Evaluation of Incisional Hernia Development in Patients Undergoing Abdominal Wall Closure Using a Suturing Device for Standardized Abdominal Closure

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Evaluation of Incisional Hernia Development in Patients Undergoing Abdominal Wall Closure Using a Suturing Device for Standardized Abdominal Closure

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Background

Several randomized controlled trials and observational studies have demonstrated that abdominal wall–related complications, such as wound dehiscence, surgical site infections, and the development of incisional hernias, can be reduced by closing the abdominal wall using a suture length–to–wound length ratio (SL/WL) of at least 4. This ratio should be achieved by using small-bites (5–8 mm fascial bites with 5 mm spacing between stitches) rather than large-bites.

The purpose of this technique is to ensure that the sutures engage only the fascial connective tissue without incorporating muscle or fatty tissue, which may undergo necrosis and provide a nidus for bacterial growth. In addition, numerous small bites distribute tension more evenly along the suture line, thereby reducing the risk of tissue tearing.

Clinical studies in which surgeons received training in this technique, as well as questionnaire-based surveys, have shown that adherence to these guidelines remains challenging. The reasons include lack of familiarity with the technique and the perception that it is time-consuming. Adherence has also been shown to be more difficult during emergency surgery, when the abdominal incision is long, and when wound closure is performed by surgical trainees.

Surgical site infections and wound dehiscence are common clinical problems, while incisional hernias affect up to 30% of patients undergoing open abdominal surgery. Approximately 50% of incisional hernias are diagnosed within one year after the index operation, and 80% within three years.

These complications are clinically significant because they prolong hospital stay and increase antibiotic use. Cancer patients who experience postoperative complications may also be unable to receive their planned chemotherapy. However, these complications can be reduced by approximately 50% through the recommended small-bites closure technique.

In addition, the final abdominal closure phase is the stage of surgery during which most needless-stick injuries to surgeons and operating room staff occur.

We have evaluated a suturing device for standardized abdominal closure, SutureTOOL (Suturion, Lund, Sweden), in four preclinical studies and one clinical study with respect to its performance and safety.

SutureTOOL has been shown to produce a reproducible small-bites suture pattern with a high proportion (95–100%) of closures achieving an SL/WL ratio of at least 4. Abdominal closure time was shorter compared with manual suturing techniques. Furthermore, none of the surgical gloves used during abdominal closure with SutureTOOL showed any puncture holes.

Clinical Study

The clinical study was conducted at Helsingborg Hospital in patients undergoing open surgery for colorectal cancer or inflammatory bowel disease.

Patients were followed throughout the perioperative period, and data was collected regarding:

- abdominal closure quality,
- closure time,
- postoperative complications, and
- perforation of surgical gloves used during abdominal closure.

The results were positive. All patients achieved adequate abdominal closure quality (SL/WL ratio ≥4), and closure time was reduced by approximately 75%. Only one patient developed a surgical site infection, and no patients experienced wound dehiscence. The mean abdominal closure time was 7.4 minutes, compared with 15–30 minutes using conventional manual techniques. The shortest closure time was just over 2 minutes, suggesting that SutureTOOL has the potential to substantially reduce overall operative time. The results of the clinical study were published in the journal *Hernia* in 2025.

Aim

The aim of this study is to evaluate the development of incisional hernias one year after surgery. Follow-up will consist of a retrospective review of computed tomography (CT) scans performed as part of routine postoperative follow-up after colorectal cancer surgery. To compare patients whose abdominal wall was closed using SutureTOOL with those who underwent manual abdominal closure, outcomes will be compared with those of historical controls. This evaluation is important to determine whether the standardized abdominal closure device can reduce the risk of incisional hernia following open abdominal surgery.

Methods

Study Design

The study protocol follows the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines. The protocol will be registered on ClinicalTrials.gov before the study begins.

The planned investigation is a retrospective case–control study based on computed tomography (CT) examinations performed as part of the routine postoperative follow-up of patients who participated in our previous clinical study, as well as patients from a historical control cohort.

CT scans obtained approximately one year after surgery will be independently reviewed by two radiologists, with the sole objective of identifying and classifying any incisional hernias according to the European Hernia Society (EHS) Classification (Muysoms FE et al., *Hernia*, 2009).

Several studies investigating the development of incisional hernias after abdominal surgery have used one-year follow-up, as approximately 50% of all incisional hernias are expected to have developed by that time.

Setting

The study will be conducted at Helsingborg Hospital and Skåne University Hospital, Lund, by researchers affiliated with Lund University, Lund, Sweden

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Study Participants

We plan to follow up:

- 38 patients who participated in the original clinical study, and
- 180 patients who underwent surgery for the same indications and who will serve as historical controls.

The inclusion and exclusion criteria will be identical to those used in the original clinical study.

Baseline characteristics of the intervention group are presented in the accompanying table.

All participants are expected to have undergone a CT examination as part of their standard postoperative follow-up. The variables to be collected are listed below. Patient inclusion will follow the study flowchart.

Inclusion Criteria

- Adults aged 18 years or older.
- Patients undergoing elective open colorectal surgery through a midline laparotomy incision at Helsingborg Hospital.

Exclusion Criteria

- Previous surgery involving a midline laparotomy incision.
- Pre-existing midline abdominal wall hernia.
- Presence of collagen vascular disease.
- Generalized metastatic cancer at the time of the index operation.
- Expected survival of less than one year.

Primary Endpoint

Incisional hernia identified by one or more of the following:

- reoperation for incisional hernia,
- diagnosis of incisional hernia documented in the medical record,
- identification of an incisional hernia during retrospective CT review.

Secondary Endpoints

- Death attributable to an abdominal wall–related complications.
- Any other abdominal wall–related complication occurring within six weeks after the index operation.

Variables

Research Question	Variable	Method
Incisional hernia after one year	Classification according to the 2009 European Hernia Society (EHS) classification	Independent review of CT scans by two radiologists
Timing of CT examination	Number of days after the index operation	Medical record review
Mortality	Yes/No; number of days after the index operation	Medical record review
Cause of death	Related to abdominal wall complication (Yes/No)	Medical record review
Reoperation	Related to abdominal wall complication (Yes/No)	Medical record review
Clinically significant incisional hernia	Yes/No	Medical record review
Demographic variables	Age, sex, BMI, previous diseases, medications, ASA classification	Medical record review
Surgical site infection	Outpatient visit for wound infection or antibiotic treatment for wound infection	Medical record review
Wound dehiscence	Reoperation for wound dehiscence or documentation in the medical record	Medical record review
Operative variables	Type of surgery, indication for surgery, and SL/WL ratio	Medical record review

Findings

Incisional hernias will be classified according to the 2009 European Hernia Society (EHS) classification. Patients found to have an incisional hernia will be informed by letter and offered an outpatient consultation. The radiologists reviewing the CT scans will be instructed to assess the images only for the presence of incisional hernias. Any incidental findings identified during the review will be managed by the physician who originally ordered the CT examination.

Data Collection

The study population will consist of two groups.

The intervention group will include the 38 patients who participated in the initial clinical study (CRO-21-149: *Clinical study evaluating the performance and safety of SutureTOOL in male and female patients undergoing elective open abdominal surgery using a suturing device for standardized abdominal wall closure*).

These patients will be identified using the study Subject Enrollment and Identification Log.

The control group will comprise 180 patients, corresponding to five times the number of patients in the intervention group.

Control patients will be identified through the surgical scheduling system Orbit at Helsingborg Hospital using the following procedure codes:

JFB30, JFB40, JFB43, JFB46, JFB50, JFB53, JFB60, JFB96, JGB00, JGB03, JGB10, JGB20, JGB30, and JGB33.

Patients will be extracted from Orbit in consecutive batches of 50 patients until 180 patients meeting the inclusion and exclusion criteria have been identified.

Data Sources

Control patients will be identified through Orbit 5 (Tietoevry Sweden AB, Kristianstad, Sweden), the surgical planning system used at Helsingborg Hospital. Operative data for all study participants will be retrieved from Orbit. Additional patient variables will be collected from

Melior (Cerner Corporation, Kansas City, MO, USA), the electronic medical record system used by Region Skåne. Retrospective review of CT images will be performed using IDS7 (Sectra AB, Linköping, Sweden).

Collected Data

Operative variables will include:

- operative time (minutes),
- ASA physical status classification,
- intraoperative blood loss (mL),
- suture length-to-wound length ratio (SL/WL),
- surgical indication, and
- whether a stoma was created during the index operation.

Demographic variables will include:

- sex,
- age,
- comorbidities,
- height, and
- weight.

Incisional hernias will be identified through both retrospective CT review and review of the medical records.

During image review, incisional hernias will be classified according to the European Hernia Society (EHS) Classification (2009).

The reviewing radiologists will be blinded to the abdominal wall closure technique used for each patient.

Additional patient-related variables concerning postoperative complications will be obtained from the medical records.

Radiological assessment will follow the 2009 European Hernia Society Classification of Incisional Hernias and will be documented using a standardized data collection form including information on:

- hernia size, and
- anatomical location.

The abdominal closure technique will remain blinded throughout the radiological review.

Bias

Selection Bias

There is a risk that patients in the intervention and control groups differ because the intervention group consists of patients operated on during 2023–2024, whereas the historical controls underwent surgery before 2023.

Differences may therefore exist in surgical practice, abdominal wall closure techniques, and operating surgeons.

Patients in the intervention group were operated on by five surgeons, and the clinical study specifically focused on abdominal wall closure, which itself may have influenced surgical performance and outcomes.

Information Bias

Information bias will be minimized by ensuring that CT examinations are reviewed according to a standardized protocol by two independent radiologists who are blinded to the abdominal wall closure technique.

Attrition Bias

Patients for the control group will be selected consecutively in batches of 50 patients, reducing the risk of systematic exclusion.

Selection Bias Between Cohorts

The same inclusion and exclusion criteria will be applied to both the intervention and control groups to maximize cohort comparability.

Baseline demographic characteristics of the two groups will be compared statistically.

Statistical Methods

The original clinical study was powered to evaluate the proportion of patients achieving an adequate abdominal wall closure using the small-bites technique.

In routine clinical practice, approximately 70% of abdominal wall closures achieve adequate quality when surgeons are aware of and actively apply the recommended technique.

The study assumed that 80% of closures would meet the predefined quality criteria, resulting in a required sample size of 38 patients.

The expected one-year incidence of incisional hernia was estimated to be:

- 20% in the historical control group, and
- 10% in the intervention group.

The non-inferiority margin was predefined as 10 percentage points.

The comparison will therefore be performed as a non-inferiority study with a 10% margin, comparing the 38 intervention patients with historical controls.

Assuming a loss of two patients from the intervention group (leaving 36 evaluable patients), a control group consisting of five times as many patients (180 controls) provides a statistical power of at least 80%.

Ethical Approval

Ethical approval is required for this study. Approval was given under the following case number DnR 2026-00853-01-917977 by the Swedish ethics review board (*Etikprövningsmyndigheten).*

Results

The results will be published in a peer-reviewed scientific journal in accordance with the STROBE reporting guidelines.

References

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