2023 ESCP Collaborating Group Audit Project:

Wound closure and SSI prevention in abdominal surgery with long term follow-up

*An international **audit** of*

Wound Closure and Surgical Site Infection Prevention Strategies

in Abdominal Surgery (WOLVERINE AUDIT)

Audit Protocol 1.0

Version 22nd November 2023

FUNDING

Funding and Support in Kind	
Ethicon	Unrestricted educational grant to the European Society of Coloproctology.
European Society of Coloproctology	Direct funding for project conduct.
This is an investigator-initiated and investigator-led project..	

STUDY OFFICE

James Keatley	Project Manager
Brett Dawson	Data Manager
Birmingham Centre for Observational and Prospective Studies Institute of Translational Medicine, College of Medical and Dental Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT.	wolverine@contacts.bham.ac.uk

AUDIT STUDY MANAGEMENT GROUP

Gabrielle van Ramshorst	Associate Professor of Surgery
Alaa El-Hussuna	Associate Professor of Surgery
Dragomir Dardanov	Management Bulgaria
Henry George Smith	Management Denmark
Mahmoud Elfiky	Management Egypt
Peter Neary	Management Ireland
Nir Horesh	Management Israel
Francesco Pata	Management Italy
Gaetano Gallo	Management Italy
Meiram Manlin	Management Kazakhstan
Mohammed Elhadi	Management Libya, Middle East and North Africa
Audrius Dulskas	Management Lithuania
Ademola Adeyeye	Management of Nigeria
Beatriz Mendes	Management Portugal
Sharfuddin Chowdhury	Management Saudi Arabia
Aya Minaya Bravo	Management Spain
Daksshitha Wickramasinghe	Management Sri Lanka
Erman Aytac	Management Turkey

University of Birmingham:

Tom Pinkney	Professor of Surgical Trials
James Keatley	ESCP Project Manager
Bryar Kadir	Senior Statistician
Laura Magill	Associate Professor of Clinical Trials

ESCP COHORT STUDIES GROUP

Alaa El-Hussuna	Associate Professor of surgery	Ana Minaya Bravo	Colorectal Surgeon
Audrius Dulskas	Surgical Oncologist	Baljit Singh	Consultant Surgeon and Honorary Senior Lecturer
Dragomir Dardanov	Senior Assistant Professor of Surgery	Elizabeth Li	NIHR Doctoral Research Fellow and colorectal registrar
Francesco Pata	Consultant Surgeon	Gabrielle van Ramshorst	Associate Professor of surgery
Gaetano Gallo	Assistant Professor of Surgery	Gianluca Pellino	Associate Professor of Surgery
Ionut Negoi	Senior Lecturer of Surgery	James Glasbey	NIHR Academic Clinical Fellow
Michael Kelly	Clinical Lecturer	Matteo Frasson	Associate Professor
Peter Neary	Professor of Surgery	Sanjay Chaudhri	Consultant Surgeon
Sue Blackwell	PhD Student	Thomas Pinkney	Professor of Surgery
Sharfuddin Chowdhury	Consultant Surgeon	Muhammed Elhadi	Junior Doctor
Beatriz Silva Mendes	General Surgery Resident	Sebastian Shaji	Consultant Gastroenterologist
Caterina Foppa	Y-ESCP Representative	Charlie Knowles	Professor of Surgery

Dion Morton	Professor of Surgery	Vanessa McCourt	Senior Association & Account Manager
Rita Perry	Data Manager	Laura Magill	Associate Professor of Clinical Trials

WOUND CLOSURE INTERNATIONAL ADVISORY COMMITTEE

Nadia Henriksen	Associate Professor of Surgery, Denmark
Manuel Lopez-Cano	Professor of Surgery, Spain
Todd Heniford	Professor of Surgery, USA
Hans Jeekel	Emeritus Professor of Surgery, the Netherlands

External expert for study protocol writing group

Luca Gordini	Consultant surgeon, Gruppo Ospedaliero San Donato Foundation, Milan, Italy

SUMMARY

Title: 2023 ESCP Collaborating Group Audit Study: Wound closure and SSI prevention in abdominal surgery with long term follow-up.

Background: The 2021 ESCP Wound Closure Survey found significant heterogeneity in common practices for abdominal wound closure and SSI prevention, including various types of fascial closure techniques and suture used, skin preparation and sterility measures taken during the surgical intervention.

Aim: To conduct a prospective, international audit in wound closure and SSI prevention following abdominal surgery. An international network will collate information on wound closure practices used and short-term 30-day outcome data. The data will also be used to help inform the design of a future interventional trial on wound closure and SSI prevention.

Design: Prospective audit: **clinician-derived baseline clinical data and short-term 30-day** outcomes for patients undergoing elective and/or emergency general and colorectal surgery.

A parallel cohort study will also be conducted (detailed in a separate protocol). The cohort study will collect patient-reported outcome data for the period from 30 days to one year after surgery

***All sites have the option to participate in either the audit alone or the cohort study.**

Centre eligibility: Any hospital or surgical unit performing elective and/or emergency general and colorectal surgery.

Patient eligibility: Adults (age 18 years and above) undergoing surgery by abdominal approach are eligible, including elective, expedited or emergency surgery by open, laparoscopic or robotic approaches with a minimum (extraction) incision length of 5 cm.

Key outcome measures*:*

Audit study: Patient, disease and operation-related factors including detailed information on wound closure techniques and SSI prevention measures.
Clinician-derived surgical outcomes data for up to 30 days post-operation

Sample size**:** Based on previous studies, 2,000 patients are expected to take part in the audit project.

List of abbreviations and definitions (in alphabetical order)

Abdominal wound dehiscence (also referred to as 'evisceration' or 'fascial dehiscence'). Defined as an unintended acute wound failure at the level of the fascia and a postoperative complication after primary closure of a laparotomy incision.

Degree of contamination during surgery
Clean: an incision in which no inflammation is encountered in a surgical procedure, without a break in sterile technique, and during which the respiratory, alimentary and genitourinary tracts are not entered.

Clean-contaminated: an incision through which the respiratory, alimentary or.genitourinary tract is entered under controlled conditions but with no contamination encountered.

Contaminated: an incision undertaken during an operation in which there is a major break in sterile technique or gross spillage from the gastrointestinal tract, or an incision in which acute, non-purulent inflammation is encountered. Open traumatic wounds that are more than 12 to 24 hours old also fall into this category

Dirty: An incision undertaken during an operation in which the viscera are perforated or when acute inflammation with pus is encountered during the operation (for example, emergency surgery for faecal peritonitis), and for traumatic wounds where treatment is delayed, and there is faecal contamination or devitalised tissue present.

Early abdominal wound failure. Defined as surgical site infection, surgical site occurrence or abdominal wound dehiscence diagnosed within 30 days postoperatively.

Incisional hernia. Defined by the European Hernia Society as "any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging".

Late abdominal wound failure. Defined as surgical site infection in presence of foreign body material or incisional hernia at one year postoperatively.

SSI: Surgical Site Infection. Defined by the CDC (Centers for Disease Control and Prevention) as infections related to a surgical procedure that occur near the surgical site within 30 days following surgery (or up to 1 year following surgery where synthetic implants are involved).

SSO: Surgical Site Occurrence. Defined as: wound cellulitis, non-healing incisional wound, skin or soft tissue ischemia, skin or soft tissue necrosis, serous wound drainage, stitch abscess, seroma, hematoma, infected or exposed mesh, surgical site infection, abdominal wound dehiscence.

INTRODUCTION

The *European Society of Coloproctology (ESCP) cohort studies group with Birmingham Surgical Trials Consortium* and *the Birmingham Centre for Observation and Prospective Studies* have developed an international network of hospitals and surgeons to deliver the *Wound Closure and Surgical Site Infection Prevention Strategies in Abdominal Surgery (WOLVERINE)* study; the last four audits conducted between 2015-2022 included thousands of surgeons from hundreds of hospitals. Our network has grown now to 70 countries.

The impact of this study can be ground-breaking not only from the perspective of patient safety and quality of life, but also because of the methodology proposed. Collecting prospective, unselected patient data and providing feedback directly to the surgeons and hospitals can inform and harmonise practice across countries and continents. We additionally plan to use this data to populate an education platform that will be disseminated across the network and beyond. A previous study carried out using this methodology, EAGLE (ClinicalTrials.gov NCT04270721), is submitted for publication. It is envisaged that this pathway could be used to improve and standardise surgical quality for many other operations and processes around surgery in the future, in countries with both well developed and less developed surgical services.

BACKGROUND

Wound closure methods following surgical intervention is a major issue and has been the focus of interest ever since surgical interventions were introduced. Historical evidence dating back to Ancient Egypt shows an interest in differing closure techniques and the materials utilized (1). From Hippocrates and Galen to Lister and Fleming, the focus and improvement in wound management has been sought (2–4). However, despite considerable improvements in patient outcomes, failure of wound healing still remains the commonest cause of surgical morbidity worldwide. The occurrence of superficial wound infection and abdominal wound dehiscence influence incisional hernia rates, impairs quality of life (QoL) and impacts healthcare expenditure (5,6,7,8)

For years there has been considerable research into both the ideal methods of wound closure and the ideal suite of interventions to reduce surgical wound infections. The use of specific suture material, the distribution of tension across the wound, and the role of adjuncts (bowel preparation, antibiotics, prophylactic mesh) have all been investigated (9). Improving patient modifiable risk factors (body mass index, smoking status, medication use) are also important factors to consider (12-17). However, complete mitigation of all patient related risk factors is not feasible. Therefore, health organisations have focused on surgery related factors, such as patient pre-operative preparation, sterile environment and interventions proven to lower the risk for surgical site infections. For example, the World Health Organisation (WHO) has published guidelines on SSI prevention, with a most recent partial update in 2018 (18). The recommendations include commonly accepted interventions including prophylactic antibacterial perioperative therapy and surgical site preparation prior to the surgical intervention, among

others. However, although these guidelines are extensive, they are based on low to moderate evidence in the vast majority of recommendations, leading to limited uptake and implementation.

Several large prospective studies have reported on varying closure techniques and their impact on incisional hernia rates. The 2015 STITCH trial, compared small and large suture bites in abdominal wound closure (19). The authors observed that those with small bites had a lower risk of incisional hernia at one year follow-up. Alternatively, the PRIMA trial compared primary abdominal fascial closure to standard closure plus prophylactic mesh (onlay or sublay). These studies demonstrated that prophylactic onlay mesh significantly reduced incidence of incisional hernias (20). These studies have had several critiques and caused substantial debate in surgical communities across the world. Additionally, the studies to date have considerable heterogeneity and limited QoL outcome data. The Match review, a meta-analysis and systematic review aimed to evaluate fascial closure materials and techniques for emergency and elective laparotomies was published in 2015 (21). Although the authors found significant heterogeneity between included studies, small bites and stitches that absorb slowly seemed to have advantages in incisional hernia prevention. The most recent guidelines of the European Hernia Society (EHS) reflect these findings, as the current recommendation of the society is to close the fascia with a continuous, small bite, slowly absorbable suture. Most of the recommendations in these guidelines, however, rely on low to moderate quality evidence (22).

The aim of this current audit is to provide global real-world data on patients, disease and operation-related factors and outcomes, which will also serve as benchmark data to set up a future interventional study on abdominal wound closure and SSI prevention.

RATIONALE FOR PROJECT

In 2023, the ESCP conducted an international survey on common practices in abdominal wound closure and SSI prevention. (23) Over 500 ESCP members, colorectal and general surgeons participated in this study. Three common clinical scenarios were described, which included contaminated emergency surgery, clean contaminated laparoscopic and open surgery. Participants were asked to indicate how they would approach each case. The study found significant heterogeneity in common practices for abdominal wound closure and SSI prevention, including various types of fascial closure techniques and sutures used, skin preparation and sterility measures taken during the surgical intervention.

This proposed audit and the parallel cohort study (detailed in a separate protocol) will be the first large scale international study to investigate the impact of wound closure and early wound complications on the long term outcomes.

Justification of patient population

There are few prospective studies on variations of practice worldwide. Randomised studies on abdominal wound closure often focus on general and clean or clean-contaminated surgery, in

absence of ostomies. Whether abdominal wound closure strategies can be fully extrapolated to colorectal surgery patients is questionable. This audit will provide data on patients who are infrequently included in randomised studies, such as patients who undergo emergency surgery and dirty surgery. In addition, the study will provide the surgical community with data regarding global heterogeneity in the uptake of various recently proposed innovations including the small bites technique, and prophylactic mesh in colorectal surgery, as well as provide contemporaneous early (30-day) operative outcomes on an unselected population.

Rationale for study design

The prospective audit will result in the generation of a large, international dataset of real-world data on wound closure and SSI prevention practices for patients undergoing abdominal surgery, and enable the first description of the global variability in practice.

A cohort study is planned to run in parallel to the audit in early 2024 and will provide contemporaneously collected data on the impact of wound infection or long term wound failure on patient-reported quality of life. The parallel cohort study will also be the first study to collect and link data on short-term wound healing issues with longer-term wound failure.

This dataset will be used to explore how differences in patients, treatment practices and preventative measures may be associated with different clinical outcomes. They cannot fully control for selection bias and interaction effects; as such, they create hypothesis-generating information rather than true evidence of effect. The data collected as part of this study will be used to inform the design of a future interventional study on abdominal wound closure and SSI incidence in the elective and expedited/emergency general and colorectal surgery patient populations.

AIMS & OBJECTIVES

Primary Audit question:

1. What is the relationship between differing wound closure materials and techniques, with the occurrence of early abdominal wound failure?

Abdominal wound failure includes surgical site infections according to Center for Disease Control classification, surgical site occurrences (which will be described excluding SSI, abdominal wound dehiscence), abdominal wound dehiscence with or without evisceration, and incisional hernia formation. (24) Abdominal wound dehiscence (also referred to as ‘evisceration’ or ‘fascial dehiscence’) is an unintended acute wound failure at the level of the fascia and is a postoperative complication after primary closure of a laparotomy incision. (25) Incisional hernia is an example of late abdominal wound failure, occurring up to 65% in high-risk groups and up

to at least 10 years after surgery (*long term follow-up of the PRIMA trial, accepted for publication in the Lancet.* (26) It was defined by the European Hernia Society as “any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging”. (27, 28)

Further audit questions:

1. What are the rates of early abdominal wound failure?
2. What are the effects of SSI prevention measures on the incidence of early abdominal wound failure?
3. What is the impact of a minimally invasive technique vs. open technique on the incidence of early abdominal wound failure?
4. What is the impact of early abdominal wound failure on the patient?
5. What is the impact of early abdominal wound failure on the duration of postoperative stay and the number of outpatient visits and unscheduled hospital visits?
6. What are the early abdominal wound failure associated costs (eg, hospital/ICU stay, unscheduled hospital visits and patient reported expenses)?
7. Which risk scores will have the highest predictive value for our primary outcomes within this cohort?

Summary of the key objectives

Audit study / Short term:

Assessing the different practices of wound closure and surgical site prevention globally

Assessing the effect of wound closure and surgical site infection prevention practices on the incidence of abdominal wound failure at 30 days.

Key outcome measures

Audit study / short term:

Methods of Wound Closure:

- Types and techniques of fascial, subcutaneous and skin closure
- Incidence and types of mesh use
- Use of SSI Prevention measures
- Incidence of abdominal wound failure at 30 days

- Length of postoperative stay
- Reoperations within 30 days
- 30-day mortality
- SSI diagnosis or management requiring ICU admission
- Unplanned readmissions within 30 days
- Need for interventional radiology procedures within 30 days
- Abdominal wound dehiscence within 30 days
- Clavien Dindo classification at 30 days
- Surgical site occurrences at 30 days

STUDY DESIGN

International prospective audit.

The audit will collect wound closure and SSI prevention measures employed, and short-term clinical outcomes up to 30 days.

Study Timelines

The audit will open to recruitment on 01st November 2023.

All participating centres must recruit for 4 weeks.

A second recruitment window will open on 02nd January 2024.

Participating sites must have started recruitment by 01st March 2024.

The study is planned to close for recruitment on the 31st March 2024.

ELIGIBILITY

Hospital inclusion criteria

Any hospital or surgical unit performing elective and/or emergency abdominal general and colorectal surgery.

Participating sites will be expected to recruit **at least 10 consecutive eligible** patients within a 4-week period.

At hospital level, data completeness of 95% will be required.

Patient eligibility

Inclusion criteria

- Adult patients (age 18 years and above) undergoing general or colorectal surgical procedures
- Elective (planned admission), expedited (within two weeks), or emergency (unplanned admission) surgery.
- General and colorectal procedures using any type of abdominal incision measuring at least 5 cm (including extraction sites).

Exclusion criteria

- Patients undergoing incisional, ventral, umbilical, and inguinal/femoral hernia repair
- Simultaneous hyperthermic intraperitoneal chemotherapy (HIPEC) and/or cytoreductive surgery
- Stoma reversal without additional laparotomy incision

Note: Each individual patient should only be included once. Following the index procedure (i.e. the procedure for study inclusion), patients undergoing additional procedures within the audit window should not be included for a second time. Data on these additional procedures will be captured as part of patient follow-up.

PATIENT IDENTIFICATION

For the audit, all consecutive adult patients who fulfil the eligibility criteria should be included. As this is an international audit, each participating country and hospital will decide how best to identify eligible patients. It is anticipated that potential participants may be identified as described below.

Potential participants may be identified:

- Pre-operatively:
    - Surgical outpatient clinics (e.g. when the patient is being booked for elective surgery)
    - Planned theatre lists (e.g. at the time of admission for surgery)
    - Emergency surgical admissions (e.g. at the time that a decision to operate is made)
- Intra-operatively
    - By operative team
- Post-operatively prior to discharge:
    - By the operating surgeon

**Ideally, potential participants will be identified pre-operatively.

PATIENT CONSENT

We anticipate that most ethics review boards will waive the requirement for patient consent, as only anonymised audit data will be collected. However, there may be variation in international regulations and it will be the responsibility of the local project lead to seek local research ethics committee advice in each participating country to determine whether informed consent should be sought.

DATA COLLECTION

The audit is designed so normal patient follow-up pathways can be utilised to obtain outcomes data. No additional visits or changes to normal follow-up should be made. However, local investigators should be proactive in identifying post-operative events (or lack thereof), within the limits of normal follow-up. These may include reviewing the patient notes (paper and electronic) during admission and before discharge to note in-hospital complications, reviewing hospital systems to check for re-attendances or re-admissions, and reviewing post-operative radiology reports, as well as the notes from the in-person outpatient review which we anticipate will occur within the 30 days post-operation in most circumstances.

Data completion and organisation

As WOLVERINE is an audit no changes to the normal patient pathway need to be instigated for it to be run.

Data Management

Information will be collected at the following times:

Short-term follow-up

- At baseline (surgeon level)
- At 30 days after the operation (surgeon level)

Data will be entered directly onto the secure electronic REDCap database by study collaborators at the participating hospital sites using pseudonymised data.

Site study collaborators will be provided with a paper copy of the eCRF to facilitate data collection. If this is used, they should then transfer data from the paper CRF into the online database (https://www.bistc.redcap.bham.ac.uk). Data management staff will check all incoming data CRFs for completeness, data consistency and compliance with the protocol. If discrepancies or missing data are identified, the data management staff will raise queries with the research team at the participating hospital via the study database.

SCHEDULE OF EVENTS

		Baseline data	After Surgery	30-day follow-up
Clinician reported audit - all patients	Patient information	✓		
	Surgery information		✓	
	Short-term Complications / reinterventions			✓

-

STATISTICAL CONSIDERATIONS

SAMPLE SIZE

Based on feasibility, we assume that each hospital provides data on at least 10 consecutive eligible patients over a 4-week recruitment period in the recruitment period November 1st – December 15th 2023. A second recruitment period will start on January 2nd 2024 until 31st of March 2024. This period will permit another 4 weeks of recruitment (the database will be closed on April 30th 2024). All centers must have started recruitment on the 1st of March 2024.

PROJECTED RECRUITMENT

Based on previous studies, 2,000 patients are expected to take part in the audit study.

ANALYSIS PLAN

Analysis will be performed after data has been cleaned and locked. The analysis will descriptively summarize the types of wound closure and SSI prevention measures, and the primary and secondary clinical outcomes in the audit and cohort study populations.

Upon completion of the data collection, we will examine the distribution of follow-up for all patients to determine its completeness and plan an appropriate course of action regarding statistical analysis, such as the use of complete case analysis with inverse probability of censoring weights or survival analysis methods (e.g., Cox proportional hazards models), if required. We will detail the specifics of these analyses in a statistical analysis plan after examining the empirical distributions of the data in a manner that is agnostic to the relationship between outcomes and treatment/wound closure exposure group.

Selected relevant risk scores for development of surgical site infections, surgical site occurrences, and abdominal wound dehiscence will be compared against the data collected in this study.

Planned additional analyses

A full statistical analysis plan will be published prior to study completion. Example of the analyses will include -

Pre-planned exploratory sub-group analyses of the primary outcome will be performed in the following groups:

At cluster (geographical) level:

Use of wound closure methods for Europe vs. non-Europe

Use of SSI prevention methods for Europe vs. non-Europe

At cluster (hospital) level:

Number of beds (<500 versus ≥500 total hospital beds).

Laparotomy volume (divided into tertiles).

Health service expenditure per capita in purchasing parity (top versus middle versus bottom tertile).

World Bank income group (high versus middle/low income country).

At patient level:

Indication for surgery (malignant versus benign, e.g. inflammatory bowel disease).

Procedure urgency (elective versus expedited/ emergency).

Age (≤65 years versus >65 years, possibly subanalysis for octogenarians).

Clinical Frailty score

National Nosocomial Infections Surveillance (NNIS) score

Operative approach (open versus minimally invasive (laparoscopy/robotic).

Primary operating surgeon experience as reported (trainee versus consultant).

Primary operating surgeon specialism as reported (general versus colorectal surgeon versus emergency surgeon).

Type and method of wound closure at fascial, subcutaneous and skin levels.

Pre-, intra-, and post-operative SSI prevention interventions used

Descriptive summary statistics will be provided for these aforementioned variables, with summaries presented by wound closure technique and other relevant groups. If possible, a separate estimated cost analysis will be performed to calculate the cost burden of SSI using a selection of available variables.

ORGANISATIONAL STRUCTURE AND OVERSIGHT

WOLVERINE AUDIT Office

The coordinating centre for WOLVERINE is based at the University of Birmingham in the Birmingham Centre for Observational and Prospective Studies (BiCOPS). Members of this group also represent the European Society of Coloproctology (ESCP) and sit on both the research committee and cohort studies committee of ESCP.

Local teams

We envisage that most hospitals opening for the audit will identify a team of up to 5 members, which may include surgical colleagues, trainee doctors, nurses, medical students, or others involved in the routine clinical care of eligible patients, depending on local circumstances. Members of this group will be responsible for the local conduct of the audit at their site, including helping to identify potential patients and record data onto the WOLVERINE REDCap database.

ETHICS & CONSENT

Audit study

Only routinely collected data will be collected in the study. Patients will not undergo any additional investigations for the purposes of this study. Clinical follow-up will be limited to review of health records up to a maximum of 30 days postoperatively.

No identifiable data will be collected on the REDCap database; the patient's clinical team will only upload anonymised data. We anticipate that most ethics review boards will waive the requirement for patient consent, as only anonymised audit data will be collected. However, there may be variation in international regulations and it will be the responsibility of local principal investigators to seek local research ethics committee advice in each participating country to determine whether informed consent should be sought.

DATA MANAGEMENT

Data will be collected in two phases. During the index admission, pre-operative and intra-operative data will be collected. Local audit leads will establish pathways in their hospitals to ensure robust data collection; for example, pre-operative data could be collected in the morning prior to surgery, with intra-operative data fields completed in theatre immediately following completion of the procedure. Alternatively, all index data could be collected in theatre, or in the post-operative ward.

Collection of post-discharge follow-up data

Patients who are discharged from hospital early may be more likely to develop a surgical site infection out of hospital and often fail to be noted or registered. A review of the participating patients' clinic visit notes and letters will therefore be mandatory for all participating hospitals. All patients will be followed-up to a maximum of 30-days postoperatively (with Day 0 being the day of surgery) by a review of their inpatient health records, routine clinic visit notes/letters, and reports for postoperative radiological investigations arranged as part of normal patient care. The study is designed efficiently so that existing patient follow-up pathways and health records can be used, with only data that is routinely collected as part of normal clinical care being captured.

DATA HANDLING AND RECORD KEEPING

Data Security and Data Protection

The security of the Study Database System is governed by the policies of the University of Birmingham. The study database will be hosted on the REDCap system managed and maintained by BiCOPS..

Data management and data security within BiCOPS will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. The audit will be conducted at collaborating sites in accordance with the country-specific data protection requirements.

Access to data will be restricted by usernames and passwords, at participating sites. Each participant will be allocated a unique study number at entry. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual will be identifiable.

CONFIDENTIALITY AND DATA PROTECTION

Any correspondence between the WOLVERINE study office and hospital sites will use the anonymous ID code only.

The linkage between the study ID code and participants will be maintained in strict confidence at participating sites. This data will not be submitted to the WOLVERINE study office and will not be sent outside of the participating site.

Confidentiality of all participant's data will be maintained and there will be no disclosure of information by which participants may be identified to any third party other than those directly involved in the treatment of the participant.

Finance

WOLVERINE is an investigator-initiated and investigator-led study. The study has been funded by the ESCP through an unrestricted educational grant received from Ethicon.

PUBLICATION POLICY

The output from this research will be published under a single corporate authorship group: “European Society of Coloproctology (ESCP) collaborating group”, manuscripts and authorships will be separated for those who contributed to the audit study and those who contributed to both the audit AND the cohort study. The following roles will be recognised within the collaborating authorship list: Study Protocol Writing group, Study Management Group, Data Management Committee, Statistical analysis, ESCP Cohort Studies and Audits Committee, ESCP Research Committee, study coordinators, Principal Investigators, co-Principal Investigators, Collaborators.

Specifically each participating hospital may include up to five collaborators for publication(s) regarding the audit study, and up to five (different or identical) collaborators for the (long term follow-up) of the cohort study on the condition that data for at least 10 consecutive patients is entered with at least 95% data completeness: the Principal Investigator; the surgical associate co-Principal Investigator; and three further collaborators supporting study delivery and data collection. An increase in the number of collaborators at a participating hospital is theoretically possible but should be regarded as highly exceptional and prospectively agreed on a case-by-case basis with the Operations Committee. All co-authors will be PubMed searchable and citable.

No hospital-level or surgeon-level data will be published whereby an individual unit or surgeon could be identified. If local investigators would like a breakdown of their own unit’s data for benchmarking purposes and local presentation/discussion, this will be available after the end of the study.

ACCESS TO FINAL DATASET

The ESCP Cohort Studies Working Group welcomes the use of the data for further research that benefits patients. Requests can be submitted to the ESCP Cohort Studies Working Group. Data Sharing is subject to ESCP approval and the appropriate safeguarding as determined by the ESCP. Any future subprojects should also comply with our policy of a single corporate authorship e.g. “European Society of Coloproctology (ESCP) collaborating group. However, authors’ contributions will be highlighted in accordance with the recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals (commonly referred to as the Vancouver Convention) by the International Committee of Medical Journal Editors (ICMJE).

REFERENCES

1. Bhattacharya S. Wound healing through the ages. Vol. 45, Indian Journal of Plastic Surgery. 2012.

2. Nicoli Aldini N, Fini M, Giardino R. From Hippocrates to tissue engineering: Surgical strategies in wound treatment. Vol. 32, World Journal of Surgery. 2008.

3. Pitt D, Aubin JM. Joseph Lister: Father of modern surgery. Vol. 55, Canadian Journal of Surgery. 2012.

4. Hobson DW, Schuh JCL, Zurawski D v., Wang J, Arbabi S, McVean M, et al. The First Cut Is the Deepest: The History and Development of Safe Treatments for Wound Healing and Tissue Repair. International Journal of Toxicology. 2016;35(5).

5. Fink C, Baumann P, Wente MN, Knebel P, Bruckner T, Ulrich A, et al. Incisional hernia rate 3 years after midline laparotomy. British Journal of Surgery. 2014;101(2).

6. Gillion JF, Sanders D, Miserez M, Muysoms F. The economic burden of incisional ventral hernia repair: a multicentric cost analysis. Hernia. 2016;20(6).

7. van Ramshorst GH, Eker HH, van der Voet JA, Jeekel J, Lange JF. Long-term outcome study in patients with abdominal wound dehiscence: a comparative study on quality of life, body image, and incisional hernia. J Gastrointest Surg. 2013 Aug;17(8).

8. van Ramshorst GH, Eker HH, Hop WC, Jeekel J, Lange JF. Impact of incisional hernia on health-related quality of life and body image: a prospective cohort study. Am J Surg. 2012;204(2).

9. Jason S Mizell. Principles of abdominal wall closure - UpToDate. UpToDate. 2019.

10. Macefield RC, Reeves BC, Milne TK, Nicholson A, Blencowe NS, Calvert M, et al. Development of a single, practical measure of surgical site infection (SSI) for patient report or observer completion. Journal of Infection Prevention. 2017;18(4).

11. Riou JPA, Cohen JR, Johnson H. Factors influencing wound dehiscence. The American Journal of Surgery. 1992;163(3).

12. Watanabe A, Kohnoe S, Shimabukuro R, Yamanaka T, Iso Y, Baba H, et al. Risk factors associated with surgical site infection in upper and lower gastrointestinal surgery. Surgery Today. 2008;38(5).

13. Goltsman D, Munabi NCO, Ascherman JA. The Association between Smoking and Plastic Surgery Outcomes in 40,465 Patients: An Analysis of the American College of Surgeons National Surgical Quality Improvement Program Data Sets. Plastic and Reconstructive Surgery. 2017;139(2).

14. Nerlekar H v., Kshirsagar AY, Reddy MP. Assessment of various factors influencing wound infection following abdominal surgery- A clinical study. Vol. 7, Journal of Critical Reviews. 2020.

15. Mäkelä JT, Kiviniemi H, Juvonen T, Laitinen S. Factors influencing wound dehiscence after midline laparotomy. The American Journal of Surgery. 1995;170(4).

16. Markel TA, Lou DC, Pfefferkorn M, Scherer LR, West K, Rouse T, et al. Steroids and poor nutrition are associated with infectious wound complications in children undergoing first stage procedures for ulcerative colitis. Surgery. 2008;144(4).

17. Hall C, Regner J, Abernathy S, Isbell C, Isbell T, Kurek S, et al. Surgical Site Infection after Primary Closure of High-Risk Surgical Wounds in Emergency General Surgery Laparotomy and Closed Negative-Pressure Wound Therapy. J Am Coll Surg. 2019;228(4).

18.
https://www.who.int/publications/i/item/global-guidelines-for-the-prevention-of-surgical-site-infection-2nd-ed

19. Deerenberg EB, Harlaar JJ, Steyerberg EW, Lont HE, van Doorn HC, Heisterkamp J, et al. Small bites versus large bites for closure of abdominal midline incisions (STITCH): A double-blind, multicentre, randomised controlled trial. The Lancet. 2015;386(10000).

20. Jairam AP, Timmermans L, Eker HH, Pierik REGJM, van Klaveren D, Steyerberg EW, et al. Prevention of incisional hernia with prophylactic onlay and sublay mesh reinforcement versus primary suture only in midline laparotomies (PRIMA): 2-year follow-up of a multicentre, double-blind, randomised controlled trial. The Lancet. 2017;390(10094).

21. Atema JJ, Gans SL, Boermeester MA. Systematic review and meta-analysis of the open abdomen and temporary abdominal closure techniques in non-trauma patients. World J Surg 2015 Apr;39(4):912-25.

22. Muysoms FE, Antoniou SA, Bury K, Campanelli G, Conze J, Cuccurullo D, de Beaux AC, Deerenberg EB, East B, Fortelny RH, Gillian J-F, Henriksen NA, Israelsson L, Jairam A, Janes A, Jeekel J , Lopez-Cano M, Miserez M, Morales-Conde S, Sanders DL, Simons MP, Smietanski M, Venclauskas L, Berrevoet F; European Hernia Society. European Hernia Society guidelines on the closure of abdominal wall incisions. Hernia 2015 Feb;19(1):1-24.

23.Chowdhury S, El-Hussuna A, Gallo G, Keatley J, Kelly ME, Minaya-Bravo A, Ovington L, Pata F, Pellino G, Pinkney T, Sanchez Guillen L, Schmitz ND, Spychaj K, Riess C, van Ramshorst GH; 2021 European Society of Coloproctology (ESCP) collaborating group. An international assessment of surgeon practices in abdominal wound closure and surgical site infection prevention by the European Society for Coloproctology. Colorectal Dis. 2023 May;25(5):1014-1025. doi: 10.1111/codi.16500. Epub 2023 Mar 31. PMID: 36747373.

24. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol 1992 Oct;13(10):606-8.

25. Lopez-Cano M et al, EHS clinical guidelines on the management of the abdominal wall in the context of the open or burst abdomen. Hernia. 2018 Dec;22(6):921-939.

26. Burger JWA, Luijendijk RW, Hop WCJ, Halm JA, Verdaasdonk EGG, Jeekel J. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg. 2004 Oct;240(4). discussion 583-5. doi: 10.1097/01.sla.0000141193.08524.e7.

27. Korenkov M, Paul A, Sauerland S et al. Classification and surgical treatment of incisional hernia. Results of an experts' meeting. Langenbecks Arch Surg 2001:386(1):65–73.

28. Muysoms FE, Miserez M, Berrevoet F et al. Classification of primary and incisional abdominal wall hernias. Hernia 2009:13(4):407–414.

29. Kanters AE, Krpata DM, Blatnik JA, Novitsky YM, Rosen MJ. Modified hernia grading scale to stratify surgical site occurrence after open ventral hernia repairs. J Am Coll Surg 2012: 215:787–793