Protocol

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# Prophylactic slowly resorbable mesh in midline laparotomy to limit incisional hernia incidence: the prospective 'Mesh Augmented Reinforcement of Abdominal Wall Suture Line (MARS)' cohort study protocol

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**Background:** Incisional hernia (IH) after abdominal surgery is a frequent surgical complication. Risk factors associated with IH are midline incisions, patients with an abdominal aneurysm of the aorta, and high BMI. Preventive measures include the use of the small-bites suture technique and/or placing a prophylactic mesh for reinforcement of the midline closure. Although recommended for high-risk patients, many surgeons are still reluctant to place a prophylactic mesh due to related complications. To counter these concerns, new synthetic resorbable meshes are being developed, such as the *Deternia Self-Gripping Resorbable Mesh* ("investigational device"). However, the effectiveness of this mesh in IH prevention has not been proved.

**Methods:** The Mesh Augmented Reinforcement of Abdominal Wall Suture Line (MARS) study is a European, multicentre, prospective, single-arm study. A total of 120 patients scheduled for elective midline laparotomy, and for that reason at risk of developing IH, will be recruited in ~12 sites after informed consent. The sample size was estimated based on greater than 80% power, two-sided alpha of 0.05, an expected 12 month IH rate of 8% and a predefined performance goal of 18% (10% clinical margin). Midline incisions will be closed by the small bites closure technique with a minimum 4:1 suture-to-wound length ratio and reinforced by mesh placement in the retrorectus position. The primary outcome will be IH occurrence at 12-month postoperatively, evaluated both clinically and by ultrasound. Secondary outcomes will include mesh-related and postoperative complications, surgical characteristics, IH incidence at 2 and 3 years after surgery, and quality of life.

**Discussion:** Currently, no conclusive evidence is available for synthetic resorbable meshes in a prophylactic setting to prevent IH. The MARS study will be the first prospective cohort study to investigate resorbable synthetic meshes and small bites closure to reduce IH incidence.

**Keywords:** hernia prevention, incisional hernia, midline laparotomy, prophylactic mesh, resorbable synthetic mesh

## Background

Incisional hernia (IH) after abdominal surgery is a frequent surgical complication. The European Hernia Society (EHS) recommends avoiding midline incisions given it imposes the highest risk of IH development. Nevertheless, this is still the preferred procedure of many surgeons, mainly due to the ease of access to all abdominal quadrants[1]. Approximately 12.8% of patients will develop an IH after any kind of midline laparotomy[2]. Each year, around 400 000 IH repairs are performed in the United States alone[3].

Diverse factors contribute to an increase in the risk of developing IH, including patient-related features [high body mass index (BMI), history of abdominal aortic aneurysm (AAA), smoking, diabetes mellitus, liver diseases][4], and surgical factors (midline incision, specific suture materials and techniques,

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postoperative surgical site infection). In these high-risk populations, the incidence of IH can be as high as 40%[5].

To address the high rate of IH following midline laparotomy, surgeons started focusing on prevention strategies and using the small-bites suture technique (i.e., the stitch bites are 5 mm with a 5 mm inter stitch space) combined with the placing of prophylactic meshes for the reinforcement of the midline closure. Both measures have been shown to reduce the incidence of IH after midline laparotomies in several randomized controlled trials[6–9]. The 'Prevention of incisional hernia with prophylactic onlay and sublay mesh reinforcement versus primary suture only in midline laparotomies' (PRIMA) trial demonstrated a significant reduction in IH incidence by using prophylactic mesh placement in onlay or sublay position compared to primary suture closure in obese patients, or patients with a history of AAA[8]. The 'Prevention of Incisional Hernias by Prophylactic Mesh-augmented Reinforcement of Midline Laparotomies for Abdominal Aortic Aneurysm Treatment' (PRIMAAT) trial also showed a significant reduction of IH incidence after retrorectus mesh positioning, compared to primary suture in AAA patients[10–12].

The use of a prophylactic mesh after midline laparotomies is currently only recommended in high-risk patient groups[1]. However, even in high-risk populations, many surgeons are still reluctant to place a prophylactic mesh. This may reflect the unwillingness to introduce a permanent foreign object in the abdominal wall and/or fear of chronic pain, fistula formation and mesh infection following postoperative complications[11].

To counter concerns over prophylactic permanent mesh use, slowly resorbable meshes have been developed. Deternia Self Gripping Resorbable Mesh (Sofradim Production S.A.S.U. [Medtronic plc company], Trevoux France) is a recently designed macroporous fully resorbable bi-dimensional poly-L-lactide, polytrimethylene carbonate copolymer (PLLA/TMC) monofilament textile mesh that nearly completely degrades in 18 to 24 months and remaining mesh fibers are nonfunctional, while residual material is resorbed in 36–60 months postimplantation[13].

In order to investigate the effectiveness of the new resorbable mesh in a prophylactic setting, the European, multicentre, prospective, single-arm Mesh Augmented Reinforcement of Abdominal Wall Suture Line (MARS) study is being conducted.

The primary objective of this study is to assess the postoperative 1-year IH incidence by both clinical examination and ultrasound imaging. Secondary objectives include mesh-related and postoperative complications, surgical characteristics, IH incidence at 2 and 3 years after surgery, and quality of life [assessed by the EuroQol-5 Dimensions-5 Level (EQ-5D-5L) questionnaire].

## Methods

### Study design

MARS is a prospective, multicentre, single-arm, pre-market, investigational clinical study that aims to assess the performance and safety of *Deternia Self-Gripping Resorbable Mesh* ("investigational device") when used for suture line reinforcement in the retrorectus space after midline laparotomy in clean and clean-contaminated fields [Center for Disease Control (CDC) Classification I and II][14].

### HIGHLIGHTS

- Prophylactic mesh use has shown effectiveness in incisional hernia prevention.
- Resorbable meshes show less susceptibility to mesh infection and prevent long-term mesh complications.
- This protocol will investigate a new resorbable mesh in a prophylactic setting that may benefit patients undergoing midline laparotomy with possibly less risk of complications seen in synthetic mesh use.

The study will include 120 patients, enrolled in ~12 sites from five countries in Europe. To avoid site/surgeon bias, each site will recruit a maximum of 30 patients. Patients will then receive midline laparotomy, performed with small bites suture technique and a continuous running slowly absorbable monofilament suture reinforced by *Deternia Self-Gripping Resorbable Mesh* ("investigational device") placed in the retrorectus space.

### Eligibility

Patients over the age of 18 at the time of consent, who will be undergoing an elective surgery with a planned midline laparotomy with retrorectus mesh placement, are eligible for participation in the study.

Preoperative exclusion criteria are:

(1) Subject is undergoing emergency surgery.
(2) Subject has a history of allergic reactions after application of PLLA/TMC.
(3) Subject is pregnant or is planning pregnancy during study duration period.
(4) Subject is unable or unwilling to comply with the study requirements or follow-up schedule.
(5) Subject is scheduled for another surgery, which would jeopardize the previous application of the study treatment.
(6) Subject has a BMI greater than 45 kg/m$^2$.
(7) Subject has any of the following medical interventions/medical conditions: uncontrolled diabetes [hemoglobin A1c (Hb1Ac) > 60 mmol/mol], cirrhosis, stoma wearers.
(8) Subjects has a concomitant ostomy (stoma creation or closure).
(9) Subject has received a mesh in a previous ventral hernia repair or has an existing ventral hernia.
(10) Subject has a life expectancy inferior to the study follow-up duration (36 months).
(11) The study procedure is a relaparotomy within 30 days of previous abdominal surgery.
(12) Subject has an American Society of Anesthesiologists (ASA) score higher than 3.
(13) Subject has participated in an investigation drug or device study within 30 days before the enrolment.
(14) Subject has current chemo and/or radiation therapy within 2 weeks before the procedure.
(15) Subject has a history of ascites.
(16) Subject has a medical condition that precludes the patient from participation in the opinion of the investigator.
(17) Subject is undergoing a vascular procedure other than AAA surgery.

Intraoperative exclusion criteria are:

(1) Subject's study procedure is in a contaminated or infected site as assessed by the investigator(s) (CDC Class three and four).
(2) Subject's abdomen is left open at the end of the procedure.
(3) Subject has an unsuspected ventral/umbilical hernia greater than 1 cm encountered at the time of laparotomy.
(4) Inability to close the patient's anterior fascia or keep the mesh securely out of the peritoneal cavity.
(5) Subject has a second-look procedure planned.
(6) Subject requires a full-thickness partial resection of the abdominal wall because of involvement in the neoplastic process or complex fistula.
(7) Subject has an inoperable tumor/poor prognosis cancer/ patient noncuratively treated.
(8) Subject has a suture length to wound length ratio less than 3.5/1.
(9) Subject has an ongoing infection at the time of the surgery, which is uncontrolled and/or requires treatment such as antibiotics.
(10) Subject was not implanted with Deternia Self Gripping Resorbable Mesh.
(11) Subject requires more than 1 mesh.

### Study device

*Deternia Self-Gripping Resorbable Mesh* is intended to be used for the reinforcement of abdominal wall soft tissues where weakness exists, in procedures involving abdominal suture-line reinforcement. The device is made of a macroporous fully resorbable bi-dimensional (PLLA/TMC) monofilament textile, with monofilament PLLA/TMC absorbable grips on one side to facilitate positioning and mesh fixation to the surrounding tissue[13].

The macroporous textile provides the strength required to withstand biomechanical stresses throughout the healing period, while allowing for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the reinforcement. Over time the PLLA/TMC mesh and grips degrade and resorb *in vivo* by hydrolysis and are metabolized by the body into $CO_2$ and $H_2O$.

### Physician's training

Two training sections on MARS study features, adopted device, retro rectus dissection, and mesh augmented procedures were organized in June and November 2022, respectively. A total of 31 participants – including principal investigators, co-investigators, and nurses – were trained by Medtronic clinical specialists and three surgeon experts and members of the study steering committee. A training video and live exercitations on cadavers were used to show the intervention procedures, focusing on retrorectus mesh placement, and small-bites techniques.

### Pre-procedure assessments

Patients' demographics, BMI, medical and abdominal surgical histories, and relevant risk factors will be collected pre-operatively. Subjects will also complete an EQ-5D-5L QoL questionnaire and a pain numeric rating scale (NRS, 0–10).

### Procedures

The mesh used in this study will be placed following the below instructions:
(1) A single mesh must be placed during each procedure.
(2) The mesh will create a posterior plane between the rectus muscle and the posterior rectus fascia.
(3) The posterior rectus fascia will be closed with a continuous running slowly absorbable monofilament suture. The mesh will be placed over the sutured closed posterior rectus fascia. It is suggested to allow an overlap of 4 cm on each side and at the extremities of the incision. The amount of overlap should be recorded in all directions. The mesh shall be placed with the grips towards the fascia (downwards).
(4) If the laparotomy incision extends caudally, below the arcuate line, the posterior plane for the positioning of the mesh will be created between the rectus muscles and transversal fascia, and the mesh will be placed over the sutured closed transversal fascia and peritoneum, and it is suggested to allow an overlap of 4 cm on each side and at the extremities of the incision. The amount of overlap will be recorded in all directions. The mesh shall not be placed with the grips in direct contact with the peritoneum.
(5) The textile self-gripping feature contributes to the fixation of the mesh to surrounding tissue for a minimum of 8 weeks and additional fixation means (suture) should be only performed at the discretion of the surgeon, depending on the surgical procedure, size of incision, and patient conditions. If sutures are needed, it is recommended to fixate the mesh at about 1 cm from the edge of the mesh with absorbable sutures.
(6) After mesh positioning and fixation, closure of the anterior rectus fascia will be performed using the best standard suture length/wound length ratio 4:1 and small-bites techniques (the stitch bites are 5 mm with a 5 mm inter stitch space) with a continuous running slowly absorbable monofilament suture. The stitch should incorporate the aponeurosis only and incorporation of fat or muscle tissue should be avoided
(7) The subcutaneous tissue and skin will be closed according to the surgeons' preference.
(8) A drain can be used at the surgeon discretion, but it is not recommended in this protocol.

Data collected at the time of the procedure will include surgical features: date of surgery, time of surgery (skin incision to end of closure), type of anaesthesia, intraoperative wound contamination class (CDC classification), surgical approach, type of surgery, fascial closure details, study device data, and time to create the retrorectus space and insert, position, and fixate the mesh if applicable. Perioperative antibiotic prophylaxis and anticoagulants use, adverse events (Ae), and device deficiencies will also be recorded.

### Follow-up

Subjects will be evaluated at discharge and at 3, 6, 12, 24, and 36 month postprocedure. Data on pain levels (evaluated via NRS), post incision Aes, anticoagulant use, clinical–physical examination for IH, and details of IH (if present) will be recorded at all timepoints. At 12, 24, and 36 month follow-up imagery (ultrasound required and computed tomography scan as desired/ needed per standard of care) will be used to diagnose IH. Subjects will also complete an EQ-5D-5L QoL questionnaire at all follow-ups after discharge.

### Primary and secondary endpoints

The study primary endpoint is to assess the *Deternia Self-Gripping Resorbable Mesh* performance in suture line reinforcement after elective midline laparotomy at 12 month postoperatively and demonstrate its efficacy in preventing IH occurrence. IH development will be evaluated both clinically and by imaging with ultrasonography (in case of discrepancy, imagery will be decisive). If there is a suspicion of hernia based on the clinical evaluation, but the ultrasound examination is negative, computed tomography scan might be performed according to site standard of care. IH is clinically defined as any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination when a Valsalva maneuver was carried out in the supine decubitus position and/or in the standing position. IH is defined, according to ultrasound examination of the midline laparotomy, as a visible gap within the abdominal wall and/or tissue moving through the abdominal wall by Valsalva maneuver.

Secondary endpoints are designed to assess device clinical safety and performance within 36 months postoperatively and include:

1. Incidence of IH at 24 and 36 month follow-up, assessed by imaging and clinical examination (in case of discrepancy imagery will be decisive).
2. Incidence of clinical IH (physical exam) at 3, 6, 12, 24, and 36 month follow-up.
3. Time to IH (from surgery time-point).
4. Time to other adverse device effects (Ade) occurrences (from skin incision time-point).
5. Incidence of all Ades (mesh and mesh-augmented reinforcement procedure) intraoperatively, at discharge, within 3, 6, 12, 24, and 36 month following the use of *Deternia Self-Gripping Resorbable Mesh*.
6. Incidence of AEs of interest: symptomatic seroma requiring action taken, hematoma needing surgical revision, surgical site infection (defined according to the CDC classification), wound dehiscence (skin and/or fascial, mesh removal) intraoperatively, at discharge, within 3, 6, 12, 24, and 36 month following the use of *Deternia Self-Gripping Resorbable Mesh*.
7. Postoperative pain at the site of surgery, evaluated with NRS score from 0 to 10 at baseline (screening), discharge and at 3, 6, 12, 24, and 36 months postoperative visits.
8. EQ-5D-5L QoL at baseline, 3, 6, 12, 24, and 36 month postoperative visits; surgeon satisfaction questionnaire postoperative on day 0.
9. Hospital length of stay (inpatient).
10. Readmission and reoperation rate related to study mesh device and/or mesh augmented reinforcement study procedures.

### Investigator selection

Investigators are qualified surgeons from five different European countries (Croatia, Germany, Netherlands, Spain, and UK) experienced in the surgical management of patients with mesh augmented reinforcement for abdominal laparotomies or in mesh placement for hernia repair.

### Statistics

The primary endpoint (incidence of IH at 12 month postoperative visit) for this single-group study will be evaluated clinically and radiologically by imagery by means of ultrasonography and be evaluated against a performance goal (PG). The PG is predefined to be 18% and was determined based on literature review, meta-analysis and clinical judgments, and selected to balance the number of patients while maintaining proof of acceptable performance[6,9,15–18].

The sample size is estimated based on greater than 80% power, one-sided alpha of 0.025, an expected 12 month IH rate of 8% (based on meta-analysis), and a pre-defined performance goal of 18% (10% clinical margin). By accounting for an attrition rate of 10% at 12 months, a total of 120 subjects will be implanted with the investigational device for this study.

Descriptive statistics will be used to summarize study outcomes. Continuous variables will be summarized using a number of subjects ($n$), mean, standard deviation, median, IQR, and ranges. Categorical variables will be summarized using counts and percentages. The primary analysis will include data from all study sites. A probability analysis across sites will be performed on the primary endpoint of the IH rate at 12 months. All tests of treatment effects will be conducted at a two-sided alpha level of 0.05 unless otherwise stated. A $P$ value less than 0.05 is considered statistically significant. Confidence intervals will be presented at the 95% level, unless otherwise stated.

The primary hypothesis is to test if the primary IH rate is below the pre-defined PG. The Clopper–Pearson exact method will be used for the primary endpoint analysis. A multivariable analysis using logistic regression with regularization and/or variable selection for model estimability will also be performed with baseline covariates including age, BMI, sex, smoking, previous abdominal surgery, type of index procedures, length of incision, and CDC classification plus others as appropriate.

### Study organization

The sponsor will utilize study monitors to ensure that the study is conducted in accordance with the study protocol, clinical trial agreements, and the applicable regulatory and local requirements. The study will also use a Clinical Events Committee to conduct a review of selected AEs in order to adjudicate them. The Clinical Events Committee will consist of a minimum of three non-sponsor employed physicians, not involved in the study.

### Enrolment status

Enrolment has started in November 2022. To date (March 2023), a total of eight patients have been enrolled.

## Discussion

Although the risks of developing an IH associated with midline laparotomy is well known and EHS recommends avoiding midline incisions whenever possible[1], this approach is still being utilized by many surgeons. Consequences stemming from the midline approach include the increase of IH repair costs, rising to more than 3.2 billion dollars annually in the USA[3]. Prevention of IH development is therefore an important medical and socio-economic issue that needs to be addressed.

Since a significant reduction was observed in patients with prophylactic mesh reinforcement, this approach seems to be a viable and feasible instrument to counter IH development[8,10]. However, postoperative infections of the prophylactic mesh may cause long-term complications[11] such as chronic infections requiring partial or complete mesh resection (with subsequent IH formation), mesh extrusion or erosion, seroma development and pain[19,20]. Furthermore, enterocutaneous fistula can form postoperatively and severely impair patient QoL[21].

Synthetic resorbable meshes - like biological ones - resorb in the human body, although they take significantly longer time compared with biosynthetic devices. This might give the abdominal wall time to strengthen its cellular matrix and collagen, while not remaining permanently attached in the abdominal wall. Also, synthetic resorbable meshes gradually degrade through hydrolysis and are less prone to infections compared with their permanent synthetic counterparts. The lower contamination rate might be explained with a weaker inflammatory reaction of the recipient, due to the specific biological configuration of the mesh[22,23].

Limitations of current study include ethical considerations that directed the study design to a single arm study instead of a randomized controlled trials (RCT) during the development of this study. This was due to the fact that significantly more patients will develop an IH if placed in a primary suture group as shown in numerous previous RCTs with their long-term follow-up[8,10–12,24]. Furthermore, informing patients during informed consent that there is a beneficial treatment available with regard to IH prevention, but adhering them to possibly primary suture allocation will impair subject enrolment. Additionally, selection bias might be introduced due to physicians choosing only patients who they are willing to risk treating without prophylactic mesh placement. Patients with obesity rates with a BMI greater than 45 are excluded since their BMI contributes to high risk of postoperative complications, confounding mesh related outcomes. These obesity rates are – for the moment – rare in Europe.

For reference, the Dutch national Central Bureau for Statistics (CBS) published the following data regarding class 3 obesity, showing a 0.9% percentage[25].

Currently, no conclusive evidence is available for the use of bio (synthetic) meshes in a prophylactic setting[22]. The aim of this study is to evaluate the performance of the slowly-absorbable synthetic Deternia Self Gripping Resorbable Mesh in patients requiring a reinforcement of the suture line following midline laparotomies in clean and clean-contaminated fields and is therefore crucial to define the clinical significance of synthetic resorbable meshes in prophylactic settings.

## Ethical compliance

This study is being conducted in accordance with the Declaration of Helsinki and local regulatory requirements. The study is registered at ClinicalTrials.gov (NCT05424484) and will be added in local regulatory databases if required by local laws. All individual hospitals participating in the study had submitted the study protocol for local approval of the study. All patients will provide written informed consent prior to enrolment or any study-related procedures and will consent for publication. Sofradim Production S.A.S.U., a Medtronic plc company (Trevoux, France) approved the protocol and consented for publication.

## Consent for publication

All patients will consent for publication. Sofradim Production S.A.S.U., a Medtronic plc company (Trevoux, France) approved the protocol and consented for publication.

## Author contributions

L.M.D. helped with the design of the protocol and initiated the writing of the protocol manuscript; J.M.M.-V. designed the protocol, drafted following protocol amendments, and is involved in patient inclusion and data gathering; E.M. helped designing the protocol and is involved in patient inclusion and data gathering; J.T. helped designing the protocol and drafted following protocol amendments; D.W. supervised the protocol manuscript and was involved in patient inclusion and data gathering; I.K. was involved in patient inclusion and data gathering and checked the protocol manuscript; J.F.L. oversaw the design of the protocol and made final revisions to the protocol manuscript. All authors read and approved the final manuscript.

## Conflicts of interest disclosure

This work was supported by Sofradim Production S.A.S.U., a Medtronic plc company (Trevoux, France). All authors (or their institutions) received support to provide input on the design of the study.

## Research registration unique identifying number (UIN)

Trial registration: ClinicalTrials.gov (NCT05424484).

## Data availability statement

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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## References

[1] Muysoms FE, Antoniou SA, Bury K, *et al*. European Hernia Society guidelines on the closure of abdominal wall incisions. Hernia 2015;19:1–24.
[2] Bosanquet DC, Ansell J, Abdelrahman T, *et al*. Systematic review and meta-regression of factors affecting midline incisional hernia rates: analysis of 14,618 patients. PLoS One 2015;10:e0138745.
[3] Poulose BK, Shelton J, Phillips S, *et al*. Epidemiology and cost of ventral hernia repair: making the case for hernia research. Hernia 2012;16:179–83.
[4] Fischer JP, Basta MN, Mirzabeigi MN, *et al*. A risk model and cost analysis of incisional hernia after elective, abdominal surgery based upon

12,373 cases: the case for targeted prophylactic intervention. Ann Surg 2016;263:1010–7.
[5] Ahmed J, Hasnain N, Fatima I, *et al*. Prophylactic mesh placement for the prevention of incisional hernia in high-risk patients after abdominal surgery: a systematic review and meta-analysis. Cureus 2020;12:e10491.
[6] Jairam AP, Lopez-Cano M, Garcia-Alamino JM, *et al*. Prevention of incisional hernia after midline laparotomy with prophylactic mesh reinforcement: a meta-analysis and trial sequential analysis. BJS Open 2020; 4:357–68.
[7] Millbourn D, Cengiz Y, Israelsson LA. Effect of stitch length on wound complications after closure of midline incisions: a randomized controlled trial. Arch Surg 2009;144:1056–9.
[8] Jairam AP, Timmermans L, Eker HH, *et al*. Prevention of incisional hernia with prophylactic onlay and sublay mesh reinforcement versus primary suture only in midline laparotomies (PRIMA): 2-year follow-up of a multicentre, double-blind, randomised controlled trial. Lancet 2017; 390:567–76.
[9] Deerenberg EB, Harlaar JJ, Steyerberg EW, *et al*. Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet 2015;386:1254–60.
[10] Muysoms FE, Detry O, Vierendeels T, *et al*. Prevention of incisional hernias by prophylactic mesh-augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment: a randomized controlled trial. Ann Surg 2016;263:638–45.
[11] Van den Dop LM, Sneiders D, Kleinrensink GJ, *et al*. Infectious complication in relation to the prophylactic mesh position: the PRIMA trial revisited. J Am Coll Surg 2021;232:738–45.
[12] Dewulf M, Muysoms F, Vierendeels T, *et al*. Prevention of incisional hernias by prophylactic mesh-augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment: five-year follow-up of a randomized controlled trial. Ann Surg 2022;276: e-217–222.
[13] Vestberg R, Lecuivre J, Radlovic A, *et al*. A novel self-gripping long-term resorbable mesh providing temporary support for open primary ventral and incisional hernia. J Mater Sci: Mater Med 2023;24:59.
[14] Garner JS. CDC guideline for prevention of surgical wound infections, 1985. Supersedes guideline for prevention of surgical wound infections published in 1982. (Originally published in November 1985). Revised. Infect Control 1986;7:193–200.
[15] Muysoms FE, Jairam A, Lopez-Cano M, *et al*. Prevention of incisional hernias with biological mesh: a systematic review of the literature. Front Surg 2016;3:53.
[16] Bali C, Papakostas J, Georgiou G, *et al*. A comparative study of sutured versus bovine pericardium mesh abdominal closure after open abdominal aortic aneurysm repair. Hernia 2015;19:267–71.
[17] Garcia-Urena MA, Lopez-Monclus J, Hernando LA, *et al*. Randomized controlled trial of the use of a large-pore polypropylene mesh to prevent incisional hernia in colorectal surgery. Ann Surg 2015;261:876–81.
[18] Caro-Tarrago A, Olona Casas C, Jimenez Salido A, *et al*. Prevention of incisional hernia in midline laparotomy with an onlay mesh: a randomized clinical trial. World J Surg 2014;38:2223–30.
[19] Rosen MJ, Bauer JJ, Harmaty M, *et al*. Multicenter, prospective, longitudinal study of the recurrence, surgical site infection, and quality of life after contaminated ventral hernia repair using biosynthetic absorbable mesh: The COBRA study. Ann Surg 2017;265:205–11.
[20] Ventral Hernia Working G, Breuing K, Butler CE, *et al*. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. Surgery 2010;148:544–58.
[21] Christopher AN, Morris MP, Patel V, *et al*. An evaluation of clinical and quality of life outcomes after ventral hernia repair with poly-4-hydroxybutyrate mesh. Hernia 2021;25:717–26.
[22] Kockerling F, Alam NN, Antoniou SA, *et al*. What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction? Hernia 2018;22:249–69.
[23] Christopher AN, Morris MP, Jia H, *et al*. Resorbable synthetic ventral hernia repair in contaminated fields: outcomes with poly-4-hydroxybutyrate mesh. Plast Reconstr Surg 2021;148:1367–75.
[24] Kohler A, Lavanchy JL, Lenoir U, *et al*. Effectiveness of prophylactic intraperitoneal mesh implantation for prevention of incisional hernia in patients undergoing open abdominal surgery: a randomized clinical trial. JAMA Surg 2019;154:109–15.
[25] Central Bureau of Statistics. 100 thousand adults with morbid obesity, 2018 Accessed 2024. https://www.cbs.nl/en-gb/news/2018/27/100-thousand-adults-with-morbid-obesity