Closure of Midline Abdominal Incisions with Small Stitches

Studies on Wound Complications and Health Economy

Daniel Millbourn
To my dear family

Anna, Gustav, Emma and Linnea
Whatever is worth doing at all, is worth doing well

Lord Chesterfield (1694-1773), England
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Abstract

Background
A midline incision inflicts minimal damage to muscles, nerves and blood supply. Postoperative complications cause patients suffering and costs for society. Midline incisions should be closed with a continuous single-layer technique and a suture length (SL) to wound length (WL) ratio over 4. It has been recommended to place stitches at least 10 mm from the wound edge. Recent studies, taking the SL to WL ratio into account, have shown that a stronger wound is produced with small stitches placed closer to the wound edge.

Aims
The aims were to study the rate of surgical site infection (SSI) and incisional hernia in relation to the use of small or large stitches; to study the effect of the SL to WL ratio and other risk factors for SSI and incisional hernia in relation to the size of stitches; and to study if the use of small stitches generates cost savings.

Materials and methods
In a non-randomised study, 1991 to 1993, the patients having their midline incisions closed with an SL to WL ratio over 4 were selected. The rate of SSI and incisional hernia was analysed in relation stitch length (SL/number of stitches). In a randomised trial, 2001 to 2006, patients were randomised to closure of midline incisions with small stitches, placed 5 to 8 mm from the wound edge, or large stitches placed at a distance of at least 10 mm. Patient and operative characteristics were recorded. The rate of SSI and incisional hernia was studied and risk factors were analysed. The proportion of patients subjected to an incisional hernia repair was identified. The mean cost for a hernia repair during 2010 was calculated. A cost analysis was performed.

Results
In the non-randomised study 368 patients were analysed. The lowest rate of SSI and incisional hernia was with a short stitch length. In the randomised trial, 356 patients were closed with small stitches and 381 with large. With small stitches SSI occurred in 17 of 326 patients (5.2%) and with large stitches in 35 of 343 (10.2%) (p=0.02). With small stitches incisional hernia was present in 14 of 250 patients (5.6%) and with large stitches in 49 of 272 (18.0%) (p<0.001). With small stitches, no risk factors could be identified. The rate of incisional hernia was lower with an SL to WL ratio over 4. A very high ratio did not affect the complication rates. With small stitches there was a cost for a longer suturing time, but a cost reduction of 1339 SEK was
generated from the societal perspective for each closure compared with large stitches.

**Conclusions**

In midline abdominal incisions closed with a continuous single-layer technique the rate of SSI and incisional hernia is lower with small stitches than with large. The rate of incisional hernia is lower with an SL to WL ratio over 4 and increasing the ratio very much above 4 does not increase the rate of complications. With small stitches no risk factors for the development of SSI and incisional hernia can be identified and cost savings are generated. The previous recommendation to use large stitches should be changed to recommend small stitches.
Sammanfattning (Summary in Swedish)

Bakgrund

Bukoperationer görs ofta via ett medellinjesnitt som ger en snabb och god åtkomst med minimal skada på muskulatur, nerver och blodcirkulation. Särkomplikationer med lidande för patienterna och ökade sjukvårdskostnader kan uppstå.


Tidigare studier har visat att medellinjesnitt blir svagare om man använder små stygn satta nära sårkanter jämfört med om man använder stora stygn. Detta har förklarats med att vävnaden nära sårkanter är försvagad av inflammation till följd av operationen. Man har därför rekommenderat användandet av stora stygn placerade minst 10 mm från sårkanter. I senare experimentella studier tog man hänsyn till kvoten mellan sutur- och sårlängd. Då var snitt sydda med små stygn, placerade 3 till 6 mm från sårkanter, starkare än sår sydda med stora stygn placerade 10 mm från kanten. Man såg även att stora stygn kan komprimera och skära igenom mjuk muskel- och fettvävnad som tagits med i stygnen. Suturen kan då slacka och sårkanterna tillåts separera. Denna separation innebär att ett ärrbräck kan bildas. En ökad vävnadsdöd i såret med stora stygn kan vara grogrund för sårinfektion. Med små stygn innefattas ingen mjuk vävnad som kan komprimeras i styggen och sårkanterna hålls säkrare ihop.

Det finns således studier som tyder på att små stygn satta nära sårkanter kan vara att föredra i stället för stora stygn, men det vetenskapliga underlaget är ännu otillräckligt.
Syfte med studierna

Syftet med studierna var att vid förslutning av medellinjesnitt studera frekvensen av sårinfektion och ärrbråck i relation till användandet av små och stora stygn.

effekten av kvoten mellan sutur- och sårlängd och andra riskfaktorer för sårinfektion och ärrbråck i relation till stygnens storlek.

om användandet av små stygn genererar kostnadsbesparinger.

Material och metod


Resultat

I den ickerandomiserade studien analyserades 368 patienter. Sårinfektion och ärrbråck var minst förekommande hos dem som hade sytts med de minsta styggen.

I den randomiserade studien syddes 356 patienter med små stygn och 381 med stora. En särbråck uppstod i gruppen med stora stygn. Med små stygn uppstod sårinfektion hos 5 % av patienterna och med stora stygn hos 10 % (p=0,02). Med små stygn uppstod ärrbråck hos 6 % av patienterna och med stora stygn hos 18 % (p<0,001).

Med små stygn tog det i medeltal 4,6 minuter längre tid att sy ihop snittet jämfört med att sy med stora stygn. Det innebar en ökad kostnad för operationen, men ur ett samhällsperspektiv genererades en kostnadsminskning på 1339 SEK per opererad patient. Det görs cirka 15 000 operationer via medellinjesnitt i Sverige årligen, vilket innebär att besparingspotentialen med små stygn motsvarar minst 20 miljoner SEK per år.

**Slutsatser**

I medellinjesnitt som försluts fortlöpende i ett lager, medför användandet av små stygn en lägre frekvens av både sårinfektion och ärrbråck jämfört med stora stygn.

Risken för sårinfektion och ärrbråck är lägre med en kvot mellan sutur- och sårlängd över 4 och att öka kvoten påverkar inte risken för komplikationer.

Med små stygn kan inga riskfaktorer för sårinfektion och ärrbråck identifieras.

Att sy med små stygn innebär kostnadsbesparingar.

Den tidigare rekommendationen att använda stora stygn bör ändras till att rekommendera små stygn.
List of publications

This thesis is based on the following papers

I  Millbourn D, Israelsson LA
   Wound complications and stitch length

II Millbourn D, Cengiz Y, Israelsson LA
    Effect of stitch length on wound complications
    after closure of midline incisions:
    a randomized controlled trial
    Arch Surg. 2009 Nov;144(11):1056-9

III Millbourn D, Cengiz Y, Israelsson LA
    Risk factors for wound complications in midline abdominal
    incisions related to the size of stitches

IV Millbourn D, Wimo A, Israelsson LA
    Cost analysis of the use of small stitches when closing
    midline abdominal incisions
    Submitted

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List of abbreviations

AAA    abdominal aortic aneurysm
BMI    body mass index (weight in kilograms divided by height in metres squared)
CI     confidence interval
cm     centimetres
min    minutes
mm     millimetres
OR     odds ratio
SD     standard deviation
SE     standard error
SEK    Swedish krona
SL     suture length
SSI    surgical site infection
USP    United States Pharmacopeia
WL     wound length
y      years
Introduction

A midline incision is frequently used in abdominal surgery. It can be rapidly made with minimal damage to muscles, nerves and blood supply. Postoperative wound complications, such as surgical site infection, wound dehiscence and incisional hernia cause patients suffering and costs for the welfare system. With, for example, more than 2 million laparotomies made annually in the USA for benign conditions alone, it seems essential to keep the rate of wound complications as low as possible. Approximately 100,000 patients annually undergo incisional hernia repair in the USA, which illustrates the magnitude of the problem.

Background

Anatomy of the ventral abdominal wall

There are four important muscles in the ventral abdominal wall. The three flat muscles have their insertion in the linea alba - a fibrous structure joining the xiphoid process to the pubic symphysis. The external oblique muscle is the most superficial flat muscle and has a medial-caudal direction. The internal oblique muscle is the intermediate muscle and has a medial-cranial direction. The innermost flat muscle is the transverse abdominis, which has a transverse direction. When the flat muscles contract, tension is exerted on the midline structures. The three-ply structure of the abdominal wall forms a strong expandable support for the abdominal viscera. The rectus abdominis muscle originates caudally from the pubic bone and has a vertical direction towards its insertion in the xiphoid process and the 5th to 7th ribs cranially. The rectus abdominis muscle is enclosed in the fibrous compartment called the rectus sheath, formed by the aponeuroses of the three flat muscles. Caudal to the arcuate line, approximately halfway between the umbilicus and the pubic bone, all aponeuroses of the flat muscles pass ventral of the rectus muscle, so in this region there is no dorsal wall of the rectus sheath.

The blood supply of the ventral abdominal wall comes from two systems. The superior and inferior epigastric arteries form a longitudinal anastomosis situated between the rectus abdominis muscle and the dorsal wall of the rectus sheath. The second system arises from the aorta as transverse segmental arteries, running between the internal oblique and transverse muscles towards the midline.

The innervation of the ventral abdominal wall consists of branches from the 7th to 12th intercostal nerves, which follow the segmental arteries.
Sectional view of the ventral abdominal wall

The midline incision

As a result of the anatomy, it is possible to perform a midline incision with minimal damage to muscles, nerves and vascular supply of the abdominal wall as these structures do not cross the midline. The midline incision provides a relatively quick and wide access to the abdominal cavity and is therefore often used in major surgery and for emergency procedures.

Alternatives to the midline incision are a paramedian incision (medial or lateral), transverse, oblique or muscle splitting incisions. All incisions except the midline incision may compromise the placement of an ostomy and this is of importance in colo-rectal surgery and in emergent bowel surgery.

There are studies reporting a lower rate of incisional hernia with lateral paramedian incisions than with midline incisions but also studies that have failed to detect any difference. Opening and closing a paramedian incision is time consuming and later re-entry may be difficult.
For procedures in the lower abdomen muscle splitting incisions as the gridiron incision and the Pfannenstiel incision are alternatives often held to be associated with a low rate of wound complications 42, 100. The rate of wound dehiscence is similar, however, with Pfannenstiel and midline incisions 56. In a Swedish survey, incisional hernia repair after muscle splitting incisions was quite frequent 83. These incisions provide limited access to the abdomen and are associated with a risk of nerve injury 99-100.

In a Cochrane review comparing transverse (including oblique) and midline incisions it was concluded that no differences in infection rates could be detected, but that the likelihood of wound dehiscence and incisional hernia appeared to be lower with transverse incisions 11. None of the included studies individually report any significant difference concerning wound dehiscence. There are only three studies available concerning incisional hernia with a follow up of more than one year 43, 52, 146, and only one of them reports a monitored suture technique 146.

Wound healing

The healing of a midline incision follows the general principles of tissue healing and is divided into three phases 121, 130. Wound healing is similar in all tissues but the time needed for its completion differs 38. Aponeurotic tissue, as in the linea alba, needs considerably longer time to heal than for example skin and mucosa.

The inflammatory phase starts immediately after the incision is made and lasts for about four days. Macrophages are involved in the phagocytic process, the removal of debris, necrotic tissue and bacteria and the mobilisation of fibroblasts to the wound, which is the primary aim of this phase. A fibrinogen rich gel in the inflammatory exudate constitutes the matrix for the future deposition of collagen. Inflammation in the surgical wound is seen within a zone up to 15 mm from the wound edge 2. During this phase the wound has no intrinsic strength and its integrity depends entirely on the suture and the suture holding capacity of the tissues 38, 62, 130.

A proliferative phase follows the inflammatory phase and it lasts for approximately three weeks 130, 142. The beginning of this second phase is defined by the local mobilisation of fibroblasts, which start collagen synthesis. The collagen deposition leads to an increase in the strength of the wound, but at the end of this phase the strength is still only 15-20% of the unaffected abdominal wall 38, 53, 121.

The following maturation phase may continue for more than 12 months 53. It is characterised by cross-linking and remodelling of collagen fibres 38, 121. Collagen synthesis continues at a high rate, but no further increase in scar mass occurs and there is a balance between synthesis and lysis. The collagen fibres undergo a reorientation dependent on traction on the wound and a
mimic affect of adjacent normal tissue. Up to the second postoperative month there is a rapid gain in wound strength, thereafter strength progressively increases, but at a slower pace. After 1 month 40-60% of normal wound strength can be expected, after 2 months 60-80% and after one year 60-90%. A normally healed wound has gained 50% of its original strength after approximately 6 weeks. After an incision the aponeurosis will never completely regain its original strength.

**Wound complications**

**Surgical site infection**

SSI presents a considerable burden to healthcare, representing about a fifth of all healthcare-associated infections. After surgery through a midline incision SSI is reported in up to approximately 15% of patients. SSI may require surgical intervention for drainage and cause symptoms that prolong the length of hospital stay. The development of infection is dependent upon the level of contamination, the extent of trauma and the amount of necrotic material in the wound.

Wounds may be divided into three classes: clean, contaminated and dirty, with an increasing risk for SSI, based on the degree of microbial contamination.

SSI may be classified as described by Horan et al and adopted by the US Centers for Disease Control and Prevention (CDC). Only infections occurring within 30 days after surgery are classified as SSI.

<table>
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<th>Classification of operative wounds - adapted from Berard</th>
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<tr>
<td><strong>Clean</strong></td>
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<tr>
<td><strong>Contaminated</strong></td>
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<tr>
<td><strong>Dirty</strong></td>
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**Definitions of surgical site infection** - adapted from Horan

<table>
<thead>
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<th>Superficial SSI</th>
<th>Deep SSI</th>
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<tr>
<td>Involves only the skin or subcutaneous tissue.</td>
<td>Involves deep soft tissues, such as the aponeurosis and muscles.</td>
</tr>
<tr>
<td><strong>Plus at least one of these criteria:</strong></td>
<td><strong>Plus at least one of these criteria:</strong></td>
</tr>
<tr>
<td>purulent drainage from the incision</td>
<td>purulent drainage from the incision</td>
</tr>
<tr>
<td>at least one of the following signs:</td>
<td>at least one of the following signs:</td>
</tr>
<tr>
<td>pain or tenderness, localised swelling, redness or heat – and the incision is opened by a surgeon</td>
<td>fever (&gt;38°C), pain or tenderness and the incision spontaneously dehisces or is opened by a surgeon</td>
</tr>
<tr>
<td>diagnosis of superficial SSI by physician</td>
<td>diagnosis of deep SSI by physician</td>
</tr>
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**Wound dehiscence**

Wound dehiscence is a complete disruption of the wound with evisceration of abdominal content demanding emergent reoperation. It usually occurs within the first 10 days when the integrity of the wound is entirely dependent on the suture and the suture holding capacity of the tissues. Wound dehiscence is reported to occur in up to 4% of midline incisions. In a wound closed with a continuous suture technique, dehiscence may occur if the suture breaks or if the anchor knots slips. Clinical and experimental studies suggest that the main mechanism is the suture cutting completely through the suture holding tissues. Wound dehiscence is associated with mortality rates of up to 35%.

**Incisional hernia**

Incisional hernia is probably the result of early separation of the wound edges complicating the collagen bridging over the defect. A separation of wound edges of 12 mm or more after 4 weeks predicts the development of incisional hernia. The defect in the aponeurosis allows preperitoneal fat or intra abdominal content to protrude. The symptoms of incisional hernia range from quite mild to emergency situations due to incarceration (6-15%) or strangulation (2%) of abdominal contents requiring immediate

After midline incisions, incisional hernia is reported in up to approximately 20% of cases 35, 161. The rate varies a lot between different reports, probably very much related to different definitions of incisional hernia used at follow up. The definition suggested by the European Hernia Society is any abdominal wall defect, with or without a bulge, in the area of a postoperative scar perceptible or palpable by clinical examination or imaging 109. Studies using this wide definition 75, 165 are likely to record a higher rate of incisional hernia than if a more narrow 134, 158 definition is used. This wide definition has been used in the present studies. At clinical examination, patients were examined supine with a relaxed and a tensed abdominal wall while lifting both legs extended and then standing with relaxed and tensed abdominal wall while straining 74.

Incisional hernia becomes apparent over time and in several studies they have continued to appear many years after the index operation 41, 97, 108. It has been suggested that there are two types of incisional hernia, one with an early onset and one with a late onset. The latter would be a consequence of weakening of an initially normally healed wound due to mechanical stress of immature collagen 37, 160. However, the late appearing hernias probably are a consequence of the definition used at the time of follow up examination. A defect in the wound will gradually develop into a protrusion and eventually a visible bulge. Late appearing hernias may therefore have developed early but be detected late. Thus, in studies defining hernia as a visible bulge at follow up, more than half will be detected later than 12 months after the operation 97, 108. If hernia is defined as a palpable defect with a bulge, less than 30% are detected late and if any palpable defect is regarded as a hernia less than 10% are detected late 23, 41.

Risk factors for wound complications

Risk factors for surgical site infection
The most important risk factor for SSI is the degree of bacterial contamination 4, 30. Gastrointestinal and emergency surgery is therefore associated with a high rate of SSI 9, 78, 129. A long operation time is also a risk factor and procedures lasting longer than two hours have been associated with a higher rate of infection 51, 85.

Patient related factors such as diabetes mellitus 27, overweight 79 and smoking 148 are associated with an increased rate of infection 102. Old age has in some studies correlated to a high rate of SSI 9, 31, 86 but has in other studies not been a risk factor 28, 79.
Risk factors for wound dehiscence and incisional hernia

The etiologic mechanisms for the development of wound dehiscence and incisional hernia are similar and so are the identified risk factors. Overweight, male sex, abdominal distension and postoperative respiratory failure are factors that increase the tension on the suture line and these factors have been associated with an increased risk of dehiscence and incisional hernia. Abdominal distension leads to elongation of the wound and this increases the pull on the suture line increasing the risk of the suture to break or the knots to slip resulting in a wound dehiscence. Soft tissue held in the suture may be compressed leading to necrosis and inflammation that weakens the wound and augments the risk of the suture cutting through the suture holding tissues. Separation of wound edges leading to an incisional hernia may be a result of an incomplete early wound dehiscence. A raised risk of incisional hernia is seen after multiple operations through the same scar and after wound dehiscence.

Smoking is a risk factor for incisional hernia. Old age, diabetes mellitus, malignant disease, malnutrition, jaundice, the use of glucocorticosteroids are factors, among others, that may delay wound healing and have been suggested to be associated with wound dehiscence and incisional hernia. In patients operated on for abdominal aortic aneurysm (AAA), the rate of incisional hernia has been reported to be high, but when taking the quality of the suture technique into account the rate has been similar in patients with AAA and in patients operated on for other diagnoses.

An SSI may delay or even reverse the normal wound healing process and is an important risk factor for the development of both wound dehiscence and incisional hernia. A severe necrotising infection may disintegrate the aponeurosis and the sutures placed in this tissue can then no longer support the wound.

The wound during the early period is entirely dependent on the suture line for its integrity and there is strong evidence that the suture technique is important for the prevention of a dehiscence or an incisional hernia.

Suture technique and wound complications

The technique used for closing a midline incision is crucial for the result and is under the total control of the surgeon.

Layered vs. single-layer technique

In a single-layer mass closure technique the stitches include all layers of the abdominal wall except the skin. Experimental studies report a higher wound bursting strength with a single-layer technique and it has in clinical
studies been associated with a lower rate of wound dehiscence compared with a layered technique. The rate of incisional hernia seems to be similar with a single-layer technique and a layered technique. Including peritoneum in the suture does not contribute to wound strength or to a lower rate of wound dehiscence or incisional hernia, but may increase the formation of adhesions. Reviews and meta-analyses favour the single-layer technique.

Continuous vs. interrupted suture technique
A continuous suture technique has in several studies produced similar rates of wound complications as an interrupted technique and most authors have favoured the continuous technique since it is easier and faster to perform. A recent meta-analysis concluded that hernia rates are lower with a continuous technique than with an interrupted one. A stronger wound is produced with a continuous technique than with an interrupted one. One possible explanation may be that in a continuous suture line, tension equilibrates along the incision, which is not possible with interrupted sutures. A continuous technique results in a higher concentration of collagen and a lower percentage of the weaker collagen type III than an interrupted technique. In an experimental study the wound tissue perfusion was similar with continuous and interrupted techniques. Continuous sutures deposits less foreign material in the wound and fewer knots, which might have relevance for the development of wound infection.

The suture material
An ideal suture material should be easy to handle, resistant to infection, inert in the tissues and already in 1920 Moynihan proposed that the ideal suture material should be absorbable. Sutures may be divided into rapidly-, slowly- and non-absorbable materials. A suture is regarded as absorbed when it maintains less than 50% of its original strength. The concept of a suture being absorbed is thus not related to the suture actually disappearing from the wound. Rapidly absorbable sutures contribute to wound strength for 3 to 20 days, slowly absorbable for 4 to 6 weeks and non-absorbable for more than 60 days. As a midline incision gains 50% of its original strength after about 6 weeks, the suture must theoretically be able to contribute to the wound strength for this period. Most studies report a higher rate of incisional hernia with rapidly absorbable sutures than with slowly or non-absorbable, but a higher frequency of suture sinuses and prolonged wound pain is detected with the latter. Slowly and non-absorbable sutures have been tested with equal herniation rates.
In multifilament sutures bacteria can escape from phagocytosis in the interstices between the threads \(^{14, 118}\) and this is probably the reason why monofilament sutures are associated with a lower rate of wound infection than multifilament \(^{3, 13, 119}\). The suture should be of the smallest possible calibre \(^{122}\). USP 2-0 has been tested experimentally \(^{18}\) and used clinically with results comparable to sutures of a greater calibre \(^{93}\).

**The knots**

The starting and finishing knots are the weakest points of the continuous suture line \(^8\). Monofilament sutures used in continuous suturing have a relatively low knot security \(^{138, 157}\). Self-locking knots are small, do not slip or significantly reduce the strength of the suture and are recommended for continuous suturing \(^{76}\).

**The tension on the suture line**

The tension placed on a continuous suture line is a part of the closure technique that is difficult to standardise. A high tension causes ischemia \(^{59, 95}\), tissue necrosis \(^{25, 95, 142}\) and a reduced collagen synthesis in the wound \(^{60, 87}\). A high tension has in clinical trials been associated with an increased risk of SSI \(^{104}\). High tension on the suture line increases the risk of the suture holding capacity of the tissue being exceeded, increasing the risk of wound dehiscence \(^{63, 116}\). Experimental studies have shown that wounds closed with low tension are stronger than wounds closed tightly \(^{1, 58, 142, 150}\). An experimental study showed that even with a deliberately loose continuous closure with a surplus of suture material the midline can heal without hernia formation \(^{71}\).

**The suture length to wound length ratio**

Jenkins found that a midline incision may lengthen 30% if abdominal distension occurs and that an adequate reserve of SL is necessary to allow for this. He found mathematical and clinical evidence for a lower risk of dehiscence with a suture length (SL) 4 times longer than the wound length (WL) \(^{84}\). The SL to WL ratio depends on the number of stitches, the size of the stitches and the tension on the suture line.

Suturing with an SL to WL ratio above 4 has in clinical trials reduced the risk of incisional hernia \(^{74, 77}\). In these studies the lowest rate of incisional hernia and SSI was seen with a ratio within the range of 4 to 5 \(^{78-79}\). Overweight is commonly identified as a risk factor for wound complications but as larger stitches are used in overweight patients and when the ratio is over 5 it might be the large stitch rather than the high ratio or the overweight per se that constitutes the risk \(^{79, 124}\). There are very few other studies investigating the effect of high SL to WL ratios, but there are experimental
and clinical studies contradicting the results of a poorer outcome with a ratio over $5^{58, 163}$.

**The size of stitches**

With a similar tension the same SL to WL ratio can be achieved with either many small stitches or with fewer large stitches. Large stitches placed at least 10 mm from the wound edge have been recommended to avoid wound dehiscence and incisional hernia $^{21, 42, 70, 94, 131}$. This recommendation was based on experimental studies showing lower wound strength with stitches placed close to the wound edge $^{18, 62, 94, 130, 142, 156}$. The suggested explanation was a weakening of the aponeurosis close to the wound edge during the inflammatory phase $^{2, 61, 70, 121}$. The fact that with a constant number of stitches the SL to WL will decrease if stitches are placed closer to the wound edge was not taken into account in these studies. An experimental study taking the ratio into account showed a stronger wound after 4 days with stitches placed 3 to 6 mm from the wound edge, when the inflammation would be at its peak, compared with stitches placed 10 mm from the wound edge $^{24}$. A more recent experimental study, also taking the ratio into account, showed a stronger wound with small stitches placed 5 mm from the wound edge compared with stitches placed 10 mm from the edge $^{54}$.

![Diagram](image.png)

*To the right an SL to WL ratio of 4 is achieved with large stitches. To achieve the same ratio with small stitches (left) the number of stitches placed in the wound must be increased.*
Contradicting the recommendation of using large stitches non-randomised studies have indicated a higher rate of wound infection \(^7\) and incisional hernia with large stitches \(^{124}\). Large stitches may be associated with a high rate of wound complications as they include not only the aponeurosis but also soft tissues as subcuticular fat and muscle, with low suture holding capacity. Separation of the wound edges predisposing for hernia formation may be a result of the stitches cutting through or compressing the soft tissues enclosed in large stitches leading to slackening of the suture. This has been clearly demonstrated in experimental studies \(^{25,54}\). These studies also provide a possible explanation for large stitches to be associated with an increased risk of SSI as with large stitches the amount of devitalized or necrotic soft tissue may be increased as a result of impaired tissue perfusion \(^{65,95}\).

A large stitch incorporates the aponeurosis (blue) as well as subcuticular fat (yellow) and muscle (red).

When traction is applied on a large stitch, subcuticular fat and muscle is compressed or cut through. The stitch then slackens and aponeurotic edges separate.

When traction is applied on a small stitch there is no compression of soft tissues and the aponeurotic edges are held in apposition.
It may be speculated whether there is a difference between small and large stitches regarding the possibility of the aponeurotic edges also being separated in the anterior-posterior direction. With a large stitch the aponeurotic structures may be overlapped with soft tissues interposed. The possibility of this occurring is likely to be lower with small stitches. This mechanism has never been evaluated in experimental or clinical studies.

Aponeurotic edges overlapped and separated by soft tissue in the anterior-posterior plane with a large stitch.

Health economy

When introducing a novel surgical technique it is important to study not only the effect on the rate of complications but also to evaluate potential economic effects of the intervention. Economic evaluations are an important source of information called for by decision makers to guide the allocation of resources. Wound complications after the closure of midline incisions cause patient suffering and generate costs for the welfare system. About 20% of patients with an incisional hernia demand repair, which together with SSI generates costs on several levels. Direct costs are produced for perioperative visits to the outpatient clinic, hospital stay, time spent in the operation theatre, surgical material, rehospitalisation and reoperation due to complications and recurrences. Indirect costs are produced for the loss of productivity during the time patients are unable to work.

Open incisional hernia repair with reinforcement of the abdominal wall with a synthetic prosthetic mesh is associated with a low recurrence rate and is cost effective.

To study the economic effects of SSI is difficult, but it has been done in several studies. A prolonged hospital stay seems to be the most significant factor and the cost for a hospitalised patient with an SSI is approximately twice as high as the cost for a patient without an SSI.
**Short summary of background**

There is strong evidence that midline incisions should be closed with a continuous single-layer technique using a slowly absorbable monofilament suture and with an SL to WL ratio above 4.

Contradictory to current clinical recommendations experimental and clinical findings indicate that the high ratio should be achieved with small stitches.

An experimental model describes a possible mechanism for large stitches to be associated with a high rate of both SSI and incisional hernia.

Further clinical studies evaluating the effect of small and large stitches on the rate of wound complications and possible economic effects are therefore well motivated.
Aims of the studies

In midline abdominal incisions closed with a continuous single-layer technique the aims were to study

the rate of surgical site infection and incisional hernia in relation to the use of small or large stitches.

the effect of the suture length to wound length ratio and other potential risk factors for surgical site infection and incisional hernia in relation to the size of stitches.

if the use of small stitches generates cost savings compared with the use of large stitches.
Materials and methods

Non-randomised study (Paper I)

From September 1991 to June 1993, patients older than 18 years operated on through a midline abdominal incision entered a prospective study. Only patients with incisions closed with an SL to WL of 4 or more were included in the present analysis.

The midline incisions were closed with a continuous single-layer technique using a monofilament suture.

Patient and operative characteristics were recorded. A BMI of 25 or higher was defined as overweight. The SL to WL ratio was calculated. The number of stitches placed in the wound was recorded for calculation of the mean stitch length (SL/number of stitches).

Patients were examined for the presence of SSI and dehiscence 14 days after the index operation and for the presence of incisional hernia after 12 months.

Randomised controlled trial (Papers II-IV)

Between January 8, 2001, and January 8, 2006, patients older than 18 years subjected to abdominal surgery through a midline incision were included in a randomised trial. Exclusion criteria were a previous abdominal midline incision, a previous abdominal incision crossing the midline, or a pre-existing ventral hernia. The incisions were closed with a continuous, single-layer technique using a slowly absorbable monofilament polydioxanone suture (PDS II, Ethicon GmbH, Germany).

Patients were randomised to closure with either small stitches using a USP 2-0 suture on a needle with a diameter of 20 mm (MH-1 needle; Ethicon GmbH, Germany) or to closure with large stitches using a USP 1 suture on a needle with a diameter of 41 mm (TP-1 needle; Ethicon GmbH, Germany).

Surgeons were instructed to produce an SL to WL ratio of at least 4 and achieving a very high ratio was encouraged. Instructions were to place small stitches 5 to 8 mm from the wound edge at an interval of less than 5 mm, only incorporating the aponeurosis and to place large stitches at least 10 mm from the wound edge. Self-locking starting and finishing knots were used.

Patient and operative characteristics were recorded. Overweight was defined as a BMI of 25 or more. The SL to WL ratio was calculated. The number of stitches placed in the wound was recorded for calculation of the mean stitch length (SL/number of stitches) and the mean stitch interval (WL/number of stitches).
Patients were examined for the presence of SSI and dehiscence after 30 days and for the presence of incisional hernia after 12 months. In papers III and IV patients with incisions closed with an SL to WL ratio under 4 were excluded as representing a failure of the suture technique. In paper III stratification was made into groups with an SL to WL ratio of 4.0–4.9, 5.0–5.9, 6.0–6.9 and 7.0 or higher.

**Cost analysis (Paper IV)**

In September 2011 it was investigated how many of the patients presenting with an incisional hernia after the index operation who, until then, had had a repair.

The economic analysis was considered from a societal perspective including both the direct costs from the perspective of the public payer as well as the indirect costs related to the loss of productivity. All patients having a first-time open midline incisional hernia repair with a mesh during 2010 were identified and costs concerning the repair were based on these patients. Cost driving parameters for the direct and indirect costs were recorded until 12 months after the hernia repair. Costs paid directly by the patient, such as the fee for outpatient visits, the cost for transport and the cost for drugs used at home, were not included in the analysis.

For patients working, it was assumed that the average wage reflected the opportunity cost for loss of productivity. From Statistics Sweden (SCB) the average monthly wage in 2010 was obtained, producing an average daily wage of 1 317 SEK. For retired patients and patients with disability pension the opportunity cost was 29.95 SEK per hour based on the Swedish Road Authority’s calculations.

**Statistics (Papers I-IV)**

IBM SPSS Statistics, version 14, 17 and 18, was used for the statistical analyses. Mean, median and standard deviation were calculated as appropriate. For univariate analysis the Fisher’s exact test, the Mann-Whitney U-test or the Kruskal-Wallis test were used as appropriate. Pearson’s two-tailed analysis was used for correlation analysis. A probability of less than 5% was accepted as significant.

Multivariate analysis was performed with multiple linear logistic regression. Surgical site infection and incisional hernia were considered dependent variables, and all other recorded variables were considered independent. The 95% confidence interval for the variable estimates was calculated. A strategy of backward reduction analysis was applied to remove non-significant interaction terms from the model.
An analysis of power was performed when designing the randomised trial. For a difference of 6% in the rate of wound infection and for a power of 80% (p=0.05), 352 patients were required in each study arm. For a difference of 10% in the rate of incisional herniation, 160 patients were required in each arm.

The health economic analysis was made as a cost analysis. A comprehensive one-way sensitivity analysis of the most important cost driving parameters was undertaken using the upper and lower limits of the 95% confidence intervals.
Results

Wound complications in relation to stitch length (Paper I)

A total of 368 patients were analysed in the non-randomised study. Mean stitch length was 4.9 cm (SD 1.3), range 2.3 to 11.6. Old age and emergency surgery correlated with a short stitch length. High BMI and a high SL to WL ratio correlated with a long stitch length. Patient and operative characteristics were otherwise similar for the three groups. (Table 1)

Table 1. Characteristics related to stitch length

<table>
<thead>
<tr>
<th>Stitch length</th>
<th>n&lt;4 cm</th>
<th>n 4-4.9 cm</th>
<th>n ≥5 cm</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient characteristics</td>
<td>Age, mean (SD), y</td>
<td>65 (13)</td>
<td>62 (15)</td>
<td>56 (18)</td>
</tr>
<tr>
<td></td>
<td>BMI, mean (SD)</td>
<td>23 (4)</td>
<td>26 (5)</td>
<td>27 (6)</td>
</tr>
<tr>
<td>Operative characteristics</td>
<td>Emergency operation, No. (%)</td>
<td>41 (40)</td>
<td>32 (27)</td>
<td>31 (21)</td>
</tr>
<tr>
<td></td>
<td>SL to WL ratio, mean (SD)</td>
<td>4.8 (0.7)</td>
<td>5.0 (0.8)</td>
<td>6.5 (1.7)</td>
</tr>
</tbody>
</table>

§ Kruskal-Wallis test; + Fisher’s exact test

Complete wound dehiscence demanding reoperation occurred in 2 of 368 (0.5%) patients, one patient sutured with a stitch length of less than 4 cm and one sutured with a longer stitch length. The rate of SSI and incisional hernia was increased with a long stitch length. (Table 2)

Table 2. Surgical site infection and incisional hernia related to stitch length

<table>
<thead>
<tr>
<th>Stitch length</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical site infection</td>
<td>4/103 (4%)</td>
</tr>
<tr>
<td>Incisional hernia</td>
<td>2/76 (3%)</td>
</tr>
</tbody>
</table>

Fisher’s exact test
Wound complications in relation to small or large stitches (Paper II)

Of 737 patients entering the randomised trial, 356 were allocated to being sutured with small stitches and 381 to large.

Wound dehiscence occurred in one patient, closed with large stitches. SSI and incisional hernia were less frequent with small stitches than with large. (Table 3)

Patient characteristics were similar between the groups. For the small stitch group, the time spent closing the wound was longer, the stitch length and stitch interval were shorter, and the SL to WL ratio was lower. (Table 4)

### Table 3. Wound complications in relation to the size of stitches

<table>
<thead>
<tr>
<th></th>
<th>Small stitches</th>
<th>Large stitches</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound dehiscence, No. (%) of patients</td>
<td>0/356</td>
<td>1/381 (0.3)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Surgical site infection, No. (%) of patients</td>
<td>17/326 (5.2)</td>
<td>35/343 (10.2)</td>
<td>0.020</td>
</tr>
<tr>
<td>Incisional hernia, No. (%) of patients</td>
<td>14/250 (5.6)</td>
<td>49/272 (18.0)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Fisher’s exact test

### Table 4. Operative characteristics related to the size of stitches

<table>
<thead>
<tr>
<th></th>
<th>Small stitches</th>
<th>Large stitches</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, mean (95% CI), min</td>
<td>135 (128 - 142)</td>
<td>135 (126 - 142)</td>
<td>0.389</td>
</tr>
<tr>
<td>Suturing time, mean (95% CI), min</td>
<td>18 (17 - 19)</td>
<td>14 (13 - 15)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stitch length, mean (95% CI), mm</td>
<td>26 (25 - 26)</td>
<td>44 (42 - 45)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stitch interval, mean (95% CI), mm</td>
<td>4.6 (4.4 - 4.7)</td>
<td>6.9 (6.7 - 7.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SL to WL ratio, mean (95% CI)</td>
<td>5.7 (5.5 - 5.8)</td>
<td>6.4 (6.3 - 6.6)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Mann-Whitney U-test
Risk factors in relation to the size of stitches (Papers I - III)

In the analysis of the non-randomised study overweight was analysed as a risk factor in relation to stitch length. With a stitch length shorter than 4 cm, incisional hernia was present in 1 of 25 (4%) overweight patients and in 1 of 21 (5%) patients without overweight (p=1.000). With a longer stitch length, corresponding figures were 21 of 113 (19%) overweight patients and 4 of 92 (4%) in others (p=0.004).

In the randomised trial an SL to WL ratio of at least 4 was achieves in 691 of 737 patients. With an SL to WL ratio over 4 incisional hernia was present in 56 of 495 (11%) patients and with a lower ratio in 7 of 27 (26%) (p=0.03). With small stitches corresponding figures were 11 of 233 (5%) patients vs. 3 of 17 (18%) (p=0.06). With large stitches corresponding figures were 45 of 262 (17%) patients vs. 4 of 10 (40%) (p=0.08).

Risk factors identified in multivariate analysis are presented in Table 5. In cases of SSI, incisional hernia was present in 1 of 16 (6%) patients with small stitches and in 11 of 27 (41%) with large stitches (p=0.02).

The rate of incisional hernia in 87 patients operated on for AAA was analysed. With small stitches an incisional hernia developed in 3 of 34 (9%) patients with AAA and in other patients in 11 of 216 (5%) (p=0.42). With large stitches 16 of 43 (37%) patients with AAA developed an incisional hernia compared with 33 of 229 (14%) among other patients (p=0.01).

Table 5. Risk factors for surgical site infection and incisional hernia

<table>
<thead>
<tr>
<th>Regression coefficient (SE)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical site infection</strong></td>
<td></td>
</tr>
<tr>
<td>Wound contamination</td>
<td>1.03 (0.48)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.01 (0.38)</td>
</tr>
<tr>
<td>Large stitches</td>
<td>0.77 (0.31)</td>
</tr>
</tbody>
</table>

| **Incisional hernia**       |             |
| Male sex                    | 0.76 (0.34) | 2.14 (1.10 – 4.15) |
| Higher BMI                  | 0.05 (0.02) | 1.05 (1.01 – 1.10) |
| Longer operation time       | 0.005 (0.002) | 1.01 (1.002 – 1.01) |
| Surgical site infection     | 1.16 (0.40) | 3.18 (1.44 – 7.02) |
| SL to WL ratio <4           | 1.32 (0.52) | 3.73 (1.36 – 10.26) |
| Large stitches              | 1.44 (0.34) | 4.24 (2.19 – 8.23) |

Results of logistic regression analysis. All recorded variables were included in the model and removed by a backward reduction strategy if not significant.
When, from the randomised trial, excluding the 46 patients sutured with an SL to WL ratio under 4, 321 patients closed with small stitches and 370 closed with large stitches remained for analysis. For both groups the maximum SL to WL ratio was 12. The median operation time was 122 minutes and patients were stratified in the analysis according to an operation time shorter or longer than 2 hours.

The rate of SSI was similar irrespective of the SL to WL ratio (Table 6). With small stitches, no significant correlation between SSI and registered variables was found. With large stitches, SSI was in univariate analysis more common in overweight patients, in diabetic patients and in contaminated or dirty wounds. (Table 7) With large stitches, the patient being diabetic and wound contamination were in multivariate analysis independent risk factors for the development of SSI (Table 8).

**Table 6. Surgical site infection related to the SL to WL ratio and the size of stitches**

<table>
<thead>
<tr>
<th>SL to WL ratio</th>
<th>Small stitches</th>
<th>Large stitches</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total, No. (%)</td>
<td>15/293 (5.1)</td>
<td>32/332 (9.6)</td>
<td>0.034</td>
</tr>
<tr>
<td>4.0 – 4.9, No. (%)</td>
<td>5/80 (6)</td>
<td>4/46 (9)</td>
<td>0.723</td>
</tr>
<tr>
<td>5.0 – 5.9, No. (%)</td>
<td>4/88 (5)</td>
<td>7/98 (7)</td>
<td>0.543</td>
</tr>
<tr>
<td>6.0 – 6.9, No. (%)</td>
<td>2/65 (3)</td>
<td>6/75 (8)</td>
<td>0.285</td>
</tr>
<tr>
<td>≥ 7.0, No. (%)</td>
<td>4/60 (7)</td>
<td>15/113 (13.3)</td>
<td>0.213</td>
</tr>
</tbody>
</table>

*Fisher’s exact test. No significant difference within columns

**Table 7. Surgical site infection related to registered variables and the size of stitches**

<table>
<thead>
<tr>
<th>Registered variables</th>
<th>Small stitches</th>
<th>Large stitches</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overweight, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>5/128 (3.9)</td>
<td>8/149 (5.4)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10/165 (6.1)</td>
<td>24/183 (13.1)</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>0.439</td>
<td>0.024</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>13/265 (4.9)</td>
<td>25/304 (8.2)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2/28 (7)</td>
<td>7/28 (25)</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>0.643</td>
<td>0.011</td>
<td></td>
</tr>
<tr>
<td>Wound contamination, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean</td>
<td>2/70 (3)</td>
<td>3/77 (4)</td>
<td></td>
</tr>
<tr>
<td>Contaminated</td>
<td>12/199 (6.0)</td>
<td>22/222 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Dirty</td>
<td>1/24 (4)</td>
<td>7/33 (21)</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>0.759</td>
<td>0.020</td>
<td></td>
</tr>
</tbody>
</table>

*Fisher’s exact test*
Table 8. Risk factors for SSI and incisional hernia with large stitches

<table>
<thead>
<tr>
<th></th>
<th>Regression coefficient (SE)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical site infection</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.27 (0.49)</td>
<td>3.55 (1.36 – 9.27)</td>
</tr>
<tr>
<td>Wound contaminated or dirty</td>
<td>0.94 (0.36)</td>
<td>2.57 (1.27 – 5.21)</td>
</tr>
<tr>
<td><strong>Incisional hernia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operation time &gt;2 hours</td>
<td>1.61 (0.47)</td>
<td>5.01 (1.99 – 12.64)</td>
</tr>
<tr>
<td>Surgical site infection</td>
<td>1.14 (0.36)</td>
<td>3.13 (1.55 – 6.34)</td>
</tr>
</tbody>
</table>

Results of logistic regression analysis. All recorded variables were included in the model and removed by a backward reduction strategy if non significant.

The rate of incisional hernia was similar irrespective of the SL to WL ratio (Table 9). With small stitches, no significant correlation between registered variables and incisional hernia was found. With large stitches, incisional hernia was in univariate analysis more common if the operation time was longer than 2 hours and if an SSI had occurred. (Table 10) With large stitches these factors were in multivariate analysis independent risk factors for the development of incisional hernia (Table 8).

Table 9. Incisional hernia related to the SL to WL ratio and the size of stitches

<table>
<thead>
<tr>
<th>SL to WL ratio</th>
<th>Small stitches</th>
<th>Large stitches</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total, No. (%)</td>
<td>11/233 (4.7)</td>
<td>45/262 (17.2)</td>
<td>0.001</td>
</tr>
<tr>
<td>4.0 – 4.9, No. (%)</td>
<td>4/60 (7)</td>
<td>7/30 (23)</td>
<td>0.038</td>
</tr>
<tr>
<td>5.0 – 5.9, No. (%)</td>
<td>3/70 (4)</td>
<td>10/83 (12)</td>
<td>0.144</td>
</tr>
<tr>
<td>6.0 – 6.9, No. (%)</td>
<td>3/56 (5)</td>
<td>9/59 (15)</td>
<td>0.126</td>
</tr>
<tr>
<td>≥ 7.0, No. (%)</td>
<td>1/47 (2)</td>
<td>19/90 (21)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Fisher’s exact test. No significant difference within columns.
Table 10. Incisional hernia related to registered variables and the size of stitches

<table>
<thead>
<tr>
<th></th>
<th>Small stitches</th>
<th>Large stitches</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2 hours</td>
<td>7/179 (3.9)</td>
<td>26/197 (13.2)</td>
<td>0.285</td>
</tr>
<tr>
<td>&gt;2 hours</td>
<td>4/54 (7)</td>
<td>19/65 (29)</td>
<td>0.004</td>
</tr>
<tr>
<td><strong>p</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical site infection, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>10/219 (4.6)</td>
<td>35/238 (14.7)</td>
<td>0.502</td>
</tr>
<tr>
<td>Yes</td>
<td>1/14 (7)</td>
<td>10/24 (42)</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>p</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fisher’s exact test

Cost savings (Paper IV)

Suturing time was longer with small stitches, but the operation time was similar. Wound length was 1.3 centimetres shorter in the group closed with small stitches than in the group closed with large stitches. Time spent for placing one stitch was similar between groups. More stitches were placed per centimetre of wound with small stitches. (Table 11)

Table 11. Operative characteristics at the index operation

<table>
<thead>
<tr>
<th></th>
<th>Small stitches</th>
<th>Large stitches</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (95% CI), min</td>
<td>135 (128 - 142)</td>
<td>136 (128 - 144)</td>
<td>0.411</td>
</tr>
<tr>
<td>Suturing time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (95% CI), min</td>
<td>18.6 (17.7 - 19.4)</td>
<td>14.0 (13.2 - 14.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Wound length,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (95% CI), cm</td>
<td>23.1 (22.6 - 23.7)</td>
<td>24.4 (23.8 - 25.0)</td>
<td>0.007</td>
</tr>
<tr>
<td>Time per stitch,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (95% CI), min</td>
<td>0.35 (0.34 - 0.36)</td>
<td>0.37 (0.36 - 0.39)</td>
<td>0.103</td>
</tr>
<tr>
<td>Stitch per cm,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (95% CI), No.</td>
<td>2.35 (2.27 - 2.40)</td>
<td>1.55 (1.50 - 1.59)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Mann-Whitney U-test
During 2010, 18 patients were identified having a first-time open midline incisional hernia repair. The total direct cost per incisional hernia repair was 59 909 SEK (Table 12). The total indirect cost per incisional hernia repair was 26 348 SEK (Table 13). Thus, the total cost per incisional hernia repair was 86 257 SEK from a societal perspective.

<table>
<thead>
<tr>
<th>Table 12. Direct costs per incisional hernia repair</th>
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</thead>
<tbody>
<tr>
<td><strong>Cost item</strong></td>
</tr>
<tr>
<td>Preoperative visit, outpatient clinic, No.</td>
</tr>
<tr>
<td>Hospitalisation for hernia repair</td>
</tr>
<tr>
<td>Surgical ward, days</td>
</tr>
<tr>
<td>Anaesthesia, min</td>
</tr>
<tr>
<td>Operation time, min</td>
</tr>
<tr>
<td>Mesh, No. per patient</td>
</tr>
<tr>
<td>Reoperation, No. per patient</td>
</tr>
<tr>
<td>Rehospitalisation without reoperation, No. per patient</td>
</tr>
<tr>
<td>Postoperative visit, outpatient clinic or emergency unit, No.</td>
</tr>
<tr>
<td>Total direct cost per incisional hernia repair</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 13. Indirect costs per incisional hernia repair</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unit cost per day</strong></td>
</tr>
<tr>
<td>Working patients, days</td>
</tr>
<tr>
<td>Retired patients, 4 hours per day, days</td>
</tr>
<tr>
<td>Total indirect cost per incisional hernia repair taking the proportion of working and retired patients into account</td>
</tr>
</tbody>
</table>
As suturing with small stitches took 4.6 minutes longer than suturing with large stitches the cost for the index operation was increased by 1 076 SEK (4.6 x (206+28)).

Of the 56 patients that presented with a hernia after the index operation 17 (30%) had an incisional hernia repair until September 2011, 3 of 11 patients (27%) sutured with small stitches and 14 of 45 patients (31%) sutured with large stitches (p=1.0).

The absolute risk of requiring an incisional hernia repair was reduced by 2.8% (14/370 – 3/321) with the use of small stitches. Thus, for each patient with a midline incision closed with small stitches, the cost for incisional hernia repair was reduced by 2 415 SEK (2.8% x 86 257) from a societal perspective. The direct cost was reduced by 1 677 SEK (2.8% x 59 909) when small stitches were used.

Taking the cost for the increased suturing time into account, the use of small stitches instead of large stitches generated a cost reduction of 1 339 SEK (2 415 - 1 076) for each patient from the societal perspective. From the perspective of the public payer a cost reduction of 601 SEK (1 677 – 1 076) was generated.

A threshold analysis from the societal perspective, dividing the cost reduction of 2415 SEK with the cost for each minute of surgery (234 SEK), indicated that an intervention that decreases the risk of requiring a hernia repair by 2.8% generates savings from a societal perspective if it does not prolong the operation time more than 10.3 minutes.

In the one way sensitivity analysis the variability concerning the length of sick leave for working patients showed the strongest effect on total costs, but even with the lower 95% CI for this variable the use of small stitches generated cost savings.
General discussion

The present clinical studies were motivated by a couple of experimental findings. Firstly it had been found that a stronger wound was produced when closure was done with small stitches compared with large stitches. Secondly an experimental model illustrated why large stitches may be associated with a higher rate of both SSI and incisional hernia.

An analysis was performed of a clinical patient material previously analysed. At that time knowledge indicating that very small stitches could be advantageous was lacking, so the author had only studied stitches longer or shorter than 5 cm and the correlation between very short stitches and wound complications was therefore overlooked. The lowest frequency of both SSI and incisional hernia was now found with the shortest stitch length of under 4 cm.

The clinical study had been designed to study the effect of the SL to WL ratio on the development of incisional hernia. A strong correlation had been found and incisional hernia was four times more frequent if the ratio was under 4. The stitch length had been measured and it was evident that surgeons had accomplished a high ratio with a stitch size over a very wide range.

The findings in the clinical study supported the experimental results and the next logical step was therefore to perform a prospective controlled randomised trial to compare the use of small and large stitches. The size of the stitches was standardised and the effect on wound complications was studied. The rate of both SSI and incisional hernia was then found to be lower with small stitches. Wound dehiscence was very rare and was not encountered with small stitches. The rate of herniation was low with small stitches even if an SSI occurred, so small stitches were obviously safe even when wound healing was hampered.

The clinical results with a lower rate of SSI were in congruence with the theoretical model of a smaller amount of devitalised soft tissue in the wound and hence a smaller nidus for infection with small stitches. The clinical results of a lower rate of herniation were in congruence with the experimental findings of a stronger wound with small stitches and a reduced risk for the suture slackening due to compression of soft tissue allowing wound edges to become separated.

Suturing with small stitches prolonged suturing time and the cost for the operation, but the cost analysis showed that the total costs were reduced from both the societal perspective and the perspective of the public payer.
In the USA about US $1 billion is annually spent on repairing incisional hernias. Considering these immense national costs it is fascinating to consider the magnitude of possible cost savings that might be achieved with a simple change in suture technique to the use of small stitches.

A way to ensure that small stitches were not placed more than 5 to 8 mm from the wound edge was sought and it was realised that with a very small needle surgeons were forced to suture with small stitches. This guaranteed the separation of the two arms of the study. The only available 150 cm long polydioxanone suture mounted on a sufficiently small needle was in size USP 2-0. Theoretically this suture size is strong enough for closing midline incisions and it had been used for this purpose previously.

Initially there was some reluctance among the surgeons towards suturing with such small stitches, such a small needle and such a thin suture. The fact that it does take longer time to accomplish an SL to WL ratio over 4 with small stitches, as the number of stitches must be increased, was also seen as negative. During the study this reluctance changed and the novel suture technique was well accepted.

The effect on the rate of wound complications of a very high SL to WL ratio, overweight and other potential risk factors when closure is done with small or large stitches had not been previously studied in a randomised trial. In the present study no correlation could be detected between a very high SL to WL ratio and wound complications. With small stitches no risk factors for SSI and incisional hernia could be identified at all but with large stitches several risk factors were identified.

A small group of patients had their wounds closed with an SL to WL ratio under 4 and a significantly higher rate of incisional hernia was detected among these patients compared with those sutured with a higher ratio. Thus, this is the second large clinical study that has identified the importance of closing midline incisions with an SL to WL ratio over 4. A third recent large study has also confirmed this.

SSI has in many reports been a risk factor for incisional hernia. Analysing all the patients in the randomised study, SSI was an independent risk factor for incisional hernia. When stratifying according to the size of stitches, SSI was identified as a risk factor for incisional hernia only with large stitches. In previous reports a higher rate of both SSI and incisional hernia in patients with an SL to WL ratio over 5 had been indicated. The analysis was however obscured, by surgeons using a mixture of stitch sizes. Wounds were in overweight patients and in patients with an SL to WL ratio over 5 closed with larger stitches than in other patients and therefore the large stitches rather than the overweight or the high ratio per se might have been the actual risk factor. This was confirmed in the present studies as infection was similar in
overweight patients and in others when closure was made with small stitches. Also, when the size of the stitches was accounted for, a high SL to WL ratio did not affect the rate of wound complications. This knowledge is important as when accomplishing a ratio over 4, no attention has to be paid to avoid a very high ratio. These findings illustrate the complex situation when analysing possible risk factors for the development of wound complications. The relevant factors of the suture technique must also be included in the analysis and if they are not, there is a definite risk of inappropriate conclusions. With factors of suture technique registered there is still a risk of not having recorded all the relevant factors.

A greater risk for incisional hernia has been reported in patients after surgery due to AAA through a midline incision. In the present study these patients did not have a higher rate of incisional hernia than others when wounds were closed with small stitches.

Future perspectives

With the use of small stitches the rate of SSI and incisional hernia was about 5%. Detecting any further significant reduction of wound complications demands a very large patient material. The vast number of patients that such a study requires makes it difficult to achieve within a reasonable time at a single centre and hard to standardise in a multicentre setting. Future studies with the present design with the aim of identifying further aspects of the suture technique that reduce the rate of wound complications are therefore unlikely to be performed. In Sweden an abdominal wall hernia register is now being started and a possible way of attaining more information about factors influencing the risk of incisional hernia would be to register the type of incision and the suture technique used for closure at the index operation. This might also be a way of achieving the desired change in suture technique.

It might be difficult to find alterations in the suture technique that would reduce the low rate of incisional hernia achieved with small stitches and an SL to WL ratio over 4. It might be possible to invent other ways of closing the abdomen. Current stapling devices most certainly cannot produce better results since the tension is then impossible to control. Other devices without sutures such as for example multiple barbs attaching to a large area of the aponeurosis without impairing vascularisation, might be possible to develop.

If, even with the use of small stitches, groups with an increased risk of incisional hernia could be identified a strategy for counteracting this should be sought. Probably, the most logical way is to evaluate the effect of a prophylactic mesh. Such attempts have been made in patients with AAA and in obese patients. It is then important to be certain that the risk
factor considered is a true risk factor and not the result of an inadequate suture technique. A prophylactic mesh cannot be considered a way to compensate for an improper suture technique.

The recommendation of placing stitches at least 10 mm from the wound edge was based on experimental studies finding a weakening of the aponeurosis within this distance from the wound edge during the inflammatory phase of wound healing. No clinical consequence of a weakening of the aponeurosis close to the wound edge could be detected in the present clinical setting. Experimental studies should be performed to assess if the previous experimental findings were more a result of the pressure exerted by the sutures than by the incision per se. It is not known whether this zone of inflammation is an invariable result of incising the aponeurosis or if it is also a result of placing sutures into the tissues. Compression of tissue is one of the factors well known to cause an inflammatory response.

Another experimental approach might be to study if the larger number of stitches placed in the wound with small stitches is actually what is needed to counteract the effect of a weakened wound. With every stitch added to the suture line the tension on each individual stitch is decreased. The risk of the suture holding capacity of a weakened tissue to be exceeded might thus be lower with more stitches placed in the wound.

Laparoscopy is increasingly performed in major abdominal surgery and inflicts less injury to the abdominal wall and subsequently possibly a lower rate of complications such as incisional hernia. However one must consider that there is a risk for port site hernias and that at present our knowledge concerning its extent is limited. Laparoscopic surgery sometimes includes hand-assisted procedures and hence a short midline incision may also be performed. Further studies are necessary to establish the actual rate of abdominal wall complications with these techniques.
Implementation

A single centre randomised trial was conducted with more than 30 junior and senior surgeons involved. After closing the randomised trial the small stitch technique is now used routinely at the department. Other centres are starting to use the technique. It is essential to study what happens when the technique is more widely exercised and a multicentre trial with an almost identical design as the present trial, including at least 12 centres in the Netherlands, is currently being conducted.\(^5\)

To measure the SL to WL ratio at every operation is an easy way to assure a sufficient quality of the suture technique. The ratio is of huge importance for the subsequent rate of postoperative complications. The studies showing the importance of a high SL to WL ratio are well known and are well accepted internationally. Despite this, in surprisingly many reports of clinical trials and studies concerning wound complications in midline incisions the ratio is not presented. It is often mentioned that the principles of upholding a SL to WL ratio of more than 4 were adhered to but generally no information on the actual ratio is presented. There is of course no way to ascertain that an adequate ratio has been achieved except by measuring and documenting it.

To the significance of a high SL to WL ratio must now be added the importance of closing wounds with small stitches. Thus, methods must be found to implement an adequate suture technique regarding both these factors. To achieve this it is probably wise to focus on surgeons in training and teach them a proper technique during the early part of their education. In Sweden the English Basic Surgical Skills Course has been adopted and slightly modified to be in congruence with Swedish conditions. During this mandatory course all Swedish residents in surgery are taught the principles outlined in this thesis.

The SL to WL ratio must be measured and the change in technique should be related to this measurement. Changing the technique into using small stitches is probably an easier task than implementing the ratio. It may be achieved by simply providing surgeons with a suture mounted on a small needle, as in the present studies, since this actually leads to closures being accomplished with small stitches.

Cost savings are generated and patient suffering is reduced if the basic principles of suturing with small stitches and an SL to WL ratio over 4 are followed. Suturing with small stitches and a high ratio can easily be achieved by individual surgeons but the choice to do so cannot be left to each individual. An effective implementation is probably only possible if professionals in charge on a local, or even on a national level, direct this change.
Conclusions

It is concluded that concerning midline abdominal incisions closed with a continuous single-layer technique

the rate of surgical site infection and incisional hernia is lower with small stitches compared with large stitches.

the rate of incisional hernia is lower with a suture length to wound length ratio over 4.

increasing the suture length to wound length ratio very much above 4 does not affect the rate of surgical site infection and incisional hernia.

no risk factors for the development of surgical site infection and incisional hernia can be identified when small stitches are used.

cost savings are generated when small stitches are used

The previous recommendation to use large stitches should be changed to recommend small stitches.
Acknowledgements

I would like to express my sincere gratitude and appreciation to all those who have supported, encouraged and helped me during my work completing this thesis. In particular I wish to thank:

Leif Israelsson, my tutor in science, my tutor in surgery, my boss and my good friend. Thank you for all your patience. The work with this thesis has now lasted for more than 10 years and while I know, that now and then, it has been hard for you waiting, finally we are here. Thank you for letting me become part of your lifetime achievement and for introducing me to the world of both surgery and science with your sharp brain, outstanding knowledge, enthusiasm and special sense of humour.

Yucel Cengiz, my co-author, colleague and good friend, for always supporting and encouraging me. Anders Wimo, my co-author, for help and assistance concerning health economics.

Peter Naredi, Professor at the Department of Surgical and Perioperative Sciences for providing the possibility for this thesis to be done.

Arthur Jänes, my colleague, research buddy and close friend. You know what it is all about and you chose, as always, the fastest lane, ending up with your Ph.D. way ahead of me. Thank you for your support, your friendship and your open home.

All present and former colleagues, friends and staff at the Department of Surgery, especially Jan-Olov Svensson, former head of the department, for accepting me as a resident and Jan Norgren for being the wise man in clinical matters. Thank you all for help including patients, for enduring endless counting of stitches and for allowing me to combine scientific and clinical work. I will be back!

Staff at the Unit for Research and Development for support and fruitful dialogue concerning research. Special thanks to Erling Englund for statistical advice and Jeanette Sundberg for practical help.

Anna-Maria Lundgren for being my extended arm at Umeå University.

Tom Halliday for careful linguistic revision.
Elisabeth Viklund, “my” nurse at the outpatient clinic, for help getting all the patients to their control visits, for your service and cooperation during all these years. I will never forget when you taught me how to put interrupted sutures in a skin wound. Thanks!

Märth-Marie Berglund for being the spider in the web solving practical problems and Ann-Christine Lindström for support during my first trembling days as a young resident running a large trial at the operating theaters.

Martin Odmark and Annie Aspvik for being such close friends to me and my family, for sharing both grey days and party days.

Andreas Thorstenson, Jonas Karlberg, Jonas Moström and all other friends from medical school at Uppsala University. We had a marvellous time there. Uppsala University, I would have loved to hear your salute...

All other friends throughout life. You have helped form me and your friendship is worth a very lot to me.

Helena Hedström my sister in-law, your dissertation inspired me to gather force enough to reach the same goal. Thanks for your advice!

Nils and Birgit Pälsson, my parents-in-law. What can I say? Thank you for invaluable support and for the care of our family and especially our children. I don’t think we could have managed this without you.

Claes and Ann-Katrin, my dear parents, Charlotta, Martin and Hanna Millbourn, my brother and sisters and Sigrid Nilsson, my adorable grandmother, for your love and support in life. I would have loved to have you closer to be able to see you more often.

Anna, my beloved wife and closest friend. Thank you for just being who you are and for giving me your time. You are amazing!

Gustav, Emma and Linnea, my wonderful children. You make me so happy and proud. All I ever want to do is to spend time with you. You are endlessly loved!

This thesis was supported by grants from the Unit for Research and Development, County Council of Västernorrland, The SJCKMS Foundation, Umeå University and Ture Stenholm’s fund for surgical research, Norrlands nation, Uppsala University.
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