BJS, 2022, 1–7
https://doi.org/10.1093/bjs/znac194
Randomized Clinical Trial

Effects of the Short Stitch Technique for Midline Abdominal Closure on Incisional Hernia (ESTOIH): Randomized Clinical Trial

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Parts of this work have been presented at the EHS-AHS Joint Congress 2021, Copenhagen, Denmark, 13–16 October 2021; published in abstract form as *Br J Surg* 2021; 108.

Abstract

Background: Incisional hernia remains a frequent problem after midline laparotomy. This study compared a short stitch to standard loop closure using an ultra-long-term absorbent elastic suture material.

Methods: A prospective, multicentre, parallel-group, double-blind, randomized, controlled superiority trial was designed for the elective setting. Adult patients were randomly assigned by computer-generated sequence to fascial closure using a short stitch (5 to 8 mm every 5 mm, USP 2-0, single thread HR 26 mm needle) or long stitch technique (10 mm every 10 mm, USP 1, double loop, HR 48 mm needle) with a poly-4-hydroxybutyrate-based suture material (Monomax®). Incisional hernia assessed by ultrasound 1 year after surgery was the primary outcome.

Results: The trial randomized 425 patients to short ($n = 215$) or long stitch technique ($n = 210$) of whom 414 (97.4 per cent) completed 1 year of follow-up. In the short stitch group, the fascia was closed with more stitches (46 (12 s.d.) *versus* 25 (7 s.d.); $P < 0.001$) and higher suture-to-wound length ratio (5.3 (2.2 s.d.) *versus* 4.0 (1.3 s.d.); $P < 0.001$). At 1 year, seven of 210 (3.3 per cent) patients in the short and 13 of 204 (6.4 per cent) patients in the long stitch group developed incisional hernia (odds ratio 1.97, 95 per cent confidence interval 0.77 to 5.05; $P = 0.173$).

Conclusion: The 1-year incisional hernia development was relatively low with clinical but not statistical difference between short and long stitches.
Registration number: NCT01965249 (http://www.clinicaltrials.gov)

Introduction

Although minimally invasive techniques are being used for a growing portfolio of surgical procedures, midline laparotomy remains the standard incision for a wide range of abdominal interventions, including multivisceral resections and emergency procedures. Incisional hernia frequently develops as a complication of this approach; 50 000 procedures for incisional hernia repair performed annually in Germany[1] indicate the size of this problem.

Healing of midline incisions is slow due to the character of the linea alba and variations in intra-abdominal pressure. It may be further compromised by clinical risk factors such as obesity, male sex, chronic obstructive pulmonary disease, smoking, or preoperative chemotherapy[2]. Following elective midline laparotomies, long-term absorbent suture materials and a continuous suture technique have been shown to reduce hernia rates[3]. Triclosan-coating to prevent wound infection has been tried in various settings but was unsuccessful using monofilament sutures in elective closures[4].

Received: February 23, 2022. **Revised:** April 13, 2022. **Accepted:** May 12, 2022

A suture-length-to-wound-length ratio greater than 4:1 reduces the probability of incisional hernia[5]. The ideal may be short stitches using small needles and thin suture materials[6,7]. A trial[8] testing this was criticized for predictability of randomization, lack of multicentricity, and primary outcome assessment (clinical examination only). The STITCH trial confirmed the effectiveness of the short stitch technique, but the follow-up was only 12 months[9]. Rodent model research suggests that high suture tension is a risk factor for a weaker wound[10], and that suture tension may regulate itself by rupturing the fascia in the initial phase[11]. More than 50 per cent of incisional hernias develop after the first postoperative year[2,12]. With 10 per cent or more developing incisional hernias in recent trials[3,13,14], laparotomy closure remains an unsolved surgical problem. These factors have led to the development of an elastic and ultra-long-term absorbent suture material made from poly-4-hydroxybutyrate (Monomax®; B.Braun Surgical, Rubi, Spain). It may avoid early-phase suture tension peaks to support the fascia. This trial investigated a short stitch *versus* traditional loop closure using poly-4-hydroxybutyrate sutures.

Methods

The design, participants, interventions, randomization, and statistics of the Effects of the Short Stitch Technique for Midline Abdominal Closure on Incisional Hernia (ESTOIH) trial have been described in detail in the published trial protocol[15] and publication of short-term results.[16]

Trial design

The ESTOIH trial was a multicentre, double-blind, controlled, parallel-group, superiority trial with 1:1 randomization conducted in Germany and Austria. It was registered with ClinicalTrials.gov on 13 October 2013 (NCT01965249)[15]. The trial was approved by all institutional review boards and performed by the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Participants

Adult patients aged ≥18 years (American Society of Anesthesiologists grades I to III) were eligible to participate in this trial when scheduled for elective, primary midline laparotomy with an incision length ≥ 15 cm, and survival was expected to be longer than 1 year. The trial protocol excluded patients undergoing emergency surgery, with a BMI ≥30 kg/m^2, pancreatic tumour patients, patients operated on for an abdominal aortic aneurysm, and patients with one or more of the following conditions: peritonitis; coagulopathy; immunosuppressive therapy at the time of surgery (more than 40 mg of a corticoid per day or azathioprine); chemotherapy within the last 2 weeks before surgery; and radiotherapy of the abdomen within the previous 8 weeks before surgery. Pregnant women, patients with severe neurological and psychiatric disease, or lack of compliance were also excluded. All participants gave written informed consent.

Two relevant changes were made to the original trial protocol after the trial had been initiated. A few months into the trial, we found that the BMI exclusion criterion—intended to guarantee the homogeneity of the trial cohort—was limiting recruitment. In this respect, Höer *et al.* had demonstrated that the risk for incisional hernia significantly increases with a BMI > 25 kg/m^2[12]. However, in that study, no further increase in hernia risk was seen when the cut-off for BMI was set at 30 kg/m^2, as most of the high-risk patients were found in the group with a BMI < 30 kg/m^2. Therefore, we removed BMI from the list of exclusion criteria in an amendment to the study protocol dated 23 September 2015. In the same revision, we changed the criterion 'pancreatic tumour patients' to 'pancreatic carcinoma', allowing the inclusion of patients with benign tumours.

Patients were recruited at nine different trials sites in Germany (seven sites) and Austria (two sites), including three university hospitals, three other tertial referral centres, and three local and regional hospitals. The trial started with six centres, and three centres joined the group after the trial had been initiated.

Interventions

The subcutaneous layer was cut with electrocautery and the linea alba was prepared free from fat at least 1 cm to each side and at both ends. The umbilicus was routinely dissected from the aponeurosis and re-fixated after fascial closure. In both study groups, elastic, extra-long-term absorbent, monofilament sutures manufactured from poly-4-hydroxybutyrate (MonoMax®) were used for closure of the rectus fascia. Specifically, in the long stitch group, the fascia was sutured continuously with 10 mm stitch intervals and 10 mm distance from the wound edge using a MonoMax® USP 1 150 cm loop with an HR 48 mm needle. This was determined to have a suture-to-wound-length ratio of approximately 4:1. Sutures overlapped in the middle and were knotted separately. In the short stitch group, a single continuous suture with 5 mm stitch intervals and 5 to 8 mm distance from the wound edge was done using a single MonoMax® USP 2/0 150 cm thread with an HR 26 mm needle. The resulting suture-to-wound-length ratio was to be greater than 5:1.

Surgeons were trained on site by the principal investigator (R.H.F.) and using training videos. The number of throws per knot were not defined, but at least six throws for the long stitch technique and a self-fixing knot for the short stitch technique were recommended in training sessions. A study nurse or other assistant counted the number of stitches intraoperatively, and digital timers were used to measure suturing time. Parameters describing the suture technique were recorded in the case report form, monitored in regular study site visits, and deviations were discussed in study group meetings to ensure homogeneity.

Outcome measures

Primary outcome

The main outcome of the ESTOIH trial was the rate of incisional hernia at 1 year (± 1 month) postoperatively. We used the European Hernia Society (EHS) definition of incisional hernia as an 'abdominal wall gap with or without a bulge in the area of a post-operative scar perceptible or palpable by clinical examination or imaging'[17]. Therefore, incisional hernia was assessed by clinical examination and ultrasound of the abdominal wall, and was noted as present when ultrasound demonstrated the hernia. Ultrasound was substituted by cross-sectional imaging (CT or MRI) when this was part of a patient's routine follow-up (e.g. for a tumour disease).

Secondary outcomes

Quality of life was analysed using the EQ-5D-5L questionnaire[18] preoperatively, as well as 30 days and 1 year postoperatively. Short-term complications such as surgical site infections (SSI), burst abdomen, wound healing disorders, seroma, haematoma, and other adverse events not directly related to wound healing, as well as the length of hospital stay, have been reported

previously[16]. In addition to these predefined outcomes, the combined rate of burst abdomen and incisional hernia was calculated.

Sample size calculation

The sample size calculation was based on the ISSAAC study (19 per cent risk of developing an incisional hernia within 1 year using a long stitch)[13] and a 69 per cent relative risk reduction using a short stitch technique[8]. The ESTOIH trial aimed to demonstrate that the short stitch suture technique decreases the 1-year incisional hernia rate by 50 per cent[19] compared to the long stitch technique. Assuming hernia rates of 19 per cent and 9.5 per cent for the respective groups, a sample size of 424 patients (212 per group) was calculated to detect this difference with a power of 80 per cent and an alpha error of 5 per cent. Including a dropout rate of 10 per cent, we planned to randomize 468 patients. Withdrawn patients were not to be replaced. To avoid centre effects, recruitment was limited to 200 patients per centre. Following an interim analysis of the primary outcome, it was decided that recruitment should end when 424 patients had been randomized.

Interim analysis

The trial protocol included no planned interim analysis. However, when monitoring of trial centres at 75 per cent of planned patient recruitment revealed that very few incisional hernias occurred and recruitment slowed down, an interim analysis was performed to determine whether the trial's aim could still be reached. The interim analysis confirmed that the hernia rate in both groups was lower than expected and that the null hypothesis could not be rejected with the planned number of patients. As extending the study cohort was not an option owing to slow recruitment, it was decided that recruitment should end when 424 patients had been randomized as planned without substituting for patients who had terminated early.

Randomization

Patients were randomized intraoperatively briefly before abdominal wall closure. They were allocated to receive either the short or the long stitch suture technique in a 1:1 ratio by opening a sealed opaque randomization envelope. The sponsor supplied envelopes according to a randomization list prepared by a statistician using the statistical software SAS 9.1 (SAS Institute Inc., Cary, NC, USA). Each envelope contained the suture material belonging to the intended suture technique and a description of that technique. Separate randomization lists were prepared for all trial sites to avoid centre-specific effects and to ensure a balanced distribution of treatments within centres (stratification). We used random blocks of different lengths. Randomization lists were sealed and locked up at the sponsor site.

Blinding

Outcome assessment was double blinded: the patient and the observer responsible for evaluating the clinical outcome were unaware of the patient's treatment group, and the observer had no access to the randomization list. Case report forms were handed to the observer by an independent person (e.g. a study nurse) not involved in outcome assessment. While surgeons performing abdominal wall closures could not be blinded, they were not involved in outcome assessment.

Statistical analysis

For this report, we analysed data available at the 1-year follow-up visit; further analyses will be conducted after completing the 3- and 5-year follow-up visits. All statistical analyses were done using SAS software version 9.4 (SAS Institute). The patient cohort is described separately for each treatment group with respect to demographic data and the baseline values of investigated parameters. Endpoints are presented as frequencies and rates; 95 per cent confidence intervals (c.i.) are given when appropriate. The χ^2 test was used for rates comparisons. Statistical significance was defined as a P value < 0.05 for the primary outcome analysis.

To control for BMI following a protocol amendment that allowed patients with a BMI > 30 kg/m^2 to participate in this study, multiple logistic regression models were calculated for incisional hernia. A stepwise backward elimination approach was used for model reduction, starting with known clinical risk factors such as diabetes or wound infection. The final model included the treatment group, BMI, and factors with a P value < 0.1.

Results

Patients

Between March 2014 and December 2019, 215 patients were randomized to the short suture technique and 210 to the long stitch suture technique. The trial ended after 425 patients were randomized; an additional patient was included owing to simultaneous inclusions in this multicentre trial. *Figure 1* describes the participant flow through the study. Baseline clinical data and procedure characteristics were similar in both study groups (*Table 1*). The majority of patients had colorectal surgery, followed by upper gastrointestinal (GI) surgery. One hundred and six different surgeons performed the procedures in this trial.

Clinic visits were scheduled for enrolment (baseline), 2 days postoperatively, on the day of discharge, at 30 days (+ 10 days), and 1 year (± 1 month) postoperatively. The 1-year follow-up ended in December 2020 and was completed by 414 patients (97.4 per cent) included in the present outcome analysis. In the short stitch group, 16 patients had a re-laparotomy during the first year (three owing to burst abdomen), five patients died, and nine withdrew their consent to participate. In the long stitch group, 28 patients underwent re-laparotomy (10 owing to burst abdomen), 10 patients died, and three withdrew their consent within the first year.

Outcomes

In the small stitch group, more stitches were performed to achieve closure of the fascia compared to the long stitch group, resulting in a higher ratio of suture length to wound length and a longer duration for wound closure (*Table 2*). At 1 year (± one month) postoperatively, seven (3.3 per cent) of 210 patients in the short stitch group and 13 (6.4 per cent) of 204 patients in the long stitch group had developed incisional hernia (odds ratio (OR) 1.97, 95% c.i. 0.77 to 5.05; $P = 0.173$). A per-protocol analysis of available cases confirmed these results, with seven (4.2 per cent) of 165 patients in the short stitch group and 13 (8.2 per cent) of 158 patients in the long stitch group having developed incisional hernia (OR 2.02, 95% c.i. 0.79 to 5.21; $P = 0.168$). We found a larger proportion of small hernias in the small stitch group, while hernias in both groups were characterized by similar locations. Hernias in the short stitch group required surgical intervention more frequently, resulting in an equal number of hernia repairs in both groups, despite the greater number of

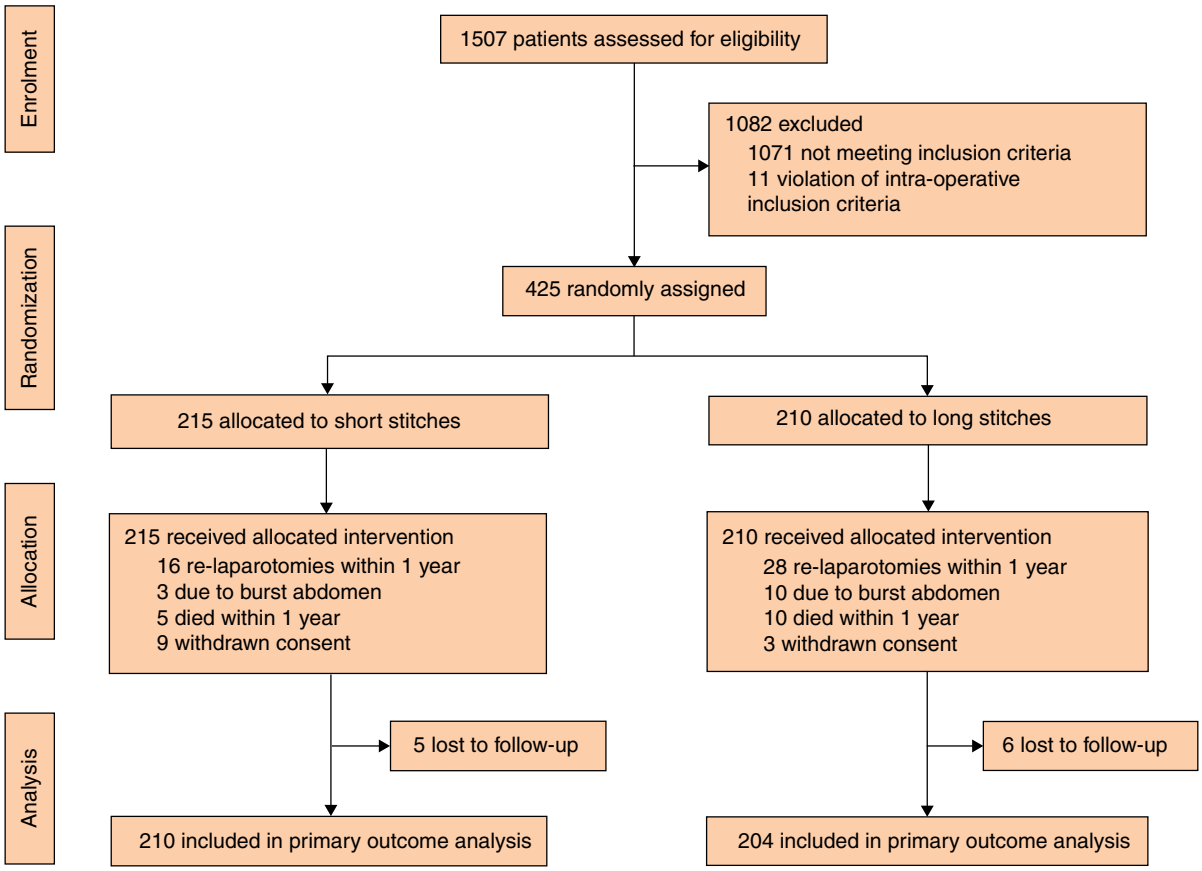

Fig. 1 CONSORT flow diagram

Table 1 Baseline demographic and clinical characteristics

	Short stitches ($n = 215$)	Long stitches ($n = 210$)
Female sex	100 (47)	93 (44)
BMI (kg/m^2)	25.4 (4.2)	25.1 (4.1)
> 30	23 (11)	25 (12)
Smoking		
Previous smoker	33 (15)	36 (17)
Current smoker	36 (17)	32 (15)
Alcohol consumption	44 (21)	64 (30)
ASA grade		
I	31 (14)	38 (16)
II	106 (49)	97 (48)
III	77 (36)	74 (36)
Missing	1 (0.5)	1 (0.5)
Type of surgery		
Colon	92 (43)	73 (35)
Oesophagus	8 (4)	7 (3)
Gastric	38 (18)	37 (18)
Pancreas	15 (7)	20 (10)
Rectum	34 (16)	43 (20)
Small intestine	11 (5)	14 (7)
Other	13 (6)	11 (5)
Comorbidities		
Abdominal aortic aneurysm	2 (1)	1 (0.5)
Chronic liver disease	6 (3)	3 (1)
Diabetes	22 (10)	19 (9)
COPD	12 (6)	8 (4)
Renal insufficiency	12 (6)	7 (3)
Tumour	158 (73)	158 (75)

Data are presented as *n* (%). BMI is presented as mean (s.d.).
COPD, chronic obstructive pulmonary disease.

Table 2 Details of suture technique

	Short stitches ($n = 215$)	Long stitches ($n = 210$)
Wound length (cm)	21.6 (4.5)	21.4 (4.0)
Number of stitches (*n*)	45.6 (12.4)	24.9 (7.0)*
Implanted suture length (cm)	113.5 (48.2)	83.1 (26.1)*
Suture length-to-wound length ratio	5.3 (2.2)	4.0 (1.3)*
Duration of fascial closure (min)	14.9 (5.9)	9.3 (4.1)*

Data are mean (s.d.).
*$P < 0.001$.

hernias in the long stitch group (*Table 3*). Hernia rates according to trial sites are reported in *Table S1*.

Short-term results from this trial, such as burst abdomen, SSIs, wound healing disorders, and length of hospital stay, have been reported previously[16]. The combined endpoint of burst abdomen and incisional hernia was reached by 10 (4.8 per cent) of 210 patients in the short stitch group and 23 (11.3 per cent) of 204 patients in the long stitch group ($P = 0.018$). *Figure S1* shows a Kaplan–Meier analysis of cumulative incidence.

Logistic regression models

Multiple logistic regression models, including BMI and treatment group, were calculated for incisional hernia and the combined

Table 3 Description of incisional hernias

	Short stitches ($n=7$)	Long stitches ($n=13$)	Total ($n=20$)
EHS Classification:			
Location			
Subxyphoidal	1	1	2
Epigastric	2	5	7
Umbilical	2	5	7
Infraumbilical	1	1	2
Suprapubic	0	0	0
Missing	1	1	2
EHS classification: size (cm)			
< 4	2	8	10
≥ 4–10	2	3	5
≥ 1	0	0	0
Missing	3	2	5
Imaging			
Ultrasound	5	9	14
CT	0	4	4
MRI	1	0	1
Missing	1	0	1
Need for surgical repair			
Yes	4	4	8
No	3	9	12

Data are reported as *n* (%). EHS, European Hernia Society.

Table 4 Multiple logistic regression models for incisional hernia and the combined endpoint of incisional hernia and burst abdomen

	OR (95% c.i.)	*P* value
Incisional hernia		
Stitch group: long stitches *versus* short stitches	1.974 (0.771–5.052)	0.156
Incisional hernia or burst abdomen		
Stitch group: long stitches *versus* short stitches	2.545 (1.174–5.519)	0.020
BMI: ≥ 30 kg/m^2 *versus* < 30 kg/m^2	2.813 (1.174–6.736)	0.018

OR, odds ratio; c.i., confidence interval.

endpoint of burst abdomen or hernia (*Table 4*). In the model for hernia, BMI ≥ 30 kg/m^2 was not a risk factor, and the influence of the stitch technique was statistically not significant. In the model for the combined endpoint of hernia or burst abdomen, the long stitch technique and BMI > 30 kg/m^2 were independently associated with an increased risk of developing the complication.

Quality of life

Valid EQ-5D questionnaires were completed by 366 patients (86 per cent) at the time of allocation, 306 patients at discharge, and 291 patients (90 per cent) at the 1-year follow-up visit. The EQ-5D scale and the EQ-5D index differed significantly 12 months postoperatively between groups (*Table S2*). Quality of life in the long stitch group was lower at every visit without a change in EQ-5D scale values from the preoperative period to 12 months postoperative (74.6 (18.1 s.d.) *versus* 74.41 (17.61 s.d.)). In contrast, the short stitch group showed an improvement in EQ-5D scale values from the preoperative period to 12 months after surgery (75.9 (18.2 s.d.) *versus* 80.4 (16.7 s.d.)). Concerning EQ-5D dimensions (*Fig. 2*), the short stitch group had a significantly better outcome than the long stitch group for pain and self-care. We observed no difference in the dimensions of mobility, activity, or anxiety after 12 months. Quality of life 1 year postoperatively was lower in patients who developed incisional hernia than in patients who did not (EQ-5D scale 70.8 (14.9 s.d.) *versus* 77.9 (17.4 s.d.); $P=0.169$).

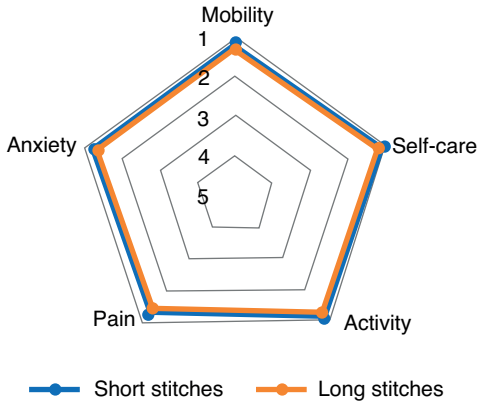

Fig. 2 Quality of life analysis 1 year after midline closure: EQ-5D-5L dimensions
The short stitch group had a significantly better outcome than the long stitch group for pain and self-care. No difference was observed for the dimensions of mobility, activity, or anxiety.

Discussion

The limitations of this study include an unexpectedly low number of incisional hernias, slow recruitment of patients due to increasing use of laparoscopic techniques, and a high number of participating surgeons (possibly resulting in heterogenous abdominal wall closure). The difference in the primary outcome parameter of incisional hernia was statistically not significant, perhaps due to the lower event rate than expected. Patient selection is one factor that may have contributed (e.g. no re-laparotomy). Studies on cadavers indicate that the load-bearing capacity of the linea alba is significantly reduced after relaparotomy, which is why these patients in particular were excluded.[20] Lower hernia rates than predicted were achieved for high-risk procedures (upper/lower GI)[21,22]. In both study groups only the fascial tissue of the linea alba (anterior sheath of the rectus muscle) was included in the suture line. The inclusion of fascia, muscle, and peritoneum (all-in-one stitch), as performed in the STITCH trial, was not recommended as it may entail a slacking effect reducing the suture tensile force[23].

Incisional hernia, when it occurs, may be obvious in some patients and challenging to detect in others. Assessment solely by physical examination, as practised in previous trials[5,8], may lead to under detection of the primary outcome. As we assessed all patients in the ESTOIH trial using ultrasound or cross-sectional imaging, as recommended in EHS guidelines[17], under detection can likely be excluded as a cause for the low hernia rate. Accuracy of detection will be further addressed with a prolonged follow-up 3 and 5 years postoperatively[17], knowing that the incisional hernia rate may increase by as much as 60 per cent from 1 to 3 years of follow-up[24]. A per-protocol analysis of available cases confirmed the primary outcome analysis but showed that patients unavailable for outcome assessment reduced the hernia rate in both groups.

A crucial aspect of wound healing refers to suture tension and associated complications[10,25]. In this regard, suture material plays a role and may have contributed to low hernia rates in the ESTOIH trial: MonoMax® is a monofilament suture fabricated from (poly-) 4-hydroxy-butyrate. It is characterized by an uncommon degree

of elasticity (90 per cent elongation *versus* 45 to 50 per cent for polydioxanone-based sutures) and ultra-long-term absorption (100 days 50 per cent basic strength retention *versus* 35 to 42 days)[13]. The increased elasticity is thought to reduce suture tension, especially during sudden increases of intra-abdominal pressure. This mechanism potentially reduces repetitive injury to the rectus fascia and, ultimately, burst abdomen and incisional hernia. Viscoelastically active sutures may accelerate healing with higher human fibroblast motility[26].

Burst abdomen may anticipate incisional hernia, and a high burst abdomen rate can bias the results for incisional hernia. Merged into a single combined endpoint found a significant advantage for the short stitch technique. While a high rate of anastomotic leaks[16] may have played a role in the development of burst abdomen in the long stitch group, this excludes burst abdomen as an explanation for the lower hernia rate in the short stitch group. Interestingly, the need for surgical repair was equal in both groups, despite the greater number of hernias in the long stitch group, which raises the question of whether a reduced number of hernias can translate into a clinical advantage. In this regard, the general quality of life, pain, and self-care after 1 year was better for the short stitch group.

Funding

This study was sponsored and funded by B.Braun Surgical SA, Rubi, Spain. The Medical Scientific Affairs department of Aesculap AG was responsible for project management, data management, statistics, study registration, and monitoring.

Acknowledgements

The preregistration can be accessed at https://clinicaltrials.gov/ct2/show/NCT01965249. We certify that the results of all preregistered analyses are reported, and that any unregistered analyses are clearly indicated as being exploratory.

Disclosure. Participating institutions received case payments from Aesculap AG to cover study costs. P.B. reports personal fees from Aesculap AG during the conduct of the study and outside the submitted work. F.K. reports personal fees from BD Bard outside the submitted work. R.H.F. reports personal fees from Aesculap AG during the conduct of the study as well as personal fees from Aesculap AG and BD BARD outside the submitted work. M.A. reports personal fees from Aesculap AG during the conduct of the study. The authors declare no other conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

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