Assessment of a Device for Standardized Laparotomy Closure

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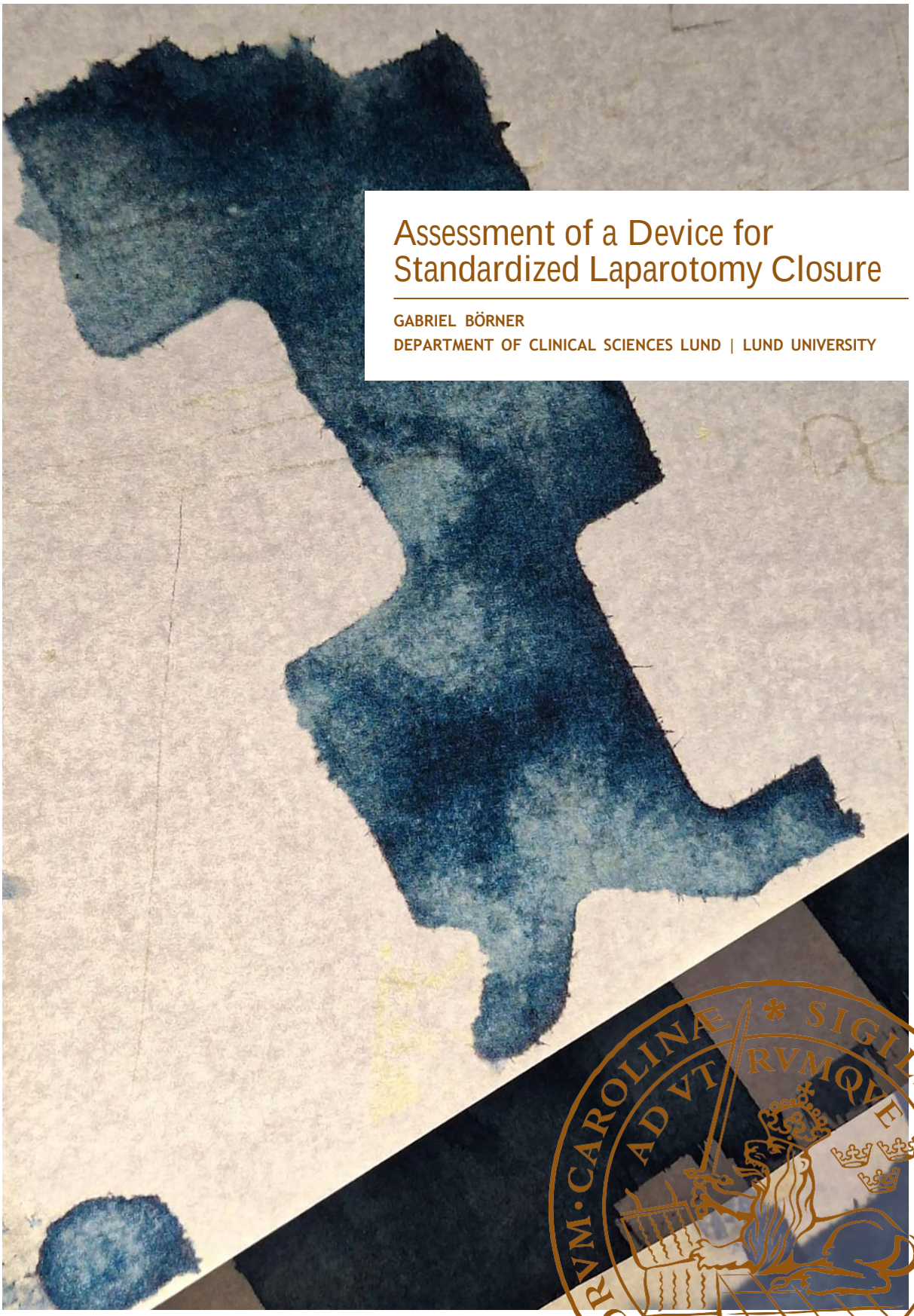

Assessment of a Device for Standardized Laparotomy Closure

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DOCTORAL DISSERTATION

Doctoral dissertation for the degree of Doctor of Philosophy (PhD) at the Faculty of Medicine at Lund University to be publicly defended on the October 3rd, 2025 13:00 at the Museum of Medical History (Medicinhistoriska museet), Helsingborg

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Introduction Common complications after surgical procedures include surgical site infection, wound rupture and incisional hernia. Wound healing can be influenced by the technique for abdominal access and closure. A Suture-Length to Wound-Length (SL/WLr) ratio ≥ 4 is advised to achieve a high-quality wound closure. This thesis describes the background and clinical realities of abdominal wall related complications as well as the development process and results from the evaluation of a novel device for standardized laparotomy closure. The aim was to assess the device from a technical, clinical and a health economy perspective.

Method SutureTOOL is a handheld single use suture applicator with the purpose of facilitating best practise for wound closure by applying a to SL/WLr ≥ 4. It was developed by the author and a MedTech team associated with Lund University and evaluated in experimental, clinical and health economy models.

Study I: Ten surgeons performed incision closures on an elk fascia model comparing SutureTOOL to NDS concerning adherence to SL/WLr 4. This was achieved in 98% for SutureTOOL and 30% for NDS. Closure time was 30% shorter when using the SutureTOOL.

Study II: Fifteen surgeons performed incision fascial closures comparing Suture TOOL to NDS in a human autopsy model. Adherence to SL/WLr of 4 was 95% for SutureTOOL and 69% for NDS. Closure time was 30% shorter when using the SutureTOOL. 12

Study III: Twenty-five surgeons and ten nurses performed needle pull-throughs in an incisional lamb-leather model comparing SutureTOOL and two different sizes of curved suture needles for needle pull-through time, medial traction and forceps force. SutureTOOL was faster and resulted in less forceps force. Study IV: Five colorectal surgeons performed laparotomy closures with SutureTOOL in a single arm study on 38 colorectal patients. The primary endpoint was adherence to SL/WLr of ≥4. Secondary endpoints included closure time and surgical site infections. All patients received a SL/WLr of at least 4. Mean closure time was 7.4 min and the shortest closure time was 2.2 min. One SSI was detected and no patient suffered from wound dehiscence.

Study V: The aim of the study was to compare the economic and clinical outcomes of laparotomy closure for patients using manual needle-driver suturing compared to SutureTOOL from a healthcare perspective in Sweden, France, UK and US. A decision tree model was developed to implement the analysis. The SutureTOOL was found to be cost-effective, reducing costs between 22% and 40% across country contexts. Savings were associated with reduced post-operative complications and reductions in operating room time.

Conclusion: Wound infection and incisional hernia are common complications to abdominal surgery. These complications can be reduced by adhering to a standardized high quality closure technique. However, even though guidelines exist, they have been difficult to implement in clinical practice. The thesis showed a high adherence to SL/WLr of 4 for SutureTOOL, performed with consistent quality and faster compared to needle-driver suturing. Suture-TOOL has the potential to reduce wound complications and would be a cost-effective intervention.

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To the Börners and the Ribbes

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Foreword

During my surgical residency, a common procedure during calls was reoperation due to wound dehiscence. In 2009, colorectal surgeon Leif Israelsson, held a fascinating lecture at my department scientific Monday meeting. He concluded that abdominal wall complications after laparotomy can be reduced if a meticulous closure technique is applied. The incision should be closed with many small stitches and with a short stitch interval. This was achieved by using a small suture needle and the suture line length should be at least four times the length of the incision. In addition, as quality control, the suture-length to the wound-length ratio should be calculated and the incision should be re-sutured if the ratio was under 4.

I believe that most colleagues found the technique cumbersome but, to some surprise, the implementation was fast, and the department has since then adhered to the technique - in a rare example of a quick uptake of a novel technique for patient safety.

The technique is now popularized as the small-bites closure technique and is advocated by several surgical societies. Unfortunately, wider uptake has been slow. Even though minimal invasive surgical techniques are common, many abdominal surgeries are performed via laparotomy and there is a pressing clinical need to make this procedure safer.

Israelsson's lecture that Monday night, sparked an idea to develop a device that could facilitate the small-bites closure technique. MedTech development is challenging. I often think that it is amazing that any idea manages to stumble across the dense forest of obstacles and become available to surgeons. Someone said that it takes 17 years for a MedTech idea to navigate to the market and the SutureTOOL system hit the market 16 years after that Monday meeting. The project has been occupying my brain with alternating intensity to much satisfaction, happiness, frustration and some despair. The list of people who have been supportive in a myriad of different ways is long as a November rain. Thank you! The project has given me an understanding of funding, MedTech development and has left me with a large and inspiring network of bright minds across the globe.

Original papers

1. Börner G, Montgomery A. Suture-Tool: A Mechanical Needle Driver for Standardized Wound Closure. World J Surg. 2020 Jan;44(1):95-99.

2. Börner G, Edelhamre M, Rogmark P, Montgomery A. Suture-TOOL: A suturing device for swift and standardized abdominal aponeurosis closure. Surg Pract Sci. 2022 Oct 5;11.

3. Börner G, Lööf E, Rogmark P, Edelhamre M. Tissue kindness: a comparison of tissue handling forces between a novel suturing device for standardized abdominal wall closure and manual needle-driver suturing. Submitted.

4. Börner G, Toft L, Rogmark P, Edelhamre M. A feasibility and safety trial investigating a device for swift and standardized median laparotomy closure. Hernia. 2025 Jun 3;29(1):196.

5. Lwin ZMT, Börner G, Verheij-Engqvist S, Keel G. A literature-based cost-effectiveness analysis of device-assisted suturing versus needle-driven suturing during laparotomy closure. Hernia. 2025 Jan 23;29(1):77.

Abbreviations

AB	Abdominal Binders
AHS	American Hernia Society
ANOVA	Analysis of Variance
CRO	Contract Research Organization
CRS	Cytoreductive Surgery
ECDC	European Centre for Disease Prevention and Control
EHS	European Hernia Society
Eto	Ethylene Oxide
g	Grams
HIPEC	Hyperthermic Intraperitoneal Chemotherapy
IFU	Instructions for Use
ISO	International Organization for Standardization
kg	Kilograms
LB	Large-bites
LF	Life Years
LN	Large Needle
MDR	Medical Device Regulation
MIS	Minimal Invasive Surgery
N	Newton
NDS	Needle-driver Suturing
OECD	Organisation for Economic Cooperation and Development
PAP	Preoperative Prophylaxis
PDO	Polydioxanone
PMCF	Post-market Clinical Follow-up
PMS	Post-market Surveillance
QUALY	Quality Adjusted Life Years
RTL	Reinforcement Suture Line
SB	Small-bites
SL/WLr	Suture-Length to Wound-Length ratio
SN	Small Needle
SSI	Surgical Site Infection
SWD	Surgical Wound Dehiscence
VAS	Visual Analogue Scale
WL	Wound Length

Abstract

Introduction

Common complications after surgical procedures include surgical site infection, wound rupture and incisional hernia. Wound healing can be influenced by the technique for abdominal access and closure. A Suture-Length to Wound-Length (SL/WLr) ratio ≥ 4 is advised to achieve a high-quality wound closure. This thesis describes the background and clinical realities of abdominal wall related complications as well as the development process and results from evaluating a novel device for standardized laparotomy closure. The aim was to assess the device from a technical, clinical and a health economy perspective.

Methods

SutureTOOL is a handheld single use suture applicator with the purpose of facilitating best practise for laparotomy closure by applying a to SL/WLr ≥ 4.
It was developed by the author and a MedTech team associated with Lund University and evaluated in experimental, clinical and health economy models.

Results

Study I: Ten surgeons performed incision closures on an elk fascia model comparing SutureTOOL to NDS concerning adherence to SL/WLr of 4. This was achieved in 98% for SutureTOOL and 30% for NDS. Closure time was 30% shorter when using the SutureTOOL.

Study II: Fifteen surgeons performed incision fascial closures comparing Suture-TOOL to NDS in a human body model. Adherence to SL/WLr of 4 was 95% for SutureTOOL and 69% for NDS. Closure time was 30% shorter when using the SutureTOOL.

Study III: Twenty-five surgeons and ten nurses performed needle pull-throughs in an incisional lamb-leather model comparing SutureTOOL and two different sizes of

curved suture needles for needle pull-through time, medial traction and forceps force. SutureTOOL was faster and resulted in less forceps force.

Study IV: Five colorectal surgeons performed laparotomy closures with SutureTOOL in a single arm study on 38 colorectal patients. The primary endpoint was adherence to SL/WLr of ≥4. Secondary endpoints included closure time and surgical site infections. All patients received a SL/WLr of at least 4. Mean closure time was 7.4 min and the shortest closure time was 2.2 min. One SSI was detected and no patient suffered from wound dehiscence.

Study V: The aim of the study was to compare the economic and clinical outcomes of laparotomy closure for patients using manual needle-driver suturing compared to SutureTOOL from a healthcare perspective in Sweden, France, UK and US. A decision tree model was developed to implement the analysis. The SutureTOOL was found to be cost-effective, reducing costs between 22% and 40% across country contexts. Savings were associated with reduced post-operative complications and reductions in operating room time.

Conclusion

Wound infection and incisional hernia are common complications to abdominal surgery. These complications can be reduced by adhering to a standardized high quality closure technique. However, even though guidelines exist, they have been difficult to implement in clinical practice. The thesis showed a high adherence to SL/WLr of 4 for SutureTOOL, performed with consistent quality and faster compared to needle-driver suturing. Suture-TOOL has the potential to reduce wound complications and would be a cost-effective intervention.

Overall aim of the thesis

Abdominal wall complications after open surgery include wound dehiscence, surgical site infection and incisional hernia and implies suffering for patients and a heavy financial burden on the health systems and society. There is a strong clinical need to prevent complications instead of treating them. The closure technique used for abdominal wall closure impacts the rate of complications and several surgical societies advocate the use of small-bites to reduce these complications. However, the compliance is slow, and many surgeons are unaware of this opportunity for disease prevention.

The overall aim of the thesis was to describe the clinical conditions and opportunities to mitigate complications related to abdominal wall closure and to describe the development process of a novel device for standardized abdominal wall closure. The thesis specifically evaluates the device from technical, clinical and health economy perspectives in different models.

Thesis at a glance

Paper	Aim	Method	Results
I. (2020) Suture-Tool: A Mechanical Needle Driver for Standardized Wound Closure	Establish proof-of-concept	Experimental study with an animal tissue model comparing device suturing to conventional needle driver suturing (NDS). Outcome measures included SL/WLr, number of stitches and suture time.	SL/WLr ≥4 was achieved in 95% using the device and 30% using NDS. Stitch-count was similar. Suture time was 30% shorter using the device compared to NDS.
II. (2022) Suture-TOOL: A suturing device for swift and standardized abdominal aponeurosis closure	Compare device suturing to NDS in a human body model	Experimental study in a human body model. Outcome measures included SL/WLr, number of stitches, suture time and glove puncture assessment.	SL/WLr ≥4 was 98% for the device and 69% for NDS. Suture time was shorter for the device. Stitch count was higher for NDS. Two glove punctures were detected—both in the NDS group.
III. Submitted Tissue kindness: a comparison of tissue handling forces between a novel suturing device for standardized abdominal wall closure and manual needle-driver suturing	Compare suturing forces using device suturing or NDS	Experimental study in a dry model assessing suturing forces and needle pull-through time for suturing with the device and curved needles.	Less forceps pressure force was detected with the device and a shorter needle-pull through time. Less medial traction force was found using the device and the small curved needle.
IV. (2025) A feasibility and safety trial investigating a device for swift and standardized median laparotomy closure	Perform a safety and performance assessment of the device	A clinical study assessing laparotomy closures with the device. Outcomes included SL/WLr number of stitches, suture time, glove puncture and short time complications.	All patients achieved the primary endpoint SL/WLr ≥4. The mean net closure time 7.4 min. The shortest NCT recorded was 2.2 min. One case of SSI was reported, and no burst abdomen was detected.
V. (2025) A literature-based cost-effectiveness analysis of device-assisted suturing versus needle-driven suturing during laparotomy closure	Perform a health economy assessment	A decision tree model was developed to perform a cost-effectiveness analysis comparing device suturing to NDS in four markets.	Device suturing was found to be cost-effective, reducing costs between 22% and 40% across country contexts.

Background

The discussion on optimal laparotomy closure dates from the early days of abdominal surgery. Chicago surgeon BB Eads stated in 1901 that “I believe that 15 per cent of all patients upon whom laparotomy has been performed, if examined five years or more thereafter, will be found to be suffering from post-operative hernia. I am convinced that this percentage is too low; yet it is sufficiently high to make the subject one of vital importance to every physician and surgeon.” [1].

Laparotomy is associated with abdominal wall complications such as wound infection, wound dehiscence and incisional hernia formation that can be reduced if small-bites laparotomy closure technique with 5-8 mm bites and a step interval of 5 mm is utilized [2-4].

Even though the recommendations are advocated in guidelines for both elective and emergency surgery this opportunity for surgeons to reduce abdominal wall complications receives low attention.

Access to the abdominal cavity and laparotomy

The word laparotomy comes from the Greek word “lapara” meaning the soft part between the ribs and hip, and the Greek word “tome” which means cut. Laparotomy thus means the surgical incision of the abdominal wall.

Short background to the laparotomy procedure

An early documented, and successful, laparotomy case was performed by Ephraim McDowell of Kentucky (1771–1830) in 1809 [5]. He was called to a 45-year-old lady to assist in the presumed delivery of twins. McDowell realized that the woman was not pregnant but was suffering from a large ovarian tumor and offered to remove the tumor as an “experiment”. The 10-kilogram heavy tumor was removed during a 25-minute-long operation without anaesthesia. The patient survived the procedure and died 32 years later. The French military surgeon, Jean Baptiste Lucien Baudens (1805–1857), acquired his experience in abdominal surgery during six years of deployment in a mobile field hospital caring for thousands of injured soldiers in Algeria [6]. Baudens treated abdominal trauma with

debridement, wound dressings and morphine with dire results, but after performing numerous autopsies, he identified visceral perforation as a common cause of death. He subsequently performed, to some success, two cases of trauma laparotomy in 1831 including bowel resection and anastomosis.

Open abdominal surgery

The annual global burden of laparotomy is counted in millions of procedures. In the US, two million patients undergo laparotomy annually and in the UK 30 000 patients undergo emergency laparotomy [7]. Abdominal procedures can be performed via open, minimal invasive (MIS) or endoscopic approaches. The method should provide optimal access to perform the planned surgical procedure while preserving function, cosmesis, and promote healing [8]. If access to the entire abdominal cavity is necessary, e.g. in trauma surgery, the midline incision is preferred. If the incision is placed correctly, it will enter the abdomen through the avascular linea alba avoiding the rectus muscle compartments. If the point of disease is the liver or biliary tree a Kocher or subcostal incision may be warranted. For cesarean section or extraction of the specimen in MIS, the Pfannenstiel incision is frequently used, which is a horizontal incision just above the pubic bone. The dissection is placed down to the anterior rectus sheath, which is divided horizontally, and the rectus muscles are sheared in the cranial-caudal direction to avoid splitting the muscles.

According to the World Health Organization, caesarean section accounts for roughly 1/3 of open abdominal surgery cases and global rates have risen from around 7% in 1990 to 21% and estimates to reach 29% by 2030 [9]. Several additional factors influence the choice of incision: patient habitus, complexity of the disease, availability of an assistant, the training and preference of the surgeon. A large proportion of procedures in the abdominal cavity will continue to require open access such as cytoreductive surgery (CRS) with or without hyperthermic intraperitoneal chemotherapy (HIPEC) for advanced cancer, speedy bleeding control in the exsanguinating trauma patient and procedures for bowel perforation or obstruction [10-12].

Minimal invasive surgery

Laparotomy and MIS rates are difficult to assess, but the trend in Sweden has been a steady increase for MIS in elective colon cancer resection and reached 70% in 2023 (figure 1a). Notably, the percentage of postoperative complications seems to be unaffected by the implementation of MIS (figure 1b). According to the Swedish National Quality Register for Bladder and Urinary Tract Cancer report from 2023, the number of patients undergoing cystectomy with MIS increased from 40% in 2020 to 60% in 2023.

Additionally, there has been reported an 8–24% conversion rate from MIS to open surgery in bowel surgery [13, 14]. For patients who undergo MIS procedures the extraction site is up to 10 cm which is essentially a laparotomy with complications like wound infection, 16.7%, and incisional hernia formation, 12.6% [15, 16].

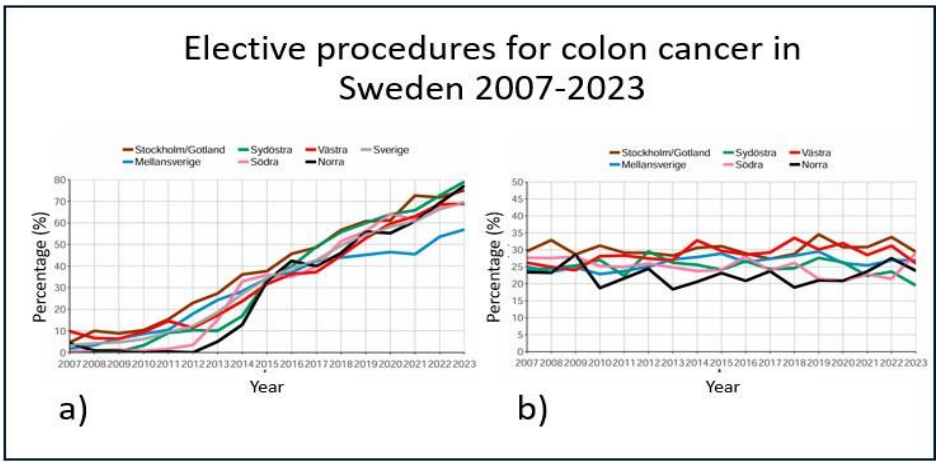

Figure 1. Figure shows a) development of minimal invasive procedures for elective colon cancer resections in the 6 Swedish regions from 2007 to 2023, and b) post-operative complications during the same years. Figures from the National Quality Report from 2023 used with permission from the Swedish Colorectal Cancer Registry.

Sharp injury

The three most common situations when sharp injuries occur are waste disposal, injections and suturing. The operating room is the second most common space for injuries [17]. Suturing is an indispensable activity in most surgical procedures. Suturing with needle driver and the semi-circular needle have an inherent risk of sharp injury probably because surgeons tend to manipulate the needle with their fingers [18].

Reporting sharp injury

Sharp injuries imply exposure to blood-borne agents and there is an issue of underreporting [19]. In a study assessing barriers of needlestick injuries reporting among surgeons, only 19% stated that they had reported all injuries and most

common reasons for not reporting was that it was too time consuming and that they appreciated the risk for transmission as low [20]. In a Swiss study from 2012, 59.5% of hospital doctors reported all sharp injuries, but there was an inverse relationship between the number of exposures and reporting, and among respondents that sustained three or more exposures, complete reporting was only 11.2% [21].

Transfer of blood-borne disease

Over 50% of intraoperative sharp injuries are due to surgical needles and the risk for a sharp injury increases with 22% per hour of operating time [22]. A majority of surgical glove perforations occur in general surgery during closure of the laparotomy wound [23]. The risk of acquiring a blood-borne disease is related to the amount of blood that is transferred during the exposure [24]. The actual risk for transferring a blood-borne disease is hard to estimate, but according to Royal Australian College of General Practitioners guidelines, the risk of transmitting a blood-borne virus from an untreated infected healthcare worker to a patient has been reported as 0.2%–13.2% for hepatitis B virus, 0.04%–4.35% for hepatitis C virus, and $2.4x10^{-6}$–$24x10^{-6}$ % for HIV. The risk of transmission from an untreated infected patient to a healthcare worker during an exposure episode has been reported to 1%–62% for hepatitis B, 0%–7% for hepatitis C, and 0.3% for HIV infection [25]. The cost for an accidental injury was estimated in 2004 to be €375 and included determination of serological status of the patient and the exposed worker, post-exposure prophylaxis and postoperative serological monitoring of the worker [26].

Regulations on sharp injuries

In the European Union there is a law since 2013 (Council Directive 2010/32/EU of 10 May 2010) which states that unnecessary use of sharp devices should be eliminated by implementing changes in practice and medical devices incorporating safety-engineered protection mechanisms shall be provided to the worker [27]. In the US, sharp protection is regulated under H.R.5178 – Needlestick Safety and Prevention Act [28]. It requires, among other things, employers to review and update exposure control plans and to consider implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. Some preventive measures are described. Double gloving reduces the perforation of the inner glove by up to 71% [29]. Blunt needles and the use of trays for passing sharp objects also reduce the risk for sharp injuries [30].

Abdominal wall complications

Laparotomy is associated with abdominal wall complications such as SSI, wound dehiscence and incisional hernia formation.

SSI

SSI occurs during the first 30 days after the index operation. United States Centers for Disease Control (CDC) has defined SSI as an infection in the part of the body where a surgery took place [31].
SSIs are classified as:

- superficial, involving only skin and subcutaneous tissue of the incision
- deep involves deep soft tissues of the incision (for example, fascial and muscle layers)

or

- involving the organ or space where the surgical treatment took place (deeper than the fascia or muscle)

To be classified as a SSI, the event should be of clinical significance, e.g. show purulent drainage or be deliberately opened by a physician, have a positive microbiological testing, and fever or localized pain and tenderness, or an abscess detected on gross anatomical examination or imaging. The first two SSI categories are related to abdominal wall closure. In lower gastrointestinal procedures, 60% of postoperative infections are superficial or deep SSI, 20% pneumonia and the remaining from urinary tract or the blood stream [32]. The incidence of SSI varies between different sources and might be underestimated. The European Centre for Disease Prevention and Control (ECDC) collects data on SSI in 9 index operations and reports 6.3% SSI in laparoscopic colon surgery and 9.6% in open colon surgery SSI [33]. In two randomized clinical trials investigating effects of different laparotomy closure techniques after major elective surgeries, the SSI rates were 21–24% (STITCH trial) and 7.7–13.2% (HART collaborative) [2, 34].

Risk factors for SSI

The risk for developing SSI is related to patient and procedure factors. Patient-related factors include male sex, higher age, smoking, diabetes and body mass index (BMI) >25 kg/m^2 [35]. Procedure related risks for SSI include emergency procedure and grade of contamination [35]. Operative time is also a risk factor for SSI and increases after three hours in colorectal surgery [36]. In laparoscopic surgery the choice of extraction site influences the risk for SSI. The risk for SSI is

3.3% if the specimen is extracted through a right or left transversal incision and 11% if the specimen is extracted through a Pfannenstiel incision [37]. ECDC performed a systematic review in 2013 and suggests that perioperative antibiotic prophylaxis (PAP) should be administrated 60 minutes prior to start of the procedure, assigning responsibility for timely administration of PAP to the anaesthesiologist, administering only a single dose of PAP and to discontinue PAP at the end of surgery [38].

A metaanalysis from 2016 showed that administration of PAP more than 120 minutes prior to, or after the incision is placed was associated with higher risk of SSI [39]. To extend the prophylaxis 24 hours prior to colon surgery has been shown to reduce SSI from 11% to 5% in a randomized trial with predominantly laparoscopic procedures [40]. To prevent SSI, an initiative to identify intraoperative measures for SSI prevention a Delphi panel including colorectal surgeons from the US and Europe was formed which recommend to avoid the midline incision, to use wound protectors and wound irrigation with aqueous iodine, pre-closure glove changes, triclosan coated sutures and closed-incision negative pressure wound therapy in high-risk, contaminated surgery [41].

Surgical wound dehiscence

Surgical wound dehiscence (SWD) is defined by World Union of Wound Healing Societies as the "separation of the margins of a closed surgical incision that has been made in skin, with or without exposure or protrusion of underlying tissue, organs or implants. Separation may occur in single or multiple regions, or involve the full length of the incision, and may affect some or all tissue layers. A dehisced incision may, or may not, display clinical signs and symptoms of infection." [42]. SWD typically occurs during the first two weeks after the index operation. SWD can be graded as:

- Dermal layer only involved, no visible subcutaneous fat
- Subcutaneous layer exposed; no fascia visible
- Subcutaneous layer and fascia exposed
- Fascial dehiscence with organ space, viscera, implant or bone exposed

SWD is also called burst abdomen or wound rupture when a complete opening of the wound exists with or without evisceration of abdominal content [43]. The incidence of complete SWD after laparotomy is 2.9% to 6.9%, and all grades of SWD was 40% in a cohort with 80% emergency cases [44-48]. SWD carries a high postoperative mortality rate (22%) and a reduced 5 years survival rate from 53.4% to 42.4% in patients undergoing elective treatment for colorectal cancer [45, 46]. In a prospective study with 82 patients developing SWD after laparotomy (82 patients after emergency surgery and 7 after elective surgery), all but 12 patients were re-

sutured, 28 patients developed incisional hernia over a period of 3 to 21 months and 23 patients died [49].

Risk factors for SWD

Risk factors for SWD include male sex, age >70 years, BMI >30, comorbidities such as chronic pulmonary disease, and generalized inflammatory disease and operating time >180 minutes [44].

Incisional hernia

According to European Hernia Society Classification of primary and incisional abdominal wall hernias from 2009, incisional hernia is “Any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging” [50]. A uniform classification is necessary to compare studies on incisional hernia formation. There is a steadily increasing body of scientific evidence on the topic of incisional hernia which might reflect its position as an important clinical challenge. In June 2025 6 135 publications were retrieved in PubMed with the search term “incisional hernia”.

A short background on incisional hernia

The first incisional hernia repair was documented by the French surgeon Pierre Nichollas Gerdy in 1836 and the first classification to differentiate primary and incisional hernias was made by another French surgeon, Edouard Quenu in 1896 [51]. Even though many publications on the topic of incisional hernia were previously published, the first paper with this search term was published by Norman S. Rothshild in 1935 [52]. It refers to incisional hernia treatment methods with pedicled flaps from the chest wall or bridging the defect with transfer of tensor fascia femoris. The paper describes two successful cases for treatment of recurrent incisional hernia with a novel method which use lateral incision in the anterior rectus sheath that allows for approximation of the fascia edges to cover the hernia. Most notably the author identified the factors for incisional hernia formation that is still valid and perhaps underestimated today: ”1) Prolonged drainage from the abdominal cavity. 2) Extensive infection of the wound. 3) Incomplete suturing of the peritoneum and the fascia, and the suturing of the fascia under undue tension.”

Incidence of incisional hernia

Incisional hernia can start to form as early as the first month after surgery and the risk of undergoing incisional hernia repair continues at least over the following decade. In a Dutch retrospective study, 64 patients who had a CT scan performed

within one month after a laparotomy, were identified and among them, 25 patients were diagnosed with early incisional hernia [53]. Several studies have assessed incisional hernia over time. In the randomized HART collaborative trial, 14.1%–17.1% of patients were diagnosed with incisional hernia by clinical examination 1 year after laparotomy, and 31% after two years [34]. Interestingly, in a subgroup of patients who underwent CT-scan for other reasons which included half of all patients, the 1-year incisional hernia rate was 47%. In a large observational study, including 297 134 patients undergoing abdominal surgery, the highest risk for incisional hernia repair was detected in colorectal patients, 10.0%, followed by hepatobiliary, 8.2%, and transplant patients, 6.8% [54]. Most patients underwent incisional hernia repair after one-year, median time to repair was 24 months, but patients underwent repair even at 96 months. In a retrospective analysis of HPB-patients, the incidence of incisional hernia diagnoses by CT scan continued to accumulate during the 96 months follow-up [55]. In a study with patients undergoing laparotomy due to combat trauma, incisional hernia rates were 10% at one year, 13.7% at two years and 19.1% after three years [56].

In retrospective studies incisional hernias are often identified by the frequency of incisional hernia repairs, but in randomized trials it is often the primary endpoint when comparing different abdominal wall closure techniques. In a retrospective study with 17 717 patients undergoing colon cancer resection between 2007 and 2016 Jensen et al. found a five year cumulated 4% incisional hernia repair after colorectal surgery [57]. Walming et al. identified 7.4% incisional hernia in 1 029 patients with unspecified method of fascia closure, furthermore they found that 43.8% of these patients underwent incisional hernia repair [58]. Tuttle et al. investigated incisional hernia formation after HIPEC surgery and found that 17% of the patients developed incisional hernia, median time of diagnosis was 245 days, and 38% of the patients underwent repair [59].

The incidence or risk of incisional hernia formation can be difficult to assess as it depends on the definition of incisional hernia, method of detection and time to follow-up.

Risk factors for incisional hernia formation

Risk factors for incisional hernia formation can be classified as pre-operative, peri-operative or post-operative, and are both patient and surgeon related. Identifying risk factors should be an important part of the responsible surgeon's pre-operative work-up and included in the decision making through the patient's clinical pathway.

Pre-operative risk factors

Pre-operative risk factors include age, male sex, BMI >25, ASA >II and comorbidities like hypertension, COPD and diabetes mellitus [60]. Malignant

indication for the surgical procedure and pre-operative chemotherapy increase the risk for incisional hernia formation [60]. In a study by Baucum et al. assessing the incisional hernia development in 491 patients with intraabdominal malignancies, 43% of patients undergoing open procedures were diagnosed with incisional hernia compared to 30% after urologic or gynaecologic cancer diagnosed by reviewing CT scans [61].

Biologic factors of the patient has been postulated to increase the risk for hernia formation, herniosis [62]. In 1967 the British-American surgeon Raymond Read operated on a 27-year-old, male patient, that had a direct groin hernia [63]. The patient lacked obvious risk factors for herniation and Read asked himself if the patient could have some unknown connective-tissue disorder. He started to assess samples of the rectus sheath from patients undergoing herniorrhaphy with direct defects and controls and found that patients with direct defects had a decrease in hydroxyproline. Additionally, he found that fibroblasts from patients with direct hernias proliferated poorly and drew the conclusion that these patients had a systemic disease with abnormal collagen. The fibroblasts play a crucial role in all stages of the wound healing process that includes inflammation, proliferation, and, finally, remodelling [64]. For instance, in diabetic patients, the fibroblasts produce deficient chemokines, which results in delayed macrophage recruitment, and partly explain why diabetic patients develop ulcers [65]. Previous surgical procedures at the site for incision increase the risk for developing incisional hernia.

Women undergoing caesarean section generally have a low risk for incisional hernia formation at 0.2% to 0.5% but the risk increases after repeat caesarean section to 3.1% to 5.6% [66]. Another risk factor for incisional hernia is a pre-existing hernia at the site for incision. In a study by Nilsson et al. that analysed patients undergoing open surgery for liver metastasis, the overall incisional hernia rate was 30.5% but in a subgroup of patients with previous incisional hernia the rate reached 70% [67].

Intra-operative risk factors

Intraoperative risk-factors for incisional hernia formation include if the procedure is emergent, the grade of contamination of the wound, the indication for performing the procedure, intra-operative blood transfusion, wound length and type of incision[60]. In a study on patients undergoing laparotomy due to peritonitis, 54.3% had developed incisional hernia after six years [68].

Surprisingly, the risk for incisional hernia repair has been reported to be similar in open and laparoscopic colorectal surgery [69]. In a study with 1 231 patients included in the Swedish Colorectal Cancer Registry between 2012 and 2016, 319 (25.9%) patients were detected with incisional hernia by CT scan at one-year follow-up and there were no difference between patients undergoing MIS or open surgery [70]. Additionally, authors identified a 45% incisional hernia rate among patients that underwent conversion from MIS to open surgery.

Cytoreductive surgery CRS and hyperthermic intraperitoneal chemotherapy HIPEC could be assumed to be a risk factor for incisional hernia formation as the procedures are long and include washing the abdominal cavity with highly toxic chemicals. As previously mentioned, Tuttle et al. analysed 155 patients undergoing CRS/HIPEC and found the incisional hernia rate to be 17% after median follow-up of 245 days [59].

Laparotomy closure with reinforcement suture line (RTL) was initially described by Hollinsky et al. in 2007 as a method to reduce the risk of fascial tear of the suture line [71]. The technique includes putting a continuous suture line parallel to the incision to better distribute the forces of the suture fascial approximation suture. Wenzelberg et al. reported a reduction in one-year incisional hernia formation from 21% in patients where the small-bites laparotomy closure technique was used to 6% when RTL was added [72]. The RTL closure technique comes with an additional closure time of 12 minutes which would be well invested with the dramatic reduction in incisional hernia formation.

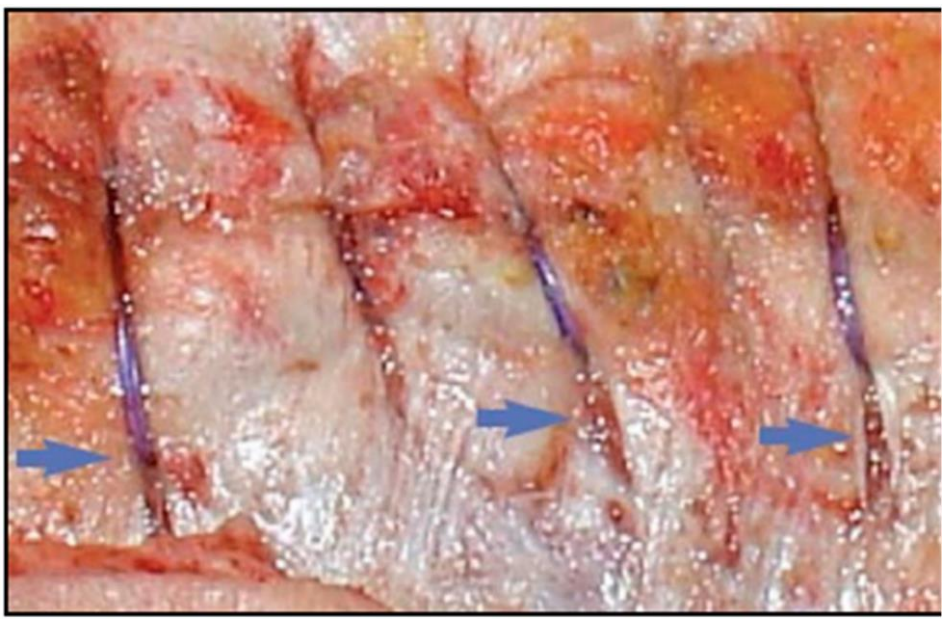

Figure 2. Blue arrows shows “button holes” due to high tension. Fortelny 2018 [73]. Reproduced with permission by Frontiers.

Suture line tension is difficult to investigate in human but, in rat studies from the 1980s Nilsson et al. and Högström et al. showed that the breaking strength of a laparotomy closure is higher when the tension in the suture line is low after a healing period [74, 75]. A recommendation is that approximation of the fascial edges should be less than 1 kg to avoid ischemia and “button holes” in the fascia (figure 2) [73].

A proxy for low tension in suturing the aponeurosis is to keep the anterior part of suture line visible.

Post-operative factors

There is a correlation between SSI and incisional hernia [60]. In a study assessing the relationship between SSI and the development of incisional hernia among 3 460 patients who underwent liver, pancreas or kidney transplantation, multivariate analysis identified SSI as an independent risk to develop incisional hernia [76]. In a cohort of 443 patients undergoing elective colorectal surgery 99 (22%) patients were diagnosed with incisional hernia [77]. Among these patients 19.3% had a deep/organ space SSI compared to 4.4% of patients without incisional hernia and authors concluded that SSI increase the risk for incisional hernia formation four times. The relationship between SSI and incisional hernia formation is complex as SSI is also related to other factors like male sex, the length of the operation, BMI, and contamination of the wound, which all influence the risk for incisional hernia [3].

Wound dehiscence occurs during the first postoperative weeks and most patients with complete disruption of the laparotomy wound undergo a reoperation. van Ramshorst et al. investigated quality of life among patients who suffered from wound dehiscence and found an 83% incisional hernia rate at 40 months follow-up [78].

Abdominal binders are prescribed by some physicians with the aim to reduce postoperative pain, evisceration and incisional hernia formation. A systematic review from 2024 found that there is a considerable variation in prescription length between different centers: 4.5% were prescribing one week, 16% 15 weeks, and 2% recommended 40 weeks [79]. Notably 1/3 of centers did not define prescription time for the abdominal binder. There were indications that abdominal binder reduced postoperative pain between second and fifth postoperative days. They concluded that the ”Current evidence on the effects of abdominal binders does not support its use after any abdominal surgery: gastrointestinal, gynaecologic, urologic, or plastic. There is little or no evidence of the benefit of an abdominal binder in reducing complications and/or recurrence. This is in line with the recommendations from the European and American Hernia Societies which do not support the use of abdominal binders [80].

Effects of abdominal wall complications

It is estimated that 1/3 of patients undergoing laparotomy suffers from abdominal wall complications [81, 82]. These complications lead to prolonged length of stay, antibiotic treatment, wound care costs and reduced quality of life [78, 83]. Abdominal wall complications can also make patients unfit to follow their planned

clinical pathway. Delayed adjuvant chemotherapy can impact survival and only 23% of patients who suffer from postoperative complications receive timely adjuvant chemotherapy [84].
In a study by Tahiri et al. 149 elderly patients selected for elective surgery were prospectively followed through the treatment process [81]. Data on comorbidities, frailty and 30-days complications were collected and authors concluded that complications have a large impact on patients' recovery. Among the 34.9% of patients who suffered from complications, 10% and 58.3% recovered after one week respectively six months compared to 30% respectively 73.7% among the patients without complications.

Impact of sex and gender on abdominal wall complications

Although there might be an agreement in the scientific community that sex refers primarily to biological factors and gender to social norms and roles, the terms are often used like interchangeables in scientific papers without a definition [85]. Even in publications investigating differences in outcomes in patients treated by female or male surgeons, it is sometimes difficult to understand how the categorization was performed [86, 87]. Commonly the participants first name is probably used as a proxy for determination of sex. A way to be more precise is to let the participants self-report their gender or sex [88]. In the passage below the same terms are used as in the referenced publications.

Several studies report higher incidence of wound dehiscence among male patients. Gili-Ortiz et al. analysed a large Spanish cohort of 323 894 patients admitted for abdominal surgery and found 2 294 diagnosed with wound dehiscence [89]. Among these patients 68% were male and 32% female, e.g. wound dehiscence was twice as common among male patients. Male patients were older and the mortality among the men was consistently higher among patients >55 years of age. Similar results were found in a Danish observational investigation with 544 patients undergoing emergency laparotomy who were prospectively followed [46]. Twenty-four patients (4.4%) were diagnosed with complete wound dehiscence, and among these, 18 patients (75%) were male. There was no difference in the number of male and female patients in the total cohort.

The German National Nosocomial Infections Surveillance System monitors surgical procedures in Germany [90]. In an analysis by Langelotz et al. from 2014, 438 050 patients operated between 2005 and 2010 with cardiac, vascular, abdominal, and orthopaedic procedures were reviewed. The overall SSI rate was 1.74% for female patients and 2.26% from male patients. In a sub-cohort with patients undergoing abdominal surgery the SSI rates were 2.92% and 4.37% for female respectively male patients. In another German study including 1 266 728 procedures across all surgical fields performed between 2008 and 2017, male patients had an overall higher ratio of SSI except in cardiovascular surgery [91]. In

a subgroup with open colon surgical procedures, the rates of SSI were 8.5% for female patients and 9.6% for male patients, which indicates less obvious sex differences.

A Japanese study randomized 584 patients undergoing elective colorectal surgery to oral or parenteral antibiotic prophylaxis and compared the incidences of SSI [92]. They found that the use of oral prophylaxis reduced SSI in colon surgery and that male sex was associated with higher rates of organ/space SSI in rectal surgery.

Almohrij et al. prospectively performed a surveillance of SSIs following 15 different operative procedures between 2014 and 2023 in Saudi Arabia, with conflicting results [93]. They identified 322 events of SSI among the 8 771 procedures performed. 80% of SSIs were identified after caesarean section, coronary artery bypass graft, herniorrhaphy, knee prosthesis, and after cholecystectomy. Most SSIs were diagnosed among female patients, 61.5%, which is reflected by the type of procedures included in the study: caesarean sections and coronary bypass surgery accounted for 47% respectively 16% of the procedures.

Few studies have assessed gender differences in incisional hernia formation after abdominal surgery specifically, but the impact of sex is often identified as a risk factor. Incisional hernia formation after open and laparoscopic colon surgery was assessed in a Danish study with 17 717 patients operated between 2007 and 2016 [69]. The median follow-up time was 4.7 years, and significantly more male patients compared to female patients underwent incisional hernia repair. In a study assessing incisional hernia formation after hepatobiliary and pancreatic surgery 654 patients were analysed [55]. A total of 83 patients, 29 female and 54 male patients, were detected with incisional hernias after a follow-up time of 24 months and there was not a statistically significant difference between the sexes.

In the Swedish registry for abdominal hernia patients report of 2023, 1 628 procedures for incisional hernia were registered between 2019 and 2023. 274 (58.5%) procedures were performed on female patients and 199 (43.9%) on male patients. The coverage rate as compared with registrations in the Swedish national patient registry was only about 20% why the data could be uncertain. Additionally, the Swedish registry for abdominal hernia only includes patients that underwent a surgical procedure why the actual incisional hernia rate should be higher. Hence there are inconsistent data on sex differences in incisional hernia.

Male sex or gender can be a factor for abdominal wall complications except for incisional hernia formation. There might be many reasons, and a clue can be to identify co-founding factors that are more common among male patients. Zwicky et al. analysed 6 603 patients from a Swiss database who underwent abdominal surgery between 2015 and 2018 [94]. They identified 649 patients diagnosed with SSIs, and among these patients 61.6% were male. There was an overall significant higher risk for male patients to be diagnosed with SSIs but this difference was eliminated after adjusting for multiple confounders including age, liver cirrhosis and alcohol abuse. The authors suggested that male patients with

more intraabdominal fat add to the complexity of the procedure and is also an ample growth media for SSIs.

The data suggests that male patients might have a higher incidence of abdominal wall related complications on a group level. However, in clinical practice this is of low relevance. Surgeons needs to make decisions and target the treatment according to the risk factors carried by the specific patient irrespectively of the patient's sex.

Suture-length/wound-length ratio and small-bites

The length of each stitch in a suture line is a function of, the length of the deployed suture (SL, figure 3g-h), the length of the wound (WL, figure 3e-f) and the tension used to approximate the tissue parts. In 1976, T.P. Jenkins recognized that there was a lack of rational explanation for postoperative wound dehiscence and investigated the mechanical prerequisites by comparing a cohort of patients operated between 1947 and 1956 with patients operated between 1957 and 1973, when a higher SL/WLr had been implemented [95]. In a subgroup of 127 patients in the latter cohort, suture-length, wound-length and stitch-count were recorded, and the SL/WLr was 4. He found only one wound dehiscence in this group compared to

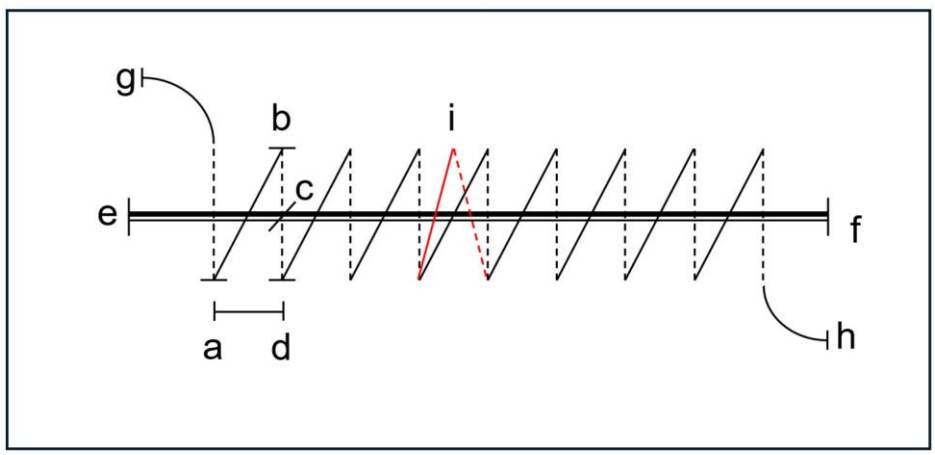

Figure 3. A geometric figure of a continuous suture line. **a-b-d**, one complete stitch. **a-d**, step-interval. **b-c**, bite-size. **e-f**, wound-length. **g-h**, suture-length. **i**, one stitch by the form of an isosceles triangle. Börner et al. [96]. Reproduced with minor alteration (red lines) by permission from Springer-Verlag.

eight in the older cohort and drew the conclusion that the SL/WLr of 4 reduced the risk for wound dehiscence. T.P. Jenkins calculated the bite-size to be 1 cm when each stitch forms an isosceles triangle (figure 3i), the SL/WLr is 4 and the stitch interval is 1 cm (figure 3a-d).

Israelsson continued to assess the relationship between SL/WLr and abdominal wall complications. In a prospective single-center study with 454 patients, SL and WL were recorded. The one-year incisional hernia rate, as diagnosed with clinical examination, was 23.7% for SL/WLr <4 and 9.0% for SL/WLr >4 [97]. The results were confirmed in a later study which partly included the same patients [98]. This study found a large variation of wound infection and incisional hernia formation between surgeons which was attributed to surgeon adherence to a SL/WLr of 4.

In a study by Varshney et al. including 100 elective and emergency patients undergoing midline laparotomy the stitch interval was 1 cm and SL/WLr 6.2 [99]. There was no wound dehiscence, the wound infection rate was 9% and incisional hernia was detected by clinical examination in five patients. Authors concluded that a SL/WLr of 6 could be recommended and that the high amount of suture thread needed for the high ratio did not increase the risk for wound infection.

The complication rate is not only influenced by the SL/WLr, but also the stitch-length (figure 3a-b-d) and bite-size (figure 3b-c), which was indicated in experimental studies that challenged the previously recommended, 10 x 10 mm large stitch.

Millbourn, in Israelsson's research group, showed that the length of each stitch correlates with wound infection and incisional hernia formation [100]. With the short stitches, with a length of <4 cm, wound infection and incisional hernia formation was 4% and 3%. For stitches with a length of 4–4.9 cm, wound infection and incisional hernia formation was 8% and 11%, and with long stitches, ≥5 cm, 16% respectively 12%. Hence the authors recommended that the SL/WLr ≥4 should be achieved with a stitch shorter than 4 cm, which now is referred to as small-bites.

Experimental studies

Several studies have evaluated the relationship between the bite-size and different proxies for burst strength of wounds.

Campbell et al. used abdominal wall from cadavers that was cut in pieces to accommodate one single stitch and conducted 346 pull-out tests with bite-sizes ranging from 3 mm to 18 mm [101]. The pull-out force increased until a bite-size of 9 mm. The 32% of the variability was due to the fascial thickness. A similar study, but conducted in a porcine abdominal wall model, assessed the influence of bite-size on the strength of the laparotomy closure put with a continuous suture line [102]. Two groups with 14 abdominal wall samples were tested, one group with large stitches (10 x 10 mm) and one group with small stitches (5 x 5 mm). The SL/WLr of all closures were recorded. The samples were put in a tensile testing machine and force was increased until dehiscence occurred. Tensile strength needed to create dehiscence was higher in the small-bites group. It was also observed that the large stitches tore through the muscle and with a subsequent slacking effect.

Experiments in rat models

The initial burst-strength of a wound is only partly essential for wound healing. Cengiz et al. conducted a study in a rat model assessing the influence of SL/WLr and stitch-interval on burst strength immediately after midline closure and after four days [103]. The stitches in the continuous suture line were put with bite-sizes of 3 mm, 6 mm, and 10 mm and all closures had a SL/WLr of 4. Burst strength immediately after closure was higher in the 10 mm compared to the 3 mm group, but after four days burst strength was higher in the 3 mm and 6 mm groups. Interestingly, the rupture occurred more often outside the suture line when closed with the 3 mm bites that had shorter step interval. Another group investigated wound tensile strength in rats 14 days after laparotomy closure [104]. Comparison was made between six groups with different combinations of the parameters: running (continuous) or single stitches, SL/WLr of 2, 4 or 8, and amount of tension in the suture line. Running suture yielded higher tensile strength compared to single stitches and running sutures with SL/WLr of 4 and 8 led to higher tensile strength compared to 2. Additionally, closures with high tension, defined as overlapping of the tissue parts, led to a lower tensile strength compared to normal tension closures when tissue parts were approximated closely.

Experimental evaluation of blood supply

A method for assessing perfusion in a sutured wound was described by Myers et al. in 1970 [105]. In a rabbit and pig model, incisions through the skin to the "deep fascia" were placed, and incisions were closed tightly or loosely. Fluorescein dye was injected intravenously, and areas of good blood supply became highlighted under ultraviolet light. The animals were sacrificed after 10 hours and up to 21 days and were injected with a mixture of contrast and gelatine. All 300 sections with the sutures were x-rayed. Immediate control with fluorescein of the wounds showed excellent staining along the wound edges except in areas around the sutures. Vascularization increased from day three to day seven, and then a gradual reduction of new vessels was formed until day 21. Most important finding was that, in tissues closed with the tight suture technique, the area around the suture was found to be avascular after seven days and the tissue was necrotic on histological examination.

A similar experiment was conducted by Kushner et al. in a porcine model [106]. Fifteen animals were anesthetized and a dissection to the abdominal fascia was placed. The different suture methods included small and large-bites, figure of eight, and were placed with a single stranded polydioxanone (0-PDS® II, Ethicon, Inc., Somerville, New Jersey, USA) or a barbed suture (STRATAFIX™ SYMMETRIC PDS™ Plus, Ethicon LLC, Guayanabo, Puerto Rico). Fluorescence studies of the midline were performed prior to cutting the midline and after midline closure was performed, with the different techniques and suture materials to be studied, and after one week of wound healing. Animals were then sacrificed, and the abdominal wall

specimens were sent for histological examination. Greatest perfusion was found with closures put with small-bites and the PDS II suture. The highest amount of neovascularity was found in specimens taken from the most cranial portion of the suture lines. It should be noted that the study included only a small sample size and that the baselines measurements had a higher variation compared to measurements after closure.

In summary, there are indications from experimental studies that a continuous suture line with a SL/WLr of at least 4, achieved with small-bites promotes wound-healing and yields stronger wounds after a healing period and that small-bites promotes perfusion.

Clinical studies investigating the effect of small-bites closure technique

Several clinical trials have compared outcomes after small and large-bites laparotomy closure, since the first studies by Israelsson and Millbourn. There is a variation in incisional hernia incidence between investigations that can be attributed to several factors including the study design, method of detection, the study population and the follow-up.

There is a long debate whether RCT is better than observational studies. A Canadian task force report in 1979 on periodic health examination, described three levels of evidence with the highest being results from a RCT to the lowest being opinions by experts [107].

The grading was further developed by Sackett et al. that divided the RCTs into studies of two different levels of evidence and introduced a grade of the recommendations, from A–C, that depended on the level of evidence that supports a certain statement [108]. Later the strength of evidence with systematic and meta-analysis are considered the highest level of evidence and basic science and translational research at the bottom of the pyramid [109]. Randomized clinical trials (RCT) tend to have better outcomes compared to observational studies maybe due to participating centers are highly motivated and specially trained in the techniques to be assessed. Limitations with RCTs include lack of generalizability due to strict inclusion criteria and small sample sizes, and short follow-up time due to the high costs related to conduct RCT [110]. There can also be a selection bias outside the strict criteria of a study due to investigators' reluctance to include patients suspected of being less likely to follow protocol. Observational investigations based on registries or retrospective cohorts have advantages they reflect the real clinical world of a disease or treatment [111]. Compared to RCTs were barriers of implementation of a treatment can be bypassed with highly motivated investigators and patients, observational studies include patients that would be excluded due to strict study criteria. Observational studies also tend to be cheaper and easier to perform and there are methods to match patients to ensure comparable groups.

The diagnosis of incisional hernia can be made by clinical examination or by imaging techniques, e.g. ultrasound, MRI, or CT, which can be a part of the patient's

normal clinical pathway or dedicated work-up for incisional hernia detection. A retrospective study by Claes compared incisional hernia rates detected with clinical examination or CT among patients after colorectal cancer resection [112]. Incisional hernia was detected in 17.4% of patients who underwent clinical examination and 35.0% in patients who underwent CT. The incisional hernia diagnosis can also be made by reviewing the patient chart for an incarceration or reoperation event, or by inviting the patient to answer a survey via mail or a phone call.

European Hernia Society launched a classification of primary and incisional abdominal wall hernias in 2009 [50]. The classification is based on the size (length and width) of the hernia defect and its position but does not define how the parameters shall be retrieved.

Patients' self-reporting of incisional hernia is influenced by the heterogeneity of the disease. Incisional hernia can be a small and asymptomatic and very large and complex hernias that impact the quality of life of the patient and can be a serious condition. The study population can influence the incidence of incisional hernia. For example, patients treated with open surgery for aortic aneurysm disease are high risk patients with >40% risk of developing incisional hernia [113].

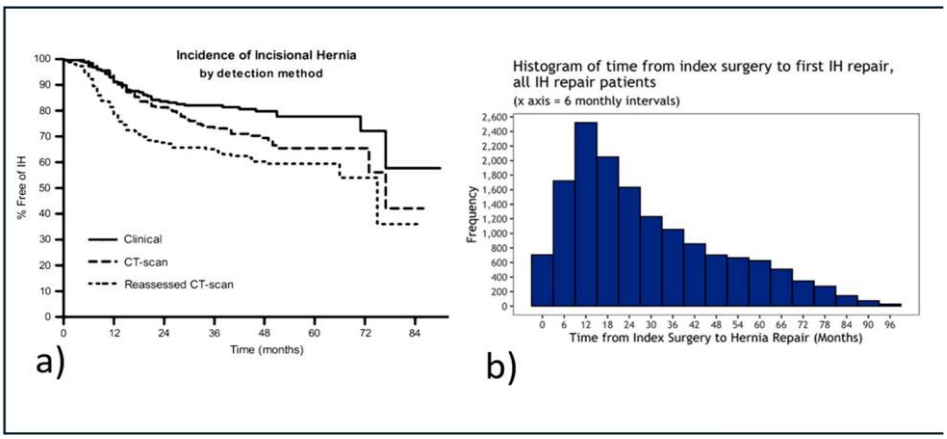

Figure 4. a) Detection of incisional hernia by clinical examination or CT-scan. Claes et. al. [112] Reproduced with permission by Springer Nature BV**. b)** Figure shows histograms with patients undergoing incisional hernia repair over time. Smith et al. [54]. Reproduced with permission by Frontiers.

The incidence of incisional hernia depends on the follow-up time and the method of detection. Roughly half of incisional hernias are detected within 24 months of follow-up, most incisional hernia repairs are performed within 36 months but incisional hernia is detected many years after the index surgery (figure 4a and figure 4b).

Additionally, there might also be a difference in how the actual investigated closures techniques were performed. The reported incision closure time and the calculated closure time per cm shows a high variation and there is a factor of two

between the extremes which might be an example of performance bias, were it could be questioned if the small-bites closure technique is executed uniformly across the different trials or even within the trials (Table 1) [114].

Table 1. Clinical trials comparing incisional hernia formation after small and large-bite closure techniques and the corresponding incision closure times.

Author	n	Fascial closure time, minutes		SB closure time per cm	Incision length, cm
		SB	LB		
Wenzelberg [72]	132	30	N/A	1.25	24
Ozcan [115]	173	15	13	0.67	22–20
Ghai [116]	90	22	16	1.19	19–18
Albertsmeier [117]	425	15	9.3	0.71	21
Mustaqrasool [118]	230	20	13	N/A	N/A
Deerenberg [2]	560	14	10	0.64	22
Millbourn [119]	737	18	14	N/A	23

n, number of patients. SB, small-bite. LB, large-bite.
Note: Wenzelberg did not include large-bite closures. Incision length obtained from communication with Millbourn.

Non-randomized clinical trials

The effect of small-bites laparotomy closure has been assessed in observational studies across different surgical disciplines (table 2).

In a cohort of 100 patients, Williams et al. assessed the relationship between SL/WLr and the risk of developing incisional hernia [120]. They found an overall adherence to SL/WLr of 4 of 77% and an incisional hernia rate of 25% in patients with a SL/WL <4 compared to 9.2% in patients with SL/WLr >4. In emergency cases the SL/WLr of 4 was reached in 60% and the authors found that failure to adhere to SL/WLr of 4 was highest when two residents performed the closure.

Some studies assessing the effect of implementing small-bites closure technique show favourable results on incisional hernia formation. Thorup et. al compared patients undergoing emergency laparotomy before and after implementation of the small-bites closure technique [121]. The patients were approached with a questionnaire that was validated to assess incisional hernia formation and was seen by a physician to confirm the diagnosis. Authors found a reduction in incisional hernia rate from 27.0% to 15.0% and a reduction in SWD from 5.6% to 2.2% after

implementation. Notably, prior to implementation, interrupted sutures were used in 39.3% of patients and to implement the small-bites technique, surgeons were instructed to use the 36 mm CT-1 needle that could be considered too large for small-bites.

Straubhar et. al. reports a similar study on patients undergoing gynaecological open surgical procedures [122]. Surgeons were trained in small-bites closure technique including a one-hour long demonstration and the recommendation to use the CT-2 needle for laparotomy closure. After a six-month implementation period patients were followed and assessed for incisional hernia formation. Incisional hernia was detected in 7.9% in the post-intervention group compared to 17.2% in patients operated before the implementation.

Table 2. Clinical non-randomized trials comparing incisional hernia formation after small and large-bites closure techniques.

Author	Year	n	Setting	Incisional hernia, n (%)		Method of detection	Follow-up time	Note
				SB	LB			
Straubha [122]	2024	255	Elective	10 (7.9)	22 (17)	RE/CR	12 months	P=0.025
de Vries [123]	2019	327	Elective, emergent	10 (7)	27 (14)	PE/RE	16.7–22.7 months	P=0.080
Thorup [121]	2019	465	Emergent	27 (15)	77 (27)	S	52 months	P=0.020
Williams [120]	2017	100	Elective, emergent	7(9.2)	6(25)	CR	1-427 days	P<0.050

n, number of participants. SB, small-bites. LB, large-bites. RE, radiological examination. CR, chart review. S, survey. PE, physical examination.

However, in contrast a Spanish study investigating the effects of training in adherence to small-bites reported different results. In this study participating surgeons went through an information stage, a training session on small-bites and thereafter an implementation assessment was prospectively performed on patients that underwent midline incisions [124]. Participants were recruited from, general surgery, gynaecology, urology, and vascular surgery. Interestingly two nurses were also included in the study. All participants recognized the importance of measuring the SL/WLr in a survey that was a part of the study, but only 52% actually did it in clinical practice. Among the 114 midline closures analysed in the study, 30.7% were performed according to the protocol with small-bites closure technique.

Randomized clinical trials

Out of six randomized clinical trials, four studies found statistically significant reduction in incisional hernia formation when small-bites closure technique was utilized (table 3). Three of the studies showed a reduction in SSI [116, 115, 119]. Albertsmeier et. al. detected no statistical differences in SSI and incisional hernia when small- and large-bites were compared.

Millbourn et al. was the first prospective trial to compare small- and large-bites closure technique. It was a single center investigation, conducted on 737 patients undergoing elective and emergent laparotomy through a midline incision [119]. Patients were semi-randomized to large- or small-bites which meant that patients were included in either group on alternating weeks. A large 41 mm diameter needle was used to put the large bites, and a small 20 mm diameter needle for the small-bites.

Table 3. Randomized clinical trials comparing incisional hernia formation after small and large-bites closure techniques.

Author	Setting	Incisional hernia, n (%)		Method of detection	F/U time, months	Note
		SB	LB			
Ozcan [115]	E	8 (9)	27 (31)	CE, CT	12	P<0.001
Fortelny [125]	E	15 (7.6)	21 (10.5)	CE, CT, MRI	36	P=0.31
Ghai [116]	N/A	3 (7)	6 (15)	US	6	P=0.14
Mustaqrasool [118]	N/A	5 (4.3)	13 (11.3)	CE	12	P=0.049
Deerenberg [2]	E	35 (13)	57 (21)	CE, US, CT	15	P=0.022
Millbourn [119]	E, Em	14 (5.6)	49 (18)	CE	12	P<0.001

E, elective. Em, emergent. SB, small-bites. LB, large-bites. N/A, not available. F/U, follow-up. CE, clinical examination. CT, computed tomography. MRI, magnetic resonance imaging. US, ultra-sonography.

This method to direct surgeons into putting the large and small-bites by corresponding sizes of needles was also used by Deerenberg et al. and Fortelny et al. [2, 125]. The authors used different needle sizes and sizes of the suture thread and it has been argued that this could have influenced the results. Another objection to these investigations is the high number of surgeons performing the procedures. In the ESTOIH trial 425 patients were included by 106 surgeons at nine hospitals and in the STITCH trial, 560 patients were included by many surgeons in ten Dutch hospitals [2, 117].

Guidelines

Guidelines have similarities with systematic reviews but often include experts' opinion and recommendations. There are three guidelines that include recommendations for laparotomy closure. European Hernia Society (EHS) published the first guidelines on abdominal wall closure in 2015 which were updated in collaboration with the American Hernia Society (AHS) in 2022 [80]. The recommendations include avoiding midline incisions but if it is used, the small-bites suturing technique with a slowly absorbable suture is suggested for closure in elective surgery. They considered the quality of evidence to be low and the recommendation to be weak. In addition, patients undergoing emergency surgery were excluded from the recommendation.

The World Society of Emergency Surgery published guidelines on closure of laparotomy in the emergency setting in 2023 [126]. The guidelines recommend laparotomy closure with a continuous suture line and SL/WLr of at least 4. The level of evidence was considered moderate and the strength of the recommendation to be strong. They also recommended the small-bites closure technique with the level of evidence considered low and the strength of the recommendation low. The EHS/AHS guidelines were transferred to the context of vascular surgery with the recommendation to use a continuous small bite suturing technique with a slowly absorbable suture [127]. The strength of the recommendation was weak and the certainty of evidence considered very low. Although guidelines state that the midline incision should be avoided, repair of incisional hernia off the midline can be difficult, especially if the site is close to bony structures which impedes the necessary mesh overlap [128].

Barriers for implementation of small-bites

Even though applying the small-bites closure technique only requires surgeons to invest an extra few minutes when closing the laparotomy wound, adaptation have been slow.

Surgeons' opinion about the small-bites closure technique has been assessed through a series of surveys in different countries and among different specialities and it is intriguing that the uptake has been found to be low among colorectal and hernia surgeons considering the close scientific relationship between the sub-specialities. A summary is presented in table 4.

Table 4. Surveys assessing abdominal wall closure techniques.

Author	Year	Country	n	Participants	Adoption of SB, %	Adoption of SL/WL ratio ≥4, %	SL/WL ratio ≥4, %
Stephens [129]	2024	Int	234	General surgeons	42	N/A	7.7
Messenger [130]	2024	UK	267	Consultants	20	N/A	N/A
Pous-Serrano [131]	2023	Spain	53	Colorectal surgeons	56	N/A	N/A
Chowdhury [132]	2023	Int	561	Colorectal and general surgeons	59–75	N/A	N/A
Paulsen [133]	2020	DK	325/83	OBS/Gyne	50–94	32.2–61.2	N/A
Fischer [134]	2019	Int	497	Surgeons	58	63	15.6
Bloemen [135]	2019	NL	402	Various	17	36	N/A

n, number of participants. Int, international., UK, United Kingdom. DK, Denmark. US, United States. NL, Netherlands. SB, small-bites. N/A, not available.

In a study from 2019 including 1 577 members of the Dutch Society for Surgery, questionnaires on the technique used to close the abdominal fascia after midline incision were circulated [135]. Among the responders 36% applied a SL/WLr ≥4,

and only 17% aimed for a step interval of 5 mm. Notably, 43% of the responders answered that they did not have a preference for SL/WLr and 68% that their closure technique was unchanged since training. During the same year, Fischer et al. reported results from a 14-question survey including 497 surgeons from Americas Hernia Society, European Hernia Society, and International Hernia Collaboration [134]. Among the responders, 58% stated that they practiced the small-bites closure technique but without measuring SL/WLr or the numbers of stitches used. Reasons for not practicing the small-bites closure technique included that it does not apply to their patient population, concerns about closure related complications and that the technique takes too long to perform.

In a Danish study, colorectal surgeons, and obstetricians/gynaecologists were invited to participate in a survey on surgical handling of the fascia [133]. Responders included 325 obstetricians/gynaecologists and 83 colorectal surgeons who stated that they used the small-bites closure technique in 47.5% respectively 93.9%. Among obstetricians/gynaecologists, 32% routinely applied a SL/WLr >4 compared to 61% of colorectal surgeons. From Spain, a similar questionnaire-based report on colorectal surgeon's closure habits was published in 2022 [131]. Among the 53 responders 94% were aware of the recommendation to use a SL/WLr ≥4 but only 55.8% performed small-bites.

In a study with surgeons from the UK, 267 consultant surgeons were either interviewed by surgical trainees in a structured way or filed a 25 question survey relating to abdominal wall closure [130]. Among the responders, 19.9% answered that they used the small-bites closure technique. Surgeons who utilized the small-bites technique were more likely to perform more than 30 midline closures annually, attending lectures on the technique and based their practice on evidence. Surgeons who did not adopt the technique declared a belief that they had "no problem" with incisional hernia and that they were uncomfortable in changing their practice.

An online survey with international responders recruited from World Society of Emergency Surgery, Fascial Traction International, and Portuguese Surgical Society networks, assessed surgeons' views on wound bundle components and closure habits in emergency laparotomy [129]. Among the surgeons, 42.2% used the small-bites closure technique and 37.1% cleared the fascia before closure. Authors also identified a large variation among responders of how the small-bites closure technique was defined.

Furthermore, there are interview-based investigations on surgeon's perception of small-bites closure technique. Lawday et al. explored the views of nine surgical consultants and registrars on small-bites closure technique using qualitative semi-structured interviews [136]. The interviews concerned the scientific evidence and its adaptation in clinical practice with focus on the STITCH trial that favourable results on incisional hernia formation after the small-bites closure. Authors identified barriers against the uptake of small-bites: The burden of complications and subsequent possible litigation following complications after a new technique had been used played a role. Some participants also required more evidence before

implementation, and another barrier could be lack of education during surgical training.

In a Canadian study using both surveys and qualitative interviews surgeons and residents' barriers and adoption of small-bites closure technique was assessed [137]. Analysis of the survey found that most participants had heard about the technique but only 26.7% reported routine use, especially for patients with increased risk to develop incisional hernia. Among the residents 28.4% reported that small-bites technique was routinely used by their superiors. The interviews revealed that surgeons continued to use the technique adopted from training and that it is difficult to change practice. Surgeons expressed concern about the strength of closure with the 2/0 suture and wondered whether trial participants were reflective of their own patients. The increase in total operating time when using the small-bites closure technique was not considered a major barrier.

In conclusion these surveys show that the implementation rate of small-bites varies across the specialities and between different countries. Highest rate of implementation was found among colorectal surgeons, possibly due to the close clinical and scientific relationship between colorectal and hernia surgeons. The quality control of calculating the SL/WLr was rarely used.

Suturing

Definition of suture

The word suture derives from the latin word sutura which means seam. Suturing is an inherent part of most surgical procedures and is performed with a penetrating part that can propel an attached thread through tissue. Suturing is used for adapting soft tissue and ligate vessels. Suture needles have been used by humans for thousands of years mainly for skin closure until major surgical procedures became feasible with the introduction of ether anaesthesia by William Morton and others in 1940s and the antiseptic surgical technique of Joseph Lister [138, 139].

The combination of a thread and a penetrating needle is a medical device called a "suture". There are two different methods of attaching the thread to the needle: the thread can be loosely fitted to the needle intraoperatively through an opening in the non-sharp end, the eye, or in the case of eye-less sutures, the thread is permanently pre-attached to the needle in a process called crimping or swaging. Eye-less sutures was described as early as 1774 but a method to produce a swaged suture was patented (US1665216A) by H.D. Morton in 1925, and commercialized by the Scottish pharmacist George Fowlie Merson (figure 5a) [140].

The legacy of George Fowlie Merson can be traced at Ethicon that produce a MERSILENE™ Polyester Fiber Suture. Eye-less needles reduce the friction when the suture needle passes through the tissue which leads to less tissue trauma. Sutures

are since 1937 manufactured according to the standard United States Pharmacopeia (USP) in the US, which regulates suture sizes, tensile and attachment strength. Suture thread diameter is described as USP size and range from 12-0 (smallest) to 10 (largest).

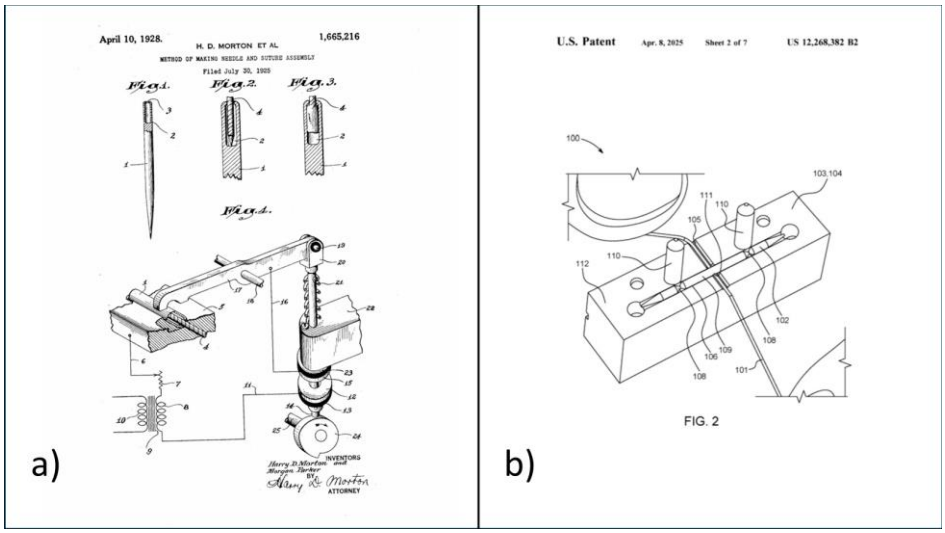

Figure 5. Figure shows **a)** the first patent filed in 1925 on a tool to permanently attach (swage or crimp) a suture thread to suture needle. **b)** patent drawing for Suturion AB crimping tool to attach the suture thread to a straight needle 100 years later. Used with permission from Suturion AB.

Suture properties

The suture can be maneuvered by a needle driver or by hand and the configuration of the suture is highly specialized for different applications. The tip of the needle can be blunt, tapered (rounded) or cutting. Blunt needles are used to protect the operator and for liver suturing, tapered needles for soft tissue adaptation like fascia closure or bowel anastomosis and cutting needles for skin closure. Suture threads can be non-absorbable or absorbable and consist of one thread or a braid.

The absorption rate defines the tensile retention strength which differs between suture thread materials [141]. During the first weeks of healing, the laparotomy wound integrity is solely dependent on the suture line. The abdominal wall fascia typically retain 40% of its preoperative tensile strength after 4 weeks and 70% after 20 weeks [142]. Guidelines recommend a slowly absorbable suture to be used for laparotomy closure to bridge between healing of the fascia and absorption of the

suture thread [80]. The retention strength after the index operation for sutures commonly used in laparotomy closure are shown in figure 6.

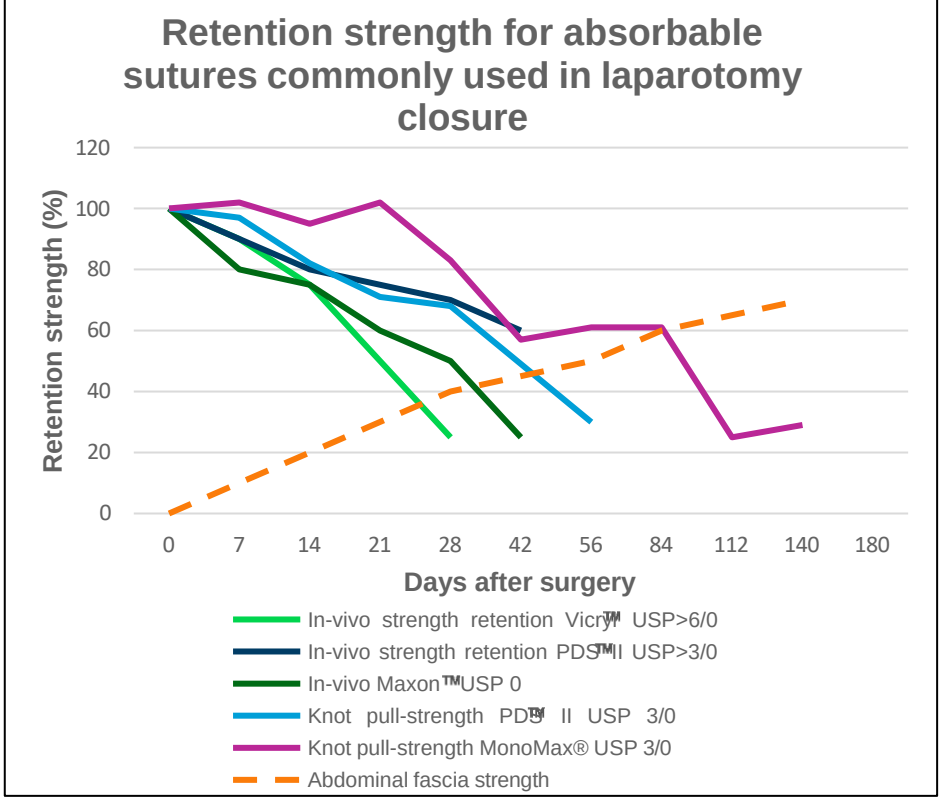

Figure 6. Figure shows retention strength over time for absorable suture and the healing fascia. Figure compiled with data from Rath et al., Odermatt et al., Covidien and Johnson&Johnson [142-145]. USP, United States Pharmacopeica. PDS, polydioxanone.

Suturing forces

Suturing is an important task in most surgical procedures. A key message when training surgeons is to manipulate the tissue as gentle as possible to reduce damage that can impair healing [146]. It is important to pay attention to all details in a surgical procedure: how and where the incision is made, minimal manipulation of the tissue during surgery and to apply a meticulous closure technique [147]. The act of suturing transfers several forces to the tissue. Firstly, when passing a suture needle through tissue the surgeon stabilizes the tissue with counter tension applied

by the forceps, *forceps force*. Secondly the forceps and the movement of the needle through the tissue will impose a horizontal force, *medial traction force*. Finally, the tension of the suture thread that approximates the tissue parts. These forces are

partly influenced by the friction between suture and tissue which can be reduced by shortening the needle and using a small diameter needle, polishing the material and apply coating [148-149]. The friction in suturing increases by the thickness of the suture thread and when using multifilament sutures [150].

Curved and straight suture needles

An inherent issue with the curved suture needle is that it is impossible to follow the perfect circular suturing pathway while maneuvering the needle with the needle holder as the needle is buried in the tissue [151]. Surgeons also tend to waver the tip of the curved needle while trying to hit the intended target [152]. Accuracy to follow the intended suture pathway is higher and the force needed to advance the needle is reduced when the needle driver grasps the needle closer to the tip compared to at the non-sharp end [153]. Another way to reduce the force involved in suturing is palm grip suturing.

The Frimand needle holder has been shown to reduce surgical stress with 62% compared to conventional needle driver suturing [154]. In clinical practice, laparotomy closure is often completed with large bore sutures (USP 1, 43-58% and USP 0 15-28%), and large needles (30 mm-48 mm) are used by most surgeons [131-132]. This is not in line with guidelines that advocate small-bites closure technique, as a small suture needle is important to utilize this technique [80, 126, 155].

Surgeon variability

There is a variation among surgeons in ability to evaluate distance which can potentially influence the adaptation to small-bites. A study by Mirzaee et al. assessed 86 laparoscopic surgeons' ability to appreciate the length of a small bowel section and found a an average error of 4.62 cm on an eight or nine cm long segment and author didn't find a relationship with age, gender, years of surgical experience or surgical volume [156] . In another study, Conway et al. assessed surgeons and trainees ability to estimate distance by eyeballing [157]. Surgeons were asked to place marks 5 mm respectively 10 mm from an indicator. The results showed a variation from 2 mm to 12 mm and 5 to 19 mm, for the 5 mm respectively 10 mm estimations. Authors found that the level of training did not influence the capability to estimate the distance.

Health economy assessment

According to Organisation for Economic Co-operation and Development (OECD) health expenditure growth among OECD countries was 2.9% between 2015 and 2019, and 3.3% between 2019 and 2021 [158]. Interestingly the health expenditure per capita differs heavily. US have the highest annual per capita expenditure at $12 555 which is about three times more than the average spending of the 38 OECD countries ($4 986). Health economics differs from standard economy theory that relies on the interaction between consumers and producers on a free market [159]. Health economy is complex, and in this context fundamentals of the free market can fail. Health economic analysis is often used to evaluate the benefit of an intervention and to make decisions on how resources should be allocated efficiently.

Different types of health economy analysis

There are five main different types of health economic analyses and the main difference is how the outcome is expressed [160]. Cost-effectiveness analysis compares two or more alternatives in terms of the relative cost and outcomes measured in a single unit, e.g. life-years gained. In a *cost-utility* analysis outcomes are expressed by health status, e.g. quality-adjusted life-years (QALYs). *Cost-benefit* analysis evaluates alternatives in terms of their relative costs and outcomes and described with a currency. *Cost-minimisation* analysis is an analysis of alternatives that have equivalent health effects. Lastly, *cost-consequence* analysis is a form of comparative economic analysis that evaluates alternatives in terms of their relative costs and outcomes, where the outcomes are not summarised in a single measure, and multiple outcomes of interest are reported. Costs and outcomes can be evaluated from patient, health provider, third-party payer (insurance company or governmental health scheme), or societal perspective [161].

A cost-effectiveness analysis is used to help the provider maximize the health care available for a minimal cost. A shortcoming is that it does not include ethical considerations. The world bank exemplifies this in a publication from 2006 with interventions that can be of high benefit for the individual, but not particularly cost-effective, including treatment of latent tuberculosis infection with isoniazid and regulations aimed at reducing alcohol abuse [162]. When calculating the costs involved in laparotomy closure, the main drivers are the cost for intraoperative sharp injuries, the time it takes to perform the closure, short and long-term abdominal wall complications.

When retrieving information about the associated costs, the scientific literature is scarce and highly diverse. The cost for sharp injuries has been calculated in different settings. In a Swedish study the cost for a single sharp injury was €272 in 2007 including investigational and treatment costs [163]. In a Belgian study from 2013 investigating the economic benefits of applying devices for sharp injury

protection, the cost of a single high-risk sharp injury was €950 for testing, administration, post exposure prophylaxis and treatment for the acquired disease, and €844 for counselling, compensation and litigation[164].

Available data on operating room minute cost range from €10.8 in France 2012 to $37 in the US 2017 [165]. The cost for wound dehiscence and incisional hernia repair also differs between markets and scientific publications reflecting the variability of the severity of the cases and cost of health care in different countries.

Health economy assessments on small-bites

There are two previous publications assessing the health economics of small-bites laparotomy closure. Millbourn included data from 2010 on closure time, the cost of incisional hernia repair with small and large-bites and the indirect cost of sick-leave, and concluded that small-bites laparotomy closure was cost-effective if the extra closure time did not exceed ten minutes [166].

A cost-utility analysis by Gokani et al. from 2018 with data from UK, included the cost for additional operating time for small-bites, costs for SSI and incisional hernia formation, and the change in Quality Adjusted Life Years (QUALY), and found that small-bites closure was cost-effective if SSI was reduced by 15% and the rate of incisional hernia formation was reduced by 3.4% [167]. The health economic benefits of utilizing the small-bites technique does not consider the patient suffering which should be the first commitment of the surgeon. In conclusion, a small change in surgeon training and behaviour can have a large impact on patient outcome on abdominal wall complications.

MedTech development

Swedish universities have three roles or obligations: to provide education, conduct research and to reach out to the public which is referred to as the third mission. A part of the third mission is to transfer research into commercially viable projects. For this purpose, the universities typically have innovation departments that guide researchers through the initial analysis of the business case and holding companies that do early investments in university-attached start-ups and support these early phase companies in business hygiene and business development. Swedish scientists own their right to their results, which differs from German scientists where the university owns the results and cares for the commercialization of a research result.

In Europe MedTech devices are regulated under the Medical Device Regulation (MDR 2017/45) which is the successor to the Medical Device Directive from 1993. The MDR is a more rigorous regulation that focus on product safety, hygiene and post-market surveillance. The MDR is a major barrier for the implementation of new MedTech devices due to the faltering approval process. Approval is conducted by notified bodies which are organizations designated to assess the conformity of products that seeks CE-approval. Conformity means that a product is compliant, ie follows the requirements of the product as stated by the MDR according to its risk level.

Classification of Medtech devices

Essentially there are three classes of MedTech products based on their risk profile according to the products intended use as regulated by the Medical Device Coordination Group [168].

Class I represents the lowest risk and class III the highest. Class I products include non-invasive products like bandages and stethoscopes and the approval process normally do not require involvement of a notified body. Class II products are moderate to high risk. Non-absorbable sutures are class IIb products, but absorbable sutures are CE-class III like other implants, if absorption time is more than 30 days. Class III includes high risk devices, e.g. pacemakers and breast implants. The required documentation increases by the risk profile of the device. Barriers for approval of a CE-class III device includes conducting a clinical trial.

The approval process can last more than a year much because of congestion of multiple approval processes within the notified bodies but also because of

indecisiveness of how to interpret the new approval regulation. MDR also regulates the responsibilities of the manufacturer of MedTech products.

Post-market surveillance (PMS) includes the continuous and pro-active activities that manufacturers are complied to perform to monitor safety and performance after the devices are released to the market. PMS includes *post-market surveillance studies* (PMCF) to retrieve data from the real-world use of the device. Data can be retrieved in different ways: through surveys or interviews with users or clinical trials which have endpoints that assess the outcome related to the claims of a certain device. MedTech development is a lengthy and costly process. It is estimated that the mean time from idea to market clearance is 17 years. Although many ideas emerge from the medical professionals, only a fraction of these ideas will ever be developed and available for medical personnel and patients.

Suturing devices

According to the consulting firm McKinsey & Company, innovation is the systematic practice of developing and marketing breakthrough products and services for adoption by customers. There are many examples of surgeons through history who have transferred an idea to a surgical device.

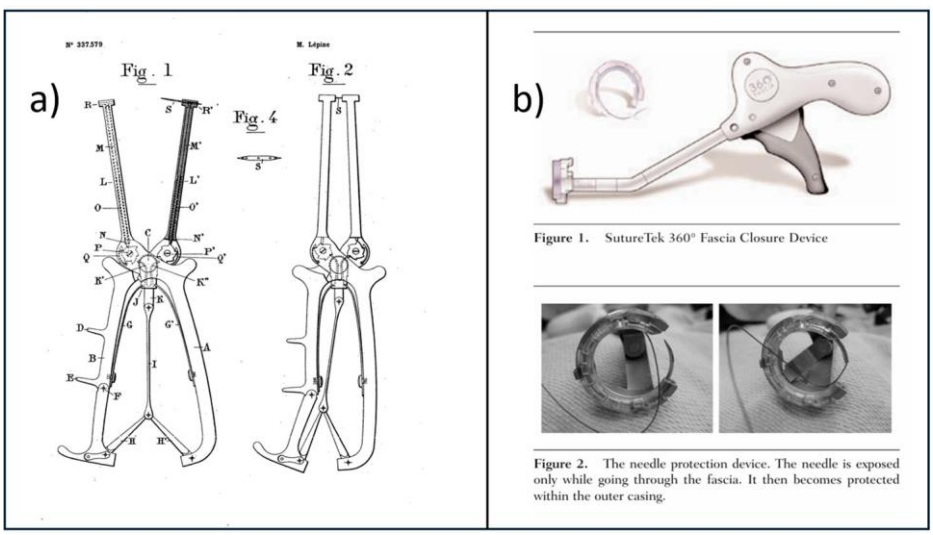

Figure 7. Figure shows **a)** a patent drawing of an early suturing device from 1903 **b)** the SutureTek 360 Fascia Closure Device. Williams et al. [169]. Figure reproduced with permission from Sage publications.

The first patented surgical suturing device with a straight needle was developed by the French inventor and manufacturer Philippe Lepine in 1903 (figure 7a). Commissioned by one of the innovative surgeons of Lyon, France, maybe Mathieu Jaboulay who experimented on xenotransplantation and was responsible for a button device for compression anastomosis as early as 1905 [170].

The dawn of laparoscopic surgery has been a driver for MedTech innovation. United States Surgical Corporation developed the Endo Stitch™ Suturing Device (Medtronic, Minneapolis, MN, US) to facilitate laparoscopic suturing [171]. The device is a semi-automatic suture applicator that in general surgery is used mainly for fundoplication. There have been attempts to develop devices for fascia adaptation. The SutureTek 360 Fascia Closure Device (SutureTek Incorporated, North Chelmsford, MA, US) used a curved needle and a non-resorbable suture thread (figure 7b). The aim of the device was to protect the operator and patient from unintentional sharp injuries and to shorten the closure time. The device was evaluated in an animal study in 2008 that found a 24% shorter closure time. There were no detected differences in accuracy of stitch placement or burst strength between the techniques [169]. SutureTEK 360 was FDA cleared but is since long redrawn from the market.

There are other initiatives that have left traces in patent registries but no scientific publications. The FastStitch or QuickStitch (Archon Medical Technologies, unknown location, US) was a student project led by Hien Nguyen, an assistant professor of surgery in the Johns Hopkins School of Medicine, that was recognized in the Johns Hopkins Gazette in 2012. FastStitch was a semi-automatic fascia closure device that should shorten closure time and reduce complications by correctly put stitches and received at least two granted patents (US 2013/0304096 A1 and WO 2015/109159 A1). A shortcoming of this device was that it needed an extra movement of a button to decide which arm the needle should be attached to at every stitch.

A potentially strong competitor is the Dutch MedTech company Mellon Medical. It was founded in 2013 and invented a suturing applicator for vascular anastomosis, but the development of vascular surgery towards endovascular procedures have diminished the market for open vascular surgery and the company set the course to further develop their invention for abdominal wall closure. They received the Eurostar grant in 2023 for a three-year research project.

SutureTOOL

The idea of a device to facilitate small-bites stitch placement was sparked when Leif Israelsson held an inspiring lecture on the advantages of the small-bites closure technique at the department of surgery at Helsingborg hospital in 2009. Israelsson, a colorectal surgeon in Sundsvall, Sweden, has spent his long research career pursuing the correct method to close the abdominal wall after open surgery. He coined the expression "short-stitch" that later became popularized as small-bites.

The novel closure technique could be perceived as cumbersome and time-consuming. The first steps to develop the SutureTOOL system, a device for swift and standardized abdominal wall closure, was taken to facilitate implementation of

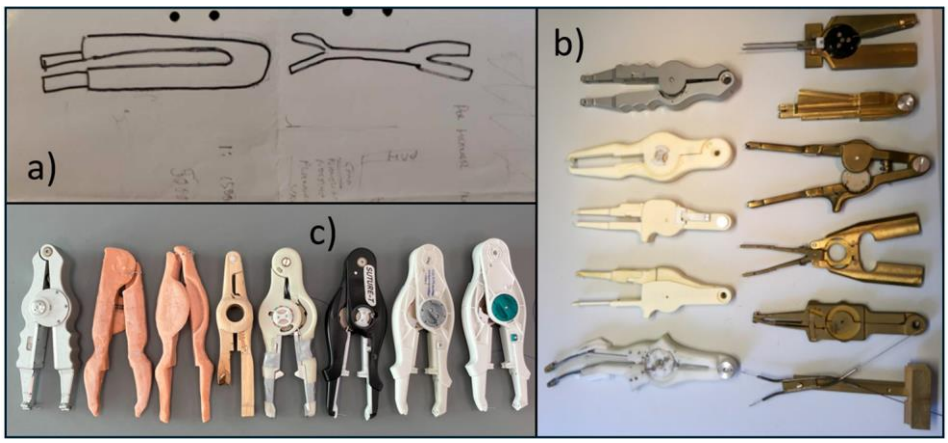

Figure 8. Figure shows SutureTOOL development through several iterations. **a)** first sketch presented to the engineer in 2010. **b)** early iterations of the SutureTOOL. The first models were made in brass. **c)** from left, stainless-steel model used in the paper I. Clay design sketches. Black handle of the type used in paper II. Far right the SutureTOOL model used in paper III and IV. Photographs by the author and Mats O. Christensson.

small-bites. Over the following 15 years, the SutureTOOL system was developed and evaluated through several iterations (figure 8b and figure 8c). In 2018 a start-up company, Suturion AB, was formed in collaboration with Lund University to further develop and commercialize the technology. The intellectual property associated with the technology is protected through both granted patents and registered design rights. The SutureTOOL system received market clearance in 2025.

The SutureTOOL system

The SutureTOOL system consists of two sterile, single-patient MedTech devices. A mechanical suture applicator and a propriety needle.

The needle (1020S)

The stainless-steel needle is double pointed and has a centrally attached polydioxanone suture thread. The needle points are tapered, and the suture material is slowly absorbable. Traditional curved suture needles have a drilled channel in the non-sharp end which is compressed around the end of the suture thread to attach it in a process called crimping or swaging. As the SutureTOOL system needle use a double pointed straight needle a different approach was developed. The suture thread is entered through a drilled hole perpendicular to the needle shaft and the adjacent metal is compressed to fixate the suture thread. When a straight metal rod is compressed and thus deformed, the rod tends to bend. A dedicated crimping tool was developed for the SutureTOOL system that counteracts the bending tendency. The suture is packaged in a paper card, placed in a foil package and subsequently sterilized in Ethylene Oxide (EtO).

The handle (1018S)

The handle is a mechanical suture applicator. It consists of 11 plastic and six metal parts and several springs and screws. After assembly and testing, it is put in a pouch and sterilized in EtO. It has an upper and lower arm and when the device is compressed the needle moves between the arms and propels the suture thread through the tissue. When the operator stops compressing the device the arms are separated by a spring and the needle pulls the suture thread through the tissue (figure 9). The handle has features to lock the device when the suturing is finished to protect the operator, and for emergency opening in case the device gets stuck.

The guide

The SutureTOOL handle has a guide in the upper arm (figure 10a). It is designed to help the operator put the small-bites stitches with bite-size of less than 8 mm and step interval of 5 mm (figure 10b).

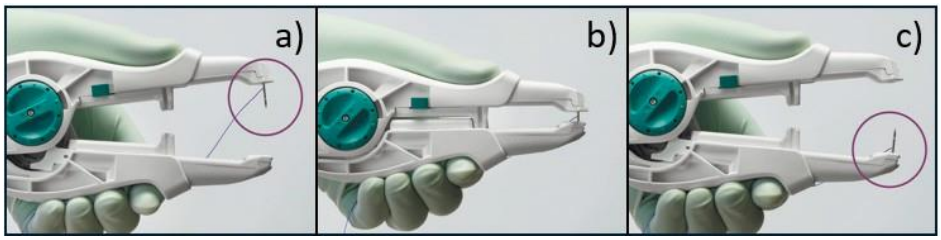

Figure 10. Figure shows **a)** a guide in the upper arm of the SutureTOOL that can help the operator to put stitches at correct interval and bites size **b)** suturing with the device in a model to illustrate how the guide directs the operator. Pictures used with permission from Suturion AB.

Papers

This thesis evaluates SutureTOOL from different perspectives (table 5). First, a proof-of-concept was performed in an animal tissue model and after encouraging results, the tests were repeated in a human body model. The third study compared suturing forces between a straight and two curved needles. The fourth study was a clinical evaluation, and the fifth study was a health economy assessment that compared device assisted closure with NDS in four different international markets. For all investigations except paper V, a protocol was developed prior to study start. An overview of the results is shown in table 6.

Ethical principles and approvals paper I–V

The World Medical Association updated the Declaration of Helsinki in 2013 [172]. Among the 15 general principles, principle 3 and 9 states that it is

"The duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research…//"

and

"The duty of the physician who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects…//"

These principles form the base for the regulation that controls medical research. No ethical approval was required to use discarded elk fascia, in paper I, according to the regional ethical review committee. For paper II ethical approval was obtained as it was performed on diseased human beings and the method included physical intervention. Paper III and V did not require ethical approval.

For paper IV, ethical approval was obtained as part of the application to Swedish Medical Products Agency to conduct a clinical trial according to ISO 14155:2020. A written consent was obtained from all patients in paper IV.

Table 5. An overview of the endpoints in paper I-V.

Papers / Outcomes	I	II	III	IV	V
Study type	**Experimental**	**Experimental**	**Experimental**	**Clinical trial**	**Health economy assess-ment**
Model	Animal tissue	Human model	Dry model	In vivo	Literature based model
SL/WLr	x	x		x	
Adherence to SL/WLr of 4	x	x		x	X
Closure time	x	x		x	X
Stitch-time			x	x	
Stitch-count	x	x		x	
Stitch-length				x	
Bite-size				x	
Learning curve		x		x	
Glove puncture		x		x	
Evaluation form	x	x		x	
Traction force			x		
Pressure force			x		
Costs for complications					x

Statistical methods paper I-V

The categorial variables of SL/WLr of 4 was presented as proportion in %. Continuous variables were presented as either median and range or mean and standard deviation. Statistical analyses were performed with Stata 14 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP) or IBM SPSS Statistics for Windows, Version 26 (Armonk, NY, USA). Significance level was set to 5%.

Paper I and II included categorical and continuous variables. Whitney's U test and Student t-test were used to analyse the continuous variables including closure

time, stitch-count and SL/WLr. In both studies the populations were relatively small, 10 participants in paper I and 15 in paper II and the number of datapoints were 40 in each group in paper I respectively 45 in paper II. Fisher's exact test was used for the comparison of adherence to the categorical variable SL/WLr of 4.

In paper III statistical analysis of variance between the groups were performed with the analysis of variance (ANOVA) procedure which can be used to compare means of more than two groups. In the ANOVA procedure, F-statistics in each group is calculated and compared with the whole group for assessment of variance between the groups. The Bonferroni method was used to determine which group that differed.

Power calculation for paper IV was based on results from paper II and an institutional review by Williams et al. assuming a 70% success rate for SL/WLr of 4 using NDS [120, 173]. We postulated a higher success rate of 83% with SutureTOOL which meant that 38 patients were required to obtain a two-sided 95% CI for the percentage of success that extends of 12% from the observed success rate.

Table 6. An overview of the results in studies I-IV.

Paper	n	Setting	SL/WLr of 4, %		SL/WLr		Closure time, mm:ss	
			ST	NDS	ST	NDS	ST	NDS
Paper I	10	Tissue model	95	30	4.5	3.8	2:54	4:05
Paper II	15	Human body model	98	69	4.6	4.4	4:46	7:05
Paper III	35	Dry model	N/A	N/A	N/A	N/A	0:34	0:39-0:44
Paper IV	5	Clinical trial	100	N/A	7.6	N/A	7.4	N/A

SL/WLr, suture-length to wound-length. mm, minutes. ST, SutureTOOL. NDS, needle-driver suturing. N/A, not applicable.

Papers I and II

Method

The first two papers of the thesis were experimental studies comparing device assisted suturing with NDS in two different abdominal wall closure models. The main research question was adherence to SL/WL ratio of 4. Data on closure time, suture length used, and stitch-count were collected. Participants were also instructed to complete an evaluation form with 11 questions on SutureTOOL handling. In paper II an assessment of the learning curve and a test for glove punctures were added.

Participants and introduction

In both studies surgeons participated according to schedule availability. In paper I, surgeons were introduced to the SutureTOOL with a two-minute-long video and practiced device assisted suturing in the model until they were comfortable to put ten stitches with ease. In paper II participants were introduced to the SutureTOOL only by holding the device and reading the instructions for use. In both papers closure assistance was performed by first author, but a research nurse instructed the participants and collected the data in paper II.

The models

In the paper I discarded elk fascia used. It was attached to a wooden model and a 12 cm incision was put. The elk fascia was cheap and durable. The fascia was harvested by the hunter during the field dressing and individually flat frozen until thawed one hour before the test. Ten surgeons performed eight closures alternating between device assisted closure and NDS. Closure assistance and data collection was performed by the author. In paper II a human body model in the autopsy setting was used. A 15 cm long incision was prepared in the model including undermining the subcutaneous fat (figure 11a). Participants performed six closures with the SutureTOOL and three closures with NDS.

Glove puncture assessment

In paper II a glove assessment test was introduced. After each incision closure, the pair of gloves were placed in pre-marked Zip bags for later assessment. All outer gloves were tested by the research nurse according to the standard "Medical gloves for single use – Part 1: Requirements and testing for freedom from holes (SSEN-455-1-2000)" with a stance specially constructed for this purpose (figure 11b).

Figure 11. Figure shows **a)** the human body model used in paper II. The subcutaneous fascia is undermined to allow for precise incision in the Linea alba and small-bites closure technique. **b)** research nurse performing glove puncture test. Photographs by the author.

Results

The primary research question for papers I and II was adherence to SL/WL of 4 which was 95% and 98% for SutureTOOL and 30% and 69% for NDS. Closure time was about 30% faster with SutureTOOL and the learning curve flattened after three incision closures (figure 12). Two gloves glove punctures were identified in in the NDS group, and no punctures in the SutureTOOL group.

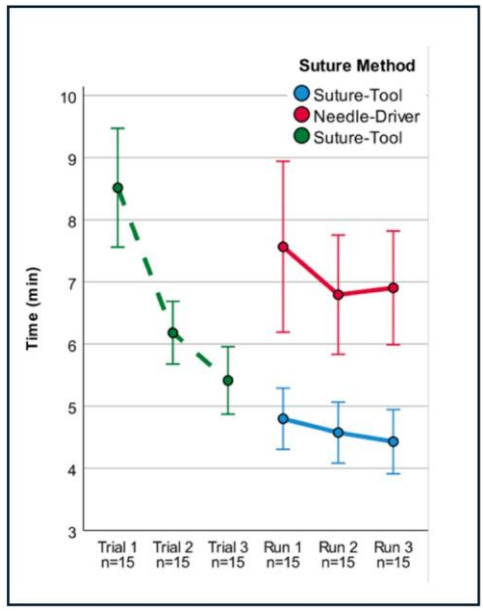

Figure 12. Learning curve assessment. Figure shows mean closure times for consecutive incision closures with SutureTOOL (green and blue) and NDS (red). Börner et al. 2022. Reproduced with permission from Elsevier.

Paper III

Manual suturing with a curved needle typically involves four phases. The needle is attached to the needle driver and the needle penetrates the tissue half ways. The needle is hereafter reinstalled in the needle driver and pulled through the tissue. This is repeated on the opposite side of the tissue to complete one stitch. With the SutureTOOL, the straight needle penetrates the tissue and the opposing arm pulls the needle through the tissue. Only two events are required to complete one stitch. A curved suture needle typically approaches the tissue in a tangential matter but the SutureTOOL system, with its straight needle, approach the tissue perpendicularly. This and the differences in actions required to put the stitches may have the potential to affect the suturing forces (figure 13a and figure 13b).

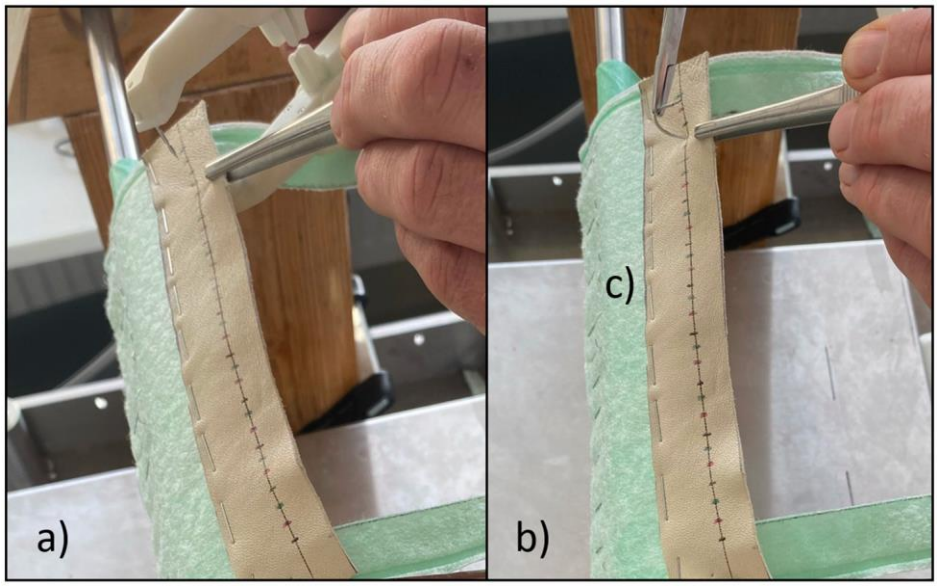

Figure 13. Figure shows the interaction between the different suturing techniques, the forceps and the suturing pad. **a)** SutureTOOL. **b)** NDS. **c)** the suturing pad made of lamb leather. Markings in red, green and black with 5 mm distance to spread the needle pull-throughs evenly over the pad. Photographs by the author.

Method

In paper III, suturing forces between three different suturing devices, a straight and two sizes of curved needles, were compared. A model to measure the forceps force required to stabilize the material and the traction force was developed (figure 14). An over the shelf load-cell, used to detect the pressure of the thumb, was attached to the forceps to measure the pressure at the thumb grip (figure 14e). The median traction force was measured by transferring the force from the suturing pad to a precision scale. Data was transferred to a computer for analysis.

The straight needle was handled by the SutureTOOL and the curved needles (large needle, LN and small needle, SN) with a manual needle driver, NDS. Participants included surgeons, urologists, gynaecologists and scrub nurses who were recruited at Helsingborg hospital. Before the test started, participants received short training in SutureTOOL and NDS suturing in a separate training model. Tests were conducted by a research student.

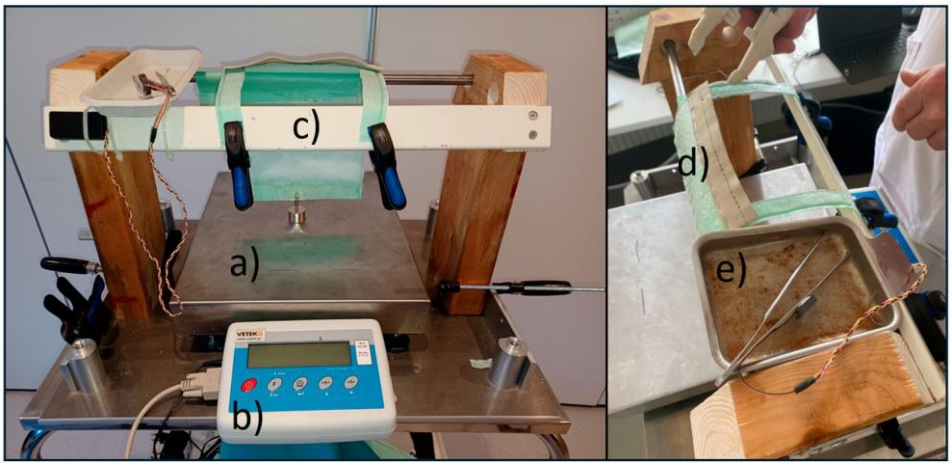

Figure 14. Figure shows a model to measure suturing forces. **a)** the precision scale. **b)** the display terminal of the precision scale that transferred the data to a computer. **c)** a stance to fix the suturing pad. **d)** the suturing pad. **e)** tray for placing the forceps between needle pull-throughs. The forceps have a black load-cell at the thumb grip that registered the force needed to stabilize the suture pad. Photographs by the author.

Results

Participants included 20 specialists, 10 scrub nurses and 5 surgical trainees. Training time was 4 minutes and 5 seconds for SutureTOOL and 2 minutes and 19 seconds

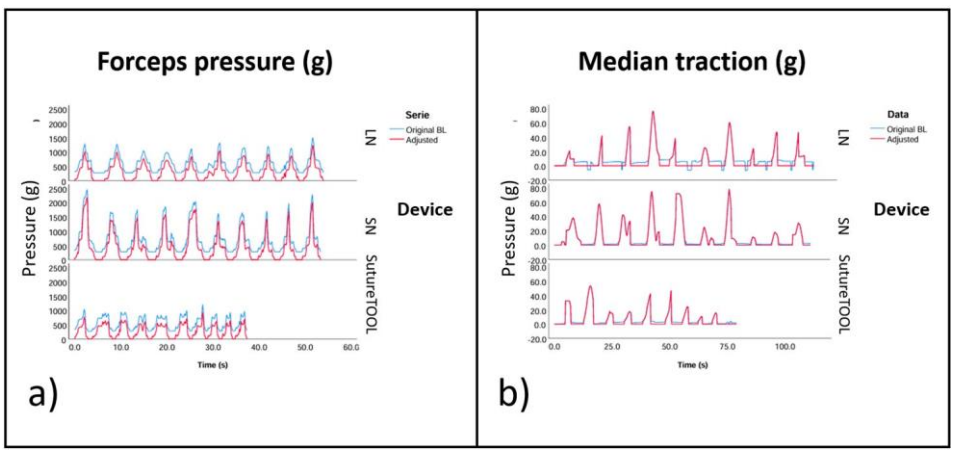

Figure 15. Measurements from participant number 27 showing **a)** forceps pressure force **b)** median traction force. Blue waves are original waves and red waves after baseline adjustment. LN, large needle. SN, small needle. g, grams. BL, baseline.

for NDS. Less pressure force was detected with SutureTOOL ($p<0.001$) compared to NDS and a shorter needle pull-through time ($p<0.001$). No differences were detected for maximum medial traction force, but medial traction force AUC was lower for SutureTOOL and SN compared to LN ($p=0.025$). Typical measurements are showed in figure 15 and results are showed in figure 16.

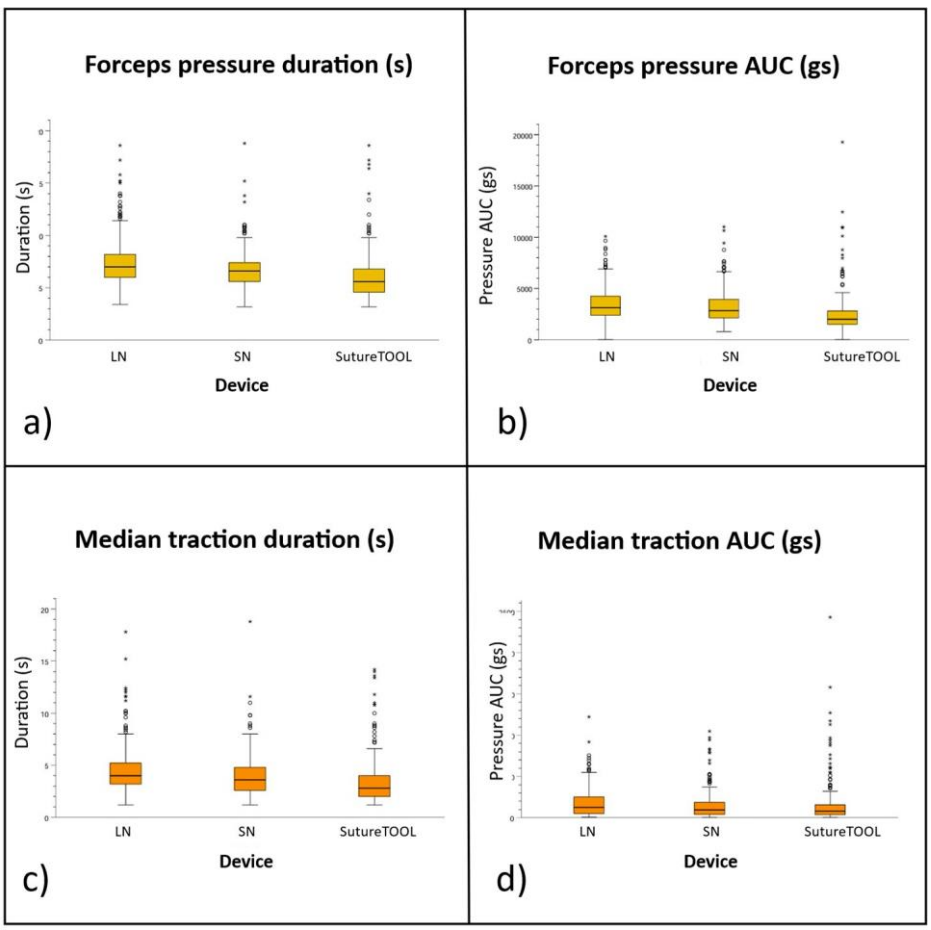

Figure 16. Figure shows **a)** forceps pressure duration **b)** forceps pressure AUC. **c)** median traction duration. **d)** median traction AUC.
LN, large needle. SN, small-needle. AUC, area under curve. s, seconds. gs, gram times seconds.

Paper IV

Method

SutureTOOL had been tested in three in vitro models and the next step was to proceed with an in vivo investigation. Paper IV was a clinical trial conducted in accordance with ISO 14155:2020(E) and the protocol was published at clinicaltrials.gov (ID NCT05695157) prior to study start. The research protocol was developed by the author, principal investigator and the contract research organization (CRO). The study was continuously externally monitored.

Primary endpoint was proportion of patients who received incision closure with SL/WL ratio of at least 4. Secondary endpoints included stitch-count, the number of sutures used, time taken to close the laparotomy, and short-term outcomes. Participants were asked to fill in the VAS. Bite-size and learning curve was also calculated as accessory outcomes.

All data were collected by the research nurse at the time of each surgical procedure. Glove puncture tests were also performed by the research nurse according to the method in paper II. Data were collected on a paper form and transferred into an electronic database for analysis. Initial analysis was performed by the CRO who compiled the investigation report.

Participants and training

Five colorectal surgeons at the colorectal unit at Helsingborg Hospital were invited to participate, three female and two males. All received training in good clinical practice and were handed a kit with the device, sutures and a dry model to practice at will a few months prior to study start.

Patients

Patients over 18 years old and selected for open surgery due to colorectal disease were identified at the multidisciplinary conference and invited to participate. Exclusion criteria included a prior midline incision or current midline hernia, pregnancy, clinical findings that interfere with the objectives of the investigation, collagen disease, disseminated disease, or a life expectancy of less than one year. Figure 17 shows a picture from the clinical trial.

Results

In all 38 patients, a SL/WL ratio ≥4 was achieved on the first attempt, thus the proportion of patients with SL/WL ratio ≥4 was 100%. Mean NCT after the three

first closures was 7.4 minutes on an average wound length of 16.2 cm. Mean SL/WL ratio was 7.6 and mean bite-size was 7 mm. Surgeons' and assistants' gloves (*n*=152) were tested, and no punctures were detected. All patients completed the 6 weeks follow-up. There was one wound infection, and no wound dehiscence was detected.

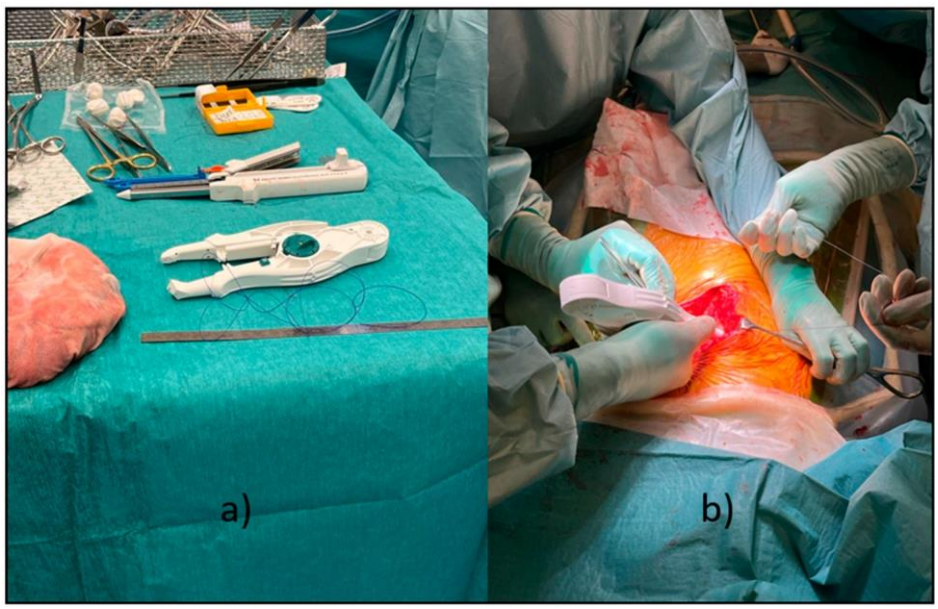

Figure 17. Pictures from the clinical trial. **a)** SutureTOOL and ETHICON™ Linear Cutter placed on the scrub nurse table **b)** the investigational device deployed in closure of a laparotomy wound. The assistant is handling the suture thread. Photographs Lena Toft.

Paper V

Method

This was a cost-effective analysis comparing the economic and clinical outcomes of SutureTOOL suturing compared to NDS representing standard care. A model tree was constructed, including the parameters sharp injury, wound infection, wound dehiscence and incisional hernia (figure 18). The model analysed data with three different closure scenarios: SutureTOOL suturing, and NDS closure with small and large bites. A base case scenario was set to with 50% adherence to small-bites. Data was sourced from published papers and one unpublished scientific paper. The analysis was performed with data from a health care perspective including suturing

materials, operating theater costs, and costs related to surgical complications, but no data on societal costs were included. Separate calculations were done with data representing four different markets: Sweden, UK, US, and France.

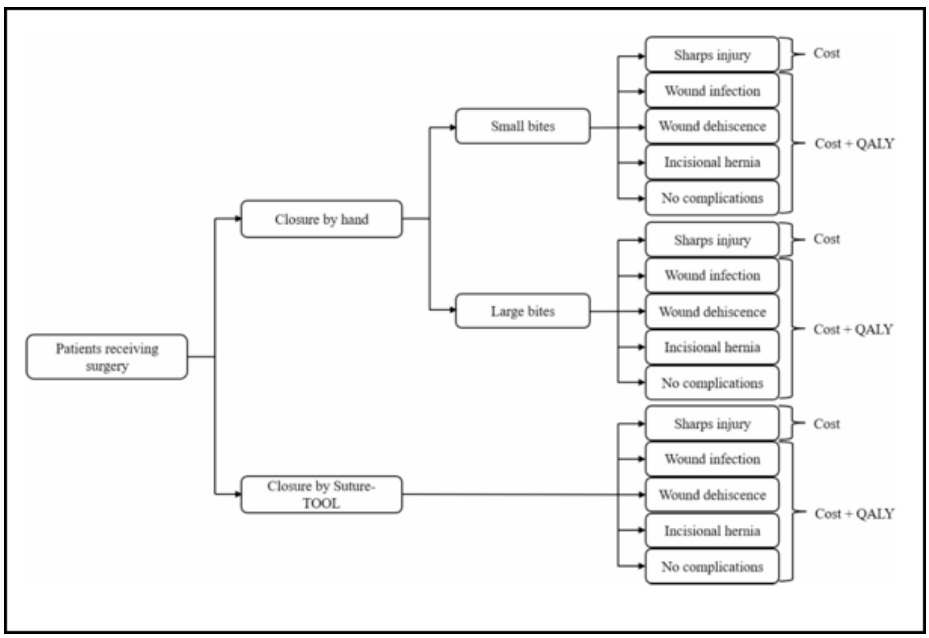

Figure 18. The decision tree model in the Health Economy assessment. Lwin et al. 2025. Used with permission from Springer-Verlag.

Results

Abdominal wall closure with SutureTOOL was cost-effective across the investigated markets by 42% in the US, 33% in Sweden, 27% in the UK, and 24% in France. The potential savings were mainly driven by the reduction in complications (figure 19).

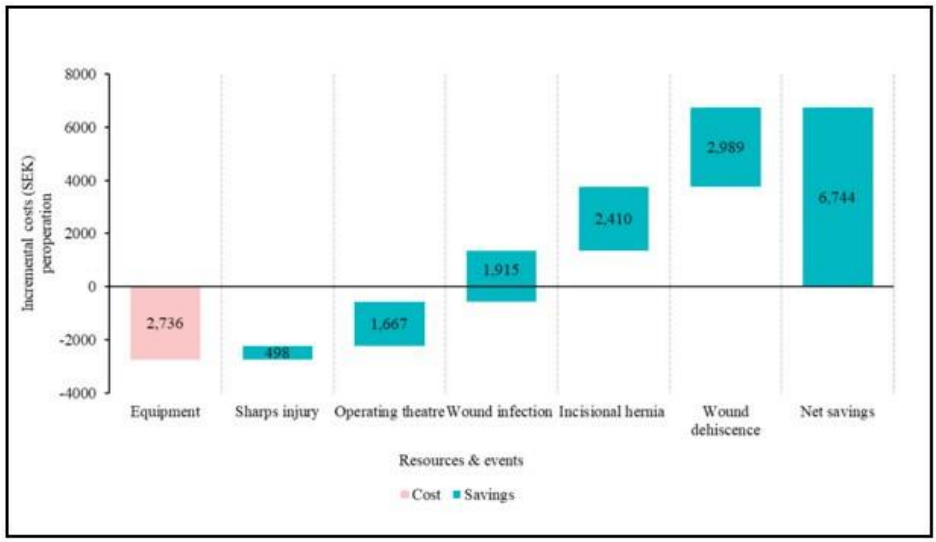

Figure 19. Figure shows results from Sweden. Equipment is the cost of the investigational device, SutureTOOL. Net savings are calculated with the assumption of 50% adherence to small-bites closure technique with NDS and 100% with SutureTOOL. Lwin et al. 2025. Used with permission from Springer-Verlag.

Study outcomes

Adherence to SL/WL of 4

The most important finding in paper I and II was that SutureTOOL secured a high adherence to SL/WL of 4 which indicated a positive proof-of-concept. The comparison of closure times included all incision closures after the initial three closures with SutureTOOL in paper II. The adherence of SL/WL of 4 was only 30%–69% for NDS and in hindsight it would have made more sense to compare incision closure times among closure with a SL/WL ratio of at least 4. As previously discussed, several studies have shown that laparotomy closure with SL/WL ≥4 can reduce the formation of incisional hernia.

The primary endpoint in paper IV was adherence to SL/WL of 4 which was achieved in all patients. The study was conducted in the surgical department at Helsingborg hospital. The department implemented the small-bites closure technique after Israelsson's lecture in 2009, and the participants were therefore accustomed to the technique. It is the department policy to measure and note the SL/WL-ratio after each laparotomy closure, but no counting of the stitches is routinely performed so the actual adherence to small-bites closure remains unknown. Wound dehiscence still occurs at the department but with unknown frequency as no department review of abdominal wall complications has been conducted yet. At the stage of implementation, closures with a SL/WL <4 were routinely re-sutured, but this is nowadays rarely reported. Surgeons who participated in the study were well trained in the small-bites closure technique which could influence the high adherence of SL/WL of 4. One important factor for the SL/WL ratio is how hard the assistant pulls the suture thread. Estimation of tension in knot tying shows a high variation among surgeons, and the fact that the participating surgeons were trained to utilize a low-tension technique probably contributed [174].

Closure time

Many tasks in medicine are time-consuming and there is a risk of reduced quality if performed in a hurry. For instance, the withdrawal time in colonoscopy is related to the polyp detection rate and an average time of ten minutes is appropriate and it should not be shorter than six minutes [175]. In surgery there are many examples that speed can impair performance. In an experimental study by von

Bechtolsheim et al., surgeons performed laparoscopic tasks in a model and found that time strain was related to more errors and the use of more force [176].

In papers I and II, closure time was about 30% shorter when using the SutureTOOL. The individual closure times for each closure in paper I and II were plotted against the corresponding SL/WL ratio to visualize the relationship between speed and quality. The dots were more assembled for SutureTOOL as reflected by the wider boxplots for NDS and it looked like there was an inverse relationship between closure speed and quality for NDS (figure 20a and figure 20b).

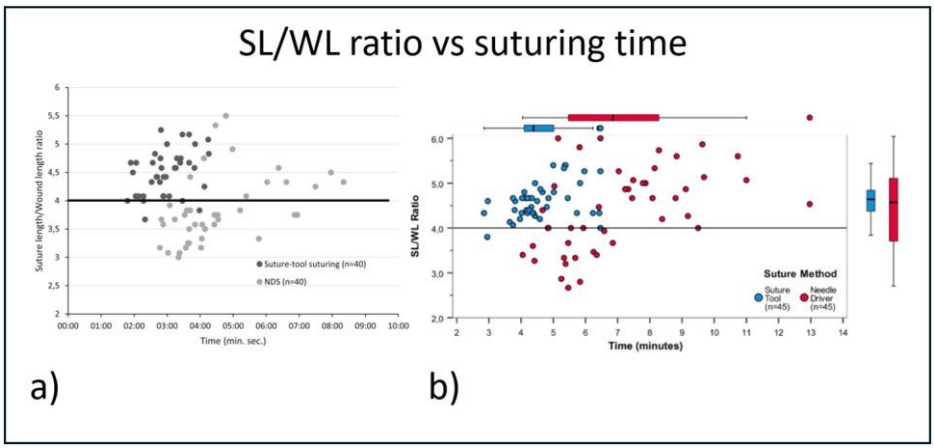

Figure 20. Figure shows SL/WLr plotted against incision closure time. **a)** paper I with 10 participants and **b)** paper II with 15 participants. Black line shows SL/WLr of 4. NDS, needle driver suturing. min, minutes. sec, seconds. Dots: Dark grey, SutureTOOL. Light grey NDS. Blue, SutureTOOL. Red, NDS. Börner et al 2020, 2022. Used with permission from John Wiley & Sons and Elsevier.

In paper III, SutureTOOL was faster compared to both sizes of curved suture needles and no excessive force was detected with SutureTOOL, which is an important information to assess safety parameters with this novel device. The difference in time is probably mostly attributed to the fewer number of activities needed to perform a single needle pull-through with SutureTOOL compared to NDS.

In paper IV, the total closure time was measured from the start knot was finalized until the last stitch was placed. The closure time for each closure and the time taken to perform study specific tasks like measuring the suture thread were recorded to calculate net closure time (NCT). The net closure time was calculated after deducting the time taken to measure the suture length after changing sutures and after the learning curve was assumed to have flattened, NCT. Mean NCT was 7.4 minutes and the shortest NCT was 2.2 minutes with consistent quality. The closure time is not routinely recorded in abdominal wall closure and the focus on this detail can have introduced a bias in closure time. Closure time after

implementation of SutureTOOL in routine surgery is yet to be assessed but can be assumed to be substantially reduced. Closure time with small-bites closure technique is reported to be 14–30 minutes (table 1) and the excess time taken for small-bites is identified as a barrier for implementation [134]. Time savings of 15 minutes per procedure can potentially make room for additional procedures or aid surgeons to fit the procedures in their planned theatre schedule. A conservative estimation of theatre minute costs ranges from €11 to $47 and a reduction in procedure time can contribute to savings of scarce health care budgets [177].

Bite-size and closure quality

The SutureTOOL has a guide that can help the surgeons to direct the stitches to be put at the recommended bite-size and step interval. A study on surgeons ability to assess distance have reported a high inter-individual variation, which can influence adherence to small-bites [157]. The bite-size can be calculated if the wound-length, suture-length and stitch-count is known. Jenkins assumed that each stitch forms an isosceles triangle when calculated the bite-size (figure 3i) [95].

Many suture lines were assessed in this thesis, and it was decided that a suture line more probably has the geometrical shape of a series of right-angled triangles and a new mathematical formula for calculating bite-size with this prerequisite was developed in collaboration with a mathematician at Malmö university (figure 3a-b-d). In addition to the complete adherence to SL/WL ratio of 4, bite-sizes were highly consistent within the recommended range of 5–8 mm across the study, and conclusion was drawn that patients received a laparotomy closure with small-bites (figure 21a).

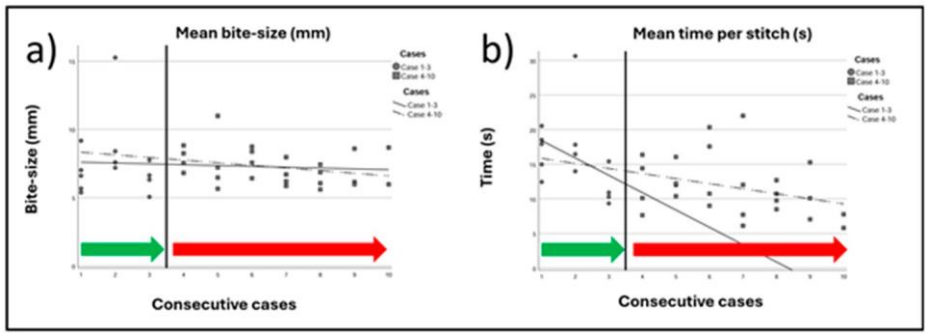

Figure 21. Figure shows **a)** the mean-bite size and **b)** the mean time per stitch in consecutive closures. mm, millimeter. s, seconds. The green arrow indicates first three closures (cases) and the red arrow, the closures (cases) after the learning curve was estimated to have flattened. Arrows added to the figure. Börner et. al. 2025. Used with permission from Springer Nature.

Learning curve

The learning curve was previously assessed in an unpublished pilot study on SutureTOOL with specialists, trainees and scrub nurses, and was found to flatten after three incision closures without prior training with the device. This assumption was used to dimension the number of participants and incision closures in paper I and II.

The actual implementation time with the device in clinical practice is probably dependent of several other factors, but the proxy of the time taken to perform individual consecutive incisional closures with acceptable quality was used as assessment of the learning curve [178]. An assessment of the learning curve is important to understand what training activities are needed for implementing a new device. A short learning curve was suspected after the first study but confirmed by visual inspection of the consecutive mean closure times in the paper II according to figure 12. No formal analysis of the learning curve was performed. This could have been addressed by stating the learning curve as plateau when the reduction in closure time between consecutive closures was less than 10%. The study situation with repetitive incision closures probably influenced the learning curve. Most surgical tasks are trained and learned over a long period of time interspaced with non-training periods.

One of the prerequisites of the clinical trial was that the participants had no previous clinical experience and only minor in vitro experience with the investigational device. Participants were handed the device, the IFU and a simple training model before study start and were encouraged to train handling of the device at will. No tests of participants ability of handling the device were performed prior to the study was started. Learnings from paper I-III indicated that the device was reasonably easy to handle and that the learning curve levelled after three closures why this was not considered a risk for patients [179, 180]. Minimal training was in accordance with our assumption that many of the tools that surgeons use are introduced unsupervised. Training is an essential part to be fluent in the many tasks of surgery but for two reasons the participants were chosen to be novices of the device. An exaggeration of the learning curve was desired to retrieve the initial opinions of the handling of the device from the participating surgeons and scrub nurses, to assess the course of implementation. If the study had been performed after implementation across surgeons in a department, different results would be anticipated. Hence, it would be interesting to track results on SL/WL ratio, bite-size and closure time over time within the framework of the required post-market surveillance.

Learning curve assessment in paper IV assumed that it would be established after three closures. The closure quality as measured by adherence of SL/WL of 4 and the consistent bites-size was consistent through the consecutive incisional closures and in this study. A comparison of mean stitch-time from participants first three cases with the following in a piece-wise linear regression model for learning curve

assessment was performed (figure 21b). There was a difference in correlation coefficient of 1.774 between the groups but it did not reach statistical significance, probably due to a limited number of participants. A consequence of this would be that the cut-off for assessing closure times before and after the effect of the learning curve was established was incorrectly decided.

Evaluation form

Participants were instructed to complete an evaluation form with 11 claims on SutureTOOL (figure 22). The statements in the evaluation form were chosen from discussions among the authors in paper I. The aim was to capture the users' subjective view of the device, from different usability aspects, in a quantifiable way over the course of the development project. The visual analogue scale (VAS) chosen as being fast to set up, simple to complete and an easy method to analyse and visualize the results.

The predecessor, graphic rating scale, was probably first described by Boring at al. in the annual American Psychological Association meeting in 1920 and referred to in a paper by Hayes and Patterson in 1921 [181]. The term VAS was popularized in the 1980s and a PubMed search with publications from 2025, shows that it is commonly used to assess pain but also other areas such as coughing, postoperative pain, pre-operative anxiety and olfaction in patients with nasal polyps. VAS is a 100 mm long line with descriptors to the far left and right that labels the extremes of the statement [182].

The participants were instructed to put a mark on the line reflecting her or his view of the statement on the scale from "disagree" to "agree". The distance from the far left to the mark was measured for all participants and described in boxplots for the corresponding statement. Median was reported in the publications. The aim was to capture the users' subjective view of the device, from different usability aspects, in a quantifiable way over the course of the development project.

Highest scores were detected for "Function is easy to understand'' (VAS 9.4 cm) respectively "Tool facilitates adherence to ratio of 4:1" (VAS 9 cm) for paper I and paper II. No statistical evaluation of the results was performed but visual inspection of the boxplots provided input for the development process. In paper I, "Device has correct weight'' (VAS 6.5 cm), received the lowest score but in paper II, VAS was 9.0 cm for the same statement. which might be reflected by the differences in device construction and weight. In paper I, a stainless-steel prototype was used but in paper II the technology was transferred to a prototype with lighter plastic parts. No validation of the evaluation form has yet been performed and it was constructed with some basic assumptions: it should be short and simple to complete and catch the design and function properties of the device.

Reviewers have commented on some statements to be leading and in hindsight it would have been valuable to have compiled the evaluation form in a structured way. Guidelines to construct questionnaires include an initial consideration phase with an assessment if available questionnaires are applicable, a development phase under an expert committee and a validation phase [183]. It is important that the statements are focused and each address only one piece of information. Participants must understand the wording of the statement and a phrase like "Tool facilitates adherence to ratio of 4:1" is maybe difficult to understand. The guidelines also refrain from using statements and recommend that items are in the form of questions. The reliability of an evaluation form can be assessed in a pilot test by letting participants complete the form more than once after an appropriate time interval. It is also important to analyse if a questionnaire measures what it is intended to measure. An expert panel can be employed to review the content of the questionnaire.

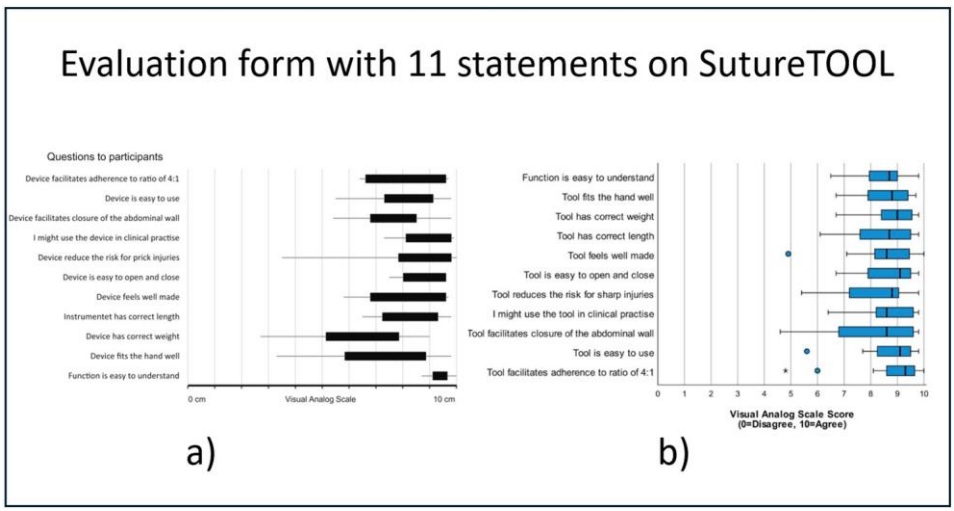

Figure 22. Figure shows the evaluation form from **a)** paper I with 10 participants and **b)** paper II with 15 participants. Börner et al. 2020, 2022. Used with permission from John Wiley & Sons and Elsevier Ltd.

Complications

It was out of scope to assess short- and long-term complications which are important outcomes for the potential clinical value of SutureTOOL. Although the study was not powered to assess complications, only one wound infection, and no wound dehiscence was detected among the included 38 patients. No device related adverse events were recorded during the study. The adherence to SL/WL ratio of 4 with small-bites was 100%, the same suture size and similar slowly absorbable suture material, 2/0 polydioxanone, as is in the standard practice within the department was

used, why a high number of complications would be surprising. Incisional hernia is an important complication and closely linked to the abdominal wall closure technique.

All but one of the patients were operated for colorectal cancer and as a part of their clinical pathway they undergo CT scan. Steps are taken to perform a follow-up with a dedicated examination of the CT scans to assess the 1-year incisional hernia rate and compare results with a control group in a non-inferiority study. A power calculation with the assumption that the intervention with SutureTOOL is less the 10% inferior would require a control group of 180 patients. Nevertheless, the results from the clinical trial needs to be re-assessed and expanded to include follow-up of complications in forementioned post-market surveillance studies after implementation in clinical practice.

Suturing forces

The intention of the study was to assess if the new method for fascia adaptation with SutureTOOL imposed more force on the tissue compared to the standard curved needles. The forces were measured as maximum force at needle pull-through (bite or stitch) and the total force. The total force was a function of adding the continuous measurements multiplied with the number of measurements during the sequence of a needle pull-through, AUC. AUC is hence a function of the duration of each needle pull-through, and the force exerted on the suture pad at each measurement. A short needle pull-through and large force would thus yield the same result as a long needle pull-through but light force. Ideally tissue handling should be fast and transfer a minimum of force to the tissue.

Results showed that the SutureTOOL was faster compared to both curved suture needles and no excessive force was detected with SutureTOOL which is an important information to assess safety parameters with this novel device. The difference in time is probably mostly attributed to the lesser number of activities that are needed to perform a needle pull-through with SutureTOOL compared to NDS.

Kirilova et al. showed, in a study with human cadaver transverse fascia specimens, that the amount of stress the fascia can tolerate is highly variable among individuals and depends also on from what anatomical site in the abdominal wall the fascia is harvested [184]. Authors found that the variation of maximum stress tolerance for the fascia ranged from 0.5 MPa to 2 MPa.

Rodrigues et al. investigated the relationship between tractive forces and tissue damage in different porcine abdominal organs [146]. The abdominal organs specimens were attached to a system built for measuring tractive force and traction was applied in steps of 50 g until the tissue was damaged. Authors found that fascia and aorta had the highest tolerance while uterus and fallopian tube had the lowest tolerance. Fascia was damaged at a median tractive force of roughly 11.5 N but the variation between samples was considerable and ranged from around 9 N to 13 N.

The maximum mean traction force in paper III study was 62 g and the highest recorded value was 440 g, which corresponds to 0.6 N and 4.3 N respectively. If the results are possible to compare, the measurements in the study suturing did not exert the forces that could rupture fascia.

Frimand Rönnow et al. used a precision scale to assess forces involved in a novel needle driver [154]. This study model was further developed with the aim of exclusively recording the medial traction force. Prior to study start, pilot tests were performed to evaluate the model, and it seemed to produce reasonable results. During the study it was realized that the model had issues in keeping baseline flat through the tests, and before analysing the data the recordings were cleared from noise and the waves were adjusted to baseline (figure 16). Participants were instructed to do 10 x 3 needle pull-throughs according to the prepared markings on the suture pad (figure 13c). Nevertheless, some recordings had less waves or more than 10 waves and the total number of recorded waves was 354, 342 and 334 for LN, SN and SutureTOOL respectively. It is possible that the clearing of noise deleted some waves, but it was decided that the influence would be negligible.

Health economy

This was a cost-effective analysis that compared data on closure time, sharp injuries and abdominal wall complications from a health providers' perspective. The study did not include the societal or indirect costs of complications.

A base case scenario was set by including costs for operating time, sharp injuries and wound complications, e.g. SWD, SSI and incisional hernia formation. Small-bites closure was assumed to be used in 100% with SutureTOOL and 50% with NDS. The 50% adherence to small-bites in the NDS group was based on the data from the experimental studies in this thesis and the surveys on surgeons' opinion on small-bites referred to above. Additionally, life-years (LF) and quality-adjusted life years (QALY) were also calculated in the scenario. The base case scenario served as benchmark with inputs from relevant clinical settings. The model was hereafter adjusted with data from Sweden, UK, US and France. The model was based on a three-year incisional hernia rate and data was adjusted accordingly. Results from adjustment for Sweden is showed in figure 19.

The data was sourced from scientific publications and collectively appreciated for validity by the study group. The project was managed by an experienced health economic researcher. The group included a PhD student in health-economy, a representative with non-medical perspective and in-depth experience of the technical and commercial aspects of small-bites and the SutureTOOL device. The author contributed with knowledge of surgery and the specific device as well as the literature related to abdominal wall closure. The ambition was to avoid cherry-picking and generally a conservative attitude was taken when choosing data sources.

The data on small-bites closure time, 14 minutes, and incisional hernia rates of small and large-bites, 13% and 21%, were obtained from the publication on the

STITCH trial [2]. Small-bites closure time with SutureTOOL was set to 6.5 minutes based on results from the clinical trial and a reduction of 1 minute with the assumption of better performance after implementation in clinical practice. Closure time for small-bites varies among publications (Table 1) but data from the STITCH trial was chosen as it is widely accepted and included data on incisional hernia formation. The STITCH trial was not powered for and failed to show a statistical difference in SSIs. Data was hence sourced from the first (semi-) randomized trial published by Millbourn in 2009 [119].

Millbourn et al. reported a total cost of incisional hernia repair ranging from 73 452 SEK to 99 061 SEK for working patients in a publication from 2014. The indirect cost for 20 to 70 days of sick leave was 13 543 SEK to 39 152 SEK which means that indirect costs for working patients undergoing incisional hernia repair roughly constitute 40% of the total cost. The indirect cost depends on the patient population's age at the time of treatment and rate of retirement, which differs between geographical areas. The mean age for patients undergoing colon surgery in Sweden is 75 years of age but in South Korea 48% of patients undergoing colorectal surgery are 40 to 59 years old [86, 185]. The funding policy for sick-leave is also highly variable between countries which influences the societal burden of complications.

LFs and QUALYs were assessed based on likelihood, mortality risk and the reduced quality of life for the related complications. Scientific sources for the duration of SSI and wound dehiscence were difficult to identify and were estimated from clinical experience. LF refers to the number of years of life that a person lives as a result of a certain treatment. QUALY refers to both the quality and quantity of a life lived. A QUALY of 1 means that a person has lived one year in perfect health and a diseased person has the QUALY of 0. Gokani et al. performed a cost-utility analysis on small- and large-bites laparotomy closure [167]. The main question was if the extra operating time required to put the small-bites was cost-effective in relation to the cost of complications. Authors found that the there was a gain in QUALYs of 0.0144 when utilizing the small-bites which equals to £482 per QUALY and draw the conclusion that small-bites was cost-effective with the regards of the extra time it takes to put the small-bites. This would correspond to annual savings of £278 000 while generating 576 QALYS per year in UK.

The health economy assessment in this thesis found that the device was cost-effective in all markets even after the cost of the device was added. The analysis did not report the economics of the QUALYs and LFs, but 0.04 respectively 0.01 was gained when device-assisted suturing with SutureTOOL was used.

Validity of the results

Internal validity concerns if results are correct for the participants in a study and errors can be systematic or random [186]. Systematic errors can be categorized as

selection, information and confounding errors. The external validity concerns if results can be applicable to other populations.

Selection bias

This thesis includes publications that have a risk of bias in several ways. In paper I to III the participants were recruited on availability, which meant that they were acquainted with the researcher and made themselves available or, on some occasions, unavailable to participate. It could be argued, that those who agreed to participate entered with a positive attitude. Selection bias is often a problem in the matching process of case cohort studies and probably in early experimental studies that have limited access to participants and scarce funding [187]. In the ideal situation, a discussion about the desired composition of the participants should have taken place, to make them representative of the target users. The participants were, however, included based on the researcher's network and on the availability of the participants.

One important goal was to include participants of both sexes with assumed different hand sizes, as the device has a certain size and design. In papers I–III 60 participants were included and among them 27 were females. Investigator bias was risk in paper I and II as first author assisted the participants. The intention in paper III was to reduce bias with a research student who conducted the tests and collected the data.

In paper II a human body model was used. This influenced the study and recruitment of participants. The study start was postponed due to the Covid-19 pandemic. The autopsy unit became a restricted area and for several months it was not possible to enter the unit. When the diseased patients were routinely tested for Covid-19 the study could start but there was an uncertainty of the availability of human bodies during the study, and daily changes in the schedule needed to be made. Some invited participants were reluctant to take part in a study on human bodies due to being uncomfortable in the autopsy setting.

Information bias

In paper I–II participants were informed about the small-bites closure technique in a written invitation. They were assumed to be familiar with the technique from their clinical practice and the oral information at the time of the test concerned mostly SutureTOOL features with the subsequent risk of information bias. A potential bias in paper IV was that the study focused on laparotomy closure quality which may have contributed to surgeons' performance in this specific task.

Confounding bias

Investigator bias is a risk in paper I and II. The author assisted the participants in suturing and collected the data at full transparency of the suturing techniques. To mitigate the risk for investigator bias, closure order could have been randomized, and a research student or colleague could have assisted the participants during the closure [114]. In the case of suturing, it would have been difficult to blind the participants for the used technique, but the closure technique could have been blinded for an external evaluator collecting the data. Participants could also have been randomized by either closure technique with the disadvantage of needing to recruit a higher number of participants. For paper II and IV a research nurse collected the data and performed the glove puncture assessment.

External validity

The recorded closure times in paper I and II were short compared to those reported in clinical investigations. In clinical practice the wounds can be longer and the access can be hampered by the patient configuration and incisions placed off the linea alba.

In paper IV concerns about the external validity of the results could be raised. This pilot study included only a limited number of participants with a supposedly positive view of small-bites closure technique, it did not include a comparator, and the study method was associated with potential biases. The participants were trained in small-bites closure technique, but in institutions where other closure techniques are deployed, this lack of routine could influence the adherence to SL/WL ratio of 4. Surgeons were well informed of the purpose of the intraoperative tasks specifically conducted within the study, such as changing the gloves and recording the time for incision closure. In clinical practice these activities will be less highlighted which might influence the outcome.

The patients in paper IV were selected for elective open colorectal procedure from a typical Swedish population. Mean BMI was 27.4 which is comparable with other studies on small-bites closure technique from Europe, but lower than what can be expected from a US population [2, 72, 125]. BMI is a risk factor for complications and more complications could be expected in a population with higher BMI. The investigation was conducted on a small number of patients in the elective setting. The reason for open surgery was most often based on surgeon preference. In an era when MIS techniques are increasingly applied, selection of patients when open approach is required could influence the outcome of complications.

Some common types of bias are related to health economy evaluations. There is a risk that relevant costs are omitted, that costs are over or underestimated or that incremental costs are overestimated [188]. The base case model used a 50% penetration of small-bites closure but there is a large variation between different

specialities and countries that needs to be taken in to account . The data input for the health economy model can be adjusted to reflect outcomes of a specific institution. The potential effect of a sponsor's intention with an evaluation also needs to be considered. To reduce the influence of the sponsor, a third part, The Swedish for Health Economics, was responsible for setting up the data model, managing the project and perform the analysis. The sponsor and authors affiliations and conflict of interest were also clearly stated when submitting the manuscript.

Conclusions

This thesis investigated a novel laparotomy closure device, SutureTOOL, through preclinical, a clinical and a health economic assessment. The overall research question was if the device could facilitate the small-bites placement with a SL/WL ratio of at least 4. Adherence to the SL/WL ratio was 95%, 98% and 100% across 40 participants which is a positive indication.

Small-bites suturing technique implies that the bite size is 5–8 mm and the interval between stitches is 5 mm which is important for healing of the laparotomy. The mean bite-size in the clinical investigation was 7 mm and the variation was low, which is also a positive indication that the device can standardize small-bites laparotomy closure.

A surgical device must be safe for patients and users. No device related adverse effects were recorded in the clinical investigation and the glove puncture assessment of a total of 242 gloves, when the SutureTOOL was used, revealed no punctures. Additionally, even though the clinical investigation was not powered for complications, the rate of wound infection and wound dehiscence seemed low which can indicate that the device is safe.

The cost of health care is steadily increasing and there is a growing population that needs to share the scarce budgets. Theatre time and complications contribute to the costs. SutureTOOL proved cost-effective in reducing closure time and potentially the costs of sharp injuries and complications.

Future aspects

The SutureTOOL propels the straight needle between the arms in a perpendicular way compared to NDS when the needle is passed through tissue tangentially. Additionally, the surgeon does not need to manipulate the needle to hit the target, and the SutureTOOL has a guide that enables small-bites placement with high accuracy. Wavering the tip of the needle in the tissue during suturing with a curved needle is a potential harm to the tissue. It is not known if wavering has clinical relevance, but it would be interesting to compare passage accuracy through tissue between SutureTOOL and NDS in a future experimental study.

Surgical procedures can be lengthy and strenuous and the risk of complications increases by the operating time and there might be a correlation to surgeon fatigue. The SutureTOOL involves less steps in placing the suture line and adherence to small-bites is high. Next steps include to study adherence to small-bites closure technique and surgical site occasions between SutureTOOL and NDS in a setting with patients undergoing long operations like CRS/HIPEC or transplantation surgery.

Several clinical studies have compared outcomes after small- and large- bites. There is a large span in closure times among these studies. Small-bites closure technique involves 5–8 mm bites in the fascia and a step interval of 5 mm and the way the technique is executed might influence the closure time. The developed mathematical formula could be used to calculate bites-size to evaluate published studies for adherence to small-bites closure technique.

Several studies have found better outcomes after surgical procedures performed by female surgeons compared to male surgeons. It would be interesting to assess the influence of surgeon’s sex on the ability to perform the small-bites closure technique.

Populärvetenskaplig sammanfattning på svenska

Avhandlingens målsättning

Öppen bukkirurgi är förknippad med sårinfektioner (10%-20%), sårruptur (3%-5%) och ärrbråck (20%-50%) vilka ger stort patientlidande, nedsatt livskvalitet och stora kostnader för sjukvården i form av reoperationer och förlängd vårdtid. Cancerpatienter som drabbas av komplikationer har ibland svårt att fullfölja sin kompletterande cellgiftsbehandling. Komplikationerna kan minskas med en omsorgsfull förslutningsteknik som också rekommenderas av internationella riktlinjer för bukförslutning. Följsamheten har dock visat sig vara låg. Tekniken går ut på att såret förslutes med en hög kvot av tråd i relation till sårets längd och med många små suturtag vilka fördelar draget över sårets längd.

I slutet av långa och ibland ansträngande operationer är bukförslutnings-momentet en undervärderad del av operationen. Den befintliga manuell tekniken är resurskrävande eftersom det tar lång tid och vid 1/5 av operationerna sker en stickskada vilket innebär oro, risk för blodsmitta och kostnader för utredningar och behandling. Tillgängligheten på operationsutrymme är begränsad och kortare operationstider kan fördela utrymmet till fler patienter.

En medicinteknisk apparat för snabb, säker och standardiserad bukförslutning, SutureTOOL, har utvecklats i samarbete med Lunds universitet. I avhandlingen utvärderades tekniken i tre experimentella, en klinisk och en hälsoekonomisk studie.

Avhandlingens metod

Den primära frågeställningen var om apparaten kunde uppfylla kvalitetskravet på bukförslutning. Övriga frågeställningar var om bukförslutningstiden kunde förkortas, om tekniken innebar att större krafter överfördes tills vävnaden, om den kunde minska risken för stickskador samt om utrustningen kunde innebära hälsoekonomiska vinster. Förslutningskvalitet och förslutningstid jämfördes mellan SutureTOOL och manuell förslutningsteknik i en studie på djurvävnad och i en studie med avlidna personer. I en enkel torrmodell jämfördes också krafterna som överförs till vävnaden vid förslutning. I en klinisk studie utvärderades bukförslutningskvaliteten och förslutningstiden. En modell med data från befintlig

vetenskaplig litteratur togs fram för att utvärdera de hälsoekonomiska effekterna av implementering av SutureTOOL.

Avhandlingens resultat

Förslutning med SutureTOOL hade 95% till 100% följsamhet till den rekommenderade kvaliteten jämfört med 30% till 69% för den manuella tekniken. SutureTOOL utövade mindre pincettkraft och jämförbar slitkraft med den manuella tekniken. I de experimentella studierna var förslutningstiden 30% kortare med SutureTOOL och i kliniska studien var förslutningstiden 7.4 minuter. Få komplikationer identifierades. Den hälsoekonomiska utvärderingen visade att SutureTOOL var kostnadseffektiv i Sverige, Frankrike, USA och Storbritannien.

Avhandlingens slutsatser

SutureTOOL visade sig kunna säkra en hög bukförslutningskvalitet och med kortare förslutningstider vilket också kunde överföras till klinisk verksamhet. SutureTOOL kan genom snabb och standardiserad bukförslutning minska risken för komplikationer och patientlidande.

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References

1. Eads BB, *I. Ventral Hernia following Abdominal Section.* Ann Surg, 1901. **33**(1): p. 1-12.
2. Deerenberg EB, Harlaar JJ, Steyerberg EW, et al., *Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial.* Lancet, 2015. **386**(10000): p. 1254-1260.
3. Alkaaki A, Al-Radi OO, Khoja A, et al., *Surgical site infection following abdominal surgery: a prospective cohort study.* Can J Surg, 2019. **62**(2): p. 111-117.
4. Shanmugam VK, Fernandez SJ, Evans KK, et al., *Postoperative wound dehiscence: Predictors and associations.* Wound Repair Regen, 2015. **23**(2): p. 184-90.
5. Hall AD, Kumar JE, Day PW, *Ephraim McDowell (1771-1830) and Jane Todd Crawford (1763-1842).* J Med Biogr, 2024: p. 9677720241286590.
6. Velez DR, *Jean Baptiste Lucien Baudens: The father of trauma laparotomy.* J Med Biogr, 2024. **32**(2): p. 177-180.
7. NELA Project Team, *Ninth Patient Report of the National Emergency Laparotomy Audit.* Healthcare Quality Improvement Partnership (HQIP). 2024.
8. Jelinek LA, Marietta M, Jones MW, *Surgical Access Incisions*, in *StatPearls*. 2025: Treasure Island (FL).
9. World Health Organization *Caesarean section rates continue to rise, amid growing inequalities in access*. 2021.
10. Wang D, Zhang G, Peng C, et al., *Choosing the right timing for interval debulking surgery and perioperative chemotherapy may improve the prognosis of advanced epithelial ovarian cancer: a retrospective study.* J Ovarian Res, 2021. **14**(1): p. 49.
11. Barrow E, Anderson ID, Varley S, et al., *Current UK practice in emergency laparotomy.* Ann R Coll Surg Engl, 2013. **95**(8): p. 599-603.
12. Ahmed A, Azim A, *Emergency Laparotomies: Causes, Pathophysiology, and Outcomes.* Indian J Crit Care Med, 2020. **24**(Suppl 4): p. S183-S189.
13. Shah PC, de Groot A, Cerfolio R, et al., *Impact of type of minimally invasive approach on open conversions across ten common procedures in different specialties.* Surg Endosc, 2022. **36**(8): p. 6067-6075.
14. Bastawrous AL, Landmann RG, Liu Y, et al., *Incidence, associated risk factors, and impact of conversion to laparotomy in elective minimally invasive sigmoidectomy for diverticular disease.* Surg Endosc, 2020. **34**(2): p. 598-609.
15. Al Dhaheri M, Ibrahim M, Al-Yahri O, et al., *Choice of specimen's extraction site affects wound morbidity in laparoscopic colorectal cancer surgery.* Langenbecks Arch Surg, 2022. **407**(8): p. 3561-3565.

16. Benlice C, Stocchi L, Costedio MM, et al., *Impact of the Specific Extraction-Site Location on the Risk of Incisional Hernia After Laparoscopic Colorectal Resection.* Dis Colon Rectum, 2016. **59**(8): p. 743-50.
17. Hosseinipalangi Z, Golmohammadi Z, Ghashghaee A, et al., *Global, regional and national incidence and causes of needlestick injuries: a systematic review and meta-analysis.* East Mediterr Health J, 2022. **28**(3): p. 233-241.
18. Bakaeen F, Awad S, Albo D, et al., *Epidemiology of exposure to blood borne pathogens on a surgical service.* Am J Surg, 2006. **192**(5): p. e18-21.
19. Nagao M, Iinuma Y, Igawa J, et al., *Accidental exposures to blood and body fluid in the operation room and the issue of underreporting.* Am J Infect Control, 2009. **37**(7): p. 541-4.
20. Kennedy R, Kelly S, Gonsalves S, et al., *Barriers to the reporting and management of needlestick injuries among surgeons.* Ir J Med Sci, 2009. **178**(3): p. 297-9.
21. Voide C, Darling KE, Kenfak-Foguena A, et al., *Underreporting of needlestick and sharps injuries among healthcare workers in a Swiss University Hospital.* Swiss Med Wkly, 2012. **142**: p. w13523.
22. Myers DJ, Epling C, Dement J, et al., *Risk of sharp device-related blood and body fluid exposure in operating rooms.* Infect Control Hosp Epidemiol, 2008. **29**(12): p. 1139-48.
23. Brough SJ, Hunt TM, Barrie WW, *Surgical glove perforations.* Br J Surg, 1988. **75**(4): p. 317.
24. Cardo DM, Culver DH, Ciesielski CA, et al., *A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Prevention Needlestick Surveillance Group.* N Engl J Med, 1997. **337**(21): p. 1485-90.
25. The Royal Australian College of General Practitioners, *Infection prevention and control guidelines for general practices and other office-based and community-based practices*. 2024.
26. Triassi M, Pennino F, *Infectious risk for healthcare workers: evaluation and prevention.* Ann Ig, 2018. **30**(4 Supple 1): p. 48-51.
27. Jennings K, Perera G, *Council Directive 2010-32 EU Sharp injury protection.* Official Journal of the European Union 2010.
28. Senate and House of Representatives of the United States of America, *PUBLIC LAW 106-430—H.R. 5178 NOV. 6, 2000 Needlestick Safety and Prevention Act.* 2000.
29. Mischke C, Verbeek JH, Saarto A, et al., *Gloves, extra gloves or special types of gloves for preventing percutaneous exposure injuries in healthcare personnel.* Cochrane Database Syst Rev, 2014. **2014**(3): p. CD009573.
30. Berguer R, Heller PJ, *Strategies for preventing sharps injuries in the operating room.* Surg Clin North Am, 2005. **85**(6): p. 1299-305, xiii.
31. Center for Disease Control,National Healthcare Safety Network, *Surgical Site Infection Event (SSI)*. 2024.

32. Wan YI, Patel A, Achary C, et al., *Postoperative infection and mortality following elective surgery in the International Surgical Outcomes Study (ISOS).* Br J Surg, 2021. **108**(2): p. 220-227.
33. European Centre for Disease Prevention and Control, *Healthcare-associated infections: surgical site infections. Annual epidemiological Report for 2021–2022.* 2025.
34. Hart Collaborative, *Incisional hernia following colorectal cancer surgery according to suture technique: Hughes Abdominal Repair Randomized Trial (HART).* Br J Surg, 2022. **109**(10): p. 943-950.
35. Marzoug OA, Anees A, Malik EM, *Assessment of risk factors associated with surgical site infection following abdominal surgery: a systematic review.* BMJ Surg Interv Health Technol, 2023. **5**(1): p. e000182.
36. Cheng H, Chen BP, Soleas IM, et al., *Prolonged Operative Duration Increases Risk of Surgical Site Infections: A Systematic Review.* Surg Infect (Larchmt), 2017. **18**(6): p. 722-735.
37. Benlice C, Stocchi L, Sapci I, et al., *Impact of the extraction-site location on wound infections after laparoscopic colorectal resection.* Am J Surg, 2019. **217**(3): p. 502-506.
38. Zweigner J, Magiorakos AP, Haag LM, et al., *European Centre for Disease Prevention and Control, Systematic review and evidencebased guidance on perioperative antibiotic prophylaxis.* 2013.
39. de Jonge SW, Gans SL, Atema JJ, et al., *Timing of preoperative antibiotic prophylaxis in 54,552 patients and the risk of surgical site infection: A systematic review and meta-analysis.* Medicine (Baltimore), 2017. **96**(29): p. e6903.
40. Espin Basany E, Solis-Pena A, Pellino G, et al., *Preoperative oral antibiotics and surgical-site infections in colon surgery (ORALEV): a multicentre, single-blind, pragmatic, randomised controlled trial.* Lancet Gastroenterol Hepatol, 2020. **5**(8): p. 729-738.
41. Ruiz-Tovar J, Boermeester MA, Bordeianou L, et al., *Delphi Consensus on Intraoperative Technical/Surgical Aspects to Prevent Surgical Site Infection after Colorectal Surgery.* J Am Coll Surg, 2022. **234**(1): p. 1-11.
42. Ousey K, *World Union of Wound Healing Societies (WUWHS) Consensus Document. Surgical wound dehiscence: improving prevention and outcomes. Wounds International.* 2018.
43. Muller-Sloof E, de Laat E, Zwanenburg P, et al., *Exploring the definition of surgical wound dehiscence in literature: a Scoping Review.* J Tissue Viability, 2024. **33**(4): p. 923-929.
44. Söderbäck H, Gunnarsson U, Martling A, et al., *Incidence of wound dehiscence after colorectal cancer surgery: results from a national population-based register for colorectal cancer.* Int J Colorectal Dis, 2019. **34**(10): p. 1757-1762.
45. Jensen KK, Oma E, van Ramshorst GH, et al., *Abdominal wound dehiscence is dangerous: a nationwide study of 14,169 patients undergoing elective open resection for colonic cancer.* Hernia, 2022. **26**(1): p. 75-86.

46. Kvist M, Jensen TK, Snitkjaer C, et al., *The clinical consequences of burst abdomen after emergency midline laparotomy: a prospective, observational cohort study.* Hernia, 2024. **28**(5): p. 1861-1870.
47. Gonzalez M, Ruffa T, Scaravonati R, et al., *Fascial dehiscence: predictable complication? Development and validation of a risk model: a retrospective cohort study.* Langenbecks Arch Surg, 2023. **408**(1): p. 50.
48. Vardhini KV, Kishan D, *Incidence and risk factors influencing morbidity and mortality in cases of burst abdomen after emergency and elective midline laparotomies.* International Surgery Journal, 2018. **5**(11).
49. Jaiswal NK, Shekhar S, *Study of burst abdomen: it's causes and management.* International Surgery Journal, 2018. **5**(3).
50. Muysoms FE, Miserez M, Berrevoet F, et al., *Classification of primary and incisional abdominal wall hernias.* Hernia, 2009. **13**(4): p. 407-14.
51. Sanders DL, Kingsnorth AN, *From ancient to contemporary times: a concise history of incisional hernia repair.* Hernia, 2012. **16**(1): p. 1-7.
52. Rothschild NS, *Treatment of Recurrent Incisional Hernia by Flaps of the Anterior Sheath of the Rectus.* Ann Surg, 1935. **101**(2): p. 754-8.
53. Burger JW, Lange JF, Halm JA, et al., *Incisional hernia: early complication of abdominal surgery.* World J Surg, 2005. **29**(12): p. 1608-13.
54. Smith L, Wilkes E, Rolfe C, et al., *Incidence, Healthcare Resource Use and Costs Associated With Incisional Hernia Repair.* J Abdom Wall Surg, 2024. **3**: p. 12452.
55. Chen-Xu J, Bessa-Melo R, Graca L, et al., *Incisional hernia in hepatobiliary and pancreatic surgery: incidence and risk factors.* Hernia, 2019. **23**(1): p. 67-79.
56. Moas V, Eskridge S, Clouser M, et al., *Incisional hernia incidence following laparotomy for combat trauma: Investigating 15 years of US war surgery.* J Trauma Acute Care Surg, 2020. **89**(2S Suppl 2): p. S200-S206.
57. Jensen KK, Emmertsen KJ, Laurberg S, et al., *Long-term impact of incisional hernia on quality of life after colonic cancer resection.* Hernia, 2020. **24**(2): p. 265-272.
58. Walming S, Angenete E, Block M, et al., *Retrospective review of risk factors for surgical wound dehiscence and incisional hernia.* BMC Surg, 2017. **17**(1): p. 19.
59. Tuttle TM, Huang JL, Kizy S, et al., *Incidence and predictors of incisional hernia after cytoreductive surgery and hyperthermic intraperitoneal chemotherapy().* Int J Hyperthermia, 2019. **36**(1): p. 812-816.
60. Itatsu K, Yokoyama Y, Sugawara G, et al., *Incidence of and risk factors for incisional hernia after abdominal surgery.* British Journal of Surgery, 2014. **101**(11): p. 1439-1447.
61. Baucom RB, Ousley J, Beveridge GB, et al., *Cancer Survivorship: Defining the Incidence of Incisional Hernia After Resection for Intra-Abdominal Malignancy.* Ann Surg Oncol, 2016. **23**(Suppl 5): p. 764-771.
62. Klinge U, Junge K, Mertens PR, *Herniosis: a biological approach.* Hernia, 2004. **8**(4): p. 300-1.
63. Read RC, *Inguinal herniation in the adult, defect or disease: a surgeon's odyssey.* Hernia, 2004. **8**(4): p. 296-9.

64. Cialdai F, Risaliti C, Monici M, *Role of fibroblasts in wound healing and tissue remodeling on Earth and in space.* Front Bioeng Biotechnol, 2022. **10**: p. 958381.
65. Sharma S, Kishen A, *Dysfunctional crosstalk between macrophages and fibroblasts under LPS-infected and hyperglycemic environment in diabetic wounds.* Sci Rep, 2025. **15**(1): p. 17233.
66. Paulsen C, Zetner D, Rosenberg J, *Incisional hernia after cesarean section: A systematic review.* European Journal of Obstetrics & Gynecology and Reproductive Biology, 2020. **244**: p. 128-133.
67. Nilsson JH, Strandberg Holka P, Sturesson C, *Incisional hernia after open resections for colorectal liver metastases - incidence and risk factors.* HPB (Oxford), 2016. **18**(5): p. 436-41.
68. Moussavian MR, Schuld J, Dauer D, et al., *Long term follow up for incisional hernia after severe secondary peritonitis-incidence and risk factors.* Am J Surg, 2010. **200**(2): p. 229-34.
69. Jensen KK, Nordholm-Carstensen A, Krarup PM, et al., *Incidence of Incisional Hernia Repair After Laparoscopic Compared to Open Resection of Colonic Cancer: A Nationwide Analysis of 17,717 Patients.* World J Surg, 2020. **44**(5): p. 1627-1636.
70. Karlsson N, Zackrisson S, Buchwald P, *Computed Tomography Verified Prevalence of Incisional Hernia 1 Year Postoperatively after Colorectal Cancer Resection.* Scand J Surg, 2021. **110**(3): p. 373-379.
71. Hollinsky C, Sandberg S, Kocijan R, *Preliminary results with the reinforced tension line: a new technique for patients with ventral abdominal wall hernias.* Am J Surg, 2007. **194**(2): p. 234-9.
72. Wenzelberg CL, Rogmark P, Ekberg O, et al., *Reinforced tension-line suture after laparotomy: early results of the Rein4CeTo1 randomized clinical trial.* Br J Surg, 2024. **111**(10).
73. Fortelny RH, *Abdominal Wall Closure in Elective Midline Laparotomy: The Current Recommendations.* Front Surg, 2018. **5**: p. 34.
74. Nilsson T, *Effect of increased and reduced tension on the mechanical properties of healing wound in the abdominal wall.* Scand J Plast Reconstr Surg, 1982. **16**(2): p. 101-5.
75. Högström H, Haglund U, Zederfeldt B, *Tension leads to increased neutrophil accumulation and decreased laparotomy wound strength.* Surgery, 1990. **107**(2): p. 215-9.
76. Smith CT, Katz MG, Foley D, et al., *Incidence and risk factors of incisional hernia formation following abdominal organ transplantation.* Surg Endosc, 2015. **29**(2): p. 398-404.
77. Murray BW, Cipher DJ, Pham T, et al., *The impact of surgical site infection on the development of incisional hernia and small bowel obstruction in colorectal surgery.* Am J Surg, 2011. **202**(5): p. 558-60.
78. van Ramshorst GH, Eker HH, van der Voet JA, et al., *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. **17**(8): p. 1477-84.

79. Michot N, Ortega-Deballon P, Karam E, et al., *Is There a Clinical Benefit of Abdominal Binders After Abdominal Surgery: A Systematic Literature Review.* J Abdom Wall Surg, 2024. **3**: p. 13506.
80. Deerenberg EB, Henriksen NA, Antoniou GA, et al., *Updated guideline for closure of abdominal wall incisions from the European and American Hernia Societies.* Br J Surg, 2022. **109**(12): p. 1239-1250.
81. Tahiri M, Sikder T, Maimon G, et al., *The impact of postoperative complications on the recovery of elderly surgical patients.* Surgical Endoscopy, 2015. **30**(5): p. 1762-1770.
82. Zoucas E, Lydrup ML, *Hospital costs associated with surgical morbidity after elective colorectal procedures: a retrospective observational cohort study in 530 patients.* Patient Saf Surg, 2014. **8**(1): p. 2.
83. Badia JM, Casey AL, Petrosillo N, et al., *Impact of surgical site infection on healthcare costs and patient outcomes: a systematic review in six European countries.* Journal of Hospital Infection, 2017. **96**(1): p. 1-15.
84. Wasserman D, Boulos M, Hopman W, et al., *Reasons for Delay in Time to Initiation of Adjuvant Chemotherapy for Colon Cancer.* J Oncol Pract. , 2015: p. 28-35.
85. Kaufman MR, Eschliman EL, Karver TS, *Differentiating sex and gender in health research to achieve gender equity.* Bull World Health Organ, 2023. **101**(10): p. 666-671.
86. Engdahl J, Öberg A, Bech-Larsen S, et al., *Short- and long-term outcome after colon cancer resections performed by male and female surgeons: A single-center retrospective cohort study.* Scand J Surg, 2024. **113**(2): p. 131-139.
87. Wallis CJD, Jerath A, Aminoltejari K, et al., *Surgeon Sex and Long-Term Postoperative Outcomes Among Patients Undergoing Common Surgeries.* JAMA Surg, 2023. **158**(11): p. 1185-1194.
88. Blohm M, McGrath A, Mukka S, et al., *Swedish female and male general surgeons differ in personality traits.* Scand J Surg, 2024: p. 14574969241299472.
89. Gili-Ortiz E, Gonzalez-Guerrero R, Bejar-Prado L, et al., *Postoperative dehiscence of the abdominal wound and its impact on excess mortality, hospital stay and costs.* Cir Esp, 2015. **93**(7): p. 444-9.
90. Langelotz C, Mueller-Rau C, Terziyski S, et al., *Gender-Specific Differences in Surgical Site Infections: An Analysis of 438,050 Surgical Procedures from the German National Nosocomial Infections Surveillance System.* Viszeralmedizin, 2014. **30**(2): p. 114-7.
91. Aghdassi SJS, Schroder C, Gastmeier P, *Gender-related risk factors for surgical site infections. Results from 10 years of surveillance in Germany.* Antimicrob Resist Infect Control, 2019. **8**: p. 95.
92. Goto S, Hasegawa S, Hata H, et al., *Differences in surgical site infection between laparoscopic colon and rectal surgeries: sub-analysis of a multicenter randomized controlled trial (Japan-Multinational Trial Organization PREV 07-01).* Int J Colorectal Dis, 2016. **31**(11): p. 1775-1784.
93. Almohrij SA, *Time of developing surgical site infections and its association with patient and procedure characteristics.* J Infect Public Health, 2025. **18**(5): p. 102734.

94. Zwicky SN, Gloor S, Tschan F, et al., *No impact of sex on surgical site infections in abdominal surgery: a multi-center study.* Langenbecks Arch Surg, 2022. **407**(8): p. 3763-3769.
95. Jenkins TP, *The burst abdominal wound: a mechanical approach.* Br J Surg, 1976. **63**(11): p. 873-6.
96. Börner G, Toft L, Rogmark P, et al., *A feasibility and safety trial investigating a device for swift and standardized median laparotomy closure.* Hernia, 2025. **29**(1): p. 196.
97. Israelsson LA, Jonsson T, *Suture length to wound length ratio and healing of midline laparotomy incisions.* Br J Surg, 1993. **80**(10): p. 1284-6.
98. Israelsson LA, *The surgeon as a risk factor for complications of midline incisions.* Eur J Surg, 1998. **164**(5): p. 353-9.
99. Varshney S, Manek P, Johnson CD, *Six-fold suture:wound length ratio for abdominal closure.* Ann R Coll Surg Engl, 1999. **81**(5): p. 333-6.
100. Millbourn D, Israelsson LA, *Wound complications and stitch length.* Hernia, 2003. **8**(1): p. 39-41.
101. Campbell JA, Temple WJ, Frank CB, et al., *A biomechanical study of suture pullout in linea alba.* Surgery, 1989. **106**(5): p. 888-92.
102. Harlaar JJ, van Ramshorst GH, Nieuwenhuizen J, et al., *Small stitches with small suture distances increase laparotomy closure strength.* Am J Surg, 2009. **198**(3): p. 392-5.
103. Cengiz Y, Blomquist P, Israelsson LA, *Small tissue bites and wound strength: an experimental study.* Arch Surg, 2001. **136**(3): p. 272-5.
104. Höer J, Klinge U, Schachtrupp A, et al., *Influence of suture technique on laparotomy wound healing: an experimental study in the rat.* Langenbecks Arch Surg, 2001. **386**(3): p. 218-23.
105. Myers BC, *Functional and angiographic vasculature in healing wounds.* 1970.
106. Kushner BS, Arefanian S, McAllister J, et al., *Examination of abdominal wall perfusion using varying suture techniques for midline abdominal laparotomy closure.* Surg Endosc, 2022. **36**(6): p. 3843-3851.
107. Spitzer W, *The periodic health examination. Canadian Task Force on the Periodic Health Examination.* Can Med Assoc J, 1979. **121**(9): p. 1193-254.
108. Sackett DL, *Rules of Evidence and Clinical Recommendations on the Use of Antithrombotic Agents.* Chest, 1989. **95**(2): p. 2S-4S.
109. Wallace SS, Barak G, Truong G, et al., *Hierarchy of Evidence Within the Medical Literature.* Hosp Pediatr, 2022. **12**(8): p. 745-750.
110. Bosdriesz JR, Stel VS, van Diepen M, et al., *Evidence-based medicine-When observational studies are better than randomized controlled trials.* Nephrology (Carlton), 2020. **25**(10): p. 737-743.
111. Faraoni D, Schaefer ST, *Randomized controlled trials vs. observational studies: why not just live together?* BMC Anesthesiol, 2016. **16**(1): p. 102.

112. Claes K, Beckers R, Heindryckx E, et al., *Retrospective observational study on the incidence of incisional hernias after colorectal carcinoma resection with follow-up CT scan.* Hernia, 2014. **18**(6): p. 797-802.
113. Barranquero AG, Molina JM, Gonzalez-Hidalgo C, et al., *Incidence and risk factors for incisional hernia after open abdominal aortic aneurysm repair.* Cir Esp (Engl Ed), 2022. **100**(11): p. 684-690.
114. Paradis C, *Bias in Surgical Research.* Annals of Surgery, 2008. **248**(2): p. 180-188.
115. Ozcan C, Colak T, Turkmenoglu O, et al., *Impact of small-bite (5 mm) fascial closure on the incidence of incisional hernia following open colorectal cancer surgery: randomized clinical trial.* Br J Surg, 2024. **111**(8).
116. Ghai GS, S H, *A Comparison of a Small-Stitch Closure With a Standard Closure in Midline Laparotomy Incisions: A Prospective Comparative Study.* Cureus, 2023. **15**(12): p. e50035.
117. Albertsmeier M, Hofmann A, Baumann P, et al., *Effects of the short-stitch technique for midline abdominal closure: short-term results from the randomised-controlled ESTOIH trial.* Hernia, 2022. **26**(1): p. 87-95.
118. Mustaqrasool T, Dikshit B, Phalgune D, *Comparison of efficacy of large tissue bites versus small tissue bites for midline abdominal wound closure.* International Surgery Journal, 2020. **7**(2).
119. Millbourn D, Cengiz Y, Israelsson LA, *Effect of stitch length on wound complications after closure of midline incisions: a randomized controlled trial.* Arch Surg, 2009. **144**(11): p. 1056-9.
120. Williams ZF, Tenzel P, Hooks WB, 3rd, et al., *Suture to wound length ratio in abdominal wall closure: how well are we doing?* Hernia, 2017. **21**(6): p. 869-872.
121. Thorup T, Tolstrup MB, Gogenur I, *Reduced rate of incisional hernia after standardized fascial closure in emergency laparotomy.* Hernia, 2019. **23**(2): p. 341-346.
122. Straubhar AM, Stroup C, Manorot A, et al., *Small bite fascial closure technique reduces incisional hernia rates in gynecologic oncology patients.* Int J Gynecol Cancer, 2024. **34**(5): p. 745-750.
123. de Vries HS, Verhaak T, van Boxtel TH, et al., *Implementation of the small bites closure of abdominal midline incisions in clinical practice is correlated with a reduction in surgical site infections.* Hernia, 2020. **24**(4): p. 839-843.
124. Pereira Rodriguez JA, Amador-Gil S, Bravo-Salva A, et al., *Small bites technique for midline laparotomy closure: From theory to practice: Still a long way to go.* Surgery, 2021. **170**(1): p. 140-145.
125. Fortelny RH, Andrade D, Schirren M, et al., *Effects of the short stitch technique for midline abdominal closure on incisional hernia (ESTOIH): randomized clinical trial.* Br J Surg, 2022. **109**(9): p. 839-845.
126. Frassini S, Cobianchi L, Fugazzola P, et al., *ECLAPTE: Effective Closure of LAParoTomy in Emergency-2023 World Society of Emergency Surgery guidelines for the closure of laparotomy in emergency settings.* World J Emerg Surg, 2023. **18**(1): p. 42.

127. Antoniou GA, Muysoms FE, Deerenberg EB, *Updated Guideline on Abdominal Wall Closure from the European and American Hernia Societies: Transferring Recommendations to Clinical Practice for Vascular Surgeons.* Eur J Vasc Endovasc Surg, 2023. **65**(6): p. 774-777.
128. Henriksen NA, Bougard H, Goncalves MR, et al., *Primary ventral and incisional hernias: comprehensive review.* BJS Open, 2024. **9**(1).
129. Stephens IJB, Kelly E, Ferreira F, et al., *Variable use of modern abdominal wall closure techniques at emergency laparotomy - an international, cross-sectional survey of surgical practice.* Eur J Trauma Emerg Surg, 2025. **51**(1): p. 141.
130. Messenger DE, Rajaretnam N, Slade DAJ, et al., *CLosure of Abdominal MidlineS Survey (CLAMSS): A national survey investigating current practice in the closure of abdominal midline incisions in UK surgical practice.* Colorectal Dis, 2024. **26**(8): p. 1617-1631.
131. Pous-Serrano S, Garcia-Pastor P, Bueno-Lledo J, *National survey of colorectal surgery units on abdominal wall closure.* Cir Esp (Engl Ed), 2023. **101**(4): p. 258-264.
132. Chowdhury S, El-Hussuna A, Gallo G, et al., *An international assessment of surgeon practices in abdominal wound closure and surgical site infection prevention by the European Society for Coloproctology.* Colorectal Dis, 2023. **25**(5): p. 1014-1025.
133. Paulsen CB, Zetner D, Rosenberg J, *Variation in abdominal wall closure techniques in lower transverse incisions: a nationwide survey across specialties.* Hernia, 2021. **25**(2): p. 345-352.
134. Fischer JP, Harris HW, Lopez-Cano M, et al., *Hernia prevention: practice patterns and surgeons' attitudes about abdominal wall closure and the use of prophylactic mesh.* Hernia, 2019. **23**(2): p. 329-334.
135. Bloemen A, De Kleijn R, Van Steensel S, et al., *Laparotomy closure techniques: Do surgeons follow the latest guidelines? Results of a questionnaire.* Int J Surg, 2019. **71**: p. 110-116.
136. Lawday S, Mattick K, Bethune R, *Does randomised evidence alter clinical practise? The react qualitative study.* BMC Health Serv Res, 2024. **24**(1): p. 862.
137. Dossa F, Speller B, Acuna SA, et al., *Use of the small-bites fascial closure technique and strategies to improve adoption: mixed-methods study.* Br J Surg, 2021. **108**(10): p. e320-e321.
138. Desai MS, Desai, S.P., *Discovery of Modern Anesthesia: A Counterfactual Narrative about Crawford W. Long, Horace Wells, Charles T. Jackson, and William T. G. Morton.* AANA J. , 2015. **83**(6): p. 5.
139. Toledo-Pereyra LH, *Joseph Lister's surgical revolution.* J Invest Surg, 2010. **23**(5): p. 241-3.
140. Kirkup J, *The history and evolution of surgical instruments. V needles and their penetrating derivatives.* Ann R Coll Surg Engl, 1986. **68**(1): p. 29-33.
141. Hussey M, Bagg M, *Principles of Wound Closure.* Operative Techniques in Sports Medicine, 2011. **19**(4): p. 206-211.

142. Rath AC, Chevrel J, *The healing of laparotomies: review of the literature.* Hernia, 1998. **2**(3): p. 145-149.
143. Odermatt EK, Funk L, Bargon R, et al., *MonoMax Suture: A New Long-Term Absorbable Monofilament Suture Made from Poly-4-Hydroxybutyrate.* International Journal of Polymer Science, 2012. **2012**: p. 1-12.
144. Covidien, *Maxon™ Monofilament Synthetic Absorbable Suture.* 2008.
145. Johnson & Johnson Medical Limited, *Absorbable sutures - The strength that you need for the choices you make.* 2020.
146. Rodrigues SP, Horeman T, Dankelman J, et al., *Suturing intraabdominal organs: when do we cause tissue damage?* Surg Endosc, 2012. **26**(4): p. 1005-9.
147. Sugarbaker PH, *Observations on opening and closing the abdominal incision for cytoreductive surgery using a self-retaining retractor to reduce the incidence of incisional hernia.* Surg Oncol, 2020. **35**: p. 5-11.
148. Edlich RF, Towler MA, Rodeheaver GT, et al., *Scientific basis for selecting surgical needles and needle holders for wound closure.* Clin Plast Surg, 1990. **17**(3): p. 583-602.
149. Byrne M, Aly A, *The Surgical Needle.* Aesthetic Surgery Journal, 2019. **39**(Supplement_2): p. S73-S77.
150. Zhang G, Zeng X, Su Y, et al., *Influence of suture size on the frictional performance of surgical suture evaluated by a penetration friction measurement approach.* J Mech Behav Biomed Mater, 2018. **80**: p. 171-179.
151. Jackson RC, Desai V, Castillo JP, et al., *Needle-Tissue Interaction Force State Estimation for Robotic Surgical Suturing.* Rep U S, 2016. **2016**: p. 3659-3664.
152. Seki S, *Accuracy of suture placement.* Br J Surg, 1987. **74**(3): p. 195-7.
153. Seki S, *Techniques for better suturing.* Br J Surg, 1988. **75**(12): p. 1181-4.
154. Frimand Rönnow CF, Jeppsson B, Thorlacius H, *Frimand Needle Holder Reduces Suturing Time and Surgical Stress When Suturing in Palm Grip.* Surg Innov, 2016. **23**(3): p. 235-41.
155. Theodorou A, Banysch M, Gök H, et al., *Don't fear the (small) bite: A narrative review of the rationale and misconceptions surrounding closure of abdominal wall incisions.* Front Surg, 2022. **9**: p. 1002558.
156. Mirzaee S, Golzarand M, Parsaei R, et al., *How accurate is the visual estimation of bowel length by endoscopic surgeons?* Front Surg, 2022. **9**: p. 1001329.
157. Conway RG, O'Neill N, Brown J, et al., *An educated guess - Distance estimation by surgeons.* Surg Open Sci, 2020. **2**(3): p. 113-116.
158. James C, *Health at a Glance 2023 - OECD Indicators*. Health at a Glance. 2023: OECD Publishing, Paris.
159. Wordsworth S, Buchanan J, Towse A, *Health Economic Perspectives of Genomics*, in *Genomics and Society*. 2016. p. 83-117.
160. Turner HC, Archer RA, Downey LE, et al., *An Introduction to the Main Types of Economic Evaluations Used for Informing Priority Setting and Resource Allocation in Healthcare: Key Features, Uses, and Limitations.* Front Public Health, 2021. **9**: p. 722927.

161. Kotsis SV, Chung KC, *Fundamental principles of conducting a surgery economic analysis study.* Plast Reconstr Surg, 2010. **125**(2): p. 727-735.
162. Jamison DB, Measham J, Alleyne G, et al., *Priorities in Health.* The International Bank for Reconstruction and Development 2006.
163. Glenngard AH, Persson U, *Costs associated with sharps injuries in the Swedish health care setting and potential cost savings from needle-stick prevention devices with needle and syringe.* Scand J Infect Dis, 2009. **41**(4): p. 296-302.
164. Hanmore E, Maclaine G, Garin F, et al., *Economic benefits of safety-engineered sharp devices in Belgium - a budget impact model.* BMC Health Serv Res, 2013. **13**: p. 489.
165. Childers CP, Maggard-Gibbons M, *Understanding Costs of Care in the Operating Room.* JAMA Surg, 2018. **153**(4): p. e176233.
166. Millbourn D, Wimo A, Israelsson LA, *Cost analysis of the use of small stitches when closing midline abdominal incisions.* Hernia, 2014. **18**(6): p. 775-80.
167. Gokani SA, Elmqvist KO, El-Koubani O, et al., *A cost-utility analysis of small bite sutures versus large bite sutures in the closure of midline laparotomies in the United Kingdom National Health Service.* Clinicoecon Outcomes Res, 2018. **10**: p. 105-117.
168. Medical Device Coordination Group, *Summary of safety and clinical performance A guide for manufacturers and notified bodies.* 2022.
169. Williams CP, Rosen MJ, Jin J, et al., *Objective analysis of the accuracy and efficacy of a novel fascial closure device.* Surg Innov, 2008. **15**(4): p. 307-11.
170. Laios K, Bontinis V, Bontinis A, et al., *Mathieu Jaboulay (1860-1913) and His Innovations in Vascular and General Surgery.* Surg Innov, 2020. **27**(1): p. 120-123.
171. Adams JB, Schulam PG, Moore RG, et al., *New laparoscopic suturing device: initial clinical experience.* Urology, 1995. **46**(2): p. 242-5.
172. World Medical Association, *World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.* JAMA, 2013. **27**: p. 4.
173. Börner G, Edelhamre M, Rogmark P, et al., *Suture-TOOL: A suturing device for swift and standardized abdominal aponeurosis closure.* Surg Pract Sci, 2022. **11**: p. 100137.
174. von Trotha KT, Grommes J, Butz N, et al., *Surgical sutures: coincidence or experience?* Hernia, 2017. **21**(4): p. 505-508.
175. Kaminski MF, Thomas-Gibson S, Bugajski M, et al., *Performance measures for lower gastrointestinal endoscopy: a European Society of Gastrointestinal Endoscopy (ESGE) quality improvement initiative.* United European Gastroenterol J, 2017. **5**(3): p. 309-334.
176. von Bechtolsheim F, Schmidt S, Abel S, et al., *Does speed equal quality? Time pressure impairs minimally invasive surgical skills in a prospective crossover trial.* Int J Surg, 2022. **104**: p. 106813.
177. Lwin ZMT, Börner G, Verheij-Engqvist S, et al., *A literature-based cost-effectiveness analysis of device-assisted suturing versus needle-driven suturing during laparotomy closure.* Hernia, 2025. **29**(1): p. 77.

178. Subramonian K, Muir G, *The 'learning curve' in surgery: what is it, how do we measure it and can we influence it?* BJU Int, 2004. **93**(9): p. 1173-4.
179. Börner G, Edelhamre M, Rogmark P, et al., *Suture-TOOL: A suturing device for swift and standardized abdominal aponeurosis closure.* Surgery in Practice and Science, 2022. **11**.
180. Börner G, Montgomery A, *Suture-Tool: A Mechanical Needle Driver for Standardized Wound Closure.* World J Surg, 2020. **44**(1): p. 95-99.
181. Shiina K, *Commentary: The Historical Roots of Visual Analog Scale in Psychology as Revealed by Reference Publication Year Spectroscopy.* Front Hum Neurosci, 2021. **15**: p. 711691.
182. Heller GZ, Manuguerra M, Chow R, *How to analyze the Visual Analogue Scale: Myths, truths and clinical relevance.* Scand J Pain, 2016. **13**: p. 67-75.
183. Tsang S, Royse CF, Terkawi AS, *Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine.* Saudi J Anaesth, 2017. **11**(Suppl 1): p. S80-S89.
184. Kirilova M, Stoytchev S, Pashkouleva D, et al., *Experimental study of the mechanical properties of human abdominal fascia.* Med Eng Phys, 2011. **33**(1): p. 1-6.
185. Lee T-H, Choo JM, Kim JS, et al., *Characteristics and outcomes of colorectal cancer surgery by age in a tertiary center in Korea: a retrospective review.* Annals of Coloproctology, 2022. **38**(3): p. 244-252.
186. Sala Serra M, Domingo Torrell L, *Validity of a study: Internal and external validity.* Cir Esp (Engl Ed), 2022. **100**(10): p. 649-651.
187. Pannucci C, Wilkins G, *Identifying and Avoiding Bias in Research.* Plastic and Reconstructive Surgery, 2010. **126**(2): p. 619-625.
188. Evers SM, Hiligsmann M, Adarkwah CC, *Risk of bias in trial-based economic evaluations: identification of sources and bias-reducing strategies.* Psychol Health, 2015. **30**(1): p. 52-71.

Paper I

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Suture-Tool: A Mechanical Needle Driver for Standardized Wound Closure

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Abstract

Introduction A laparotomy is commonly required to gain abdominal access. A safe standardized access and closure technique is warranted to minimize abdominal wall complications like wound infections, burst abdomen and incisional hernias. Stitches are recommended to be small and placed tightly, obtaining a suture length-to-incision length (SL/WL) ratio of C 4:1. This can be time-consuming and difficult to achieve especially following long trying surgical procedures. The aim was to develop and evaluate a new mechanical suture device for standardized wound closure.

Methods A mechanical suture device (Suture-tool) was developed in collaboration between a medical technology engineer team with the aim to achieve a standardized suture line of high quality that could be performed speedy and safe. Ten surgeons closed an incision in an animal tissue model after a standardized introduction of the instrument comparing the device to conventional needle driver suturing (NDS) using the 4:1 technique. Outcome measures were SL/WL ratio, number of stitches and suture time.

Results In total, 80 suture lines were evaluated. SL/WL ratio of C 4 was achieved in 95% using the Suture-tool and 30% using NDS ($p \setminus$ 0,001). Number of stitches was similar. Suture time was 30% shorter using the Suture-tool compared to NDS (2 min 54 s vs. 4 min 5 s; $p \setminus 0.001$).

Conclusions The mechanical needle driver seems to be a promising device to perform a speedy standardized high-quality suture line for fascial closure.

Introduction

Surgical procedures of the abdominal cavity commonly require open surgical access. These patients have a risk of abdominal wall complications such as wound infection, burst abdomen and incisional hernia formation. Incisional hernia is a frequent long-term problem with an incidence between 10 and 69% depending on the type of surgery, type of incision, length of surgery, comorbidities, method of follow-up and patient characteristics [1, 2]. In patients undergoing elective open abdominal surgery through a midline laparotomy, an incisional hernia was seen in around 12% after 1 year and the incidence increases gradually to [20% after 3 years [3]. Many factors for the development of an incisional hernia are patient dependent, but the surgical technique when opening and closing the abdomen at laparotomy is another important risk factor for wound complications. A midline laparotomy should always be kept strict to the midline without entering the muscular compartments that would create weak areas. The closure

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technique is also a factor that can be influenced. It is recommended that the suture length-to-wound length (SL/WL) ratio is C 4 and that the ratio is acquired with small stitches put tightly [4]. This might be time-consuming and difficult to achieve following long and trying surgical procedures.

A device for producing a ''mechanical'' suture line has previously been used for laparoscopic surgery, especially to perform a fundoplication (Endo Stitch™ Suturing Device, Medtronic, Minneapolis, Minnesota, USA). There is, however to our knowledge, no available suturing device for standardized closure of the abdominal wall aponeurosis. The aim of this study was to develop and evaluate a suture device for standardized abdominal wound closure.

Materials and method

Mechanical needle driver—Suture-tool

Suture-tool was developed in collaboration with an engineer team. It is a hand-held ''sewing machine'' using a double pointed needle with a centrally attached thread (Fig. 1). Suture-tool has a guide that facilitates correct stitch placement. Jaws are compressed to pass the needle through the tissue, and thereafter, the needle is automatically picked up by the opposing jaw. Hereafter, Suture-tool is let open releasing the tissue. The sequence is repeated on the other side of the incision, and thus, a complete stitch is performed according to Fig. 2.

Abdominal wall model

The model used prepared fascia from elk abdominal wall mounted in a wooden box. Elk fascia resembles human abdominal wall midline aponeurosis. A 12-cm-long incision was prepared in the fascia (Fig. 3).

Suture-tool suturing

Surgeons were introduced to Suture-tool and the technique of suturing by watching an instruction film. Suturing was practiced and participants were licensed to participate in the study when 10 stitches were made with ease.

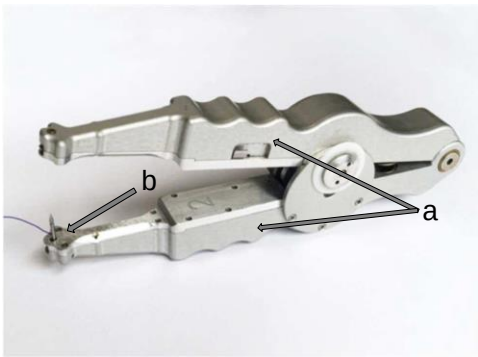

Fig. 1 Suture-tool is hand-held and hand-powered and consists of two jaws (a). Each jaw has a distally placed hole that locks the needle (b). While compressing the device the needle is automatically transferred from one jaw to the other. The needle is double ended with a centrally attached thread

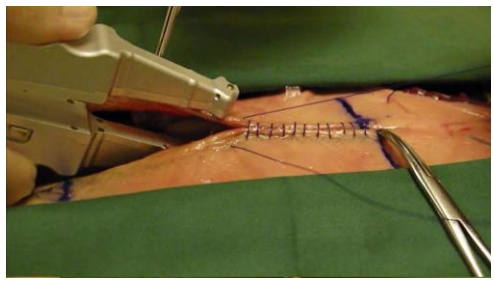

Fig. 3 Device suturing in the animal tissue model. Start and endpoints of the suturing course marked with blue ink. Start knot is replaced by fixating the thread with a clamp not to include tying time in the test

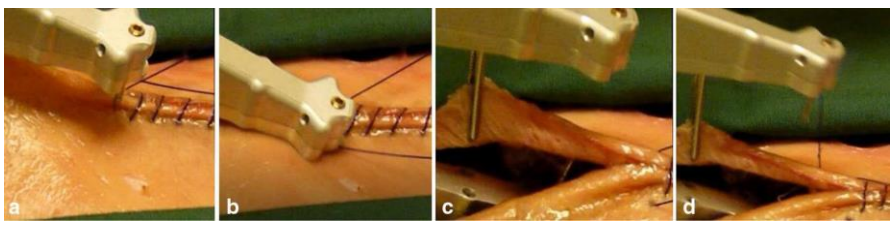

Fig. 2 Suture-tool technique with straight needle. a Device positioned for an ''over-stitch.'' b Device compressed and needle passed through tissue. c Device opened and positioned for an ''under-stitch.'' d Needle transferred to upper jaw completing a whole stitch

Needle driver suturing, NDS

A needle driver (Mayo-Hegar 16 cm, Stille AB, Sweden) and a 36-mm-semicurved CT-1 1/2 circle taper-point PDS II needle (Ethicon, Sommerville, NJ, USA) was used to produce the manual suturing. The NDS sequence is described in Fig. 4.

Test protocol

The surgeons were recorded for subspecialty, years as licensed surgeon, gender and handedness. The suture was 70 cm long for both techniques. Sutures were anchored at start and finish with clamps. Participants were instructed to aim for a SL/WL ratio of C 4. Number of practiced closures with Suture-tool was recorded. The test included closing 8 incisions alternating between Suture-tool and NDS. Number of stitches, remaining suture length and suturing time were registered.

Surgeon's evaluation of the instrument

A questionnaire was constructed including 11 questions on construction and handling of the Suture-tool using visual analog scales for evaluation by test participants according to Fig. 5.

Ethical consideration

The regional ethical review committee was contacted for ethical approval. No approval was needed to use elk fascia.

Statistics

Differences between Suture-tool suturing and NDS regarding number of stitches, SL/WL ratio, suturing time were tested using Mann–Whitney's *U* test. To assess differences in the proportion of SL/WL ratio between device suturing and NDS, the Fisher's exact test was used. Statistical significance was considered for p values \ 0.05. Statistical analyses were performed in Stata 14 (StataCorp.

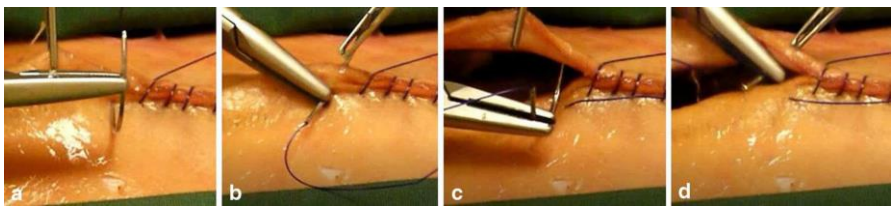

Fig. 4 NDS suturing technique with curved needle. a Needle grasped by the needle driver and positioned for an ''over-stitch.'' b Needle passed through the tissue supported by the forceps (b). Needle grasped by the needle driver and repositioned for an ''under-stitch'' (c). Needle passed through the second tissue supported by the forceps completing the whole stitch

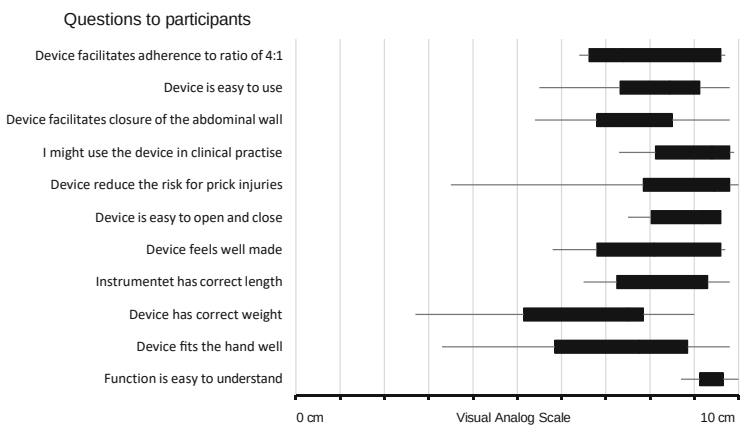

Fig. 5 Evaluation questionnaire. All participants filled in a questionnaire. Questions were answered by putting a mark on a visual analog scale from 0 cm (disagree) to 10 cm (agree). Results are presented as horizontal boxplot indicating the range of the answers. Participants agreed on that the device could help adherence to a SL/WL ratio of 4 and that the device can reduce prick injuries. The widest range was observed at questions concerning device design (''Device have correct weight'' and ''Device fits hand well'') stressing that further development needs to be done

2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.)

Results

Characteristics of participants

Ten surgeons participated and had a median experience as ''licensed'' surgeons of 9 (1–25) years and were sub-specialized as general (n = 4), vascular (n = 3) or colorectal surgeons (n = 3). All were right-handed. Three were females. They used in median 4 (3–8) incision closures for practice with Suture-tool.

Suturing test

In total, 80 incision closures were completed, 40 using each technique. Variables including number of stitches and length of suture used, comparing Suture-tool to NDS, are reported in Table 1. Median SL/WL ratio was 4.5 using the Suture-tool and 3.8 using NDS (p \ 0,001). A SL/WL ratio of C 4 was reached in 95% of suture lines using the Suture-tool versus 30% using NDS (p \ 0.001). Suturing time was 2 min 54 s using the Suture-tool and 4 min 5 s using NDS (p \ 0.001) (Fig. 6).

Evaluation of suture-tool

The evaluation of the instrument by the participants was overall positive according to Fig. 5. The median VAS score was above 8 cm in 8 of 11 domains. The highest score was achieved for ''Function is easy to understand'' (VAS 9.4 cm). The lowest score was seen for instrument design ''Device has correct weight'' (VAS 6.5 cm) and ''Device fits the hand well'' (VAS 7.2 cm)

Discussion

Incisional hernia imposes a large economic and social burden globally. It is of increasing interest to prevent rather than repairing incisional hernias. This can be achieved by intraoperative actions for quality of both wound incision and suture technique. This study demonstrates that the Suture-tool substantially facilitates a speedy performance of a standardized abdominal wall closure achieving a high frequency of SL/WL ratio of C 4 compared to NDS.

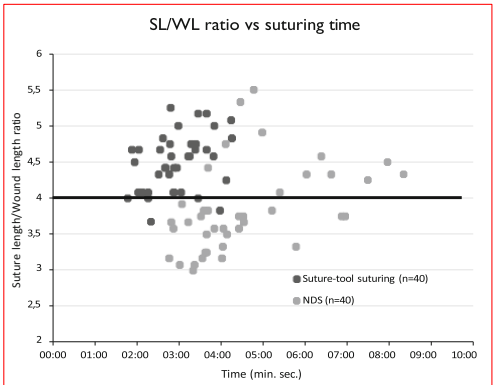

Fig. 6 Suture lines performed in an animal tissue model plotted for suture length/wound length ratio in relation to suture time. Suture-tool suturing was faster (p \ 0.001) and had higher adherence to SL/WL ratio [4:1 (p \ 0.001)

A surgical technique with SL/WL ratio of C 4 deployed with small stitches put tightly is the recommended method and can be used in all patients [4]. Disadvantages are longer time for closure, technique is user dependent, and optimal ratio can be challenging to achieve, especially when incision is long and at emergency surgery, but also for concentration difficulties after long operations.

A strength of the study is that surgeons of various experience participated in the testing showing the same high performance. A limitation is that it was performed on a prepared fascia where the suturing process was not affected by other abdominal wall structures like skin and subcutaneous fat. The traction of the thread by the assistant was not standardized which could also influence the thread length used. This is though in accordance with a conventional clinical situation.

Table 1 Suture variables comparing Suture-tool suturing to conventional needle driver suturing (NDS)

	Suture-tool suturing (n = 40)	NDS (n = 40)	p values
Suture time min. sec.; median (range)	2 m 54 s (1 m 48 s–4 m 16 s)	4 m 5 s (2 m 47 s–8 m 21 s)	p \ 0.001
SL/WL ratio median (range)	4.5 (3.7–5.3)	3.8 (3–5.5)	p \ 0.001
SL/WL ratio C 4 %	95% (38/40)	30% (12/40)	p \ 0.001
Number of stitches median (range)	25 (21–35)	26 (21–35)	p = 0.125
Length of suture centimeter: median (range)	54.4 (44–63)	45 (36–66)	p \ 0.001

Prophylactic mesh augmentation (PMA) has been advocated in patients with high risk of developing an incisional hernia, for instance patients undergoing aortic aneurysm surgery, obese patients and patients undergoing colorectal surgery. Several studies have shown reduced incisional hernia formation with PMA [5]. The disadvantages of PMA are the risk of mesh infection, longer operating time and that mesh implantation requires specific surgical skills.

The questionnaire used to evaluate the instrument was useful in identifying ergonomic details that could be improved. Suture-tool is redesigned and made lighter and slimmer.

Suture-tool is a promising device to perform a speedy standardized high-quality suture line for fascial closure. Further studies are needed to evaluate the device in the clinical setting. We plan a comparative Suture-tool to NDS study in the autopsy setting to assess whether findings can be repeated in humans. Results from these studies will provide scientific grounds for a clinical study.

Acknowledgments Open access funding provided by Lund University.

Funding Stig och Ragna Gorthon foundation.

Compliance with ethical standards

Conflict of interest GB is CEO and founder of Suturion AB; AM has no disclosures.

Statement of animal rights The regional ethical review committee was contacted, and no ethical approval was needed to use elk fascia from a local distributor.

References

1. Henriksen N, Deerenberg E, Venclauskas L et al (2018) Meta-analysis on materials and techniques for laparotomy closure: the MATCH review. World J Surg 42:1666–1678. https://doi.org/10.1007/s00268-017-4393-9
2. Patel S, Paskar D, Nelson R et al (2017) Closure methods for laparotomy incisions for preventing incisional hernias and other wound complications. Cochrane Database Syst Rev 11:CD005661
3. Fink C, Baumann P, Wente M et al (2014) Incisional hernia rate 3 years after midline laparotomy. Br J Surg 101(2):51–54
4. Deerenberg E, Harlaar J, Steyerberg E et al (2015) Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet 26(386):1254–1260
5. Borab Z, Shakir S, Lanni M et al (2017) Does prophylactic mesh placement in elective, midline laparotomy reduce the incidence of incisional hernia? A systematic review and meta-analysis. Surgery 161(4):1149–1163

Paper II

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Suture-TOOL: A suturing device for swift and standardized abdominal aponeurosis closure

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ABSTRACT

Introduction: Surgeons can reduce incisional hernia formation by adhering to standardized techniques for incisional wound closure. This is often neglected by the time a long operation is to be ended and can lead to the risk of developing an incisional hernia or a wound rupture. To address this issue, a suturing machine (Suture-TOOL) was developed for swift and standardized abdominal closure. The aim was to compare the user safety, speed, and suturing quality between Suture-TOOL and manual Needle-Driver suturing.

Method: Fifteen surgeons who were specialists in surgery, urology, and gynaecology as well as surgical trainees were invited. The Suture-TOOL was presented to the surgeons who read the instructions for use before starting the test. Each surgeon closed nine 15 cm-long incisions in a human body model; six with Suture-TOOL and three with the Needle-Driver technique. Gloves were examined for puncture damage. Endpoints were suture-length/wound-length (SL/WL)-ratio, closure time, number of stitches, learning curve, and glove puncture rate. A VAS-evaluation concerning different Suture-Tool user impressions was completed.

Results: A SL/WL-ratio ≥4 was 98% for Suture-TOOL versus 69% for Needle-Driver ($p < 0.001$). Suture time was shorter for Suture-TOOL ($p < 0.001$). Wound stitch count was higher for Needle-Driver ($p = 0.013$). The median SL/WL-ratio was similar between groups. The learning curve plateaued after three closures using Suture-TOOL. Two glove punctures were detected—all in the Needle-Driver group. Suture-TOOL received high VAS scores for all measured functionalities.

Conclusion: Suture-TOOL is a promising device for clinical use. It is safe, easy, and fast resulting in a high-quality suture lines with a short learning curve and a high functionality ranking.

Introduction

Incisional hernia imposes a large socio-economic burden worldwide. It is a common complication to abdominal surgery and affects up to 35% of the patients [1]. Some patients with incisional hernia are reluctant or unfit to undergo further surgery. To live with an incisional hernia has a significant impact on health-related quality of life (QoL) and body image [2,3]. Incisional hernia formation after primary midline incisional closure is reported to be 17% after three years [4]. Many factors for incisional hernia are patient-dependent including age, BMI, and sex [5].

Two important factors are the precise primary midline incision and the closure technique. To reduce incisional hernia development, it is recommended that the suture-length to wound-length ratio (SL/WL) be ≥4. The ratio should be acquired with small bites placed tightly (5 mm bites 5 mm apart) [6–8]. The rationale for small bites is to include only the aponeurosis in the suture line—this has been experimentally shown to give less wound edge separation compared to large bites [9]. Small bites also give a higher tensile strength [10]. The technique of achieving SL/WL of ≥4 with small bites is roughly 30% more time-consuming than using larger bites [6,7].

Although there are scientific evidence and guidelines to support the use of small bites and the SL/WL of ≥4, the adherence is rare; there is a large amount of individual variation among surgeons [11,12]. Thus, there is a need for an incision closure method that is safe, easy to learn, available to many users, and suitable for different clinical settings. Ideally, the method should work in the hands of different users and be reproducible. The method should also be fast.

A suturing device for swift and standardized abdominal closure (Suture-TOOL) was developed to align the differences in an interpersonal performance [13]. The device has been further developed and

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re-designed with input from several potential users including different surgeons and scrub nurses. Re-design included adaptation for manufacturing in plastic materials, slimmer tip, lower device weight and a needle construction with less friction. The aim was to compare Suture-TOOL to manual Needle-Driver suturing concerning adherence to SL/WL ratio ≥4, incisional closure time, and glove punctures in a realistic test bed consisting of a human body model.

Methods

This is an experimental study comparing Suture-TOOL and Needle-Driver suturing in a human model. The study was performed at the Autopsy Unit at the Department of Pathology, Skåne University Hospital, Lund, Sweden. A midline incisional closure model was prepared using adult humans selected for autopsy. Ethical approval was obtained from the Swedish Ethical Review Authority (2019-04626). Bodies of both sexes without a previous midline incision and who tested negative for Covid-19 were included. The primary endpoint was adherence of SL/WL-ratio ≥4. Secondary endpoints were introduction time, incisional closure time, Suture-TOOL learning curve, and glove puncture rate.

Suture-TOOL

Suture-TOOL was developed by a surgeon (author 1) in collaboration with a medical technology development team associated with Lund University. It is an automatic hand-held hand-powered suture device, which uses a double-ended needle with a centrally attached polydioxanone (PDO) thread (Fig. 1) [13]. The purpose of Suture-TOOL was to facilitate a speedy, safe, and standardized suture line for aponeurosis adaptation.

Suture techniques

The aim was to achieve a SL/WL-ratio ≥4. A 90-cm-long thread was used for both techniques. The Suture-TOOL and Needle-Driver techniques for incision closures are described in Fig. 2. To facilitate the use of small bites in the Needle-Driver group the CT-2 needle on a 2-0 Monocryl® (Ethicon, Somerville, NJ, USA) suture was used.

Study model

A separate autopsy room was used. Bodies were put on the autopsy table and draped with surgical sheaths. Body weight and subcutaneous fat layer thickness was recorded. A 20-cm midline incision was made through the skin and subcutaneous tissue. *Linea alba* was dissected free from subcutaneous fat exposing 2 cm of the rectus fascia. A 15-cm midline incision was carefully made to avoid entering the rectus muscle compartments. Abdominal content was protected using a cloth. Time for preparation of the midline, undermining the subcutaneous fat, was not included in the suturing time.

The study team consisted of a surgeon, an assistant, and an observing research nurse. The surgeon was positioned on the left side and the assistant on the opposite. The observer was positioned cranially to the body. Suturing was performed in a caudal-to-cranial direction.

Test surgeons

Specialists in surgery, gynaecology, urology, and surgical trainees were invited according to availability. The participants had not been exposed to the Suture-TOOL before. Age, sex, surgical specialty, years in surgical practice, dexterity, and glove size were recorded.

Study design

The study design was introduced to the surgeons via email which included pictures and written instructions on how to perform the suture line according to SL/WL-ratio ≥4 with small bites. At the autopsy unit, the test surgeons were introduced to the Suture-TOOL by holding the device while reading the Instructions for Use (IFU). Three Suture-TOOL handling features (device check, needle loading, and forceps operating area) were highlighted and pointed out by the observing research nurse educated in the study design including suture techniques. All further questions were addressed to the IFU. Introduction was finished when the surgeon felt confident in using Suture-TOOL according to IFU. The introduction time was recorded.

The first three runs with Suture-Tool were regarded as practice incisional closures (runs). Each surgeon performed six runs within the test: three with Suture-TOOL and three with Needle-Driver alternating between the techniques. Runs were performed without a start and stop knot. The thread was secured with a clamp. Suture time was defined as the time from the first stitch passing through the aponeurosis until the final stitch. The remaining thread length and number of stitches were recorded and blinded to the surgeon.

Biogel® Eclipse gloves (Mo¨lnlycke Health Care, Go¨teborg, Sweden) were used. Surgeons with latex allergy added a latex free glove liner. For the six test closures, surgeons shifted gloves after each run, and the gloves were collected in pre-marked Ziplock bags.

After the test session, the surgeon completed a visual analogue scale (VAS) based evaluation survey with eleven statements on Suture-TOOL impressions (Fig. 3). Each statement was scored on a continuous 100-

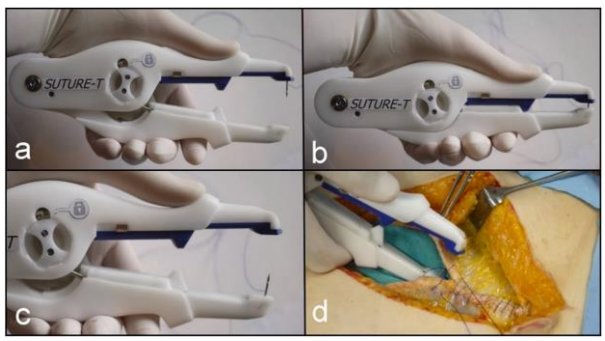

Fig. 1. Suture-TOOL handling a. Needle in upper jaw b. Compressed to transfer the needle to the lower jaw c. Opened and needle is positioned in the lower jaw d. Positioned to close a midline incision.

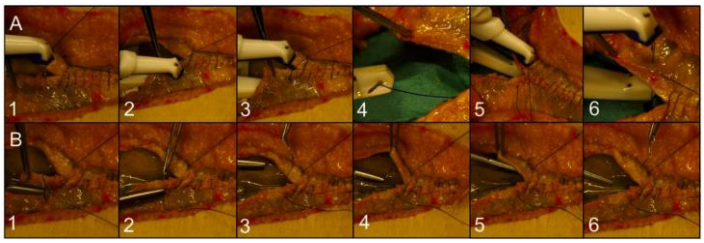

Fig. 2. A. Suture-TOOL suturing sequence 1. Contralateral aponeurosis grasped by forceps and Suture-TOOL positioned for an overstitch 2. Compressed and needle passed through the tissue 3. Needle is transferred to the lower jaw 4. Ipsi-lateral aponeurosis is grasped by the forceps and Suture-TOOL is repositioned 5. Suture-TOOL compressed 6. Needle passed through the tissue and transferred to the upper jaw and one complete stitch is performed B. Manual Needle-Driver (Mayo-Hegar 16 cm, Stille AB, Sweden) suturing sequence. 1. Contralateral aponeurosis grasped by forceps 2. Semi-curved needle is passed through the tissue 3. The needle is grasped by forceps 4. The needle is grasped by the needle driver 5. The needle is passed through ipsi-lateral aponeurosis 6. The needle is grasped by forceps and one complete stitch is performed.

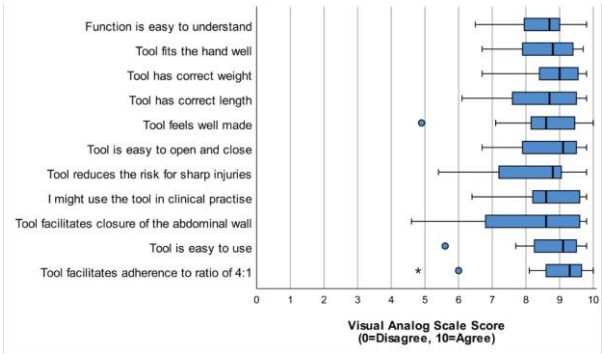

Fig. 3. Figure presents 11 Suture-TOOL statements from a total of 15 users on a VAS scale. Median VAS scores with interquartile range and outliers for different Suture-TOOL functions and usability. Outliers are marked plotted as a small ring and extreme outliers as a star.

mm VAS scale.

Glove integrity test

Glove integrity was tested using the standard "Medical gloves for single use – Part 1: Requirements and testing for freedom from holes (SS-EN- 455-1-2000)". A vertically positioned filling tube holding more than 1000 ml of water was positioned in a test tube holder. The glove was attached to the lower opening of the tube and filled with 1000 ml of blue dyed water. If no leak was detected after two minutes, then the glove was determined to be intact.

Statistical analysis

This analysis used IBM SPSS Statistics for Windows, Version 26 (Armonk, NY, USA). All study measurements were reported as either means with standard deviation (SD) or median (range).

Power calculations for the primary endpoint and adherence to SL/WL ratio ≥4 was based on results from two studies [13,14] that showed that the proportion of adherence to SL/WL ≥4 was 0.95 for Suture-TOOL suturing and 0.7 for Needle-Driver. To detect a 5% difference with 80% power, 43 closures would be needed for each suturing technique, and thus 15 surgeons (3 closures/technique/surgeon) were required.

Continuous variables were compared using Student t-test and categorical variables using Fishers Chi^2-test. All tests were two-sided, and $p<0.05$ was considered significant.

Results

Fourteen bodies (five females and nine males) were used in the study. The mean body weight was 81 (SD 23.6) kg, and the mean subcutaneous fat layer thickness was 2.4 (SD 0.7) cm. A total of 15 surgeons participated: seven general surgeons, two gynaecologists, one urologist, and five surgical trainees. Four were female. Mean age was 38 (SD 7.9), mean years in surgical practice was 8.8 (SD 6.7), and median glove size was 7.5 (6–7.5).

Suturing and glove tests

The mean theoretical introduction time of Suture-TOOL was 13:00 minutes (SD 5.2). After three runs, the suture time for Suture-TOOL plateaued for all users (learning curve; Fig. 4). Mean suturing time for Suture-TOOL was 4:46 (minutes: seconds; SD 0:54) and for Needle-Driver was 7:05 (minutes: seconds; SD 1:59) ($p<0.001$). The SL/WL ratio ≥4 was reached in 44/45 (98%) with Suture-Tool and 31/45 (69%) with Needle-Driver ($p<0.001$). Mean stitch count was 30.0 for Suture-TOOL and 33.7 for Needle-Driver suturing ($p<0.013$). The suture time and achieved SL/WL ratio in the test runs are displayed in Fig. 5. There were 180 gloves tested for leakage. Two leaks were detected—both in the Needle-Driver group ($p=0.497$).

Evaluation of Suture-TOOL

All surgeons completed the survey. All statements received a median

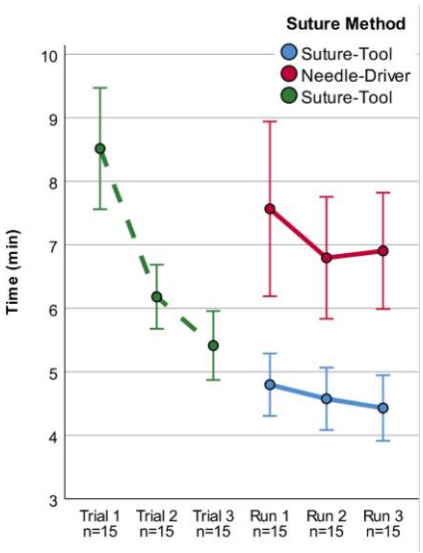

Fig. 4. Learning curve for 15 surgeons performing three runs each with Needle-Driver and six runs with Suture-TOOL suturing. Mean suture time is displayed with 95% confidence interval.

VAS >8.6. The highest scores were given to "Tool facilitates adherence to ratio of 4:1" VAS 9.3 [6–10]; "Tool is easy to open and close" VAS 9.1 (6.8–9.8); "Tool is easy to use" VAS 9.1 (5.6–9.8); and "Tool has the correct weight" VAS 9.0 (6.1–9.8) (Fig. 3).

Discussion

Surgeon vigilance and attention to detail during the intraabdominal part of a surgical procedure can be difficult to maintain after long and strenuous surgeries. The lack of focus can affect the surgeon's ability to uphold the surgical technique for abdominal wall closure required to prevent wound complications. If the task of closing the abdomen could be facilitated by a device for swift and standardized high-quality closure of the abdomen, then it would be a valuable solution to an often neglected challenge. Here, the Suture-TOOL suturing device is evaluated in terms of those requirements.

The study assesses the new generation of Suture-TOOL in a human body model with skin, subcutanesous fat, aponeurosis, bowel content and body fluids. This was important for several reasons: we needed to evaluate the device in a realistic test bed with different users caracteristics, we needed to evaluate the device for unexpected adverse events and mechanical/design issues and we wanted more user input for further development of design and user manual.

Surgeons' adherence to wound closure recommendations is an influential factor for incisional hernia formation. Assessment of surgeons' attitudes reveal several reasons for avoiding guideline recommendations: "Not familiar enough with methods to correctly execute", "Time consuming", "Not reimbursed", and "Concerns about closure-related complications" [11]. A recent Dutch study stated that only 35% of surgeons pursue a SL/WL-ratio ≥4 [12]. This study also showed that trainees in surgery and trauma, vascular, and paediatric surgeries were less likely to achieve a SL/WL ratio ≥4 compared to gastrointestinal and oncologic surgeons. This should increase surgeons' awareness of the abdominal wall closure quality.

Several risk factors for wound complications have been described including obesity and smoking [15,16]. Patients undergoing surgery for colorectal cancer and aortic aneurysm have an increased risk for incisional hernia development [17,18]. Another subgroup with increased risk is patients undergoing laparotomy due to combat trauma [19]. The surgeon performing the procedure is also a risk factor [20]. Williams et al. published a study of 100 consecutive open abdominal surgeries and found that adherence to the SL/WL-ratio ≥4 was lower if the residents closed the abdomen without the supervision of a senior surgeon [14].

Adherence to a SL/WL-ratio ≥4 was 98% for all surgeons using Suture-TOOL. The confidence interval for Suture-TOOL was smaller for both suture time and SL/WL-ratio compared to Needle-Driver suturing. There is a suspicion that exposure of rectus muscles by a non-precise midline incision (surfing) when entering the abdominal cavity is a risk factor for incisional hernia formation. The Suture-TOOL method involves a distinct entrance through the *linea alba* to avoid "surfing". Linea alba was dissected free from subcutaneous fat exposing 3 cm of the rectus fascia, Fig. 1d. In the clinical setting we anticipate that an undermining of 1 cm will be sufficient to accommodate Suture-TOOL and to facilitate a precise incision. The possible relationship between "surfing" and incisional hernia formation should be addressed in another setting.

Suture-TOOL suturing time was 31% shorter compared to Needle-Driver suturing. This represents a reduction in operative time of seven minutes if extrapolated to data on suturing times in a clinical setting [6]. Reducing the operating room time is important for several reasons: It is associated with postoperative complications [21,22] and surgical

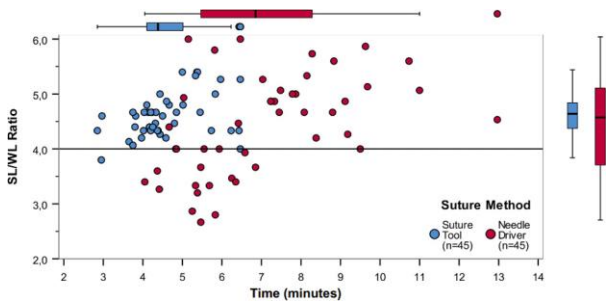

Fig. 5. Incision closures performed in a human body model plotted for Suture Length/Wound Length (SL/WL) ratio in relation to suture time. In the margins Tukey's boxplots show median and interquartile range. 1

resources needs to be optimally utilized. Every minute spent in the operating room is cost driving.

In a recent experimental study by Conway, surgeons estimation on 5mm and 10mm spacing was investigated [23]. The range of estimates for a 5mm distance estimation task was 2.01 to 11.69mm, and for a 10mm task, the range was 4.82 to 19.19mm reflecting that space estimation is difficult. Suture-TOOL has a guide for correct stitch placement. In the present study surgeons were instructed to achieve SL/WL-ratio ≥4 by putting stitches 5mm from the incision and 5mm apart. Correct stitch placement in the model would yield 30 stitches in the 15cm long incision. Mean stitch count was 30.0 for Suture-TOOL and 33.7 for Needle-Driver suturing suggesting that Suture-TOOL facilitates correct stitch placement.

Sharp injury protection in surgery is important to minimize transferring of blood-borne diseases [24]. It has been shown that half of the intraoperative sharp injuries are caused by suture needles and a majority of incidents are with junior surgeons [25,26]. In a Danish questionnaire study, the most common causes for intraoperative sharp injuries were inattentiveness, use of fingers instead of instruments, poor space, and injury inflicted by a colleague [27]. An important feature of the Suture-TOOL is that it keeps the user's hands away from the needle. Two glove punctures were detected—both in the Needle-Driver group. The overall low puncture rate might have been influenced by surgeons being focused on the single task of incision closure but the study was not designed to show a difference in glove puncture rate but was reported according to study protocol.

There is a difference in suture thread handling between Suture-TOOL suturing and Needle-Driver suturing: Suture-TOOL suturing method produce less twisting of the suture and no risk for the needle driver to interfere with the suture thread. This might avoid damaging the suture thread and reduce the risk for suture breakages and subsequent wound rupture which could be an important benefit of the Suture-TOOL device. A suture burst strength comparison study is considered to be included in a future model study.

There are several devices for closure of trocar sites after laparoscopic surgery, e.g., VersaOne™ Fascial Closure System (Medtronic, Minneapolis, USA), Lapro-Shark™ Laparoscopic Fascial Port Closure Device (Brainchild Surgical Device, New York, United States), and LaproClose Trocar Site Closure (LaproSurge Ltd., Watford, UK). These devices place only a few fascial stitches. There is also a sewing machine for laparoscopic surgery, Endo Stitch™ Suture Device (Medtronic, Minneapolis, USA), that facilitates intraabdominal stitching typically while performing fundoplication. However, none of these devices addresses closing the abdomen after open surgery, and, to the best of our knowledge, there is no commercially available device for this task.

The surgeon survey included statements on Suture-TOOL performance and design. All statements received a high median VAS (>8.6) implicating a high user satisfaction with Suture-TOOL. Surgeons ranked "Tool is easy to use", "Tool facilitates a SL/WL-ratio ≥4", and "Tool is easy to open and close" with the highest VAS. These properties are important to achieve an optimal abdominal closure for the patient. However, two users did not agree to the same extent. Both had the smallest glove size, which could have interfered with device handling. However, their technical performance was comparable to the other test surgeons. Surgeons' evaluation is important for ergonomic developments. In general, surgeons prefer instruments that are hassle-free, safe, fast, and easy to learn. The questionaire was developed by the authors for the first study on Suture-TOOL. In hindsite a more neutral language would have been preferable as some statements may be considered leading.

Andrew de Beaux emphasized that closing the abdomen after surgery is a crucial and integrated part of the surgical procedure that needs to be done with meticulous technique via an experienced surgeon to avoid complications. He stated that "closing time is not coffee time" [28].

Our study indicates that closing the abdomen after open surgery with Suture-TOOL is fast, easy to learn, and reproducible.

Conclusion

Suture-TOOL is a promising device for standardized abdominal wall closure. Studies in a clinical setting are forthcoming to further assess device handling, postoperative complications such as wound infections, burst abdomen, and incisional hernia development.

Funding

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Disclosures

Monocryl sutures were provided by Ethicon.

GB is founder of Suturion AB. The authors declare that they have no other known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The category in which the manuscript is being submitted

Original research article

Contributing

GB, AM and ME set up the study design. GB collected the data. Statistical analysis performed by GB and PR. All authors collaborated in interpreting the data and writing the manuscript.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

GB are founder of Suturion AB that developed the Sutre-TOOL device.

ME, PR and AM have no conflict of interest

Acknowledgments

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References

[1] Claes K, Beckers R, Heindryckx E, Kyle-Leinhase I, Pletinckx P, Claeys D, Muysoms F. Retrospective observational study on the incidence of incisional hernias after colorectal carcinoma resection with follow-up CT scan. Hernia 2014; 18(6):797–802.

[2] 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):144–50. Aug.

[3] Jensen KK, Emmertsen KJ, Laurberg S, Krarup PM. Long-term impact of incisional hernia on quality of life after colonic cancer resection. Hernia 2020;24(2):265–72. Apr.

[4] Wiegering A, Liebetrau D, Menzel S, Bühler C, Kellersmann R, Dietz UA. The incidence of incisional hernia after aortic aneurysm is not higher than after benign colorectal interventions: A retrospective control-matched cohort study. Gefasschirurgie 2018;23(Suppl 1):23–31.

[5] Itatsu K, Yokoyama Y, Sugawara G, Kubota H, Tojima Y, Kurumiya Y, Kono H, Yamamoto H, Ando M, Nagino M. Incidence of and risk factors for incisional hernia after abdominal surgery. Br J Surg 2014;101(11):1439–47. Oct.

[6] Millbourn D, Cengiz Y, Israelsson LA. Effect of stitch length on wound complications after closure of midline incisions: a randomized controlled trial. Arch Surg 2009;144(11):1056–9. Nov.

[7] Deerenberg EB, Harlaar JJ, Steyerberg EW, Lont HE, van Doorn HC, Heisterkamp J, Wijnhoven BP, Schouten WR, Cense HA, Stockmann HB, Berends FJ, Dijkhuizen FPH, Dwarkasing RS, Jairam AP, van Ramshorst GH, Kleinrensink GJ, Jeekel J, Lange JF. Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet 2015;386(10000):1254–60. Sep 26.

[8] Thorup T, Tolstrup MB, Go¨genur I. Reduced rate of incisional hernia after standardized fascial closure in emergency laparotomy. Hernia 2019;23(2):341–6. https://doi.org/10.1007/s10029-019-01893-0. Apr.
[9] Cengiz Y, Blomquist P, Israelsson LA. Small tissue bites and wound strength: an experimental study. Arch Surg 2001;136(3):272–5. Mar.
[10] Harlaar JJ, van Ramshorst GH, Nieuwenhuizen J, Ten Brinke JG, Hop WC, Kleinrensink GJ, Jeekel H, Lange JF. Small stitches with small suture distances increase laparotomy closure strength. Am J Surg 2009;198(3):392–5. Sep.
[11] Fischer JP, Harris HW, Lo´pez-Cano M, Hope WW. Hernia prevention: practice patterns and surgeons' attitudes about abdominal wall closure and the use of prophylactic mesh. Hernia 2019;23(2):329–34. Apr;.
[12] Bloemen A, De Kleijn R, Van Steensel S, Aarts F, Schreinemacher MHF, Bouvy ND. Laparotomy closure techniques: do surgeons follow the latest guidelines? Results of a questionnaire. Int J Surg 2019;71:110–6. Nov.
[13] Bo¨rner G, Montgomery A. Suture-tool: a mechanical needle driver for standardized wound closure. World J Surg 2020;44(1):95–9. Jan.
[14] Williams ZF, Tenzel P, Hooks 3rd WB, Hope WW. Suture to wound length ratio in abdominal wall closure: how well are we doing? Hernia 2017;21(6):869–72. Dec.
[15] Henriksen NA, Helgstrand F, Vogt KC, Jorgensen LN, Bisgaard T, Hernia Database D, Vascular Registry D. Risk factors for incisional hernia repair after aortic reconstructive surgery in a nationwide study. J Vasc Surg 2013;57(6): 1524–30. Jun;1530.e1-3.
[16] Sørensen LT, Hemmingsen UB, Kirkeby LT, Kallehave F, Jørgensen LN. Smoking is a risk factor for incisional hernia. Arch Surg 2005;140(2):119–23. Feb.
[17] Basta MN, Kozak GM, Broach RB, Messa 4th CA, Rhemtulla I, DeMatteo RP, Serletti JM, Fischer JP. Can we predict incisional hernia?: Development of a surgery-specific decision-support interface. Ann Surg 2019;270(3):544–53. Sep.
[18] Baucom RB, Ousley J, Beveridge GB, Phillips SE, Pierce RA, Holzman MD, Sharp KW, Nealon WH, Poulose BK. Cancer survivorship: defining the incidence of incisional hernia after resection for intra-abdominal malignancy. Ann Surg Oncol 2016;23(Suppl 5):764–71. Dec.
[19] Moas V, Eskridge S, Clouser M, Kurapaty S, Dyke C, Souza J. Incisional hernia incidence following laparotomy for combat trauma: investigating 15 years of US war surgery. J Trauma Acute Care Surg 2020;89(2S Suppl 2):S200–6. Aug.
[20] Gislason H, Søreide O, Viste A. Wound complications after major gastrointestinal operations. The surgeon as a risk factor. Dig Surg 1999;16(6):512–4.
[21] Owen RM, Perez SD, Lytle N, Patel A, Davis SS, Lin E, Sweeney JF. Impact of operative duration on postoperative pulmonary complications in laparoscopic versus open colectomy. Surg Endosc 2013;27(10):3555–63. Oct.
[22] Procter LD, Davenport DL, Bernard AC, Zwischenberger JB. General surgical operative duration is associated with increased risk-adjusted infectious complication rates and length of hospital stay. J Am Coll Surg 2010;210(1). Jan 60–5.e1–2.
[23] Conway RG, O'Neill N, Brown J, Kavic S. An educated guess - distance estimation by surgeons. Surg Open Sci 2020;2(3):113–6. Apr 30.
[24] Hanmore E, Maclaine G, Garin F, Alonso A, Leroy N, Ruff L. Economic benefits of safety-engineered sharp devices in Belgium - a budget impact model. BMC Health Serv Res 2013;13:489. Nov 25.
[25] Myers DJ, Epling C, Dement J, Hunt D. Risk of sharp device-related blood and body fluid exposure in operating rooms. Infect Control Hosp Epidemiol 2008;29(12): 1139–48. Dec.
[26] Bakaeen F, Awad S, Albo D, Bellows CF, Huh J, Kistner C, Izard D, Triebel J, Khan M, Berger DH. Epidemiology of exposure to blood borne pathogens on a surgical service. Am J Surg 2006;192(5):e18–21. Nov.
[27] Nelsing S, Nielsen TL, Nielsen JO. Percutaneous blood exposure among Danish doctors: exposure mechanisms and strategies for prevention. Eur J Epidemiol 1997; 13(4):387–93. Jun.
[28] de Beaux AC. Abdominal wall closure. Br J Surg 2019;106(3):163–4. Feb.

Paper IV

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ORIGINAL ARTICLE

A feasibility and safety trial investigating a device for swift and standardized median laparotomy closure

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Abstract

Purpose Abdominal wall complications can be reduced by adhering to guidelines for midline laparotomy closure. However, implementation of guidelines can be challenging. To address this issue, a laparotomy closure device for swift and standardized abdominal closure was developed. The study evaluated the quality of the suture, safety, and speed of the device in a clinical setting.

Methods A prospective, one-armed investigation was carried out. Five surgeons participated in the study. The introduction to the device involved reading the user instructions and unsupervised dry lab training. Thirty-eight patients with colorectal disease, selected for laparotomy, were recruited. The primary endpoint was the proportion of patients that received a fascial closure with a suture-length to wound-length (SL/WL) ratio ≥ 4. Secondary endpoints included suturing time, glove puncture rate, wound infection (SSI), burst abdomen, and other adverse events. Follow-up included physical examination during hospital stay and postoperative visit and chart review six weeks postoperatively.

Results All patients achieved the primary endpoint SL/WL ratio ≥ 4. The mean suturing time was 10.5 min, while the mean net closure time (NCT) was 7.4 min. The shortest NCT recorded was 2.2 min. Net mean closure speed was 27 s/cm. There were no glove punctures. One case of SSI was reported, and no burst abdomen was detected. The learning curve stabilized after the third fascial closure.

Conclusion The SutureTOOL is a promising device for clinical application. It is perceived as safe, user-friendly, and fast, yielding a standardized laparotomy closure with a brief learning curve. The next steps involve a multi-center randomized trial to evaluate the potential impact of SutureTOOL on short- and long-term complications related to abdominal wall closure.

Keywords Incisional hernia prevention · Suturing technique · Innovation · Abdominal wall closure · Laparotomy

Introduction

Laparotomy is tied to abdominal wall complications such as surgical site infection (SSI), wound dehiscence, and incisional hernia (IH) formation [1–3]. These complications impact the length of stay, antibiotic treatment, cost of wound care, and more importantly, the patient's quality of life [1, 4]. Only 23% of patients with postoperative complications timely received the necessary adjuvant chemotherapy, a factor that can strongly affect survival [5].

While many surgical procedures utilize minimally invasive techniques (MIS), a significant proportion still necessitate open access. This includes debulking surgery, rapid bleeding control in trauma patients, and procedures for bowel perforation or obstruction [6–8]. One-third of open abdominal cases come from Caesarean sections. The global rates of Caesarean sections are projected to rise from 7% in 1990 to 29% by 2030 [9].

Additionally, the conversion rates from MIS to open surgery in bowel procedures range from 8 to 24% [10, 11]. The extraction site can exceed 10 cm, which essentially equates to a laparotomy, and is susceptible to complications such as SSIs (16.7%) and IH formation (12.6%) [12, 13].

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Several clinical trials demonstrate that the technique of fascia closure significantly influences complications [14–16]. The fascia should be approximated using a suture-length to wound-length (SL/WL) ratio of ≥ 4, achieved through small-bites (5–8 mm fascial bites with a step-interval of 5 mm). This technique should employ a continuous suture line using a slowly absorbable suture [17]. Despite these recommendations being advocated in both elective and emergency surgery guidelines, the potential to reduce abdominal wall complications has received low attention [17, 18]. According to surveys performed with surgeons in Canada, The Netherlands and UK, only one fourth of surgeons utilize the small-bites technique [19–21]. Reasons for not adopting small-bites include a lack of familiarity with the methods needed to execute correctly (25%) and the perception that it takes too long (13%) [22]. Among surgeons who have received training and claim to apply this technique, only 31% manage to do so in actual clinical practice [23].

Suturing carries an inherent risk of sharp injury and exposure to blood-borne agents, with an accompanying issue of underreporting [24]. Over 50% of intraoperative sharp injuries are attributable to surgical needles, and the risk of a sharp injury increases by 22% per hour [25]. Most intraoperative sharp injuries occur during the closure of laparotomy wounds [26].

To address these clinical needs, a device for quick and standardized abdominal wall closure has been developed. Pre-clinical studies have demonstrated that the device can achieve an SL/WL ≥ 4 in 95–98% of cases, with a closure time that is 30% shorter compared to the traditional manual needle driver suturing technique [27, 28]. In addition, a glove test revealed no punctures following device suturing [28].

This study aimed to perform a safety and performance assessment of the device in the clinical setting.

Method

Trial design

The study was a prospective, single-centre, one-armed investigation of clinical performance and safety, assessing a device for laparotomy closure. The protocol was published on clinicaltrials.gov (ID NCT05695157) before study initiation.

Participating surgeons

Five surgeons were invited to participate in the study. All surgeons were specialists and had been affiliated to the institution colorectal team for at least 2–8 years. Participating surgeons had no previous experience with the investigational device. One months before study start, surgeons were provided with a kit including one device, one printed instruction for use, two sutures, a forceps and a 30 × 30 cm large wooden model. The model was framed with fabric with a 20 cm long cut resembling an abdominal incision. Surgeons were instructed to read the instructions for use and practise until they felt comfortable using the device. No supervision or follow-up was performed. No examination was performed prior to clinical use and surgeons received no intraoperative proctoring.

Study population

Patients aged 18 years and older, who were selected to undergo elective open surgery through midline laparotomy for colorectal disease and could fully comprehend the nature and purpose of the investigation, were invited to participate. All participants signed an informed consent form. Exclusion criteria included a prior midline incision or current midline hernia, pregnancy, clinical findings that interfere with the objectives of the investigation, collagen disease, disseminated disease, or a life expectancy of less than one year. Data on sex, age, height and weight, patient comorbidities, the indication for surgery, the operation performed, and the American Society of Anesthesiologists physical status classification (ASA) were collected.

Outcomes

The primary endpoint was the proportion of patients with SL/WL ≥ 4. SL/WL was calculated by dividing the length of the suture used by the length of the laparotomy wound after closure.

Secondary endpoints included stitch-count, the number of sutures used, time taken to close the laparotomy, and a self-evaluation of the device using a visual analogue scale (VAS). Other intraoperative endpoints were incision not aligned with the midline, exposure of the rectus muscle, thickness of subcutaneous fat, glove puncture rate, re-operation, and unscheduled post-surgery visits. Safety endpoints comprised adverse events, SSI, and burst abdomen defined as post-operative separation of the abdominal musculo-aponeurotic layer.

Accessory outcomes

The study protocol involved measuring the length of each suture, and the extra time required for these measurements was recorded and extracted to analyze the net closure time (NCT) – both generally, and specifically for closures performed after the learning curve was surmounted.

The mean stitch length was computed by dividing the total suture-length by the stitch-count.

Bite-size, *bs*, was calculated with the formula $bs = \frac{sl^2 - wl^2}{4 \cdot sc \cdot sl}$ where *sl* is suture-length, *wl* is wound-length and *sc* is stitch-count, assuming that the individual stitches form a right-angled triangle (Fig. 1). Stitch-time was calculated by dividing incision closure time with stitch-count for each incision closure.

A previous study with the investigational device indicated that the suture time stabilized after three incision closures [28]. To assess the learning curve piecewise linear regressions were performed for cases 1–3 and 4–10 respectively for mean bites-size and mean-time per stitch according to Fig. 2.

Investigational device

The SutureTOOL (Suturion, Lund, Sweden) is a sterile, single-use, handheld, mechanical laparotomy closure device equipped with a double-pointed needle. The study was performed prior to market approval. This needle features a centrally attached suture thread of 130 cm long polydioxanone 2/0. The device includes a guide that enables small-bite stitch placement, specifically 5–8 mm fascial bite-size and a step-interval of less than 5 mm (Fig. 3a). The first author, in collaboration with Lund University, Lund, Sweden, was involved in its development.

Technique of laparotomy closure

The intervention was restricted to the laparotomy closure portion at the end of the operation. The midline fascia was dissected free from subcutaneous fat one cm laterally to the incision. The length of the incision and subcutaneous fat layer was measured. Before the incision closure, both the surgeon and assistant switched to new surgical gloves. After this, the laparotomy closure was carried out with the device. The length of the suture was measured before use, as well as the remaining length after laparotomy closure. Closure time was documented from the completion of the first knot to the last stitch. Patients underwent the colorectal surgical procedure according to the local protocol, and the skin was adapted with skin staplers.

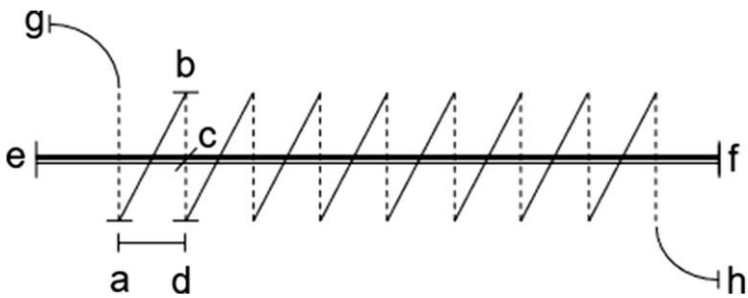

Fig. 1 Figure shows a sequence of stitches in a continuous suture line. *abd* is one complete stitch, stitch-length. ad is the distance between two stitches, step interval. *bc* is bite-size. *ef* is wound-length (WL) and *gh* is the suture-length (SL) deployed in the wound for the laparotomy closure

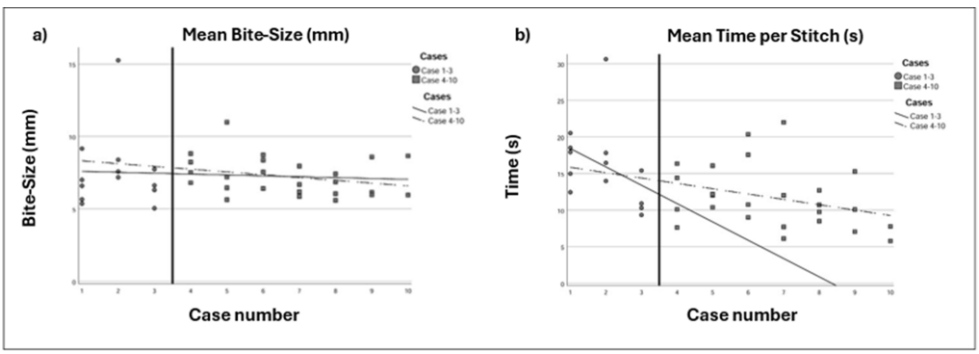

Fig. 2 Figure shows all data points for a) bite-size (n = 38) and b) time per stitch (n = 38), for consecutive laparotomy closures (surgeons performed 1, 8, 9, 10 and 10 individual cases). Lines follow mean values. Straight lines follow cases 1–3 and dashed lines follow cases 4–10. mm, millimetre. s, seconds

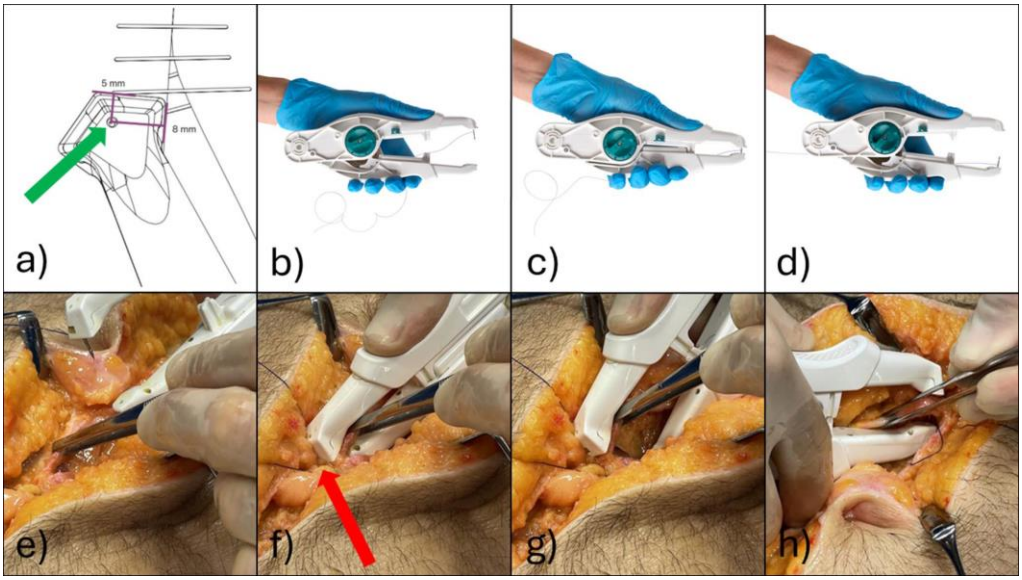

Fig. 3 The figure shows the handling of the investigational device. **a)** Figure shows the front of the device's upper arm from above. The device has a guide at the front of the upper arm that facilitates small-bites placement. The guide is positioned adjacent to the previous stitch and with the lateral side towards the incision. Distance from the needle hole (green arrow) to the front of the guide is 5 mm and distance from the needle hole to the side of the guide is 8 mm. **b**) The device with a double-pointed needle attached in the upper arm. **c**) When the device is compressed the needle is transferred to the lower arm. **d**) Needle attached in the lower arm **e**) The forceps grab the contralateral edge of the midline aponeurosis. **f**) The guide (red arrow) is directed to the previous stitch. **g**) The lower arm of the device is released and the suture thread is pulled through the aponeurosis. **h**) The device is moved to the ipsilateral side of the incision to complete the stitch

Glove puncture test

The gloves of the surgeon and theatre nurse were collected after each laparotomy closure and labelled for identification. For the assessment, a filling tube capable of holding over 1000 ml of water was vertically placed in a test tube holder. The glove was attached to the lower opening of the tube and filled with 1000 ml of water. The glove was deemed intact if no leak was detected after 2 min.

Follow-up

The research nurse, who is also a qualified stoma nurse, conducted the follow-up, which included a physical assessment and a chart review of SSI, burst abdomen, and other adverse events upon discharge and at a scheduled visit between 4–6 weeks. Unscheduled visits were identified through chart reviews at 6 weeks. Wound assessment was performed according to Center for Disease Control—Surgical Site Infection Criteria [29].

Coordination, monitoring and data collection

The finalisation of the study protocol, study documentation, and primary data analysis were performed by a clinical research organisation (CRO) (CROSS Research S.A., Arzo, Switzerland). A research nurse conducted data collection in the operating theatre and during follow-ups, entering data in a paper-based case report form (CRF). This CRF was subsequently sent to the CRO and transferred into an electronic database for analysis. The study was externally monitored by a third part (Clinical Trial Consultants, Stockholm, Sweden). It should be noted that no part of the intervention was blinded.

Statistical analysis

The statistical analysis was conducted using SAS® version 9.3 (TS1M1) for Windows®, or a newer version. The calculation of the sample size was based on a 70% success rate in SL/WL of 4, which is observed in common clinical practices, paired with the assumption that a SL/WL of 4 would be achieved in 83% of cases involving device-assisted

laparotomy closure [28, 30]. Analysis of accessory outcomes was performed with IBM SPSS Statistics v26.

Ethical considerations

The clinical investigation was conducted following the general principles of ISO 14155:2020(E) – Clinical Investigation of Medical Devices for Human Subjects – GCP, as of July 2020, the European Regulation 2017/745 on Medical Devices, and MDCG 2020–10/1 Rev. 1. Study approval, which included ethical approval, was obtained from the Swedish Medical Products Agency (CIV-ID 22–09–040607).

Results

The screening process included 41 patients for inclusion. However, two patients opted not to participate, and one patient was excluded because the study staff was not available during the scheduled surgery time. Baseline and surgical procedure data can be found in Table 1.

Table 1 Demographic and procedure data on 38 patients undergoing elective median laparotomy due to colorectal disease

Demographic and procedure data	Total (n = 38)
Sex ratio (M:F)	19:19
Age (years)	74 (9)
ASA	
I	2
II	25
III	11
IV	0
Comorbidities	
Diabetes mellitus	12
Hypertension	20
Respiratory disorders	5
Anemia	3
Height (cm)	170 (9)
BMI (kg/m^2)	27.4 (4.6)
Indication for surgery	
Colon or rectal cancer	36
Benign disease	2
Performed procedure	
Right hemicolectomy	24
Left hemicolectomy	2
Sigmoid resection	6
Rectum resection	3
Other	3
Stoma formation	5

Values are n, number of patients, unless otherwise indicated. ASA, American Society of Anesthesiologists physical status classification. BMI, body mass index. SD, standard deviation

Intraoperative outcomes

In all patients, a SL/WL ≥ 4 was achieved on the first attempt, thus the proportion of patients with SL/WL ≥ 4 was 100%. The mean thickness of subcutaneous fat was 36.9 mm (standard deviation (SD) 12.5).

All incisions were along the midline, but the impact on rectus muscle exposure was excluded from the analysis due to a misunderstanding.

The gloves of surgeons and assistants (n = 152) were tested and no leaks were detected. Further secondary intraoperative endpoints are reported in Table 2.

Surgeons

The study involved the participation of three female and two male surgeons. They performed one, eight, nine, ten, and ten closures respectively. After each laparotomy closure, the surgeons completed the VAS evaluation form (Fig. 4). The operating surgeon completed the questionnaire after each patient, yielding between 1 to 10 completed questionnaires from each of the five participating surgeons. The mean response of each surgeon is presented as colour-separated dots on individual statements in the figure.

Follow-up

All patients completed the 6-week follow-up. One patient had a superficial incisional SSI treated with negative

Table 2 Intraoperative outcomes

Outcome	All patients (n = 38)	After learning curve (n = 25)
Patients with SL/WL ≥4	38	25
SL/WL ratio	7.6 (2.3)	7.2 (2.1)
Wound length (cm)	16.1 (3.6)	16.2 (2.1)
Stitch count	41.4 (15.1)	39.8 (16.3)
Number of sutures used	1.6 (0.6)	1.5 (0.7)
Incision closure time (min)	10.4 (5.1)	9.0 (5.0)
NCT/incision length (s/cm)	31.6 (12.2)	26.7 (10.6)
NCT (min)	8.6 (3.7)	7.4 (3.5)
NCT (min), Median (range)	8.1 (2.2–23.6)	6.5 (2.2–23.6)
Stitch-length (cm)	3.0 (0.7)	3.0 (0.5)
Bite-size (mm)	7 (2)	7 (1)

Values are mean, SD unless otherwise indicated. SL/WL, suture length/wound length. SD, standard deviation. NCT, net closure time. min, minutes. s, seconds. Bite size is calculated by assuming each stitch forms a right-angle triangle

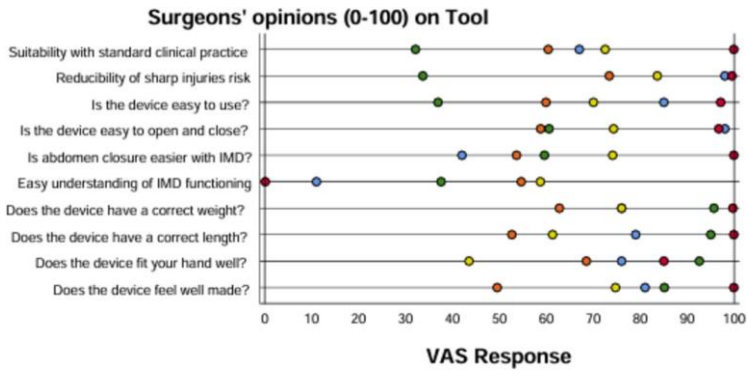

Fig. 4 Surgeons'opinion about the investigational device. Each coloured dot indicates the individual surgeon's mean response (1–10 responses) after laparotomy closure (n = 38). IMD, investigational Medtech device

pressure treatment and antibiotics which resolved after 4 weeks. During the final visit, an additional patient was diagnosed with a superficial SSI that resolved by wound care. No patients suffered from a burst abdomen, and there were no other abdominal wall-related complications detected. One patient was re-operated due to suspicion of an anastomotic leak. Two patients received negative pressure treatment due to seroma formation and re-operation respectively. Unscheduled visits were made postoperatively by three patients to their general practitioners and four underwent emergency room visits for wound unrelated issues. Two patients did unscheduled outpatient clinic visits for wound management. The number of post-surgery visits and re-operations fell in line with normal clinical practice and did not raise any safety concerns.

Adverse events

No patients discontinued the study due to adverse events.

Accessory analysis

The overall mean bite-size was 7 mm (SD 2.0), and the mean bite-size of consecutive closures are shown in Fig. 2a.

The mean NCT for all closures was 8.6 (SD 3.7) min, and the mean NCT for consecutive closures 4–10 was 7.4 (SD 3.5) min.

Regression coefficient for bites-size cases 1–3 and 4–10 respectively was −0.061 and – 0.192 and this dif- ference was −0.131 (95% CI −1.469 – 1.208). There was a change in regression coefficient for stitch-time between cases 1–3 and 4–10 respectively from −2.505 to −0.730, but this difference 1.774 did not receive significance level (95% CI −1.490- 5.039) (Fig. 2a).

Discussion

The risk of complications in abdominal wall closure can be reduced if surgeons adhere to the recommendations of the European and American hernia societies, as well as the World Society of Emergency Surgery. These guidelines advocate for abdominal incision closure with a SL/WL of 4 or more, achieved through the use of small-bites [17, 18].

In contrast to clinical practice, all patients in this study, which evaluated device-assisted laparotomy closure, received a SL/WL ≥ 4, thereby meeting the requirements from the guidelines. Pereira-Rodríguez et al. reported a mere 31% success rate in achieving small-bites after formal training, while an audit of institutional practice by Williams et al. found that laparotomy closure with SL/WL ≥ 4 was achieved in 76% of cases, but only in 46% of emergent cases [23, 30]. In another study, Golling et al. demonstrated the difficulty in achieving high SL/WL with small-bites. After an initial failure, the study was restarted and, following training, instances of small-bites with SL/WL ≥ 4 increased to 87%. However, the study's goal of a SL/WL > 6 was only achieved in 44% of cases [31].

The mean SL/WL in the current study was 7.3, which is higher compared to the 2015 STITCH trial (SL/WL of 5.0), and the 2009 Millbourn et al. trial (SL/WL of 5.7), both of which showed a reduction in IH formation when small-bites were applied [3, 14]. Although the optimal range for the SL/WL ratio for laparotomy closure has yet to be identified, there are indications that a ratio > 7:1 might be safe. Harlaar et al. demonstrated that the initial burst strength in a porcine abdominal wall model was higher with small-bites with an SL/WL of 6.9 (range 5.0–8.6) [32]. Furthermore, in a rodent model, Höer et al. showed that closures with an SL/WL ratio of 4:1 to 8:1 yielded the highest tensile strength after 14 days [33].

Each stitch length in a suture line depends on the interval between stitches, the size of each bite, and the pull tension on the suture thread. A study by Millbourn et al. demonstrated a correlation between stitch length, SSI, and IH formation [34]. With stitch lengths of less than 4 cm, the rates of SSI and IH formation were found to be 4% and 3% respectively, compared to 8% and 11% for stitch lengths of 4–4.9 cm, and 16% and 12% for stitch lengths greater than or equal to 5 cm. Thus, to achieve an SL/WL ratio greater than or equal to 4, the recommended practice is to use stitches shorter than 4 cm, with an individual bite-size of 5–8 mm, a method now referred to as "small-bites". In our current study, the mean stitch length was 3 cm, with a mean bite-size of 7 mm – within the desired range of 5–8 mm. The consistency of the bite-size in consecutive incision closures throughout the study suggests that the investigational device can standardize the placement of small-bites (Fig. 2a).

Abdominal fascial closure using the small-bites method is a time-consuming task, generally ranging from 14 to 30 min in elective abdominal procedures, even when the surgeons are familiar with the closure technique [3, 35, 36]. The overall mean closure time in this study was 10.4 min, which included specific measurements of the length of the new suture whenever more than one suture was used. To better reflect common clinical practice, the first three closure times and any additional time spent measuring the suture were deducted in a separate analysis. This adjustment indicated a median NCT of 6.5 min for an average 16 cm long incision. In a survey about knowledge and attitudes toward hernia prevention, Fisher et al. found that one of the reasons for not using the small-bites closure technique was its time-consuming nature [22]. Numerous clinical studies have documented the time needed for manual laparotomy closure, finding that small-bites typically take approximately 30% longer than large-bites. However, the most rapid closure time in our study was just 2.2 min for a 12 cm incision, suggesting that the device may considerably reduce closure time and potentially lower barriers to using small-bites.

Clinical trials involving the small-bites closure technique advocate the dissection of subcutaneous fat to expose the midline and facilitate a precise incision at the intersecting aponeuroses of the three vertical abdominal muscles, also known as the linea alba [36, 37]. This is essential to avoid opening the rectus muscle compartments and to ensure that the small-bites closure only involves the fascial edges [38]. However, there have been concerns that undermining the subcutaneous fat could potentially increase the risk of postoperative seroma and subsequent SSI. Despite these concerns, Albertsmeier et al. and Wenzelberg et al. recorded superficial SSI rates of 3.3% and 7.5% respectively in the small-bites groups and found low rates of seroma formation. Therefore, their findings suggest that the dissection of the fascia to facilitate small-bites closure seems safe [36, 39].

Sharp injury is common in open surgery when surgeons manipulate the needle with their hands or during the passing of sharp instruments. Suture needles account for 77% of intraoperative sharp injuries and half of the glove punctures occur during laparotomy closure [26, 40]. The study tested all surgeon and assistant gloves and no punctures were detected which is in line with findings in a pre-clinical study showing no punctures in 90 gloves when the investigational device was used [28]. This is an important finding as the prevention of sharp injuries is crucial for surgeon and staff safety.

The learning curve for surgery can be defined as the "time taken and/or the number of procedures an average surgeon needs to be able to perform a procedure independently with a reasonable outcome" [41]. Tracking the progression of stitch-time while maintaining closure quality can serve as a measurement of this learning curve. Per the protocol, the surgeons involved in the study received only minimal training in using the device before its in vivo application. As all laparotomy closures in the study had a SL/WL ≥ 4 and the bite-size was deemed to be consistent, we based the learning curve on stitch-time. In a pre-clinical study, the device's learning curve was found to stabilize after three incision closures [28]. In this study we compared mean stitch-time from surgeons first three cases with the following in a piece-wise linear regression model (Fig. 2b). The difference of 1.774 did not reach significance level, probably due to small sample size. A short learning curve is vital for clinical implementation, especially considering the cautious adoption of the manual small-bites closure technique within the surgical community.

Some weaknesses of the study need to be addressed. First, the two previous publications on the device included a questionnaire with ten statements evaluating surgeon opinions of the device presented on a VAS scale [27, 28]. In the previous presentations, which included a total of 25 participants answering one set of statements each, all statements received VAS scores above 8. The highest scores were given to "Function is easy to understand" (VAS 9.4) and "Tool facilitates adherence to ratio of 4:1" (VAS 9.3). In the present study, surgeons completed the questionnaire after each patient, yielding between 1 to 10 completed questionnaires from each of the five surgeons (Fig. 4). Interpretation was difficult, and comparison with previous opinion presentations was not possible. Responses exhibited high individual variation, but overall they seemed to lean towards the right, indicating a favourable opinion about the device. However, a significant finding was that "Easy understanding of the IMD (device) functioning" received the lowest scores. This issue needs to be addressed in the IFU and device training. This first-in-man clinical trial had a limited sample size and a small number of participating surgeons to address the primary endpoint, the proportion of patients receiving a laparotomy closure with SL/WL ≥ 4. Common clinical outcomes in abdominal wall closure technique research, such as burst abdomen, SSI, and IH formation, were beyond the scope of this study. Although short-term clinical data was collected to monitor adverse events, the study was not sufficiently powered

to analyze and compare these outcomes in detail. Nonetheless, no burst abdomen was detected, and only one clinically significant SSI and one seroma were observed.

This was the fourth time we did structured testing of the device with surgeons within a scientific protocol. Previous studies provided us with an appreciation of the learning curve why we decided to reduce training. Surgeons managed to close all incisions with the correct SL/WL ratio, but the minimal training and lack of intraoperative proctoring probably had negative impact on closure time and efficiency. The device seems intuitive and surgeons experienced in laparotomy closure can understand how it works. For introduction in standard clinical practise, training needs to be far more thorough, and intraoperative proctoring might be needed to secure correct use of the device.

The study reveals that participating surgeons realized a 100% SL/WL ≥ 4 ratio with small-bites, demonstrating a potential to reduce abdominal wall complications. Suturing was determined to be faster than conventional laparotomy closure, and no glove punctures were detected, thus posing no safety issues for the surgeon.

SutureTOOL have the potential to raise attention to abdominal wall closure and to impact surgeons closing habits. It would be interesting to assess surgeons' opinion about abdominal wall closure technique across different surgical communities after market introduction of the SutureTOOL. To address the potential impact on abdominal wall related complications, a large-scale, randomized, multi-center trial would be ideal to track SutureTOOL impact on SSI, burst abdomen and one year incisional hernia formation.

In conclusion, SutureTOOL represents a promising advancement in laparotomy closure, potentially enhancing surgical practice by providing a faster, safer, and standardized approach.

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Authors contributions All authors contributed substantially according to International Committee of Medical Journal Editors, ICMJE, recommendations. The authors' contributions to the study and manuscript according to CRediT taxonomy are as follow:

Conceptualization: GB, LT, ME Data curation: LT, ME Formal analysis: GB, PR, ME Funding acquisition: GB Investigation: LT, ME Methodology: GB, LT, PR, ME Project administration: LT, ME Supervision: ME Validation: LT, PR, ME Visualization: GB, PR Writing – original draft: GB, ME Writing – review & editing: GB, LT, PR, ME].

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Declarations

Conflict of interest GB is the inventor, founder, and shareholder in Suturion AB, Lund, Sweden. LT, PR, and ME report no conflicts of interest.

References

1. Alkaaki A, Al-Radi OO, Khoja A, Alnawawi A, Alnawawi A, Maghrabi A, Altaf A, Aljiffry M (2019) Surgical site infection following abdominal surgery: a prospective cohort study. Can J Surg 62(2):111–117. https://doi.org/10.1503/cjs.004818
2. Shanmugam VK, Fernandez SJ, Evans KK, McNish S, Banerjee AN, Couch KS, Mete M, Shara N (2015) Postoperative wound dehiscence: Predictors and associations. Wound Repair Regen Mar-Apr 23(2):184–190. https://doi.org/10.1111/wrr.12268
3. Deerenberg EB, Harlaar JJ, Steyerberg EW, Lont HE, van Doorn HC, Heisterkamp J, Wijnhoven BP, Schouten WR, Cense HA, Stockmann HB, Berends FJ, Dijkhuizen FPH, Dwarkasing RS, Jairam AP, van Ramshorst GH, Kleinrensink GJ, Jeekel J, Lange JF (2015) Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet 386(10000):1254–1260. https://doi.org/10.1016/S0140-6736(15)60459-7
4. van Ramshorst GH, Eker HH, Hop WC, Jeekel J, Lange JF (2012) Impact of incisional hernia on health-related quality of life and body image: a prospective cohort study. Am J Surg 204(29):144–50. https://doi.org/10.1016/j.amjsurg.2012.01.012
5. Wasserman DW, Boulos M, Hopman WM, Booth CM, Goodwin R, Biagi JJ (2015) Reasons for Delay in Time to Initiation of Adjuvant Chemotherapy for Colon Cancer. J Oncol Pract 11(1):e28-35. https://doi.org/10.1200/JOP.2014.001531
6. Wang D, Zhang G, Peng C, Shi Y, Shi X (2021) Choosing the right timing for interval debulking surgery and perioperative chemotherapy may improve the prognosis of advanced epithelial ovarian cancer: a retrospective study. J Ovarian Res 14(1):49. https://doi.org/10.1186/s13048-021-00801-4
7. Barrow E, Anderson ID, Varley S, Pichel AC, Peden CJ, Saunders DI, Murray D (2013) Current UK practice in emergency laparotomy. Ann R Coll Surg Engl 95(8):599–603. https://doi.org/10.1308/rcsann.2013.95.8.599
8. Ahmed A, Azim A (2020) Emergency Laparotomies: Causes, Pathophysiology, and Outcomes. Indian J Crit Care Med. 24(Suppl 4):S183–S189. https://doi.org/10.5005/jp-journals-10071-23612
9. https://www.who.int/news/item/16-06-2021-caesarean-section-rates-continue-to-rise-amid-growing-inequalities-in-access Accessed 12 December 2024

10. Shah PC, de Groot A, Cerfolio R, Huang WC, Huang K, Song C, Li Y, Kreaden U, Oh DS (2022) Impact of type of minimally invasive approach on open conversions across ten common procedures in different specialties. Surg Endosc 36(8):6067–6075. https://doi.org/10.1007/s00464-022-09073-5
11. Bastawrous AL, Landmann RG, Liu Y, Liu E, Cleary RK (2020) Incidence, associated risk factors, and impact of conversion to laparotomy in elective minimally invasive sigmoidectomy for diverticular disease. Surg Endosc 34(2):598–609. https://doi.org/10.1007/s00464-019-06804-z
12. Al Dhaheri M, Ibrahim M, Al-Yahri O, Amer I, Khawar M, Al-Naimi N, Ahmed AA, Nada MA, Parvaiz A (2022) Choice of specimen's extraction site affects wound morbidity in laparoscopic colorectal cancer surgery. Langenbecks Arch Surg 407(8):3561–3565. https://doi.org/10.1007/s00423-022-02701-7
13. Benlice C, Stocchi L, Costedio MM, Gorgun E, Kessler H (2016) Impact of the Specific Extraction-Site Location on the Risk of Incisional Hernia After Laparoscopic Colorectal Resection. Dis Colon Rectum 59(8):743–50. https://doi.org/10.1097/DCR.0000000000000632
14. Millbourn D, Cengiz Y, Israelsson LA (2009) Effect of stitch length on wound complications after closure of midline incisions: a randomized controlled trial. Arch Surg 144(11):1056–9
15. Thorup T, Tolstrup MB, Gögenur I (2019) Reduced rate of incisional hernia after standardized fascial closure in emergency laparotomy. Hernia. 23(2):341–346. https://doi.org/10.1007/s10029-019-01893-0
16. de Vries HS, Verhaak T, van Boxtel TH, van den Heuvel W, Teixeira MB, Heisterkamp J, Zimmerman DDE (2020) Implementation of the small bites closure of abdominal midline incisions in clinical practice is correlated with a reduction in surgical site infections. Hernia 24(49):839–843. https://doi.org/10.1007/s10029-019-01995-9
17. Deerenberg EB et al (2022) Updated guideline for closure of abdominal wall incisions from the European and American Hernia Societies. Br J Surg 109(12):1239–1250. https://doi.org/10.1093/bjs/znac302
18. Frassini S et al (2023) ECLAPTE: Effective Closure of LAParoTomy in Emergency-2023 World Society of Emergency Surgery guidelines for the closure of laparotomy in emergency settings. World J Emerg Surg 18(1):42. https://doi.org/10.1186/s13017-023-00511-w
19. Dossa F, Speller B, Acuna SA, Adessky R, Facey M, Baxter NN. (2021) Use of the small-bites fascial closure technique and strategies to improve adoption: mixed-methods study. Br J Surg. 108(10):e320-e321. https://doi.org/10.1093/bjs/znab205
20. Bloemen A, De Kleijn RJCMF, Van Steensel S, Aarts F, Schreinemacher MHF, Bouvy ND (2019) Laparotomy closure techniques: Do surgeons follow the latest guidelines? Results of a questionnaire. Int J Surg 71:110–116. https://doi.org/10.1016/j.ijsu.2019.09.024
21. Messenger DE, Rajaretnam N, Slade DAJ; CLosure of Abdominal MidlineS Survey (CLAMSS) Collaborative, Abdominal Wall Subcommittees of the Association of Coloproctologists of Great Britain and Ireland (ACPGBI) and the British Hernia Society (BHS), The Dukes' Club. CLosure of Abdominal MidlineS Survey (CLAMSS): A national survey investigating current practice in the closure of abdominal midline incisions in UK surgical practice. Colorectal Dis. 26(8):1617–1631. https://doi.org/10.1111/codi.17081
22. Fischer JP, Harris HW, López-Cano M, Hope WW (2019) Hernia prevention: practice patterns and surgeons' attitudes about abdominal wall closure and the use of prophylactic mesh. Hernia 23(2):329–334. https://doi.org/10.1007/s10029-019-01894-z
23. Pereira Rodríguez JA, Amador-Gil S, Bravo-Salva A, Montcusí-Ventura B, Sancho-Insenser JJ, Pera-Román M, López-Cano M (2021) Small bites technique for midline laparotomy closure: From theory to practice: Still a long way to go. Surgery 170(1):140–145. https://doi.org/10.1016/j.surg.2020.12.007
24. Nagao M, Iinuma Y, Igawa J, Matsumura Y, Shirano M, Matsushima A, Saito T, Takakura S, Ichiyama S (2009) Accidental exposures to blood and body fluid in the operation room and the issue of underreporting. Am J Infect Control 37(7):541–4. https://doi.org/10.1016/j.ajic.2009.01.009
25. Myers DJ, Epling C, Dement J, Hunt D (2008) Risk of sharp device-related blood and body fluid exposure in operating rooms. Infect Control Hosp Epidemiol 29(12):1139–48. https://doi.org/10.1086/592091
26. Brough SJ, Hunt TM, Barrie WW (1988) Surgical glove perforations. Br J Surg 75(4):317. https://doi.org/10.1002/bjs.1800750408
27. Börner G, Montgomery A (2020) Suture-Tool: A Mechanical Needle Driver for Standardized Wound Closure. World J Surg 44(1):95–99. https://doi.org/10.1007/s00268-019-05179-5
28. Börner G, Edelhamre M, Rogmark R, Montgomery A (2022) Suture-TOOL: A suturing device for swift and standardized abdominal aponeurosis closure. Surg Practice Sci. 11. 100137ISSN 2666–2620,https://doi.org/10.1016/j.sipas.2022.100137
29. https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf accessed september 2022
30. Williams ZF, Tenzel P, Hooks WB 3rd, Hope WW (2017) Suture to wound length ratio in abdominal wall closure: how well are we doing? Hernia 21(6):869–872. https://doi.org/10.1007/s10029-017-1667-y
31. Golling M, Breul V, Zielska Z, Baumann P (2024) The 6:1 short stitch SL-WL-ratio: short term closure results of transverse and midline incisions in elective and emergency operations. Hernia 28(2):447–456. https://doi.org/10.1007/s10029-023-02927-4
32. Harlaar JJ, van Ramshorst GH, Nieuwenhuizen J, Ten Brinke JG, Hop WC, Kleinrensink GJ, Jeekel H, Lange JF. Small stitches with small suture distances increase laparotomy closure strength. Am J Surg. 2009 Sep;198(3):392-5. https://doi.org/10.1016/j.amjsurg.2008.10.018
33. Höer J, Klinge U, Schachtrupp A, Töns C, Schumpelick V (2001) Influence of suture technique on laparotomy wound healing: an experimental study in the rat. Langenbecks Arch Surg 386(3):218–23. https://doi.org/10.1007/s004230000196
34. Millbourn D, Israelsson LA (2004) Wound complications and stitch length. Hernia 8(1):39–41. https://doi.org/10.1007/s10029-003-0159-4
35. Ghai GS, S H (2023) A Comparison of a Small-Stitch Closure With a Standard Closure in Midline Laparotomy Incisions: A Prospective Comparative Study. Cureus. Dec 6;15(12):e50035https://doi.org/10.7759/cureus.50035
36. Wenzelberg CL, Rogmark P, Ekberg O, Petersson U (2024) Reinforced tension-line suture after laparotomy: early results of the Rein4CeTo1 randomized clinical trial. Br J Surg. 111(10):znae265. https://doi.org/10.1093/bjs/znae265
37. Fortelny RH (2022) The Best Closure Technique Without Mesh in Elective Midline Laparotomy Closure. J Abdom Wall Surg 1:10962. https://doi.org/10.3389/jaws.2022.10962
38. Sugarbaker PH (2020) Observations on opening and closing the abdominal incision for cytoreductive surgery using a self-retaining retractor to reduce the incidence of incisional hernia. Surg Oncol. 35:5–11. https://doi.org/10.1016/j.suronc.2020.07.002
39. Albertsmeier M, Hofmann A, Baumann P, Riedl S, Reisensohn C, Kewer JL, Hoelderle J, Shamiyeh A, Klugsberger B, Maier TD, Schumacher G, Köckerling F, Pession U, Weniger M, Fortelny RH (2022) Effects of the short-stitch technique

for midline abdominal closure: short-term results from the randomised-controlled ESTOIH trial. Hernia 26(1):87–95. https://doi.org/10.1007/s10029-021-02410-y
40. Tokars JI, Bell DM, Culver DH, Marcus R, Mendelson MH, Sloan EP, Farber BF, Fligner D, Chamberland ME, McKibben PS et al (1992) Percutaneous injuries during surgical procedures. JAMA 267(21):2899–904
41. Subramonian K, Muir G (2004) The 'learning curve' in surgery: what is it, how do we measure it and can we influence it? BJU Int 93(9):1173–4. https://doi.org/10.1111/j.1464-410X.2004.04891.x

Paper V

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ORIGINAL ARTICLE

A literature-based cost-effectiveness analysis of device-assisted suturing versus needle-driven suturing during laparotomy closure

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Abstract

Purpose Small-bites suturing technique for laparotomy closure is now recommended as the standard of care. However, uptake of the practice remains slow. A medical technology called the SutureTOOL has been developed which can facilitate implementation of small-bites. The aim of the study was to compare the economic and clinical outcomes of laparotomy closure for patients using manual needle-driver suturing versus device-assisted suturing (SutureTOOL) following open abdominal surgery.

Methods This cost-effectiveness analysis comparing device-assisted suturing to needle-driver suturing was performed from a healthcare perspective within Sweden, France, the UK, and the US. A decision tree model was developed to implement the analysis.

Results The SutureTOOL was found to be cost-effective, reducing costs between 22% and 40% across country contexts. Savings were associated with reduced post-operative complications and reductions in operating room time. Improvements in quality of life were minimal and not clinically significant, likely because of the short time horizon.

Conclusion Cost-effectiveness was largely due to cost savings. Prior to procurement, hospitals should test the device to ensure that small-bite rates and reductions in operation time are replicable within their clinical context. If so, the device will improve quality of care for laparotomy wound closure.

Keywords Laparotomy · Sutures · Cost-effectiveness analysis · Surgical equipment

Introduction

Minimally invasive techniques have become standard for many abdominal procedures, but open-access laparotomy remains common, and sometimes essential, especially in complex tumor debulking procedures, trauma and emergency surgery and child delivery through cesarean Section. [1]. Laparotomy is associated with a high risk for abdominal wall complications such as wound infection (17–29% [2]) wound dehiscence (2,2–5,6% [3]) and incisional hernia formation (21%-31,8% [4]).

One fourth of patients undergoing incisional hernia repair will need a re-recurrence hernia repair and the risk of persistent pain after repair is 9–19% at one year follow-up [5, 6]. Patients with incisional hernia have reduced quality of life, suffer from impaired physical function including limitations to exercise and sex life [7]. The annual US cost for incisional hernia repair alone increased from $3.2 billion 2006 to a staggering $7,3 billion in 2011 and the individual and societal burden of abdominal wall complications is heavy,

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making identification and implementation of preventive measures a priority [8, 9].

Other abdominal wall complications occur because of impaired wound healing. How well a wound will heal is affected not only by patient factors such as comorbidities and wound contamination, but also surgeon attentive factors such as tissue handling and suturing tension [10]. The risk of such complications including wound dehiscence, wound infection and incisional hernia formation are reduced when a slowly resorbable suture is used, and the suture line is continuous with a suture-length-to-wound-length ratio (SL/WL ratio) of at least 4 and is deployed with small-bites [2, 11–13].

The abdominal wall is typically closed in two layers – the fascial layer and the skin – when the intra-abdominal part of the operation is finalized. The size of a bite is the distance from the wound's edge to the point of entry of the needle [14]. Small-bites avoid incorporation of fatty tissue and muscle into the bite. In clinical trials this is achieved by instructing the surgeon and using a smaller suture-needle that restricts bite size [11, 13]. Large-bites have a bite size > 10 mm and a step interval of 10 mm. For large-bites, a larger suture needle is used that incorporates more tissue. The length of the suture deployed in the wound should be measured and divided with the length of the wound to calculate the SL/WLratio which should be at least 4. In practice, small-bites implies fascial bites of five to eight millimeters and interval steps of five milimeters. The effectiveness of the small-bites technique has been assessed in several clinical trials, both in elective and emergency settings, and small-bites is now recommended by the Joint European and American Hernia Societies guidelines from 2022 and the World Society of Emergency Surgery guidelines from 2023 [15, 16].

Even though the clinical benefit of small-bites has been recognized in guidelines since 2015, uptake of the practice by surgeons remains uncommon. In a questionnaire-based Dutch study from 2019, less than one quarter of the responders practiced fascial bites with steps < 5 mm and only 35% preferred a suture-length to wound length ratio of 4:1 [17]. In a survey from 2019 where respondents included members of Americas Hernia Society, European Hernia Society and the International Hernia Collaboration, 19% stated they did not practice small-bites because it doesn't apply to the patient population, 24% stated they were not familiar with the technique, and 13% stated the procedure takes too long [18]. Thus any developments that allow for the quicker and more efficient implementation of the small-bites technique could facilitate and improve uptake.

To facilitate implementation of the small-bites technique a suturing device, SutureTOOL (Suturion, Lund, Sweden) has been developed for swift and standardized laparotomy closure [19]. The device was developed by the second author (GB) in collaboration with Lund University, Lund Sweden. The device is a sterile, single use, handheld, mechanical laparotomy closure device with a double pointed needle. The suture needle has a centrally attached 130 cm long polydioxanone 2/0 suture thread. SutureTOOL has a guide that facilitates small-bites stitch placement – a 5–8 mm bites size and a 5 mm step interval. SutureTOOL and device suturing is explained in Fig. 1. Small-bites are enabled by a guide that indicates the measurements of small bites and facilitates correct stitch placement. Suture time, defined as the duration from the first stitch to the final stitch in the aponeurosis, is generally longer for small-bites suturing compared to large-bites suturing. However, the SutureTOOL has been shown to reduce suture time while ensuring small-bites suturing [19, 20]. It has been evaluated in preclinical studies where a SL/WL ratio of 4 was achieved in 95–98% of patients and in a recently completed first-in-man clinical trial where a SL/WL of 4 was achieved in 100% of patients.

To our knowledge there are two previous publications assessing the health economic cost-effectiveness of small-bites. Millbourn et al. [21] included data from a Swedish randomized clinical trial (2001–2006) comparing postoperative complications after laparotomy closure with small-bites and large-bites on patients undergoing laparotomy for colorectal cancer. The health economic analysis was performed from a societal perspective, included direct and indirect costs, and found a cost reduction of 2,415 SEK in patients that had a midline incision with small-bites, approximately $230 in 2013. Gokani et al. [22] performed a cost-utility analysis to compare outcomes after small-bites and large-bites technique for laparotomy closure and the change in quality-adjusted life years (QALYs) with the UK public health provider National Health Service (NHS) perspective rather than a societal perspective. The study assessed the cost implications of adopting small-bites as standard practice and the impact of small-bites as standard practice on QALY measures. The analysis of the added operation time (4,6 min) cost for small-bites suturing (£92 per patient) deemed small-bites to be cost-effective provided a decrease in absolute wound infection rates by more than 15%, or absolute incisional hernia rates by more than 3.4%. While SutureTOOL facilitates small-bite laparotomy closure, the additional equipment comes with a cost and changes how the procedure is performed. The cost-effectiveness of the SutureTOOL, accounting for these changes, has not yet been explored to inform procurement decisions.

The aim of the study was to compare the economic and clinical outcomes of two laparotomy closure techniques performed on patients undergoing open abdominal surgical

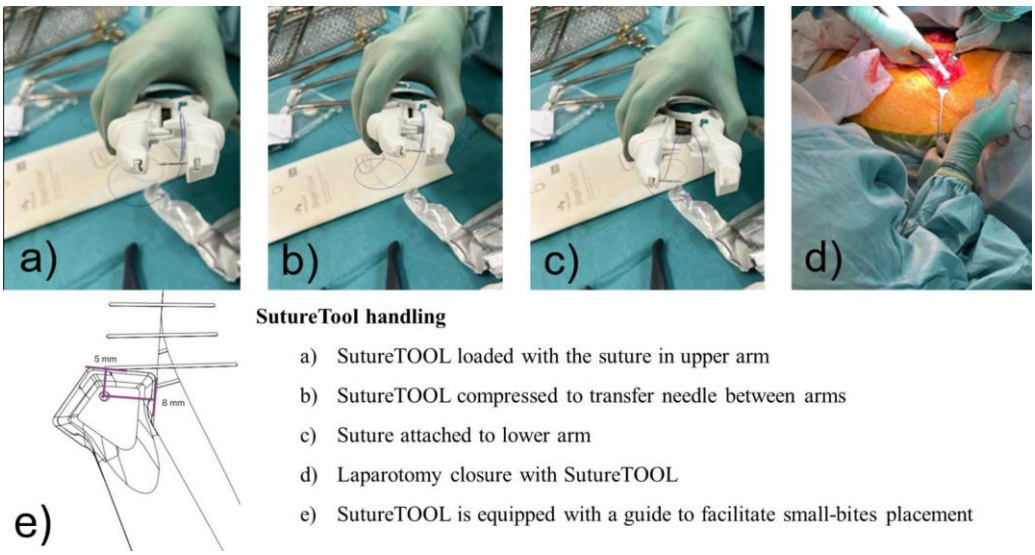

Fig. 1 Description of SutureTool handling

procedures: needle-driver suturing (manual suturing) as standard care and device-assisted suturing (SutureTOOL).

Methods

Study design

This was a cost-effectiveness analysis comparing the economic and clinical outcomes of device-assisted suturing as compared to those of needle-driver suturing as standard care. Thus, the study population includes patients undergoing laparotomy closure. It should be noted that all data used in this model analysis was taken from published peer-reviewed literature, and no primary data was collected for this evaluation. The analysis was performed from a healthcare perspective as decisions to procure the device will likely be made from this perspective, and it is a conservative analytical decision to forgo a societal perspective. Societal effects likely pertain to productivity loss and patient/caregiver travel costs associated with long-term impacts of complications. Needle-driver suturing is the current standard in each country context, and the evidence suggests that the SutureTOOL reduces operation time and increases the percentages of operations performed using small-bites – thus reducing complication rates. Resource use and unit costs data were sourced from four country contexts: Sweden, France, The United Kingdom, and The United States. The analysis is therefore performed separately for each country-context.

A decision tree model was developed in Microsoft Excel (version 24.04) to implement this comparison, and the analysis was performed over a time horizon of 3 years where year-one begins at the index operation. This timeframe was sufficient to capture key postoperative healthcare-perspective costs and outcomes [23], particularly those associated with incisional hernias which tend to present between one and three years following the operation. Inputs to the model were obtained through a targeted literature review and through expert opinion.

Model structure

A decision tree model was constructed to assess the probability and impact of complications associated with each laparotomy closure technique (Fig. 2). Surgeons' adherence to the recommendation of small-bites suturing significantly influences complication rates, including wound infection, wound dehiscence, and incisional hernia [2, 13]. Previous experimental and clinical studies have estimated that small-bites achieved by manual needle-driver suturing can vary from 30% to 76% [20, 24, 25] while the SutureTOOL ensured 95–98% small-bites suturing [20]. In our base-case analysis, we assumed that small-bites were used in 50% of needle-driver sutures and 100% of sutures by the SutureTOOL. In a recent un-published clinical trial, 100% of the 38 laparotomy closures achieved SL/WL-ratio of at least 4

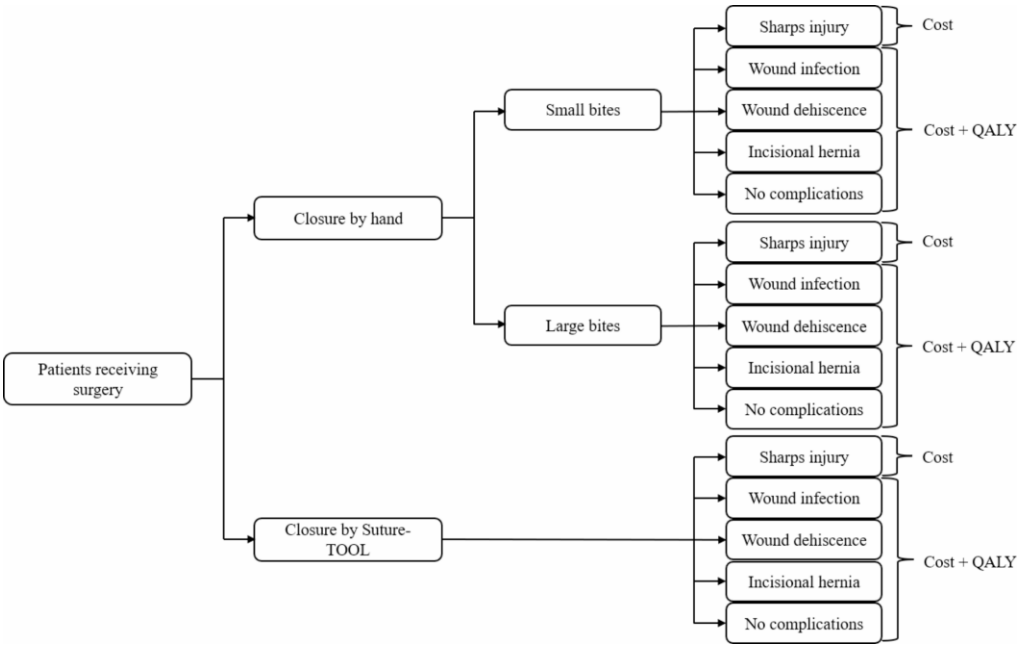

Fig. 2 Decision tree model

with the SutureTOOL. Costs and outcomes were calculated for each suturing technique.

The probabilities of surgical complications were estimated from annual event risks reported in the published literature (Table 1). Sharps injury is an intra-operative complication, and wound infection and dehiscence occur within the first year following the operation – most within the first six weeks. Most incisional hernias manifest within the first three years after surgery, and studies indicate that the risk for incisional hernia is generally distributed over three years: 40% in the first year, another 40% in the second year, and the remaining 20% in the third year [23]. Approximately 65.3% of hernia do not require surgical repair [26].

The frequencies of the three high-cost surgical complications – wound infection, wound dehiscence, and incisional hernia – have substantial implications for model results. While previous studies are somewhat consistent in the general range of estimates of event frequencies, the difference in event rates between small and large bites is somewhat inconsistent (see Supplementary Materials 2). We therefore identified what we see as the most appropriate event rates for the analysis, and include best- and worst-case scenario analyses within the Supplementary Materials 2. Deerenberg et al. [11] was a randomized controlled trial (RCT) published in the Lancet in 2015. The target outcome of the trial was incisional hernia, and the article was thus used to source IH rates for small and large bites in the base-case analysis.

We chose not to use the STITCH study [11] results for wound infection in the base case of our study as we regard the results from Millbourn et al. [13] as a more appropriate choice. In the STITCH study, wound infection rates were considered secondary outcomes, whereas the Millbourn et al. [13] study was powered specifically to assess wound infection, which was among the trial's primary outcomes. Milbourn also had the largest sample size and was conducted in Sweden, a country included in our analysis.

Wound dehiscence rates were obtained fromAlbertsmeier et al. [27], a recent RCT conducted in 2022. The results were not statistically significant, but the p-value was 0.0513, just outside of statistical significance. Wound dehiscence was the main outcome of the study.

Efficacy

The main outcomes used to assess the clinical efficacy of each surgical intervention were Life years (LY) and quality-adjusted life years (QALY). The QALY serves as a comprehensive metric, encompassing both the quantity and quality of life experienced by individuals. This composite measure integrates health-related quality of life and life expectancy,

Table 1 Suture time and complication risks by suturing technique

Parameters	Values	Sources
Suture time (min)		
Small-bites	14	[11]
Large-bites	10	[11]
SutureTOOL	6.5	Unpublished clinical trial
Sharps injury (%)		
Small-bites	17.0	[28]
Large-bites	17.0	[28]
SutureTOOL	0.0	[19]
Wound infection (%)		
Small-bites	5.0	[13]
Large-bites	10.0	[13]
SutureTOOL	5.0	Assumed same as small bites
Wound dehiscence (%)		
Small-bites	1.0	[27]
Large-bites	5.0	[27]
SutureTOOL	1.0	Assumed same as small bites
Incisional hernia (%)		
Small-bites	32.5	Calculated from Deerenberg [29] Deerenberg et al. [11] and Brandl et al. [23], See Supplementary Materials 1
Large-bites	52.5	
SutureTOOL	32.5	Assumed same as small-bites
% IH presenting in		
1st year	40.0	[23]
2nd year	40.0	[23]
3rd year	20.0	[23]
% IH non-operative	65.3	[26]

Table 2 Utility values and mortality risk of surgical complications

Parameters	Values	Sources
Utility		
Wound infection	0.56	[30]
Wound dehiscence	0.53	[30]
Incisional hernia	0.75	[31]
Duration of health state		
Wound infection	0.038	Estimate of co-author clinician
Wound dehiscence	0.076	Estimate of co-author clinician
Incisional hernia	0.5	Assumption
Mortality risk (%)		
Wound infection	2.9	[32]
Wound dehiscence	16.0	[33]
Incisional hernia	0.2	[34]

enabling a holistic evaluation of treatment efficacy. A health weight, also called a utility weight, reflects an individual's quality of life and is measured on a scale from 0 (indicating deceased status) to 1 (indicating perfect health). Utility values, alongside their respective duration and mortality risk of surgical complications, were used in the calculation of LYs and QALYs in this study, and are presented in Table 2.

Costing

This study included direct costs incurred from a healthcare system perspective, including suturing materials, operating theater expenses, and costs related to surgical complications. Manual suturing was assumed to require two sutures per abdominal wound operation on average. For device-assisted suturing (SutureTOOL), the cost included both the device itself and the sutures. Operating theater costs were calculated on a per-minute basis, while costs associated with surgical complications were estimated per event. All costs except those associated with incisional hernia were incurred during the operation or within the first year after operation. Costs related to incisional hernia were spread over a 3-year period, reflecting the accumulated risks over time. Unit costs, along with their respective sources for each study country, are presented in Table 3.

Base case analysis

In the base-case scenario, model inputs were set to best mirror a typical patient cohort and relevant clinical settings. Patients were assumed to have an average baseline age of 70 years, consistent with the demographic commonly undergoing abdominal surgeries [4]. A discount rate of 3% was applied to emphasize direct cost comparisons.

Sensitivity analysis

To assess the robustness of the model and identify key model drivers, deterministic sensitivity analyses were performed by systematically adjusting key parameters by ± 50%. This analysis involved altering one parameter at a time while holding all others constant to assess the impact of each variable on model results.

Model validation

To bolster the reliability of the decision tree model, a comprehensive validation process was conducted. Internal validation involved rigorously checking the model's calculations and logic, model walk throughs, extreme value tests, and sensitivity analyses testing the stability of outcomes against variations in key parameters. The model underwent face validity through expert review by a panel of healthcare economists, and surgeons, who assessed the assumptions, data sources, and methodologies used. Calibration was performed by adjusting parameters to match observed data from Sweden, UK, US, and France.

Table 3 Unit costs

Parameters	Sweden (SE)		UK (£)		US ($)		France (€	
	Values[#]	Sources	Values[#]	Sources	Values[#]	Sources	Values[#]	Sources
Manual suturing*	128.00	Assumption	11.40	Assumption	12.00	Assumption	11.40	Assumption
SutureTOOL[†]	2864.00	Market Price	266.70	Market Price	$381	Market Price	290.70	Market Price
Operating theater cost (per min)	303.18	[21]	21.03	[22]	47.02	[35]	10.78	[36]
Sharps injury	2929.41	[37]	435.45	[38]	2604.92	[39]	262.41	[40]
Wound infection	80005.95	[41]	4891.58	[42]	23501.37	[43]	3767.73	[44]
Wound dehiscence‡	180820.01	[33]	11055.38	[45]	53115.02	Assumption	8515.37	Assumption
Incisional hernia	59044.69	[21]	1881.78	[22]	30712.05	[46]	6500.74	[47]

*Estimated from the cost of two sutures in each country context

†Sutures are included in the cost of device – 2 sutures according to a completed, yet unpublished, clinical trial

‡ The ratio of dehiscence-to-wound-infection-costs in US was applied to the wound infection costs in all other countries

[#]All costs have been updated to 2024 prices using country-specific HICPs for healthcare

Table 4 Outcomes of abdominal operation by suture techniques

Results per patient	Manual suturing	SutureTOOL	Difference
Suture time (min) per patient	12	6.5	-5.5
Incidence (%)			
Sharps injury	17.0	0.0	-17.0
Wound infection	7.18	4.79	-2.39
Wound dehiscence	2.48	0.83	-1.65
Incisional hernia	31.06	14.95	-16.11
Life-Years	2.81	2.82	0.01
QALYs	2.46	2.50	0.04
Cost per patient			
Sweden (SEK)	20,724	13,980	-6,744
UK (£)	1,159	849	-310
US ($)	7,194	4,198	-2,996
France (€)	1,353	1,032	-321
Incremental cost per QALY gained		Dominant*	

*The SutureTOOL is dominant over manual suturing in all study countries

Results

Base case analysis

Device-assisted suturing (SutureTOOL) showed a reduction in operation-theatre time by 5.5 min per patient as compared to manual suturing (Table 4). The SutureTOOL also eliminated the risk of sharps injury during surgeries. In terms of post-operative outcomes, the use of the SutureTOOL was associated with a reduction, in absolute terms, in several complications: wound infections by 2.39%, wound dehiscence by 1.65%, and incisional hernia by 16.11%. Consequently, device-assisted suturing generated an estimated savings of 0.01 life years or 0.04 quality-adjusted life years (QALYs) per patient.

The reduction in suture time resulted in lower operational theater costs and decreased cost for surgical complications and their associated expenses. The total cost per patient using the SutureTOOL was lower than that of manual suturing in all study countries with savings of SEK 6,744 in Sweden, £310 in the UK, $2,996 in the US, and €321 in France. Additionally, the incremental cost per QALY gained was negative in all of these countries, indicating lower costs for each QALY gained. This indicates that the SutureTOOL is cost-effective when compared to manual suturing.

Sweden

In Sweden, the use of the SutureTOOL for laparotomy closures resulted in potential savings of SEK 6,744 per operation (Fig. 3). The device significantly reduced operating time, saving an estimated SEK 1,667 per operation. It also minimized the risk of sharps injuries to surgical providers, preventing potential costs of approximately SEK 498 per operation. Additionally, post-operative benefits included a reduced likelihood of wound infections (SEK 1,915), wound dehiscence (SEK 2,989), and incisional hernias (SEK 2,410).

United Kingdom

In the UK, the implementation of the SutureTOOL resulted in potential cost savings of £310 per operation (Fig. 4). The device substantially reduced operating time, saving an estimated £116 per operation. It also decreased the risk of sharps injuries to surgical providers, avoiding potential costs of approximately £74 per operation. Additionally, post-operative benefits included a lower likelihood of wound infections (£117), wound dehiscence (£182), and incisional hernias (£76).

United States

In the US, the introduction of the SutureTOOL resulted in potential cost savings of $2,996 per operation (Fig. 5).

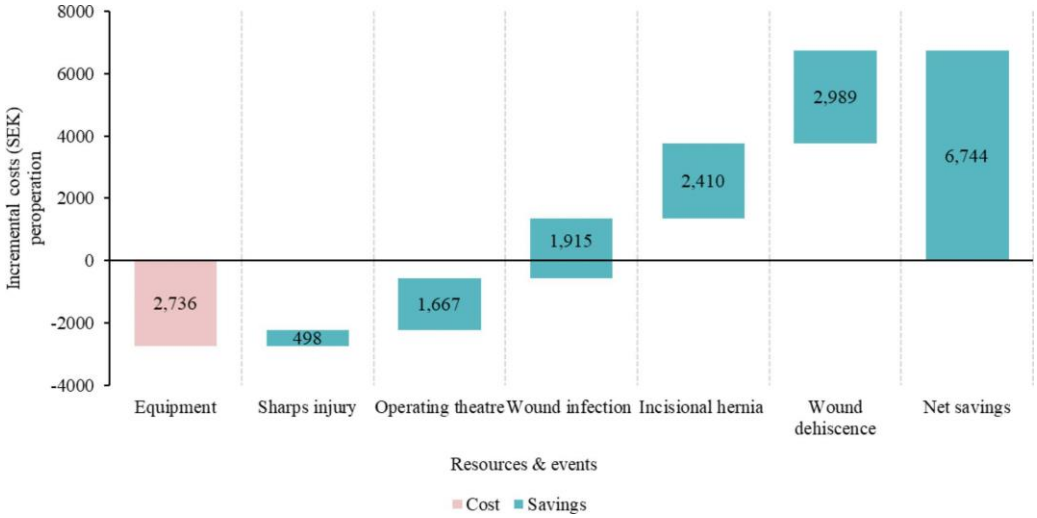

Fig. 3 Incremental costs of using the SutureTOOL laparotomy closures compared to manual suturing in Sweden

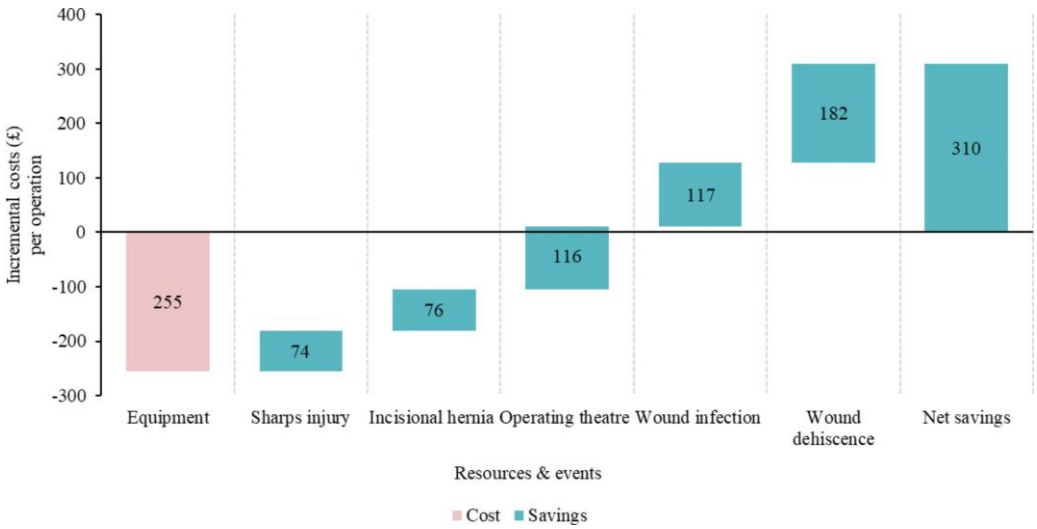

Fig. 4 Incremental costs of using the SutureTOOL in laparotomy closures compared to manual suturing in the UK

Intra-operatively, the device notably decreased operating time, saving $259 per operation. It also reduced the risk of sharps injuries to surgical providers, avoiding potential costs of approximately $443 per operation. Additionally, post-operative benefits included a decreased likelihood of wound infections ($558), wound dehiscence ($870), and incisional hernias ($1,235).

France

In France, the integration of the SutureTOOL demonstrated promising potential cost savings of €321 per operation (Fig. 6). The device decreased operating time, saving €59 per operation. It also lowered the risk of sharps injuries to surgical providers, avoiding potential costs of approximately €45 per operation. Post-operative benefits included reduced

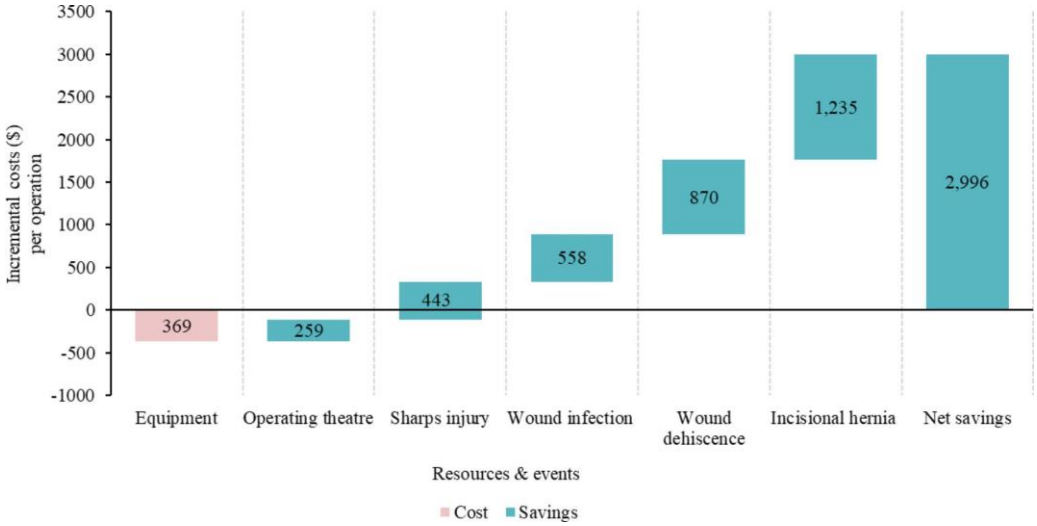

Fig. 5 Incremental costs of using the SutureTOOL in laparotomy closures compared to manual suturing in the US

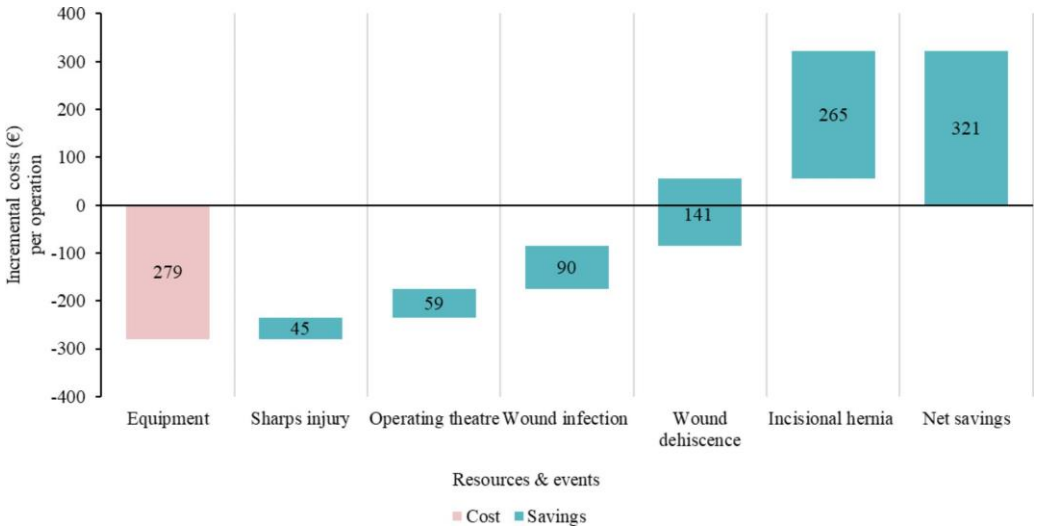

Fig. 6 Incremental costs of using the SutureTOOL in laparotomy closures compared to manual suturing in France

likelihoods of wound infections (€90), wound dehiscence (€141), and incisional hernias (€265).

Sensitivity analysis

Sensitivity analyses identified key model drivers, including the proportion of manual needle-driver suturing procedures utilizing the small-bites technique, as well as the risks of wound infection, dehiscence, and incisional hernia (Fig. 7). The proportion of small-bites procedures directly influences laparotomy closure integrity and associated complication rates. Additionally, the analysis is sensitive to post-operative complication risks.

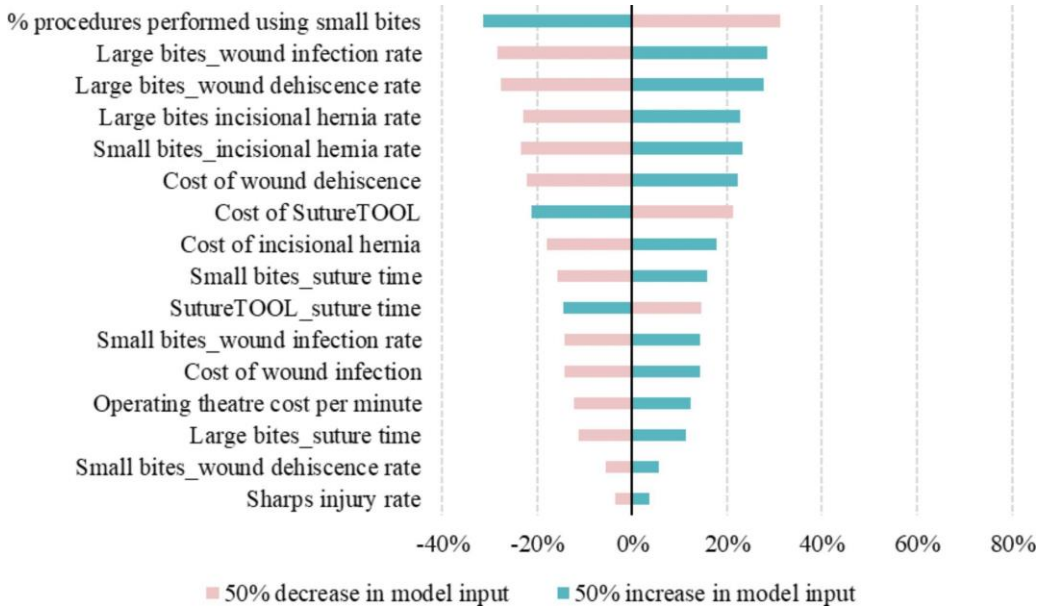

Fig. 7 Tornado diagram presenting the deterministic sensitivity analyses

Discussion

This study indicates that from a healthcare perspective device-assisted suturing, with the SutureTOOL, is cost-effective as compared to manual needle-driver suturing. The results indicate that using the SutureTOOL for laparotomy closures can reduce operation theatre time, thereby improving operational efficiency and lowering costs associated with theatre use. Additionally, the intervention led to a reduction in complication rates, highlighting its potential to enhance patient safety and reduce healthcare expenses. Through ensuring the use of small bites, the use of the SutureTOOL reduced the risk of sharps injuries to surgical providers, mitigating related costs, and lowered the incidence of surgical complications such as wound infections, wound dehiscence, and incisional hernia, positively impacting patient recovery and healthcare resource utilization. Finally, the analysis indicates that the SutureTOOL improves survival. In contexts where at least half of patients are operated on with large bites, for every thousand patients operated on with the SutureTOOL, an estimated three lives are saved, along with the acquisition of nine quality-adjusted life years (QALYs). The results indicate substantial cost-saving potential across multiple countries. SutureTOOL is estimated to reduce costs associated with laparotomy closure by 42% in the US, 33% in Sweden, 27% in the UK, and 24% in France.

Direct costs (operating theatre costs) associated with laparotomy closure are notably reduced, because of reductions in operating time, in all countries except France where the cost of the device is higher than estimated operating theatre costs. Savings grow further when considering the impact of avoided complications, and further still when including avoided incisional hernias beyond the first year. In Sweden, total savings increase substantially when incisional hernias occurring in the second and third years are included. In all country contexts, cost savings from incisional hernias are substantially reduced because 65% of patients are estimated to not need re-operation, and savings would be higher in contexts with higher re-operation rates. Additionally, costs of complications associated with incisional hernia were not included to avoid double counting, as these costs were included with incidents of wound infection and dehiscence.

The unit cost of wound infection emerges as the highest among considered surgical complications across all studied countries, except France where it is the second highest after incisional hernia. Notably, the unit cost of incisional hernia exceeds that of wound dehiscence in Sweden and France, while the reverse is true in the US and UK. This variation in cost distribution leads to slight differences in overall net savings across different countries. These nuanced differences underscore the well-established importance of contextually

valid event rates and unit-cost data if the analysis is to effectively inform decision making [48].

Key model drivers included the percentage of procedures performed using small-bites, wound infection rates, dehiscence rates, and incisional hernia rates. These parameters significantly influence the model's results and warrant careful consideration in clinical decision-making. These key parameters may change as model inputs are tailored to other countries or provider settings. Regardless, these inputs reflect critical aspects of surgical practice and technique and underscore the importance of adopting evidence-based approaches to laparotomy closure.

This study was performed under a set of methodological limitations. Variations in healthcare practices and costs between countries and providers will affect results, and large variations could lead to changes in key model drivers. In France for example, the authors' clinical contacts indicated that the per-minute operating room cost is too low, however the most relevant literature available indicated a cost of 10.78 Euros [36]. It is crucial that decision makers carefully consider their own clinical context and adjust the analytical approach accordingly. The analysis assumed that 50% of wound closures are performed with small-bites, which was a key model driver. The sensitivity analysis (Fig. 7) suggests that an increase in the percentage of small-bites in provider settings is associated with less cost-effectiveness when implementing the suture tool. A Dutch study reported that only 24% of clinicians perform interval steps of 5 mm or less [17]. If this rate reflects international practice, our analysis indicates our results are conservative, particularly with respect to savings associated with avoided surgical complications. No other studies were found that reported small-bites rates. Clinical settings with higher proportions of small-bites will see less savings in terms of avoided complications and more gains associated with time savings. The opposite would be true when large-bites are the dominant practice, and, importantly, these changes in savings are sensitive to variation across clinical contexts with respect to surgical complication rates and suture time. The time improvements associated with the use of SutureTOOL will also vary across contexts depending on surgical methods, the experience of clinicians, and unit costs of resources. Another key assumption included the limited time horizon and subsequent exclusion of long-term complications. As a result, the actual survival benefits could exceed the reported values, further emphasizing the potential positive impact on patient outcomes when the SutureTOOL is adopted for use. Finally, at the core of this analysis is the SutureTOOL's ability to effectively produce SL/WL of at least 4 with small-bites suturing, reduce suture time and protect users from sharps injury. Sharps injuries often occur at the end of long and sometimes strenuous procedures, and the risk increases with 22% per hour as an operation proceeds [49]. Suturing is the most common intraoperative task where sharps injury occurs and laparotomy closure at the end of the operation where risk of injury is high [50–52]. Thus, laparotomy closure is responsible for the majority of glove punctures [52]. One feature of the SutureTOOL is that the needle track does not interfere with the user's fingers. Glove puncture assessment has been an endpoint in SutureTOOL studies, and no punctures were recorded among 45 laparotomy closures [19].

Evidence indicates that the SutureTOOL ensures a SL/WL of at least 4 and can help surgeons adhere to guidelines for laparotomy closure and thus have the potential of reducing abdominal-wall complication rates and operating time. Prior to procuring the SutureTOOL, providers should be careful to ensure that these effects carry over into their clinical operations, and to consider the financial impact of operating time reductions according to their own per-minute operating theater costs. The SutureTOOL has been evaluated in two pre-clinical trials and one pre-market clinical trial. Within these study contexts, participants received minimal training with the SutureTOOL system. Performance could possibly be further enhanced when the practice is well-established in a broader clinical setting [19, 20]. These findings provide valuable insights into the potential benefits of adopting the SutureTOOL in clinical practice, supporting its integration as a valuable medical technology for enhancing surgical outcomes and patient care.

Conclusion

The results of this cost-effectiveness analysis suggest that the SutureTOOL is a cost-effective intervention largely due to the substantial savings generated through reduced operation time and abdominal wall-related complications. Hospitals considering this analysis as a basis for decision making should be careful to test the device within their clinical context to ensure (1) that reductions in operation time are replicable within their clinical context, and (2) that the device consistently delivers a SL/WL ratio of at least 4 with small-bites sutures for laparotomy closure among their providers. Consistent achievement of a SL/WL ratio of at least 4 with small-bites has been shown to reduce complication rates, and the costs savings of avoided events together with those of reductions in operating room time can improve the quality of care for patients undergoing laparotomy closure.

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Declarations

Conflict of interest Gabriel Börner is the founder and Chief Medical Officer of Suturion AB, and Sophia Verheij-Engqvist is an employee at Suturion AB. Smile Incubator, an incubator in Sweden, provided funding to Suturion AB to finance this health economic study. Suturion AB used the Smile funds to contract The Swedish Institute for Health Economics to lead the health economic study. Zin Min Thet Lwin is employed as a research analyst, and George Keel as a research manager, at the Swedish Institute of Health Economics.

References

1. Cherkasov M, Sitnikov V, Sarkisyan B, Degtirev O, Turbin M, Yakuba A (2008) Laparoscopy versus laparotomy in management of abdominal trauma. Surg Endosc 22:228–231. https://doi.org/10.1007/s00464-007-9550-z
2. de Vries HS, Verhaak T, van Boxtel TH, van den Heuvel W, Teixeira MB, Heisterkamp J, Zimmerman DDE (2020) Implementation of the small bites closure of abdominal midline incisions in clinical practice is correlated with a reduction in surgical site infections. Hernia 24:839–843. https://doi.org/10.1007/s10029-019-01995-9
3. Thorup T, Tolstrup MB, Gögenur I (2019) Reduced rate of incisional hernia after standardized fascial closure in emergency laparotomy. Hernia 23:341–346. https://doi.org/10.1007/s10029-019-01893-0
4. HART Collaborative (2022) Incisional hernia following colorectal cancer surgery according to suture technique: Hughes Abdominal Repair Randomized Trial (HART). Br J Surg 109:943–950. https://doi.org/10.1093/bjs/znac198
5. Hoffmann H, Köckerling F, Adolf D, Mayer F, Weyhe D, Reinpold W, Fortelny R, Kirchhoff P (2021) Analysis of 4,015 recurrent incisional hernia repairs from the Herniamed registry: risk factors and outcomes. Hernia 25:61–75. https://doi.org/10.1007/s10029-020-02263-x
6. Köckerling F, Koch A, Lorenz R, Schug-Pass C, Stechemesser B, Reinpold W (2015) How long do we need to Follow-Up our Hernia patients to find the real recurrence rate? Front Surg 2:24. https://doi.org/10.3389/fsurg.2015.00024
7. Hill S, Bullock J, Sanders DL (2023) Quality of Life with a Hernia-A Novel Patient Led Study. J Abdom Wall Surg 2:11214. https://doi.org/10.3389/jaws.2023.11214
8. Poulose BK, Shelton J, Phillips S, Moore D, Nealon W, Penson D, Beck W, Holzman MD (2012) Epidemiology and cost of ventral hernia repair: making the case for hernia research. Hernia 16:179–183. https://doi.org/10.1007/s10029-011-0879-9
9. Shubinets V, Fox JP, Lanni MA, Tecce MG, Pauli EM, Hope WW, Kovach SJ, Fischer JP (2018) Incisional Hernia in the United States: Trends in Hospital encounters and corresponding Healthcare charges. Am Surg 84:118–125
10. Högström H, Haglund U, Zederfeldt B (1990) Tension leads to increased neutrophil accumulation and decreased laparotomy wound strength. Surgery 107:215–219
11. Deerenberg EB, Harlaar JJ, Steyerberg EW, Lont HE, van Doorn HC, Heisterkamp J, Wijnhoven BP, Schouten WR, Cense HA, Stockmann HB, Berends FJ, Dijkhuizen FPH, Dwarkasing RS, Jairam AP, van Ramshorst GH, Kleinrensink GJ, Jeekel J, Lange JF (2015) Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet 386:1254–1260. https://doi.org/10.1016/S0140-6736(15)60459-7
12. Jensen TK, Gögenur I, Tolstrup MB (2022) High rate of incisional hernia observed after mass closure of burst abdomen. Hernia 26:1267–1274. https://doi.org/10.1007/s10029-021-02523-4
13. Millbourn D, Cengiz Y, Israelsson LA (2009) Effect of stitch length on Wound complications after Closure of Midline incisions: a Randomized Controlled Trial. Arch Surg 144:1056–1059. https://doi.org/10.1001/archsurg.2009.189
14. Theodorou A, Banysch M, Gök H, Deerenberg EB, Kalff JC, von Websky MW (2022) Don't fear the (small) bite: a narrative review of the rationale and misconceptions surrounding closure of abdominal wall incisions. Front Surg 9:1002558. https://doi.org/10.3389/fsurg.2022.1002558
15. Deerenberg EB, Henriksen NA, Antoniou GA, Antoniou SA, Bramer WM, Fischer JP, Fortelny RH, Gök H, Harris HW, Hope W, Horne CM, Jensen TK, Köckerling F, Kretschmer A, López-Cano M, Malcher F, Shao JM, Slieker JC, de Smet GHJ, Stabilini C et al (2022) Updated guideline for closure of abdominal wall incisions from the European and American Hernia societies. Br J Surg 109:1239–1250. https://doi.org/10.1093/bjs/znac302
16. Frassini S, Cobianchi L, Fugazzola P, Biffl WL, Coccolini F, Damaskos D, Moore EE, Kluger Y, Ceresoli M, Coimbra R, Davies J, Kirkpatrick A, Di Carlo I, Hardcastle TC, Isik A, Chiarugi M, Gurusamy K, Maier RV, Segovia Lohse HA, Jeekel H et al (2023) ECLAPTE: Effective Closure of LAParoTomy in Emergency—2023 World Society of emergency surgery guidelines for the closure of laparotomy in emergency settings. World J Emerg Surg 18:42. https://doi.org/10.1186/s13017-023-00511-w
17. Bloemen A, De Kleijn R, Van Steensel S, Aarts F, Schreinemacher MHF, Bouvy ND (2019) Laparotomy closure techniques: do surgeons follow the latest guidelines? Results of a questionnaire. Int J Surg 71:110–116. https://doi.org/10.1016/j.ijsu.2019.09.024
18. Fischer JP, Harris HW, Lopez-Cano M, Hope WW (2019) Hernia prevention: practice patterns and surgeons' attitudes about abdominal wall closure and the use of prophylactic mesh. Hernia 23:329–334. https://doi.org/10.1007/s10029-019-01894-z
19. Börner G, Edelhamre M, Rogmark P, Montgomery A (2022) Suture-TOOL: a suturing device for swift and standardized abdominal aponeurosis closure. Surg Pract Sci 11:100137. https://doi.org/10.1016/j.sipas.2022.100137
20. Börner G, Montgomery A (2020) Suture-Tool: a mechanical needle driver for standardized Wound Closure. World J Surg 44:1. https://doi.org/10.1007/s00268-019-05179-5
21. Millbourn D, Wimo A, Israelsson LA (2014) Cost analysis of the use of small stitches when closing midline abdominal incisions. Hernia 18:775–780. https://doi.org/10.1007/s10029-013-1135-2
22. Gokani SA, Elmqvist KO, El-Koubani O, Ash J, Biswas SK, Rigaudy M (2018) A cost-utility analysis of small bite sutures versus large bite sutures in the closure of midline laparotomies in the United Kingdom National Health Service. Clinicoecon Outcomes Res 10:105– 17. https://doi.org/10.2147/CEOR.S150176
23. Brandl A, Laimer E, Perathoner A, Zitt M, Pratschke J, Kafka-Ritsch R (2014) Incisional hernia rate after open

abdomen treatment with negative pressure and delayed primary fascia closure. Hernia 18:105–111. https://doi.org/10.1007/s10029-013-1064-0
24. Bloemen A, De Kleijn RJCMF, Van Steensel S, Aarts F, Schreinemacher MHF, Bouvy ND (2019) Laparotomy closure techniques: do surgeons follow the latest guidelines? Results of a questionnaire. Int J Surg 71:110–116. https://doi.org/10.1016/j.ijsu.2019.09.024
25. Williams ZF, Tenzel P, Hooks WB, Hope WW (2017) Suture to wound length ratio in abdominal wall closure: how well are we doing? Hernia 21:869– 72. https://doi.org/10.1007/s10029-017-1667-y
26. Hrebinko KA, Huckaby LV, Silver D, Ratnayake C, Hong Y, Curtis B, Handzel RM, van der Windt DJ, Dadashzadeh ER (2024) Predictors of acute incisional hernia incarceration at initial hernia diagnosis on computed tomography. J Trauma Acute Care Surg 96
27. Albertsmeier M, Hofmann A, Baumann P, Riedl S, Reisensohn C, Kewer JL, Hoelderle J, Shamiyeh A, Klugsberger B, Maier TD, Schumacher G, Kockerling F, Pession U, Weniger M, Fortelny RH (2022) Effects of the short-stitch technique for midline abdominal closure: short-term results from the randomised-controlled ESTOIH trial. Hernia 26:87–95. https://doi.org/10.1007/s10029-021-02410-y
28. Mischke C, Verbeek JH, Saarto A, Lavoie MC, Pahwa M, Ijaz S (2014) Gloves, extra gloves or special types of gloves for preventing percutaneous exposure injuries in healthcare personnel. Cochrane Database Syst Rev:Cd009573. https://doi.org/10.1002/14651858.CD009573.pub2
29. Deerenberg EB Reply to Comment to: A systematic review of the surgical treatment of large incisional hernia., Georgiev-Hristov T (2015) A. Celdran. Hernia 2015; 19:89–101. Hernia 19:1021. https://doi.org/10.1007/s10029-015-1417-y
30. Asencio F, Aguilo J, Peiro S, Carbo J, Ferri R, Caro F, Ahmad M (2009) Open randomized clinical trial of laparoscopic versus open incisional hernia repair. Surg Endosc 23:1441–1448. https://doi.org/10.1007/s00464-008-0230-4
31. Fischer JP, Basta MN, Wink JD, Krishnan NM, Kovach SJ (2015) Cost-utility analysis of the use of prophylactic mesh augmentation compared with primary fascial suture repair in patients at high risk for incisional hernia. Surgery 158:700–711. https://doi.org/10.1016/j.surg.2015.02.030
32. Wan YI, Patel A, Achary C, Hewson R, Phull M, Pearse RM (2021) Postoperative infection and mortality following elective surgery in the International Surgical outcomes Study (ISOS). Br J Surg 108:220–227. https://doi.org/10.1093/bjs/znaa075
33. van Ramshorst GH, Eker HH, van der Voet JA, Jeekel J, Lange JF (2013) 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 17:1477–1484. https://doi.org/10.1007/s11605-013-2233-2
34. Lindmark M, Löwenmark T, Strigård K, Gunnarsson U (2022) Major complications and mortality after ventral hernia repair: an eleven-year Swedish nationwide cohort study. BMC Surg 22:426. https://doi.org/10.1186/s12893-022-01873-9
35. Childers CP, Maggard-Gibbons M (2018) Understanding costs of care in the operating room. JAMA Surg 153:e176233–e. https://doi.org/10.1001/jamasurg.2017.6233
36. Raft J, Millet F, Meistelman C (2015) Example of cost calculations for an operating room and a post-anaesthesia care unit. Anaesth Crit Care Pain Med 34:211–215. https://doi.org/10.1016/j.accpm.2014.11.002
37. Glenngard AH, Persson U (2009) Costs associated with sharps injuries in the Swedish health care setting and potential cost savings from needle-stick prevention devices with needle and syringe. Scand J Infect Dis 41:296–302. https://doi.org/10.1080/00365540902780232
38. Trueman P, Taylor M, Twena N, Chubb B (2008) The cost of needlestick injuries associated with insulin administration. Br J Community Nurs 13:413–417. https://doi.org/10.12968/bjcn.2008.13.9.30911
39. O'Malley EM, Scott RD 2nd, Gayle J, Dekutoski J, Foltzer M, Lundstrom TS, Welbel S, Chiarello LA, Panlilio AL (2007) Costs of management of occupational exposures to blood and body fluids. Infect Control Hosp Epidemiol 28:774–782. https://doi.org/10.1086/518729
40. Saia M, Hofmann F, Sharman J, Abiteboul D, Martí M, Burkowitz J (2010) Needlestick injuries: incidence and cost in the United States, United Kingdom, Germany, France, Italy, and Spain. Biomed Int 1:41–49
41. Sveriges (2019) Kommuner och Regioner. Vårdrelaterade infektioner
42. NICE (2018) Surgical site infections: prevention and treatment. Health economic model report
43. de Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB (2009) Surgical site infection: incidence and impact on hospital utilization and treatment costs. Am J Infect Control 37:387–397. https://doi.org/10.1016/j.ajic.2008.12.010
44. Lamarsalle L, Hunt B, Schauf M, Szwarcensztein K, Valentine WJ (2013) Evaluating the clinical and economic burden of healthcare-associated infections during hospitalization for surgery in France. Epidemiol Infect 141:2473–2482. https://doi.org/10.1017/s0950268813000253
45. Hughes J, Costello M, Belshaw M, Horton H, Styche T (2021) The burden of dehisced wounds in the community: using early results from a multi-centre service evaluation to propose a standard of care to improve patient outcomes and safeguard wound-care budgets. Br J Healthc Manage 27:16–25. https://doi.org/10.12968/bjhc.2020.0150
46. Fischer JP, Basta MN, Mirzabeigi MN, Bauder AR, Fox JP, Drebin JA, Serletti JM, Kovach SJ (2016) A risk model and Cost Analysis of Incisional Hernia after Elective, abdominal surgery based upon 12,373 cases: the case for targeted prophylactic intervention. Annals of Surgery 263.
47. Gillion JF, Sanders D, Miserez M, Muysoms F (2016) The economic burden of incisional ventral hernia repair: a multicentric cost analysis. Hernia 20:819–830. https://doi.org/10.1007/s10029-016-1480-z
48. Eisman AB, Kilbourne AM, Dopp AR, Saldana L, Eisenberg D (2020) Economic evaluation in implementation science: making the business case for implementation strategies. Psychiatry Res 283:112433. https://doi.org/10.1016/j.psychres.2019.06.008
49. Myers DJ, Lipscomb HJ, Epling C, Hunt D, Richardson W, Smith-Lovin L, Dement JM (2016) Surgical Team Stability and Risk of Sharps-related blood and body fluid exposures during Surgical procedures. Infect Control Hosp Epidemiol 37:512–518. https://doi.org/10.1017/ice.2016.12
50. Nelsing S, Nielsen TL, Nielsen JO (1997) Percutaneous blood exposure among Danish doctors: exposure mechanisms and strategies for prevention. Eur J Epidemiol 13:387–393. https://doi.org/10.1023/a:1007369016717
51. Tokars JI, Bell DM, Culver DH, Marcus R, Mendelson MH, Sloan EP, Farber BF, Fligner D, Chamberland ME, McKibben PS et al (1992) Percutaneous injuries during surgical procedures. JAMA 267:2899–2904
52. Brough SJ, Hunt TM, Barrie WW (1988) Surgical glove perforations. Br J Surg 75:317. https://doi.org/10.1002/bjs.1800750408

GABRIEL BÖRNER is a surgeon and endoscopist at Helsingborg Hospital, Sweden. This thesis addresses the incidence, cause and measures to prevent abdominal wall complications related to open surgery. It includes five papers evaluating a novel device for standardized laparotomy closure in experimental, a clinical and a health economy model.

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