopic procedure, a polypropylene mesh was fixed intraperitoneally. The laparoscopic technique started with the establishment of a CO<sub>2</sub>-pneumoperitoneum. Distant from previous incisions a 30° laparoscope and two or three additional 5 or 10 mm trocars were inserted, as far as possible from the hernia defect. Adhesions at or around the defect were taken down carefully, using blunt and sharp dissection, to allow sufficient surface to place a mesh. Resection of the hernial sac was not performed. After adhesiolysis, a polypropylene mesh was introduced into the abdominal cavity. It was fixated to the circumference of the defect with an overlap of at least 3 cm. Fixation was performed by using tackers (Origin Med-systems, Menlo Park, CA, USA) and/or transfascial sutures that were positioned by means of an Endoclose-needle<sup>®</sup> (United States Surgical Cooperation, Norwalk, CT, USA).

Regarding postoperative complications, mild infection was defined as redness and pussy discharge from the wound, while severe infection was defined as fever with positive bacterial culture of the mesh. Seroma was defined as postoperative accumulation of fluid at the site of the former hernial sac.

Statistical analysis was based on the intention-to treat principle. Percentages were compared using Fisher's exact test. The Mann-Whitney-U test was used to evaluate hospital stay. Cumulative incidence of recurrence of incisional hernia was determined using Kaplan Meier curves and compared with the logrank-test.  $P=0.05$  (two-sided) was considered the limit of significance.

## Results

A total of 101 patients, 25 in the laparoscopic group and 76 in the open group, were included in the study. The two groups were homogeneous in terms of age, sex, Body Mass Index, history of previous abdominal surgery, number of previous incisional hernia repairs and size of the hernial defect (table 1). Median operating time was 120 minutes in the laparoscopic group (range 90-160) and 110 minutes in the open group (range 45-203), which was not statistically significant.

Table 1. Patient characteristics

	Laparoscopic	Open
Number of patients	25	76
Age (yrs)	63 (33-79)	57 (29-85)
Male/female ratio	13/12	40/36
Body Mass Index (kg/m <sup>2</sup> )	30 (20-35)	28 (21-44)
Number of previous abdominal operations:		
1	12	34
2	7	19
3	6	24
Number of previous incisional hernia repairs:		
0	16	57
1	6	16
2	1	4
3	2	0
Diameter of hernial defect (cm)	5 (2-10)	5 (1-30)

*Data given are number of patients or median (range).*

Intraoperative complications occurred in five patients (7%) in the open group (bowel perforation n=2, serosal damage n=2, superficial hepatic rupture n=1) and in two patients (8%) in the laparoscopic group (intestinal perforation, n=2), which was not statistically different. In the two patients with bowel perforations in the open group, the perforation was closed and a polypropylene mesh was placed subfascially. In the two patients with peroperative bowel perforation in the laparoscopic group, the procedure was converted to open surgery and the bowel injury was repaired. In one of these patients, the defect of the abdominal wall was closed by means of a suture repair, while the other patient underwent mesh repair. Prophylactic antibiotics were continued for 5 days in these patients. Another laparoscopic procedure was converted because of severe adhesions, rendering a conversion rate of 12% (3/25).

In the laparoscopic procedures, the mesh was fixated by tackers solely in 16 patients and by a combination of tackers and transfascial sutures in six patients.

Median postoperative hospital stay was 4 days (range 1-11) after the laparoscopic procedure and 5 days (range 1-19) after an open repair. This difference was not statistically significant ( $P=0.28$ )

Postoperative complications are shown in table 2. Postoperative wound infection developed in 11 patients in the open group, and in one patient in the laparoscopic group, in whom the procedure had been converted to an open repair ( $p=0.29$ ). Wound infection was considered mild in eight patients, but was severe in four patients, including all three patients in whom a mesh was placed after intraoperative bowel injury. In three of the patients with mesh infection, conservative treatment with drainage and antibiotics was successful. The fourth patient however, in whom open incisional hernia repair had been complicated by two peroperative bowel perforations, developed two enterocutaneous fistulas. For this reason, the patient was reoperated at 7 months postoperatively. During this reoperation, the mesh was removed and a partial small bowel resection was performed, followed by primary suture of the fascia. After this, the patient recovered well.

Seroma was the most frequent complication in both groups, with an incidence of 17% in the open, and 36% in the laparoscopic group (not statistically different,  $P=0.09$ ). In most of the patients, the seroma resolved spontaneously, or after one or two aspirations. However, one patient in the laparoscopic group developed a persisting seroma that only resolved after 12 aspirations.

Other postoperative complications consisted of urinary retention ( $n=1$ ), pneumonia ( $n=2$ ) and pulmonary embolism ( $n=1$ ). All were treated successfully. Three patients died during follow-up. Their causes of death were related to malignancy and not the incisional hernia repair.

Nine patients (eight in the open group and one in the laparoscopic group) were readmitted to the hospital. Readmission was for symptomatic recurrent incisional hernia ( $n=6$ ), reoperation for enterocutaneous fistula ( $n=1$ ) and severe wound infection ( $n=2$ ).

At the time of conducting the study, 94 patients (93%) underwent physical examination at the outpatient department. One patient from the laparoscopic group and 6 patients from the open group could not be traced or did not respond to the invitation. In these patients, the general practitioner was contacted and follow-up was defined as the last physical examination that was performed.

Table 2. Postoperative complications and recurrences

	Open surgery	Laparoscopic surgery	<i>P</i> -value
<b>Early postoperative complications:</b>			
Seroma/hematoma	13 (17)	9 (36)	<i>n.s.</i>
Wound infection:	(15)	(4)	<i>n.s.</i>
- Mild	7	1	
- Severe	4	0	
Ileus	3	1	
Urine retention	1	1	
Pneumonia	2	0	
Pulmonary embolism	0	1	
Median follow-up (months)	17	15	
<b>Recurrence</b>	14 (18)	4 (16)	<i>n.s.</i>
Readmission	8 (11)	1 (4)	<i>n.s.</i>
Re-operation	6 (8)	1 (4)	<i>n.s.</i>
Indication:			
- Recurrence	5	1	
- Enterocutaneous fistula	1	0	

*Values in parentheses are percentage. ns= not statistically significant*

During a median follow-up time of 17 months in the open group (range 1-46) and 15 months in the laparoscopic group (range 1-44), there were 14 recurrences after open repair and four after laparoscopic repair. Six of these recurrences (two in the open group and four in the laparoscopic group) had not been detected before and were only diagnosed at per-protocol physical examination. The time of occurrence of these recurrences could be determined retrospectively in the patient interview. Calculated with the Kaplan Meier method, the 2-year cumulative incidence of recurrence was 18% after open repair and 15% after laparoscopic repair, which was not statistically different ( $p=0.91$ ). There was no significant relation between initial diameter of the hernial defect and recurrence rate. All four recurrences in the laparoscopic group occurred in the first series of 7 laparoscopic incisional hernia repairs which were performed in each hospital. In one of these cases the laparoscopic procedure had been converted to an open procedure. The other three recurrences after a laparoscopic

procedure occurred in the group of 16 patients in whom the mesh was fixated with tackers solely (3/16=19%). No recurrences were seen in the six patients in whom the mesh was fixated by a combination of tackers and transfascial sutures.

Only five of the patients with recurrence (all within the open group) underwent repair of the recurrent hernia, all in an open procedure with a mesh. One patient in the laparoscopic group underwent reoperation because of suspicion of a recurrent incisional hernia, but at reoperation no recurrence could be detected and a blind hernial sac that was filled with fluid was resected.

## Discussion

Laparoscopic repair of incisional hernia has been studied by several authors. Results of all published comparative studies on open and laparoscopic incisional hernia repair are shown in table 3.<sup>13-18</sup>

In these studies, operating time of laparoscopic incisional hernia repair varied, which appeared related to the laparoscopic experience of the operating team. In the present study, operating time was comparable in both groups, although surgeons had limited experience with laparoscopic incisional hernia repair.

During both open and laparoscopic incisional hernia repair, the most delicate part of the procedure is the adhesiolysis, during which the bowel may be injured. In our series, bowel injury was encountered in 8% in both groups. In other series, comparable percentages were reported after both open incisional hernia repair (0-7%) and laparoscopic repair (0-14%).<sup>13-18</sup> Probably, the incidence of peroperative bowel injury will decrease with growing experience of the surgeon.

Table 3. Overview of published comparative studies between laparoscopic and open ventral incisional hernia repair:

	DeMaria et al. <sup>13</sup>		Ramshaw et al. <sup>14</sup>		Carbajo et al. <sup>15</sup>		Holzman et al. <sup>16</sup>		Park et al. <sup>17</sup>		Chari R et al. <sup>18</sup>	
Study design	Prospective not randomised		retrospective		Prospective randomised		Retrospective		Prospective not randomised		matched case- control	
	Lap	open	lap	open	Lap	open	Lap	Open	Lap	Open	lap	open
No. of patients	21	18	79	174	30	30	22	16	56	49	14	14
Material of mesh	ePTFE	PP	ePTFE	Suture or mesh	ePTFE	8 ePTFE 22 PP	PP	10 PP 1 ePTFE 5 suture	44 PTFE 12 PP	3 ePTFE 42 PP 4 Vicryl	ePTFE	PP
Operating time (min)			58	82	87*	112*	129	98	96*	79*	124	78
Blood loss (ml)			17	70							68	168
Peroperative bowel injury			3	2		2	1	0		1	2	1
<b>Hospital stay (days)</b>	<b>0.8*</b>	<b>4.4*</b>	<b>1.7</b>	<b>2.8</b>	<b>2*</b>	<b>9*</b>	<b>1.5</b>	<b>3.9</b>	<b>3.4*</b>	<b>6.5*</b>	<b>5</b>	<b>5.5</b>
<b>Postoperative complications:</b>												
- Woundinfection	2 (10)	6 (33)	2 (3)	11 (6)	0	5 (17)	0	1 (7)	2 (4)	3 (6)	1 (7)	0
- infected mesh removed	1	0	0	5	0	3	0	0	0	0	1	0
- Hematoma/ Seroma	9 (43)	4 (22)	2 (3)	12 (7)	4 (13)	26 (87)	1 (5)	0	2 (4)	6 (12)		
- Other complications	2	3	5	15	1	1	3	3	4	6		1
<b>- total</b>	<b>62%</b>	<b>72%</b>	<b>20%</b>	<b>27%</b>	<b>17%*</b>	<b>90%*</b>	<b>23%</b>	<b>31%</b>	<b>18%*</b>	<b>37%*</b>	<b>14%</b>	<b>7%</b>
Mean follow-up (months)	12-24	12-24	21	21	27	27	20	19	24	54		
<b>Recurrence</b>	<b>5%</b>	<b>0%</b>	<b>3%</b>	<b>20%</b>	<b>0</b>	<b>6%</b>	<b>9%</b>	<b>13%</b>	<b>11%</b>	<b>35%</b>		

Lap= laparoscopic incisional hernia repair, open= open repair. ePTFE=polytetrafluoroethylene, PP=polypropylene, Vicryl=polyglactin, Values in parentheses are percentage. \*=statistically significant difference between open and laparoscopic group

Most published comparative studies reported less wound infections after laparoscopic repair, compared to open repair.<sup>13-15,17,18</sup> The same trend was seen in the present study, with 4% postoperative wound infection in the laparoscopic group and 15% in the open group. This difference was however not statistically significant, which may be due to the small number of patients in the laparoscopic group. Possibly, the combination of a smaller porte d' entrée for micro-organisms and the absence of the need for large tissue dissection in laparoscopic repair may contribute to a lower risk for infection after this minimally invasive procedure.

In both the present study and other comparative studies, the most frequent complication after incisional hernia repair was the formation of a seroma or a hematoma, with reported incidences between 2 and 36% for the laparoscopic group and between 4 and 87% for the open group<sup>13-18</sup>. The large spreading in incidence of this complication is remarkable, and is probably due to differences in definition of this complication. The most plausible explanation for the occurrence of seroma is the collection of fluid in a persisting hernial sac or in the cavity remaining after removal of the hernial sac. Seroma can be drained by aspiration, but resolves spontaneously in most cases. Therefore, resection of the hernial sac does not seem indicated in laparoscopic incisional hernia repair. To differentiate seroma from recurrent incisional hernia, which can be clinically difficult in obese patients, an ultrasound or computed tomography (CT) has been advocated.

Reoperation was performed in seven patients (six in the open group and one in the laparoscopic group). One of these patients had developed an enterocutaneous fistula after an open procedure. Although this complication has been previously reported after intraperitoneal mesh placement in some case-reports, it is a very rare complication with a long-term incidence of about 1%.<sup>9,19-21</sup> Its occurrence is mostly restricted to cases in which the mesh was placed in an infected abdomen.<sup>21</sup> In the patient in the present study who developed the enterocutaneous fistula, the mesh was also placed in a contaminated abdomen, since the incisional hernia repair had been complicated by two bowel perforations. Thus, if the abdomen is contaminated, the risk for developing enterocutaneous fistula is probably increased. Therefore, in these patients it is recommended to prevent intraperitoneal placement of the mesh and continue prophylactic antibiotics for several days.

Hospital stay is an important parameter to assess postoperative recovery, and was reduced after laparoscopic repair in three comparative studies<sup>13,15,17</sup>. However, although a trend



towards a reduction of hospital stay after laparoscopic repair was found in the present study, this difference was not statistically different.

Compared to the findings of other authors, the present study identified a higher recurrence rate after laparoscopic repair.<sup>13-18</sup> The explanation for this is unclear, although it is remarkable that all recurrences in the present study occurred in the first series of 7 repairs. For this reason, a learning curve may have played a role in the higher incidence of recurrence after laparoscopic repair. Another factor is formed by the fixation method of the mesh. Since all recurrences in the laparoscopic group occurred in the patients in whom the mesh was fixated with tackers solely, addition of transfascial sutures to fixate the mesh may decrease recurrence rates. Unfortunately, the group with fixation of both tackers and transfascial sutures in the present study was too small to draw any conclusions on this hypothesis.

Another factor which may have played a role in the higher recurrence rate in the present study is the fact that in most other studies follow-up was not performed by means of physical examination<sup>13-16,18</sup>. As was shown by the present study, six of the eighteen recurrences, which had developed, were only diagnosed at the per-protocol physical examination at the outpatient department at the time of conducting the study. Therefore, physical examination is essential to perform adequate follow-up.

In the present study, no significant difference was found between recurrence rates after laparoscopic or open incisional hernia repair, which was confirmed by other authors.<sup>13,15,16,18</sup> However, two comparative studies found less recurrences after laparoscopic repair than after open repair.<sup>14,17</sup> In contrast to the present study, in both of these studies mesh material varied between the open and laparoscopic group, and both studies also included patients in the open group in whom open repair was conducted by primary suture without using a mesh<sup>14,17</sup>. As was shown by various authors, incisional hernia repair without the use of a mesh is associated with higher incidences of recurrences.<sup>3,8,22,23</sup> In addition, both of these studies included a variety of incisional hernias, while the present study only included incisional hernias that had developed after midline laparotomy.

In conclusion, laparoscopic incisional hernia repair appears an effective technique, as safe as the open procedure. Although not statistically significant, a trend was seen towards less postoperative wound infection and shorter hospital stay after laparoscopic incisional hernia repair, compared to open mesh repair. Recurrence rates were comparable between laparoscopic and open incisional hernia repair with mesh.

To establish if laparoscopic incisional hernia repair is associated with less postoperative pain and faster return to normal activity and work (compared to open incisional hernia repair with mesh), we are currently performing a prospective randomised multicenter trial in the Netherlands that is coordinated by the Erasmus University Medical Centre Rotterdam.

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## CHAPTER 7

### Tensile strength of mesh fixation in laparoscopic incisional hernia repair

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*Surg Endosc 2002;16:1713-16*

## Abstract

*Background:* Fixation of mesh is crucial for successful laparoscopic incisional hernia repair. In the present experimental study, tensile strength of helical titanium coils (tackers) and transabdominal wall sutures was assessed in a pig model.

*Methods:* Thirty-six full thickness specimens (5x7 cm) of the anterior abdominal wall of nine pig cadavers were randomised for fixation of a polypropylene mesh (7x7 cm) by either tackers or transabdominal wall sutures. The number of fixation points varied from one to five per 7 cm tissue length, with distances between fixation points of 2.3, 1.8, 1.4 and 1.2 cm respectively. The force required to disrupt mesh fixation (tensile strength) was measured by a dynamometer. Statistical analysis was performed using Wilcoxon Rank Sum test and Spearman rank correlation test.

*Results:* Mean tensile strength of mesh fixation by transabdominal wall sutures was significantly greater than that by tackers for each number of fixation points; 67N versus 28 N for a single fixation point ( $p<0.001$ ), 115 N versus 42 N for two fixation points ( $p<0.001$ ), 150 N versus 63 N for three fixation points ( $p<0.05$ ), 151 N versus 73 N for four fixation points ( $p<0.05$ ), and 150 N versus 82 N for five fixation points ( $p<0.05$ ). Increasing the number of fixation points over 3 per 7 cm (distance between fixation points of 1.8 cm) did not improve tensile strength.

*Conclusion:* Tensile strength of transabdominal wall sutures is up to 2.5 times greater than the tensile strength of tackers. Therefore, use of transabdominal wall sutures for mesh fixation appears preferable in laparoscopic incisional hernia repair.

## Introduction

Laparoscopic incisional hernia repair appears associated with less postoperative pain, shorter hospital stay and earlier return to normal activities than conventional surgery.<sup>1-5</sup> However, recurrence rates up to 11 % have been reported after laparoscopic incisional hernia repair and remain a source of concern.<sup>5</sup> To reduce recurrence rates, proper fixation of the mesh and sufficient overlap of the prosthesis are important factors<sup>6,7</sup>.

For laparoscopic fixation of the mesh, several techniques are available. Currently, the most frequently used techniques involve fixation with tackers or transabdominal sutures. Tackers are titanium helical coils with tissue penetration depth of maximal 3.8 mm. Transabdominal sutures penetrate all layers of the abdominal wall, and therefore enable fixation of the mesh to the entire fascio-muscular layer of the abdominal wall. In the present study, tensile strengths of fixation with tackers and transabdominal sutures were compared and the optimal distance between fixation sites was determined. For this purpose, a pig cadaver model was used.<sup>8</sup>

## Methods

The anterior abdominal wall of nine pig cadavers (31-37 kg, 4 male, 5 female) was excised post-mortem. In all pigs, a full-thickness incision was made, extending from the left lateral margin of the abdominal wall to the lower margin of the lowest ribs and to the right lateral margin of the abdomen. Subsequently, the abdominal wall incision was horizontally extended at the level of the pubic bone. Thus, a full-thickness specimen of the entire abdominal wall was acquired. The abdominal wall was kept at 5° C for 12 hours. Subsequently, 6 full thickness transverse specimens of 5 by 7 cm were excised. These 6 specimens were excised bilaterally from both sides of the linea alba; 2 at the level caudally to the semicircular line (level I), 2 directly cranially to the semicircular line (level II) and 2 cranially to level II (level III) (Figure 1).

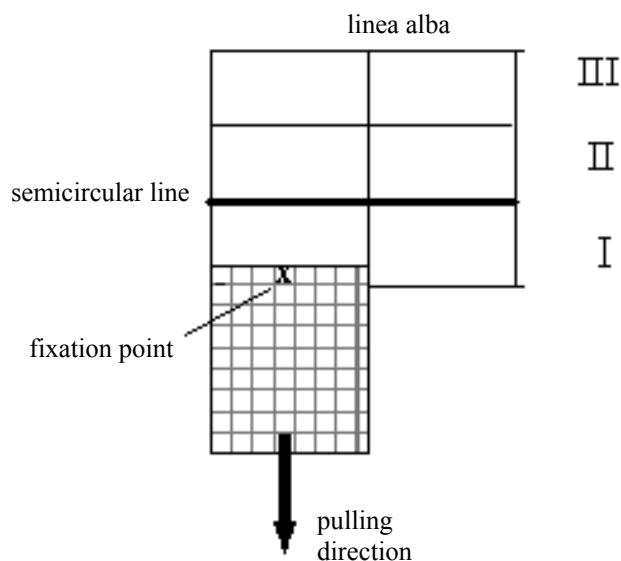
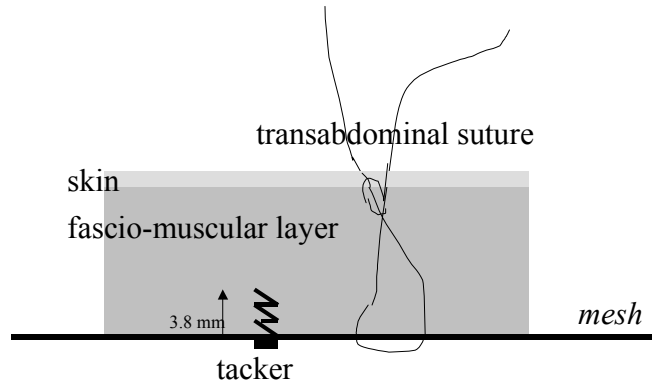


Figure 1. Division of the abdominal wall and mesh fixation

A polypropylene mesh (Prolene, Ethicon, Cincinnati, Ohio, USA) of 7 by 7 cm was fixed to each specimen, at 1.5 cm from the caudal margin and 3.5 cm from the lateral margin (Figure 1). For each horizontal level (I, II, or III), specimens were randomised for fixation with tackers (Pro Tack 5 mm, Auto Suture, United States Surgical Corporation, Norwalk, CT, USA) or transabdominal Prolene 0 sutures (Ethicon, Cincinnati, Ohio, USA) (Figure 2). Transabdominal sutures were inserted by a special device (Endoclose<sup>®</sup>, Surgical Corporation, Norwalk, CT, USA). A skin incision of 2 mm was made and the Endoclose needle was inserted to pull the suture through the abdominal wall and mesh. After release of the suture on the intra-abdominal side, the device was withdrawn in the subcutis and re-inserted through the fascia at 0.7 cm distance from the first entry. The suture was placed in the tip of the device and pulled out. The suture was tied with 5 alternating knots.





*Figure 2. Fixation of mesh with helical tacker or transabdominal suture*

After the mesh was fixed, the cranial side of the abdominal specimen was clamped. The caudal margin of the mesh was grasped by moveable clamps, connected to a dynamometer. (Figure 3). The measurements of the dynamometer were electronically stored. The mesh was pulled in the direction of the caudal margin of the section, with a continuous rate of 100 mm/min. The force required to disrupt the fixation of the mesh was measured with the dynamometer and registered. The mode of detachment was documented.

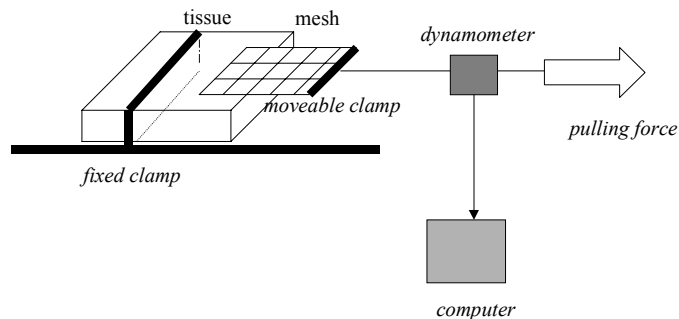


Figure 3. measurement of tensile strength.

At first, the pullout test was performed in 18 specimens recovered from 3 anterior abdominal walls. In each test, the mesh was fixed at a single site by either a tackler or a transabdominal suture. Subsequently, the number of fixation sites was stepwise increased. Fixation sites were equally divided over the width of the section (7 cm). Testing with 2 fixation sites (space between fixation sites of 2.3 cm) was performed in 18 sections (3 abdominal walls). Testing with 3, 4 or 5 fixation sites (space between fixation sites of respectively 1.8 cm, 1.4 cm and 1.2 cm) was performed in 6 sections (one abdominal wall) for each number of fixation sites.

#### *Statistical analysis*

For all variables, mean values were calculated. Fixation with tackers was compared to fixation with transabdominal sutures using a paired and two-sided Wilcoxon Rank Sum test. A difference of  $p < 0.05$  was considered statistically significant. To assess if the strength of the fixation increased by increasing the number of fixation sites, a Spearman rank correlation test was done. A correlation of 0 was considered as no correlation, whereas a correlation of 1 was considered a very strong correlation.

## Results

For each number of fixation points, mean tensile strength of fixation by transabdominal sutures was significantly higher than mean tensile strength of fixation by tackers, as is shown in table 1. Tensile strength of a single transabdominal suture was 67 N (range 46-87), which was significantly higher than mean tensile strength of a single tacker of 28 N (range 27-57,  $p < 0.001$ , table 1). No significant difference was found between tensile strength of fixation caudally to the semicircular line (section I) and cranially to the semicircular line (section II and III).

Table 1. Comparison of bursting strength of fixation with increasing number of tackers or transabdominal sutures per 7 cm tissue length.

Number of fixationpoints	Mean bursting strength tacker (range)	Mean bursting strength suture (range)	P-value
1 (n=18)	28 N (24-34)	67 N (46-87)	<0.001
2 (n=18)	42 N (27-57)	115 N (71-170)	<0.001
3 (n=6)	63 N (61-65)	150 N (125-175)	<0.05
4 (n=6)	73 N (64-80)	151 N (113-194)	<0.05
5 (n=6)	82 N (62-87)	150 N (123-168)	<0.05

Cause of detachment of fixation with tackers was either deformation of the tacker in 56% of cases, or tissue disruption in 44% of cases. Detachment of fixation with a transabdominal suture was caused by tissue disruption in 56% of cases, and by breakage of the suture in 44% of cases. The mesh did not disrupt in any experiment.

In both groups, strength of the fixation increased when two or three fixation points were used, compared to fixation by a single fixation point (correlation of 0.84 for tackers and 0.80 for transfascial sutures,  $p < 0.001$ ). However, addition of more than three fixation points per 7 cm tissue length did not increase tensile strength significantly in either group (correlation of 0.53,  $p = 0.15$ , for tackers and correlation of -0.05,  $p = 0.89$ , for transabdominal sutures). Thus, reducing the interval between fixation points below 1.8 cm was not associated with greater tensile strength.

## Discussion

In incisional hernia repair, proper fixation of the mesh is important to prevent incisional hernia recurrence. The ideal fixation method must guarantee sufficient strength to withstand pressures that can be generated in the abdomen during coughing and straining.

The first device that was developed for laparoscopic mesh fixation was the endostapler (e.g. Endopath EMS endoscopic multifeed stapler<sup>®</sup> or Endo Hernia stapler<sup>®</sup>, Medical Industry).<sup>9</sup> With this device, the mesh is fixed with titanium staples with tissue penetration depth of 2 to 4.8 mm, dependent of the size of staple that is used. However, the shear force resistance of a mesh fixed by a stapler was found to be up to four times as low as that of a mesh fixed by a tacker in an experimental study (7.5 N versus 34.0 N for two fixation points).<sup>10</sup> Further, use of staples can cause twisting and compression of tissue containing pain transmitting nerves, which may result in painful lesions.<sup>10</sup> Therefore, fixation with staples was not preferred.

In the present study, tensile strength of fixation with tackers was compared to fixation by transabdominal sutures. It was shown that mean tensile force of a transabdominal suture was up to 2.5 times that of a tacker. Thus, fixation by transabdominal sutures provides significant stronger fixation than fixation with tackers solely, and will, therefore, possibly prevent recurrent incisional hernia. Since many surgeons nowadays perform mesh fixation only with tackers during laparoscopic repair, recurrence rates might drop when transabdominal sutures are employed.<sup>3,11</sup> In order to facilitate mesh positioning during the surgical procedure, tackers can be used to position the mesh around the hernial defect. However, in order to fixate the mesh adequately, addition of transabdominal sutures is preferred.

The number of fixation sites is another important factor. To a certain extent, increasing the number of fixation sites reduces the maximal force per single fixation point. However, as was shown by the present study, addition of more than three fixation points per seven cm length did not lead to further increase in bursting strength. In the present study, optimal distance between fixation points was therefore 1.8 cm. In the clinical situation, ideal distance between fixation points can be estimated by dividing the surrounding of the mesh covering the hernial defect ( $2\pi r$ ) by 7 and multiplying this number by 3. This leads to the formula:  $((2\pi r)/7) \times 3 = 2.7r$  (table 2).

Table 2. Estimation of optimal number of fixation points per diameter of mesh covering the hernial defect.

diameter (cm)	optimal number of fixation points (2.7 r)
4	5
6	8
8	11
10	13
12	16
14	19
16	22

*diameter = 2r*

In conclusion, tensile strength of transabdominal sutures is up to 2,5 times as high as tensile strength of tackers. Therefore, in order to prevent incisional hernia recurrence, addition of transabdominal sutures in mesh fixation is important, as well as the use of an adequate number of fixation points.

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## CHAPTER 8

### Prevention of adhesion to prosthetic mesh: comparison of different barriers using an incisional hernia model.

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*Annals of Surgery* 2003; 237:123-8

## Abstract

*Background:* Incisional hernia repair frequently involves the use of a prosthetic mesh. However, concern exists about development of adhesions between viscera and the mesh, predisposing to intestinal obstruction or enterocutaneous fistulas. The aim of this study was to assess whether use of anti-adhesive liquids or coatings could prevent adhesion formation to the mesh.

*Method:* In 91 rats, a defect in the muscular abdominal wall was created, and a mesh was fixed intraperitoneally to cover the defect. Rats were divided in five groups; polypropylene mesh only (control group), addition of Sepracoat<sup>®</sup> or Icodextrin<sup>®</sup> solution to polypropylene mesh, Sepramesh<sup>®</sup> (polypropylene mesh with Seprafilm coating), and Parietex Composite mesh<sup>®</sup> (polyester mesh with collagen coating). Seven and 30 days postoperatively, adhesions were assessed and wound healing was studied by microscopy.

*Results:* Intraperitoneal placement of polypropylene mesh was followed by bowel adhesions to the mesh in 50% of the cases. A mean of 74% of the mesh surface was covered by adhesions after 7 days, and 48% after 30 days. Administration of Sepracoat or icodextrin solution had no influence on adhesion formation. Coated meshes (Sepramesh and Parietex composite mesh) did not have any bowel adhesions ( $p=0.04$ ). In addition, Sepramesh was associated with a significant reduction of the mesh surface covered by adhesions after 7 and 30 days. Infection was more prevalent after use of Parietex composite mesh, with concurrent increased mesh surface covered by adhesions after 30 days (78%,  $p=0.03$ ).

*Conclusion:* Sepramesh significantly reduced mesh surface covered by adhesions and prevented bowel adhesion to the mesh. Parietex Composite mesh prevented bowel adhesions as well, but increased infection rates in the current model.



## Introduction

Incisional hernias occur in 5-20% after abdominal surgery.<sup>1-4</sup> In incisional hernia repair, the introduction of tension-free techniques by using prosthetic material has reduced recurrence rates, from up to 50% to less than 24%.<sup>5-9</sup> However, foreign materials, such as prosthetic mesh, represent a strong stimulus for the development of permanent adhesions.<sup>10</sup> Particularly if the mesh is placed intraperitoneally, concern exists about development of adhesions between bowel and mesh. These adhesions can cause serious complications, such as intestinal obstruction and enterocutaneous fistulae.<sup>11-14</sup>

The aim of the present study was to assess whether adhesions due to intraperitoneal mesh can be prevented by the use of physical barriers that can be applied laparoscopically. For this purpose, we assessed if intraperitoneal administration of liquid physical barriers composed of hyaluronic acid (Sepracoat<sup>®</sup>, HAL-C; Genzyme Corporation, Cambridge, MA) or Icodextrin solution (Extraneal<sup>®</sup>, Baxter Healthcare Inc.) could prevent adhesions to a polypropylene mesh, without interfering with wound healing and tissue incorporation of the mesh. In addition, we studied the ability of specifically coated meshes, Sepramesh<sup>®</sup> (Genzyme Corporation, Cambridge, MA) and Parietex<sup>®</sup> Composite mesh (Sofradim, France), to prevent adhesions.

## Methods

### *Animals*

Ninety-one male inbred rats of the Wistar strain, weighing 250-300 gram, were obtained from Harlan, Zeist, The Netherlands. They were bred under specific pathogen free conditions, kept under standard laboratory conditions (temperature 20-24° C, relative humidity 50-60%, 12 hours light/12 hours dark), fed with laboratory diet (Hope Farms, Woerden, the Netherlands) and water ad libitum. The experimental protocol adhered to rules laid down by the Dutch Animal Experimentation Act and was approved by the Committee in Animal Research of the Erasmus University Rotterdam. Non-powdered gloves were used routinely in the experimental procedure.

### *Operative procedure*

Following initial sedation with ether, each animal received intraperitoneal injection of 0.15 mL ketamine (100 mg/mL) and 0.04 mL xylazine (20 mg/mL). The abdomen was shaved and cleaned with alcohol 70%.

The experiments were performed in a validated rat-model, described previously by Alponat et al. and Hooker et al.<sup>15,16</sup> In all animals, laparotomy was performed using a midline incision of 4 cm. Skin flaps were raised and a standardised 1.5 x 2.5 cm longitudinal full thickness defect consisting of fascia, muscle and peritoneum was created.

### *Experiment 1*

In 20 rats, the defect of the abdominal wall was repaired with a polypropylene mesh (Prolene, Ethicon Inc., Somerville, NJ, USA) of 2.5 x 3.5 cm that was fixed intraperitoneally with 8 interrupted Prolene 5.0 sutures. Subsequently, the rats were randomised between no additional treatment (control group, n=10) and addition of 4 mL Sepracat<sup>®</sup> solution (n=10) intraperitoneally. In all animals, the skin was closed with continuous 4-0 polyglactin suture (Vicryl, Ethicon). Seven days postoperatively, adhesions were scored.

### *Experiment 2*

In 20 rats, the defect of the abdominal wall was repaired with a polypropylene mesh (Prolene, Ethicon Inc., Somerville, NJ, USA) of 2.5 x 3.5 cm that was fixed intraperitoneally with 8 interrupted Prolene 5.0 sutures. After placement of the mesh, the rats were randomised between no additional treatment (control group, n=10) and addition of 4 mL icodextrin 7.5% solution (Extraneal<sup>™</sup>, Baxter Healthcare Inc.) intraperitoneally (n=10). In all animals, the skin was closed with continuous 4-0 polyglactin suture (Vicryl, Ethicon). To prevent leakage of the liquid icodextrin solution, the skin of the animals was additionally closed with Histoacryl<sup>®</sup> glue. Seven days postoperatively, adhesions were scored.

### *Experiment 3*

Thirty rats were randomly divided into three groups. In group I (n=10), the defect was repaired with a polypropylene mesh (Prolene, Ethicon Inc., Somerville, NJ, USA) of 2.5 x 3.5 cm. In group II (n=10) the defect was repaired with a polypropylene mesh, coated with hyaluronic acid and carboxymethylcellulose on the visceral side of the mesh (Sepramesh<sup>™</sup>,

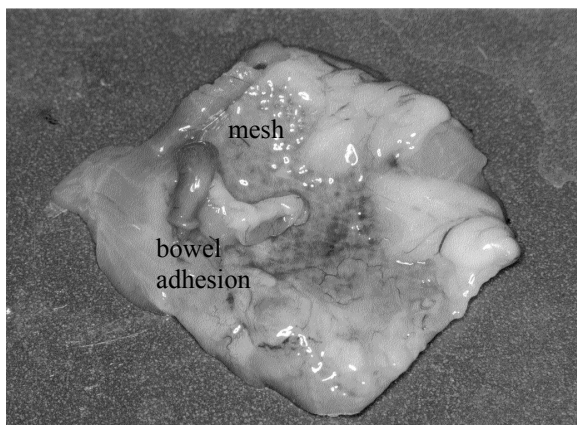
Genzyme Corporation, Cambridge, MA). In group III, the defect was repaired with a polyester mesh with a collagen coating on the visceral side (Parietex<sup>TM</sup> Composite mesh, Sofradim, France) Meshes were fixed intraperitoneally with 8 interrupted Prolene 5.0 sutures and skin was closed with continuous 4-0 polyglactin suture (Vicryl, Ethicon). Seven days postoperatively, adhesions were scored.

#### *Experiment 4*

Experiment 4 was identical to experiment 3 and was performed in 21 rats (7 rats in each group) Adhesions were assessed after 30 days, instead of 7 days.

#### *Scoring of adhesions, infection and incorporation.*

Seven or 30 days postoperatively, all rats were sacrificed and had an autopsy. A median skin incision was created and the abdominal cavity was entered through a U-shaped incision, extending caudal and lateral to the mesh. The presence of adhesions between bowel and the mesh was assessed. For each rat it was documented whether bowel adhesions were present or not. After that, the mesh was excised and both bowel and omental adhesions were sharply cut. The surface of the mesh that was covered by bowel- and/or omental adhesions was assessed (Figure 1.) For this purpose, the mesh surface was divided in 6 sections. Each section was subsequently subdivided in 6 fields, and for each field the percentage of the surface covered by adhesions was estimated.



*Figure 1. Dense bowel adhesion to the mesh.*

Density of adhesions was scored according to Zühlke classification.<sup>17</sup> Infection was defined as pus coming from the mesh and wound. Incorporation of the prosthesis in the abdominal wall was scored by dividing the circumference of the mesh in 10 segments, and subsequently determining the number of segments in which the mesh was not incorporated in the abdominal wall. Two independent investigators, who were blinded to the group assignment of the rats, performed scoring of adhesions and incorporation. In case of interobserver variance, the mean was scored.

### *Histology*

Of each group, three meshes with the adjoining abdominal wall were fixed in 10% neutral buffered formalin for at least one hour. After routine tissue processing, sections were cut at 4 to 6  $\mu\text{m}$  and stained with hematoxylin and eosin. Sections were microscopically studied, and incorporation of the mesh in the surrounding tissue and inflammatory reaction were assessed for each group. The grade of inflammation was assessed using a semi quantitative scoring system, the inflammation grading scale.<sup>16</sup> Grade 1 on this scale represents mild inflammatory reaction with giant cells, occasional scattered lymphocytes and plasma cells. Grade 2 represents moderate reaction with giant cells and increases numbers of admixed lymphocytes, plasma cells, eosinophils and neutrophils, while grade 3 represents severe inflammatory reaction with microabscesses present.

### *Statistical analysis*

Statistical analysis was performed using Mann-Whitney U-test for independent samples. A p-value of less than 0.05 was considered to be statistically significant.

## Results

During the study, two animals died before the end of the experiment on the fourth and fifth day postoperatively of unknown causes (third experiment). In all animals, adhesions of the omentum to the prosthetic mesh were seen to some extent. These adhesions could only be lysed by sharp dissection (Zühlke classification 3).<sup>17</sup> No herniations of viscera between mesh and abdominal wall were seen.

With polypropylene mesh, bowel adhesions to the mesh were seen in 50 to 60% of all animals. After 7 days, a mean surface of 74 to 88% of the mesh was covered by adhesions. (Table 1). Instillation of Sepracoat solution in the peritoneal cavity did not significantly reduce the surface of the polypropylene mesh which was covered by adhesions (68% versus 82%,  $p=0.07$ ), and could not prevent bowel adhesions to the mesh (table 1). Instillation of icodextrin 7.5% solution did not reduce surface of the mesh which was covered by adhesions either (90% versus 88%). Further, icodextrin solution had no influence on formation of bowel adhesions to the mesh (table 1).

When Sepramesh was used, a significant reduction of the mean percentage of mesh surface covered by adhesions was found after seven days (55% versus 74%,  $p=0.01$ ), as well as after 30 days (25% versus 48%,  $p=0.03$ ), compared to the control group. In addition, none of the animals with Sepramesh developed adhesions between bowel and the mesh, compared to 57% of the animals with polypropylene mesh ( $p=0.04$ , table 1).

Table 1. Adhesion formation and mesh incorporation

Exp	Group	<i>n</i>	Mean % of mesh surface covered by adhesions (range)	<i>P</i>	no of rats with bowel adhesion	<i>P</i>	Mean % of mesh not incorporated (range)	<i>P</i> -value	Infection	<i>P</i> -
1	Control	10	82% (56-99)		5/10		7% (0-40)		0	
	Sepracoat	10	68% (42-86)	$P=0.07$	4/10	n.s.	12% (0-30)	n.s.	0	n.s.
2	Control	10	88% (72-100)		6/10		11% (0-55)		0	
	Icodextrin	10	90% (55-100)	n.s.	5/10	n.s.	16% (0-50)	n.s.	0	n.s.
3	Control	10	74% (27-94)		5/10		3% (0-30)		0	
	Sepramesh	9	55% (8-78)	$P=0.01$	0/9	$P=0.04$	6% (0-20)	n.s.	0	n.s.
	Parietex	9	63% (3-100)	n.s.	0/9	$P=0.04$	13% (0-10)	n.s.	40%	$P=0.02$
4	Control	7	48% (22-56)*		4/7		33% (10-60)		0	
	Sepramesh	7	25% (0-53)§	$P=0.03$	0/7	n.s.	19% (0-40)	n.s.	14%	n.s.
	Parietex	7	78% (3-100)&	$P=0.03$	0/7	n.s.	4% (0-20)	n.s.	57%	$P=0.02$

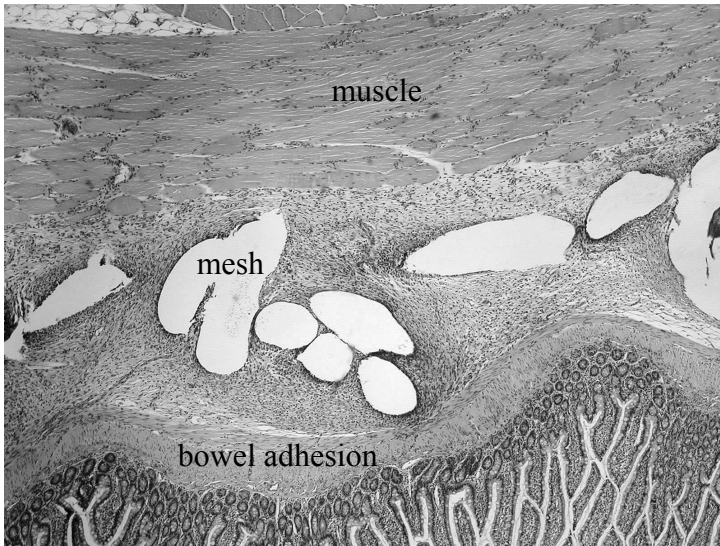
Comparison of mean % of mesh surface covered by adhesions at 7 and 30 days postoperative.

(Experiment 3 versus 4: \*  $P=0.01$ , §  $P=0.02$ , &  $P=n.s.$ )

With Parietex composite mesh there were no bowel adhesions to the mesh either ( $p=0.04$ ). However, in the Parietex mesh group, infection rate was 57% at 30 days postoperatively, compared to 0% in the control group ( $p=0.02$ ). In addition, the percentage of mesh surface covered by adhesions was higher in the Parietex mesh group (78%) than in the control group (48%,  $p=0.03$ , table 1).

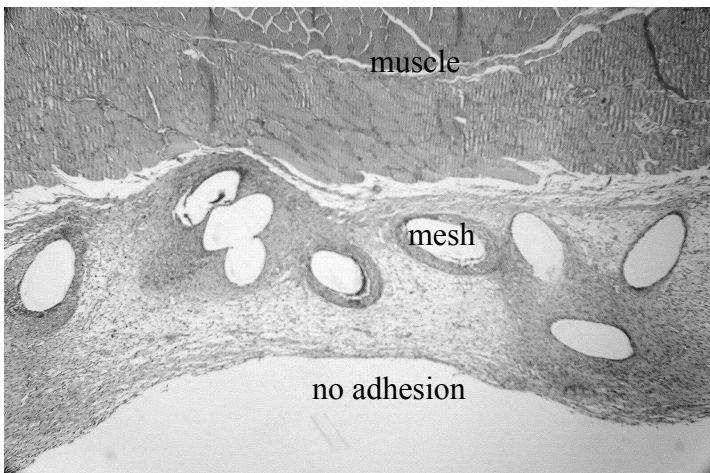
Histologic evaluation in each control group showed foreign body reaction with giant cells and increased numbers of admixed lymphocytes, plasma cells, eosinophils and neutrophils. (grade 2 on the inflammation grading scale). A comparable reaction was found in the groups with the addition of Sepracoat or icodextrin to a polypropylene mesh and in the group with Sepramesh (figure 2). However, in the group with Parietex mesh, a more severe inflammatory reaction was found, with the presence of many admixed inflammatory cells and microabscesses (grade 3 on the inflammation grading scale, figure 2). Incorporation of the mesh was similar in all study groups.

Figure 2. Light microscopy of histology at 7 days postoperative, with polypropylene mesh (A), Sepramesh (B) and Parietex Composite mesh (C).



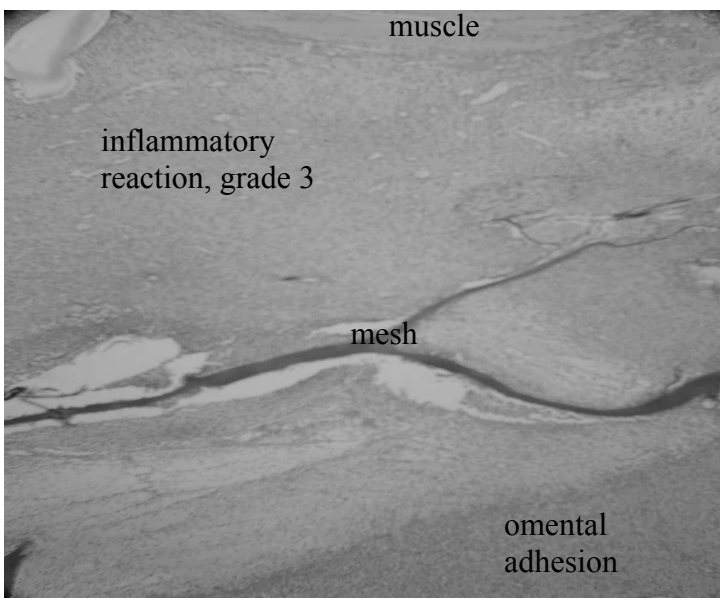
A

Dense bowel adhesion to polypropylene mesh (mesh represented by holes).



B

No adhesion to Sepramesh (mesh represented by holes)



C

The collagen membrane of Parietex Composite mesh has not been fully absorbed yet (purple line) An extensive inflammatory reaction is seen.

## Discussion

The reduction of recurrence rates following reinforcement of the abdominal wall by meshes in incisional hernia has promoted the use of mesh.<sup>9</sup> Polypropylene is most commonly used, because it is easy to handle and relatively low in costs. Because polypropylene causes a pronounced and persistent inflammatory reaction, the mesh is well incorporated in the surrounding tissue of the abdominal wall. However, for the same reason, polypropylene causes a strong stimulus for the formation of adhesions.<sup>19,20</sup>

Adhesion formation is part of the normal healing process and is observed following 90-100% of all abdominal surgical procedures.<sup>21,22</sup> Surgical trauma and foreign body reaction inhibit plasminogen activator activity. This inhibition is followed by reduced fibrinolysis, which results in increased deposition of fibrin matrix.<sup>23,24</sup> The fibrin matrix gradually matures into an organised fibrous adhesion over the course of approximately 5 days.<sup>25</sup> With time, the extent of adhesions decreases by approximately 30%, as was also found in the present study (experiment 4 compared to 1,2 and 3).<sup>26</sup>

In the rat, intra-abdominal adhesions form within 24 hours after the operation, and after 7 days, no new adhesions are formed.<sup>18,27</sup> Therefore, adhesion formation in the present study was evaluated after 7 days. In the experiments with the coated meshes, adhesion formation was also assessed after 30 days, in order to evaluate the anti-adhesive effect after resolution of the coating.

### *Liquid anti-adhesive:*

Sepracoat is a viscous solution composed of 0.4% hyaluronic acid in phosphate buffered saline (PBS). Hyaluronic acid is a glycosaminoglycan that is naturally found in the human body in connective tissue, synovial fluid and vitreous humour. The Sepracoat solution coats tissues with a temporary, protective layer, and is completely resorbed from the abdomen within five days.<sup>28</sup> After gynaecologic surgery without a mesh, Sepracoat was found to lessen intra-abdominal adhesion formation.<sup>28</sup> In the present study, Sepracoat did not significantly decrease incidence of bowel or omental adhesions to the mesh.

Icodextrin solution is a biodegradable glucose polymer solution, which has been registered for peritoneal dialysis. Although iso-osmolar, icodextrin induces ultrafiltration through colloid osmosis. Through the attraction of fluid into the abdominal cavity, it is supposed to



separate damaged surfaces while post-surgical regeneration takes place, thereby preventing formation of adhesions between surgical surfaces. Icodextrin is metabolised by amylase to oligosaccharides and remains in the human abdominal cavity for at least 3 to 4 days.<sup>29</sup> In contrast to the present study, in which we found no effect of icodextrin on adhesion formation, Verco et al. reported less adhesions after administration of icodextrin in a uterine horn model in rabbits.<sup>30</sup> In the rat, intra-abdominal amylase concentration is higher than in the rabbit, which may lead to shorter intraperitoneal residence time of icodextrin in the rat.

### *Coated meshes*

Recently, coated meshes, with a protective layer on the visceral side of the mesh, have been introduced in surgery. The aim of the protective layer is to provide sufficient separation between the mesh and viscera while regeneration takes place, without impeding tissue ingrowth of the mesh on the other side.

Sepramesh is composed of a polypropylene mesh that is coated with a bioresorbable membrane of hyaluronate and carboxymethylcellulose, which are bonded by polyglactide/polyglycolide. The anti-adhesive membrane remains in place for up to seven days.<sup>31</sup> Subsequently, the membrane is absorbed. As was shown in the present study, Sepramesh significantly reduced adhesion formation to the mesh after 7 days, as well as after 30 days, when the membrane was completely absorbed. In addition, adhesion of viscera to the mesh was prevented after 7 days. After 30 days, the same trend was seen, although not statistically significant due to limited sample size.

In a rat- and rabbit model, a bioresorbable membrane of hyaluronate and carboxymethylcellulose (Seprafilm) has already been reported to diminish adhesion formation significantly.<sup>15,16,18,32</sup> However, this membrane is not applicable in laparoscopic incisional hernia repair because of technical difficulties with the introduction and positioning of the sticky membrane. The soluble form of Seprafilm (Sepracoat) would be easier to apply laparoscopically, but did not reduce adhesions in the present study. A possible explanation for this discrepancy between the results of Sepracoat and Seprafilm is the difference in intra-abdominal lifetime. Sepracoat persists at its site of application for only approximately 24 hours, while Seprafilm remains in place for at least 7 days.<sup>28,31</sup> Thus, intra-abdominal residence time might be an important factor and may have to exceed at least 7 days.

The Parietex composite mesh is a polyester mesh, which is coated with an absorbable and hydrophilic film on the visceral side. The film is composed of a solution of oxidised bovine atelocollagen type I, polyethylene glycol and glycerol.<sup>33</sup> Within three weeks, the film is completely resorbed, and a new peritoneal covering is formed over the mesh.<sup>33</sup> In the present study, the hydrophilic film provided significant protection against bowel adhesions after 7 days. The same trend was seen after 30 days, although not statistically significant due to limited sample size. Reduction of adhesions with the use of Parietex composite mesh was also found by Mutter et al.<sup>33</sup> However, in the current study, Parietex composite mesh was more easily infected than the other meshes and showed a stronger inflammatory response. With infection and increased inflammatory reaction, concurrent increase of the surface of the mesh that was covered by adhesions was seen. A stronger inflammatory reaction with increased incidence of infection and formation of enterocutaneous fistulas (16%) with the use of polyester mesh was also found in a clinical study by Leber et al.<sup>11</sup>

In conclusion, Sepramesh significantly reduced adhesion formation and prevented bowel adhesion to the mesh in the early postoperative period, without interfering with wound healing and tissue incorporation of the mesh. Parietex Composite mesh reduced bowel adhesions to the mesh as well, but provoked a stronger inflammatory reaction in the current model. Addition of liquid physical barriers as Sepracoat or icodextrin did not prevent adhesion of omentum or bowel to a polypropylene mesh. Future clinical studies are indicated to assess the promising results of coated meshes.

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## CHAPTER 9

Prevention of adhesion formation to polypropylene mesh  
by collagen coating: a randomised controlled study  
in a rat model of ventral hernia repair.

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*Surg Endoscopy 2004; 18: 681-5*

## Abstract

*Introduction:* In laparoscopic incisional hernia repair with intraperitoneal mesh, concern exists about the development of adhesions between bowel and mesh, predisposing to intestinal obstruction and enterocutaneous fistulae. The aim of this study was to assess whether the addition of a collagen coating on the visceral side of a polypropylene mesh can prevent adhesion formation to the mesh.

*Method:* In 58 rats, a defect in the muscular abdominal wall was created, and a mesh was fixed intraperitoneally to cover the defect. Rats were divided in two groups; polypropylene mesh (control group) and polypropylene mesh with collagen coating (Parieten<sup>®</sup> mesh). Seven and 30 days postoperatively, adhesions and amount and strength of mesh incorporation were assessed. Wound healing was studied by microscopy.

*Results:* With Parieten mesh, the mesh surface covered by adhesions was reduced after 30 days (42% versus 69%,  $p=0.01$ ), but infection rate was increased after both 7 ( $p=0.001$ ) and 30 days ( $p=0.03$ ), compared to the polypropylene group with no mesh infections. If animals with mesh infection were excluded in the analysis, the mesh surface covered by adhesions was reduced after 7 days (21% vs 76%,  $p=0.02$ ), as well as after 30 days (21 vs 69%,  $p<0.001$ ). Percentage of mesh incorporation was comparable in both groups. Mean tensile strength of mesh incorporation after 30 days was higher with Parieten mesh.

*Conclusion:* Although the coated Parieten mesh was more susceptible to mesh infection in the current model, a significant reduction of adhesion formation was still seen with the Parieten mesh after 30 days, with comparable mesh incorporation in the abdominal wall.



## Introduction

In incisional hernia repair, use of prosthetic mesh is usually advocated, since it reduces recurrence rates significantly.<sup>7,15,17,18,23</sup> Mesh repair can be accomplished in an open procedure but can also be performed laparoscopically. Because large abdominal incisions and extensive tissue dissection are avoided in laparoscopic incisional hernia repair, less wound infection, faster recovery and shorter hospital stay are likely.<sup>2,3,8,22,25</sup> However, because intraperitoneal mesh placement is inherent to laparoscopic incisional hernia repair, concern exists about the formation of adhesions between bowel and mesh. These adhesions can cause chronic pain and serious complications, such as intestinal obstruction and enterocutaneous fistulas.<sup>5,11,14,19</sup> In addition, adhesions between bowel and mesh may render future laparotomies extremely difficult. For many surgeons, concern about these complications is a drawback to adopt laparoscopic incisional hernia repair. Therefore, development of a mesh that prevents adhesion formation is warranted.

The aim of this study was to assess whether the addition of a collagen coating on the visceral side of a polypropylene mesh can prevent adhesion formation to the mesh.

## Method

### *Animals*

Fifty-eight male inbred rats of the Wistar strain, weighing 315-350 gram, were obtained from Harlan, Zeist, The Netherlands. They were bred under specific pathogen free conditions, kept under standard laboratory conditions (temperature 20-24° C, relative humidity 50-60%, 12 hours light/12 hours dark) and fed with laboratory diet (Hope Farms, Woerden, the Netherlands) and water ad libitum. The experimental protocol adhered to rules laid down by the Dutch Animal Experimentation Act and was approved by the Committee in Animal Research of the Erasmus University Rotterdam. Non-powdered gloves were used routinely in the experimental procedure.

### *Operative procedure*

Anesthesia was performed with isoflurane inhalation anesthesia. The abdomen was shaved and cleaned with alcohol 70%. The operative procedure was performed under clean but non-sterile conditions.

The experiments were performed in a validated rat-model, described previously by Alponat et al. and Hooker et al.<sup>1,9</sup> In all animals, laparotomy was performed using a midline incision of 4 cm. Skin flaps were raised and a standardised 1.5 x 2.5 cm longitudinal full thickness defect consisting of fascia, muscle and peritoneum was created.

The 58 rats were randomly divided into two groups. In group I (control group) a polypropylene mesh (Prolene, Ethicon Inc., Somerville, NJ, USA) of 2.5 x 3.5 cm was fixed intraperitoneally with 8 interrupted Prolene 5.0 sutures. In group II, the defect was repaired with a polypropylene mesh with a collagen coating on the visceral side (Parieten<sup>TM</sup> mesh, Sofradim, France). This mesh was fixed intraperitoneally with 8 interrupted Prolene 5.0 sutures as well. In all rats, skin was closed with steel clips (Mikron Autoclips 9 mm, Stoelting Co. Illinois, USA). Postoperatively, all rats received painmedication with intramuscular buprenorfine 0.05 mg/kg for one day.

### *Scoring of adhesions, and infection.*

After 7 days, 28 rats (14 out of each group) were sacrificed. The remaining 28 rats were sacrificed at 30 days postoperatively.

An autopsy was performed in all rats. A median skin incision was made and the abdominal cavity was entered through a U-shaped incision, extending caudal and lateral to the mesh. The presence of adhesions between bowel and the mesh was assessed. For each rat presence of bowel adhesions to the mesh was documented. Hence, the mesh was excised and adhesions were sharply cut. The surface of the mesh that was covered by adhesions was assessed. For this purpose, the mesh surface was divided in 6 sections. Each section was subsequently subdivided in 6 fields, and for each field the percentage of the surface covered by adhesions was estimated. Density of adhesions was scored according to Zühlke classification.<sup>30</sup> Infection was defined as pus coming from the mesh and wound, and confirmed with bacterial culture. Two independent investigators, who were blinded to the group assignment of the rats, performed scoring of adhesions and incorporation. In case of interobserver variance, the mean was scored.

### *Incorporation of the mesh and tensile strength*

Incorporation of the prosthesis in the abdominal wall was scored by dividing the circumference of the mesh in 10 segments, and subsequently determining the number of segments in which the mesh was not incorporated in the abdominal wall.

Tensile strength was measured by a dynamometer. One of the lateral margins of the abdominal wall was fixed in a clamp, with the mesh still in situ but not in the clamp. The contralateral side of the mesh was grasped by moveable clamps, connected to the dynamometer (Figure 1). The mesh was pulled away from the contralateral abdominal wall, with a continuous rate of 100 mm/min. The force required to disrupt the mesh from the abdominal wall was measured with the dynamometer and registered electronically.

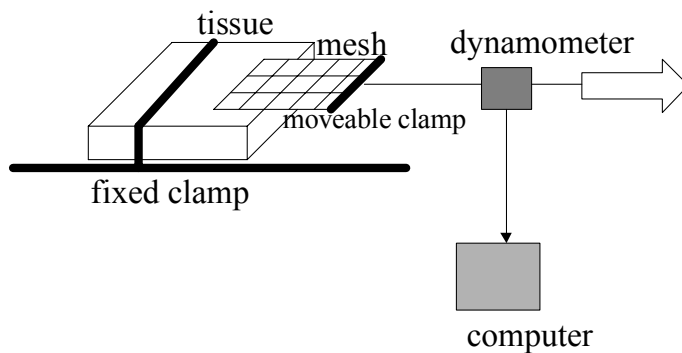


Figure 1. Measurement of tensile strength with dynamometer.

### *Histology*

Of each group, three meshes with the adjoining abdominal wall were fixed in 10% neutral buffered formalin for at least one hour. After routine tissue processing, sections were cut at 4 to 6  $\mu\text{m}$  and stained with hematoxylin and eosin. Sections were microscopically studied, and incorporation of the mesh in the surrounding tissue and inflammatory reaction were assessed for each group. The grade of inflammation was assessed using a semi quantitative scoring system, the inflammation grading scale.<sup>9</sup> Grade 1 on this scale represents mild inflammatory reaction with giant cells, occasional scattered lymphocytes and plasma cells. Grade 2 represents moderate reaction with giant cells and increased numbers of admixed

lymphocytes, plasma cells, eosinophils and neutrophils, while grade 3 represents severe inflammatory reaction with microabscesses present. Further, histologic evaluation was performed to assess whether the collagen coating was still present at 7 days postoperatively and had resolved completely at 30 days postoperatively.

### Statistical analysis

A sample size of 13 was needed to detect a 15% difference of mesh surface covered by adhesions at an alpha level of 0.05 and 90% power. Statistical analysis was performed using Mann-Whitney U-test for independent samples. A p-value of less than 0.05 was considered to be statistically significant.

## Results

During the study, two animals died before the end of the experiment. Both animals belonged to the control group (polypropylene) and were sacrificed at 5 days postoperatively because of wound dehiscence. At autopsy, urinary retention was found in one of these animals and in the other animal a suture had inadvertently tied the colon to the mesh. No herniations of viscera between mesh and abdominal wall were seen in the current study.

Study results are shown in table 1.

Table 1. Comparison of adhesion formation, infection and mesh incorporation between Prolene and Parieten mesh.

	7 days postoperatively			30 days postoperatively		
	<b>Prolene</b> n=14	<b>Parieten</b> n=14	<i>p-value</i>	<b>Prolene</b> n=14	<b>Parieten</b> n=14	<i>p-value</i>
% of mesh covered with adhesions in all rats (range)	76% (47-97)	63 % (0-100)	n.s.	69% (38-92)	42 % (0-100)	0.01
Number of rats with infection (%)	0/14 (0%)	8/14 (57%)	0.001	0/14 (0%)	4/14 (29%)	0.03
% of mesh covered with adhesions, excluding rats with infection (n)	76% (47-97) (n=14)	21 % (0-58) (n=6)	0.02	69% (38-92) (n=14)	21% (0-53) (n=10)	<0.001
Number of rats with bowel adhesion (%)	2/14 (14%)	0/14 (0%)	n.s.	0/14 (0%)	0/14 (0%)	n.s.
Mean tensile force (N)	40 (38-61)	30 (13-43)	n.s.	29 (16-42)	44 (31-53)	0.006
% of mesh incorporated	88% (85-100)	91% (75-100)	n.s.	59% (40-75)	65% (20-90)	n.s.

When Parieten mesh was used, a significant reduction of the mean percentage of mesh surface covered by adhesions was found after 30 days, compared to the polypropylene group (42% versus 69%,  $p=0.01$ ). If animals with mesh infection were excluded in the analysis, the mean percentage of mesh surface covered by adhesions was significantly reduced after 7 days, as well as after 30 days postoperatively, ( $p=0.02$  and  $p<0.001$  respectively) (Figure 2).

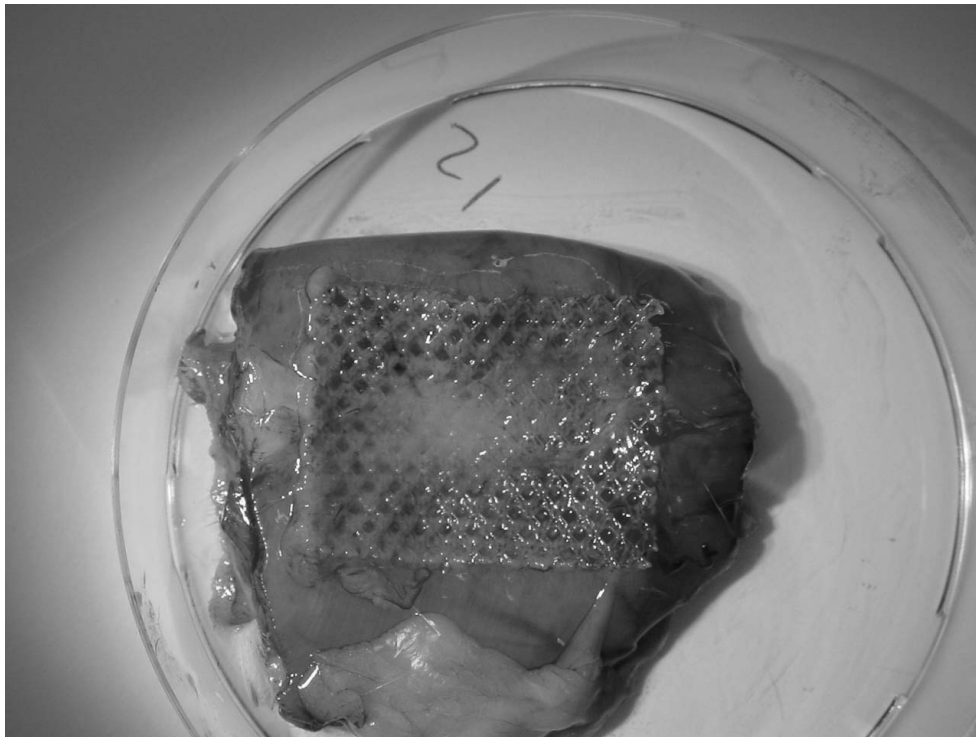


Figure 2. Parieten mesh without adhesions at 7 days postoperatively.

In all animals with adhesions to polypropylene mesh, adhesions could only be lysed by sharp dissection (Zühlke classification 3).<sup>30</sup> However, in animals with adhesions to Parieten mesh, part of the adhesions that were scored could easily be lysed by blunt dissection (Zühlke classification 1 and 2).

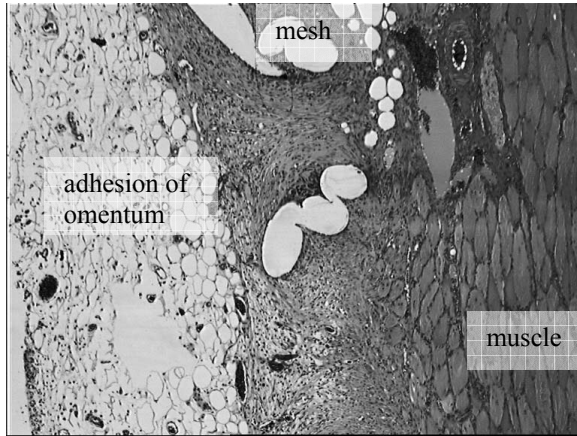
With polypropylene mesh, bowel adhesions to the mesh were seen in 14% of all animals at 7 days postoperatively and in none at 30 days postoperatively, while none of the animals with Parieten mesh developed adhesions between bowel and the mesh.

In the Parieten mesh group, infection rate was significantly higher than in the polypropylene mesh group at both 7 and 30 days postoperatively. Bacterial cultures revealed infections with *Staphylococcus Aureus*, *Escherichia Coli* and *Streptococcus Agalactiae*. No association was found between the chronological order of surgical treatment and infection. In all animals with infection, the mesh surface was completely covered with adhesions.

The percentage of the circumference of the mesh that was incorporated in the underlying tissue was comparable in both study groups. However, the strenght of incorporation, represented by the mean tensile strength, was significantly higher with Parieten mesh than with polypropylene mesh at 30 days postoperatively ( $p=0.006$ ).

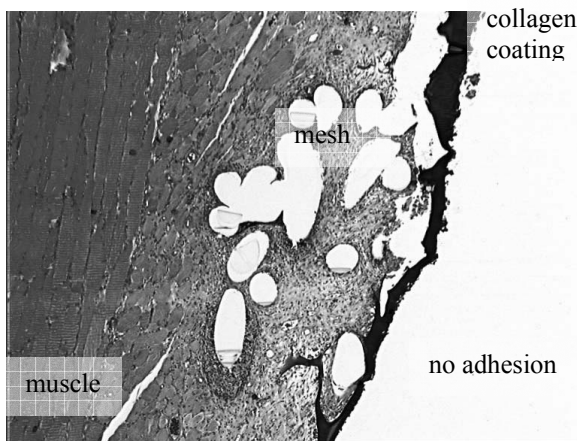
Histologic evaluation in the polypropylene groups showed foreign body reaction with giant cells and increased numbers of admixed lymphocytes, plasma cells, eosinophils and neutrophils around the pores of the mesh. Thus, the inflammatory reaction was scored as grade 2 on the inflammation grading scale after 7, as well as at 30 days postoperatively. A comparable reaction was seen in the Parieten group. At 7 days postoperatively, the collagen coating was still present in the Parieten group, but at 30 days it had resolved completely (Figure 3).

Figure 3. Light microscopy of histology, with polypropylene mesh (Prolene) (A), and collagen coated polypropylene mesh (Parieten Composite mesh) (B and C).



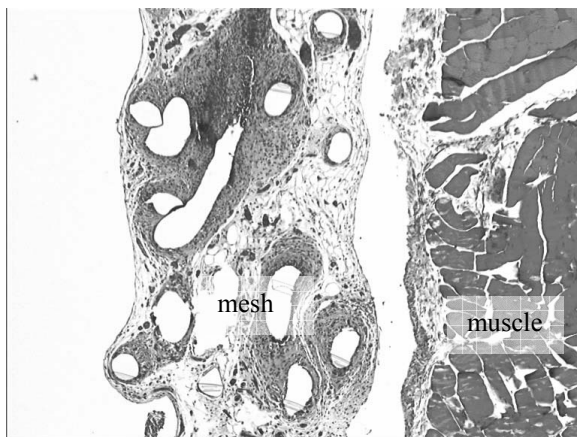
**A**

Polypropylene mesh (represented by holes), at 7 days postoperatively, with omental adhesion.



**B**

Parieten mesh at 7 days postoperatively, without adhesions. Collagen coating is still in situ



**C**

Parieten mesh at 30 days postoperatively, without adhesions. Collagen coating has resolved

## Discussion

The ideal mesh in incisional hernia repair must provide sufficient tissue ingrowth, in order to prevent incisional hernia recurrence and mesh migration. In addition, the mesh must prevent formation of adhesions to the mesh to prevent serious morbidity. However, it is difficult to combine these requirements in one mesh material, since the very characteristics that promote incorporation of the mesh, also induce adhesion formation.<sup>4</sup>

Polypropylene mesh is a material that is commonly selected for incisional hernia repair, because it is easy to handle, relatively low in costs and it retains its strength for indefinite periods of time.<sup>12,20</sup> As was shown by the present study, it has a low susceptibility to infection, since none of the polypropylene meshes was infected, even though the procedure was performed under clean but non-sterile conditions. Further, if a polypropylene mesh does get infected, this can generally be treated adequately with drainage and antibiotics, without removal of the mesh.<sup>15,16,27-29</sup>

As was confirmed in the present study, polypropylene causes a pronounced and persistent inflammatory reaction and is well incorporated in the surrounding tissue of the abdominal wall. However, because of the pronounced inflammatory reaction, polypropylene also causes a strong stimulus for the formation of adhesions.<sup>4,10,13</sup> This was confirmed by Franklin et al., who re-laparoscoped some patients after laparoscopic incisional hernia repair with polypropylene mesh and reported approximately one-third of patients with mild adhesions and one-third with severe adhesions.<sup>6</sup>

Recently, coated meshes, with a protective layer on the visceral side of the mesh, have been developed. The aim of the protective layer is to provide sufficient separation between the mesh and viscera while regeneration takes place, without impeding tissue ingrowth of the mesh on the other side.

The Parieten composite mesh is a polypropylene mesh, which is coated with an absorbable and hydrophylic film on the visceral side. The film is composed of a solution of oxidised bovine atelocollagen type I, polyethylene glycol and glycerol.<sup>21</sup> Within three weeks, the film is completely resorbed, and a new peritoneal covering is formed over the mesh.<sup>21</sup> Therefore,



adhesion formation in the present study was also evaluated after 30 days, when resolution of the coating was complete.

As was shown in the current study, a significant reduction of adhesion formation was seen after application of the collagen coated Parieten mesh, if the mesh did not get infected. However, significantly more infections were seen with the use of Parieten mesh in the current model. With infection, increase in inflammatory reaction was seen, with concurrent increase of the surface of the mesh that was covered by adhesions to 100%. For that reason, the percentage of the mesh that was covered with adhesions was also calculated for rats without mesh infection. However, even with inclusion of the infected meshes, there still was a significant reduction of adhesion formation at 30 days postoperatively with the Parieten mesh.

It is remarkable that the Parieten mesh, which also consists of polypropylene, has an increased susceptibility to infections, compared to the uncoated polypropylene mesh. Therefore, the increased susceptibility of the Parieten mesh to infections in the current model may be caused by the addition of the anti-adhesive collagen coating. The collagen coating on Parieten mesh is the same coating that is applied on the polyester Parietex composite mesh. In a recent study in our laboratory, the Parietex composite mesh was also found to be more easily infected than the polypropylene control group in a rat model.<sup>24</sup>

In the current model, we chose to perform the procedure under clean but non-sterile conditions, in order to determine the susceptibility of the mesh to infections. However, this does not reflect the procedure in the way it is performed in human patients, since the procedure in human patients is always performed under sterile conditions. In addition, most surgeons apply antibiotic prophylaxis with mesh placement, as is advocated.<sup>26</sup> Therefore, the occurrence of mesh infection with the use of Parieten mesh in human patients could be less than in the current rat model. However, this has to be determined by further clinical studies.

In conclusion, a significant reduction of adhesion formation was seen with the use of the collagen coated polypropylene mesh (Parieten<sup>®</sup> mesh), compared to the uncoated polypropylene mesh (Prolene<sup>®</sup>), although the Parieten mesh was more susceptible to mesh infection in the current model. The percentage of the mesh that was incorporated in the abdominal wall was comparable in both groups, but after 30 days the strength of mesh incorporation was significantly higher with the Parieten mesh.

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## CHAPTER 10

### GENERAL DISCUSSION

## Prevention of incisional hernia

Prevention of incisional hernia is crucial in order to reduce the incisional hernia problem.

Of the determined risk factors with regard to incisional hernia, only operation related risk factors can be influenced by the surgeon. As was shown in chapter II of this thesis, the type of incision for laparotomy is a relevant risk factor for the development of incisional hernia. Lateral paramedian incisions are associated with a lower incidence of incisional hernia than midline incisions. However, most surgeons prefer a midline incision, because traditional teaching dictates median laparotomy, which also requires less time than lateral paramedian incisions. Morbidity of an incisional hernia and subsequent repair, however, outweigh the time saved by a midline incision.<sup>1-7</sup> The lateral paramedian incision deserves reconsideration in open surgery which does not require rapid entry or wide exposure of the abdominal cavity.

An additional incision-related factor is the length of the incision. In theory, longer incisions increase the risk for wound failure, because a larger area must heal. In 1979, Pollock found an increased risk for incisional hernia appearance for incisions larger than 18 cm (31%), compared to incisions smaller than 18 cm (8%).<sup>8</sup> Based on this theory, it would be expected that small laparoscopic incisions of 0.5 to 1 cm will be associated with a concurrent small risk for incisional hernia. Several studies, which were predominantly case reports, were published on this subject.<sup>9-12</sup> In retrospective studies, an incisional hernia incidence of 0.02-3.0 % is reported after laparoscopy.<sup>13-18</sup> Two comparative retrospective studies found a reduced incidence of incisional hernia after a laparoscopic versus an open procedure for bowel resection (2.3 versus 12.8%) and cholecystectomy (1.6 versus 5.9%).<sup>19-20</sup> Mean follow-up in these studies was 2.7 and 3 years in the laparoscopic group and 2.4 and 8 years in the open group. Thus, although more studies are needed to confirm these results, increased use of laparoscopy instead of laparotomy may be an important step to decrease incisional hernia incidence.

Wound closure is another important variable in the development of incisional hernia. In order to achieve secure wound closure, adequate suture material and technique should be applied.

Suture material for laparotomy closure was evaluated in chapter III of this thesis. There was no difference in incisional hernia incidence between slowly absorbable sutures and non-

absorbable sutures. However, slowly absorbable sutures induce less wound pain and suture sinus than non-absorbable sutures and should therefore be preferred.

To evaluate the impact of fascial suture technique on development of incisional hernia incidence, various randomised trials comparing interrupted and continuous sutures have been performed.<sup>21-27</sup> Reduction of operating time, use of fewer knots, and a better distribution of tension along the suture line are possible advantages of continuous sutures. However, if the suture cuts through the fascia or if the knot loosens, loosening of the entire wound may occur if a continuous suture is used.

As was shown in chapter III of this thesis, only one randomised controlled trial showed a significantly higher incidence of incisional hernia after the use of interrupted sutures, compared to continuous sutures.<sup>23</sup> Other trials, as well as the meta-analysis described in chapter III, did not identify significant differences. No advantages of alternative suture techniques, such as "Smead Jones" or "figure of 8" were found.<sup>21,22,24-27</sup> It must however be remarked that most randomised controlled trials comparing interrupted and continuous suture techniques varied both suture technique and material within one trial, which makes the outcomes of these trials hard to interpret.<sup>22-27</sup> Because continuous suture technique is easier and faster than interrupted suture technique it should be preferred.

The suture length/wound length ratio should be at least 4:1 to ensure reliable healing of the abdominal wall.<sup>28-29</sup> The use of large tissue bites and the placement of many stitches through the aponeurosis can achieve this.<sup>28</sup> However, as was shown by the experimental study of Cengiz et al, tissue bites can be excessive as well.<sup>30</sup> They found that wound bursting strength in rats was greater when sutures were placed 3 to 6 mm from the wound edge, than at a distance of 10 mm.<sup>30</sup> Excessive tissue bites appear to increase tension on the aponeurosis, with consequent tearing. In humans however, the ideal distance of tissue bites has not been determined yet and still has to be studied.

After wound dehiscence closure, a cumulative incidence of incisional hernia of 69% after 10 years was found (chapter IV). No significant difference was observed between the use of fast-, slowly- or non-absorbable sutures. Probably, the fascial quality is so poor in patients who develop wound dehiscence, that later development of incisional hernia is almost

inevitable. Therefore, it might be beneficial to reinforce the abdominal wall with prosthetic mesh in patients with wound dehiscence.

However, about 40% of patients with wound dehiscence have wound- or intra-abdominal infection. As was shown in chapter V, synthetic graft placement in the presence of infection has a high risk of complications, such as mesh infection, intra-abdominal abscess, enterocutaneous fistula and even mesh migration through the bowel with subsequent bowel perforation.

Although several authors suggested that the use of absorbable meshes would prevent the occurrence of these mesh-related complications, use of absorbable mesh was associated with comparable complication rates as non-absorbable mesh in the study described in chapter V.<sup>31-</sup>

<sup>34</sup> In the group with absorbable polyglactin mesh (Vicryl), incidence of mortality due to progressive abdominal sepsis was even higher than in the group of patients with non-absorbable meshes. Since the study was not randomised, the higher incidence of mortality in the group with absorbable polyglactin mesh might reflect confounding by indication. However, a factor that may contribute to the high incidence of progressive abdominal sepsis with the use of absorbable polyglactin mesh is the multifilament structure of this mesh, compared to the monofilament structure of the polypropylene mesh. As is known, multifilament material is more susceptible to infection than monofilament material and the use of a multifilament foreign body in an infected environment may increase bacterial load on the mesh.<sup>35-37</sup>

Because of the high incidence of complications after use of mesh in infected environment, synthetic graft placement for wound dehiscence or large abdominal wall defects in the presence of infection should be avoided if possible. Alternative methods for temporary abdominal content containment have to replace use of mesh in these patients. For this purpose, sterile plastic bags can be used, but also the “dynamic retention technique” with multiple layers of a bowel bag, dressings and retention sutures is an option.<sup>38</sup>

Recently, a new device was developed for temporary abdominal closure, the VAC<sup>®</sup> abdominal dressing. With this technique, foam that is encapsulated with a non-adhesive layer is placed over the bowel and under the edges of the fascia. On top of this, foam with small perforations is placed and covered with a drape. This is connected to a vacuum suction system that creates a local negative pressure on the wound, thereby enabling evacuation of abdominal fluids. Since the non-adhesive layer is placed under the fascia, the bowel cannot



adhere to the fascia and therefore the surgeon can approximate the fascia after several days if the intra-abdominal swelling is reduced. With this technique, wound dehiscence which cannot be closed primarily, in the presence of infection, may be treated without the use of mesh. In addition, with the use of this device, formation of incisional hernia after open abdomen treatment may be reduced. Although first results with this newly developed device are very promising, its use still has to be studied and evaluated.<sup>39,40</sup>

## Repair of incisional hernia

### *Suture repair*

Following suture repair of incisional hernia, recurrence rates up to 54% have been reported and thus are very disappointing.<sup>41-45</sup> One of the main reasons for this high failure rate is that in most suture repair techniques, tissues are closed under tension.<sup>46</sup> Tension on the fascial edges may lead to tissue ischemia and sutures cutting through the fascia, resulting in wound healing failure.<sup>46</sup> Another important factor is the presence of poor quality of the fascia, which may be due to collagen diseases, increased age or multiple previous laparotomies.<sup>47-58</sup> In patients with poor quality of the fascia, sutures are more likely to tear out and risk of incisional hernia recurrence is very large if the fascia is not reinforced with prosthetic material.

Rectus sheath techniques such as the “Ramirez component separation technique” provide tension-free hernia repair without the use of prosthetic mesh.<sup>59</sup> An advantage of the Ramirez technique is that the original anatomy of the abdominal wall is restored, with medial displacement of normally innervated muscle allowing dynamic resistance against the abdominal pressure.<sup>60</sup> However, for the application of Ramirez techniques, extensive tissue plane dissection is often needed, which may result in increased incidence of wound complications. To prevent seroma or hematoma formation, prolonged suction drainage is often needed, with a reported average of 7 days postoperatively.<sup>61</sup> Although results of Ramirez technique are hopeful, with recurrence rates of 0-8.6%, only small retrospective studies have been published.<sup>59-61</sup> A prospective randomised trial was recently started in the Netherlands, comparing Ramirez repair with prosthetic repair with ePTFE dual mesh plus

with holes. However, this trial was aborted preliminary after inclusion of 37 patients, because of the high risk of seroma formation and secondary infection with ePTFE dual mesh.<sup>62</sup> Thus, future randomised trials comparing Ramirez technique with other techniques are still desired.

### *Mesh repair*

Mesh repair of incisional hernias is associated with lower recurrence rates than suture repair, even in small hernias with a surface of less than 10 cm<sup>2</sup>.<sup>63</sup> Prosthetic mesh allows a tension free repair and reinforces the fascia. Therefore, mesh repair is generally regarded as the method of choice for all elective incisional hernia repairs.<sup>63-67</sup> However, even after mesh repair, recurrence rates up to 34% have been reported.<sup>45</sup>

Various causes for hernia recurrence after mesh repair can be identified. In many patients with incisional hernia, multiple fascial defects or weak patches exist in the scar tissue. If the entire previous incision is not opened, these defects or fragile zones may be overlooked and recurrence will easily develop next to the repaired hernia.<sup>68</sup>

Wound infection after incisional hernia repair impairs wound healing, predisposing to recurrent disease.<sup>46</sup> To reduce wound infections, administration of prophylactic antibiotics 30 minutes before repair has been advocated.<sup>69,70</sup>

Recurrences occur frequently at the lateral margin of the mesh.<sup>71,72</sup> Reasons for these recurrences can be insufficient ingrowth of the mesh in the fascia, inadequate overlap between mesh and fascia, or insufficient mesh fixation.<sup>71,72</sup> If ingrowth of the mesh in the fascia is poor, as is seen in ePTFE mesh repair, buttonhole recurrent hernias may occur between fixating sutures.<sup>72,73</sup> To prevent this complication, use of a double row of sutures has been recommended for ePTFE-mesh repair.<sup>72</sup> Regarding mesh size and mesh overlap, Klinge et al. showed in experimental studies in dogs that polypropylene meshes can shrink down to 30-50% of the original size.<sup>74</sup> This finding stresses the importance of adequate overlap of mesh and fascia. However, although most authors propose an overlap of at least 3 cm, no studies accurately assessed required overlap.<sup>63,75-79</sup>

Mesh fixation seems another important variable to predict development of incisional hernia recurrence. However, data comparing different suture materials or techniques for mesh repair are lacking.

Apart from insufficient overlap and mesh fixation, recurrence is more likely with mesh structures that are inelastic, because stiff meshes may fold or roll up due to the continuous movement of the mobile and flexible abdominal wall.<sup>80</sup> Large pore meshes (pores larger than 1 mm) are associated with a diminished fibrotic reaction, and thus elasticity is preserved with these meshes. They are therefore advocated if the mesh is used to reinforce the abdominal wall if the defect is closed largely by suturing. If a large abdominal defect with insufficient muscular covering has to be bridged, stronger meshes with higher tensile strength are needed.

### *Laparoscopic incisional hernia repair*

Laparoscopic incisional hernia repair avoids large abdominal incisions and extensive tissue dissection and may be associated with less wound infection, reduced postoperative pain, faster recovery and shorter hospital stay. However, although a trend was seen towards decreased infection rates after laparoscopic incisional hernia repair, differences in the study described in chapter VI of this thesis and in other comparative studies were not statistically significant.<sup>81-85</sup> This might be caused by the small number of patients in most of these series, which stresses the need for larger comparative studies.

At laparoscopy, there is a better visual detection of other subclinical fascial defects, and therefore there may be a theoretical advance for laparoscopic incisional hernia repair to reduce recurrence rates. In the comparative studies of Ramshaw et al. and Park et al., a significant reduction was indeed seen after use of laparoscopic repair (3 versus 20% and 11 versus 35% respectively).<sup>83,85</sup> However, other studies, including the study described in chapter VI of this thesis, did not identify a significant reduction.<sup>81,82,84</sup>

Assessment of the value of laparoscopic incisional hernia repair requires randomised trials comparing laparoscopic and open mesh repair with sufficient power. The COLIBRI study has been started at the Erasmus Medical Centre in Rotterdam, randomising 200 patients to either laparoscopic- or open incisional hernia repair with a sublay polypropylene mesh. All patients with a hernial defect with a diameter between 3 and 15 cm are included. To avoid learning curve effects for laparoscopic incisional hernia repair, surgical experience with at least 100 laparoscopic procedures, including at least 10 laparoscopic incisional hernia repairs is required. Clinical outcome, quality of life and costs are recorded.

Reduction of recurrence after laparoscopic incisional hernia repair can possibly be established by improving mesh fixation. As shown in chapter VII of this thesis, tensile strength of fixation with transabdominal sutures is up to 2.5 times as high as tensile strength of fixation with tackers, and therefore addition of transabdominal sutures is important to improve mesh fixation. However, transabdominal wall sutures may cause prolonged abdominal wall pain at the suture site.<sup>86,87</sup> Incidence of this pain is reported in up to 23% of the patients.<sup>87</sup> If suture site pain occurs, it can be treated with local injection of bupivacaine with epinephrine and lidocaine at the circumference of the suture site at the level of the abdominal musculature. Carbonell et al. described a complete relief of symptoms with this treatment in 92% of the patients.<sup>87</sup>

### *Mesh position and associated problems*

Discussion still exists about the preferred position of the mesh. The mesh can be placed in a sublay position to the fascia, in a prefascial retromuscular position, or in front of the rectus sheath (onlay position). Although many studies on incisional hernias have been performed, trials randomising different mesh positions do not exist. Therefore, choice for mesh position is often based on personal experience and conviction. To determine optimal mesh position future randomised trials are mandatory.

If the mesh is placed in a sublay position to the fascia, a true tension-free repair can be performed if the fascial edges are not closed. However, in this position, the mesh is often placed intraperitoneally, because peritoneal covering cannot be accomplished in up to 70% of patients.<sup>88</sup> In laparoscopic repair, the mesh is always placed intraperitoneally, in a sublay position to the fascia. Intraperitoneal mesh placement can induce visceral adhesions to the mesh, which may lead to intestinal obstruction or formation of enterocutaneous fistulas.<sup>45,89-93</sup> Concern about these complications is a drawback for some surgeons to adopt laparoscopic incisional hernia repair. Therefore, development of meshes that are non-adhesive is desired.

Use of anti-adhesive liquids such as Sepracoat or Icodextrin solution could not prevent formation of bowel adhesions to the mesh in an experimental model (chapter VIII). Possibly,

these fluids are absorbed too soon, and therefore do not persist at their site of application long enough to prevent adhesion formation.

Use of meshes with an anti-adhesive coating on the visceral side of the mesh, such as Parietex composite mesh (polyester mesh with collagen coating) and Sepramesh (polypropylene with Seprafilm coating) showed a significant reduction of adhesions to the mesh, compared to uncoated polypropylene mesh (Prolene) (chapter VIII). Bowel adhesions were found in 50% of uncoated polypropylene meshes, compared to no bowel adhesions with the use of Parietex or Sepramesh. However, with Parietex composite mesh, significantly more infections were found.

Since polyester mesh is associated with a stronger inflammatory reaction than polypropylene mesh, it was hypothesised that the increased infection rate was caused by the polyester nature of this mesh.<sup>94</sup> For that reason, another newly developed mesh composed of a polypropylene mesh with the same collagen coating as the Parietex mesh, called Parieten mesh, was studied in the same experimental model (chapter IX). Remarkably, a similar increased infection rate was seen with the use of Parieten mesh (coated polypropylene) as with the Parietex mesh (coated polyester mesh). Thus, the increased susceptibility to infection of this mesh in the experimental model that was used is probably caused by the collagen coating, instead of the polyester nature of the Parietex mesh.

Still, even with the increased infection rates of the Parietex and Parieten meshes, a reduction in adhesion formation was seen. Because mesh procedures in human patients are performed under sterile conditions (and not under clean but non-sterile conditions as in the experimental model) infection rates of these meshes may be reduced with its use in human patients. Preliminary results in clinical studies seem positive, although these studies are retrospective and small.<sup>95-97</sup> Moreno-Egea et al found no infections in 20 patients with laparoscopic incisional hernia repair using Parietex composite mesh.<sup>95</sup> Aube et al. assessed adhesions to intraperitoneal Parietex composite mesh with ultrasound at 1 year postoperatively and found a low rate of peritoneal adhesions of 14%.<sup>96</sup> In concordance with these results, Arnaud et al. found a significant reduction of visceral adhesions to the Parietex composite mesh (18%) compared to Mersilene mesh (77%) in respectively 51 and 22 patients with postoperative ultrasound after intraperitoneal mesh placement.<sup>97</sup> Thus, clinical use of coated meshes seems promising and should be studied further.

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## CHAPTER 11

### Summary and conclusions

## Summary

Incisional hernia occurs in up to 20% of patients after laparotomy and is therefore the most common complication after abdominal surgery. Incisional hernia repair is associated with recurrence rates up to 54%. To reduce incidence and recurrence rates of incisional hernia, prevention of incisional hernia and improvement of incisional hernia repair are warranted.

### **Prevention of incisional hernia**

In *chapter I*, etiology and risk factors for the development of incisional hernia are discussed. Although incisional hernia becomes apparent over time, an early onset of incisional hernia is most likely. Patient-related and operation-related risk factors play a role in the pathogenesis of incisional hernia. Patient related risk factors are obesity, increased age, collagen diseases, diabetes mellitus, obstructive jaundice, multiple previous laparotomies and pulmonary disease. An important operation-related factor is the occurrence of wound infection. In addition, surgical techniques for abdominal incision and fascial closure are important factors.

In *chapter II*, correlation between type of abdominal incision and incidence of incisional hernia is discussed. For this purpose, a review of all randomised-controlled trials was conducted. In several trials, the lateral paramedian incision was compared to the generally used midline incision. All trials showed a significant reduction of the incidence of incisional hernia to 0-1% after the use of the lateral paramedian incision. Therefore, the lateral paramedian incision should be reconsidered as the incision of choice in elective abdominal surgery.

In *chapter III*, the impact of abdominal fascia closure technique on incisional hernia incidence was studied. For this purpose, a meta-analysis of 15 prospective randomised studies, with a total of 6573 patients, was performed. Suture materials were categorized as rapidly-, slowly- or non-absorbable. Closure by continuous rapidly absorbable sutures was followed by significantly more incisional hernias than closure by continuous slowly-absorbable sutures or non-absorbable sutures. No difference of incisional hernia incidence was found between slowly-absorbable versus non-absorbable sutures, although more wound



pain and more suture sinuses were observed after the use of non-absorbable sutures. Available data suggested similar outcomes with continuous and interrupted sutures, but continuous sutures required less time.

Therefore in order to reduce incisional hernia incidence without increasing wound pain or suture sinus, slowly-absorbable continuous sutures appear preferable for fascial closure.

In *chapter IV*, the incidence and risk factors for the development of incisional hernia after wound dehiscence were studied in a cohort study of 168 patients. All patients had physical examination at the time of conducting the study. After a median follow-up of 37 months, 55 of the remaining 126 patients developed an incisional hernia. The cumulative incidence of incisional hernia was 69% at 10 years. Significant independent risk factors were aneurysm of the abdominal aorta and severe dehiscence with evisceration. No differences were found between rapidly- slowly- or non-absorbable suture materials, or the use of interrupted or continuous sutures.

In order to investigate consequences of mesh placement in the presence of intra-abdominal infection, a cohort study was performed in 18 patients. In this study, described in *chapter V*, the safety of different prosthetic meshes in wound dehiscence repair with coexisting abdominal infection was assessed. Mesh materials included polyglactin (n=6), polypropylene (n=8), polyester (n=1), or a combination of a polypropylene mesh with a polyglactin mesh on the visceral side (n=3). All patients developed complications, consisting mainly of clinical signs of mesh infection (77%), intra-abdominal abscess (17%), enterocutaneous fistula (17%) or mesh migration through the bowel (11%). Mesh removal was necessary in 8 patients (44%). Within 4 months postoperatively, 6 patients (33%) had died because of progressive abdominal sepsis. The incidence of progressive abdominal sepsis was significantly higher in the group with absorbable polyglactin mesh than with non-absorbable mesh (67% versus 11%). Compared to non-absorbable meshes, absorbable meshes had no better outcome regarding complications and mortality rate. Because of the high rate of mesh-related complications, mesh placement in the presence of intra-abdominal infection should be avoided if possible.

## Repair of incisional hernia

Use of a prosthetic mesh has significantly reduced recurrence rates of incisional hernia repair, but mesh repairs are still associated with recurrence rates of up to 34%. Most widely used mesh materials are polyester, polypropylene and polytetrafluoroethylene (PTFE). The mesh can be placed either in a sublay position to the fascia, in a retromuscular prefascial position, or in a premuscular (onlay) position.

Recently, the technique of laparoscopic incisional hernia repair was introduced. The first studies on laparoscopic incisional hernia repair reported low recurrence rates of 0-11%. However, in most of these studies, follow-up was short and not performed by physical examination.

In *chapter VI*, open and laparoscopic mesh repairs were compared in a cohort study. A total of 101 patients, 25 in the laparoscopic group and 76 in the open group, were included, and physical examination was performed in all patients at the time of conducting the study.

Although not statistically significant, a trend was seen towards less postoperative wound infection (4% versus 14%) and shorter hospital stay (3.8 versus 5.0 days) after laparoscopic incisional hernia repair compared to open repair with mesh. Recurrence rates were comparable in both groups, with a 2-year cumulative incidence of 18% after open repair and 15% after laparoscopic repair. Recurrences in the laparoscopic group only occurred in the first series of 7 repairs, in which mesh fixation was only accomplished with tackers (helical titanium coils).

Because mesh fixation appears crucial in the prevention of recurrences after laparoscopic incisional hernia repair, tensile strengths of laparoscopic mesh fixation methods were compared in *chapter VII*. For this purpose, tensile strengths of mesh fixation with (tackers) and transabdominal wall sutures were assessed in a pig model. Thirty-six full thickness specimens of the anterior abdominal wall of nine pig cadavers were randomised for fixation of a polypropylene mesh by either tackers or transabdominal wall sutures. The force required to disrupt mesh fixation (tensile strength) was measured by a dynamometer. Mean tensile strength of mesh fixation by transabdominal sutures was significantly greater than that by tackers (67N versus 28 N for a single fixation point, 115 N versus 42 N for two fixation

points, 150 N versus 63 N for three fixation points, 151 N versus 73 N for four fixation points, and 150 N versus 82 N for five fixation points). Thus, because tensile strength of transabdominal sutures is superior to tensile strength of tackers, addition of transabdominal sutures appears preferable for mesh fixation in laparoscopic incisional hernia repair.

In laparoscopic incisional hernia repair, the mesh is always placed intraperitoneally. However, concern exists about development of adhesions between bowel and the mesh, predisposing to intestinal obstruction or enterocutaneous fistulas. The aim of the study described in *Chapter VIII* was therefore to assess whether use of anti-adhesive liquids or coatings could prevent adhesion formation to the mesh. In 91 rats, a defect in the muscular abdominal wall was created, and a mesh was fixed intraperitoneally to cover the defect. Rats were divided in five groups; polypropylene mesh only (control group), addition of Sepracoat<sup>®</sup> or Icodextrin<sup>®</sup> solution to polypropylene mesh, Sepramesh<sup>®</sup> (polypropylene mesh with Seprafilm coating), and Parietex Composite mesh<sup>®</sup> (polyester mesh with collagen coating). Seven and 30 days postoperatively, adhesions were assessed and inflammatory reaction was scored by microscopy.

In the polypropylene group, bowel adhesions to the mesh were found in 50% of the rats, while no bowel adhesions to the mesh were observed with the use of Sepramesh<sup>®</sup> and Parietex Composite mesh<sup>®</sup>. However, infection rate was increased upon employment of Parietex Composite mesh<sup>®</sup> (57% versus 0%). Mesh surface covered by adhesions was reduced with use of Sepramesh compared to polypropylene mesh, after seven days (55% versus 74%,  $p=0.01$ ), as well as after 30 days (25% versus 48%,  $p=0.03$ ). Addition of Sepracoat<sup>®</sup> and Icodextrin<sup>®</sup> solution failed to reduce adhesion formation.

In *chapter IX*, the experimental incisional hernia rat model described in chapter VIII was used to assess the anti-adhesive effect of a collagen coating on the visceral side of a polypropylene mesh. Fifty-eight rats were divided in two groups; polypropylene mesh (control group) and polypropylene mesh with collagen coating (Parieten<sup>®</sup> mesh). Seven and 30 days postoperatively, adhesions and amount and strength of mesh incorporation were assessed.

In the current model, the Parieten mesh was more susceptible to mesh infection than the polypropylene mesh (57 versus 0% after 7 days, and 29% versus 0% after 30 days). However, a significant reduction of mesh surface covered by adhesions in the Parieten group was still seen after 30 days (42% versus 69%,  $p=0.01$ ), with comparable mesh incorporation in the abdominal wall. If animals with mesh infection were excluded in the analysis, the mesh surface covered by adhesions was reduced after 7 days (21% vs 76%), as well as after 30 days (21 vs 69%).

## Conclusions

### **Prevention** of incisional hernia:

1. Use of the lateral paramedian incisions, instead of midline incisions, can reduce incidence of incisional hernia. Therefore, the lateral paramedian incision deserves reconsideration in open elective surgery in which adequate exposure can be accomplished with this incision (chapter II).
2. Incidence of incisional hernia is increased after the use of rapidly- absorbable sutures for closure of midline laparotomy. There is no difference of incisional hernia incidence after use of slowly absorbable sutures or non-absorbable sutures. Slowly absorbable sutures are preferable because they induce less wound pain and suture sinus than non-absorbable sutures (chapter III).
3. After wound dehiscence repair, the majority of patients develops incisional hernia, regardless of suture material or technique (chapter IV). Wound dehiscence repair with mesh should be avoided in abdominal wall defects with co-existing abdominal infection, since it is associated with high incidence of mesh-related complications such as mesh infection, formation of enterocutaneous fistula and mesh migration through the bowel, regardless of the use of absorbable or non-absorbable mesh material (chapter V).

### **Repair** of incisional hernia:

4. Open mesh repair and laparoscopic incisional hernia repair are associated with comparable recurrence rates. Possibly, these recurrence rates can be reduced by improvement of mesh fixation methods (chapter VII)
5. In laparoscopic incisional hernia repair, tensile strength of mesh fixation with tackers is significantly less than tensile strength with transabdominal sutures. Therefore, addition of transabdominal sutures is preferable in laparoscopic incisional hernia repair (chapter VII)
6. In an experimental model, coated meshes prevented bowel adhesions to intraperitoneal mesh (Sepramesh, Parietex composite mesh and Parieten mesh), and reduced mesh surface that was covered by adhesions significantly (Sepramesh and Parieten mesh), compared to polypropylene mesh. However, Parietex and Parieten mesh were associated with increased infection rate in the experimental model (chapter VIII and IX).

## Samenvatting

Littekenbreuken vormen de meest voorkomende complicatie na een buikoperatie. Na een mediane laparotomie is de incidentie 10-20%. Herstel van een littekenbreuk is geassocieerd met een teleurstellend hoog recidiefpercentage tot 54%. Om de incidentie van littekenbreuken en recidiefpercentages van littekenbreukherstel te verminderen, zijn preventie en verbetering van de operatieve behandeling van deze complicatie noodzakelijk.

### Preventie van littekenbreuken

In *hoofdstuk I* worden de oorzaken en risicofactoren voor het ontwikkelen van een littekenbreuk beschreven. Hoewel de meeste littekenbreuken pas na verloop van tijd zichtbaar worden, is het waarschijnlijk dat veel littekenbreuken toch al vroeg na de operatie ontstaan. Bij de ontwikkeling van een littekenbreuk spelen zowel patient-gerelateerde als operatie-gerelateerde risicofactoren een rol. Patient-gerelateerde risicofactoren zijn obesitas, hogere leeftijd, collageenziekten, diabetes mellitus, obstructieve icterus, meerdere voorafgaande laparotomieën en longziekten. Een belangrijke operatie-gerelateerde risicofactor is het optreden van een wondinfectie na laparotomie. Daarnaast speelt de chirurgische techniek voor openen en sluiten van de buik een belangrijke rol.

Voor het openen van de buik kan gebruik gemaakt worden van verschillende chirurgische incisies. In *hoofdstuk II* wordt het verband tussen deze verschillende incisies en het optreden van een littekenbreuk onderzocht. Voor dit doel werd een review gemaakt van alle gerandomiseerde onderzoeken op dit gebied. In meerdere onderzoeken werd de paramediane incisie vergeleken met de in het algemeen gebruikte incisie in de midlijn. Elk van deze trials toonde een significante reductie aan van de incidentie van littekenbreuken na gebruik van de laterale paramediane incisie, met een incidentie 0 tot 1%. Om deze reden dient de paramediane incisie overwogen te worden als voorkeursroute voor electieve buikchirurgie.

In *hoofdstuk III* wordt de invloed van de chirurgische techniek voor het sluiten van de buik op het optreden van littekenbreuken bestudeerd. In deze studie werd een meta-analyse verricht van 15 gerandomiseerde studies met een totaal van 6573 patiënten. Hechtmaterialen werden

verdeeld in de categorieën snel-, langzaam- en niet-oplosbaar. Na sluiten van de buik met een snel-oplosbare voortlopende hechting werden significant meer littekenbreuken gezien dan na sluiten met voortlopende langzaam- of niet-oplosbare hechtingen. Tussen langzaam- en niet-oplosbaar hechtmateriaal werd geen verschil gezien in de incidentie van littekenbreuken. Wel werden na gebruik van niet-oplosbare hechtingen meer draadfistels en meer wondpijn gezien. De beschikbare data vonden vergelijkbare incidenties van littekenbreuken na gebruik van voortlopende en geknoopte hechtingen, hoewel gebruik van voortlopende hechtingen minder tijdrovend was.

Op basis van bovenstaande uitkomsten wordt geadviseerd de fascie te sluiten met een langzaam oplosbare voortlopende hechting, zodat de incidentie van littekenbreuken kan worden gereduceerd zonder dat daarbij de kans op draadfistels en wondpijn toeneemt.

In **hoofdstuk IV** worden de incidentie en risicofactoren voor het ontwikkelen van een littekenbreuk na herstel van een platzbauch bestudeerd in een cohort-studie van 168 patiënten. Elk van deze patiënten die een platzbauchcorrectie had ondergaan werd, indien mogelijk, op het moment van de studie lichamelijk onderzocht. Tweeënveertig patiënten (25%) overleden binnen 60 dagen na de operatie. Van de resterende 126 patiënten ontwikkelden 55 een littekenbreuk, na een mediane follow-up van 37 maanden. De cumulatieve incidentie voor het ontwikkelen van een littekenbreuk na herstel van een platzbauch was 69% na 10 jaar. Significante onafhankelijke risicofactoren waren een eerdere operatie voor een aneurysma van de abdominale aorta en het optreden van een ernstige fasciedehiscentie met evisceratie van de darmen buiten de buik. Er werd geen verschil gevonden tussen de gebruikte hechttechniek voor het platzbauchherstel; vergelijkbare uitkomsten werden gevonden na gebruik van voortlopende en geknoopte hechtingen en ook werd geen verschil gezien tussen gebruik van snel-, langzaam-, of niet-oplosbaar hechtmateriaal. Bij enkele patiënten werd een niet-oplosbare mat geplaatst bij platzbauchherstel, maar ook van deze patiënten ontwikkelde de meerderheid een littekenbreuk.

In totaal werd bij 18 patiënten uit de in hoofdstuk IV beschreven studie een mat geplaatst in een geïnfecteerde buik. Om de veiligheid van plaasting van oplosbare en onoplosbare matten in een geïnfecteerde buik te bestuderen werd een cohort-studie verricht van deze 18 patiënten. Deze studie wordt beschreven in **hoofdstuk V**. Bij 6 patiënten werd een oplosbare polyglactin

mat geplaatst, bij 8 een onoplosbare polypropylene mat, bij 1 patient een onoplosbare polyester mat en 3 patiënten ontvingen een “sandwich”mat van polypropylene aan de buikwandzijde en polyglactin aan de viscerale zijde. Alle patiënten ontwikkelden complicaties. De meest voorkomende complicaties waren een klinische wondinfectie (77%), intra-abdominale abcesvorming (17%), vorming van enterocutane fistels (17%) en migratie van de mat door de darm (11%). Bij 8 patiënten (44%) was verwijdering van de mat noodzakelijk. Binnen 4 maanden postoperatief waren 6 patienten (33%) overleden onder het beeld van een progressieve abdominale sepsis. De incidentie van progressieve abdominale sepsis was significant hoger in de groep die behandeld was met een oplosbare polyglactin mat, vergeleken met de groep die een onoplosbare mat had gekregen (67% versus 11%). Vergeleken met onoplosbare matten hadden de oplosbare matten derhalve geen betere uitkomst met betrekking tot het optreden van mat-gerelateerde complicaties en mortaliteit. Vanwege de hoge incidentie van mat-gerelateerde complicaties in deze patiëntengroep wordt geadviseerd matplaatsing in patiënten met een intra-abdominale infectie ten allen tijde te vermijden.

### **Herstel van littekenbreuken**

Hoewel gebruik van een kunststof mat bij littekenbreukherstel het recidiefpercentage significant vermindert is ook littekenbreukherstel met een mat nog steeds geassocieerd met hoge recidiefpercentages tot 34%.

De matten die bij littekenbreukcorrectie worden gebruikt zijn meestal gemaakt van polyester, polypropylene of polytetrafluoroethylene (PTFE). De mat kan in verschillende posities ten opzichte van de fascie worden geplaatst. De meest gebruikte positie is de dorsale ligging ten opzichte van de fascie (sublay), maar ook een retromusculaire prefasciale positie (dorsaal van de rectus-spier maar ventraal van de achterste rectusfascie) of premusculaire positie (onlay) zijn mogelijk.

Een recent geïntroduceerde techniek voor littekenbreukherstel is de laparoscopische littekenbreukcorrectie. De eerste resultaten van deze techniek zijn veelbelovend, waarbij recidiefpercentages van 0 tot 11% worden gemeld. Echter, in de meeste studies waarin de laparoscopische littekenbreukcorrectie wordt beschreven is de follow-up kort en is geen protocollaire follow-up door middel van lichamelijk onderzoek verricht.



In **hoofdstuk VI** worden de laparoscopische en open littekenbreukcorrectie door middel van een mat met elkaar vergeleken in een cohort-studie. Totaal werden 101 patiënten in de studie geïnccludeerd, te weten 25 in de laparoscopische groep en 76 in de open groep. Op het moment dat de studie werd verricht werden alle patiënten lichamelijk onderzocht op de polikliniek.

Hoewel wel er geen statistisch significante verschillen werden gevonden tussen beide groepen werd wel een trend gezien naar minder wondinfecties in de laparoscopische groep (4% versus 14%) en een kortere opnameduur (3.8 versus 5.0 dagen), vergeleken met de open correctie met mat. De recidiefpercentages waren vergelijkbaar in beide groepen, met een 2-jaars-cumulatief recidiefpercentage van 18% na open herstel met mat en 15% na laparoscopisch herstel. Opvallend was dat alle recidieven in de laparoscopische groep optraden in de eerste serie van 7 patiënten bij wie de mat alleen met tackers was gefixeerd. Er werden geen recidieven gezien in de groep patiënten waarin de mat laparoscopisch was gefixeerd door een combinatie van tackers en transfasciale hechtingen.

Omdat matfixatie een cruciale rol lijkt te spelen bij de preventie van recidieven na laparoscopische littekenbreukcorrectie worden in **hoofdstuk VII** de trekkrachten van laparoscopische matfixatiemethoden met elkaar vergeleken. Voor dit doel werd de trekkracht van matfixatie met behulp van tackers en transfasciale hechtingen met elkaar vergeleken in een varkensmodel. Zesendertig full-thickness preparaten van de buikwand van varkenscadavers werden gerandomiseerd voor fixatie van een polypropylene mat met tackers of transfasciale hechtingen. De kracht die nodig was om de mat los te trekken (trekkracht) werd gemeten met behulp van een dynamometer. De gemiddelde trekkracht van transfasciale hechtingen was significant hoger dan de trekkracht van de tackers, ongeacht het aantal fixatiepunten (67N versus 28 N voor 1 fixatiepunt, 115 N versus 42 N voor 2 fixatiepunten, 150 N versus 63 N voor 3 fixatiepunten, 151 N versus 73 N voor 4 fixatiepunten en 150 N versus 82 N voor 5 fixatiepunten). Derhalve kan geconcludeerd worden dat de trekkracht van transfasciale hechtingen superieur is ten opzichte van de trekkracht van tackers. Toevoeging van transfasciale hechtingen ten behoeve van een betere matfixatie lijkt wenselijk bij laparoscopische littekenbreukcorrectie.

Bij laparoscopische littekenbreukcorrectie wordt de mat altijd intraperitoneaal geplaatst. Bij deze matpositie is direct contact tussen darmen en mat mogelijk, waarbij gevreesd wordt voor de ontwikkeling van adhesies tussen darm en mat, met als gevolg daarvan het ontstaan van een intestinale obstructie of enterale fistel. Het doel van de in **hoofdstuk VIII** beschreven studie is om te onderzoeken of de vorming van adhesies aan de mat kan worden voorkomen door toevoeging van anti-adhesieve vloeistoffen of coatings aan de mat. In 91 ratten werd een buikwanddefect gecreëerd waarin een mat intraperitoneaal werd gefixeerd. De ratten werden verdeeld in 5 groepen: een groep met een polypropylene mat (controle groep), een groep met toevoeging van Sepracoat<sup>®</sup> vloeistof of Icodextrin<sup>®</sup> vloeistof aan een polypropylene mat, een groep met Sepramesh<sup>®</sup> (polypropylene mat met Seprafilm coating), en een groep met Parietex Composite mesh<sup>®</sup> (polyester mat met collagene coating). Zeven en 30 dagen postoperatief werden adhesies aan de mat gescoord en werd de ontstekingsreactie onderzocht met behulp van histologie.

In de groep met een polypropylene mat werden adhesies van de darm aan de mat in 50% van de ratten aangetroffen. Dit was significant meer dan in de groep met een Sepramesh<sup>®</sup> of Parietex Composite mesh<sup>®</sup>, waarbij in geen van de ratten adhesies tussen mat en darm werden gevonden. Bij gebruik van de Parietex Composite mesh<sup>®</sup> werden echter wel meer infecties gezien (57% versus 0% in de controle groep). Bij gebruik van Sepramesh was de oppervlakte van de mat die bedekt was met adhesies gereduceerd ten opzichte van de polypropylene mat, zowel na 7 dagen (55% versus 74%,  $p=0.01$ ), als na 30 dagen (25% versus 48%,  $p=0.03$ ). Toevoeging van Sepracoat<sup>®</sup> of Icodextrin<sup>®</sup> vloeistof liet geen reductie zien van de adhesievorming aan de mat.

In **hoofdstuk IX** wordt het in hoofdstuk VIII beschreven model gebruikt om te onderzoeken of toevoeging van een antiadhesieve collagene coating aan de viscerale zijde van een polypropylene mat de vorming van adhesies aan de mat kan voorkomen. Achtenvijftig ratten werden verdeeld in twee groepen: een groep met polypropylene mat (controle groep) en een groep met een polypropylene mat met een collagene coating (Parieten<sup>®</sup> mat). Na 7 en 30 dagen werden de adhesies aan de mat gescoord. Tevens werd de ingoey van de mat in de buikwand bepaald door meting van de trekkracht.

In het gebruikte model was de Parieten mat meer vatbaar voor matinfecties dan de polypropylene mat (57% versus 0% na 7 dagen en 29% versus 0% na 30 dagen). Ondanks deze hoge infectiepercentages werd in de Parieten groep echter nog steeds na 30 dagen een reductie gezien van het percentage van de mat dat bedekt was met adhesies (42% versus 69%,  $p=0.01$ ). Als proefdieren die een matinfectie ontwikkelden werden geëxcludeerd uit de analyse was het percentage van de mat dat bedekt was met adhesies zowel na 7 als na 30 dagen significant gereduceerd (respectievelijk 21% versus 76% en 21% versus 69%). De ingroei van de mat in de buikwand was vergelijkbaar in beide groepen.

## Conclusies

### **Preventie** van littekenbreuken:

1. Gebruik van de laterale paramediane incisie in plaats van de midlijn incisie voor een laparotomie kan de incidentie van littekenbreuken verminderen. Om deze reden dient de laterale paramediane incisie overwogen te worden voor open electieve abdominale chirurgie waarbij via deze incisie voldoende exposure kan worden verkregen. (hoofdstuk II).
2. De incidentie van littekenbreuken neemt toe indien voor het sluiten van een mediane laparotomie een snel-oplosbaar hechtmateriaal wordt gebruikt. Bij gebruik van langzaam- of niet-oplosbaar hechtmateriaal is de incidentie van littekenbreuken het laagst. Omdat de langzaam-oplosbare hechtmaterialen minder wondpijn en draadfstels veroorzaken dan niet-oplosbare materialen verdienen zij de voorkeur voor het sluiten van de buik (hoofdstuk III).
3. Na een platzbauchcorrectie ontwikkelt de meerderheid van de patiënten een littekenbreuk, onafhankelijk van het gebruikte hechtmateriaal of de gebruikte hechttechniek (hoofdstuk IV). Platzbauchcorrectie met een mat moet worden vermeden in patiënten met een abdominale infectie omdat dit geassocieerd is met een hoge frequentie van mat-gerelateerde complicaties zoals matinfectie, vorming van enterocutane fistels en matmigratie door de darm, ongeacht het gebruik van een oplosbare of onoplosbare mat (hoofdstuk V).

**Herstel** van littekenbreuken:

4. Open littekenbreukcorrectie met mat en laparoscopische littekenbreukcorrectie zijn vooralsnog geassocieerd met vergelijkbare recidiefpercentages. Mogelijk kan het aantal recidieven worden gereduceerd door verbetering van de fixatiemethoden van de mat (hoofdstuk VII).
5. Indien laparoscopische littekenbreukcorrectie wordt verricht is matfixatie met behulp van transfasciale hechtingen sterker dan matfixatie met behulp van tackers. Toevoeging van transfasciale hechtingen verdient dan ook de voorkeur (hoofdstuk VII)
6. In een experimenteel model konden gecoate matten darmadhesies aan een intraperitoneale mat voorkomen (Sepramesh, Parietex composite mesh en Parieten mesh), en werd een significante reductie gezien van het percentage van de mat dat bedekt was met adhesies (Sepramesh en Parieten mesh), vergeleken met een polypropylene mat. Gebruik van Parietex en Parieten mesh was echter geassocieerd met een verhoogd infectierisico (chapter VIII en IX).

## Dankwoord

Bij de totstandkoming van dit proefschrift hebben velen een bijdrage geleverd. Al deze personen wil ik bedanken voor hun inzet en prettige samenwerking. Enkele personen wil ik in het bijzonder bedanken.

Professor Bonjer, Jaap, dank voor het vertrouwen en de vrijheid die ik kreeg bij het doen van mijn onderzoek. Ondanks je drukke bezigheden was je altijd bereid met mij over de inhoud van de artikelen te discussieren en gezamenlijk stukken door te nemen. Het is erg prettig samen te werken met iemand die met je “meedenkt”. Reeds in een vroeg stadium stimuleerde jij het houden van voordrachten op internationale congressen, wat erg motiverend werkte. Jouw coaching op zowel wetenschappelijk als klinisch terrein was erg inspirerend en ik bewonder de enorme energie waarmee je zoveel dingen weet te combineren.

Professor Jeekel, dank voor de gelegenheid die u mij bood om onderzoek te doen op uw afdeling en de begeleiding bij het tot stand komen van dit proefschrift. Veel bewondering heb ik voor uw nimmer aflatende wetenschappelijke enthousiasme, waar onder andere de oprichting van de “buiksluitgroep” uit is voortgekomen. Met veel plezier heb ik deelgenomen aan alle “brainstormsessies” en kijk ik uit naar de toekomstige ontwikkelingen...

De leden van de promotiecommissie, Prof. dr. R.P. Bleichrodt, Prof. dr. ir. C.J. Snijders en Prof. dr. O.T. Terpstra, bedank ik voor de beoordeling van het manuscript.

Ewout Steyerberg: jij bent voor mij onmisbaar geweest bij de statistiek van meerdere hoofdstukken uit dit proefschrift. Met behulp van voor-mij-niet-te-begrijpen computerprogramma's wist je in een record-tempo vaak de meest ingewikkelde statistische bewerkingen voor elkaar te toveren. Heel veel dank hiervoor, want zonder jou was dit nooit gelukt! Ook Wim Hop dank ik voor de zorgvuldige statistische bewerkingen van hoofdstuk 6 uit dit proefschrift.

Peggy de Vos van Steenwijk: jij bent voor mij een ware steun en toeverlaat geweest. Je efficiënte en secure manier van werken hebben mij in de maanden dat je me hielp enorm veel verder geholpen, waarvoor dank!

Pim Burger, ook jij hebt een belangrijke rol gespeeld bij meerdere hoofdstukken in dit proefschrift (en ook twee artikelen buiten het bestek van dit boekje) waarvoor ik je zeer dankbaar ben. Ik vind het erg leuk dat jij mijn “opvolger” in het littekenbreukonderzoek bent geworden en wens je veel succes met je eigen boekje.

Fred Bonthuis; als medewerker van het Laboratorium voor Experimentele Chirurgie heb je een belangrijke bijdrage geleverd aan het uitvoeren van de rattenstudies. Je was altijd bereid te helpen, waarvoor veel dank.

Dr. Gert Jan Klein-Rensink wil ik danken voor de mogelijkheid om de experimenten op de afdeling Anatomie uit te voeren in een bijzonder gezellige sfeer. Dankzij u en dr. Lange is de chirurgische anatomie weer nieuw leven ingeblazen en u beiden wil ik bedanken voor het plaatsnemen in de grote commissie.

Eric Hazebroek, mijn onmiskenbare “room-mate”, en Wietske Vrijland, mijn voorgangster, wil ik danken voor hun hulp, gezelligheid en inspiratie. Het was een groot plezier om samen met jullie, Philippe Wittich, Nicole Bouvy, Larissa Tseng en Mireille Knook deel uit te maken van de “Bonjer Group”. Dankzij jullie waren de buitenlandse tripjes altijd extra mooi! Ruben Veldkamp en Mano Gholgesaei dank ik voor het voortzetten van de Colibri- en LEVEL-trial. Dankzij jullie en jullie opvolgers kunnen deze trials worden voltooid.

Collegae in het Laboratorium voor Experimentele Chirurgie: Arend Aalbers, Amir Mearadji, en Helma van Grevenstein: jullie brachten de humor in het onderzoeksjaar!

De chirurgen en collegae van het Ikazia dank ik voor hun morele steun om dit proefschrift te voltooien naast het werk in de kliniek. In het bijzonder Dr Weidema, dank voor het plaatsnemen in de grote commissie en uw inzet als opleider voor de assistenten in het Ikazia.

Mijn paranimfen; Marcelle van Geel en Lieke Welling: jullie beiden dank ik voor de onvoorwaardelijke vriendschap en jullie steun bij mijn promotie. Ik ben er trots op dat jullie

bij de verdediging naast me staan en had me geen betere paranimfen kunnen wensen! Lieke wil ik speciaal bedanken voor het doorworstelen van dit proefschrift en de minutieuze controle van de statistiek...

Mijn ouders wil ik bedanken voor hun liefde, steun en interesse. Jullie hebben mij altijd gestimuleerd en geholpen om te worden wat ik wilde. Het is voor mij heel fijn om te weten dat ik altijd op jullie kan rekenen. Liesbeth: bedankt voor de computer-hulp-lijntjes als ik weer stampvoetend achter een computer zat die niet deed wat ik wilde...

Tot slot, lieve Jurgen, indirect heb jij een grote bijdrage geleverd aan dit boekje door mij te stimuleren onderzoek te gaan doen en door het vertrouwen dat je me gegeven hebt. Het is fantastisch te mogen leven met iemand zoals jij!

## Curriculum Vitae

Martijne van 't Riet werd geboren op 23 augustus 1973 te Utrecht. Het Voorbereidend Wetenschappelijk Onderwijs volgde zij aan het Christelijk Streeklyceum te Ede. In 1991 werd aangevangen met de studie Geneeskunde aan de Rijksuniversiteit Leiden. Tijdens haar studie was zij werkzaam bij Stichting Bio Implant Services, waar zij cornea- en hartexplantaties uitvoerde ten behoeve van weefseldonatie. In 1998 haalde zij het artsexamen. Na ruim een jaar als AGNIO chirurgie in het Erasmus Medisch Centrum - Dijkzigt gewerkt te hebben kreeg zij op 1 januari 2000 een aanstelling als arts-onderzoeker op de afdeling Heelkunde (hoofd: Prof. Dr. J. Jeekel). Daar was zij verantwoordelijk voor de coordinatie van de Colibri-trial (CORrectie LIttekenBREuken: laparoscopisch versus open) en richtte zij de LEVEL-trial op (Liesbreuken: Endoscopisch VERSus Lichtenstein). In deze periode verrichte zij tevens een deel van de studies beschreven in dit proefschrift. In 2001 begon zij met de opleiding tot algemeen chirurg in het Erasmus Medisch Centrum – Dijkzigt (opleider: Prof. dr. H.J. Bonjer) en continueerde zij het onderzoek. Vanaf 1 maart 2003 vervolgde zij haar opleiding in het Ikazia Ziekenhuis te Rotterdam (opleider Dr. W.F. Weidema).





