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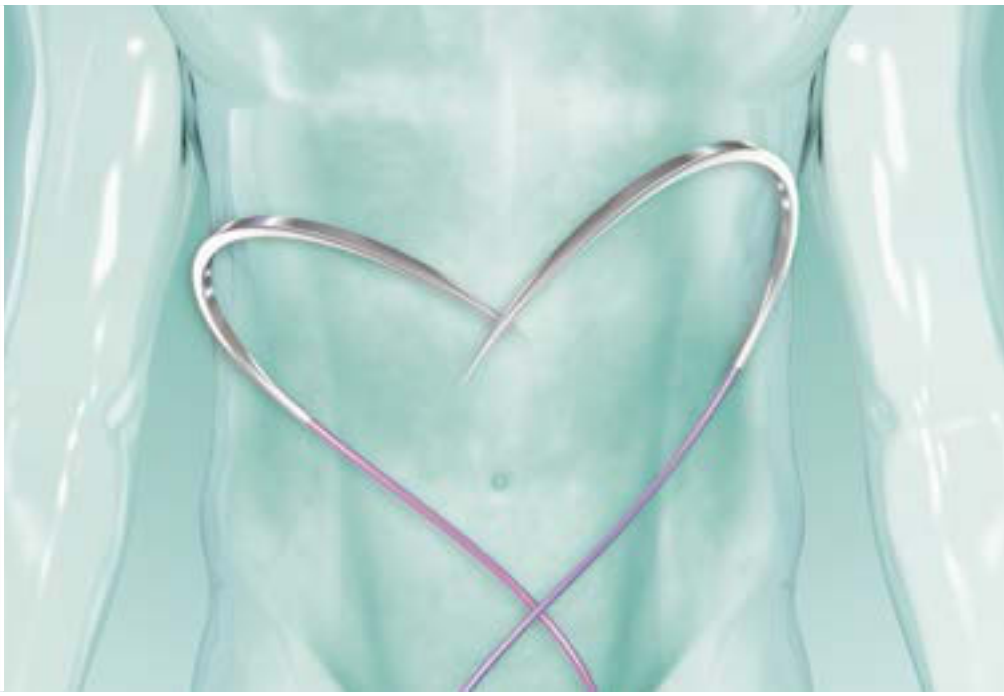
Abdominal Wall Closure



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Abdominal Wall Closure

Rationale

Median laparotomy is a standard technique of gaining access to the abdominal cavity and requires an adequate closure of the abdominal wall. A great number of different suture materials and techniques are used for the reconstruction of the abdominal wall integrity, but the ideal suture material and the best technique for closing the abdominal fascia has yet not been determined. This lack of a widely accepted surgical standard for abdominal wall closure (AWC) leads to an incidence of abdominal wall hernia up to 20 % (range 9 to 20 %).[1-3] Whereby, incisional hernias often require repair, with postoperative recurrence rates as high as 45 %, further contributing to additional complications.[4] Furthermore, burst abdomen is observed in 1-3 % of the patients within the first days after laparotomy.[5-8]

There are several potential risk factors which may have an influence on the occurrence of incisional hernias, like wound healing disorders, wound infections, obesity, chronic bronchitis or diabetes mellitus.[9-11] However, wound infections remain the most significant early postoperative complication because they develop in 3-21 % of patients undergoing median laparotomy, within the first 30 days postoperative depending on the type of surgery performed.[12-19] Therefore, prevention of wound healing complications would reduce the incidence of dehiscence and herniation in abdominal wounds substantially.
At present most surgeons favour a monofilament non-absorbable or a slowly absorbable suture as the most suitable suture material for closing abdominal wounds after midline laparotomy. There are several studies which showed that slowly absorbable monofilament sutures are the best choice for fascial closure in a running suture technique.[20,21]

Several synthetic absorbable suture materials with different absorption profile and tensile strength have been developed in the past. Most of these commercially available suture materials are absorbed within 70 to 180 days in the body, but these suture materials also loose 50 % of their tensile strength during the first 14 to 30 days.[22] However, investigations showed that the abdominal fascia regain only 70 % of its original strength within one year after a primary median laparotomy.[23] Therefore, the absorption profile of current available suture material might be too fast and prolonged suture support would be necessary for adequate closure of the abdominal wall.[23,24]

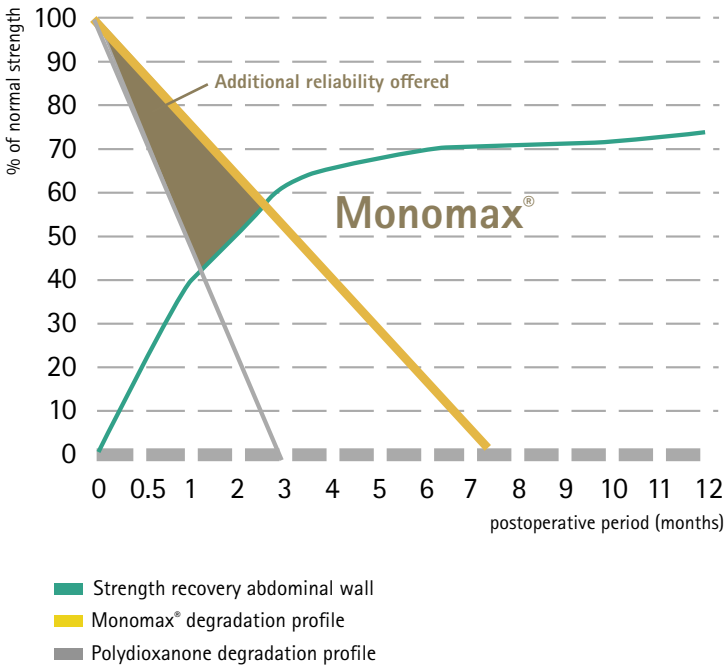
Rationale

An ultra-long term absorbable, flexible, monofilament suture might help to reduce the complications which often occur after median laparotomy. According to its smoothness, the monofilament might reduce bacterial adherence leading to wound infections in comparison to rough multi filament sutures.[25] Furthermore, a high elasticity and flexibility might support the mechanics of the abdominal wall and can reduce the risk of tear of the suture from the tissue.[26,24] Due to its ultra-long absorption profile and its high tensile strength this kind of suture material would give the fascia more time to heal and to regain a higher strength which might reduce the rate of incisional hernia compared to other commercially available long-term absorbable suture materials.[26]

Therefore, a new ultra-long term absorbable monofilament suture material with high flexibility and elasticity was developed by B. Braun. Monomax® is an ultra-long lasting, absorbable, flexible monofilament with superior initial strength, with a predictable and constant degradation rate. It consists of the bioabsorbable polymer poly-4-hydroxybutyrate and its degradation products are less acidic but already present in humans as metabolites. Monomax® shows superiority in knot and linear tensile strength retention compared to other long-term absorbable suture materials, meaning that Monomax® is well suitable for abdominal wall closure given extra stability because of its long lasting strength retention. An animal study in which the abdominal wall was closed using USP 1 sutures showed that the handling and suturing properties of Monomax® were rated as equal or better compared to a long-term absorbable control suture material. Summarizing the histological, biomechanical and wound healing analysis of the mentioned animal study, the study proved that Monomax® suture material is at least as safe as a long-term absorbable suture which is commonly used for abdominal closure. All toxicological and biological measures indicated an excellent biocompatibility and functionality for this suture. Therefore, the properties of Monomax® favour especially the application of Monomax® for abdominal wall closure after midline laparotomy due to its long lasting strength, its flexibility and elasticity. A clinical multicentre study was performed to show the safety and efficacy of Monomax® for abdominal closure after a primary median laparotomy.[27,28]

Monomax® is a violet, ethylene oxide sterilized suture which fulfils all requirements of the European and US Pharmacopoeia as well as the Medical Device Directive 93/42 and current GMP guidelines. It is available in the USP sizes USP 1, USP 0 and USP 2/0. Monomax® looses 50 % of its tensile strength retention after 90 days and after 180 days the total tensile strength retention has gone. The total mass absorption is completed approximately 13 months after implantation.

Figure 1: Abdominal wall strength recovery versus Monomax® and Polydioxanone suture material degradation profile.



Clinical Evidence

Abdominal wall closure (AWC)

Various randomized studies have evaluated techniques and suture materials for abdominal fascia closure but controversy remains, leaving surgeons uncertain about the ideal method to close abdominal wounds and therefore, optimally preventing incisional hernias. Selecting an appropriate suture material may lessen postoperative complications such as incisional hernia or burst abdomen, after median laparotomy. This folder summarizes the current actual clinical data.

1.1 Systematic Review & Meta-Analysis (SR & MA) comparing different suture techniques and suture materials

INLINE is the most recent systematic review (2010) with meta-analysis identifying the best choice of suture technique and suture material for elective midline laparotomy closure in regard to incisional hernia rate **(Diener et al.[20])**
In total, 5 systematic reviews and 14 trials including 7711 patients were analysed. Here, different suture techniques (continuous versus interrupted) and different suture materials (rapidly vs slowly versus non absorbable) with a follow-up of at least 12 months were compared. Further parameters such as wound dehiscence, suture sinus, wound infection and wound pain were analysed.

INLINE found a significantly lower hernia rate following elective abdominal closure using a running suture technique rather than interrupted suture (8.4 % vs 12.6 %). Furthermore, slowly absorbable suture materials produced significantly fewer hernias than rapidly absorbable sutures (8.1 % vs 10.8 %). In contrast to previous meta-analyses the INLINE paper found absorbable suture materials to be superior to non-absorbable sutures regarding the rate of incisional hernias (6.1 % vs 26.3 %) with slowly absorbable sutures producing significantly less hernias than rapidly absorbable sutures. In respect to the secondary outcome the following data were found:
Wound dehiscence and wound infection did not show a significant difference between continuous and interrupted sutures. However, the interrupted technique was superior to the continuous suture technique in regard to wound pain and suture sinus. A significantly lower rate of suture sinus was found for absorbable suture in comparison to non-absorbable sutures. No difference between these suture materials was observed in wound dehiscence, wound pain and wound infection. The analysis of slowly versus rapidly

absorbable suture material showed significantly higher rates in wound dehiscence, suture sinus, and wound infection in the slowly absorbable group. The authors concluded that no further trials should be conducted for the evaluation of the technique for elective midline fascia closure. The closure of the abdominal wall during emergency settings as well as the treatment of high risk patients should be the aim of further clinical studies.

The meta-analysis of **van`t Riet et al. 2003**[29] showed that slowly absorbable continuous sutures appear to be the optimal method of fascia closure to reduce the incidence of incisional hernias without increasing wound pain or suture sinus frequency. All trials with a follow-up of at least one year that randomized patients with midline laparotomy to close the abdominal fascia by different suture techniques and suture materials were subjected to meta-analysis. Primary objective was the formation of incisional hernias, secondary objectives were wound dehiscence, wound infections, wound pain and suture sinus formation. Abdominal wall closure by using continuous rapidly absorbable suture was followed by a significant higher incidence of incisional hernias than closure by continuous slowly absorbable sutures or non-absorbable suture material. No difference in incisional hernia incidence was found between slowly absorbable and non-absorbable sutures, but more wound pain and more suture sinuses occurred after the use of non-absorbable suture material. The authors suggest, that the ideal suture technique to reduce the incisional hernia rate appears to be mass closure using a continuous suture, with an adequate suture length to wound length ratio of at least 4:1. The suture material should be slowly absorbable.

Rucinski et al.[30] reported no significant difference in relation to the outcome features of dehiscence and infection when absorbable suture material was compared with non-absorbable material. Furthermore, in regard to the probability of hernia formation no difference was seen when monofilament absorbable material was compared with non-absorbable material. However, a higher incidence was demonstrated when braided absorbable suture was used. They also reported a higher incidence for incision pain and suture sinus formation when non-absorbable suture was used. In accordance to the meta-analysis of van`t Riet, this meta-analysis published by Rucinski et al.[30] also concludes that an absorbable monofilament suture material is superior to non absorbable suture for abdominal closure and that a mass closure is the optimal technique for fascial closure after laparotomy.

In contrast to van´t Riet[29] and Rucinski[30], **Hodgson et al.**[31] showed in their meta-analysis a significant lower occurrence of incisional hernias when non-absorbable suture were used. In agreement with the other two meta-analysis, Hodgson et al. also point out that suture sinuses und wound pain was lower when absorbable sutures were used. They also could not find any difference in the incidence of wound dehiscence and wound infections with respect to the suture material. Subgroup analysis indicated no difference in relation to incisional hernia between polydioxanone and polypropylene, but polyglactin showed an increased wound failure rate. The authors postulate that the ideal suture is-non absorbable and the ideal technique is continuous for reducing the rate of incisional hernias.

The meta-analysis of **Weiland et al.**[32] was done to choose the best abdominal closure. In this review different suture techniques such as continuous versus interrupted and non absorbable suture versus absorbable suture material were compared in relation to infection, incisional hernia formation and dehiscence. The authors conclude that continuous closure with non-absorbable suture should be used to close abdominal wounds. However, if infection is expected interrupted sutures are preferred. Mass closure was superior to layered closure. This meta-analysis by Weiland is discussed controversely, because it failed to comply with most of the methodological requirements supported by a recent consensus. The search strategy was less than explicit, non-randomised trials and poor-quality studies were included in this study, decreasing the validity of their results. The quality of the randomised controlled trials included in this analysis was not assessed. Interpretation of the results is difficult because individual study characteristics were not described.

Clinical Evidence

INSECT Trial

The three armed, multi-centre, intra-operatively randomised, controlled patient blinded trial (INSECT) evaluated different techniques to close the abdominal wall.[33,34] In total 625 patients were enrolled in this study who were planned for an elective primary median laparotomy. The aim of the INSECT trial was to compare the frequency of incisional hernias one year postoperatively, between two continuous suture techniques with different slowly absorbable monofilaments (MonoPlus® and PDS®) and an interrupted suture technique using an absorbable, braided suture material (Vicryl®). The aim of the trial was to answer the question if the continuous abdominal wall closure with a slowly absorbable material is superior to the interrupted suture technique with a braided, fast absorbing thread. All participating centres were trained. Primary endpoint was the frequency of incisional hernias within 1 year after surgery diagnosed by clinical examination and confirmed by ultrasound. For the INSECT trial an incisional hernia rate of 13 % was expected for the interrupted group and 4 % for the continuous groups. Complications and safety parameters were used as secondary parameters.

The abdominal wall of 210 patients was closed with interrupted Vicryl®, 205 patients received continuous PDS® and in 210 patients the closure of the abdominal wall was performed using continuous MonoPlus® suture material **(Seiler et al.[21])**. The primary analysis showed an incidence of incisional hernia of 15.9 % in the Vicryl® group, 8.4 % in the PDS® group and 12.5 % in the MonoPlus® group. Furthermore, no significant difference was seen in the three groups in respect to burst abdomen (2 % Vicryl® 3 % PDS®, 4 % MonoPlus®), wound infection (12.7 % Vicryl®, 19.4 % PDS®, and 16.3 % MonoPlus®), pulmonary infections (4.4 % Vicryl®, 2.5 % PDS®, 2.5 % MonoPlus®) and 1 year mortality (7.9 % Vicryl®, 5.5 % PDS®, 7.9 % MonoPlus®). The length of the incision did not differ within the three groups, but the time for abdominal wall closure was significantly shorter in the continuous suture groups compared to the interrupted group. There was no correlation between the wound infection rate and the rate of incisional hernia; however, a higher wound infection rate as expected was observed in the study. The only parameter which correlates with the risk for the development of an incisional hernia was a BMI ≥ 27 kg/m^2. Burst abdomen did not occur more frequently in the centres with more than 12 % incidence of incisional hernias compared to those with less or equal than 12 %.

INSECT failed to demonstrate any significant reduction of incisional hernia within one year when the abdominal wall was closed with continuous slowly absorbable monofilament suture material compared to an interrupted rapidly absorbable braided suture material. But the inclusion of the INSECT data to pre-existing meta-analysis leads to the finding that a running suture technique significantly reduces the rate of incisional hernias following elective abdominal wall closure in comparison to the interrupted technique. It was also found that slowly absorbable suture materials produced significantly fewer hernias than fast absorbable suture.[20]

Conclusion:
A slowly absorbable suture material in the continuous suture technique should be used for midline closure after elective median laparotomy to decrease common surgical complication.

Table 1: Meta-Analysis comparing different suture techniques and suture materials

Author	Year	Number of patients	Comparison	Incisional hernia	Follow-up
Diener et al.	2010	N = 7711	Continuous vs Interrupted Absorbable vs Non-absorbable	C < I; p = 0.001 A < N; p = 0.02	1 year
van´t Riet et al.	2002	N = 5638	Continuous vs Interrupted Absorbable vs Non-absorbable	C + N < C + RA; p = 0.001 C + SA < C + RA; p < 0.009	1 year
Rucinski et al.	2007	N = 5851	Absorbable vs Non-absorbable	N < A; p < 0.0001	NR
Hodgson et al.	2000	N = 5145	Absorbable vs Non-absorbable	N < A	NR
Weiland et al.	1998	N = 12249	Continuous vs Interrupted Absorbable vs Non-absorbable	no sign. difference	NR

C: continuous, I: interrupted, A: absorbable, N: non-absorbable,
RA: rapidly absorbable, SA: slowly absorbable, <: superior, NR: not reported.

1.2 Transverse versus midline incision for abdominal wall closure

There are two possibilities to enter the abdominal cavity for major open elective surgery: the midline and the transverse approach. But there is no consensus regarding the strategy for closure of the abdominal fascia after midline and transverse incisions. Several clinical studies have been performed to determine which incision might be the best for elective abdominal surgery.[35-39] In addition, a Cochrane review indicated that transverse incisions lead to a lower pain rate and a lower frequency of pulmonary complications than the midline incision but failed to demonstrate clear advantage for the reduction of incisional hernias.[40]

POVATI Trial (ISRCTN60734227)

The aim of the POVATI trial conducted by Seiler et al.[35] was to analyse the outcome of the midline incision versus transverse incision for elective laparotomy in terms of postoperative pain, complications and incisional hernia rate.
The authors performed a randomized, patient and observer blinded, equivalence study in one centre in Germany. The primary end-point was the consumption of analgesia 24 hours after surgery and pain by using the Visual Analogue Scale (VAS). Secondary parameters were the complication rates in the short term and long term follow-up. In total, 200 patients were enrolled in the study. The midline incision group contain 101 patients and 99 patients were randomized to the transverse incision group. No difference was seen in the consumption of analgesia and the pain rate in both treatment groups. Also the mortality rate after

Clinical Evidence

30 days and 1 year postoperatively was similar with both incision types; p = 0.99. Furthermore, no significant difference was observed in regard to the length of hospital stay and the incisional hernia rate. More wound infections occurred in the transverse group (13 vs 8, p = 0.48).

Halm et al.[36] analysed, if the transverse incision might be an alternative to a midline incision in regard to incisional hernia rate, surgical site infections postoperative pain and hospital stay after cholecystectomy. Primary endpoint of the study was the incisional hernia rate 1 year postoperatively and secondary endpoints included the documentation of pain and the cosmetic result.
In total 150 female patients were randomly allocated to transverse (N = 75) or midline incision (N = 75). In both treatment arms a fast absorbable suture material was used in the interrupted suture technique to close the fascia. In total 60 patients in the midline group and 63 patients in the transverse group completed their 1 year follow-up. Significantly more patients in the midline group reported pain until three days postoperatively (p < 0.0001) but the use of analgesia was similar in both treatment groups. The cosmetic result was rated significantly better in the transverse group compared the midline group; p < 0.0001. Postoperative complication rate was comparable in both treatment arms, p = 0.30 and also the length of hospital stay was similar; p = 0.70. Only one incisional hernia was observed in the patients undergoing a transverse incision (1.7 %) in contrast, nine hernias were detected in the midline group (14.5 %) which was found significant; p = 0.017. No correlation was seen between the incisional hernia rate and the incidence of surgical site infection; p = 0.07. The study indicates that a transverse incision should be considered as the preferred incision in acute and elective surgery of the upper abdomen in which laparoscopic surgery is not an option.

Table 2: Studies comparing midline versus transverse incision

Author	Year	Incision number of patients	Incisional hernia	Wound infection	Pain	Follow-up
Seiler et al.	2009	Transverse: 99 Midline: 101	8 % 12.8 %	15 % 4.9 %	T = M	1 year
Halm et al.	2009	Transverse: 75 Midline: 75	1.7 % 14.5 %	4 % 9 %	T < M	1 year
Proske et al.	2005	Transverse: 47 Midline: 47	NR	T = M	T < M	2 years
Inaba et al.	2004	Transverse: 137 Midline: 139	NR	NR	T < M	
Brown et al.	2005	Total: 3464	T = M	T = M	T < M	

T: transverse, M: midline, =: comparable, >: higher, <: lower, NR: not reported

1.3 Ultra-long absorbable versus long term absorbable suture material for abdominal wall closure

The aim of the **ISSAAC Trial**[27,28] was to investigate the safety and efficacy of Monomax® suture material for abdominal wall closure after median laparotomy. The study was conducted as a historically controlled, multi-centre trial analysing the effect of an ultra-long absorbable, flexible, monofilament suture in regard to burst abdomen, wound infection and incisional hernias compared to common long-absorbable, non-flexible, monofilaments of polydioxanone. Four centres located in Germany recruited 150 patients undergoing an elective median laparotomy. These four centres have also participated in the INSECT trial. Therefore, the patients receiving MonoPlus® or PDS® for abdominal wall closure in the INSECT trial which have been included by these four centres served as the control group for ISSAAC trial.
Primary endpoint of the study was a combined endpoint: the frequency of wound infection and burst abdomen until day of discharge. As secondary parameter the wound infection occurring until 30 days, the incisional hernia rate until one and three years and the length of postoperative stay were recorded. The study was registered under www.clinicaltrials.gov and the study protocol has been published in BMC Surgery in 2008.[27]

The clinical data were published by **Albertsmeier et al.**[28] The ISSAAC group included in total 150 patients and the control group consists of 141 patients. The incidence of burst abdomen and wound infection until day of discharge was 7.3 % in the ISSAAC group and 11.3 % in the INSECT control group; p = 0.31. The length of postoperative hospital stay was comparable in both treatment groups. More wound dehiscence occurred until 30 days postoperatively in the INSECT group than in the ISSAAC group (7 % vs 2.0 %). The rate of incisional hernia one year postoperatively was reduced in the ISSAAC group (14 %) compared to the INSECT control group (21.3 %) but the differences were not significant. Furthermore, the number of fascial gaps was higher in the INSECT group (N = 28, 19.9 %) in comparison to the ISSAAC group (N = 17, 11.3 %), whereas the rate of protruding sac was similar in both groups (ISSAAC: 10.7 % vs INSECT: 10.6 %). The three-years data are waited for end of 2011.

The ISSAAC study could show that the ultra-long term absorbable, elastic, monofilament suture material, Monomax® is safe and efficient for abdominal wall closure after median laparotomy.

1.4 Effect of the stitch length of the outcome of abdominal wall closure

After closing the midline incision after a median laparotomy a high wound infection rate has been observed in several clinical studies.[21] Therefore, several surgeon addressed the question if the stitch length might have an influence of the wound infection rate and also on the incisional hernia rate after abdominal wall closure. In an animal study performed by **Harlaar et al.**[41] it was shown that the tensile force with short stitches was significantly higher than with larger stitches. Therefore, small stitches may be useful to prevent the development of a burst abdomen or an incisional hernia after midline laparotomy.

Millbourn et al.[42] performed a randomized trial to investigate the effect of short stitches versus long stitches for midline incision closure. In both groups a suture length to incision length ratio of at least 4:1 was used. A continuous, monofilament, absorbable polydioxanone suture material was applied for midline closure. In the short stitch group the stitches were placed 5-8 mm from the wound edge and in the long stitch group the stitches were at least placed 10 mm from the edge of the wound. A continuous, interdermal, absorbable, monofilament was used to close the skin. The main outcome measure were incisional hernias, wound dehiscence and surgical site infections. Surgical site infection and wound dehiscence were recorded after four weeks after surgery. Incisional hernias were recorded 12 months postoperatively.

In total 737 patients undergoing an elective or an emergent midline incision were enrolled in the study. By randomization 381 patients were allocated to the long stitch group and 356 patients to the short stitch group. One patient in the long stitch group was observed with a wound dehiscence. Surgical site infection occurred in 35 patients in the long stitch group and in 17 patients in the short stitch group (10.2 % vs 5.2 %; p = 0.02). The rate of incisional hernia was significantly lower in the short stitch group compared to the long stitch group (5.6 % vs 18.0 %; p < 0.001). A multivariate analysis demonstrated that a long stitch was an independent risk factor for the development of a surgical site infection as well as for an incisional hernia. The risk for a wound infection was twice as high and the risk of incisional hernias was four times as high in the long stitch group. The authors recommended that midline incisions should be closed with a single layer, running monofilament suture and that the suture length to wound length ratio should be at least 4:1. This

Clinical Evidence

ratio should be achieved with short stitches that incorporate the aponeurosis only. Current recommendations of placing stitches at least 10 mm from the wound edge should be changed to avoid patient suffering and wound complications.

In another trial **Millbourn and colleagues**[43] explore potential risk factors for wound complications in midline abdominal incisions in relation to the wound closure with small or large stitches. The same sutures techniques were used as mentioned above.[42]

In total 321 patients were randomised to the short stitch group and 370 patients to the large stitch group. The following parameter were documented in both groups: surgical site infection and incisional hernias. Significant more surgical site infection occurred in the large stitch group compared to the short stitch group (9.6 % vs 5.1 %, $p = 0.034$). In addition, the rate of incisional hernia was lower in the short stitch group than in the large stitch group (4.7 % vs 17.2 %, $p < 0.001$). No risk factors for wound infection and incisional hernia could be identified after the use of short stitches. In contrast, with large stitches wound contamination or a diabetes were independent risk factors for a wound infection and a long operation time and surgical site infection were independent risk factor for the development of incisional hernias. Furthermore, wound infections were more common in overweight patient receiving large stitches.
The authors concluded that no risk factors for wound infections and incisional hernias could be identified with short stitches.

Stitch trial (NCT01132209)

Harlaar et al.[44] will perform a multi-centric, randomized, double blinded trial to compare short stitches versus long stitches for abdominal wall closure. A continuous, absorbable polydioxanone suture material will be applied in both groups. In the short stitch group the bite width is 0.5 cm and the intersuturing space is 0.5 cm, in the large stitch group the bite width is 1 cm and the intersuture spacing is 1 cm. In the small stitch technique twice as many stitches will be placed per sutured cm therefore, a smaller and thinner needle will be used in this group.

They hypothesize that short stitches will significantly reduce the incisional hernia rate. The primary endpoint of the trial is the incisional hernia rate after 1 year. Secondary parameter included the postoperative complication rate, wound pain, burst abdomen, surgical site infection, costs and quality of life. Wound infections will be assessed after 1 month and hernias after 1 year postoperatively. Ten centres will participate in the trial. In total 576 patients undergoing an elective midline incision will be randomly allocated to both treatment arms. This study will provide further clinical evidence to support the preference of either a continuous suture technique with short stitches or large stitches to prevent common surgical complications.

The **ESTOIH Study (NCT01965249)** an international, multicenter, randomized controlled trial analyses the effect of the suture technique on the occurrence of incisional hernias. Hypothesis of the study is that the short stitch technique will reduce the incisional hernia after 1 year about 50 % in comparison to the long stitch technique. Centers located in Germany and in Austria participate and in total 468 patients will be randomised either to the short stitch suture technique or to the long-stitch suture technique. In both treatment groups the abdominal wall will be closed using the extra-long term absorbable, elastic monofilament suture Monomax®.

Short Stitch Technique: Monomax® USP 2/0, 150 cm, HR 26
Long Stitch Technique: Monomax® USP 1, 150 cm loop, HR 48

The short-term complications as well as the long-term complication will be recorded. Primary endpoint of the study is the incisional hernia rate after 1 year postoperative. As secondary parameters the burst abdomen rate, the wound infection rate, wound healing disorders and the incisional hernia occurring after 3 and 5 years will be analysed. An ultra-sound examination will be done to detect an incisional hernia. In addition costs and patient quality of life will be analysed using the EQ-5D-5L questionnaire. After discharge the patients will be examined after 30 days, 1 year, 3 and 5 years postoperatively. The study is registered under www.clinicltrials.gov. Publication of the study protocol is available in TRIALS.[45]

Table 3: Studies comparing short stitches versus large stitches

Author	Year	Patients (N)	Incisional hernia	Wound infection	Follow-up
Millbourn et al.	2011	Short: 356 Long: 381	5.6 % 18 %	5.2 % 10.2 %	12 months
Millbourn et al.	2009	Short: 321 Long: 370	4.7 % 17.2 %	5.1 % 9.6 %	12 months
Harlaar et al.	2011	Short: 288 Long: 288			12 months

Conclusion:
The clinical data showed that short stitches (< 10 mm) can reduce the rate of wound infection and the rate of incisional hernia in comparison to large stitches (≥ 10 mm). No risk factors for wound infections and incisional hernias could be identified with short stitches. In contrast, with large stitches wound contamination or a diabetes were independent risk factors for a wound infection and a long operation time and surgical site infection were independent risk factor for the development of incisional hernias. Furthermore, wound infections were more common in overweight patients receiving large stitches.

Clinical Evidence

1.5 Abdominal wall closure in high risk patients

The literature shows that obese patients and patients with an abdominal aortic aneurysm undergoing an open laparotomy carry a high risk to develop postoperatively an incisional hernia. The incisional hernia rate in this subpopulation lies between 20 %-50 %.[46-52] Therefore, several clinical trials have been performed in the past to investigate if the placement of a prophylactic mesh would reduce the incisional rate in comparison to suture repair. This topic is of high scientific interest because as can be seen in www.clinicaltrials.gov additional clinical studies are currently conducted.

PRIMA Trial (NCT00761475)

Jeekel and colleagues perform a randomized controlled trial (PRIMA Trial) to investigate if the use of a preventive polypropylene mesh after primary laparotomy in high risk patients may reduce the incidence of incisional hernias.

In this study 460 high risk patients (obesity, abdominal aortic aneurysm) will be included. These patients will be randomized into three groups. In one-hundred patients the midline fascia will be closed by using an long-term absorbable suture material (group 1, MonoPlus®) in the continuous suture technique. In 180 patients a polypropylene mesh (Optilene® Mesh LP 6 x 35 cm) will be placed in sublay position and the fixation of the mesh will be performed by using fibrin glue (group 2). In group 3 another 180 patient will receive a preventive polypropylene mesh (Optilene® Mesh LP 6 x 35 cm) in onlay position and the mesh is fixed by using fibrin glue. The patients will be examined 1, 3, 12 and 24 months after surgery. The hypothesis is that a prophylactic mesh will reduce the postoperative incisional hernia rate in comparison to the suture. Further parameters which will be analysed in the three different treatment groups are the postoperative complication rate, quality of life and cost effectiveness.

PRIMAAT Trial (NCT00757133)

Berrevoet and colleagues perform a randomized controlled trial to analyze, if a preventive polypropylene mesh can reduce the rate of incisional after midline laparotomy in high risk patients with aortic aneurysm treatment.
In total 120 patients will be enrolled. The patients will be randomized in two groups each consisting of 60 patients. In group 1 the midline incision is closed with slowly absorbable suture material using the continuous suture technique with a 4:1 suture length to incision length ratio. Group 2 will receive a preventive lightweight polypropylene mesh in sublay position. The posterior and anterior fascia sheet will be sutured using a slowly absorbable suture material. The primary endpoint of the trial is the incisional hernia rate 2 years postoperatively. In addition as secondary parameters the incisional hernia rate after one and five years, the duration of the surgery, the occurrence of complications after one month postoperatively and the postoperative pain using the VAS at 12, 24, 48, 72, 96 and 120 hours, 4 weeks and 3 months after surgery will be documented.

AIDA Trial (NCT01353443)

Debus and colleagues investigate in their multi-centric, randomized trial, if a prophylactic mesh will reduce the incisional hernia rate in patients undergoing an elective open midline abdominal aortic aneurysm repair in comparison to a conventional suture (10 % vs 30 %). Furthermore, they will also test if an ultra-long term absorbable monofilament suture material with high elasticity and flexibility (Monomax®) will not be inferior in regard to incisional hernia in comparison to a conventional long-term absorbable polydioxanone suture material (MonoPlus®). The Optilene® Mesh Elastic (10 x 35 cm) from B. Braun will be used as a preventive mesh and will be fixed by absorbable suture material in the interrupted suture technique (MonoPlus®). The primary objective is the incisional hernia rate after 48 months postoperatively. Furthermore, wound complications rate, pain, quality of life and incisional hernia rate after 3, 6 and 12 months will be compared in the different treatment arms. In total 282 patients will be enrolled in the study and allocated to the three different treatment arms (MonoPlus® suture, Monomax® suture, Optilene® prophylactic mesh group). Patients will be examined after discharge 3, 6, 12 and 24 months postoperatively. The detection of incisional hernia will be assessed by ultrasound. In total 10 centers in Germany participate in the trial.

Bevis et al.[46] investigated in their randomized clinical trial whether a prophylactic mesh placement could reduce the incisional hernia rate in patients after open abdominal aortic aneurysm (AAA) surgery in comparison to suture repair.
Three different hospitals participated in the trial. Patients (N = 85) undergoing an elective open AAA were randomly allocated to mass closure (N = 45) or to preperitoneal mesh repair (N = 40).

A polypropylene mesh with a size of 15 x 15 cm was cut into the half and trimmed to shape. It was fixed by 4 polypropylene sutures to the posterior rectus sheath, one superior, one inferior and two laterally where the two mesh pieces overlapped. The abdominal fascia was closed in all patients with a non-absorbable suture material in a 4:1 suture length to incision length ratio. The primary outcome was the incisional rate within 3 years postoperatively. Secondary outcome included the length of surgery, the complication rate and the rate of reoperation due to an incisional hernia repair. The patients were examined 1, 6, 12 months after surgery and thereafter annually until 3 years postoperatively. The presence of an incisional hernia was determined by ultrasound imaging. There were 3 deaths in the mesh group and two in the suture group. In both groups 2 patients had a wound infection. There was no mesh infection. The incisional hernia rate was significantly higher in the suture group than in the mesh group (37 % vs 13.5 %), p = 0.022. Incisional hernias developed much earlier in the suture group in comparison to the mesh group (408 vs 743 days, p = 0.022). Four patients receiving suture material were re-operated due to an incisional hernia compared, to only one in the mesh group. The authors concluded that prophylactic mesh repair significantly reduced the rate of incisional hernia following an elective open AAA repair without increasing the complication rate.

El-Khadrawy et al.[47] used a prophylactic non-absorbable mesh reinforcement of midline closure in high risk patients to detect whether fixing the wound with mesh is risky on a short term basis and whether it is protective on a long term basis. In total 40 patients with a high risk to develop an incisional hernia after an elective midline laparotomy were included in the study. The patients were equally distributed into two treatment groups by randomization. In all patients the peritoneum was closed with continuous, rapidly absorbable, braided suture material. Thereafter, in group 1 a polypropylene mesh was place preperitoneally and fixed with suture material. The midline incision was closed by using a non-absorbable suture by mass closure of the linea alba. Group 2 received only non-absorbable sutures for fascia closure. In both groups the subcutaneous tissue was closed by absorbable suture material and the skin was closed by interrupted sutures. The patients were examined after discharge, 2 weeks postoperatively and then every month for 6 months, finally every 3 months until 3.5 years postoperatively. Seromas and hematomas were detected after 10 days after surgery by ultrasound.

Subcutaneous seroma and chronic pain were more often seen in the prophylactic mesh group than in the suture group. However, the incisional rate was lower in the mesh group in comparison to the suture group (5 % vs 15 %). Furthermore, more surgical site infections were observed in the suture group compared to the mesh group (20 % vs 10 %). The authors conclude that the use of a prophylactic mesh is safe and effective in high risk patients to prevent incisional hernias.

Stryzelcyk et al.[48] analyzed the postoperative hernia prophylaxis in open bariatric surgery. Morbid obese patients (N = 77) were enrolled in the study. The aim of the study was to analyze the incisional hernia rate in patients who received a non-absorbable polypropylene suture material for abdominal wall closure in comparison to patients in whose a prophylactic polypropylene mesh was placed in sublay position. In the mesh group the peritoneum and the posterior fascia was closed by a continuous polydioxanone suture. A mesh which was 2 cm longer and 8 cm wider than the fascia defect was fixed on the posterior fascia by interrupted polypropylene sutures. The anterior fascia was then sutured with continuous polypropylene suture material. In both groups the skin was closed with a continuous subcutaneous absorbable suture. The follow-up of the patients was at least 6 months. The incisional hernia rate, wound leakage, bleeding or other complications were recorded. Development of a hernia was detected via ultrasonography.

In total 36 patients were randomly allocated to mesh repair and 38 patients to suture repair. The development of an incisional hernia was observed in 8 patients of the non-mesh group and in none patient of the mesh group (21 % vs 0 %). The length of hospital stay was similar in both treatment arms, p = 0.092. No serious complication was seen in either group. The incidence of seromas and minor wound leakage was comparable in both groups (14 % mesh group vs 11 % suture group). The authors concluded that using a prophylactic mesh in open bariatric surgery prevents the development of incisional hernias regardless from the extent of obesity. Surgeons should consider to use this procedure more often in this subpopulation.

Gutiérrez et al.[52] performed a study in 2003 to evaluate the usefulness of placement of a supra-aponeurotic polypropylene mesh in the primary closure of laparotomies with a high risk for incisional hernia.

Clinical Evidence

One-hundred patients with a high postoperative risk to develop an incisional hernia were included in this study. In all cases, closure of the laparotomy was accomplished with continuous suture using a non-absorbable, monofilament and in alternative 50 patients a polypropylene mesh was placed on the aponeurosis. The mesh was fixed to the aponeurotic surface with separate stitches using absorbable suture material. The edges of the mesh extended past the line of the incision by 3 cm in all directions. Patients were assessed 3 years after surgery. Examination included abdominal wall palpation to detect the possible existence of incisional hernia. In case the results were not conclusive an abdominal CAT was taken.

Twelve patients were disregarded for the purpose of this study. Of the remaining 88 patients, 44 were included in the group with simple closure of the abdominal wall and the other 44 received a prophylactic mesh. Secondary endpoints (haematoma, seroma, infection) arising within the first 30 days of surgery were not statistically significant between the two groups. Three years postoperatively five patients in the simple abdominal closure group showed incisional hernia (11.3 % incidence) while none occurred in the group of patients with abdominal closure with a mesh ($p = 0.002$).

The authors believe that the placement of a supra-aponeurotic polypropylene mesh in the primary closure of the abdominal wall in patients whose general characteristics indicate a substantial risk of incisional hernia is an extremely useful surgical technique, allowing reduction of the high rate of incisional hernia in such patients and the consequent decrease in the associated morbidity and mortality rates.

Conclusion:
The use of a prophylactic polypropylene mesh for primary closure of laparotomies in high risk patients seems to be helpful and effective to decrease the incisional hernia rate.

Table: 4 Studies comparing suture versus prophylactic mesh in high risk patients

Author	Year	Patients	Mesh type	Incisional hernia	Follow-up
Bevis et al.	2010	N: 40 Mesh N: 45 No mesh	Polypropylene	13.5 % 37 %	3 years
Strzelczyk et al.	2009	N: 36 Mesh N: 38 No mesh	Polypropylene	0 % 21 %	6 months
El-Khadraway et al.	2009	N: 20 Mesh N: 20 No mesh	Polypropylene	5 % 15 %	more than 20 months
Gutierrez et al.	2003	N: 50 Mesh N: 50 No mesh	Polypropylene	0 % 11.3 %	36 months
Strzelczyk et al.	2002	N: 12 Mesh N: 48 No mesh	Polypropylene	0 % 20 %	12 months
Jänes et al.	2004	N: 27 Mesh N: 27 No mesh	Polypropylene	4.7 % 50 %	12 months
Jänes et al.	2004	N: 27 Mesh N: 27 No mesh	Polypropylene	0 % 44 %	12 months

Key Messages

- Abdominal wall closure after a midline laparotomy should be performed by using the continuous suture technique with a long-term absorbable suture material, whereby the suture length to wound length rate should be at least 4:1.[20,53]
- A systematic review showed that there is no difference between midline and transverse incision regarding incisional hernia and wound infection rate.[40] Two other publications indicated that the incisional hernia rate is higher after midline compared to transverse incision.[35,36]
- The application of short stitches (< 10 mm) can reduce the rate of wound infections and incisional hernias in comparison to large stitches.[42-44]
- For high risk patients the use of a prophylactic polypropylene mesh can decrease the rate of incisional hernia after an elective midline laparotomy.[46-50,52]
- The ultra-long term absorbable, elastic, monofilament suture material Monomax® is recommended for abdominal wall closure. Due to its properties it is very suitable for closing the abdominal wall and can reduce the rate of incisional hernia in comparison to other polydioxanone sutures which commonly are used for midline closure.[27,28]

Abstracts

Ann Surg. 2010 May;251(5):843-56.

Elective midline laparotomy closure: the INLINE systematic review and meta-analysis.

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Comment in:
Ann Surg. 2011 Aug;254(2):387; author reply 387-9.

OBJECTIVE: To evaluate the optimal technique and material for abdominal fascia closure after midline laparotomy, first by means of a precisely defined study population and follow-up period and second by the surgically driven aspects.

METHODS: Overview of existing systematic reviews and meta-analysis of randomized controlled trials. A systematic literature search (Medline, Embase, and The Cochrane Central Register of Controlled Trials) was performed to identify randomized controlled trials in elective and emergency populations comparing suture techniques (continuous vs. interrupted) and materials (rapidly vs. slowly vs. non absorbable). Random effects conventional and cumulative meta-analyses were calculated and presented as odds ratios and the corresponding 95 % confidence intervals.

RESULTS: Five systematic reviews and 14 trials including 7711 patients (6752 midline incisions) were analyzed. None of the systematic reviews differentiated elective versus emergency laparotomy. The analysis of available primary studies revealed significant lower hernia rates using a continuous (vs. interrupted) technique (OR: 0.59; P = 0.001) with slowly absorbable (vs. rapid-absorbable) suture material (OR: 0.65; P = 0.009) in the elective setting, which was in contrast to the conflicting results of existing systematic reviews. No statistical heterogeneity was detected in the elective setting (I = 0 %). Seven studies incorporating elective and emergency procedures revealed inconclusive and heterogeneous results (I = 45 %-85 %). No studies have evaluated closure methods solely in the emergency setting so far.

CONCLUSION: No further trials should be conducted for evaluation of technique and available materials for elective midline abdominal fascial closure, according to the results of our cumulative meta-analysis. Future trials will have to define the optimal closure strategy in the emergency setting and relevance of new suture materials and other strategies such as the use of prophylactic mesh in targeted subpopulations.

Br J Surg. 2002 Nov;89(11):1350-6.

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

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BACKGROUND: Various randomized 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 1 year that randomized 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 studies were identified with a total of 6566 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.

Am Surg. 2001 May;67(5):421-6.

Closure of the abdominal midline fascia: meta-analysis delineates the optimal technique.

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The current surgical literature has not clearly demonstrated an optimal technique for abdominal closure. Prospective randomized studies published between 1980 and 1998 were analyzed and the relevant data derived from those studies were pooled for statistical evaluation. The outcome variables of dehiscence, infection, hernia formation, suture sinus formation, and pain were studied and the probability of their occurrence in association with different techniques was calculated. In relation to the outcome features of dehiscence and infection no statistically significant difference was seen when absorbable suture material was compared with non-absorbable material. In regard to the probability of hernia formation no statistically significant difference was seen when monofilament absorbable material was compared with non-absorbable material. There was, however, a higher incidence of hernia formation when braided absorbable suture material was used. In addition there was a higher incidence of incision pain and suture sinus formation when non-absorbable suture material was used. Absorbable monofilament suture material is superior to both absorbable braided and non-absorbable suture for abdominal fascial closure. A continuous mass (all-layer) closure with absorbable monofilament suture material is the optimal technique for fascial closure after laparotomy.

Abstracts

Ann Surg. 2000 Mar;231(3):436-42.

The search for an ideal method of abdominal fascial closure: a meta-analysis.

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BACKGROUND AND OBJECTIVE: The ideal suture for abdominal fascial closure has yet to be determined. Surgical practice continues to rely largely on tradition rather than high-quality level I evidence. The authors conducted a systematic review and meta-analysis of randomized controlled trials to determine which suture material and technique reduces the odds of incisional hernia.

METHODS: MEDLINE and Cochrane Library databases were searched for articles in English published from 1966 to 1998 using the keywords "suture", "abdomen/surgery", and "randomized controlled trials". Randomized controlled trials, trials of adult patients, and trials with a Jadad Quality Score of more than 3, comparing suture materials, technique, or both, were included. Two independent reviewers critically appraised study quality and extracted data. The reviewers were masked to the study site, authors, journal, and date to minimize bias. The primary outcome was postoperative incisional hernia. Secondary outcomes included wound dehiscence, infection, wound pain, and suture sinus formation.

RESULTS: The occurrence of incisional hernia was significantly lower when non-absorbable sutures were used. Suture technique favoured non-absorbable continuous closure. Suture sinuses and wound pain were significantly lower when absorbable sutures were used. There were no differences in the incidence of wound dehiscence or wound infection with respect to suture material or method of closure. Subgroup analyses of individual sutures showed no significant difference in incisional hernia rates between polydioxanone and polypropylene. Polyglactin showed an increased wound failure rate.

CONCLUSIONS: Abdominal fascial closure with a continuous non-absorbable suture had a significantly lower rate of incisional hernia. The ideal suture is non-absorbable, and the ideal technique is continuous.

Am J Surg. 1998 Dec;176(6):666-70.

Choosing the best abdominal closure by meta-analysis.

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BACKGROUND: Local custom, rather than evidence-based medicine, dictates how a surgeon closes abdominal wounds. Closures might be more secure if grounded on statistical data.

MATERIALS AND METHODS: A meta-analysis of 12,249 patients with abdominal wound closures was made. Infections, hernias, and dehiscences were compared examining continuous versus interrupted closures, continuous (absorbable versus non-absorbable), interrupted (absorbable versus non-absorbable), and mass versus layered.

RESULTS: Continuous absorbable closures showed more hernias (P = 0.0007). Dehiscences were significantly more with continuous non-absorbable suture (P = 0.01). Interrupted non-absorbable closures showed a higher incidence of hernias and dehiscences (P = 0.0002, P = 0.04). Mass closures produced significantly less hernias and dehiscences when compared with layered closures (P = 0.02, P = 0.0002).

CONCLUSIONS: Continuous closures with non-absorbable suture should be used to close most abdominal wounds. However, if infection or distention is anticipated, interrupted absorbable sutures are preferred. Mass closures are superior to layered closures.

Chirurg. 2006 Mar;77(3):267-72.

Operative standardization in randomized controlled surgical trials. Meeting of the INSECT trial.

Knaebel HP, Kirschner MH, Reidel MA, Büchler MW, Seiler CM.

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BACKGROUND: INSECT is an internationally registered, three-armed, multicentre, intraoperatively randomised model trial of the Study Centre of the German Surgical Society. The interventions being compared are running suture technique with slowly absorbable monofilament suture material (PDS® vs MonoPlus®) and interrupted technique with a braided, rapidly absorbable suture material (Vicryl®). The primary endpoint is the rate of incisional hernias 1 year postoperatively.

MATERIAL AND METHODS: A total of 25 surgeons from 24 different institutions at all levels of care evaluated the theoretical and practical sessions of the surgical investigator meeting using 25 criteria, including course organisation, content, and speaker evaluation, and a categorical grading system from 1 (very good) to 6 (insufficient).

RESULTS: Distribution of the 625 grades was: very good (1) n = 367, good (2) n = 207, satisfactory (3) n = 39, adequate (4) n = 2, and "No statement" n = 10. The average score for the investigator meeting was 1.5.

CONCLUSION: The participants felt they were successfully prepared theoretically and practically for trial interventions and conduct by attending the meeting. Clear explanation of the measures for treatment equivalence before and during trials is mandatory in randomised controlled surgical trials.

Abstracts

BMC Surg. 2005 Mar 8;5:3.

Interrupted or continuous slowly absorbable sutures – design of a multi-centre randomised trial to evaluate abdominal closure techniques INSECT-trial [ISRCTN24023541].

Knaebel HP, Koch M, Sauerland S, Diener MK, Büchler MW, Seiler CM; INSECT Study.

Group of the Study Centre of the German Surgical Society.

BACKGROUND: The closure of the abdomen after median laparotomy is still a matter of debate among surgeons. Further well designed and performed randomised controlled trials determining the optimal method of abdominal fascial closure are needed.

DESIGN: This is a three armed, multi-centre, intra-operatively randomised, controlled, patient blinded trial. Over 20 surgical departments will enrol 600 patients who are planned for an elective primary abdominal operation. The objective of this study is to compare the frequency of abdominal incisional hernias between two continuous suture techniques with different, slowly absorbable monofilament materials and an interrupted suture using an absorbable braided suture material at one year postoperatively.

CONCLUSION: This trial will answer the question whether the continuous abdominal wall closure with a slowly absorbable material with longitudinal elasticity is superior to the continuous suture with a material lacking elasticity and to interrupted sutures with braided thread.

Ann Surg. 2009 Apr;249(4):576-82.

Interrupted or continuous slowly absorbable sutures for closure of primary elective midline abdominal incisions: a multicenter randomized trial (INSECT: ISRCTN24023541).

Seiler CM, Bruckner T, Diener MK, Papyan A, Golcher H, Seidlmayer C, Franck A, Kieser M, Büchler MW, Knaebel HP.

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Comment in:
Ann Surg. 2009 Oct;250(4):656; author reply 656-7.

OBJECTIVE: In patients undergoing midline incisions, the abdominal fascia can be closed with a continuous or interrupted suture using various materials. The aim of this study is to compare: (1) interrupted technique with rapidly absorbable sutures and (2) continuous techniques with different slowly absorbable sutures, focusing on the incidence of incisional hernias within 1 year.

SUMMARY OF BACKGROUND DATA: A meta-analysis suggested that the incidence of incisional hernias can be more effectively reduced with slowly absorbable continuous sutures.

METHODS: Multicenter randomized surgical trial with 3 parallel groups. Patients were scheduled for primary elective midline incisions. All surgeons were trained (4:1 suture wound length in continuous groups) and monitored. Primary end point, measured within 1 year after surgery, was the frequency of incisional hernias diagnosed by clinical examination and confirmed by ultrasound. Complications and safety were used as secondary end points. This study has been registered with the ISRCTN Register (INSECT: ISRCTN24023541).

RESULTS: Conducted on 625 randomized patients (210 interrupted Vicryl®, 205 continuous polydioxanone suture (PDS®), 210 continuous MonoPlus®), the primary analysis showed an incidence of 28 incisional hernias (15.9 %) versus 15 (8.4 %) versus 22 (12.5 %) for the 3 closure techniques, respectively (P = 0.09). No significant difference was observed between the 3 groups with regard to burst abdomen (4 [2.0 %] vs. 6 [3.0 %] vs. 8 [4.0 %], P = 0.46), wound infection (26 [12.7 %] vs. 39 [19.4 %] vs. 33 [16.3 %], P = 0.19), pulmonary infections (9 [4.4 %] vs. 5 [2.5 %] vs. 5 [2.5 %], P = 0.46), serious adverse events (63 [30.0 %] vs. 57 [27.8 %] vs. 61 [29.1 %], P = 0.89), and 1-year mortality (16 [7.9 %] vs. 11 [5.5 %] vs. 16 [7.9 %], P = 0.54).

CONCLUSIONS: The incidence of incisional hernias and the frequency of wound infection was higher than expected in all groups. New concepts need to be developed and studied to substantially reduce the frequency of incisional hernias.

Abstracts

Ann Surg. 2009 Jun;249(6):913-20.

Midline versus transverse incision in major abdominal surgery: a randomized, double-blind equivalence trial (POVATI: ISRCTN60734227).

Seiler CM, Deckert A, Diener MK, Knaebel HP, Weigand MA, Victor N, Büchler MW.

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OBJECTIVE: There are 2 main types of access for patients requiring major open, elective abdominal surgery: the midline or the transverse approach. The aim of this study is to compare both approaches by focusing on postoperative pain, complications, and frequency of incisional hernias.

SUMMARY BACKGROUND DATA: A recent Cochrane review suggested that transverse incisions may be less painful but incisional hernia rates do not differ.

METHODS: Randomized, patient- and observer-blinded, monocentric, equivalence clinical trial. Patients were scheduled for elective primary abdominal incisions. Composite primary end point measured 48 hours after surgery was the total amount of analgesics (piritramide) required in the last 24 hours and pain (Visual Analogue Scale). Secondary end points were early-onset and late complications. This study is registered in the ISRCTN registry and has the ID number ISRCTN60734227.

RESULTS: Two hundred patients (101 midline and 99 transverse) were randomized. Both incision types resulted in similar amounts of required analgesics (95 % confidence interval [-0.38; -0.33] was included in the equivalence level). For the Visual Analogue Scale, both the 95 % and 90 % CI (0-10) were neither within the equivalence levels nor were their differences significant at the 5 % level. No relevant differences between midline and transverse incisions were observed for 30-day mortality (2 vs. 2, P = 0.99), mortality after one year (15 vs. 23, P = 0.15), pulmonary complications (13 vs. 17, P = 0.43), median length of hospital stay (11 vs. 12 days, P = 0.08), median time to tolerance of solid food (12 vs. 14 days, P = 0.30), and incisional hernias after one year (13 vs. 8, P = 0.48). More wound infections occurred in the transverse group (15 vs. 5, P = 0.02).

CONCLUSION: The decision about the incision should be driven by surgeon preference with respect to the patient's disease and anatomy.

Hernia. 2009 Jun;13(3):275-80.

Incisional hernia after upper abdominal surgery: a randomised controlled trial of midline versus transverse incision.

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OBJECTIVES: To determine whether a transverse incision is an alternative to a midline incision in terms of incisional hernia incidence, surgical site infection, postoperative pain, hospital stay and cosmetics in cholecystectomy. Incisional hernias after midline incision are commonly underestimated but probably complicate between 2 and 20 % of all abdominal wall closures. The midline incision is the preferred incision for surgery of the upper abdomen despite evidence that alternatives, such as the lateral paramedian and transverse incision, exist and might reduce the rate of incisional hernia. A RCT was preformed in the pre-laparoscopic cholecystectomy era the data of which were never published.

METHODS: One hundred and fifty female patients were randomly allocated to cholecystectomy through midline or transverse incision. Early complications, the duration to discharge and the in-hospital use of analgesics was noted. Patients returned to the surgical outpatient clinic for evaluation of the cosmetic results of the scar and to evaluate possible complications such as fistula, wound dehiscence and incisional hernia after a minimum of 12 months follow-up.

RESULTS: Two percent (1/60) of patients that had undergone the procedure through a transverse incision presented with an incisional hernia as opposed to 14 % (9/63) of patients from the midline incision group (P = 0.017). Transverse incisions were found to be significantly shorter than midline incisions and associated with more pleasing appearance. More patients having undergone a midline incision, reported pain on day one, two and three postoperatively than patients from the transverse group. The use of analgesics did not differ between the two groups.

CONCLUSIONS: In light of our results a transverse incision should, if possible, be considered as the preferred incision in acute and elective surgery of the upper abdomen when laparoscopic surgery is not an option.

BMC Surg. 2008 Jul 21;8:12.

A historically controlled, single-arm, multi-centre, prospective trial to evaluate the safety and efficacy of Monomax® suture material for abdominal wall closure after primary midline laparotomy. ISSAAC-Trial [NCT005725079].

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BACKGROUND: Several randomized controlled trials have compared different suture materials and techniques for abdominal wall closure with respect to the incidence of incisional hernias after midline laparotomy and shown that it remains, irrespective of the methods used, considerably high, ranging from 9 % to 20 %. The development of improved suture materials which would reduce postoperative complications may help to lower its frequency.

DESIGN: This is a historically controlled, single-arm, multi-centre, prospective trial to evaluate the safety of Monomax® suture material for abdominal wall closure in 150 patients with primary elective midline incisions. INSECT patients who underwent abdominal closure using MonoPlus® and PDS® will serve as historical control group. The incidences of wound infections and of burst abdomen are defined as composite primary endpoints. Secondary endpoints are the frequency of incisional hernias within one year after operation and safety. To ensure adequate comparability in surgical performance and recruitment, the 4 largest centres of the INSECT-Trial will participate. After hospital discharge, the investigators will examine the enrolled patients again at 30 days and at 12 +/- 1 months after surgery.

CONCLUSION: This historically controlled, single-arm, multicentre, prospective ISSAAC trial aims to assess whether the use of an ultra-long-lasting absorbable monofilament suture material is safe and efficient.

TRIAL REGISTRATION: NCT005725079.

Abstracts

Arch Surg. 2009 Nov;144(11):1056-9.

Effect of stitch length on wound complications after closure of midline incisions: a randomized controlled trial.

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Comment in:
Arch Surg. 2010 Jun;145(6):599; author reply 599-600.
Arch Surg. 2010 Jun;145(6):600; author reply 600-1.

HYPOTHESIS: In midline incisions closed with a single-layer running suture, the rate of wound complications is lower when a suture length to wound length ratio of at least 4 is accomplished with a short stitch length rather than with a long one.

DESIGN: Prospective randomized controlled trial.

SETTING: Surgical department.

PATIENTS: Patients operated on through a midline incision.

INTERVENTION: Wound closure with a short stitch length (ie, placing stitches < 10 mm from the wound edge) or a long stitch length.

MAIN OUTCOME MEASURES: Wound dehiscence, surgical site infection, and incisional hernia.

RESULTS: In all, 737 patients were randomized: 381 were allocated to a long stitch length and 356, to a short stitch length. Wound dehiscence occurred in 1 patient whose wound was closed with a long stitch length. Surgical site infection occurred in 35 of 343 patients (10.2 %) in the long stitch group and in 17 of 326 (5.2 %) in the short stitch group (P = .02). Incisional hernia was present in 49 of 272 patients (18.0 %) in the long stitch group and in 14 of 250 (5.6 %) in the short stitch group (P < .001). In multivariate analysis, a long stitch length was an independent risk factor for both surgical site infection and incisional hernia.

CONCLUSION: In midline incisions closed with a running suture and having a suture length to wound length ratio of at least 4, current recommendations of placing stitches at least 10 mm from the wound edge should be changed to avoid patient suffering and costly wound complications.

TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT00508053.

Hernia. 2011 Jun;15(3):261-6.

Risk factors for wound complications in midline abdominal incisions related to the size of stitches.

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BACKGROUND: Midline abdominal incisions should be closed continuously with a suture length (SL) to wound length (WL) ratio above 4 using small stitches. The effect on the rate of wound complications of a very high ratio and other potential risk factors when closure is performed with small stitches is unknown.

METHODS: Patients operated on through a midline incision were randomised to closure with small stitches, placed 5-8 mm from the wound edge and less than 5 mm apart, or with large stitches, placed more than 1 cm from the wound edge. Patient and operative variables were registered. Surgical site infection and incisional hernia were recorded.

RESULTS: Three hundred and twenty-one patients were randomised to closure with small stitches and 370 with large stitches. Infection and herniation were less common with small stitches. With small stitches, no risk factors for infection or herniation were identified. With large stitches, wound contamination and the patient being diabetic were independent risk factors for infection, and long operation time and surgical site infection were risk factors for herniation. A very high SL to WL ratio did not affect the complication rates.

CONCLUSIONS: In midline abdominal incisions closed with small stitches, no risk factors for surgical site infection or incisional hernia were identified. Increasing the ratio very much above 4 had no adverse effects on the rate of wound complications. The higher rates of infection and herniation with an SL to WL ratio over 5 and in overweight patients in previous reports were probably related to wounds being closed with large stitches.

Br J Surg. 2010 Oct;97(10):1497-502.

Randomized clinical trial of mesh versus sutured wound closure after open abdominal aortic aneurysm surgery.

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BACKGROUND: Incisional herniation is a common complication of abdominal aortic aneurysm (AAA) repair. This study investigated whether prophylactic mesh placement could reduce the rate of postoperative incisional hernia after open repair of AAA.

METHODS: This randomized clinical trial was undertaken in three hospitals. Patients undergoing elective open AAA repair were randomized to routine abdominal mass closure after AAA repair or to prophylactic placement of polypropylene mesh in the preperitoneal plane.

RESULTS: Eighty-five patients with a mean age of 73 (range 59-89) years were recruited, 77 (91 per cent) of whom were men. There were five perioperative deaths (6 per cent), two in the control group and three in the mesh group (P = 0.663), none related to the mesh. Sixteen patients in the control group and five in the mesh group developed a postoperative incisional hernia (hazard ratio 4.10, 95 per cent confidence interval 1.72 to 9.82; P = 0.002). Hernias developed between 170 and 585 days after surgery in the control group, and between 336 and 1122 days in the mesh group. Four patients in the control group and one in the mesh group underwent incisional hernia repair (P = 0.375). No mesh became infected, but one was subsequently removed owing to seroma formation during laparotomy for small bowel obstruction.

CONCLUSION: Mesh placement significantly reduced the rate of postoperative incisional hernia after open AAA repair without increasing the rate of complications.

Abstracts

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Prophylactic prosthetic reinforcement of midline abdominal incisions in high-risk patients.

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BACKGROUND/AIM: Incisional hernia is one of the major elements of morbidity after abdominal surgery, with high incidence in vertical midline abdominal incisions. However, the risk of developing an incisional hernia can be increased due to the patient's related factors; therefore, more consideration has to be given to the choice of incision, wound closure and wound healing to protect against incisional hernia, especially in high-risk patients. In this study, we used prophylactic subfascial non-absorbable mesh reinforcement of midline closure in high-risk patients to detect whether fixing the wound with mesh is risky on a short-term basis and whether it is protective on a long-term basis.

PATIENTS AND METHODS: From October 2000 to December 2002, 40 high-risk patients liable to develop postoperative incisional hernia underwent elective abdominal operations through midline abdominal incisions at the Department of Surgery, Gastroenterology and Laparoscopic Unit, Tanta University Hospital, Egypt. They were randomly divided into two groups; group A: patients for whom the midline abdominal incisions were closed by conventional method and reinforced by subfascial polypropylene mesh (20 patients); and group B: patients for whom the midline abdominal incisions were closed by conventional method only (20 patients) with a follow up period of more than 20 months.

RESULTS: There was no significant difference (P = 0.075) in both groups regarding the age, sex and the average risk factor. Twenty-three patients (57.5 %) presented with more than one risk factor (11 in group A and 12 in group B). The upper midline abdominal incisions were reported in 33 patients (19 upper and 14 extended upper). There was no significant difference between the overall local and systemic complications in both groups (P = 0.4082). However, the subcutaneous seroma and chronic wound pain were greater in patients with prophylactic meshthan those without mesh. One group A patients (5 %) and three group B patients (15 %) developed postoperative incisional hernia during the follow up period.

CONCLUSION: Prophylactic subfascial non-absorbable mesh reinforcement of midline closure in high-risk patients can be used safely and effectively to provide extrinsic strength of the wound without relying too much on the defective development of its own intrinsic strength and to prevent subsequent incisional hernia. There was no risk in the use of the mesh regarding local and systemic complication. However, the final statement should await the outcomes of the long-term follow up of the studied cases.

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Randomized clinical trial of postoperative hernia prophylaxis in open bariatric surgery.

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BACKGROUND: Postoperative hernia following bariatric procedures is more common than in other groups of surgical patients, and remains a serious problem. Gastric bypass is the most often performed bariatric procedure and, despite the increasing popularity of a laparoscopic approach, many morbidly obese patients are still offered open procedures. The aim of this study was to assess the effects of prophylactic polypropylene mesh in morbidly obese patients undergoing gastric by-pass surgery.

METHODS: The study randomized 74 patients undergoing open Roux-en-Y gastric bypass into two groups: wound closure with (n = 36) or without (n = 38) a polypropylene mesh. Mean(s.d.) body mass and body mass index in the mesh group were 137.3(24.5) kg and 46.2(7.1) kg/m^2 and in the non-mesh group were 139.0(24.9) kg and 46.8(7.6) kg/m^2 respectively. In the non-mesh group, the wound was closed with a polypropylene suture. Patients in the mesh group had in addition a polypropylene mesh inserted in a sublay manner.

RESULTS: Patients were followed up for at least 6 (range 6-38) months. Hernia developed in eight patients in the non-mesh group but in none in the mesh group. The duration of hospital stay was similar in both groups: mean(s.d.) 8.4(3.2) and 10.3(5.9) days (P = 0.092). There were no serious complications in either group.

CONCLUSION: The use of a mesh prevented hernia development and did not lengthen hospital stay.

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Primary closure of laparotomies with high risk of incisional hernia using prosthetic material: analysis of usefulness.

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Incisional hernia continues to be a serious postoperative complication in abdominal surgery. We present a prospective randomised study to evaluate the usefulness of placement of a supra-aponeurotic polypropylene mesh in the primary closure of laparotomies with a high risk of incisional hernia. Closure of a vertical laparotomy in 100 patients was accomplished with continuous suture using non-reabsorbable material, with placement of a polypropylene mesh on the aponeurotic surface in 50 patients. Three years after surgery, five patients in the group without the mesh had suffered incisional hernia. No incisional hernia was detected in the group in which closure was made using the mesh (P = 0.02). Use of prosthetic material (polypropylene mesh) in the primary closure of laparotomies with a high risk of incisional hernia is useful for reduction of the rate of incisional hernias.

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