ORIGINAL SCIENTIFIC REPORT



Prophylactic Intraperitoneal Onlay Mesh Reinforcement Reduces the Risk of Incisional Hernia, Two-Year Results of a Randomized Clinical Trial

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Abstract

Background Incisional hernias still are a major concern after laparotomy and are causing substantial morbidity. This study examines the feasibility, safety and incisional hernia rate of the use of a prophylactic intraperitoneal onlay mesh stripe (IPOM) to prevent incisional hernia following midline laparotomy.

Methods This prospective, randomized controlled trial randomly allocated patients undergoing median laparotomy either to mass closure of the abdominal wall with a PDS-loop running suture reinforced by an intraperitoneal composite mesh stripe (Group A) or to the same procedure without the additional mesh stripe (Group B). Primary endpoint was the incidence of incisional hernias at 2 years following midline laparotomy. Secondary endpoints are were the feasibility, the safety of the mesh stripe implantation including postoperative pain, and the incidence of incisional hernias at 5 years.

Results A total of 267 patients were included in this study. Follow-up data 2 years after surgery was available from 210 patients (Group A = 107; Group B = 103). An incisional hernia was diagnosed in 18/107 (17%) patients in Group A and in 40/103 (39%) patients in Group B (p < 0.001). A surgical operation due to an incisional hernia was conducted for 12/107 (11%) patients in Group A and for 24/103 (23%) patients in Group B (p = 0.039). In both groups, minor and major complications as well as postoperative pain are reported with no statistically significant difference between the groups, even in contaminated situations.

Conclusions This first randomized clinical trial indicates that the placement of a non-absorbable IPOM-stripe with prophylactic intention may significantly reduce the risk for a midline incisional hernia.

Trial registration Ref. NCT01003067 (clinicaltrials.gov)

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Introduction

Incisional hernia is one of the most frequent postoperative complications in abdominal surgery causing substantial morbidity and even mortality [1-3]. Moreover, patients with incisional hernia reached lower quality of life scores compared to individuals without incisional hernia [4]. The incidence varies in the literature from 4.2 to 15.2% [5–8]. For specific subgroups (e.g. patients with an abdominal aneurysm or obesity), incidences up to 39% have been reported [4, 9]. A recently published systematic review and meta-regression conducted by Bosanquet et al. [10] summarized the incidence of incisional hernia from 56 papers, including a total of 14,618 patients. They calculated that 12.8% of patients had an incisional hernia after a mean follow-up of 23.7 months after surgery. However, only approximately 5% of patients required further surgery due to incisional hernia after midline laparotomy. Long-term results reported a cumulative incidence of incisional hernia after repair of wound dehiscence of 69% after 10 years [6]. Mudge and Hughes [4] reported in a 10-year follow-up that one-third of the incisional hernias occur after 5-10 years. Besides the negative impact of incisional hernia regarding the patients' quality of life, the direct costs of hernia repair and indirect cost (sick leave) are an important burden for the health care system [11].

Based on a meta-analysis [12] the European Hernia Society recommends a continuous suture closure with a monofilament, slowly absorbable suture after elective laparotomy. No recommendations were given on the optimal technique to close emergency laparotomy incisions [13].

Relevant and proven risk factors for incisional hernia are obesity, wound infection, advanced age, malnutrition, and chemotherapy, regular treatment with steroids and/or immunosuppressants [14–17]. There is only scarce evidence for other probable risk factors such as liver disease, renal failure, connective tissue disorders.

Various studies with the idea of placing a mesh for closure of vertical laparotomy with prophylactic intention to prevent incisional hernia have been published. These studies have been analysed in two different systemic reviews [18, 19]. However, none of these studies have analysed the use of intraperitoneal onlay alloplastic mesh. The use of intraperitoneal onlay mesh is widely accepted especially in laparoscopy as a promising procedure for incisional hernia repair [14].

To our knowledge, this is the first randomized controlled trial which evaluates the effectiveness as well as the safety and feasibility of an intraperitoneal onlay mesh stripe after midline incision to prevent incisional hernia, particularly after colorectal surgery.

Methods

This monocentric, parallel-group randomized, controlled, open-labelled trial started in June 2008. Patients undergoing median laparotomy were randomly allocated either to abdominal wall mass closure with a PDS-loop running suture and with additional IPOM (Group A) or the same procedure without the additional IPOM (Group B) in an allocation ratio of 1:1.

Participants

All patients with a planned median laparotomy were assessed prior to surgery for eligibility and signed a written informed consent. A previous laparotomy was no exclusion criteria. Exclusion criteria were pregnancy, perforation of a hollow viscus, drug addiction, life expectancy less than 5 years due to an advanced tumour stage, known allergy to mesh material, planned second laparotomy, age under 18 years and incapacitated patients. The classification of wound contamination was assigned according to Table 1, which is based on the classification according to Altemeier [20]. Patients with a contamination grade IV were excluded from this study.

Data on patients' characteristics were collected using a pre-interventional case report form.

Interventions

The material used for abdominal wall closure in both groups were late-absorbable monofilament polydioxanone loop sutures (PDS II size 1; EthiconTM by Johnson & JohnsonTM, New Brunswick, NJ, USA) with a new suture every 10 cm. The closure technique consisted of a single-layer continuous suture technique with picking up all layers

 Table 1
 Classification of wound contamination adapted from

 Altemeier

Grade I	No inflammation
	Alimentary and genitourinary tract not entered
Grade II	Gastrointestinal tract entered with no significant spillage
	Appendectomy
	Vagina entered
	Genitourinary tract entered in absence of infected urine
	Biliary tract entered in absence of infected bile
Grade III	Gross spillage from gastrointestinal
	Colorectal tract entered with no significant spillage
	Entrance of genitourinary or biliary tracts in presence of infected urine or bile
Grade IV	Acute bacterial inflammation
	Faecal contamination
	Perforated viscus encountered

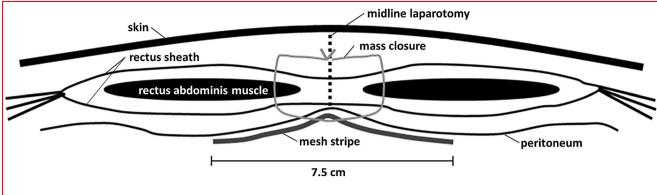


Fig. 1 Illustration of midline abdominal wall closure with intraabdominal onlay mesh stripe (Group A); fixation of the mesh stripe in the midline with the all layer continuous mass closure

of the abdominal wall apart from subcutaneous fat and skin (peritoneum, posterior rectus sheath, rectus muscle and anterior rectus sheath). The stitches were done every centimetre with a distance to the midline of at least one centimetre, according to the Jenkins rule [21] with a thread to incision length ratio of 4:1. The length of the thread was not measured. The length of the laparotomy was measured before closure of the abdominal wall.

For Group A, a 7.5 cm wide ParietexTM composite mesh (CovidienTM, Dublin, Ireland) was additionally used, a three-dimensional mesh with an absorbable, hydrophilic film on the visceral side consisting of porcine collagen, polyethylene glycol and glycerol aiming to minimize adhesions and visceral erosion by the surface directed towards the abdominal cavity [22]. The abdominal wall was closed with an all layer continuous suture in the same technique as in Group B. But, in addition, the mesh stripe was grasped by the PDS-loop and fixed in the midline (Fig. 1). The edges of the mesh stripe overlapped the line of the incision by 4 cm, each towards the chest and the pubic symphysis. Since such a mesh stripe is not currently available, a 20×15 cm ParietexTM composite mesh was divided longitudinally into two halves and the two resulting parts were sutured together using three single stitches (SurgiproTM, size 4-0; CovidienTM).

The abdominal wall closure was finished with a subcutaneous continuous suture using absorbable material (VicrylTM, size 3-0; EthiconTM); the skin was closed using a skin stapler (ProximateTM; EthiconTM). Subcutaneous drains were not used.

The abdominal wall closures were performed by all surgeons of the department and by residents under supervision, following the detailed, above-mentioned protocol. All surgeons were instructed by the principal investigator and adequately trained for mesh-stripe implantation.

Outcomes

Data on intraoperative findings were collected using an operative case report form. The data included study group, length of midline incision, length of the mesh stripe, numbers of PDS-loops used for the closure of the fascia and classification of the wound contamination.

Data on postoperative complications were collected using a postoperative case report form.

The primary endpoint was the incidence of incisional hernia (definition below) 2 years after midline laparotomy.

Secondary endpoints are the feasibility and safety of the mesh implantation, even in contaminated situations, the postoperative pain, and the rate of incisional hernias at 5 years postoperative.

Clinical examinations were planned at 6 weeks, 2 years and 5 years postoperatively, including ultrasound of the abdominal wall at 2 and 5 years. For the current analysis, the results of all examinations at 6 weeks and 2 years after surgery are included.

Postoperative pain was recorded by visual analogue scale (VAS) from 0 to 10 cm.

Definition of incisional hernia

Incisional hernia was clinically defined as any visible and/ or palpable "blowout" within a distance of 3 cm from the midline abdominal scar. The ultrasonic criteria of incisional hernia were a visible gap within the abdominal wall and/or "tissue moving through the abdominal wall by Valsalva manoeuvre" and/or a detectable "blowout". For the diagnosis of incisional hernia, either clinical criteria, or ultrasound criteria or both had to be fulfilled. The study did not distinguish between single and multiple incisional hernias.

Sample size and blinding

A minimum sample size of 230 was calculated to obtain an expected significant difference in the incidence of incisional hernia of 3 versus 15% with an alpha error of 0.05 and a power of 80%. This number was increased to approximately 270 patients to account for loss of follow-up.

The patients as well as the outcome assessors were informed about the allocated intervention after the surgery. Thus, no blinding was performed in this study.

Randomization

Two hundred and eighty closed envelopes (140 for Group A and 140 for Group B) were randomly placed in a box and numbered sequentially from 1 to 280. Patients were randomized during surgery just before abdominal closure, by opening the next envelope according to its number. If the patient had an exclusion criterion only found during surgery (i.e., contamination grade IV), they were excluded from randomization; hence, no randomization envelope was opened. Therefore, all patients underwent the allocated intervention.

Statistical methods

Groups were tested for difference by χ^2 test or Fisher's exact test for qualitative data and Mann–Whitney *U* test for quantitative data, as appropriate. The significance level was set to 5%. Statistical analyses were performed using Stata version 10.1 (StataCorp; College Station, TX, USA).

The study was approved by the ethics committee of Basel and Baselland (EKBB Ref-No. 364/07) and is registered at www.ClinicalTrials.gov (Ref-No. NCT01003067).

Results

From June 2008 to May 2013, a total of 267 patients were randomly allocated to the two different groups; 131 patients to Group A (intervention, i.e. with IPOM) and 136 patients to Group B (control, i.e. without IPOM). All patients received the allocated procedure.

The patients' characteristics are presented in Table 2 and are well-balanced between both groups.

Six patients in Group A and 11 patients in Group B missed an appointment or did not want to be re-examined. Twenty-six patients died before the follow-up 2 years after treatment. The reasons for death within 2 years in Group A were multiorgan failure (n = 2), cardiac arrhythmia (n = 1) and cerebral infarction (n = 1). In Group B, the

 Table 2
 Patients' characteristics [39]

	[]	
	Group A (with additional IPOM)	Group B (without additional IPOM)
Patients	131	136
Demographics		
Male/female	60/71	56/80
BMI (95% CI)	25.8 (25.0-26.7)	26.6 (25.8-27.4)
Smoker	43 (32.8%)	42 (30.9%)
Age (95% CI)	64.1 (61.9–66.4)	65.1 (63.1–67.1)
Co-morbidities		
Malignant tumour	42 (32.1%)	50 (36.8%)
Diabetes	13 (9.9%)	14 (10.3%)
Renal insufficiency	3 (2.3%)	2 (1.5%)
Peripheral artery disease	10 (7.6%)	11 (8.1%)
Aortic aneurysm	13 (10.1%)	12 (8.8%)
Steroids/ immunosuppression	5 (3.8%)	10 (7.4%)
Previous median laparotomy	16 (12.2%)	21 (15.4%)
Wound contamination (Alte	emeier)	
Grade I	39 (29.8%)	40 (29.4%)
Grade II	31 (23.7%)	32 (23.5%)
Grade III	61 (46.6%)	64 (47.1%)
Emergency	2 (1.5%)	4 (2.9%)
Length of laparotomy (cm, 95% CI)	27.7 (26.8–28.5)	28.7 (27.9–29.6)

No statistical analysis to identify group differences was performed as recommended by the CONSORT guidelines [30]

reasons for death within 2 years were: multiorgan failure (n = 6), intestinal ischaemia (n = 2), bleeding after thoracic puncture (n = 1) and myocardial infarction (n = 1). Therefore, 210 patients attended the follow-up examination 2 years after initial surgery (Fig. 2). The follow-up of each of these 210 patients included clinical examination and abdominal wall ultrasound.

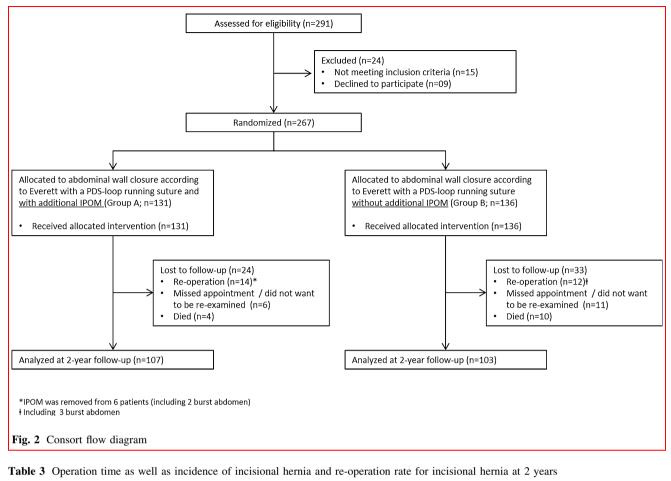
Primary endpoint

The results with regard to the primary endpoint and the operation times are outlined in Table 3.

Secondary endpoints

The results regarding morbidity and mortality at 6 weeks after surgery are presented in Table 4.

In Group A, six meshes had to be removed during follow-up due to the following situations: burst abdomen (n = 2), wound sinus tract due to mesh infection (n = 2), bowel perforation not related to the implanted mesh (n = 1), retroperitoneal infection (n = 1). But in the two



	Group A (with additional IPOM)	Group B (without additional IPOM)	p value
Operation time in minutes (95% CI)	282 (264–300)	293 (273–313)	0.43
Incisional hernia	18/107 (17%)	40/103 (39%)	< 0.001
Re-operation for incisional hernia	12/107 (11%)	24/103 (23%)	0.02

patients with *wound sinus tract* only, the mesh stripe itself was the reason for the re-operation. Hence, *wound sinus tract due to mesh infection* occurred in 2/131 (1.5%).

In both groups, the patients complained of marginal postoperative pain after 6 weeks (VAS in Group A 1.2 vs. 1.0 in Group B) and 2 years (VAS in Group A 0.25 vs. 0.27 in Group B). During the study period, 26 patients (14 of group A with additional mesh) had to be re-operated for varying reasons. Most of patients of Group A were found to have no or only minor adhesions due to the mesh. Adhesiolysis was estimated to be not more difficult than without the presence of a mesh stripe.

The results of the 5-year follow-up are to be expected in May 2018.

No risk factors for incisional hernias could be identified due to too small sample size for each risk factor.

Discussion

Similar to the treatment of incisional hernia per se, some authors proposed the use of meshes for closure of the abdomen after midline incision [18, 19]. However, no randomized clinical trial is available that investigates the use of a non-absorbable mesh in the IPOM technique for prevention of incisional hernia, although IPOM is an accepted modern concept in abdominal incisional hernia closure [14]. Therefore, the intention of this study was to evaluate a simple prophylactical reinforcement of the

Table 4 Perioperative complications

	Group A (with additional IPOM)	Group B (without additional IPOM)	p value
Minor complications			
Haematoma	3 (2.3%)	3 (2.2%)	n.s.
Seroma	2 (1.5%)	2 (1.5%)	n.s.
Subcutaneous infect	4 (3.1%)	1 (0.7%)	n.s.
Major complications			
Bowel perforation	0 (0%)	1 (0.7%)	n.s.
Intraabdominal abscess	2 (1.5%)	1 (0.7%)	n.s.
Anastomotic leakage	3 (2.3%)	1 (0.7%)	n.s.
Burst abdomen	2 (1.5%)	3 (2.2%)	n.s.
Re-operation (within 30 days)*	4 (3.1%)	6 (4.4%)	n.s.
Death (30-day mortality)*	2 (1.5%)	2 (1.5%)	n.s.

n.s. not significant

* Identical to re-operation and death within 6 weeks

abdominal wall by an intraperitoneal non-absorbable mesh stripe, fixed by integration into the mass closure of the abdominal wall.

In the present study, the follow-up at 2 years after surgery revealed a significant reduction of incisional hernias from 40% with a mass closure alone to 17% with a reinforcement of the mass closure with a mesh stripe in IPOM technique. Although both figures seem to be high and higher than predicted, the difference remains remarkable and supports the hypothesis that a stripe of IPOM may reduce the risk for incisional hernia. Several reasons for the rather high hernia rate seen in this study may be discussed: the incidence of incisional hernias is determined by patient population, length of follow-up and especially the method of hernia diagnosis.

Furthermore, in the present study, large bites (according to Jenkins rule [21]) were used for standard abdominal closure. After finishing the accrual period of the present study, this technique turned out to lead to a higher incisional hernia rate compared to small bites as reported by Deerenberg et al. [23]. The reported hernia rate of 21% at one year postoperative in the group of patients with large bites is comparable to the incisional hernia rate of the nonmesh group in the present study of 39% at two years postoperatively. It could be speculated that the difference in the observed incisional hernia rates would have been lower-but still relevant-if this new small bite technique would have been applied. Previous studies [24, 25] demonstrated an increasing risk of incisional hernia over the years. Similar to the present study, incisional hernia was detected not only by clinical examination but also by ultrasound. The increased sensitivity of ultrasound compared to clinical examination to detect mostly

asymptomatic hernia is already published [26]. In the present study, clinical suspected hernias could often be verified by ultrasound. Additionally, Pereira et al. [27] reported a rate of 40.9% of incisional hernia after a median follow-up of 19 months in patients with open colorectal carcinoma resection if CT scan was used for detection. These discouraging figures found by meticulous follow-up investigations underline the necessity and importance of intensifying the search for a reliable concept of abdominal wall closure following midline laparotomy. The herewith proposed mesh-stripe reinforcement for abdominal wall closure seems to provide some progress, but still offers potential for further improvement. Optimum width, optimum material and optimum fixation device of the mesh stripe need to be determined in future.

Whether alternative prophylactic mesh reinforcement techniques such as sublay mesh or prefascial onlay mesh implantation provides better results remains speculative in the light of a very recent randomized controlled study, reporting a incisional hernia rate of 18 and 13% after sublay and onlay mesh reinforcement with a 2-year follow-up [28].

Aiming to avoid a selection bias, all patients with midline laparotomy were assessed for eligibility regardless of type and urgency of surgery. Furthermore, patients with a contaminated situation without infection such as in colorectal surgery were not excluded from this trial. Concerns regarding higher infection rates after IPOM in contaminated abdominal cavities could not be confirmed by the literature when starting the present study. In the meantime, a matched case–control study showed that implantation of a prophylactic non-absorbable intraperitoneal mesh is safe and feasible even in patients with peritonitis [29].

Similarly, the presented data shows no significant differences in postoperative mortality and morbidity between the group allocated to standard midline closure and the group with reinforcement with prophylactic IPOM. It is noteworthy that there was no higher risk of infection within the first 6 weeks in the group allocated to reinforcement with prophylactic IPOM when compared to the control group. The two infections in 131 (1.5%) implanted mesh stripes were delayed and presented with wound sinus tracts. In one patient, the wound sinus tract occurred after a second laparotomy (42 months after mesh implantation) and in the second patient the wound sinus tract developed 27 months postoperatively. After unsuccessful antibiotic treatment and mesh removal, no further wound sinus tracts occurred. The incidence of mesh infection in the present study was lower than the rates of mesh infection reported for mesh implantation in ventral hernia repair with different mesh positions [30-34]. Nevertheless, the described mesh fixation technique without lateral fixation could lead to enterocutaneous fistulation, as the edge and the uncoated side of the mesh could come into close contact with the bowel. This rare but relevant risk must be weighed against the benefit of reinforcement and compared to other measures to prevent incisional hernia. However, no entero-cutaneous fistula occurred in the present study.

It has to be mentioned that similar to intraperitoneal mesh placement for ventral hernia, re-operations might be more challenging due to intraperitoneal adhesions but without higher complication rates [35].

The fact that patients with a wide spectrum of abdominal surgeries were enrolled in the study, and that biases seem to be unlikely in this randomized controlled trial, may enhance the validity and applicability of the conclusions drawn. Of course, the mentioned rare but serious adverse events have to be weighed against the benefit of prophylactic intraperitoneal onlay mesh placement.

Furthermore, the implantation of the IPOM-stripe was minimally time consuming and no special equipment is required. No adverse events during mesh implantation such as bowel lesion were reported. Accordingly, no difference in the operation time was found between the two study groups. Longer operation times for prophylactic mesh implantation had been found in other studies using a sublay-technique [36, 37]; however, in only one study, this difference was significant [38].

A trend towards increased chronic pain after mesh implantation has been reported in the past [18]. However, in the present study, no difference in postoperative pain was measured between Groups A and B at 6 weeks and 2 years postoperatively by the use of VAS.

In this study, not all patients with a diagnosed incisional hernia required surgical treatment. In both study groups, approximately 60% of the detected incisional hernias only were amended to hernia surgery, which is comparable to the results of Bosanquet et al. [10]. Small hernia size, lack of symptoms and lack of motivation of the patient are the common explanations for deferred surgery.

Limitations

This study might be underpowered with regard to any difference in adverse events, since, as expected, adverse events fortunately have a lower incidence than the primary endpoint (i.e. incisional hernia).

Conclusions

The high rate of incisional hernias in this study implies that the percentage of incisional hernia following midline laparotomy may currently be underestimated. The reinforcement of the abdominal wall closure in the midline by a non-absorbable intraperitoneal mesh stripe in onlaytechnique is a simple procedure that significantly reduces the risk of incisional hernia in general surgical patients. Concerns of many surgeons of using IPOM together with bowel resection do not seem to be justified. The 5-year follow-up results regarding this new technique are awaited.

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Compliance with ethical standards

Conflict of interest Brosi Philippe, MD, Glauser Philippe M., MD, Speich Benjamin, PhD, Käser Samuel A., MD, and Maurer Christoph A, MD have no conflicts of interest or financial ties to disclose.

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