

# Incisional Hernia Prevention

Issue Editor

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# Incisional Hernia Prevention

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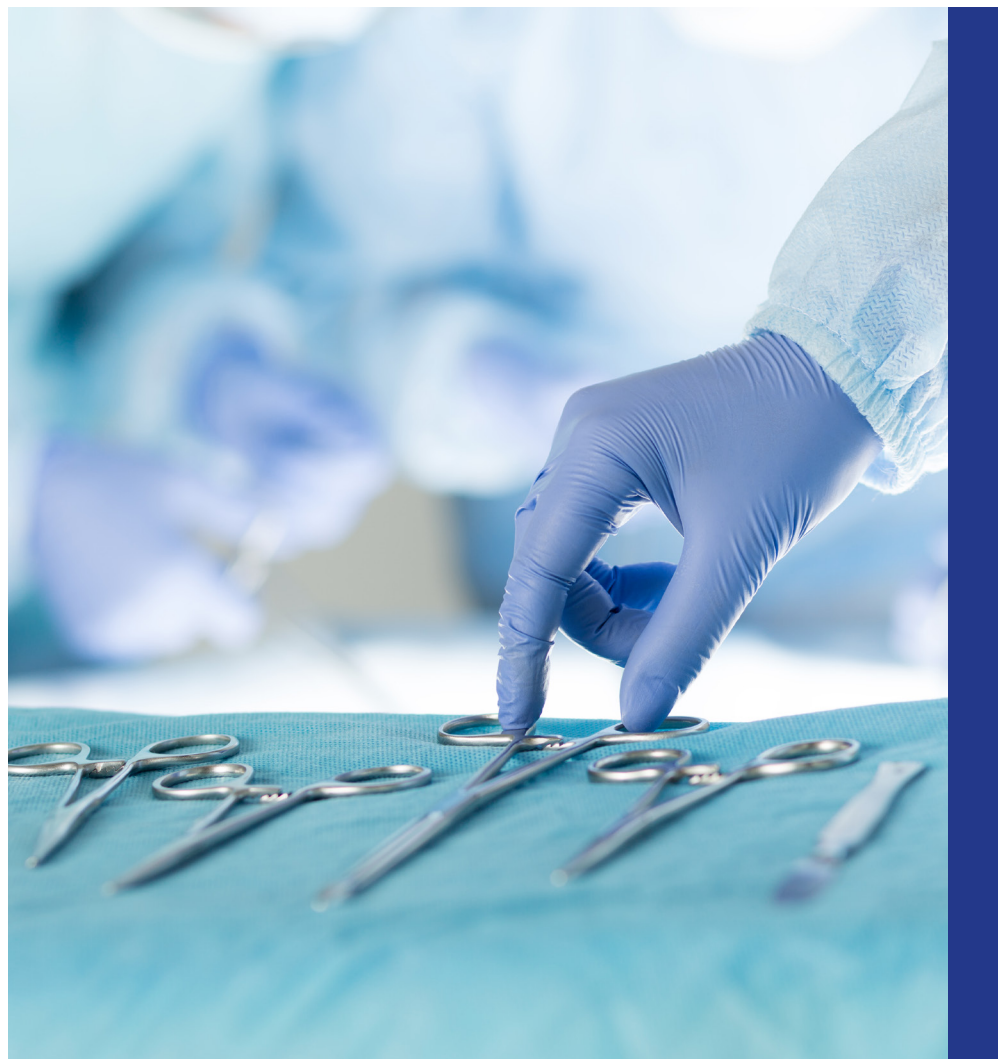
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Manuel López-Cano, Editor-in-Chief of the Journal of Abdominal Wall Surgery (JAWS), official journal of the European Hernia Society (EHS) and together with the Editorial Team are excited to announce the inaugural Special Issue entirely dedicated to the prevention of incisional hernias in the abdominal wall. This is a topic of current interest for all surgeons, not only for those interested in abdominal wall surgery. This Special Issue presents the latest cutting edge reviews, original research and opinion papers from the leading experts in the field.



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# Editorial: Incisional Hernia Prevention

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**Keywords:** incisional hernia, laparotomy, prophylaxis, parastomal, trocar

## Editorial on the Special Issue

### Incisional Hernia Prevention

Incisional hernia (IH) is a health problem of the first order, with a significant impact on the lives of patients who suffer from it and with high economic and social costs at all levels. Therefore, it is not surprising that in the last decade many efforts have been dedicated to knowing more and better all the aspects related to its prevention. Most of these aspects are covered with the articles published in this Special Issue about the prevention of IH and they can be divided into general and specific aspects.

Among the general aspects: the definition of high-risk patients who may benefit from the prevention of IH (Pereira-Rodríguez et al.); innovations in prostheses for the prevention of IH (Harris); analysis of the best non-mesh closure technique for an elective midline laparotomy (Fortelny) or what is the degree of implementation of prosthetic meshes in the prevention of IH (Durbin et al.). Other more specific aspects can be: IH prevention at trocar sites when using minimally invasive surgical techniques (de Beaux and East); anatomical location in the abdominal wall of a laparotomy and its influence on the opening and/or closure of the abdominal wall (Medina Pedrique et al.) or how can IH be prevented in the context of oncological diseases that require cytoreductive surgery and Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (Wenzelberg et al.).

The increase in knowledge about the prevention of IH and how to apply it at general and specific levels may lead to a greater increase in the cost-effectiveness of abdominal surgery, a reduction in morbidity, and better health-related quality-of life of our patients. We are aware that even today the late complications of surgeries that require opening and closing of the abdominal wall (i.e., IH) tend to be relegated to the background when the safety of a specific intraabdominal surgical intervention is evaluated. However, these complications (i.e., IH) play a decisive role in the quality of life of the patient and in the costs of the process and we must prevent them as much as possible.

Although this Special Issue does not cover all the aspects that can be considered in the prevention of IH, it does offer a fairly comprehensive overview. We hope it will be helpful to interested readers and help improve the prevention of IH in patients requiring laparotomy.

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# Incisions in Hepatobiliopancreatic Surgery: Surgical Anatomy and its Influence to Open and Close the Abdomen

Manuel Medina Pedrique<sup>1</sup>, Álvaro Robin Valle de Lersundi<sup>1</sup>, Adriana Avilés Oliveros<sup>1</sup>, Sara Morejón Ruiz<sup>1</sup>, Javier López-Monclús<sup>2</sup>, Joaquín Muñoz-Rodríguez<sup>2</sup>, Luis Alberto Blázquez Hernando<sup>3</sup>, Javier Martínez Caballero<sup>1</sup> and Miguel Ángel García-Urena<sup>1\*</sup>

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Incisions performed for hepato-pancreatic-biliary (HPB) surgery are diverse, and can be a challenge both to perform correctly as well as to be properly closed. The anatomy of the region overlaps muscular layers and has a rich vascular and nervous supply. These structures are fundamental for the correct functionality of the abdominal wall. When performing certain types of incisions, damage to the muscular or neurovascular component of the abdominal wall, as well as an inadequate closure technique may influence in the development of long-term complications as incisional hernias (IH) or bulging. Considering that both may impair quality of life and that are complex to repair, prevention becomes essential during these procedures. With the currently available evidence, there is no clear recommendation on which is the better incision or what is the best method of closure. Despite the lack of sufficient data, the following review aims to correlate the anatomical knowledge learned from posterior component separation with the incisions performed in hepato-pancreatic-biliary (HPB) surgery and their consequences on incisional hernia formation. Overall, there is data that suggests some key points to perform these incisions: avoid vertical components and very lateral extensions, subcostal should be incised at least 2 cm from costal margin, multilayered suturing using small bites technique and consider the use of a prophylactic mesh in high-risk patients. Nevertheless, the lack of evidence prevents from the possibility of making any strong recommendations.

**Keywords:** incisional hernia, incisional hernia prevention, hepatobiliary surgery, mesh prevention, subcostal incisions

## INTRODUCTION

Incisional hernias (IH) consist of any abdominal defect in the vicinity of a postoperative scar that can be detected by clinical examination or by radiographic studies (1). There is no doubt that incisional hernias are an important public health issue, due to an estimated incidence of up to 37% (1), and also due to the implications they have on the patient's quality of life. The patient's symptoms may include pain, limitation of daily life activities, skin problems due to ulceration/infection, incarceration, and other complaints that may require an elective or even emergent surgical procedure (2).

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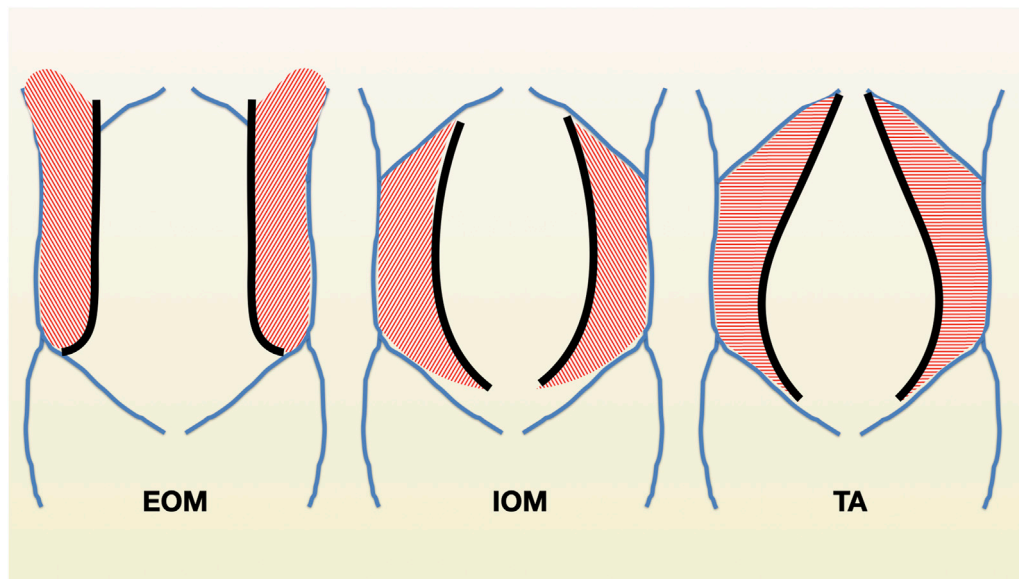
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**FIGURE 1** | Schematic representation of the myoaponeurotic limits of the external oblique muscles (EOM), internal oblique muscle (IOM) and transversus abdominis (TA).

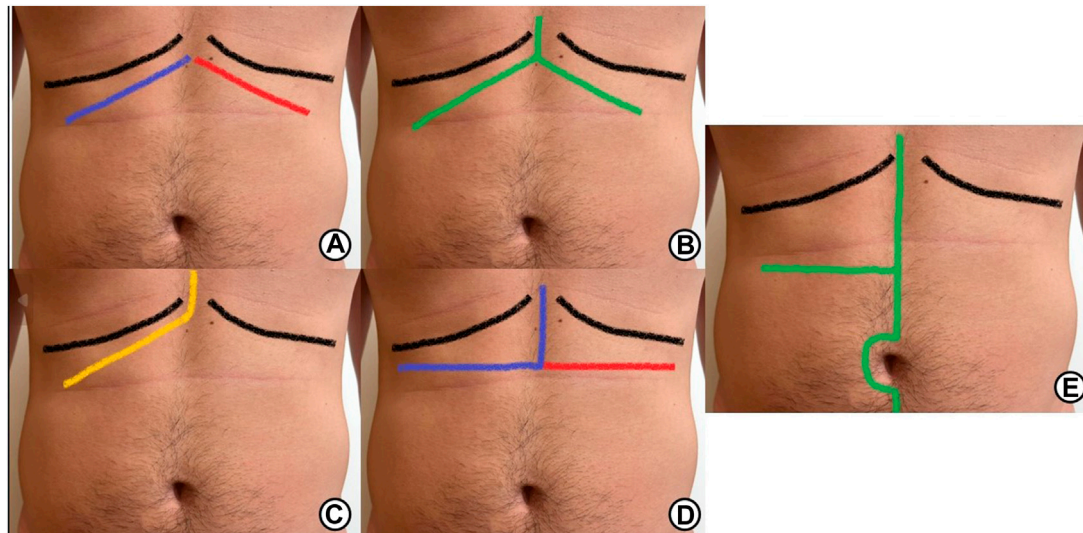
Although it has been indicated that IH seems to be more frequent after midline incisions than off-midline wounds (3), hernias after hepato-bilio-pancreatic (HPB) surgery using subcostal or transverse incisions are considered complex and their subsequent repair may be a challenging procedure (4–6). HPB surgeries may also require a combination of midline and lateral incisions that may make it even more difficult to repair (7, 8). The combination of the different type of incisions made in each patient and the scarcity of the evidence available hinders any attempt to establish which is the best incision to avoid herniation in HPB surgery, or what can we do to decrease the risk of IH formation. The increasing anatomical knowledge from the applications of component separation techniques that can be used to treat IH after HPB (9, 10), has also suggested us to critically evaluate the potential damage to anatomical structures in HPB surgery and its influence in the morphology and the function of the abdominal wall. The purpose of this narrative review is to provide an updated analysis on the current HPB incisions from an anatomical perspective in order to raise awareness among HPB surgeons of the potential influence of their different incisions and their closures on the development of IH.

## SURGICAL ANATOMY

The anterior abdominal wall has been classically described as and hexagonal area that is limited by the xiphoid process and the costal margin superiorly, the pubic bone and the inguinal ligaments inferiorly, and has a lateral extension back to the quadratus lumborum and the erector spinae muscle (11, 12). Within these limits, various muscular groups overlap and give functionality to the abdominal wall. The muscles have been also

divided into midline group: rectus abdominis (RM) and the pyramidalis muscle, and anterolateral group: external oblique muscle (EOM), internal oblique muscle (IOM) and transversus abdominis muscle (TA). The RM is the main component of the midline muscle group. Both muscles originate from the pubic crest and go from bottom to top to insert in the xiphoid process and the anterior surface of the 5th–7th costal cartilages (12). In the superior hemiabdomen, the RM has a slightly oblique direction towards lateral and is enveloped between the anterior and posterior rectus sheaths. The main component of the anterior rectus sheath is the aponeurotic insertion of the EOM on linea alba. The understanding of the myoaponeurotic limit of the EOM may help to better approximate the borders incised when closing this layer (**Figure 1**). The IOM fibers run perpendicular to those of the EOM and their aponeurotic insertion divides into anterior and posterior lamellas. The anterior lamella fuses the aponeurotic insertion of the EOM forming the anterior rectus sheath. The posterior lamella of the IOM contributes to the posterior rectus sheath. In the superior hemiabdomen, the posterior rectus sheath is made of this posterior lamella and the TA. The fibers of TA run horizontally and almost reach the midline in the epigastric area. The myoaponeurotic limit of the TA muscle is called linea semilunaris. While the space between EOM and IOM can be easily dissected without injuring any vascular or neural structures, the space between TA and IO muscle is quite difficult to dissect and the branches of the intercostal nerves run along this space. While outside the linea semilunaris, the space between the peritoneum and TA muscle can be effortlessly developed due to the abundant preperitoneal fat (13), medial to the linea semilunaris the peritoneum is really attached to the posterior rectus sheath and cannot be separated independently.

Knowledge of the anatomy is crucial when performing incisions or closing them in the upper abdominal wall, since



**FIGURE 2 |** Different types of incisions used in HPB surgery: **(A)** Lines of incision of unilateral right subcostal (Kocher incision, blue line) and bilateral subcostal incision (Blue and red lines). **(B)** Lines of incision of a bilateral subcostal incision with superior vertical midline extension (Mercedes-Benz). **(C)** Line of incision of an extended subcostal right incision or J incision. **(D)** Lines of incision of a reverse L incision (blue line) and a reverse T incision (blue and red line). **(E)** Line of incision of a right transverse incision with vertical extension.

entering the abdomen *via* a Kocher or a Chevron incision implies division of several muscles and in some cases of the vascular and nervous supplies that give functionality to the abdominal wall. Therefore, the two main long-term consequences after these lateral incisions are: hernias, muscle denervation (14, 15). Incisional hernia happens when there is a defect of the musculoaponeurotic layers of the abdominal wall, which responds to several risk factors similar to incisional hernia formation in other locations (p.e: obesity, surgical site infection, inadequate closure technique or impaired wound healing). Bulging occurs as a consequence of injury to the nerves that leads to denervation and subsequent atrophy of the lateral abdominal wall muscles. The consequence of this injury translates into a bulge in the surgical scar with no real fascial defect (15). Most of times, both consequences arise together: a fascial defect with an associated muscle atrophy.

## INCISIONS IN HPB SURGERY

The main goal of any incision in surgery is to provide adequate exposure for the planned procedure while being sufficient to address any change due to intraoperative findings or complications. Other concerns include the preservation of abdominal wall functionality as well as allowing abdominal wall healing minimizing the risk of abdominal wall disruption or a posterior hernia formation (16). The need for quick access, accounting for previous scars/cosmetic results while minimizing postoperative pain are also important factors to take into consideration.

In HPB surgery, several incisions have been described to approach the upper abdomen. We will provide a brief description of each, while also naming a few anatomical key

points to take into consideration when performing or closing them.

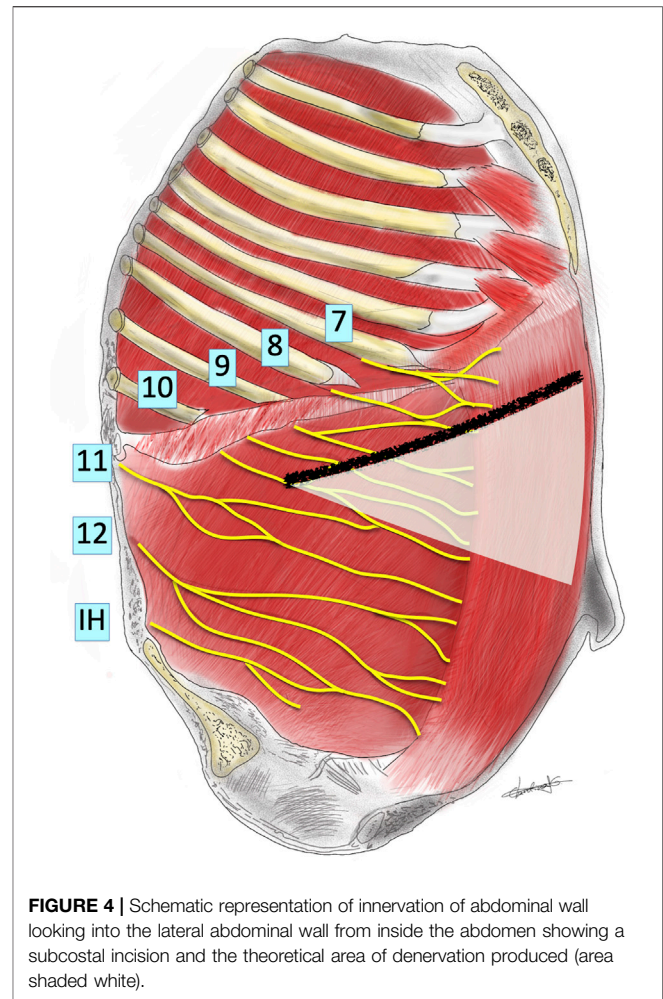
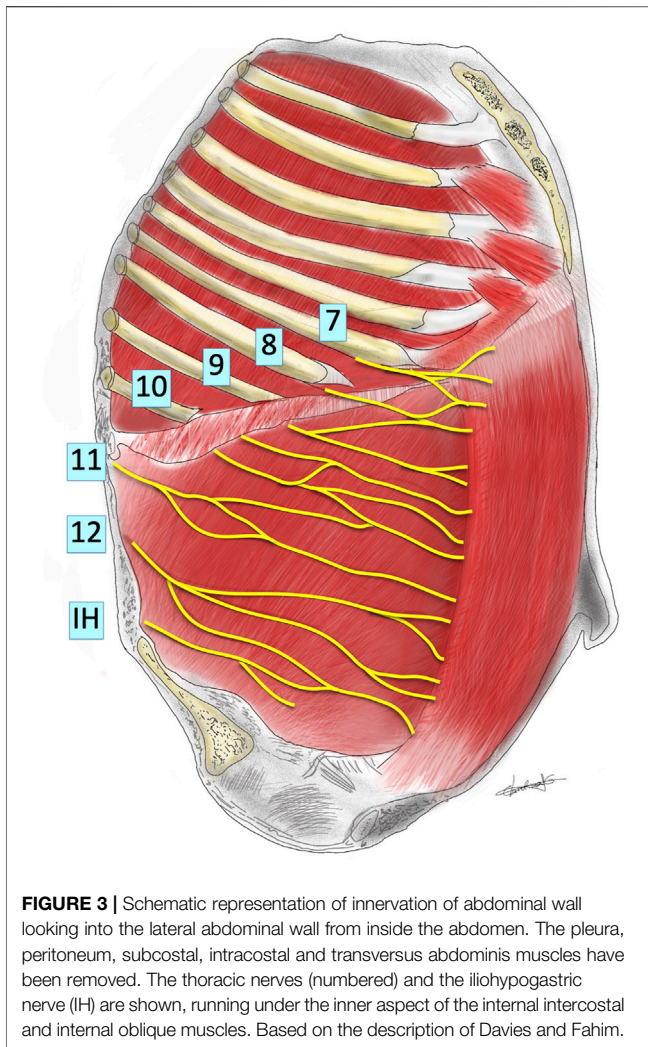
### Midline Incision

The most commonly used incision in open surgery, the midline incision is done along the craniocaudal axis at the linea alba. Since the midline is an avascular plane, risk of nerve or muscular injury is very low (16). Although it has widespread use across all areas of surgery, it is not the most common incision used to perform HPB procedures. Chen-Xu et al found in a retrospective study that midline incision was used in HPB surgery in 16% out of 444 patients (17). Nevertheless, the midline component of some hybrid incisions used in HPB surgery is at a high risk of incisional hernia formation (6).

### Oblique Incisions

A Kocher incision is defined as a subcostal incision performed 2 cm parallel to the costal border, either at the right or left side of the abdomen (Figure 2). This incision divides the anterior rectus sheath, the RM, and the posterior rectus sheath. It requires cautery or ligation of the superior epigastric vessels which are usually divided into 2 or 3 branches along the rectus muscle (18–20). If extended laterally, the 3 lateral abdominal wall muscles are also divided. It is one of the most used incisions in HPB as it provides great exposure to hard-to-reach structures such as the suprahepatic veins, cava vein, biliary tract, pancreas, duodenum, or even the spleen. This wound can be extended to the other side, named a bilateral subcostal or **Chevron incision** (18–20), and it can also extend superiorly at the midline towards the xiphoid process, called the **Mercedes-Benz incision** (Figure 2) (18–20). Despite its advantages in HPB surgery, subcostal incisions tend to produce more





postoperative pain and have a less satisfactory cosmetic outcome than midline incisions (16).

When performing these incisions, special care must be taken as muscular (RM, EOM, IOM and TA), vascular and neural structures can be injured and could have influence on the development of IH, like the intercostal nerves and the lateral border of the rectus sheaths where, as mentioned before, the lateral wall muscles insert forming the anterior and posterior rectus sheaths. According to anatomical descriptions (11, 21, 22), branches of the 7th, 8th, 9th, and probably 10th intercostal nerves must be systematically cut when performing subcostal incisions (Figures 3, 4). If the incision is extended more laterally, branches from 11th and 12th nerves could also be injured. So, the motor innervation of the supraumbilical segment of the rectus muscles is impaired to the extent of the injury of these intercostal nerves, causing ipsilateral rectus muscle and TA atrophy at the supraumbilical area (16).

Probably this type of incision almost perpendicular to the direction of the nerves may not be considered an ideal one from an anatomical point of view. The remaining EOM may also participate in the IH formation by its contraction perpendicular

to the direction of the incision, while the IOM direction of fibers runs parallel to the incision (11, 21–23). From an anatomical point of view, the less we extend laterally the incision the less probability of injuring more nerves (Figure 3). When feasible, it would be advisable to extend the incision to the contralateral side better than performing a more lateral extension.

## Hybrid Incisions

These incisions are defined by the combination of both midlines/vertical and transverse laparotomies. They are usually named by the form of the incision. The most used incision of this type in HPB surgery is a J-shaped incision (Figure 2), which consists of a right subcostal incision with a medial to cranial extension to the xiphoid process. Other hybrid incisions used are the Makuuchi incision or reverse-L, a reverse-T incision, and a right transverse incision with vertical extension (Figure 2) (24).

The consequence of a transverse incision is quite similar to a subcostal, although the incision only runs parallel to the TA muscle. This incision may preserve innervation to the segment of the rectus muscle above the scar but, laterally, can injure 11th and 12th branches that are considered the most important innervation contributors to the anterior abdominal wall (2, 23).

The vertical extension of a subcostal (Kocher) or transverse incision has been traditionally considered a “hernia-formation” incision. In fact, in the recent systematic review by Davey (23), hybrid incisions seemed to develop more IH than transverse incisions, although the quality of the studies included had significant methodological weaknesses. Probably, the reason may be the addition of the lateral traction on both sides through the midline scar to an already weakened subcostal or transverse incision as previously mentioned.

Based on anatomy, recommendations on how to make these incisions can be summarized in the following.

- Establish beforehand a proper wound size for adequate exposure, trying to be as conservative as possible (18–20).
- Avoid vertical extension of a transverse incision.
- Avoid lateral extension, or disruption of the intercostal space between the 11th and 12th ribs (2).
- Distance the incision at least 2–3 cm from the costal margin. Performing the incision too close to the subcostal area might not allow to preserve sufficient fascia for closure (11, 19).
- Make sure to perform adequate hemostasis to avoid hematoma formation, especially when dividing muscle fibers (2). The superior epigastric artery divides in branches around the region of the sixth costal cartilage. It passes inferolateral and pierces the posterior rectus sheath to lie on the posterior surface of the rectus abdominis muscle. When performing subcostal incisions, this artery or its branches should be carefully controlled after dividing the rectus muscle (11, 19).
- The nerves of the anterior abdominal wall run parallel to the muscle fibers and to the vascular supply, from lateral to medial. To avoid injury, when possible, follow the path of the nerves towards the midline and try to preserve them (2).

## INCISIONAL HERNIA AFTER HPB SURGERY

### Incidence

Several studies have reported the incidence of incisional hernia after HPB surgery (25). Nilsson et al. documented an incidence of 30.5%, in which 3 incisions were reviewed: midline-only incisional hernias appeared in 84.6%, midline plus subcostal or lateral incisional hernias appeared in 10.3%, and finally subcostal only incisional hernias showed up in 3.8% (26). Togo et al. published a retrospective review of 626 patients that underwent partial hepatectomy *via* median, J-shaped, right transverse with vertical extension incisions (RTVE) and bilateral transverse incision or reverse-T. The frequency of incisional hernia for each incision was 6.3% for midline, 4.7% for J-shaped incision, 5.4% for RTVE, and 21.7% for reverse-T incision (27). It would have been interesting to detail what component of the hybrid incisions was affected the most, either the midline or the lateral component of the wound. Chen-Xu et al. described the incidence of incisional hernia after HPB surgery in a retrospective review of 696 patients. They described the frequency of incisional hernia in those patients submitted to pancreatic surgery

(incidence of 10.5% at 24 months of follow-up) and those submitted to hepatobiliary surgery (incidence of 27% at 72 months of follow-up). The most performed incision in their study was the J-shaped incision (64.7%). Overall incidence was estimated at 21.6%, which is a very significant number of patients that develop this complication during their follow-up. They also studied potential risk factors for incisional hernia occurrence in these patients, detailing that for pancreatic surgery a height greater than 167.5 cm, a subcutaneous fat >23.3 mm, and wound infection/dehiscence increased frequency. In hepatobiliary surgery, risk factors identified were a BMI >26.0 kg/m<sup>2</sup> and having a perirenal fat pad >14.7 mm (17). Both of these variables correlate with the fact that obesity is an important predisposing factor for incisional hernia development. Finally, Davey et al. in a recent systematic review pooled a total of 5,427 patients and reported an incidence for incisional hernia of 15% in those patients with hybrid incisions (J-shaped, Mercedes-Benz, reverse-L, reverse-T, and RTVE) at 42 months of follow up, compared to a pooled incidence for incisional hernia of 6% for those patients with transverse incisions with a mean follow up of 17.5 months (23).

A more recent study carried out by Lida et al. retrospectively reviewed 1,057 patients who underwent open hepatectomy *via* J-shaped, reverse L-shaped, reverse T-shaped, and Mercedes-Benz incision. They had a reported incidence of 5.9% during 3 years of follow-up, and associated risk factors for IH development were age ≥65 years, diabetes mellitus, and albumin levels <3.5 g/dL. They also differentiated which incision had a greater incidence of IH: out of the 62 patients who developed an IH, 25 of them appeared in the midline component of the incision (40.3%), 13 appeared in the central part of the incision (21%), 15 formed in the transverse aspect of the incision close to the midline (24.2%), and the remaining 9 formed on the right edge of the wound (14.5%) (28). These results further support that the midline component of these incisions has the highest risk of developing an IH.

Memba et al. performed a systematic review of 8 studies about IH prevention in open HPB surgery. 6 of them were retrospective and the remaining 2 were prospective cohorts. Most of them shared the primary variable of IH incidence, while also evaluating risk factors for IH formation in this group of patients. They found a pooled IH incidence that ranged from 7.7% to 38.8%. They also described risk factors according to statistical significance and found that a high BMI, surgical site infection, ascites, Mercedes or reversed T incisions, and previous IH were related to a higher risk of developing an IH (29).

There is no doubt that incisional hernia negatively impacts the quality of life of the patient. The abdominal bulge, pain, and discomfort limits daily activities, and complications like incarceration and obstruction may occur. Also, symptomatic incisional hernias have an indication of surgical repair, which increases the costs of healthcare, taking also in consideration the morbidity associated with incisional hernia repair. Therefore, a strategy to prevent this from happening is important, with an emphasis on a proper abdominal wall closure technique tailored to each patient undergoing surgery.

### Risk Factors

The most important moment to identify who is at risk to develop an IH is during the preoperative consultation. Several risk factors

like BMI  $>26.0 \text{ kg/m}^2$ , a height  $>167.5 \text{ cm}$ , diabetes mellitus, malnutrition, smoking, and anemia have been correlated positively with IH formation. Correction of these factors plays a vital role to prevent IH formation. Chen-Xu et al. also described a positive correlation between IH formation and perirenal fat thickness  $>14.7 \text{ mm}$ , and subcutaneous fat  $>23.3 \text{ mm}$ . Both factors further support the concept that a higher BMI and obesity have an important impact on a higher incidence of IH (17). A more recent study published by Nagaoka et al. identified the presence of intramuscular adipose tissue in patients who underwent hepatic resection as a significant risk factor for IH formation after surgery, with up to 20% of the patients developing an IH at 3 years follow-up (30). One of the most detailed descriptions of risk factors associated with a higher IH incidence in HPB surgery is published by Memba et al. They collected most of the data available on this topic and found that a high BMI was the most mentioned factor in most studies that also had a positive correlation with IH formation. Secondary to BMI came surgical site infection and the presence of ascites/cirrhosis. And finally, the incision type, being the Mercedes and the reverse-T incisions the most related to IH appearance. Many other risk factors were described with low association with IH incidence, such as previous hernia surgery, running versus mass suture closure of the abdominal wall, preoperative chemotherapy, superficial wound dehiscence, subcutaneous and perirenal fat thickness, and malignancy, among others (29).

## CLOSING THE INCISIONS

Adequate closure in HBP surgery is essential to ensure wound healing and prevent IH formation. Appropriate identification of sheaths and muscle layers that are closed adequately along the incisions can be considered a must. When closing incisions that extend outside the lateral border of the posterior rectus sheath, we can make 3 main types of closure: a mass closure can be performed taking together 3 layers with the same bites, a 2 layer that takes a first layer with TA and IOM and a second layer with EOM or a three-layer closure taking independently the three muscle layers. This closure follows to the midline with a mass closure or a two-layer closure of the anterior and posterior rectus sheaths. We would recommend to use a multilayered closure in all circumstances. Additionally, the incorrect apposition of borders and the inappropriate reconstruction of the lateral border of the posterior rectus sheath where the IOM divides into the anterior and posterior lamella might also contribute to inadequate wound healing. In order to avoid this mistake, we recommend to observe the myofascial limits of the EO e IE muscle to provide an adequate orientation (**Figure 1**).

There is a discussion about whether a layered closure is better than a mass closure. Zhang et al. published a prospective study where they compared patients undergoing liver resection that were closed *via* a mass continuous suture vs. a layered interrupted suture. They found no differences regarding IH formation, but did describe a longer closure time for interrupted layered suture (31). A recent trial has shown a significant reduction of SSI using layer closure (32). Long-term results have not yet been published comparing these methods

of closure. Several studies and guidelines have published recommendations to reduce the risk of IH when closing incisions, mostly directed to midline wounds, but that can be extrapolated to lateral and hybrid incisions. European Hernia Society guidelines recommend a continuous small-bites suture technique with a slowly absorbable suture for closure (Tissue bites of 5–9 mm from the wound edges limited to aponeurosis only, with stitches placed 5 mm apart from one another in a continuous suturing technique, using a 2–0 size thread). This technique provides a low-tension closure that guarantees sufficient tissue perfusion for proper wound healing. The small-bites technique also implies a suture length to wound length ratio of 4:1 (33). This may have some caveats when addressing transverse or hybrid wounds, as there are more planes to take into consideration when closing the incision. Also, surgeons must take into consideration that using small bites outside the linea semilunaris may be difficult due to the lack of proper aponeurosis, since the 3 lateral muscles are covered by a weak fascia. A study that retrospectively compared conventional suture with small bites failed to demonstrate a statistically significant difference in the incisional hernia rate (34). Davey et al analyzed various studies addressing this topic, one of them being the INLINE meta-analysis, that suggests that a running suture with a slowly absorbable material has lower IH incidence in midline laparotomies. The INSECT trial however showed no difference between suture types. The pooled data favored the use of slowly absorbable or non-absorbable with a continuous suture to decrease IH rates (23). Memba et al also reviewed available literature addressing closure methods in HPB surgery, one if them is a Cochrane review from 2017. It showed that the quality of evidence available is low and could not determine what was the best type of suture or closure technique in HPB surgery. They concluded that studies tend to lean towards using small bites with a running suture for fascial closure, as this has demonstrated benefits in reducing IH in midline laparotomies (29). This could be extrapolated to subcostal incisions but requires studies to generate evidence and recommendations. Again, the literature at our disposal is small, no comparative studies exist, and the ones published are very heterogeneous.

Numerous reports document the use of a prophylactic mesh to prevent incisional hernia formation. Although it is a topic that not all surgeons agree on, there is literature that supports their use in patients at high risk of IH formation after midline incisions. The EHS has recently published their updated guidelines for closure of abdominal wall incisions and stated that mesh augmentation after suture closure of a midline incision in elective surgery can be considered to reduce IH formation when compared to primary suture closure only, without any significant increase of surgical site infection (33). Nevertheless, the quality of evidence is low, with a weak strength of recommendation. Also, there are no RCT studies so far that compare the use of prophylactic mesh vs. primary suture closure in not midline incisions.

Our group performed a comparative cohort study on the use of prophylactic meshes to prevent IH in bilateral subcostal laparotomies (6). We compared 57 patients who retrospectively were closed with primary suture only, with 58 patients in which a prophylactic mesh was used when closing the laparotomy. The method of closure was the same



**TABLE 1 |** Future research topics for incisional hernia in HPB surgery.

Potential areas of research	
Type of incision	Extended vs. midline augmentation Subcostal vs. transverse
Closure of the incision	Layer vs. Mass Small bites vs. large bites Absorbable vs. non-absorbable vs. antibiotic coating Mesh augmentation
Patient Reported Outcomes	Incidence of incisional hernia Quality of life reported outcomes

for both groups, using a standard 2-layer protocol with a running slowly absorbable monofilament suture of Poly-4 Hydroxybutyrate, in a 4:1 ratio, with stitches spaced 1 cm from each other and 1 cm from the wound edge. The first layer included the closing of the IOM, TA, and the posterior rectus sheath medially. The second layer encompassed the closing of the EOM, its fascia, and the anterior rectus sheath. The mesh was placed in the space between the internal and external oblique muscles, and when extending medially it was placed retromuscular over the posterior rectus sheath. At 24 months, IH incidence was lower in the mesh group than in the control group (1.72% vs. 17.54%), with no statistical difference in morbidity and mortality. This means that mesh implantation can be safely placed as a prophylactic measure to prevent IH in subcostal incisions often used in HPB surgery. Another study that supported the use of mesh as prevention comes also from Spain. This study retrospectively compared a cohort of patients undergoing emergency subcostal incisions with suture closure vs. a similar cohort with an onlay mesh reinforcement (35). They also found a significant difference in incisional hernia rate between groups: 3.8% in the mesh group vs. 19.1% in the suture group. Interestingly, there was no difference in wound morbidity between groups. RCTs are necessary to offer more evidence on the use of mesh in HPB surgery.

## SUMMARY

The choice of incision type for open HPB surgery is usually a straightforward decision based on the target organ, the type of patient, the proposed surgery, and the surgeon's preference.

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Non-midline or oblique incisions are most commonly used, as they can provide adequate exposure and are associated with less risk of incisional hernia formation (2). However, subcostal or hybrid incisions have drawbacks that have not been fully studied and could present difficulties when performing or deciding how to close the abdomen. It is necessary to know the anatomy of the abdominal wall in this region, as the overlapping muscles and the presence of the neurovascular supply are at risk of injury (11, 12). We were able to identify in the literature a few noteworthy points to take into consideration when approaching these incisions: preventing vertical extension of a transverse or oblique incision, leaving enough fascia to perform a proper closure, avoid too lateral extension to avoid injury to intercostal nerves (2, 11, 19), and the application of the principles of abdominal closure of midline (small bites, mesh prophylaxis) to these lateral wounds. By accounting for these variables, we may decrease the risk of IH, and also may have a positive impact on reducing bulging incidence (2). However, there are still many other questions that need to be answered in randomized clinical trials (Table 1): which incision is better, how can we adequately do these incisions, how is the best way to close.

## AUTHOR CONTRIBUTIONS

MM, JM-R, JL-M, and LB have written text. AA and SR have made bibliography search. JM and MG-U have contributed correcting text, making discussion and figures elaboration.

## CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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# Abdominal Closure With Reinforcing Suture Decreases Incisional Hernia Incidence After CRS/HIPEC

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**Background:** Cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) entails several risk factors for incisional hernia (IH). A few reports available showing incidences between 7% and 17%. At our institution fascia closure has been performed in a 4:1 suture to wound length manner, with a continuous 2-0 polydioxanone suture (PDS-group) or with a 2-0 polypropylene suture preceded by a reinforced tension line (RTL) suture (RTL-group). Our hypothesis was that these patients might benefit from reinforcing the suture line with a lower IH incidence in this group. The aim was to evaluate the 1-year IH-incidence of the two different closures.

**Methods:** Patients eligible for inclusion were treated with CRS/HIPEC between 2004 and 2019. IH was diagnosed by scrutinizing CT-scans 1 year  $\pm$  3 months after surgery. Additional data was retrieved from clinical records and a prospective CRS/HIPEC-database.

**Results:** Of 193 patients, 129 were included, 82 in the PDS- and 47 in the RTL-group. RTL-patients were 5 years younger, had less blood loss and more frequent postoperative neutropenia. No difference regarding sex, BMI, recent midline incisions, excision of midline scars, peritoneal cancer index score, complications ( $\geq$ Clavien-Dindo 3b), or chemotherapy. Ten IH (7.8%) were found, 9 (11%) in the PDS- and 1 (2.1%) in the RTL-group ( $p = 0.071$ ).

**Conclusion:** An IH incidence of 7.8% in patients undergoing CRS/HIPEC is not higher than after laparotomies in general. The IH incidence in the PDS-group was 11% compared to 2% in the RTL-group. Even though significance was not reached, the difference is clinically relevant, suggesting an advantage with RTL suture.

**Keywords:** incisional hernia, abdominal closure, reinforcing suture, reinforced tension line suture, hyperthermic intraperitoneal chemotherapy

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## INTRODUCTION

Cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (CRS/HIPEC) is an extensive procedure for treating different peritoneal surface tumor spread as mesothelioma, pseudomyxoma peritonei (PMP) and gastrointestinal malignancies (peritoneal carcinomatosis, PC) (1). These patients face numerous risks for early postoperative complications related to

advanced malignant disease, extensive surgery and intra-operative chemotherapy. With improved outcome and long-term survival, long-term sequelae become increasingly important to prevent.

IH is one of the most common complications after abdominal surgery with varying incidences. In a large meta-analysis by Bosanquet (2), incidences between zero and 36% were found and in the randomized controlled STITCH trial, comparing large-bite to small-bite closure, the IH-incidences at 1 year were 21% and 13%, respectively (3). IH causes morbidity, reduced quality of life, and need for reconstructive surgery (2-6).

Patients treated with CRS/HIPEC have several factors associated with increased risk for developing IH. They have often undergone earlier midline laparotomies; CRS/HIPEC surgery requires long midline incisions, often combined with excision of any previous scars; they are exposed to long operation times and; they receive intraperitoneal chemotherapy, resulting in prominent intestinal swelling and increased intraabdominal pressure at closure as well as secondary immunosuppression and low postoperative albumin levels (2, 5, 7, 8, 9).

Until now, only a few articles on IH after CRS/HIPEC surgery are available, reporting IH incidences between 7% and 17%. Results so far are difficult to compare. The number of patients evaluated vary between 155 and 282 with follow-up times between 8 and 38 months. Furthermore, the criteria for inclusion, and the modality for IH diagnosis vary. The preconceived suspicion of high IH rates after CRS/HIPEC have so far not been verified. Within this group of patients, higher age, higher BMI, female gender, neoadjuvant chemotherapy and fascial dehiscence (FD) seem to be independent risk factors for developing IH (5, 10, 11).

The gold standard technique for fascial closure after midline incisions today is the small-bite 4:1 suture to wound length ratio technique described and evaluated by Milbourn (9), and recommended in the European Hernia Society guidelines on closure of abdominal wall incisions (12). In 2007, Hollinsky described the Reinforced Tension Line (RTL) technique for treating IH, and reported promising results (8). Agarwal evaluated the RTL-technique in patients with acute peritonitis and found significantly lower rates of fascial dehiscence (FD) with RTL-closure compared to standard closure (13). Recently Lozada-Hernández published results from a randomized controlled trial with 3-year follow-up comparing the RTL-technique to mass closure technique in 104 patients with high risk for IH development, and found significantly lower IH incidence after using RTL-closure (9.8% vs. 28.3%) (14). Even if the scientific basis for the RTL-technique still is frail, the theoretical basis is appealing and the technique has been used at our institution in situations where reinforcement of the incision line is desirable, and mesh reinforcement is deemed unsuitable.

Fascia closure after CRS/HIPEC-procedures has been performed in either of two ways at our institution. In the earlier period, a continuous 2-0 polydioxanone (PDS) suture in a 4:1 manner was standard. Since 2016, a 2-0 polypropylene (PP) RTL-suture followed by a 4:1 closure with the same suture material, has been the predominant method.

We hypothesized that CRS/HIPEC-operated patients might benefit from reinforcing the suture line rendering a lower incidence of IH compared to patients closed with the standard continuous PDS suture. The primary aim of this study was to evaluate and compare the 1-year computed tomography (CT) detected IH-incidence of the two different closure techniques. Secondary aims were to evaluate possible risk factors for IH and to describe the incidence of fascial dehiscence (FD).

## MATERIALS AND METHODS

### Study Design and Aim

This is a retrospective, single-centre study from the Department of Surgery, Skåne University Hospital, Malmö, Sweden. Patients treated with CRS/HIPEC between September 2004 and September 2019 through a midline laparotomy, were eligible for inclusion. The primary aim was to evaluate the IH incidence with CT performed 12 ± 3 months after surgery and to compare the IH incidences between the two closure techniques. IH was defined according to the EHS definition (15) as “any abdominal wall gap with or without a bulge in the area of a postoperative scar, perceptible or palpable by clinical examination or imaging.” CT-scans were scrutinized for IH by three independent examiners (two surgeons and one radiologist). In case of discrepancy between the examiners’ interpretations, a discussion was carried out to reach consensus.

Patients closed in a different way than with the two techniques of interest or with existing midline mesh or hernia; patients deceased or re-operated within 9 months after surgery for any reason, and; patients not investigated with a CT scan 12 ± 3 months after surgery were excluded from the statistical analysis.

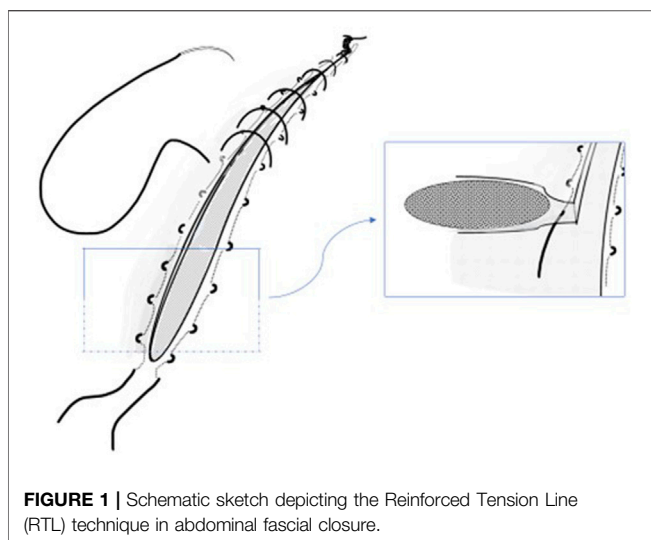
Secondary aims were to evaluate possible risk factors for IH and to describe the incidence of FD.

The RTL-technique was used in a few patients 2013–2016 and from 2017, it has been the predominant method. The study thereby reflects two fascia closure techniques but, to some extent, also two time periods of CRS/HIPEC-surgery at our institution.

### Fascia Closure Techniques

The fascia closure was performed in a 4:1 manner with either a continuous 2-0 PDS suture according to the description by Millbourn et al. (9) (PDS-group) or with a 2-0 PP suture, preceded by a RTL-suture of PP according to Hollinsky et al (8) (RTL-group).

The 4:1 technique has been the standard fascia closure technique at our department for many years. Data on the SL/WL ratio is however, not routinely recorded. In this series, the same surgeon has either performed or supervised all operations and fascia closure has been performed in the same way, with or without the RTL suture. PDS is our standard suture for fascial closure if no prophylactic measure for prevention of IH is deemed necessary. The RTL technique was initially introduced at our department as an alternative to the use of prophylactic mesh, e.g., in emergency surgery in high risk patients, and a non-absorbable material (PP) was chosen to mimic the mesh material.



The RTL-suture is, according to the original description, placed within the condensed linea alba when possible. This means that the RTL suture is threaded within the fascia, parallel to the incision on both sides, starting and finishing at the caudal end of the incision, where the suture-ends are left untied at first. Since many patients have undergone earlier laparotomies or previous midline incision for the same malignancy, excision of scar tissue and linea alba many times leads to incision of both the anterior and posterior rectus fascia. In case the rectus sheath is opened, and the muscle exposed, the RTL suture is used to close the fascial layers. The following continuous 4:1 closing suture is placed just outside and including the RTL-suture in every stitch. Mass closure including muscle was not intended. Finally, the RTL suture is tied (**Figure 1**).

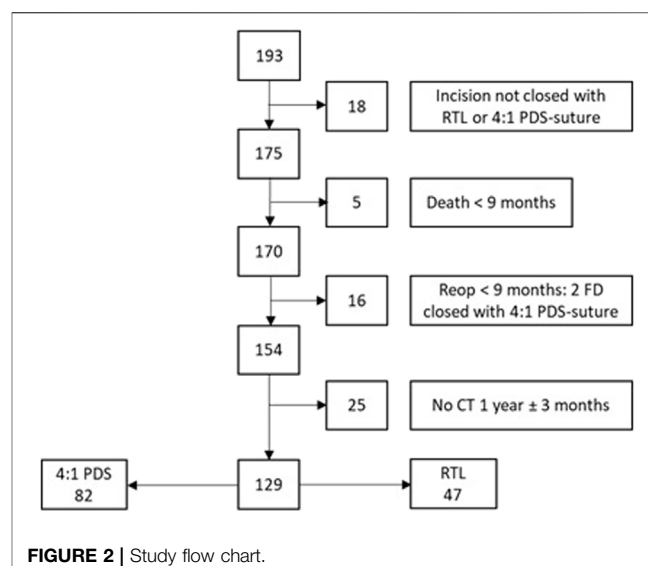
## Data Variables and Ethical Approval

Patient data were retrospectively retrieved from clinical records and from a prospective CRS/HIPEC-database. Retrieved data variables are shown in **Tables 2, 3**. The carcinomatosis was staged by use of the Peritoneal cancer index score (PCI), described by Jaquet and Sugarbaker (16). The completeness of surgical extirpation of cancer deposits was classified by use of the Completeness of cytoreduction score (CC-score) introduced by Sugarbaker (17), where CC0 is defined as no remnant disease, CC1 as remaining nodules less than 0.25 cm, CC2 nodules as 0.25–2.5 cm and CC3 as nodules exceeding 2.5 cm or confluent. Postoperative complications were classified according to the Clavien-Dindo classification from 2004 (18).

The Swedish Ethical Review Authority (Dnr 2020-03504) approved the study. In this retrospective study based on CT-scans and data from clinical records, informed consent was not required.

## Statistical Analyses

Data was analysed using IBM SPSS Statistics version 26.0.0.1. Continuous variables were expressed as mean with standard



**TABLE 1** | Indications for CRS/HIPEC.

CRS/HIPEC indication, n (%)	
Colon cancer	64 (49.6)
Appendix cancer	33 (25.6)
Rectal cancer	15 (11.6)
Peritoneal pseudomyxoma	12 (9.3)
Small bowel cancer	3 (2.3)
Fallopian tube cancer	1 (0.8)
Malignant mesothelioma	1 (0.8)

deviation (SD) or as median with interquartile range (IQR). Comparison between groups was calculated with Student's t test, Pearson's chi-square test or Fisher's exact test, as appropriate. A p-value of  $\leq 0.05$  was considered statistically significant.

## RESULTS

A total of 193 CRS/HIPEC-treated patients were identified, of which 64 patients were excluded, leaving 129 patients for analysis: 82 in the PDS-group and 47 in the RTL-group (**Figure 2**).

### Patient Baseline Characteristics

The indication for CRS/HIPEC-treatment was colorectal and appendix cancer in 87% of the cases (**Table 1**). We found no significant differences for patient baseline characteristics besides RTL-patients being 5 years younger (**Table 2**).

### Peri-/Postoperative Characteristics and Incisional Hernia Incidence

Perioperative and postoperative findings, measures and complications were similar between groups. The only

**TABLE 2 |** Preoperative characteristics.

	Total n = 129	RTL n = 47	PDS n = 82	p-value
Preoperative characteristics				
Female, n (%)	67 (52%)	23 (49%)	44 (54%)	0.605
Age, mean (SD)	57 (26.8)	54 (13.2)	59 (12.3)	0.026
ASA 1	20 (15.5%)	7 (14.9%)	13 (15.9%)	
ASA 2	77 (59.7%)	31 (66.0%)	46 (56.1%)	
ASA 3	32 (24.8%)	9 (19.1%)	23 (28.0%)	0.260*
Body Mass Index, BMI	26.0 (4.1)	26.3 (4.5)	25.8 (3.9)	0.573
Obesity BMI $\geq 30$ kg/m <sup>2</sup>	23 (18.1%)	11 (23.4%)	12 (15.0%)	0.235
Chronic obstructive pulmonary disease, COPD, n(%)	8 (6.2%)	3 (6.4%)	5 (6.1%)	0.948
Ischemic coronary heart disease, ICHD	35 (27.1%)	10 (21.3%)	25 (30.5%)	0.257
Diabetes Mellitus, DM	11 (8.5%)	3 (6.4%)	8 (9.8%)	0.509
Immunosuppression therapy	6 (4.7%)	1 (2.1%)	5 (6.1%)	0.303
Hemoglobin (g/L)	132 (17.8)	133 (19.5)	131 (16.8)	0.599
Serum creatinin	72 (14.3)	71 (14.7)	73 (14.1)	0.447
Serum albumin (g/L)	38 (5.6)	39 (5.5)	38 (5.7)	0.203
Earlier midline laparotomy	38 (40.9%)	13 (37.1%)	25 (43.1%)	0.533
Midline laparotomy within 8 weeks <sup>†</sup>	36 (27.9%)	12 (25.5%)	24 (29.3%)	0.901
Neoadjuvant chemotherapy	32 (24.8%)	12 (25.5%)	20 (24.4%)	0.855

ASA 1 + ASA 2 vs ASA 3.

<sup>†</sup>Laparotomy associated with the present malignancy, within 8 weeks before CRS/HIPEC-surgery.

difference found was less blood loss and more frequent neutropenia in the RTL-group. Ten patients (7.8%) were diagnosed with an IH: 9 (11%) in the PDS- and 1 (2.1%) in the RTL-group ( $p = 0.071$ ) (Table 3). Two cases of FD were noted, both in the PDS group.

## Risk Factor Assessment

Data was grouped according to IH status (IH and no IH) and the variables in Table 2, 3 were analysed. In univariate analysis the presence of cardiovascular disease was higher among patients developing an IH,  $p = 0.024$ . No other differences were found. No multivariate analysis was carried out due to the few IH in this study.

## DISCUSSION

This retrospective study compares IH incidences for gold-standard 4:1 PDS closure to RTL-suture plus 4:1 closure with PP, in patients treated with CRS/HIPEC for carcinomatosis. The total CT-detected IH incidence at 1 year was 7.8%. Nine of the IH were found in the PDS group and only one in the RTL group. The results represent a clinically relevant, albeit not statistically significant, difference between the closure techniques. In addition to these findings of IH at 1 year, it is noteworthy that there were two patients suffering a FD, both in the PDS-group.

IH is the most common long-term complication after abdominal surgery. IH causes increased morbidity, reduced quality of life, and need for further surgical interventions (2, 5, 6), sometimes as emergency operations due to obstruction, incarceration, and strangulation (4). Patients treated with CRS/HIPEC exhibit several factors associated with increased risk for IH (2, 5, 8, 9) and are thereby believed to develop IH to a greater extent. However, from the few

studies on IH following CRS/HIPEC, incidences of 7%–17% are reported (5, 7, 10, 11) which do not exceed incidences after laparotomies in general (2, 3).

In this study CT-diagnosed IH at 1-year was found in 7.8% overall. 11% in the PDS-group is in the range of previous reports whilst 2% in the RTL-group stands out as low. Comparison of incidences between available studies must be made with caution due to diverting study protocols, different follow-up times and modality for IH diagnosis. CT has a higher sensitivity for IH diagnosis than physical examination (19) but will, on the other hand, certainly detect some clinically irrelevant IH. Even if uncertainty remains as to the real IH incidence following CRS/HIPEC procedures, it seems as if the IH risk is not elevated as could be expected, but rather surprisingly low.

In earlier studies on IH after CRS/HIPEC operations, higher age, higher BMI, female gender, FD, neoadjuvant chemotherapy and HIPEC in ovarian cancer have been shown to be independent risk factors for developing IH (5, 7, 10, 11). In the univariate analysis, none of the above mentioned variables were found to be risk factors for IH. The only risk factor for IH development found in univariate analysis was the presence of cardiovascular disease. The few IH in this study did not allow for a multivariate analysis and whether cardiovascular disease is an independent risk factor was thus not possible to investigate (20).

There seem to be factors balancing the effect of factors associated with increased IH incidences present in CRS/HIPEC patients. We do not have one plausible explanation, but the patients assessed for a CRS/HIPEC procedure are thoroughly evaluated and, beside their malignancy, must be relatively healthy to be considered for such extensive and complication prone surgery. In the available studies the median age varied between 52 and 60 years, median BMI between 24 and 29, presence of cardiopulmonary disease

**TABLE 3 |** Perioperative and postoperative characteristics and incisional hernia incidence.

	Total n = 129	RTL n = 47	PDS n = 82	p-value
Perioperative findings				
Peritoneal cancer index, PCI, mean (SD)	11 (8.1)	9 (7.9)	12 (8.1)	0.087
Resection of midline scar, n (%)	93 (73.2)	32 (68.1)	61 (76.3)	0.316
Duration of surgery (min), mean (SD)	606 (181.4)	591 (170.3)	616 (188.8)	0.472
Blood loss (mL), mean (SD)	1156 (1165.6)	800 (695.6)	1394 (1347.1)	0.007
Complete Cytoreduction				0.412*
CC0	117 (95.9%)	45 (97.8%)	72 (94.7%)	
CC1 + CC2	5 (4.1%)	1 (2.2%)	4 (5.3%)	
Postoperative outcomes				
Neutropenia (WBC < 1x10 <sup>9</sup> /L), n (%)	14 (10.9%)	9 (19.1%)	5 (6.1%)	0.022
Complication severity				0.717**
Clavien-Dindo 1	44 (34.1%)	14 (29.8%)	30 (36.6%)	
Clavien-Dindo 2	61 (47.3%)	24 (51.1%)	37 (45.1%)	
Clavien-Dindo 3a	17 (13.2%)	6 (12.8%)	11 (13.4%)	
Clavien-Dindo 3b	4 (3.1%)	1 (2.1%)	3 (3.7%)	
Clavien-Dindo 4a	3 (2.3%)	2 (4.3%)	1 (1.2%)	
Clavien-Dindo 5	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Adjuvant chemotherapy	69 (53.5%)	24 (51.1%)	45 (54.9%)	0.901
Incisional hernia development				
CT-verified hernia	10 (7.8%)	1 (2.1%)	9 (11%)	0.071

\*CC0 vs CC1 + CC2.

\*\*Clavien-Dindo 1–3a vs Clavien-Dindo 3b–5 (need for interventions in general anesthesia, ICU treatment or death).

and diabetes mellitus was reported in two studies as 26% and 33%, and 8% and 10%, respectively. In four of the five studies ASA were reported and more than 70% of the patients were classified as ASA 1 or 2. These findings indicate that the CRS/HIPEC patients reported so far may have less preoperative IH risk factors than the general laparotomy patient. CRS/HIPEC are highly specialized procedures performed or supervised by a few very experienced surgeons. All articles are single tertiary referral centre reports, which ensures conformity of the surgical strategy within the studies, including the abdominal closure technique. Another theoretical explanation to the relatively low IH incidence is the extensive formation of adhesions following peritonectomy and chemotherapy, which may distribute increased intraabdominal pressure more evenly to the abdominal wall and thereby prevent focused tension on the closed midline incision.

Despite the fact that IH incidence after CRS/HIPEC so far has not been shown to be increased compared to laparotomies in general, it is of importance to prevent the morbidity linked to IH in this group of heavily burdened patients. Mesh is successfully used for reinforcement of the suture line after laparotomy in patients with high risk for IH (21). Use of mesh in CRS/HIPEC patients might imply an increased risk for wound complications and delayed start of adjuvant chemotherapy (22). Reinforcing the suture line with a RTL suture as in this study, is far less evaluated (8, 13, 14) but is far less extensive and does not imply the same risks as mesh reinforcement and is thereby an appealing alternative worth evaluating.

FD seems to be more frequent after CRS/HIPEC than after laparotomies for other causes, with reported incidences of 4%, 5.3% and 7.1% (5, 10, 23). The consequences of a FD are more

serious than for an IH and thereby of even greater importance to prevent. In this study we only found 1.6% FD where both patients belonged to the PDS-group. It takes a much larger cohort to find out if the use of an RTL-suture offers protection against fascial dehiscence.

There are some weaknesses with this study. The drawbacks of a retrospective design are to some extent counteracted by data retrieval from a prospective database and by the standardized surgical technique achieved by the participation of one senior surgeon at all operations. We have not had the intention to describe the true IH incidence over time but rather at 1 year, a time when approximately half of the surviving patients are likely to have developed an IH. The cumulative incidence is thereby for sure underestimated. CT-scans were made for cancer treatment follow-up without Valsalva manoeuvre, which also may underestimate IH incidence to some extent. The RTL-technique was mainly used from 2017 and onwards which reflects the latter period of CRS/HIPEC operations at our department, and may thereby reflect increased procedural skill, possibly affecting the results. The use of different suture materials, i.e., PP in the RTL-group and PDS in the PDS-group has a historical explanation at our department. The RTL technique was initially introduced as an alternative to the use of prophylactic mesh, e.g., in emergency surgery in high risk patients, and a non-absorbable material (PP) was chosen to mimic the mesh material. Besides the RTL-suture, the choice of PP may have contributed to the better outcome for this group.

We find the study results encouraging and the RTL plus 4: 1 closure with non-absorbable suture has become standard for fascial closure in patients operated for peritoneal carcinomatosis with CRS/HIPEC at our institution.



## DATA AVAILABILITY STATEMENT

The raw data supporting the conclusion of this article will be made available by the authors, without undue reservation.

## ETHICS STATEMENT

Swedish Ethical Review Authority (Dnr 2020-03504) approved the study. In this retrospective study based on CT-scans and data from clinical records, informed consent was not required.

## AUTHOR CONTRIBUTIONS

CW has contributed by planning the study, collecting and analyzing data, and preparing the manuscript. UP has contributed by assisting in planning the study, analyzing data, and preparing the manuscript. IS has contributed by assisting in planning the study, collecting data, and preparing the manuscript. OE has contributed by assisting in planning the study and scrutinizing CT scans. PR has contributed by assisting in planning the study, collecting and analyzing data and preparing the manuscript.

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## CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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# Defining High-Risk Patients Suitable for Incisional Hernia Prevention

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**Keywords:** prophylactic mesh, incisional hernia prevention, risk factors, small bites, laparotomy complications

## INTRODUCTION

There is a 9%–20% incisional hernia (IH) rate 1 year after midline laparotomy (1, 2) increasing up to 22.4% after 3 years of follow-up (3). Several prospective studies (4–7), meta-analyses (8, 9) and guidelines (10) advise or have demonstrated that the use of prophylactic mesh (PM) reduces IH. Despite all these studies, the use of PM has not been spread worldwide (11). Among other reasons, this is because it is unknown for which patients the potential benefits outweigh the risks of complications when using a PM. Likewise, there are several concerns among surgeons regarding which complications can occur using a PM (remarkably chronic pain and infection) (12). Due to these, it is necessary to determine diseases, patients and situations where high risks of IH justify consideration of using a PM.

This paper aims to review as an opinion article the scientific data on situations, patients and diseases with a higher risk of IH in which PM should be considered.

## HIGH-RISK RELATED SITUATIONS

### Emergency Laparotomy

In almost all studies focused on risk factors for IH, emergency laparotomy has a higher risk of IH than elective laparotomy. In two studies comparing emergency to elective laparotomy, a Hazard ratio (HR) of 2.31 (13) and a Odds ratio (OR) of 4.71 (14) respectively were demonstrated. This risk can be even worse in patients when other risk factors are present at the emergency laparotomy (15). In presence of peritonitis IH can reach 50% (16) or when an ostomy is associated the risk is 6 times increased (OR 5.8;  $p = 0.01$ ) (17).

Systematic abdominal wall closure with small bites (SB) technique significantly reduces fascial dehiscence (FD) (6.6% vs. 3.8%) (6) and IH (27% vs. 15%) (18) in emergency laparotomy. Moreover, the use of PM in these situations, especially in the presence of other risk factors, reduces even more the incidence of FD and IH (19–21).

### Redo Laparotomy/Early Abdominal Reoperation

Reoperation during the same episode due to surgical complications is one of the worst situations in terms of development of IH. Some studies have shown incidence rates even higher than 50% after both emergency (20) and elective (22) surgery, also demonstrating that in this scenario using a PM can reduce IH incidence (20).

In the external validation of the HERNIA score (23), patients with earlier abdominal operation had an IH incidence of 55.3%, and this factor was added in the formula with 3 points (high risk group patients were defined as > 9 points).

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A previous laparotomy is also an IH risk factor, though it is not comparable to reoperations in terms of IH incidence and does not influence FD.

## Ostomy

The creation of an ostomy during midline laparotomy has been pointed out as a high-risk factor for IH development (24). Timmermans et al. found ipsilateral rectus abdominal muscle atrophy to the ostomy as the main cause of IH formation in those patients. Moreover, the study underlined high rates of IH: 37% if diagnoses were by physical examination and 48.3% with CT scan. This also highlights that the incidence of IH can reach up to 58% when it was performed as an emergency midline laparotomy (OR 5.8%;  $p = 0-016$ ) (17).

## Contamination Grade

The contamination grade and its correlation to IH is another risk factor associated, probably due to the high risk of development of a wound infection (13, 25).

In an observational study with a large cohort of patients, CDC wound grades III or IV (13) were associated with an increased risk of IH in univariate OR 2.29 ( $p = 0.001$ ) and multivariate analysis HR 2.26 ( $p = 0.001$ ).

In fact, all the risk situations described above (emergency, redo laparotomy and ostomy) are commonly associated with higher grades of contamination (26).

## HIGH-RISK FACTORS RELATED TO PATIENTS

### Age

Elderly age emerges as risk factor for IH and FD in several studies both in univariant and multivariant analysis (HR 1.30 for every 10-years increase) and HR of 2.96 in patients older than 70 years for FD (13). When age has been analysed as an isolated risk factor after midline laparotomy only, there were statistically significant differences in long-term outcomes when age was over 75 years old (27).

In our opinion, the patient's age as an isolated data to decide on using a PM is not enough. We should consider other associated risk factors and elderly age would probably act as an indirect indicator of patients' health status.

### Obesity

Obesity is a well-known risk factor and correlates directly with IH. There is a large number of studies describing the role of BMI over  $25 \text{ kg/m}^2$  as an IH risk factor and this appears as one of the items used to evaluate for the majority of predictive scores (14, 22, 23, 28). BMI is a deciding factor regardless of other factors when considering using a PM, given its high association with IH incidence (mainly over  $30 \text{ kg/m}^2$ ) when performing a midline laparotomy. In one study (13), univariate analysis was associated with 2.29 OR (IC 95% 1.5–3.51;  $p < 0.001$ ) when the patient was overweight (BMI  $25-30 \text{ kg/m}^2$ ) and 2.81 (IC 95% 1.42–5.52;  $p = 0.002$ ) when BMI  $> 30 \text{ kg/m}^2$ . Multivariate analysis showed an increased HR of 1.76 ( $p = 0.001$ ).

Studies investigating prophylaxis (29) showed a decrease in IH incidence after midline laparotomy when the patient had  $> 30 \text{ kg/m}^2$  BMI (76%–13%;  $p = 0.001$ ).

## Smoking

Tobacco consumption due to its wound healing alterations and direct relation to chronic obstructive pulmonary disease (COPD) is one of the risk factors detected in many IH risk investigations (26). However, other studies have shown no relation as an independent risk factor for IH (13). Again, in our opinion, smoking without other associated risk factors cannot be considered alone to decide on using prophylactic measures after midline laparotomy.

## Nutritional Status

It seems that malnutrition should be a prognostic factor for IH. However, there is a lack of studies comparing categorically nutritional status, albumin blood levels and IH risk. Therefore, there is no solid evidence to consider the nutrition status as a parameter to predict IH development.

## Collagen Diseases (Abdominal Aortic Aneurism)

The high rate of association of IH after midline laparotomy in collagen disease patients related to abdominal aortic aneurism (AAA) has been widely demonstrated in studies of high scientific evidence (30–32). In this scenario, IH can reach up to 30%–60%. However, in a large study on risk factors (13) it did not show statistical significance.

In the studies on using PM after open AAA repair, a significant reduction (49.2% vs. 0.0%) was demonstrated when a PM was used in a retromuscular plane (33, 34).

Therefore, the presence of an AAA in every open procedure should be considered alone as an indication on using a PM even if there are no other risk factors associated.

## Associated Morbidity

A high number of comorbid conditions, such as hypertension, diabetes mellitus, COPD, heart disease, cancer, depression and hepatopathy have been related to IH (14, 35).

As a single risk factor, no one of them seems to have enough power to decide on using prophylactic measures. In the multivariate analysis of the Itatsu et al. study, no relation of any associated comorbidity showed a statistically significant relation with IH. Nevertheless, in the development of a predictive IH model (14), more than two Elixhauser comorbidities, COPD, ASA status, cancer and liver disease were associated with a higher risk of suffering an IH.

## HIGH-RISK PATHOLOGY

### Resection of Intra-abdominal Malignancy

Cancer surgery has a significantly higher risk of IH (OR 1.25;  $p = 0.003$ ) (14). Moreover, previous oncological surgery (13) (HR1.33;  $p < 0.001$ ) and metastatic cancer (OR 0.77  $p =$

0.0009) (35) have both been revealed as risk factors in univariant analysis.

In a major study investigating IH incidence in patients surviving after surgery for abdominal malignancy, where 1,847 CT scans from 491 were revised (36), 41% of occurrences of IH were diagnosed with an incidence range between 23% (after nephrectomy) and 62% (after hepatectomy).

## Colorectal Surgery

Colorectal surgery is one of the most common risk factors for IH found in most studies. After colorectal surgery the incidence of IH can reach between 35% and 50% (35–37) with also undesirable rates of FD (3.9%–5.2%) (38).

In the research to create a score for FD (25), colorectal surgery showed the highest incidence (5.2%) and in the final score system receives 1.4 points of a total of 10.6.

In the univariate study, compared to other gastrointestinal operations, colorectal surgery is the one with the highest association to IH risk (OR 1.83;  $p < 0.001$ ) (13) though without reaching statistical significance in the multivariate analysis.

The relationship with higher IH incidence would be probably a consequence of other comorbidities or situations that are present in patients (elderly age, wound contamination, and surgical site infection) acting as IH risk factors. Colorectal surgery is the most common type of surgery related to wound complications both in univariant (OR 7.08) and multivariate (OR 3.21) (26).

Some researchers (29, 35) have focused on using predictive scores or algorithms to select suitable patients for PM use, showing good results in terms of IH (OR 7.58;  $p > 0.0001$ ) (35) and FD (4.6% vs. 0%;  $p = 0.03$ ) prevention (29). Comparable results have been demonstrated in a randomized control trial of both elective and emergency colorectal resection, where the IH relative risk reduction of 62% and an absolute risk reduction of 22% when using PM after midline laparotomy.

## Liver Transplantation

Accumulated incidence after liver surgery can reach up to 27% after 72 months of postoperative follow-up (39). When looking specifically at liver transplantation, remarkably, IH is one of the most common long-term complications with an incidence of between 5% and 40% (40, 41). Due to the comorbidities in patients with terminal liver diseases, these patients have several risk factors for IH development (42). Also, the treatment with immunosuppressors increases the risk of IH and surgical site complications (43, 44). All these facts provide patients with an important decrease in quality of life (41).

## Bariatric Surgery

Incidence of IH after bariatric surgery has been reported to be as high as 25% (45) and 50% in superobese patients (46). PM has proven to be effective and safe in two randomized control trials (47, 48) and one metaanalysis with a global reduction to a third of the risk for IH (OR 0.30;  $p = 0.004$ ) (49).

## SCORES SYSTEMS

Due to the heterogeneity of the risk factors and the difficulties involved in standardizing the decision making, some authors have designed predictive models using score systems to evaluate the tailored risk of IH and FD. The main concern with some of these scores is the use of postoperative variables in the calculation, which reduces the potential of the scores to help the surgeon in the pre or perioperatively decision process and only helps to advise the patient, implement prehabilitation or maintain longer follow-up in risky patients.

### HERNIAscore

The Hernia score (28) was created using a cohort of 625 patients with a median follow-up of 42 months. Independent predictive factors detected in this study were: laparotomy or assisted laparoscopy, COPD, and BMI. By using the equation:  $4 \times \text{laparotomy} + 3 \times \text{HAL} + 1 \times \text{COPD} + 1 \times \text{BMI} \geq 25$ , three risk groups were created: low risk (0–3 points), 5.2%; moderate (4–5 points), 19.6%; and several risks (more than 6 points), 55%.

Afterward, the Hernia score was modified and validated using a new equation where a previous laparotomy was added to it:  $1 \times (\text{BMI} \geq 25) + 1 \times (\text{COPD}) + 5 \times (\text{extended laparoscopy}) + 6 \times (\text{laparotomy}) + 3 \times (\text{earlier abdominal operation})$ . Risk groups were defined as: low risk (score 0–6.9 points) 6.9%; medium risk (7.0–9 points), 35.6%; and high risk ( $\geq 9$  points), 57.5% IH incidence.

### PENN Hernia Risk Calculator

By using a database of 78,030 patients from 3 high-volume hospitals in Pennsylvania, 558 variables were analyzed in 29,739 eligible patients. Data from a group that needed IH repair with those who did not were compared (14). As a result, an individualized model using 16 variables (type of surgery, age, race, BMI, surgical and pathological characteristics) was designed. Related to the risk, four groups were created: low, medium, intermediate, and high risk.

### Other Scores

One of the first attempts to develop a predictive score was focused on predicting abdominal wound dehiscence (25). This score used preoperative and postoperative characteristics, hindering the application from preventing, or from helping with decision-making regarding, PM use. This risk model using only preoperative characteristics was applied to a 176 patients' cohort without reaching predictive values (50).

In a retrospective study on colorectal surgery where 30,741 patients were included, an actionable model of IH prediction was produced. The groups generated were: low (3.9%); moderate (7%); high (12.6%); and extreme risk (19.8%). It is interesting to point out that 30% of patients included in the study were from high and extreme high-risk groups which indirectly shows the high probability of IH after colorectal surgery.

In a prospective study with 332 patients analyzed after open surgery for colorectal cancer (31), an algorithm including



patients' BMI and risk factors for IH was analyzed to help surgeons with decisions on PM use. As a result, the proper use of the algorithm decreased the incidence of IH (OR 4.41;  $p < 0.001$ ).

## DISCUSSION

The development of an IH is a major problem after abdominal surgery. It correlates with a decrease in patients' quality of life, frequently needs repairing, and produces an increase in healthcare costs (51, 52).

To decrease the incidence of IH with prevention seems a key issue. Thus, to provide tools enabling the surgeons, before the operation, to individualize and advise the risk of IH to the patients may help surgeons and patients make a shared decision regarding the best prevention strategy.

From our point of view it is remarkable that there are situations that by themselves need special attention: emergency surgery, redo laparotomy, contaminated surgery, and ostomy creation.

Emergency surgery has a high risk of IH that is even higher when other risk factors are combined. The analyzed studies, despite their low quality of evidence, demonstrated that a PM prevents both FD (19) and IH (20). A well designed prospective and randomized study seems essential.

Redo laparotomy has been poorly investigated and clearly demands high quality studies to confirm it as a high-risk group and to define the best prevention strategy.

Contaminated surgery, due to the high frequency of wound infection in CDC grades III and IV (12%–20%) (53) and the association with IH development, is the most controversial situation. Although we have some evidence regarding the safety on using a mesh in contaminated fields (20, 29, 54, 55), many surgeons are reluctant to use a PM for the risk of prostheses infection (12).

In our opinion, when closing a laparotomy during a surgery that is an emergency, redo, contaminated, or associated with an ostomy, two data points should be considered: the contamination grade and the patient's risk factors. In a contaminated or infected operation with a controlled sepsis focus in a patient with associated risk factors for IH, we recommend considering using a PM to prevent FD and IH as well. At least, if PM is not used, surgeons should try to accurately close the laparotomy. Nevertheless, the scientific community needs to pay attention and provide higher evidence quality studies on this important issue.

Regarding patient risk factors: obesity and AAA have enough evidence to strongly suggest, if the situation allows it, the use of a PM (33, 34) to prevent IH even in the absence of associated risk factors.

Individually, the rest of the risk factors analyzed do not have such a strong association with IH to recommend PM use when present. Nevertheless, some authors have demonstrated that the presence of several risk factors at the same time increases the predisposition to develop IHs. This presumes a summative effect of risk factors and, from our point of view, when two or more risk factors are present, using a PM may be justified.

In cancer, colorectal, transplantation or bariatric surgery, special concern must be taken when performing the laparotomy. A tailored approach should be utilised with these patients considering their IH risk factors and considering the use of one of the predictive scores mentioned above can be useful. Thus, we believe that in elective surgery a careful analysis should be taken to choose IH preventive measures like avoiding midline incisions, performing SB technique, or using a PM, as it is also suggested in the EHS guidelines on abdominal wall closure (10).

The SB closure technique should be the selected technique for all midline elective laparotomies, given current evidence in the literature. Some studies have demonstrated the effectiveness and safety of SB use in reducing IH (4, 5). However, there is a recent randomized prospective study (56) where no statistical significant difference in IH reduction after 1-year follow-up was reached (3.3% vs. 6.4%;  $p = 0.173$ ). Notwithstanding, when FD was added to IH, the difference was considered statistically significant (4.8% vs. 11.3%;  $p = 0.018$ ). In another study, performed in low-risk IH patients (57) with 2-years follow-up, lower IH incidence in the SB group was revealed without statistical differences (3.6% vs. 12.1%;  $p = 0.20$ ). The same authors performed another study in high-risk patients (58), demonstrating that when using PM after a median follow-up time of 29.3 months, IH incidence decreased (HR 11.79;  $p < 0.0001$ ) independently of the closure technique (small or large bites). They also outline that the worst results were obtained when laparotomies were closed with neither SB nor PM.

It is notable that predictive scores developed up to now (14, 23, 25, 28, 35) have some limitations, for example they have been studied in retrospective cohorts, and one study (14) calculated IH as only those patients who needed a repair, as a result the real incidence was probably underestimated. Moreover, all of them have been created to predict IH and not to help on the decision to use a PM. With all this information, in our opinion, predictive scores only can be used as a guidance tool to help in patients' shared decision process or with research.

In conclusion, there are different situations, types of operation or patients who have a higher risk of developing an IH. Emergency, redo, contaminated or ostomy association, midline laparotomies; obesity, AAA, two or more comorbidities; cancer, colorectal, transplantation and bariatric surgery, have a high risk of IH. Predictive score and considering surgical characteristics provide us with a guide to select the best approach, the best closure technique or whether or not to use a PM, and can help to share the decision making process with our patients.

## AUTHOR CONTRIBUTIONS

JP-R is major contributor to writing the manuscript, JP-R and AB-S were involved in the design of the study and drafting of the manuscript; AB-S, NA-A, and SA-G collected and analyzed data, and MP-R and AB-S critically revised the manuscript till the final

version was reached. All the authors read and approved the final manuscript.

## CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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# If Evidence is in Favor of Incisional Hernia Prevention With Mesh, why is it not Implemented?

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**Keywords:** prevention, hernia, mesh, incisional, implementation

## INTRODUCTION

Incisional hernias are associated with increased cost to the patient and hospital, and decreased quality of life for patients. Furthermore, the rate of hernia recurrence increases with each subsequent repair, which further compounds this cost and morbidity (1). The rate of incisional hernia requiring operative intervention in high-risk patients approaches 70%, costing the United States greater than \$3 (2). billion dollars (2, 3). The true incidence of incisional hernia ranges with estimates from 2% to 50% and are due to both surgical and patient factors (4). In a study conducted from 2010 to 2014 utilizing a Nationwide Readmission Database analyzing 15, 935 patients undergoing incisional hernia repair, 19% of them were readmitted within 1 year of their index operation. Of these patients, 35% required reoperation and overall, 5% of them had recurrence of their incisional hernia and intensified the burden to patients and on the healthcare system (5). Incisional hernias develop in 13% (0%–36%) of all patients after any type of midline abdominal incision and one third (35%) will undergo subsequent repair. More-over, signs of a stabilized incidence (not an increasing incidence) in the USA were recently reported (6–8). While some risk factors for incisional hernia formation are non-modifiable, there has recently been an interest in surgical modifiable risk factors that can help decrease the incidence of incisional hernia.

One of the most important risk factors for formation of incisional hernia that the surgeon can impact relates to the closure of the abdominal incision. The two most studied factors associated with abdominal wall closure and hernia prevention relate to the suturing technique of the abdomen and the use of prophylactic mesh augmentation (PMA). There is strong evidence to support using specific suturing techniques, such as the so-called short stitch technique, as well as the use of prophylactic mesh (6). Despite well-supported evidence and recent guidelines, skepticism and a perceived lack of adoption of certain surgical techniques that could impact incisional hernia rates remain.

This paper reviews and explores some presumed reasons why hernia prevention techniques are not followed despite evidence to support their practice. Possible reasons for the lack of adoption are explored, ranging from distrust in the evidence to concern of complication, cost, and societal factors. Strategies to help improve awareness and mitigate some of these factors are also discussed, with some recommendations given on how to move this area forward in the future.

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## METHODS

A review of the literature including meta-analyses, randomized controlled trials, prospective cohort studies, and surveys was performed related to hernia prevention, including abdominal wall closure and prophylactic mesh, focusing on reasons why surgeons do not adhere to evidence-based practices. Secondary to paucity of published literature on this subject, expert opinions and theories based on opinion and experiences were hypothesized.



**TABLE 1 |** Review of literature with common reasons documented on reasons PMA is not used.

Study [Ref]	Type of Publication	Publication Date	Type of support (1–4)*	Summary
(1)	Systemic literature review	July 2015	Financial 2	Cost-utility analysis of Primary Suture Closure (PSC) vs. PMA for laparotomy closure demonstrates PMA to be more effective, less costly, and overall, more cost-effective than PSC
(4)	Systemic Literature Search	November 2020	Lack of knowledge/expertise (4)	Evidence supports PMA, with significant reduction in incisional hernia rate. Implementation is limited. Surgeons should be questioning why they are not using mesh reinforcement, specifically in high-risk patients
(9)	Systematic literature search	January 2022	Technique 4	Recommendations for elective midline closure technique. Guidance in selecting the optimal approach and location of abdominal wall incisions
(10)	Survey	April 2019	Technique 4	Applications of hernia prevention principles and their controversy
(15)	Prospective Cohort Study	February 2018	Complications 3	The use of PMA in colorectal surgery, when using an algorithm for patient selection, is an effective measure for prevention of IH- at the expense of other known possible complications
(18)	Multicenter double-blind randomized controlled trial	Aug 2017	Lack of Evidence 1	Randomization of 480 patients for closure: PSC, onlay or sublay. There was a significant reduction in incidence of IH with onlay mesh reinforcement- showing potential to become standard of treatment in high-risk patients
(20)	Randomized control trial	May 2021	Complications 3	PMA is not associated with increased incidence, severity, or need of infectious complications compared to PCS
(21)	Multicenter randomized control trial	April 2016	Lack of Evidence 1 Technique 4	PMA during AAA repair is safe and effective in preventing IH, with proven 2 years follow up and only added mean operative time of 16 min
(22)	Meta-analysis	June 2020	Lack of Evidence 1	PMA using onlay technique, specifically in high-risk patients, leads to significant reduction in IH

\*1. Lack of evidence/literature.

2. Financial.

3. Complications.

4. Lack of training/knowledge/expertise.

## RESULTS

The reasons behind the lack of use of PM for IH prevention have not been well studied. We found four main reasons cited by surgeons (**Table 1**). The first reason is a perceived lack of evidence and literature base to support its use. While there is strong and emerging evidence to support PM in subsets of populations, the data tends to be short term and clustered to European centers. This leads surgeons to question the long-term outcomes, as well as the applicability to their practice. The second reason is concerns over financial implications of using PM. While every country has different healthcare systems and finances, the addition of mesh at an index operation often financially impacts the hospital system and surgeon, which is currently unfavorable in many instances and can lead to long-term positive financial implications being overlooked. The third reason is that surgeons seem concerned about complications associated with prophylactic procedures, especially mesh-related complications in the context of current medicolegal climates present in many countries today. Lastly, while the placement of mesh and knowledge of the abdominal wall may seem routine to hernia surgeons, many other surgeons lack the training, knowledge, and expertise to place PM, which likely contributes to its limited use.

## DISCUSSION

This review highlights some of the often-cited reasons why hernia prevention principles are not practiced. Addressing these

concerns will increase implementation and help facilitate these techniques becoming more widely practiced.

It is very unlikely to change surgeons' practices if they do not believe in what they are doing or do not feel that their current practice is optimal. Disbelief and lack of awareness of current evidence are cited reasons for why surgeons have failed to embrace hernia prevention strategies. A recent survey by Fischer et al. explored reasons why surgeons did not practice current hernia prevention strategies (1). A total of 497 surgeons were included in the survey, most of whom do practice some of the recommended suturing techniques. Slowly absorbing sutures were used by 81% of respondents with 63% stating they closed using a 4:1 suture to wound (S:W) length ratio (although they did not routinely measure) and 58% stating they used the short stitch technique (although they did not routinely measure) (10, 11). Only 3% and 4% of respondents stated they have never heard of the 4:1 S:W length ratio and the short stitch technique, respectively. While these numbers relay adherence to suturing techniques, it must be remembered that this survey is likely biased and may not represent current practices in the United States and Europe, as this survey was sent to members of the European and American Hernia Society, as well as through an online Facebook group mostly comprised of hernia surgeons. It is also important to note that while the majority of surgeons stated they used a 4:1 S:W length ratio and short stitch technique, only 16% and 14%, respectively, of respondents reported measuring their ratios, which is a recommended practice (16, 10). There was less familiarity and trust of the literature for the use of PMA, with 11% of respondents stating they were unfamiliar with the



literature and 23% of respondents stating they were unconvinced of the efficacy of the use of PMA.<sup>10</sup> Despite this, it has been proposed that high-risk patients, including those with morbid obesity, diabetes, and hypertension, could provide the most cost-effective and efficient way to target individuals that could benefit from PMA (1).

While there is evidence to support abdominal wall closures techniques and PMA, well-designed prospective randomized trials are needed. Replicating short stitch technique trials in a more diverse patient population that includes obese patients is also needed, as this patient population was not captured in many of the initial studies. Given the associated risks and concerns of PMA, this may not be appropriate for all patients, but utilizing risk calculators to identify high-risk patients who would benefit from more aggressive prevention strategies is needed. Additionally, ideal closure methods for emergent surgeries are another understudied group. Ultimately, algorithms and guidelines on when to use specific prevention strategies in specific clinical situations will be helpful in guiding and supporting surgeons.

Cost is often a barrier for new procedures and devices to overcome prior to widespread adoption. This variable can be difficult to elucidate and is frequently used to support one's bias or opinion without performing a comprehensive cost-benefit analysis, which accounts for the long-term cost savings associated with preventative strategies. Alli V et al. used a large administrative database with over 14,000 patients to show that incisional hernia were common and increased the cost of care for individuals from 97% to 310% over 3 years (17). Gillion et al. reported the cost burden of incisional hernias in France and found that reducing the incidence of incisional hernia by 5% could result in a national cost savings of 4 million euros per year (18). Despite these data, cost is often cited as a cause for concern for lack of adoption of some hernia prevention principles. Even in comparing suture closure methods where the cost of a prosthetic material is not being considered, some surgeons argue the extra time it takes to perform a short stitch suture closure may be associated with higher operating room costs. Interestingly, the STITCH trial noted an increase of only 16 min between methods (19). The main cost concerns, however, relate to the use of prophylactic mesh as a cost-saving endeavor in hernia prevention despite good evidence to the contrary.

Time associated with the placement of PMA has also been cited as a reason why surgeons may not want to perform, although in the survey by Fischer et al. only 6% of respondents state this was the reason for not practicing (10). Studies have reported that the extra time for mesh placement ranges between ten to 20 min and is dependent on the technique performed (17–20). One way to address this barrier to adoption is to make the technique of PMA straightforward and reproducible. Onlay techniques, which have been shown to have similar efficacy in the PRIMA trial and easier and quicker fixation strategies, are being studied to help to try to improve efficiency (12).

An additional financial consideration for these techniques is reimbursement. This is further complicated by the concept of closing teams in which a surgical team will participate in the abdominal closure alone for a primary abdominal operation, such

as Abdominal Aortic Aneurysm repair, which is the setting in which PMA is employed rather than during incisional hernia repair in which mesh placement is included in the primary procedure code. Whether PMA is performed by a closing team or the primary surgeon, it is important that the providers employing hernia prevention strategies are compensated for their time and expertise. A significant development for this was the approval of CPT code specifically for PMA, 0437T. This tracking code is reportedly beginning to help surgeons get reimbursed and, with additional use and outcome data, will hopefully transition to a reliable reimbursement code for performing PMA.

Related to cost, it is imperative that surgeons performing hernia prevention strategies, such as PMA, get reimbursed for their work and hopefully the tracking code will soon become a permanent code. Healthcare policymakers and insurers will also need to help ensure that ultimately what is good for the patient can be safely implemented into practice through a holistic approach to patient care.

Another often-cited reason for the lack of adoption of hernia prevention techniques is a concern for associated complications. This most often relates to the use of prophylactic mesh, but also regarding the concern that small stitch techniques may lead to abdominal dehiscence or burst abdomen, especially in the obese population. Another concern relates to the use of mesh in patients that may not have gotten a hernia and the overtreatment that would occur by using the mesh. In these patients, you subject a patient to potential mesh related complications and infectious complications for no reason, hence why risk prediction models are so important in these patients.

The use of prophylactic mesh is particularly sensitive towards today's medical legal climate, highlighted by class action lawsuits for mesh failures. The survey by Fischer et al. saw that the most common reason for not using PMA was fear of mesh infection or mesh-related complications, cited by 46% of respondents (10). Although there is a large amount of fear related to the use of PMA, data regarding its benefits should be thoughtfully considered. The concept of "primum non-nocere: first do no harm" can be seen from both aspects of using or not using prophylactic mesh. As the data from the PRIMA trial suggests, the use of prophylactic mesh decreases risk of incisional hernia formation among high-risk patients. However, it is important to note that we do not know what risk of hernia development justifies using prophylactic mesh and therefore should be cautious in applying this concept broadly without discretion (22).

There have been two landmark randomized controlled trials (RCT) assessing incidence of incisional hernia after midline laparotomy. The PRIMA trial included 480 patients across 12 different countries undergoing elective midline laparotomy for abdominal aortic aneurysm repair or with body mass index of 27 kg/m<sup>2</sup> or higher and incidence of incisional hernia formation over a two-year follow-up period. Patients were randomly assigned to one of three groups, including primary suture repair, sublay mesh repair, or onlay mesh repair. A significant reduction in the incidence of incisional hernia was achieved with onlay mesh reinforcement compared with sublay mesh reinforcement and primary suture only. There was

no difference in rate of infection, re-intervention, or re-admissions between groups (12). This study suggests that PMA in an onlay fashion should be a new standard treatment for high-risk patients undergoing midline laparotomy. Van den Dop et al. further elucidated that there is no increased incidence, severity, or need for invasive treatment of infectious complications in the PRIMA trial PMA group compared to suture closure (13).

Another multicenter RCT by Muysoms et al. assessed the incidence of incisional hernia at two-year follow-up after conventional closure versus PMA with a large-pore polypropylene mesh in a retromuscular fashion for patients undergoing midline laparotomy for elective abdominal aortic aneurysm repair. There were no adverse effects seen related to PMA, apart from an increased mean time to closure of the abdominal wall for the PMA group compared with the control group. Specifically, this was 46 min compared to 30 min, and there was a significant reduction in incidence of incisional hernia from 28% in the conventional closure group to 0% in the PMA group (14). Both RCTs suggest that PMA results in decreased incidence of incisional hernia, with no difference in infectious complication rate.

Studies have shown that lack of education contributes to the low use of prophylactic mesh. In the survey by Fischer et al. 11% were unfamiliar with the literature, 24% were familiar but would still not use, 12% were unfamiliar enough with the methods to correctly execute, and 23% were unconvinced of the benefits (10).

This would suggest that education for the general surgeon population should be two-fold. First would require education about the safety and efficacy of using prophylactic mesh. Safety concerns mainly include concern for elevated surgical site infections (SSI) with the use of prophylactic mesh. 46.9% of surgeons surveyed do not use prophylactic mesh due to concern for SSI or other mesh complications. Systematic reviews by Depudyt et al. and Jairam et al. showed no difference in overall infection when evaluating RCTs and cohort studies (15, 4). There is also evidence indicating that prophylactic mesh has a lower rate of SSI compared to mesh that is placed for the repair of an incisional hernia. The second part of surgeon education would be addressing unfamiliarity with surgical techniques. This is a less common reason for not using prophylactic mesh, however it is still prevalent with 12% of surgeons reporting not being comfortable with mesh insertion (neither sublay nor onlay) (10). Although sublay mesh is known to be more physiological, it is also more technically demanding than onlay mesh repairs. The 2017 PRIMA follow-up study determined that onlay mesh and sublay mesh were equivalent in effectiveness (12). The ability to place mesh in either position may lead to more surgeons adopting the use of prophylactic mesh placement, depending on their comfort level with either procedure. In the small percentage of surgeons that are unfamiliar with either, it will be important to encourage CME, videos, and other learning opportunities to help increase surgeons' comfort levels, so they use mesh more routinely.

Teaching and education are also important components of ensuring new techniques related to hernia prevention get

implemented safely. Education and training must be available at all levels, including medical students, residents, and fellows as well as practicing surgeons with methods based on each learner's needs. It is imperative that education is performed as a surgical community and not siloed, as many surgical subspecialties will need to be involved. To leverage expertise, partnerships with surgical societies, along with industry and surgical educators, should be established.

Lastly, and most importantly, we as surgeons must be vigilant to ensure that we care for our patients in the best way possible and take part in shared decision-making related to hernia prevention. This involves making sure we are up-to-date on new technologies, practicing evidence-based medicine, and following our outcomes. There are many groups and societies that have implemented or are in the process of implementing registries for abdominal wall closure and prophylactic mesh. These registries are important for patient safety and will help with research, including long-term outcomes.

In conclusion, there are several cited reasons why hernia prevention strategies are not implemented. While some of the reasons have validity and need attention, most are due to lack of awareness and unwarranted fear. Efforts are currently underway to help promote hernia prevention principles. These need to be expanded through the support of many stakeholders, including surgeons, industry, societies, and healthcare policymakers. Ultimately, by working together, we can make a major impact on patient care and help alleviate the burden of incisional hernias.

## AUTHOR CONTRIBUTIONS

Manuscript preparation-all authors. Critical review-WH. All authors contributed to the article and approved the submitted version.

## CONFLICT OF INTEREST

WH-Honorarium from WL Gore, BD, intuitive, Medtronic for consulting/research.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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# Thoughts on Trocar Site Hernia Prevention. A Narrative Review

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**Background:** Laparoscopic and robot-assisted surgery is now common place, and each trocar site is a potential incisional hernia site. A number of factors increase the risk of trocar site hernia (TSH) at any given trocar site. The aim of this paper is to explore the literature and identify the patients and the trocar sites at risk, which may allow target prevention strategies to minimise TSH.

**Methods:** A pub med literature review was undertaken using the MeSH terms of “trocar” OR “port-site” AND “hernia.” No qualifying criteria were applied to this initial search. All abstracts were reviewed by the two authors to identify papers for full text review to inform this narrative review.

**Results:** 961 abstracts were identified by the search. A reasonable quality systematic review was published in 2012, and 44 additional more recent publications were identified as informative. A number of patient factors, pre-operative, intra-operative and post-operative factors were identified as possibly or likely increasing the risk of TSH. Their careful management alone and more likely in combination may help reduce the incidence of TSH.

**Conclusion:** Clinically symptomatic TSH is uncommon, in relation to the many trocars inserted every day for “keyhole” surgery, although it is a not uncommon hernia to repair in general surgical practice. There are patients inherently at risk of TSH, especially at the umbilical location. It is likely, that a multi-factored approach to surgery, will have a cumulative effect at reducing the overall risk of TSH at any trocar site, including choice of trocar type and size, method of insertion, events during the operation, and decisions around the need for fascial closure and how this is performed following trocar removal.

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**Keywords:** trocar site, port site, incisional, hernia, prevention

## INTRODUCTION

Laparoscopic and more recently robot-assisted laparoscopic surgery for both benign and malignant conditions of the abdomen has become common place. This was seen from the early 1990’s with the rapid change in practice from open to laparoscopic cholecystectomy (1). Much of the early surgery involved a camera port placed at the umbilicus, and a variety of other ports inserted to allow not only diagnostic but therapeutic interventions. As opposed to one incision, much of laparoscopy involves several small incisions, with each trocar site a possible incisional hernia site. Incisional hernia at a trocar site is often referred to as a “trocar site hernia” (TSH), and it is perhaps better referred to as this rather than a “port site hernia,” as PSH can be confused with the abbreviation for parastomal hernia.

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The prevalence of TSH is unclear (2, 3). Imaging such as ultrasound and CT scans appear to diagnose many more TSH than are clinically detectable, and also help clarify the diagnosis when a TSH is clinically suspected (4–7). For example, the TSH incidence in laparoscopic bariatric surgery is usually said to be low single figures of a percent (4). However, in a prospective cohort series with ultrasound follow in a similar study population, one or more of the trocar sites had developed a TSH in 34% of patients (8). This finding has to be set against a follow up CT scan study in a similar study population (the CT scan was done for other reasons but was reviewed for the study). The study included 244 patients, with 732 port sites of 11 or 12 mm diameter, but only 2 fascial defects were identified—all non-palpable, asymptomatic and plugged with fat (9). Clinical versus imaging diagnosis, and the protocol for the imaging, such as with or without Valsalva, may influence detection of TSH. While many small TSHs may have a long natural history of developing into a clinically overt hernia, the explosion in laparoscopic surgery over the last 30 years has not resulted in a similar explosion in the number of TSHs presenting to the surgeon for repair. Indeed, TSH is still a relatively uncommon hernia requiring surgical repair.

Nevertheless, TSHs are evident, and many that present with symptoms of a bulge and/or pain, do require repair, including a small number that present acutely, sometimes within days of the original surgery. Thus, prevention of TSH is likely to be of benefit to patients undergoing laparoscopic surgery. The aim of this narrative review, was to provide an overview of steps along the patient journey that might reduce the risk of TSH. These include possible pre-operative factors, patient risk factors, intra-operative factors as well as post-operative events.

## METHODS

A pub med literature review was undertaken on 29 August 2022. The MeSH terms of “trocar” OR “port-site” AND “hernia” was undertaken. There was no attempt at limitation of the search. Papers of any study type including case reports, human and animal research, any language were allowable in the initial search. The title and abstract of the papers from the literature search were scanned by both authors, and possible papers for inclusion selected. Where there was disagreement this was discussed, and generally the abstract included for full text review. Further full text articles were excluded if duplicate information or were not relevant to this review. The focus of this paper was pure TSH, and incisional hernias related to specimen extraction sites, where the trocar site was enlarged, were not included in this review. It was hoped that a reasonable quality systematic or narrative review on TSH in the last 10 years would be identified, and thus limit this review to an update with more recent publications.

A number of topics were considered when reviewing the abstracts and full text papers. These topics were re-operative or patient factors, trocar location, technique of trocar insertion, trocar type, size, length of operation, closure of trocar site and post-operative rehabilitation.

## RESULTS AND DISCUSSION

The Prisma flow chart of the publications reviewed is shown in **Figure 1**. The quality of evidence was generally low, with over half (24 of the 45 publications included) retrospective cohort series. A systematic review published in 2012 was identified (2), and this was used to eliminate studies published prior to this date.

### Pre-Operative or Patient Factors

TSHs are in essence a particular form of incisional hernia. It is not surprising that general risk factors for incisional hernia are also seen for TSH. Namely smoking, obesity, connective tissue disorders, systemic disease such as diabetes mellitus, immunosuppression, the elderly or frail, and sarcopenia, along with rectus diastasis and a history of a previous hernia elsewhere (10–13).

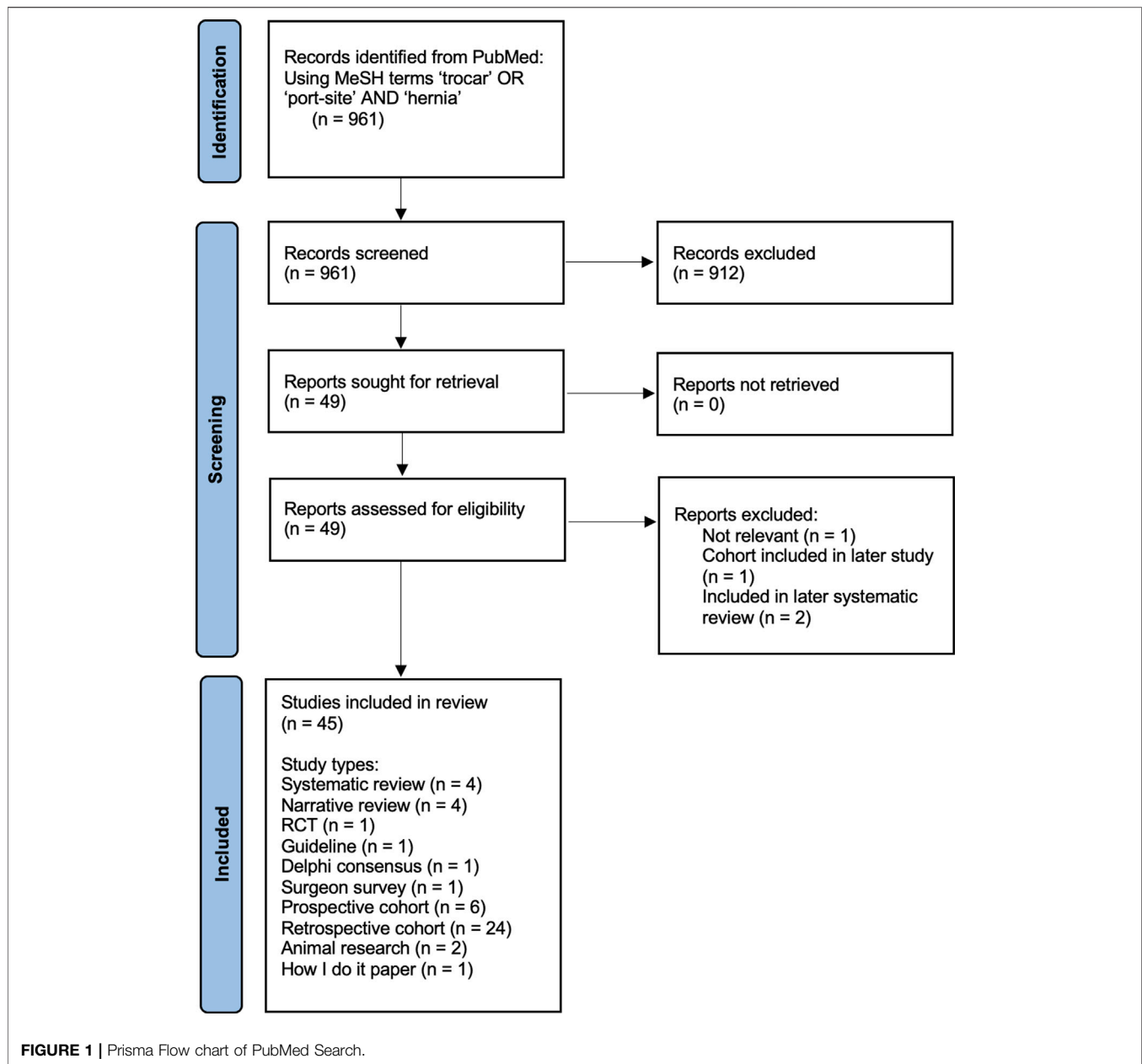
Of interest to this paper on TSH, is the conflicting evidence around pre-existing hernias at the site of the trocar or hernias elsewhere on the abdominal wall. The presence of an umbilical hernia is a risk factor for a TSH at the umbilicus (13, 14). But the water is muddied on this topic by nomenclature. Is the resultant hernia a TSH, a recurrent umbilical hernia or indeed more correctly termed an incisional hernia? And how the umbilical hernia was managed in terms of closure at the end of the operation may also influence the TSH rates. But in a study of umbilical TSH after laparoscopic TAPP inguinal hernia surgery, umbilical TSH was related to the pre-operative presence of an umbilical hernia, rectus abdominis diastasis and surgery for a recurrent inguinal hernia (13).

For many of these patients, pre-habilitation with weight loss, exercise, reducing immunosuppression drugs where possible and reducing the degree of sarcopenia will likely reduce the TSH rate, although evidence that such interventions reduce TSH is lacking in this area. Avoidance of the umbilicus when there is a concomitant umbilical hernia may reduce the TSH rate. Although the patient will still have their umbilical hernia—so it could be argued that in patients with an umbilical hernia, this is the preferred site so that umbilical hernia repair can be incorporated into the surgery.

### Trocar Location Choices: Umbilicus, Midline, off Midline

The umbilicus has been for many laparoscopic operations, the first port insertion site, the usual camera location and often in addition, the specimen extraction location. Given the common co-existence of an umbilical hernia, it is not surprising that the umbilicus seems to be the most common site of TSH (14–16). In a cohort series of laparoscopic bariatric operations undergoing follow up CT scanning, performed prone, the umbilicus was by far the commonest site of TSH (17). However, at the time of writing the study (17), none of the patients identified with a TSH had undergone repair, with nearly all were asymptomatic. Yet in bariatric surgery, most surgeons now would try and avoid the umbilicus, not necessarily purely for TSH prevention, but the fact that the umbilical site is often too far away from the operative field in the left upper quadrant.





Similarly, epigastric trocars, used in the common operation of laparoscopic cholecystectomy, has a TSH incidence muddled by this trocar location often being enlarged for gallbladder extraction (12). But trocars inserted in the midline do seem to have a higher TSH rate, even when closure of the linea alba defect is attempted. The midline insertion is often quick, and the relatively avascular midline does have some advantages over the risk of bleeding when trocars are inserted through the belly of the rectus muscle for example, and especially in the lower half of the abdomen where the inferior epigastric vessels are at risk of injury. In the end of the day, port location is partly determined by the operation being undertaken, but TSH can be reduced if the midline is avoided (18).

### Trocar Insertion Technique: Open v Closed

The open or cut down technique, especially for the first camera port has been promoted as a standard of care at the umbilicus. Again, prevention of a TSH is not the main factor here, rather safe entry to the abdominal cavity. However, open insertion techniques “under vision” are not so easy away from the umbilicus, especially in the obese. While an open cutdown will likely result in a larger “hole” in the abdominal wall, the ability to see the aponeurotic layers at the time of formation and place sutures accurately into these at the beginning of the operation may mitigate against this in terms of risk of TSH. The insertion of sutures at the end of the procedure, particularly when vision down a deep hole and identification especially of the posterior aponeurotic layer, may be less than ideal. A study comparing an

open technique versus direct trocar insertion did report a lower incidence of TSH with the direct entry technique (19). Similarly, a study looking at lateral sited trocars reported similar findings (20).

## Trocar Type Bladed/Cutting v Noncutting

Previous reviews have suggested that there is some evidence that cutting blades are associated with a higher TSH risk, compared to more “blunt” or tissues separating trocars (2, 16). Cutting trocars do in general pass more easily through the abdominal wall, but the use of less force during insertion may allow overshoot once the tip of the trocar is in the abdominal cavity. And a cutting tip is more likely to cut through a vessel in the abdominal wall on insertion, rather than push it aside as the trocar is inserted. The pressure effect of the trocar on the tissues may tamponade the vessel until the trocar is removed, and then bleeding commences. So there are reasons to avoid the use of cutting trocars, and they do seem to be less commonly available now.

A porcine animal model has demonstrated that a cutting trocar produces a similar size hole in the fascia compared to tissue separating trocars (21). While that may be true, the effect of cutting the tissues rather than spreading it on insertion, may be compounded over the course of the surgery as the instrument in the trocar is manipulated and forces applied to the abdominal wall.

## Trocar Size: 12, 11, 10, 8, 5 mm

Port size, particularly in the midline does seem to influence TSH. However, TSH are reported even for the 8 mm robot-assisted trocars (22, 23), and indeed, more rarely, in 5 mm trocar sites (24).

Not surprisingly, large single port trocars, again often placed at the umbilicus, are associated with an increase in the TSH as reported in recent systematic reviews (25, 26). However, a number of cohort series have not demonstrated much if any difference in TSH between multi-port and single-port laparoscopic surgery (27).

## Trocar Insertion: Vertical v Angled Towards Operative Field

In general, it is good surgical practice to insert a trocar vertically or perhaps more accurately, perpendicularly to the abdominal wall. Sometimes, a more angled approach, especially where surgery is undertaken in a limited area, such as a laparoscopic cholecystectomy or fundoplication, allows less torque feedback from the abdominal wall, making instrument manipulation through the trocar easier as there is less friction resistance to the instrument in the trocar. However, if the tip of the instrument works sometimes in the upper abdomen, and sometimes in the lower, then as the instrument and thus trocar is manipulated, there can be enlargement of the “hole” with tearing of the tissues of the abdominal wall. So careful insertion, under vision, taking stock of the likely location of surgery within the abdomen, and angling the trocar appropriately, may help reduce the secondary trauma the port may cause during the surgery. However, there is

no evidence in the literature to support this common sense approach.

In robot-assisted surgery, an additional element is “port training.” This is a process at the start of surgery, and if the bed position is changed, where each arm of the robotic platform has to be educated about the pivot point or fulcrum—the part of the trocar held by the abdominal wall muscles—around which the robot arms perform their movement. If the pivot point, is not set correctly, then the trocar will pivot around a different set point, potentially causing shearing injury to the abdominal wall, enlarging the defect in the abdominal wall musculature/fascia.

The “Z approach” has been described to trocar insertion, with the location of the hole in the superficial fascia does not quite line up with the deep hole (28). However, no evidence around TSH prevention is presented in this paper to be able to make further comment on this.

## Length of Operation

A number of studies have commented on an increasing TSH rate with increasing length of surgery (2, 24). Again, this is a difficult factor on its own to unravel. Longer operations are likely to be more difficult, involving more manipulation of the instruments and thus the trocars, and result in a more tired or distressed surgeon at the time of trocar site closure. Incorrect port training in robot assisted surgery may also compound this, the longer the operation continues. Which of these factors, if any, contribute to the higher TSH rate, is unknown.

## Closure of the Trocar Site and What Technique?

It is generally accepted that closure of the umbilical trocar site, most midline trocar sites of 10 mm or more, and any port site that is enlarged for specimen extraction (this is a specific trocar site situation and is not discussed further) is good practice (18). An international consensus group had 86.8% agreement that closure of 15 mm ports in all patients was necessary (29). The closure of 10 mm and upwards (and also 8 mm in some robotic operations) trocar sites off the midline is less clear cut, with a broad spectrum of opinion from the “never close” to the “always close” surgeon (29, 30). A retrospective cohort series after laparoscopic sleeve gastrectomy, suggested that closure of the trocar site reduced the TSH incidence by two thirds (31). Another retrospective cohort group in a similar study population reported that closure of the 12 mm epigastric port halved the TSH incidence (32).

A number of closure techniques of trocar sites are described, including direct visualisation and simple suture as a single stitch or a figure of 8 stitch (33). Various needle types, and techniques to pass sutures either blindly or under some vision are reported with good results on short term follow up (34–40). Incorporating haemostats into the suture closure is also described (41, 42). A small series of 15 cases using a “mini-IPOM-plug” reported “good” 6 months outcomes (43). But none of these techniques, including some that have been in use for many years, have gained widespread adoption in surgical practice.

As mentioned above, the umbilicus is a relatively high risk site for TSH. Add in additional factors that makes the patient at

higher risk for TSH in general, then perhaps mesh augmentation of the trocar site hernia would be a good idea. One of the few more recent randomised controlled trials, compared prophylactic mesh closure (intra-peritoneal polypropylene omega-3 mesh) versus suture at the umbilicus after laparoscopic cholecystectomy in patients identified as “high-risk” (44). 106 patients were randomised; 92 were included in the final analysis. The TSH rate was reduced in the mesh group to 4.4% compared to 31.9% in the suture group. The wound infection rate was lower in the mesh group (0% v 8.5%), but no other differences between the two groups were noted. The mesh used in this study has now been withdrawn from the market. In a non-randomised study of single port sleeve gastrectomy, both permanent and absorbable mesh reduced the TSH rate at 1 year (45). What mesh, which location of the abdominal wall, what mesh size, in which patient and so on remains unclear from the current literature.

Other techniques for trocar site closure are being considered. A recent study described “controlled heat-induced collagen denaturation” in a living pig model (46). Only 12 trocar sites in 3 pigs were reported on, so more work for sure is required before this potentially enters clinical practice.

## Post-Operative Rehabilitation

There is no literature to help advise specifically on the prevention of TSH after surgery. Return to normal activities of daily living, work and sport is encouraged within the level of discomfort of the patient as is the advice following abdominal surgery in general. Activities that significantly increase intra-abdominal pressure, such as coughing, sneezing and jumping from a height, cannot be influenced to any great degree apart from the latter! Blaming the patient for doing too much too soon, is not an excuse for the resultant TSH.

## SUMMARY DISCUSSION

Clinically symptomatic TSH is uncommon, in relation to the many trocars inserted every day for “keyhole” surgery. The evidence around prevention of TSH is poor. Much of the literature is retrospective cohort studies and case reports with short term follow up from the original surgery. Prospective cohort series or interventional trials under the rigors of a RCT are few in number.

There will be patients inherently at risk of TSH, especially at the umbilical location, and to a lesser extent the whole of the midline. It is likely, that a multi-factored approach to surgery, will

have a cumulative effect at reducing the overall risk of TSH at any trocar site, including choice of trocar type and size, method of insertion, events during the operation, and decisions around the need for fascial closure and how this is performed. Symptomatic TSH appears to be a lot lower than the true TSH rate, which is reassuring. Closure of a trocar site at the end of an operation appears to be surgeon individualised, from the “never closers,” to the “always closers” of 10 mm ports and above. Nevertheless, TSH repair remains a not uncommon elective and emergency hernia operation in view of the volumes of laparoscopic and robot-assisted surgery worldwide.

Future studies should focus on identifying the trocar sites at risk, which is likely to be a combination of patient factors, trocar site, trocar type and so on as mentioned above. This may help identify which trocar sites can be left unclosed, which trocar sites that merit additional mesh augmentation. One of the more difficult areas to examine, which may well be an important element in the risk of TSH, is the surgeon as a risk factor. Knowledge about patients at risk, and training in the operative elements and decision making around trocar type, site, insertion technique and effective closure where necessary tailored to the patient, will likely help reduce the surgeon as an additional risk factor.

## AUTHOR CONTRIBUTIONS

AB and BE were involved in design, literature search, and preparation of the manuscript.

## CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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# The Best Closure Technique Without Mesh in Elective Midline Laparotomy Closure

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**Introduction:** The risk of developing an incisional hernia after primary elective median laparotomy is reported in the literature as being between 5 and 20 percent. The basic of an optimal outcome after midline incision is the appropriate closure technique with or without a prophylactic mesh. The objective of this paper is to critically examine the various closure techniques and, in particular, to present a detailed comparison of the long stitch and short stitch techniques.

**Method:** Based on the available literature, the characteristics of the different closure techniques are described in detail, advantages and disadvantages are compared, and the current status of a practicable recommendation is discussed. Special attention is paid to the criteria of the short stitch technique, such as the suture to incision length ratio, number of stitches and distances, as well as suture material.

**Results:** For elective midline closures, the use of a continuous closure using a slowly absorbable suture material in the small-bites technique with suture to wound ratio of at least 5:1 result in significantly lower risk of complications such as bursting abdomen and less incisional hernia rates compared to the large-bites technique.

**Conclusion:** Based on the present evidence in midline closure after elective laparotomy the small bites technique can be recommended to significantly reduce the rate of incisional hernia.

**Keywords:** elective midline closure, small bites, large bites, incisional hernia prevention, stitch technique

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## INTRODUCTION

Despite the advancement of minimally invasive techniques in visceral surgery, conventional midline laparotomy remains the standard approach for major surgery as well as emergency procedures. Over the past decades, there has been debate about the best possible closure technique and the suture material to be preferred. After the review by Diener et al. (1) in 2010, it was evident that the continuous suture technique with long-term absorbable suture is to be preferred in elective midline closure. Analogous to Diener's review the published Cochran review of 2017 (2) summarized that monofilament sutures can be considered for abdominal closure to reduce the risk of incisional hernia and absorbable sutures can be considered to reduce the risk of chronic drainage from the wound. However, due to the lack of evidence, these reviews did not include a discussion or recommendation regarding the stitching technique with small or large bite. In 2017, the MATCH review by Henriksen et al. (3) followed, which included the randomised controlled trials by Millbourn et al. (4) and the

STITCH trial (5) in a subgroup analysis. The cumulative incisional hernia rate for the small bite technique has been significantly lower at 9.45% compared to 19.30% for the large bite technique ( $p = 0.005$ , OR 0.41; 95% CI 0.19, 0.86). The conclusion from this review to be drawn is that using a slowly absorbable suture material and a continuous suture technique with small tissue stitches lead to a significant reduction in the incisional hernia rate compared to a technique with large stitches. The recently published update of the EHS guidelines for closure of the abdominal (6) based on two RCT studies (4,5) include only one strong recommendation regarding the suture technique to use a continuous suture technique in elective midline closure. All other topics, like small or large bite technique, suture material, were graded with a weak recommendation due to the lack of high evidence based on GRADE recommendation (7). Now, however the recently published data of the ESTOIH study (8,9) are available and might change the evidence in some degree. In the short-term results (8) a significantly lower risk for burst abdomen was found in the cox proportional hazard model [HR 0.1783 (0.0379–0.6617),  $p = 0.0115$ ] after short bite technique. The incisional hernia rate after 1 year (9) revealed 4.24% after small bite and 8.23% after large bite technique ( $p = 0.14\%$ ). Although the difference was not significant, the results were significantly better compared with the Millbourne and STITCH study. Even if the prevention of potential sources of complications is to be seen as multifactorial, at least the surgical closure technique as a standardized procedure remains an essential factor for an uncomplicated wound healing of the abdominal wall.

However, even given that the short stitch technique seems to be evident, the technique is still slightly different in the three studies mentioned above. In addition to the suture technique, the suture material used in combination with the needle size, shape and thickness is another important factor. Standardization is therefore an essential issue to achieve comparability of studies in the future (10). Moreover, the greatest risk factor for an uncomplicated course of midline closure, among many other factors, still seems to be the surgeon himself (11).

## Opening of the Midline

To achieve the best possible conditions for abdominal wall closure, an exact midline opening is essential. This implies that the crossing fiber bundles of the linea alba should be targeted as centrally as possible, i.e., at the crossing point, and thus the integrity of the linea alba should be preserved. Only in this way the anchoring of the suture in the aponeurotic tissue is ensured during suture closure. The safest landmark for the start of the incision is the umbilical ridge, which after detachment reveals a natural opening that represents the exact midline of the linea alba. Therefore, the incision should always be performed at this point. Another criterion is the detachment of subcutaneous fatty tissue in front of the linea alba or anterior sheath of the rectus muscle before opening over a distance of 1 cm on both sides, as well as cranially and caudally. Only then the crossing fibers of the linea alba are invisible and an exact midline incision can be safely performed without splitting the anterior and posterior sheath. This special

technique was also a crucial part of the ESTOIH study protocol (12).

## Experimental Background of Closure Techniques

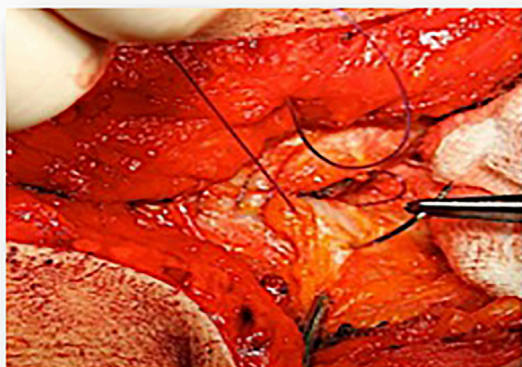
The small bite technique was first investigated experimentally by Israelsson and his scientific group in 2001. In this experimental study published by Cengiz (13) the advantages of the small bite technique in terms of bursting strength compared to the long bite technique could be demonstrated significantly. The burst strength after small bites technique was 3-fold higher than after the large bites. Harlaar also impressively highlighted the advantages of the short-stitch technique in his experimental study (14). The so-called slacking effect was demonstrated with the large bite technique in the all-in-one stitch version. This could be avoided by including only the fascia without muscle tissue. As early as 2000, Höer and his team demonstrated the importance of tensile loading of the suture closure regarding blood supply, deposition of mature collagen and scar healing (15,16,17,18). The slacking effect has also been described here, which can be avoided by reducing the tensile load on the suture line. These experimental studies have also pointed out the advantage of the continuous suture over the interrupted suture technique.

## Suture Tension

The problem of surgeon control of suture tension remains difficult. The direct correlation of suture tension, blood flow and wound healing has been experimentally demonstrated by Höer et al. (19). Based on the studies on the tensile strength of the intact linea alba by Hollinsky et al. (20), a maximum horizontal traction of 10 N corresponding to 1 kg tensile load is possible. This value decreases by 30% in the case of a scar after laparotomy. Thus, it seems clear that the tensile load applied to the suture line should not exceed 1 kg. This limit is confirmed in the clinical works of Klein et al. (21) and Dragu et al. (22) in relation to the choice of procedure for incisional hernias. Therefore, verification of the applied suture tension seems to be an absolute problem. A study by Höer et al. (23) and Schachtrupp et al. (24) measured suture tension under simulation of fascial closure. The results of the surgeons involved were sobering regarding the specifications and reproducibility. The conclusion of this study was that it is hardly possible to meet the target values without measuring the suture tension (tensiometer).

The experimental study of Klink et al. (25) in a rodent model obtained that non-elastic monofilament sutures rapidly loose tension independently of the sutured tissue. Based on these results high tension seems to be associated by the force to the sutures by the surgeon. This hypothesized approach of reduced tissue compression resulting in less local tissue damage, thus achieving improved wound healing, is a fundamental part of preventing complications by the surgeon himself. A direct indication of low suture tension is the recommendation of an adaptive traction at the suture line, as recommended by Israelsson and implemented in the protocol of ESTOIH study (12).

If the suture tension of the fascial suture plays a decisive role for an undisturbed healing process, the surgeon should be able to



**FIGURE 1** | Small bites technique.

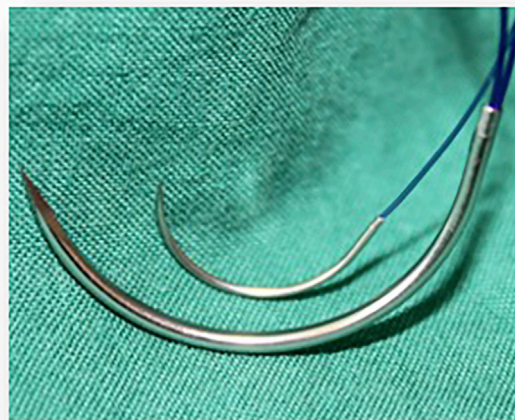
determine the tension of the fascial suture with the aid of, e.g., tensiometry or, in a simplified way, by the indicator of the visible suture bridges after completion of the closure (**Figure 1**). Another aspect is a continuous suture technique over the entire incision without interrupting suture ties. This ensures undisturbed suture tension on the entire suture closure according to abdominal compliance. Therefore, sufficient suture length must also be considered in order to be able to perform the entire closure suture with one suture material. These requirements were met in the ESTOIH study with the use of a 150 cm long suture material. The frequently used technique with two sutures simultaneously from the cranial and caudal sides with knotting in the middle of the joining sutures must therefore be considered critically.

### Needle Size, Needle Diameter and Suture Size

The size and especially the diameter of the needle used is directly related to the stitch defect set around the fascia. For this reason, the use of a loop suture with a resulting large calibre needle (e.g., HR 48) is always associated with a large defect in the tissue (**Figure 2**). Since the publications of Israelsson, the use of small size and diameter needles (e.g., HR26) has become common in the short stitch technique. The size of the suture material used is usually 0 or 1 for loop sutures but should be preferably 2/0 for the short stitch technique. The tensile strength of a suture is still very often associated by surgeons with the thickness of the suture and the technique of long stitches or even interrupted sutures. Although the rate of burst abdomen did not differ significantly between the short and long suture techniques in the Millbourn and STITCH studies, the hazard ratio in the ESTOIH study showed a 7-fold reduction in the risk of developing a burst abdomen when the short suture technique was used.

### Suture to Wound Length Ratio

First, one must consider that the SL-WL ratio, cannot be clearly defined, since any ratio can be achieved by varying either the tissue bites or the distances or the intervals between the stitches,



**FIGURE 2** | Suture/Needle: Large bites technique: Suture MonoMax® USP 1, 150 cm loop, Needle HR 48 Small bites technique: Suture MonoMax® USP 2-0, 150 cm, Needle HR 26.

or both variables. These variations will result in an endless number of ways to achieve this ratio. Therefore, only the precise definition of the number of stitches, the stitch distances, the suture material consumption and the resulting specification of the SL-WL ratio together can enable a verifiable standardization of a short stitch technique (**Table 1**).

Höer et al. (15) demonstrated in experimental studies that the SL-WL ratio, suture tension and suture technique have been shown to have a significant influence on the mechanical strength of the incision. Small bites closures with a SL-WL ratios of 4:1 and 8:1 led to the highest tensile strength after 14 days (mean  $20.99 \pm 3.24$  N/cm and  $19.62 \pm 1.47$  N/cm, respectively). The importance of low tension on the suture line resulted in significantly weaker scars, regardless of the suturing technique used. In agreement with clinical data, it could be experimentally demonstrated that running closure of midline laparotomies with a SL-WL ratio above 4:1 while avoiding high suture tension had a significant positive effect on the mechanical strength of the incision.

In an experimental study in pigs, Kushner et al. (26) were able to demonstrate the benefits of blood perfusion in small bite closure already demonstrated by Höer et al. (15). In this study, in addition to small and large bites with PDS suture, a barbed suture (Stratafix™) using the same techniques and additionally an interrupted figure of 8 with PDS were examined by laser-induced fluorescence angiography regarding tissue perfusion immediately after closure and 1 week later. The results revealed a significant increase in tissue perfusion after small bite closure with PDS suture. In contrast, neither the interrupted figure of 8 nor the barbed suture significantly increased tissue perfusion at 1 week. Consequently, it seems that there is no advantage for midline closure with either the figure of 8 interrupted or the barbed suture technique. In a prospective study by Israelsson et al. (27) the

**TABLE 1** | Small bites technique in detail.

"Small bites"-technique:

- Suture material: monofilament, elastic, slowly absorbable
- Size: 2/0
- Continuous suture technique
- Only fascia including
- Suture/wound-length ratio  $\geq 5:1$
- First stitch distance to incision  $> 1$  cm
- Stitch to incision 5–8 mm
- Stitch to stitch: 4–5 mm
- Stitch length  $\leq 2,5$  cm
- Adaptive suture tension ( $\leq 1$  kp)
- Cave  $>$  "button holes"
- Visible suture bares

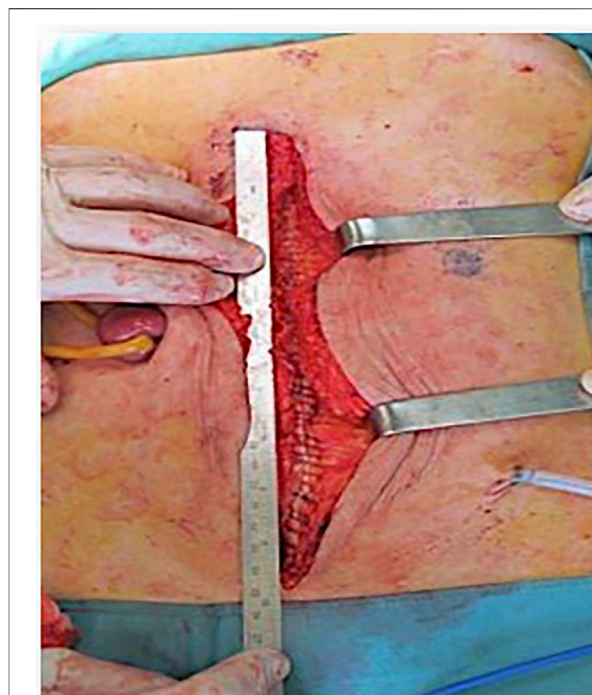
**TABLE 2** | Incisional hernia rate in comparison Millburn-, STITCH- and ESTOIH study.

Technique	Incisional hernia		
	MILLBOURN	STITCH	ESTOIH
Long stitch	18%	21%	8.23%
Short stitch	5.6% sign.	13% sign.	4.24% n.sign.

suture length to wound length ratio  $<4$  was identified as independent risk factor for the development of incisional hernia in comparison to  $\geq 4$  (23.7% versus 9%;  $p = 0.001$ ).

## Impact of Suture Material

After the stitch and suture technique, the suture material is certainly the decisive factor with regard to the stability of the fascial closure. Since the systematic review by Diener et al. (1) and the recently published updates of the guidelines for abdominal wall closure (5), the continuous closure technique by small bites technique with the use of a slowly absorbable suture material is recommended. Consequently, the use of a monofilament suture material is also to be preferred. When assessing the quality criteria, the bursting strength of the suture material is erroneously used as an essential quality criterion. In view of the compliance of the abdominal wall and the associated stresses on the midline closure, it seems reasonable to use an equally elastic suture material for the continuous closure. In comparing the properties of the various suture materials that are preferably used for abdominal wall closure, Albertsmeier et al. (28) compared poly-4-hydroxybutyrate (MonoMax®) with polydioxanone (PDS®, MonoPlus®) in their publication. The comparison regarding elongation (elasticity) detects a clear advantage of poly-4-hydroxybutyrate with 90% to a maximum of 50% for polydioxanone. The basic strength retention of 50% up to 100 days is also significantly longer compared to 42 and 35 days for polydioxanone. An additional criterion to be considered is the mass absorption time, which at 390 days is almost twice as long for poly-4-hydroxybutyrate as for polydioxanone and thus supports wound healing over a

**FIGURE 3** | Small bites closure with ruler.

long period. The increased elasticity can be expected to reduce suture tension, especially during a sudden increase in intra-abdominal pressure such as during coughing, weeping, or jumping. This mechanism potentially reduces reiterative injury to the rectus fascia, ultimately leading to burst abdomen and, in the long-term, to incisional hernia. In another study, France et al. (29) was able to demonstrate that a viscoelastically active suture can accelerate wound healing due to a significant increase in the motility of human fibroblasts and thus lead to improved scar formation.

## Clinical Evidence

To date, three randomized controlled trials have been published on the short versus long stitch technique in midline laparotomy (4,5,9). Although the short stitch technique seems not to differ significantly in the protocols in these studies, the 1-year outcome between the Millbourn study, the STITCH-trial and the ESTOIH study is markedly different with 5.6% versus 13% versus 4.23% regarding the incisional hernia rate (Table 2). Obviously, there must be a specific cause behind, which is extremely complex to analyse retrospectively.

An important parameter for a specific analysis could be the ratio of suture to wound length in the short stitch technique group. Even though this ratio is not an absolute value for the exact performance of a short stitch technique, since the ratio of used suture material to incision length ultimately only provides an indirect measure depending on the number of stitches, stitch



Incision length	15cm	20 cm	25cm	30cm
Number of Stitches	34	44	54	64
Suture Material applied	≥ 75cm	≥ 100cm	≥ 120cm	≥ 150cm

**FIGURE 4 |** Small bites: Suture to Wound Length - Ratio (≥5:1) Example: incisional length, number of stitches, applied suture material.

distance and circumference, it is still the most important parameter for the closure technique that needs to be recorded (Figures 3, 4). When comparing this ratio across the three studies, the highest value for short stitch technique was 5.7 in the Millbourn study, followed by 5.3 in the ESTOIH study and 5.0 in the STITCH study. These differences may seem small at first sight but could be related to the significantly different incisional hernia rates. As Israelsson has clearly demonstrated the importance of this ratio in several studies (27,30), the lowest limit for this ratio seems to be above 4:1 for the short stitch technique.

A further essential factor could be the properties of the suture material, as previously mentioned. In the Millbourn study and the STITCH study, an identical suture material made of polydioxanone (PDS®) was applied. In the STITCH study, a polydioxanone with triclosan coating (PDS plus®) was apparently used to reduce infection complications. The different infection rates of the two studies, especially the high infection rates of more than 20% in both groups in the STITCH trial, are difficult to interpret, but the relationship between infection and risk of incisional hernia must be considered (Supplementary Material).

During the ESTOIH study, the poly-4-hydroxybutyrate (Monomax®) suture material was used, which differs significantly from the polydioxanone material. The high elasticity of this suture material in combination with an ultra-long resorption time are criteria that appear to be beneficial in midline closure. A synergistic component of suture technique in small bite and the elasticity of the suture material can provide healing of the midline closure supported over a longer period of time, resulting in a stable scar. According to the data of the ESTOIH study, the choice of suture material seems to have a potential effect by using a highly elastic and ultra-long-lasting resorbable material. However, the adequately applied suture technique is a basic prerequisite for a complication-free outcome.

## STANDARDISATION, TRAINING AND IMPLEMENTATION

One of the most important steps in implementing a new surgical method is standardization. As in many examples of visceral surgery, e.g., Shouldice plasty, the modification of a surgical method not only leads to different results, but also

prevents a scientific comparison between them. Therefore, the exact definition of the individual surgical steps is of enormous importance. In the case of the short stitch technique for elective midline closure, standardization begins with the performance of the median laparotomy, as described in this review. The best possible closure can only be achieved and guaranteed after the best possible midline incision has been made. Therefore, a protocol for elective midline closure should include the incision technique. During the ESTOIH study, this important part was described in detail and communicated and trained with all study centers before the start of the study.

Conway et al. (31) demonstrated that neither trainee nor surgeons are able to estimate the distances recommended in small bite technique with accuracy. Therefore, the need of surgical training to achieve such skills is fundamental.

An experimental study by Lesch et al. (10) impressively demonstrated the advantages of standardizing defect closures in short- and long-term techniques. Various parameters regarding the durability of a repair were used. The strongest significant improvement was demonstrated by standardizing the suture technique.

In a study by Pereira Rodriguez (32), after hands-on training on a suture simulator model with the participation of 74 surgeons, a survey was conducted after 1 year to evaluate the implementation of the short-stitch technique in elective midline laparotomy. Of 114 median laparotomies, 30.7% were performed using the short-stitch technique, which had a lower incisional hernia rate of 3.6% versus 12.1% compared to the long-stitch technique. Nevertheless, despite hands on training, the implementation seems to be poor without further incentives. Another study by Thorup et al. (33) reported that following the introduction of a standardized small bites technique in acute midline laparotomies, the incidence of burst abdomen decreased from 5.6% to 2.2% and the incidence of incisional hernia declined from 27% to 15% after 2 years of follow-up compared to a historical cohort using different closure methods. Both studies clearly highlight the importance of standardization and consistent implementation to reduce incisional hernias.

## DISCUSSION

Median laparotomy remains the standard approach in open visceral surgery and is associated with high rates of incisional hernia. In summary of the existing literature, the short stitch



technique is significantly superior to the long stitch technique and should therefore be implemented in a standardized technique. This requires training and feedback to avoid technical errors and slow learning curves with complications such as suture rupture and burst abdomen. The time required for closure using the short-stitch technique must not and should not be an argument against this procedure. As can be seen from the studies, this is an investment of 5–6 min compared to the long stitch technique, which has no relation to the follow-up costs in case of complications or even the repair of a incisional hernia. The cost-benefit analyses as described by several authors (34,35,36) clearly show the advantage of the short stitch technique. Irrespective of the costs related to the treatment of incisional hernias, the personal fate of the patient must be considered and taken as an important factor. The established risk factors for the development of incisional hernias, such as the presence of a collagen metabolic disorder, BMI >27, AAA, and other comorbidities, should be considered in any laparotomy and will influence the closure procedure. The use of prophylactic mesh procedures is increasingly discussed and recommended for these risk factors (6). The evidence on these procedures is based primarily on the significant results of numerous studies that have followed closure exclusively with long stitch procedures (37,38,39). Therefore, in the future, as already implemented in ongoing studies, a short stitch procedure should always be used as the basis for this mesh-augmented closure. Thus, every midline laparotomy, regardless of risk factors, should be closed using a short stitch technique as a matter of principle in order to sustainably reduce the scar hernia rate in the future.

The universal introduction of the short stitch technique, as with many new surgical procedures, cannot be communicated solely by publications, but only by offering workshops and training courses as a standardized procedure (31,32,33). Even in the setting of emergent laparotomies, short stitch techniques have an immediate and impactful effect on reducing complications (33).

Thus, the biggest challenge remains to disseminate the short stitch technique in a standardized technique and to implement it not only in open visceral surgery, but also in gynecological, urological and vascular surgery.

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## CONCLUSION

In the summary of the existing literature, the short stitch procedure should be considered the standard procedure for closure after elective midline laparotomy to reduce the incisional hernia rate. Only appropriate standardization and teaching of this technique by means of training can ensure widespread implementation of this method in the midterm.

## AUTHOR CONTRIBUTIONS

The author confirms being the sole contributor of this work and has approved it for publication.

## CONFLICT OF INTEREST

The author received an honorarium from Aeskulap/B.Braun for lectures and workshops.

## PUBLISHER'S NOTE

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## SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontierspartnerships.org/articles/10.3389/jaws.2022.10962/full#supplementary-material>

**Supplementary Image S1** | SSI rate in comparison Millburn-, STITCH- and ESTOIH study.

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# Innovations for Incisional Hernia Prevention

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Incisional hernias are the most frequent long-term complication of abdominal surgery, resulting in considerable patient morbidity and increased health care costs. These hernias frequently result from excessive tension concentrated at points along the suture line of the abdominal closure. While ample research is focused on developing improved repair materials, the optimal solution to the problem of incisional hernias is prevention. Accordingly, some investigators have postulated that incisional hernias can be prevented by distributing tension more evenly along the fascial closure. Herein we describe two novel and ingenious strategies for the improved distribution of tension when closing abdomens (T-Line® Hernia Mesh and the REBUILD Bioabsorbable™) that were conceived of and developed by surgeons.

**Keywords:** incisional hernia, prevention, invention, tension, fascial closure

Dear Editors,

Incisional hernias are the most frequent long-term complication of abdominal surgery, resulting in considerable patient morbidity and increased health care costs. There are 4–5 million abdominal incisions (laparotomies) performed annually in the United States with hernias resulting after approximately 25% of these procedures (1–3). Importantly, incisional hernias result in severe morbidity beyond the cosmetic deformity of a visible bulge in the anterior abdominal wall, including intestinal obstruction, bowel ischemia, enterocutaneous fistula and significant limits on a patient's physical activity and gainful employment. Consequently, there are over 400,000 incisional hernia repairs performed each year in the United States making it one of the five most common procedures performed by general surgeons. The increase in US health care costs due to incisional hernia repair is estimated to currently exceed eight billion dollars per year, not including the cost of unemployment benefits for this moderately young patient population. Research and clinical experience indicate that incisional hernias frequently result from excessive tension concentrated at points along the suture line of the abdominal closure. These zones of excessive tension produce focal areas of tissue ischemia, decreased wound healing, and “cheese wiring”—sites of anchor point failure where sutures can tear or pull through myofascial tissue (**Figure 1**). Suture cheese wiring can occur at 6–14 N/cm, pressures that are routinely exceeded since peak abdominal pressures when coughing, sneezing, or vomiting are often greater than 32 N/cm.

Despite the magnitude and significance of incisional hernias, research focused on their prevention is sparse. While many studies and current research efforts are focused on improved repair materials, the optimal solution to the problem of incisional hernias is prevention. Notably, some investigators have postulated that incisional hernias can be prevented by more evenly distributing tension along the fascial closure. Support for this simple hypothesis comes from the well-known observation that closing laparotomies using a continuous suturing technique is associated with a decreased incisional hernia rate as compared to an interrupted suture closure (4). Herein we describe two novel and ingenious strategies to distribute tension more evenly

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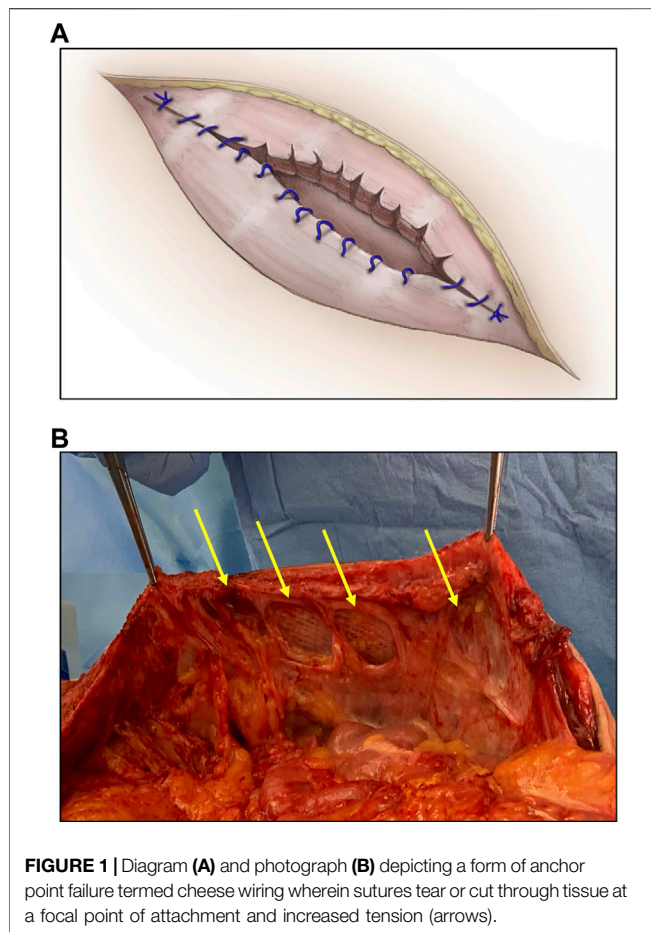
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when closing abdomens that were conceived of and developed by surgeons. T-Line® Hernia Mesh (Deep Blue Medical Advances, Inc., Durham, NC) and the REBUILD Bioabsorbable™ System (AbSolutions Med, Inc., Mountain View, CA) represent deep insights born of clinical experience as the foundation for unique solutions to a common problem, further highlighting the tradition of the surgeon-inventor.

## T-LINE® HERNIA MESH

T-Line Hernia Mesh is a standard weight (89 g/m<sup>2</sup>), super macroporous (>2.6 mm<sup>2</sup>), polypropylene (prolene) mesh with integrated mesh extensions located at 2-cm intervals along the lateral borders of the prosthetic (Figure 2). Invented by a plastic surgeon, Howard Levinson sought to combine how he was taught to repair tendons in the hand with nature's strategy for stabilizing tall trees (Figure 3). Similar to the roots of a tree, the T-Line Hernia Mesh extensions increase the surface area across which the prosthetic is anchored. Consequently, the mesh extensions

serve to spread the tension and shear forces over a larger area thereby significantly reducing focal anchor point stress and cheese wiring. While the T-Line Hernia Mesh achieves ~3-fold stronger anchoring strength than currently available meshes (5), the anchoring strength of the mesh extensions should increase over time as they incorporate with adjacent host tissue. When placed as an onlay, the mesh extensions can be sewn into the adjacent fascia using a quick, self-locking backstitch which secures the extensions and avoids the need for bulky suture knots (Figure 4). Mesh tension is set by sewing the contralateral extensions into tissue, thereby allowing the surgeon to control how tightly the mesh is stretched across the tissue. Notably, the prosthetic has the breaking strength of standard weight prolene mesh, but the handling characteristics of a lightweight mesh due to the specific way in which the mesh fibers are woven together.

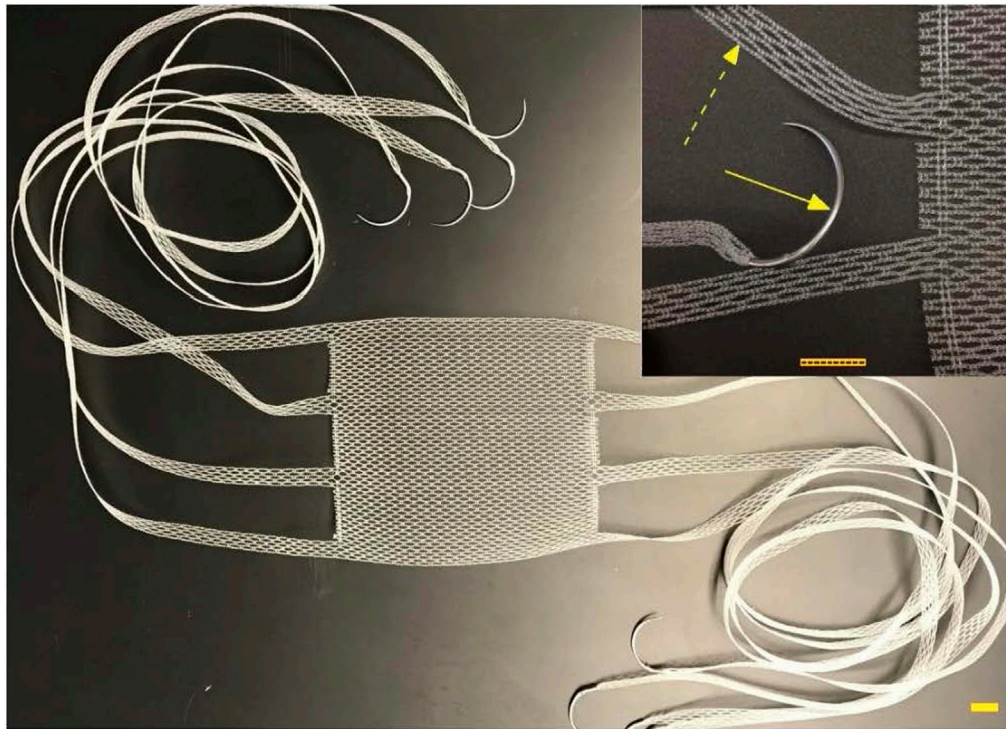
An early clinical report involving 18 patients (12 women, mean age 57 years) indicates that the mesh is safe. The surgical site occurrence rate in this high-risk population was favorable with two seromas (11%) and one superficial surgical site infection (6%). While there were no early recurrences, longer follow-up is necessary to determine the product's effectiveness in terms of hernia prevention and the avoidance of chronic mesh infection.

In summary, T-Line® Hernia Mesh translates an observation from nature into a prosthetic design with three important features. First, the integrated mesh extensions effectively eliminate anchor point failure and cheese wiring, two common reasons hernia repairs fail. Second, the macroporous prosthetic material has the tensile strength of standard weight prolene mesh, yet the handling characteristics of a lightweight mesh, which render it easy to use and allow it to readily conform to any variations in the topography of the anterior abdominal wall fascia (Figure 5). Third, the option to remove and reposition the mesh extensions highlights the flexibility of the product, supporting the frequent need for surgeons to be creative when repairing complex ventral hernias. Accordingly, the inventor and Deep Blue Medical Advances, Inc. are expanding the potential applications of this novel technology by introducing a product combined with an adhesion barrier that will be suitable for placement within the peritoneal cavity, plus a biodegradable version for use when looking to avoid placing a permanent mesh.

## REBUILD BIOABSORBABLE™

The REBUILD Bioabsorbable™ is a sterile, single-use implantable device designed for closure of midline abdominal incisions, also co-invented by a plastic surgeon. Dan Jacobs has long been fascinated by the anatomy and function of the anterior abdominal wall, and dubious of traditional teaching around how to best close laparotomy incisions. Convinced that there had to be a better way than conventional suture techniques, Jacobs drew inspiration from how we tie our



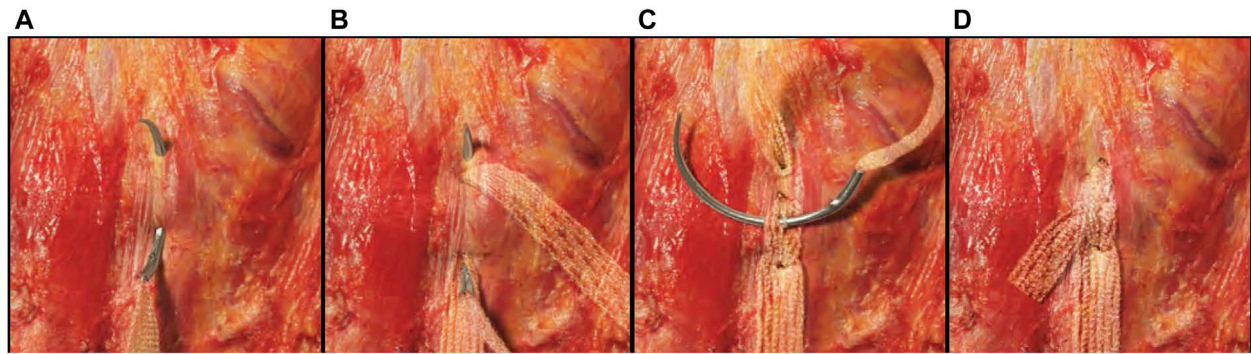


**FIGURE 2 |** T-line Hernia Mesh: 0.5 cm wide extensions emanating from body of textile with GS21 needles swaged on ends of extensions. Scale bar equals 1 cm; GS-21 needle (solid arrow); integrated mesh extension (dashed arrow). Photo used with permission from Deep Blue Medical Advances, Inc.

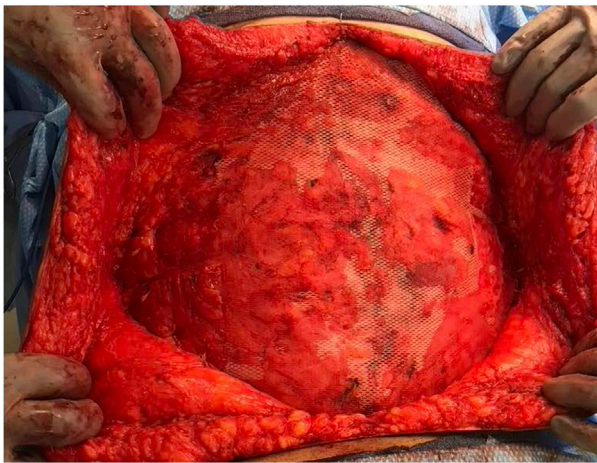


**FIGURE 3 |** Diagram illustrating the root system that provides anchor strength for the tree.



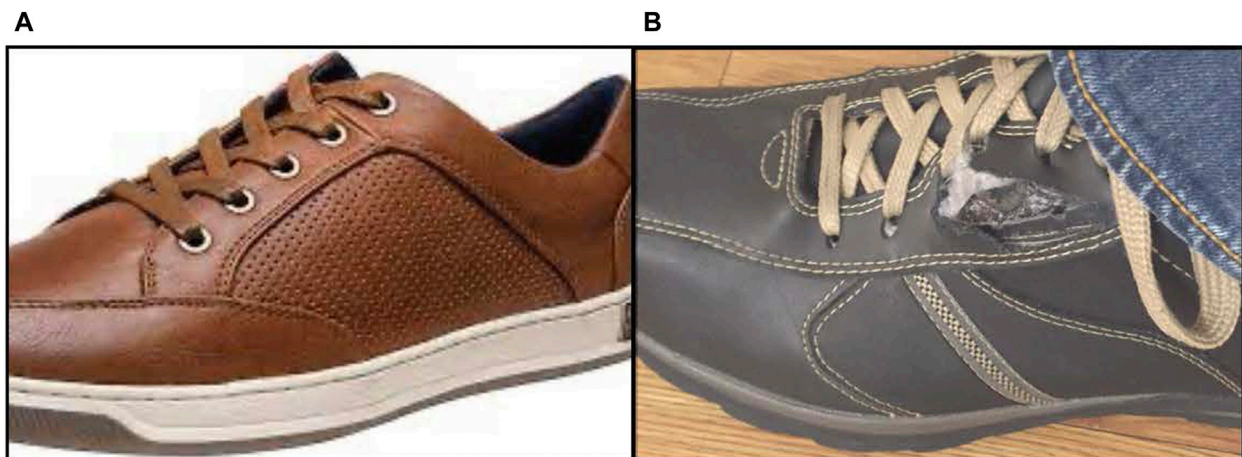


**FIGURE 4 |** Lock-stitch technique. **(A)** The first bite of the self-locking stitch can be a shallow bite lateral to the edge of the mesh. The extension would then be pulled to create the desired amount of tension on the mesh body. **(B)** The needle is then passed through a center portion of the extension where the first bite entered the fascia and placed slightly deeper through the tissue exiting just lateral to the exit of the first bite. **(C)** The second bite is pulled to create a snug loop around the fascia. The needle is then passed through a center pore of the extension where it exits on the first bite. **(D)** The extension is drawn snug to complete the self-locking stitch, and the excess extension is cut.

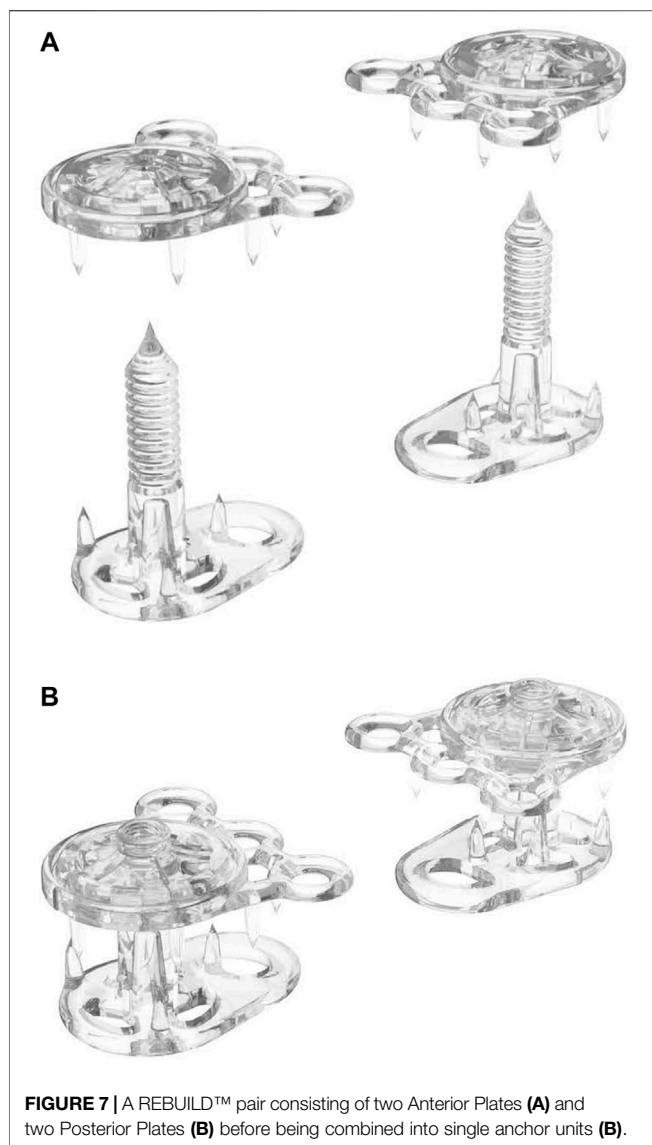


**FIGURE 5 |** Intraoperative photograph of an onlay mesh repair of a complex ventral hernia using T-Line® Hernia Mesh.

shoes! Or, more precisely, how reinforced eyelets prevent shoelaces from tearing through the shoe itself (**Figure 6**). Noting that reinforced eyelets effectively distribute the tension from tightly tied shoelaces, he sought to transfer this simple, yet elegant solution to closure of the abdominal wall. After several design iterations and prototypes, each REBUILD™ unit (think pair of opposing shoe eyelets) consists of two Anterior Tension Distribution (Anterior) Plates and two Posterior Tension Distribution (Posterior) Plates (**Figures 7A,B**). The Posterior Plate has one prong which is 26 mm tall and three 5.5-mm tines. The Anterior Plate also has five 5.5-mm tines. This suture tension distribution system provides 16-fold the tissue contact area compared to a standard 1 cm by 1 cm, USP #1 running suture closure. The Anterior and Posterior Plates are manufactured from poly-lactide-co-glycolide (PLGA), a biodegradable polymer that is physically strong, highly biocompatible, and whose building blocks are commonly used in suture material (Vicryl). PLGA undergoes bulk degradation by hydrolysis of its ester linkages, resulting in



**FIGURE 6 |** Reinforced eyelets **(A)** prevent shoelaces from tearing through **(B)**.

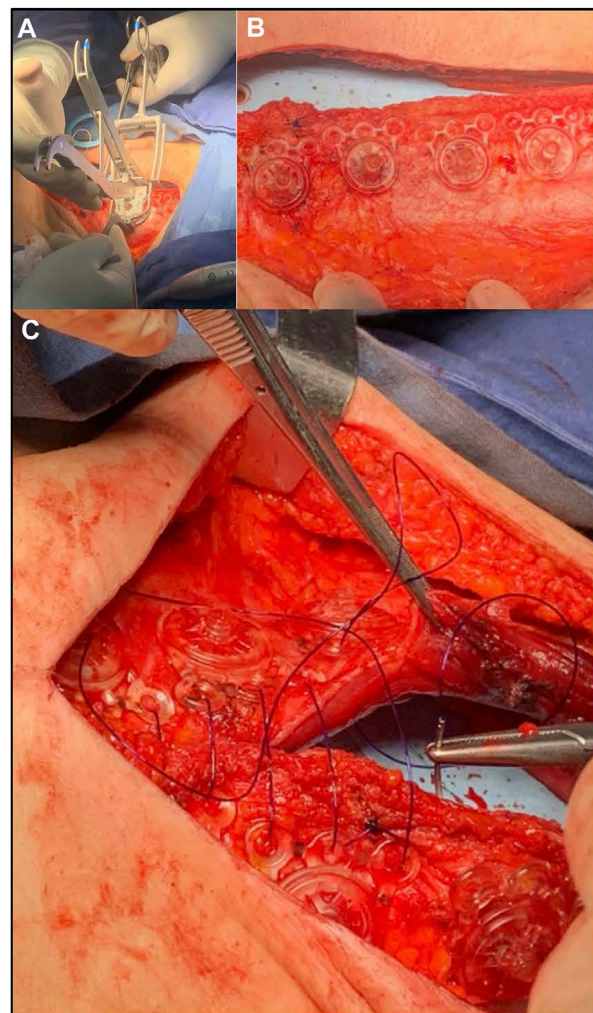


**FIGURE 7** | A REBUILD™ pair consisting of two Anterior Plates (A) and two Posterior Plates (B) before being combined into single anchor units (B).

the release of lactate and glycolate which are eliminated from the body after further metabolism.

A pair of Posterior Plates, with their central soft tissue fixation posts are inserted through the abdominal wall tissue directly opposite each other across the midline incision (**Figure 8A**). The Anterior Plates are simultaneously ratcheted to the fixation post of the Posterior Plate to create a single anchor. A series of these anchors are positioned along the midline incision (**Figure 8B**), the system is secured with suture placed through the device's eyelets (**Figure 8C**), and the excess fixation posts are trimmed (**Figure 8C**).

Porcine animal studies were conducted comparing REBUILD to standard suture technique, and although the number of animals is small (two REBUILD test animals and one suture control), the difference in midline integrity at 1 year is dramatic (**Figure 9**). MRI at 37 days in a separate pig demonstrates in vitro devices in the coronal view and contiguous rectus muscle without a gap at that midline in axial view (**Figure 10**). While this novel medical device is not FDA



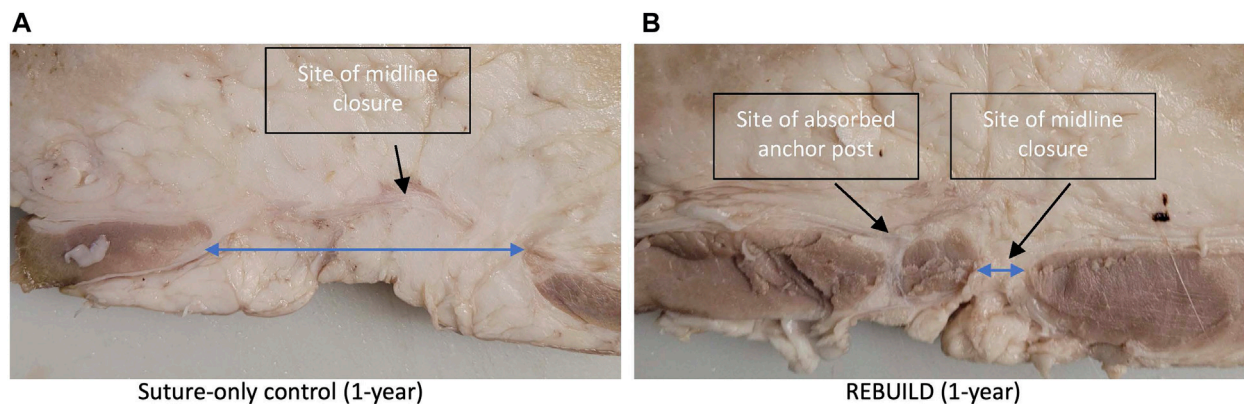
**FIGURE 8** | Photographs of REBUILD™ use during surgery. A Posterior Plate with its central soft tissue fixation post is being inserted through the abdominal wall tissue (A), with simultaneous ratchet fixation of an Anterior Plate on post of the Posterior Plate to create a module. A series of these modules are positioned along the midline incision (B), the system is secured with suture placed through the anchor module eyelets, and the excess fixation posts trimmed (C). The REBUILD™ system is provided with deployment tools made from stainless steel (A).

approved and thus not yet commercially available, clinical testing is underway with excellent early results.<sup>1</sup>

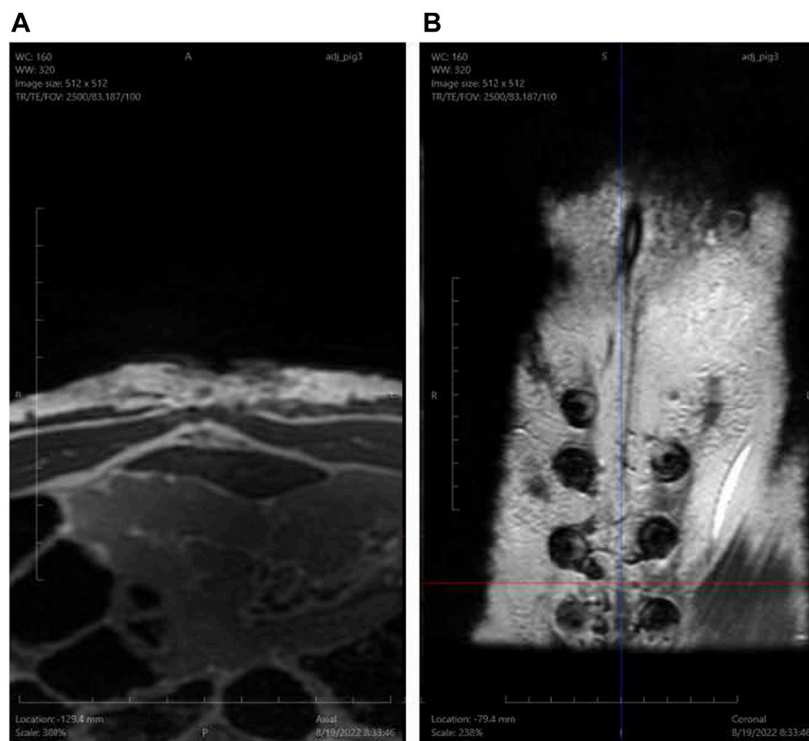
In summary, T-Line® Hernia Mesh and the REBUILD Bioabsorbable™ leverage simple but effective methods of dispersing force with the goal of mitigating myofascial tissue ischemia and injury, and thus preventing incisional hernias. Whereas the design strategies are very different, both are ingenious translations of common, everyday observations into clinically significant innovative tools that surgeons can use to

<sup>1</sup>Principal Investigator: Luis Palacios, MD: Surgical Oncology; Instituto de Cancerología “Las Americas”—AUNA; Medellin, Columbia.





**FIGURE 9 |** Axial slices of the porcine abdominal walls one year after an animal was closed with standard running suture technique **(A)** compared to an animal closed with REBUILD plus suture **(B)**. Suture-only closure demonstrates a wide gap between the medial borders of the rectus muscles (long blue arrow) versus the narrow gap between the muscles present in the REBUILD-plus-suture closure (short blue arrow). Average gap measurements are 52.6 mm for running suture and 13.5 mm for REBUILD + suture.



**FIGURE 10 |** MRI images of the abdomen 37 days after REBUILD-plus-suture closure of the abdominal wall in a porcine model. **(A)** Cross-sectional view demonstrates contiguous rectus muscle without a gap between the medial borders of the rectus muscles. **(B)** Coronal view demonstrates *in vivo* placement of REBUILD Anterior Plates in the subcutaneous (prefascial) plane.

improve outcomes for patients having abdominal surgery. Furthermore, these devices harken echoes of Theodor Kocher, Alexis Carrel, Michael DeBakey, Patricia Bath, Thomas Fogarty, and numerous other surgeon inventors whose commitment, determination, focus, imagination, and creative spirit benefit us daily.

## DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

## ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the University of California, San Francisco and NYU Langone Medical Center. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

## AUTHOR CONTRIBUTIONS

The entire manuscript was written by HH.

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## CONFLICT OF INTEREST

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