UNIVERSITY OF COPENHAGEN
FACULTY OF HEALTH AND MEDICAL SCIENCES

PhD Thesis

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Abdominal exercises after stoma surgery: towards a rehabilitation effort with the intention of preventing parastomal bulges

This thesis has been submitted to the Graduate School of Health and Medical Sciences, University of Copenhagen, November 22, 2019.

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Acknowledgments

I would like to thank all those who helped and supported me during this PhD project.

First, I want to thank my supervisors – Thordis Thomsen, Anders Vinther, Anne Kjærgaard Danielsen, and Ismail Gögenur – for supervision and guidance, and for support during trying periods, when funding was uncertain or whenever I received rejections.

Second, I want to thank the coauthors on the three scientific papers – Tobias Wirenfeldt Klausen, Tine Alkjær, Tyge Nordentoft, Emma Possfelt-Møller, and Marianne Krogsgaard – for professional discussion and collaboration on these exciting research projects.

A big thank you to the stoma care nurses at Herlev Hospital and Rigshospitalet – Gerd F. Bille, Anette Skytte, Birgitte D. Andersen, Anne Marie Frandsen and Jannie Mortensen – for invaluable help with recruitment and practical issues in the conduct of the projects.

I want to express my gratitude to the departments involved in the project:
Department of Surgical Gastroenterology, Rigshospitalet, Denmark;
Department of Gastroenterology, Herlev and Gentofte Hospital, Denmark; and
Department of Physiotherapy and Occupational Therapy, Herlev and Gentofte Hospital, Denmark.

I want to thank the steering group of the PreParE project (Prevention of Parastomal Bulging in Patients with an Enterostoma) – Henning Granslev and Gisela Schjøtt from the Danish Stoma Association, the PhD supervisors, Bo M. Christensen, Jens Hillingsø, Susanne Dansholm, Jannie Mortensen, Hanne F. Skall – for initiating and supporting the PhD project under PreParE.

I want to thank all funders for supporting the PhD project: The Research Foundation of the Capital Region of Denmark; Toyota-Fonden, Denmark; The Research Council, Herlev and Gentofte, Denmark; and Rigshospitalet, Denmark.

During the PhD project, I have been grateful for the company of my colleagues at both The Department of Gastroenterology, 12th floor (before I had to move office), Herlev Hospital, and at the research unit in Section 7831, Rigshospitalet.

Last, a special thank you to my family and friends for offering their support and showing their interest in my PhD endeavors.

List of scientific papers

The thesis is based on three scientific papers, which can be found in the appendices:

I. Andersen RM, Klausen TW, Danielsen AK, Vinther A, Gogenur I, Thomsen T. Incidence and risk factors for parastomal bulging in patients with ileostomy or colostomy: a register-based study using data from the Danish Stoma Database Capital Region. Colorectal Dis. 2018;20(4):331-40.

II. Andersen RM, Thomsen T, Danielsen AK, Gogenur I, Alkjær T, Nordentoft T, Possfelt-Møller E, Vinther A. Evaluation of abdominal exercises after stoma surgery: a descriptive study. *Submitted to Disability and Rehabilitation.*

III. Andersen RM, Danielsen AK, Vinther A, Krogsgaard M, Gogenur I, Thomsen T. Patients' experiences of abdominal exercises after stoma surgery: a qualitative study. *Submitted to Disability and Rehabilitation.*

Table of contents

Resumé på dansk (Summary in Danish)

Stomi på tarmene udføres kirurgisk i behandling af sygdomme som kræft og inflammatorisk tarmsygdom. Parastomal buledannelse er en komplikation efter stomioperation, der medfører problemer med at få stomiposer til at sidde, ændringer til fysisk udseende, nedsat livskvalitet samt mulige smerter og bivirkninger. Mulighederne for forebyggelse og behandling af parastomale buler er begrænsede, og mange mennesker med stomi må leve med deres bule. Træningsøvelser for mavemusklerne har interesse som en måde potentielt at forebygge parastomal buler på, men denne tilgang er kun undersøgt i begrænset omfang. I et ph.d.-projekt med tre studier blev følgende observeret: (i) I en gruppe af 5000 patienter udviklede 36% en parastomal bule inden for det første år efter operation; (ii) Mavetræningsøvelser var mulige ud fra målinger af smerte, ubehag og sværhedsgrad, og fra 2 uger efter operation førte visse øvelser til omfattende involvering af mavemusklerne; (iii) Træningsøvelser for mavemusklerne var nemme og blev modtaget positivt, men barrierer til træning nødvendiggjorde hjælp og vejledning i mavetræningsøvelser efter stomioperation. Ph.d.-projekt giver værdifuld information til brug i klinisk praksis og skaber solidt fundament for fremtidig undersøgelse af mavetræningsøvelser til at forebygge parastomale buler efter stomioperation.

Summary in English

Surgical stomas on the intestines are created in the treatment of diseases like cancer and inflammatory bowel disease. Parastomal bulging is a complication after stoma creation that leads to problems fitting stoma appliances, changes in physical appearance, reduced quality of life, and potential pain and harm. The options for treating or preventing bulges are limited, and many people with a stoma must live with their bulge. Abdominal exercises receive interest as a way to potentially prevent parastomal bulges, but this method has rarely been investigated at this point. In a PhD project with three studies, the following was observed: (i) In a sample of 5,000 patients, 36% developed a parastomal bulge within the first year after surgery; (ii) Abdominal exercises were feasible based on pain, discomfort, and difficulty, and from 2 after surgery, certain exercises thoroughly involved the abdominal muscles; (iii) The abdominal exercises were easy, and the attitudes toward them were positive, but the barriers to exercise necessitated help and guidance with abdominal exercises after stoma surgery. This PhD project provides valuable information for clinical practice and lays a solid foundation for future investigations into abdominal exercises for preventing parastomal bulges after stoma surgery.

Abbreviations

ADIM	Abdominal drawing in maneuver
ASA score	American Society of Anesthesiologists physical status classification system
CI	Confidence interval
EMG	Electromyography
EO	External oblique muscle
IO	Internal oblique muscle
RA	Rectus abdominis muscle
RCT	Randomized controlled trial
Ref	Reference
TrA	Transversus abdominis muscle

Introduction

The creation of a surgical stoma is a life-altering event with a marked impact on the lives of the people receiving a stoma. A stoma alters physical appearances and changes how feces exits the body. There is a stigma surrounding stomas (1-3) and many myths about what it means to have one. Stomas make noises, and the stoma bag may be difficult to hide, making people with a stoma self-conscious. A stoma negatively affects quality of life (4, 5) and for some, the presence of a stoma can lead to isolation (2). For those with a stoma who experience the complication of ‘parastomal bulging’, their problems often worsen, and new ones occur.

Background

Surgical stomas

Intestinal stomas are formed to divert the flow of feces in the treatment of disease (6). There are two types of intestinal stomas, named after the part of the intestines involved: ileostomies (ileum) and colostomies (colon). In Denmark, an estimated 4,000 surgical stomas are created annually (7), with most being ileostomies or colostomies, and the rest being on the urinary system (urostomies). For reference, the number of new stomas in the United States has been estimated at 100,000 to 130,000 per year (8, 9). The many people living with a stoma include younger people, often with inflammatory bowel disease (10), a term that includes Crohn’s Disease (11) and ulcerative colitis (12). Based on local numbers from the Capital Region of Denmark, cancer is the most common diagnosis, accounting for slightly more than half the stomas created (13). Stomas can be intended as either permanent or temporary at the time of surgery. Temporary stomas are created to divert and protect anastomoses and prevent sepsis (14, 15), but around 6–32% of intended temporary stomas end up being permanent (14). The history of surgical stomas goes back more than 200 years (16, 17), and surgical techniques, stoma care, and the management of complications are still evolving.

Parastomal bulging

Parastomal bulging is a common complication after stoma surgery that can be caused by a parastomal hernia, a subcutaneous prolapse, or a weak abdominal wall (18-20). Parastomal bulging differs from parastomal hernias in that hernias are characterized by the presence of a hernia sac (21). The distinction between the two terms – parastomal bulging and parastomal hernia – in published literature can be difficult (22). A lack of reported criteria for the assessment of parastomal hernias (22) can make it unclear if parastomal bulging and parastomal hernias are differentiated in a scientific study. Historically, different definitions of parastomal hernias have been used (23). Existing literature on the incidence of parastomal bulging, specifically, is sparse, and it is necessary to review parastomal hernias for an estimate of incidences. The reported incidences of parastomal hernias vary from 0% to 48% depending on the stoma type and length of follow-up (24-30). There is evidence that radiological assessments with computed tomography lead to a higher rate of parastomal hernias than clinical assessments (31-34).

A parastomal bulge can be associated with a number of problems, including the fitting of stoma appliances, leakage, skin problems, and an impaired quality of life (18). In cases where the bulge is caused by a parastomal hernia, there is a risk of pain, discomfort, incarceration (35), strangulation, perforation, and obstruction (24). In a case with no or mild symptoms, treatment may be conservative (25). If symptoms or complications related to a parastomal bulge or hernia are severe, the patient may be offered surgical repair, which contains a risk of morbidity and mortality (35). There is also a substantial risk of recurrence following hernia repair (25, 35). Thus, many patients learn to live with their bulge and the problems that come with it.

Prevention of parastomal bulging

In the existing literature, investigation into the prevention of parastomal bulging has focused on parastomal hernias. Different positions of the stoma do not appear to affect the rate of parastomal hernias (36). Other surgical techniques for parastomal hernia prevention has been investigated as well (37). The prophylactic use of a peristomal mesh when the stoma is formed appears to reduce the incidence of parastomal hernias (38-40), although not all randomized controlled trials (RCTs) have come to the same conclusion (41). Many patients with a stoma do not receive a peristomal mesh, as a mesh is usually placed when creating permanent sigmoid colostomies during elective surgery. An investigation of other prophylactic measures is important, and non-surgical modalities for the prevention of parastomal hernias and bulging have also received interest.

Abdominal exercises after stoma formation

Abdominal exercises to strengthen the abdominal wall muscles may reduce the incidence of parastomal bulging. The rationale is that stoma creation causes a weakness in the abdominal wall muscles (42), which potentially increases the risk of a bulge. By strengthening the abdominal muscles, the risk of parastomal bulging may then be reduced. Abdominal exercises are thus recommended for parastomal hernia prevention by the Association of Stoma Care Nurses UK (43). Based on a literature search of PubMed (MEDLINE), CINAHL, and PEDro – combined with reference and citation searches – three studies (44-46) investigating abdominal exercise intervention after stoma surgery were identified (**Table 1**). In all three studies, the intervention consisted of abdominal exercises in combination with support garments and advice on lifting and the risk of parastomal hernia development (44-46).

Table 1. Existing studies on abdominal exercises after stoma surgery			
Study	**Description**	**Abdominal exercises**	**Parastomal hernia rate (follow-up), n**
Thompson and Trainor, 2005 (44)	Prospective trial with retrospective control	Starting 3 months after surgery: pelvic tilting; knee rolling; sit-ups	I: 14% (1-year), n=114* C: 28% (1-year), n=87*
Thompson and Trainor, 2007 (45)	Repeat of Thompson and Trainor, 2005, using same control	Starting 3 months after surgery: pelvic tilting; knee rolling; sit-ups	I: 17% (1-year), n=99*
North, 2014 (46)	Prospective trial with retrospective control	Starting at discharge: abdominal drawing in maneuver; pelvic tilting; knee rolling	I: 15% (1-year), n=100 C: 23% ("over 5 years"), n=500
I = intervention group C = control group *denotes number analyzed, deceased patients excluded from analysis			

None of the studies applied a randomized design or attempted to adjust for confounding factors. It is unclear how parastomal hernias were assessed in the three studies and whether parastomal bulging by other causes – for example, subcutaneous prolapse – were included. Even if all three studies show a reduced incidence of parastomal hernias with intervention, the level of evidence is very low, and the effect of abdominal exercises on the incidence of parastomal bulging is largely unknown. Also, little is known about the harms of abdominal exercises after stoma formation, and restrictions on physical activity and exercise may vary between hospitals in the same region. In a study regarding incisional hernias, there were differing opinions about levels of postoperative physical activity among surgeons (47).

For abdominal exercises after stoma surgery, it is important that the exercises match both the physical capabilities of the patient and the local restrictions applied after surgery. Both restrictions and capabilities change with time after surgery, and exercise progression is important for continuously ensuring that the patient receives the most from his or her exercise efforts. None of the three studies in **Table 1** provide information on abdominal exercises in the immediate postoperative stage, when patients are still hospitalized, and none included exercise progression in their interventions. Thus, there is a need for knowledge of the suitable exercises at different stages after stoma surgery, including the first postoperative days and weeks, as the existing studies begin at discharge or later (46).

With such limited knowledge, both patients and health professionals face uncertainty regarding abdominal exercises after stoma surgery. A recent survey demonstrated a lack of engagement in abdominal exercises (48), but we need further knowledge of this lack and the potential barriers that exist. To better plan and deliver abdominal exercises for patients with a newly formed stoma, we require a better understanding of the patients' perspectives on abdominal exercises.

Abdominal muscles and muscle activity

The abdominal muscles of interest in this PhD project are the rectus abdominis (RA), internal oblique (IO), external oblique (EO), and transversus abdominis muscle (TrA). The RA is located medially and stretches from the pubic bone to the sternum. The EO, IO, and TrA comprise the three layers of muscle in the abdominal wall, encircling the lower part of the torso from the thoracolumbar fascia (49) to the linea alba. In enterostomy procedures, the stoma is usually positioned to pass lateral to or through the RA (36). Colostomies are often on the left side of the abdomen and ileostomies on the right side. Before surgery, stoma care nurses typically mark the site of the stoma to make the stoma visible and accessible for the patient during stoma care.

There are different types of muscle contractions (50), which are characterized by the change in muscle length. The muscle changes length in concentric contractions (shortening) and eccentric contractions (lengthening). In isometric contractions, the muscle stays the same length but with an increase in muscle tension. The physiology of muscle contraction includes a depolarization and repolarization of motor units (51), leading to detectable electrical changes – motor unit action potentials – which can be measured with electromyography (EMG) (51, 52). This measured EMG signal is the sum of the motor unit action potentials from the muscle(s) at the anatomical site of the measurement, a measure of muscle activity. The TrA muscles are believed to stabilize the trunk of the body during movement of the extremities (53, 54), and TrA muscle activity is a proxy of this stabilizing function.

Little is known about the impact that abdominal surgery and a defect in the abdominal wall caused by a stoma may have on the function of the abdominal muscles. Stoma surgery may affect the long-term ability of TrA muscles to contract on the side of the body where the stoma is placed (55). A study using CT found alterations to the RA muscle in patients with a colostomy (56), with a thickening on the stoma side. Bed rest and deconditioning after surgery are also commonly associated with an overall decrease in muscle function (57, 58). Thus, there seems to be an appreciation that stoma surgery can impact the abdominal wall in ways that are not totally clear (59).

Rationale

Parastomal bulging is considered a common complication, but the estimates in the existing literature have not been sufficiently precise and have focused on parastomal hernias, a subset of parastomal bulges. A more precise estimation of the incidence of parastomal bulging would make the size of the problem clearer. Additionally, the options for preventing or treating parastomal bulges are limited (23). Abdominal exercise is a potential preventive measure with interesting results, but it has only weak evidence so far. To understand the benefits and harms of abdominal exercises for parastomal bulging, an RCT is necessary. For exercise intervention to better succeed at preventing parastomal bulges, we need more information on the choice and progression of exercises as well as the patients' perspective on abdominal exercises after stoma surgery.

Objectives

Overall objectives

The overall objectives of this PhD project are as follows:

- Determine the incidence of parastomal bulges after the creation of an ileostomy or colostomy.
- Qualify the choice of exercises and explore patients' perspectives of abdominal exercises after stoma surgery for future use in research on the effect of abdominal exercises for the prevention of parastomal bulging and in clinical practice.

Specific objectives

The specific aims of the studies described in the three included papers are as follows:

Study I: To investigate the incidence of parastomal bulging in patients with an ileostomy or colostomy in the first year after surgery, as well as the association between surgery- and patient-related variables and the risk of parastomal bulging.

Study II: To evaluate the feasibility of abdominal exercises after stoma creation on the parameters of muscle activity, pain, discomfort, and the difficulty of performing the exercises.

Study III: To investigate patients' experiences with and attitude toward exercises for the abdominal muscles after stoma surgery.

Methods

This PhD project was part of the project, *PreParE - Prevention of Parastomal Bulging in Patients with an Enterostoma*, consisting of two PhD projects with a joint steering group. The methods used in the PhD project are described in this section. A more in-depth description of the methods can be found in each of the papers under **Appendices**.

Study design

The PhD project consisted of three studies: (I) a register-based study on the incidence and risk factors of parastomal bulging; (II) a descriptive study evaluating abdominal exercises at different time points after stoma surgery; and (III) a qualitative study where patients were interviewed about their experiences and opinions on abdominal exercises after stoma surgery. A brief overview of the three studies is shown in **Table 2**. Participants for Study III were recruited from the participants in Study II.

Table 2. Overview of the PhD project			
Study	**Study I**	**Study II**	**Study III**
Aim (shortened)	To investigate the incidence and risk factors for parastomal bulging in patients with an ileostomy or colostomy	To investigate the feasibility of exercises for the abdominal muscles after colostomy or ileostomy creation	To explore experiences with and attitude toward abdominal exercises after stoma surgery
Study design	Register-based	Descriptive	Qualitative
Setting	Capital Region of Denmark	Inpatient wards and outpatient clinics at Rigshospitalet and Herlev Hospital	Inpatient wards and outpatient clinics at Rigshospitalet and Herlev Hospital
Population	Patients with a newly created ileostomy or colostomy	Patients who had undergone stoma creation in the last 12 weeks	Patients from Study II
Outcome measures	• Cumulative incidence of parastomal bulging • Risk of parastomal bulging	• Muscle activity • Pain • Discomfort • Difficulty • Muscle thickness • Adverse events	Not applicable

Setting

The PhD project was a clinical research project conducted at two hospitals – Herlev Hospital and Rigshospitalet – in the Capital Region of Denmark. Five hospitals in the region routinely perform stoma surgery and have a stoma care function, including Rigshospitalet and Herlev Hospital. Most patients with a newly created stoma are seen by stoma care nurses while still hospitalized and invited to follow-up visits in the outpatient clinic following discharge. Patients are followed in stoma care clinics for a year after surgery.

Stoma care nurses in the Capital Region of Denmark are responsible for the registration of patient data in the Danish Stoma Database Capital Region ("Stoma Database"), a clinical database established in 2007 (7). The Stoma Database includes clinical variables from the time of surgery on all patients with a stoma in the region. Complications and other variables, including parastomal bulges, are registered at follow-up visits to the stoma care clinics.

Study I was conducted using the Stoma Database, and Studies II and III were conducted at Rigshospitalet and Herlev Hospital.

Study I

Participants

For Study I, patients in the Stoma Database (2007-2016) with ileostomies and colostomies were eligible for inclusion. Patients with no data from their follow-up visits were excluded, as they would not be able to contribute meaningfully to the planned analyses.

Variables and data sources

The study included data from both the Stoma Database and the Danish Anaesthesia Database (60) (**Figure 1**). The primary outcome was parastomal bulging, assessed clinically by stoma care nurses and registered in the Stoma Database at a follow-up visit. Stoma care nurses in the Capital Region of Denmark assess if a parastomal bulge is present at regular visits beginning around postoperative day 30, typically continuing up to a year after surgery. Other variables from the Stoma Database included age, gender, body mass index, diagnosis, ileostomy/colostomy, laparoscopy/open surgery, elective/acute surgery, stoma marking, prophylactic peristomal mesh, and placement through a separate incision in laparoscopic surgeries. From the Danish Anaesthesia Database, the variables smoking status, alcohol consumption, and American Society of Anesthesiologists physical status classification system (ASA score) (61) were included. Data from the two databases were extracted and delivered by the databases and linked with the Danish Central Person Register numbers and date of surgery.

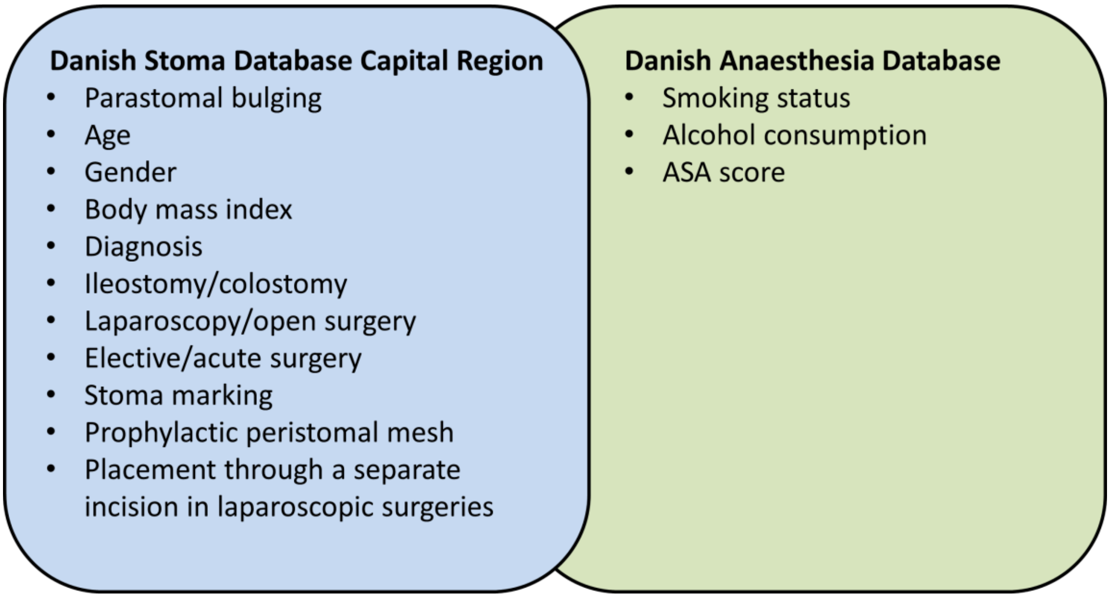


Figure 1. Included variables from the two databases.

Statistical methods

Statistical survival analysis was used to estimate the cumulative incidence of parastomal bulges within the first year after surgery. We plotted the standard Kaplan-Meier estimate, as well as an estimate with death and stoma reversal as “competing risks” (62-64). Patients who had died or had their stoma reversed before developing a parastomal bulge were no longer at risk of developing one. The competing risks account for this factor statistically, providing a more reliable estimate of the incidence of parastomal bulging.

Cox regression models (65, 66) were used in the analysis of risk factors. Estimates of the risk of parastomal bulging were calculated using multivariable models to adjust for confounding from the other included variables. This approach to analyzing the risk factors included many variables and was exploratory in nature; thus, the results should be interpreted with caution. Support from existing literature or future studies is needed to draw firm conclusions on the association between the included variables and the risk of getting a parastomal bulge.

Study II

Participants

Participants for Study II were recruited from patients who had received an ileostomy or colostomy at either Rigshospitalet or Herlev Hospital within the 12 weeks before the day of participation. All the participants joined a single individual test session, during which they performed a set of exercises and underwent EMG and ultrasound measurements. Participants were placed in one of three groups depending on the number of days since their stoma was surgically created (**Figure 2**): the Early group (0–2 weeks after surgery); Intermediate group (2–6 weeks after surgery); or Late group (6–12 weeks after surgery). Abdominal exercises differed between the groups to account for the differences in physical capabilities at the various stages after surgery. In each group, the participants performed a set of 10 or 11 exercises.

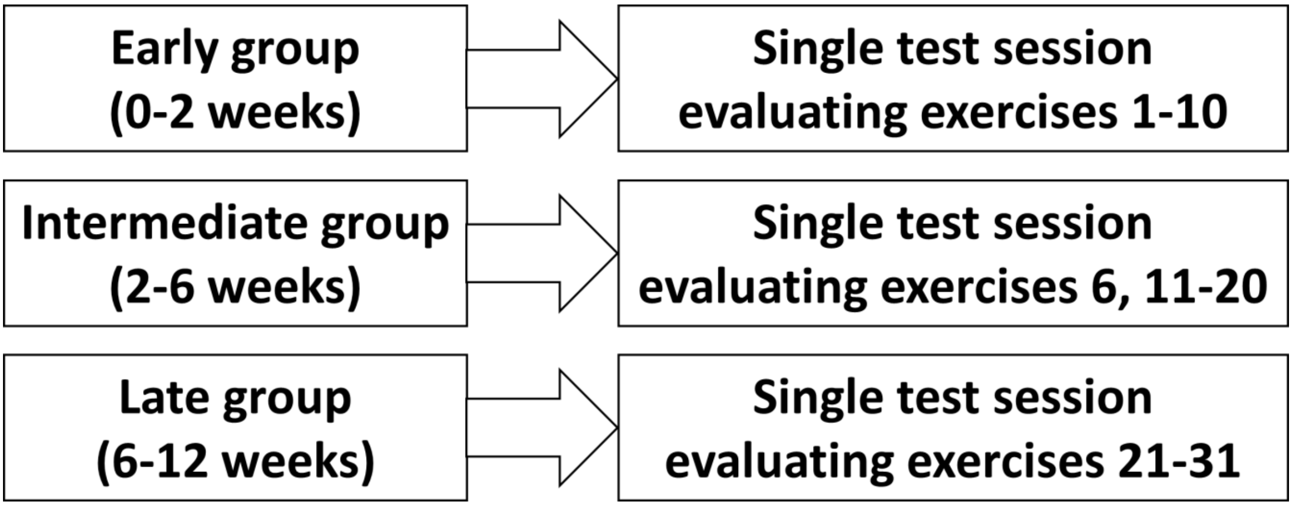


Figure 2. Overview of the design for Study II. Exercises are shown in Figures 5–7. (Figure from Paper II)

Patients were recruited from both outpatient clinics and inpatient wards at the two hospital sites, Rigshospitalet and Herlev Hospital. Stoma care nurses and nurses in the respective departments helped identify potential participants from the patients having a new stoma or coming to the stoma care clinic for a follow-up visit. Patients where included in Study II based on the following eligibility criteria, with additional criteria for the participants in the Early group based on the Danish Society of Anaesthesiology and Intensive Care Medicine (DASAIM) recommendation for discharge criteria (67).

Inclusion criteria

- Adults, 18 years old or older
- Ileostomy or colostomy created within the number of days prior as follows:
  - Early group: 1–14 days
  - Intermediate group: 15–42 days
  - Late group: 43–84 days
- Approval of inclusion from a colorectal surgeon at the corresponding hospital based on an assessment of the participant’s complications, medical condition, and general condition.
- Early group only, DASAIM criteria (67):
  - Respirations per minute: 10–30
  - Saturation: > 89%
  - Systolic blood pressure: 90–220 mmHg
  - Resting heart rate: 50–120
  - Awake and aware
  - Subjective pain rating on a 10-point numeric rating scale (68): < 3
  - No nausea or mild nausea
- Intermediate group and Late group:
  - Pain at tolerable level, subjectively
  - Nausea at tolerable level, subjectively

Exclusion criteria

- Pregnancy
- Breast feeding
- Medical condition prohibiting the performance of any abdominal exercises
- Complications or restrictions prohibiting the exercises
- Cognitively unable to give informed consent

- Unable to achieve a sitting position with minimal help from one person and sit without support

Potential participants, including some who had yet to undergo surgery, were assessed for eligibility and provided oral and written information. All the participants gave their written consent prior to participating. We aimed for 10 participants or more in each group, which was believed to provide a reasonable description of muscle activity in the chosen abdominal exercises.

Test sessions: abdominal exercises and outcome measurements

The test sessions lasted between 1 and 1.5 hours. The sessions started with the collection of demographic information on the participant. From there, the test sessions followed this procedure:

1. Bilateral measurement of TrA thickness, resting and active, with ultrasound imaging.
2. Preparation of EMG measurements.
3. Performance of up to 11 different abdominal exercises while recording EMG signals and the registration of pain, discomfort, and difficulty for each exercise.

Ultrasound measurements of TrA thickness

TrA thickness was measured bilaterally with ultrasound imaging as the participant lay in a crook position. Participants were instructed in an abdominal drawing in maneuver (ADIM) beforehand (55, 69-71), which serves to voluntarily activate the TrA. Three images were taken during both rest and activity (ADIM) on each side of the abdomen (stoma and opposite side), resulting in four sets of three images for each participant (**Figure 3**). The TrA thickness of each image was measured immediately after the test session had ended. The mean of each set of three measurements was used to assess resting TrA thickness, active TrA thickness, and contraction ratio, which was calculated as the active thickness divided by the resting thickness (70, 72).

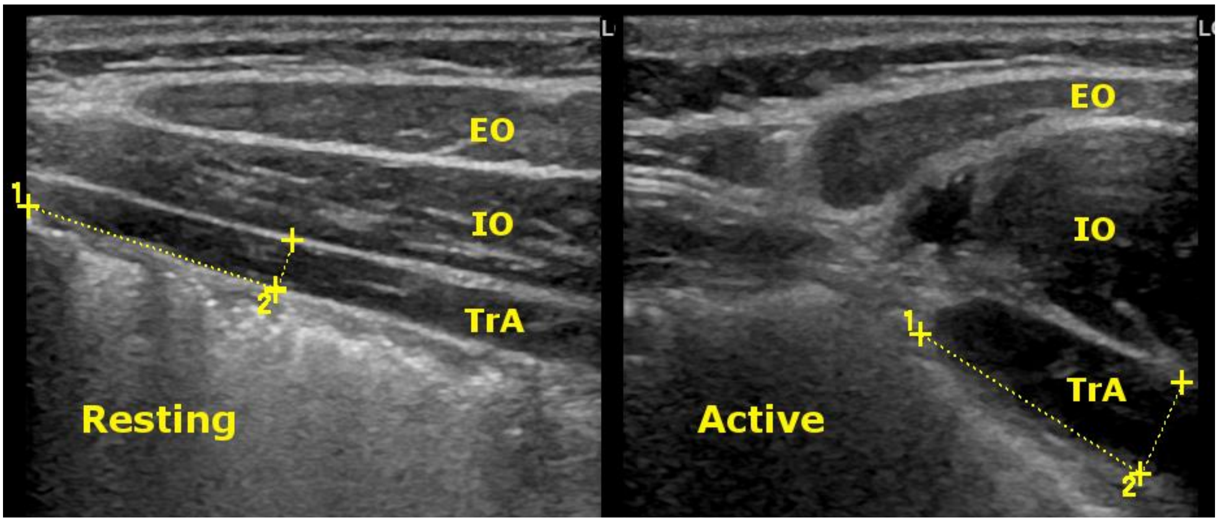


Figure 3. Measurement of the transversus abdominis muscle (TrA) with ultrasound imaging. Resting thickness is shown on the left side, active thickness on the right. Other abdominal muscles – external oblique (EO) and internal oblique (IO) – are also shown. (Figure from Paper II)

EMG preparation

EMG measurements were prepared prior to exercise performance based on a procedure specified and piloted beforehand. The procedure involved the preparation of the skin and placement of surface electrodes in pairs of two with an interelectrode distance of 2 centimeters (51, 73). Electrodes were placed to record the EMG signals of the RA, EO, IO, and TrA muscles on both sides of the abdomen. The sites for electrode placement – shown in **Figure 4** – were specified beforehand based on prior EMG studies and common practice (51, 74-77). Signals from the IO and TrA muscles were measured with the same electrode pair, as the combined signals from the muscles were recorded at this position (74-76, 78). The signal quality was inspected, and any necessary steps of the preparation procedure were repeated before moving on to the exercises.

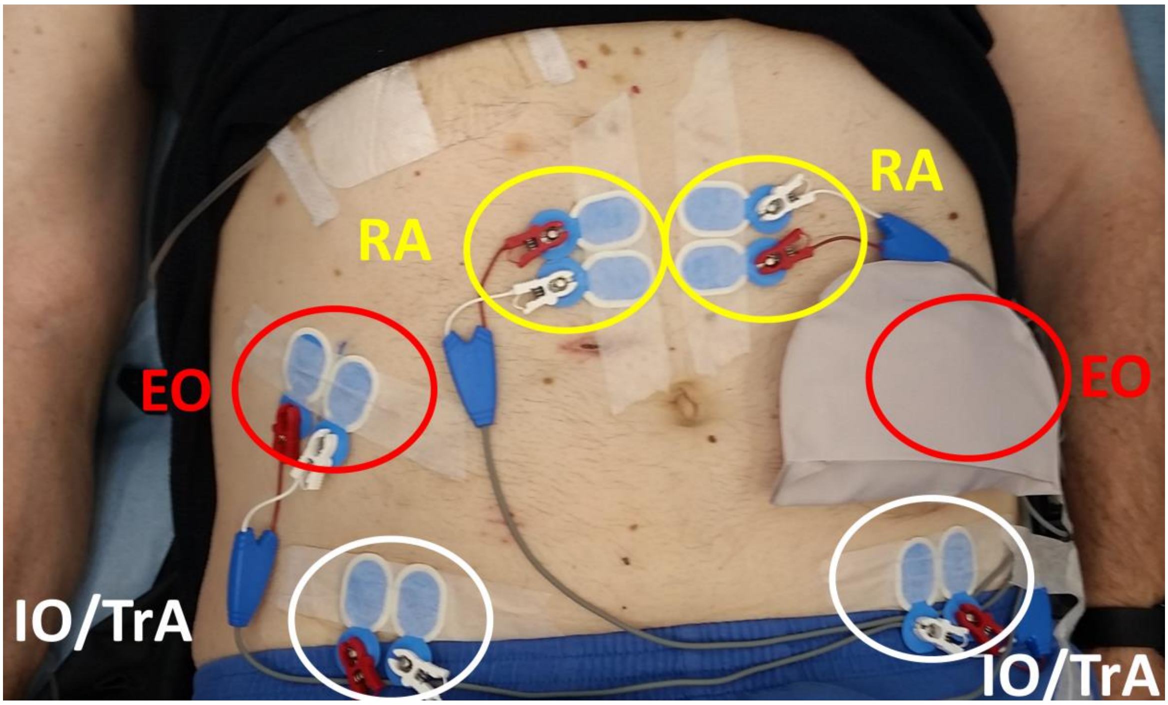


Figure 4. Placement of surface electrodes for EMG measurements. RA = rectus abdominus muscle, EO = external oblique muscle, IO/TrA = internal oblique and transversus abdominis muscles. The electrode for the left EO is placed behind the stoma bag and not visible in this image.

Abdominal exercises

The patient's group determined the abdominal exercises they had to perform. **Figures 5–7** show the exercises performed in each group. After EMG preparation, the participants performed one exercise at a time. They were first shown and instructed in the exercise and asked to do a practice attempt. If the participant performed the exercise as intended, they proceeded to a real attempt with the recording of EMG signals. Depending on the exercise, participants did one or two repetitions of each exercise during EMG recording. Immediately after, participants were asked to rate pain on a 0–10 numeric rating scale (68), discomfort on a 0–10 numeric rating scale (68), and difficulty on a 5-point Likert scale from "1, very easy" to "5, very difficult." The PhD student registered his assessment of the patient's difficulty on the same 1–5 scale. The test session then continued with the next exercise.

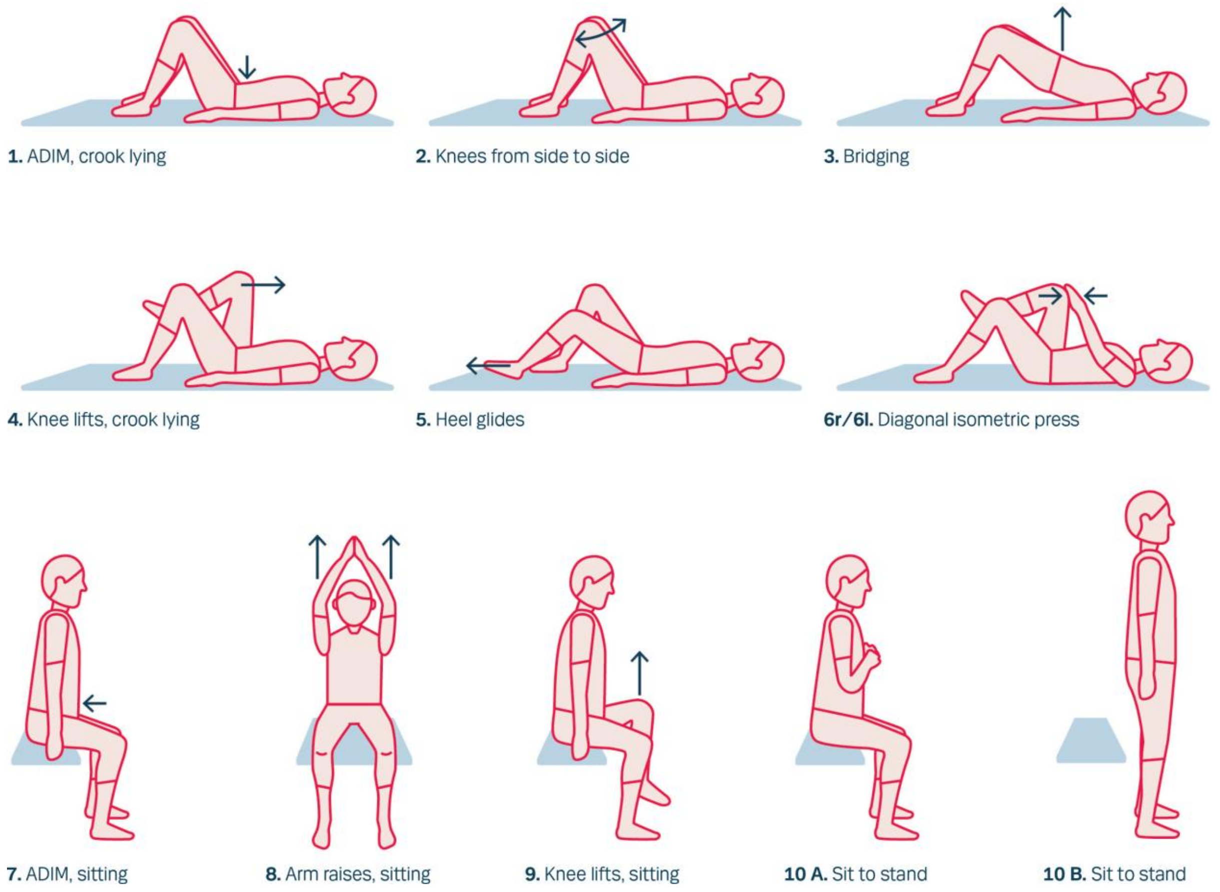


Figure 5. Early group exercises. (Figure from Paper II)

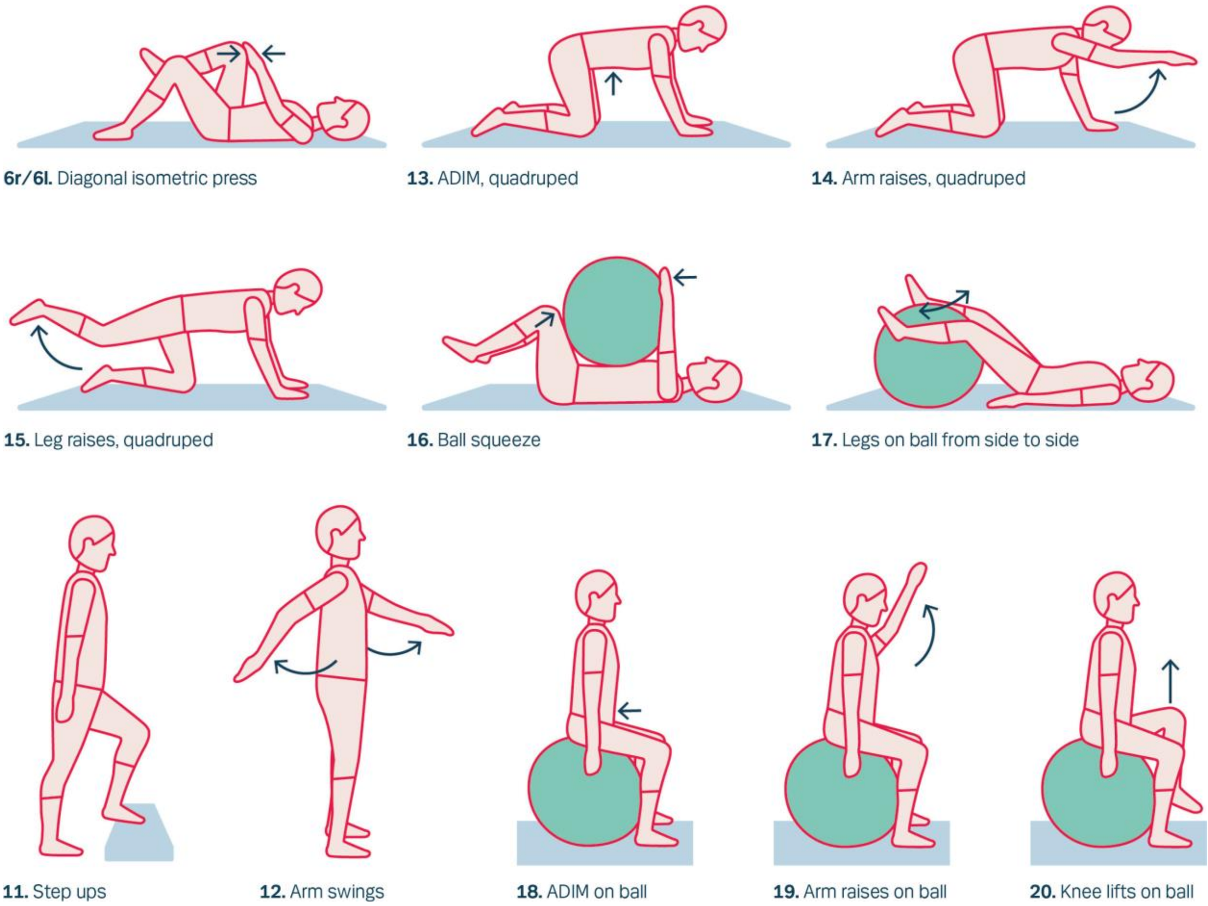


Figure 6. Intermediate group exercises. (Figure from Paper II)

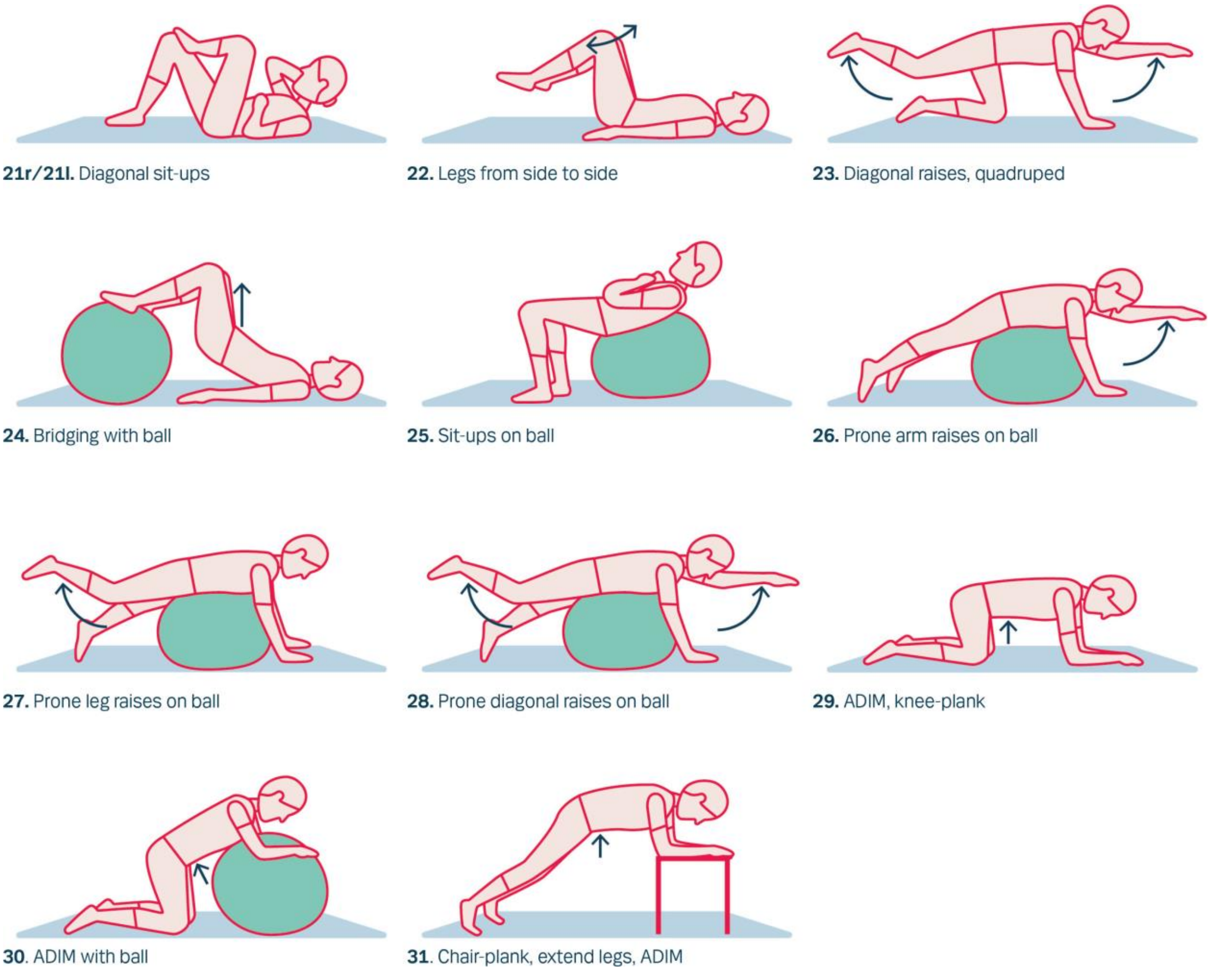


Figure 7. Late group exercises. (Figure from Paper II)

Analysis

The recorded EMG signals were processed after participant recruitment had concluded; artifacts (external noise on the signal) were removed, and the signals were filtered (high-frequency signals minimized) and rectified (amplitudes converted to the same direction) to create “linear envelopes” (79). We used a dichotomous outcome of “muscle activity or not” based on the predetermined onset criteria of mean baseline (resting) activity plus six standard deviations for a duration of at least 0.2 seconds (80, 81). For each muscle in each exercise, it was determined if the recorded muscle activity (signal) reached the onset criteria. Muscle activity, TrA thickness, and the clinical outcomes of pain, discomfort, and difficulty were presented descriptively.

Study III

Participants

Study III was built to include patients who had participated in Study II, featuring an individual semi-structured interview. Thus, participants in Study III had all recently undergone stoma surgery and attempted abdominal exercises as part of Study II. Recruitment for Study III started about halfway through Study II and was based on the following eligibility criteria:

- Participation in Study II
- Willing to participate in an interview
- Danish language skills
- Physically able to endure an interview of about 30 minutes
- Cognitively able to understand questions and respond meaningfully

The goal was to include 10–15 participants. The participants received written and oral information specific to Study III, and all signed a written consent form. The recruitment from Study II through Study III is shown in **Figure 8**.

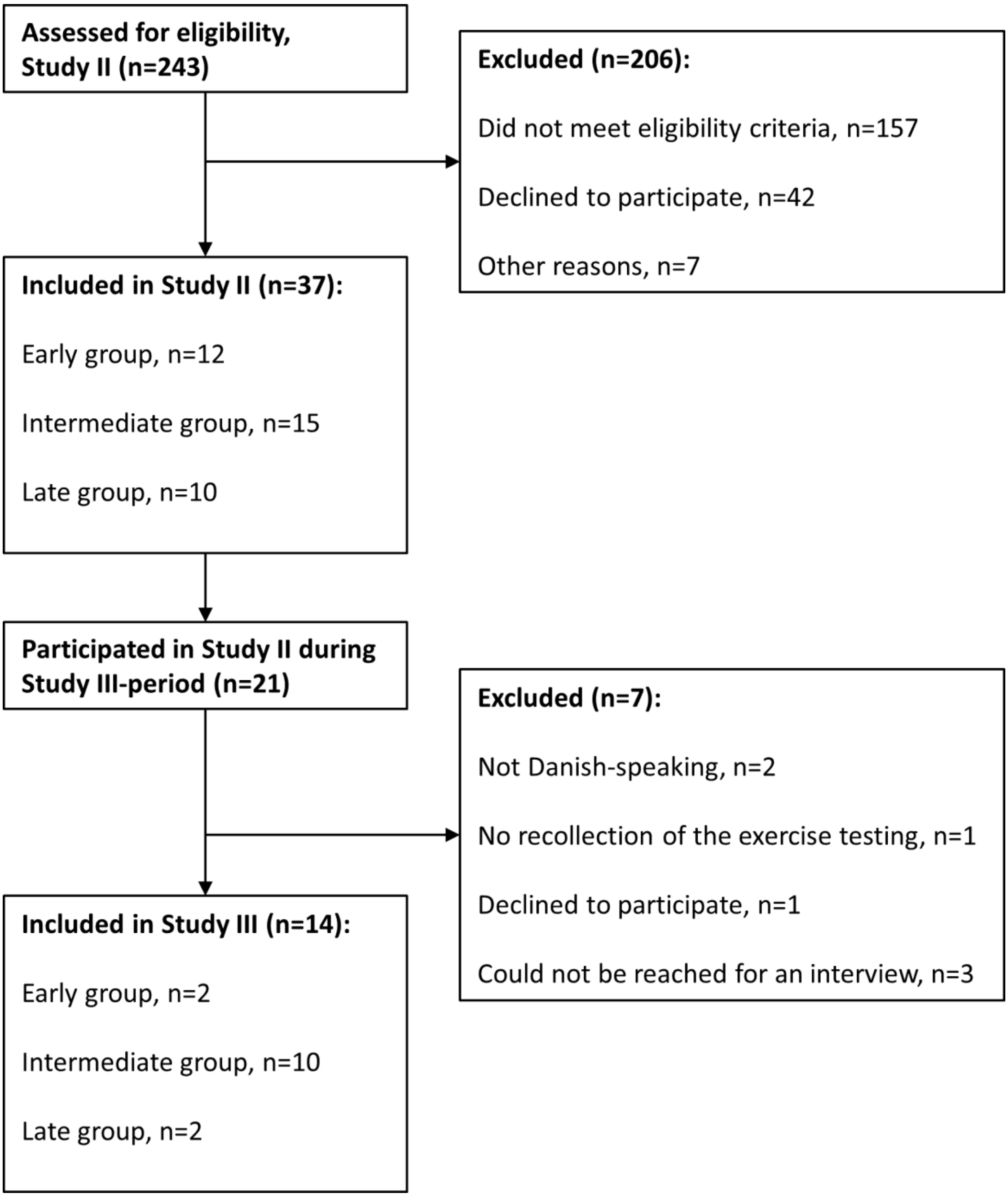


Figure 8. Flow diagram, Study II and Study III.

Data collection and analysis

A descriptive generic qualitative research approach (82) was used in Study III. Semi-structured interviews were conducted by the PhD student in a hospital setting. The interview guide used for the interviews was updated throughout the study period as interviews were conducted and the PhD student received feedback on interviews from supervisors. The PhD student's subjective preconceptions were documented prior to the interviews and considered during the interviews, analysis, and manuscript writing. Interviews were recorded and later transcribed to text verbatim (83). These transcriptions were analyzed with inductive content analysis (84-86), which is suitable for the analysis of manifest content (87).

Results

A summary of the results from each paper is presented in this section. A more comprehensive description of the results can be found in each of the papers under **Appendices**.

Study I

Study I had a sample of 5019 patients with a median age of 66 years old; 47% were women and 58% with cancer. Furthermore, 55% percent of the participants underwent surgery with creation of a colostomy, while the rest had an ileostomy.

Cumulative incidence

A plot of the cumulative incidence of parastomal bulging is shown in **Figure 9**. Based on the competing risks estimate, the cumulative incidence of parastomal bulging was 36.2%, with a 95% confidence interval (CI) of 34.4–38.0% 400 days after stoma surgery. Alternatively, there was a 36.2% probability of developing a parastomal bulge within the first 400 days after surgery. Furthermore, 100 days after surgery, the cumulative incidence was 12.4% with a 95% CI of 11.4%–13.4%.

Risk factors for parastomal bulging

For the exploratory analysis of risk factors, **Table 3** shows the adjusted risk estimates in the form of hazard ratios with 95% CIs. Hazard ratio values of 1 indicate no difference in risk between having or not having the exposure variable, such as the variables ASA score, smoking, type of surgery (elective/emergency), body mass index, and stoma marking, where adjusted analysis showed no difference in risk. An increased risk of a parastomal bulge was found for advanced age, male gender, colostomy, laparoscopy, diverticulitis, and alcohol consumption. Decreased risk was found for placement in a separate incision, inflammatory bowel diseases, and peristomal mesh. For peristomal mesh and alcohol intake, the CIs of the adjusted estimates contained values very close to 1, demonstrating a minimal increase or decrease in risk within the range of likely values (88, 89).

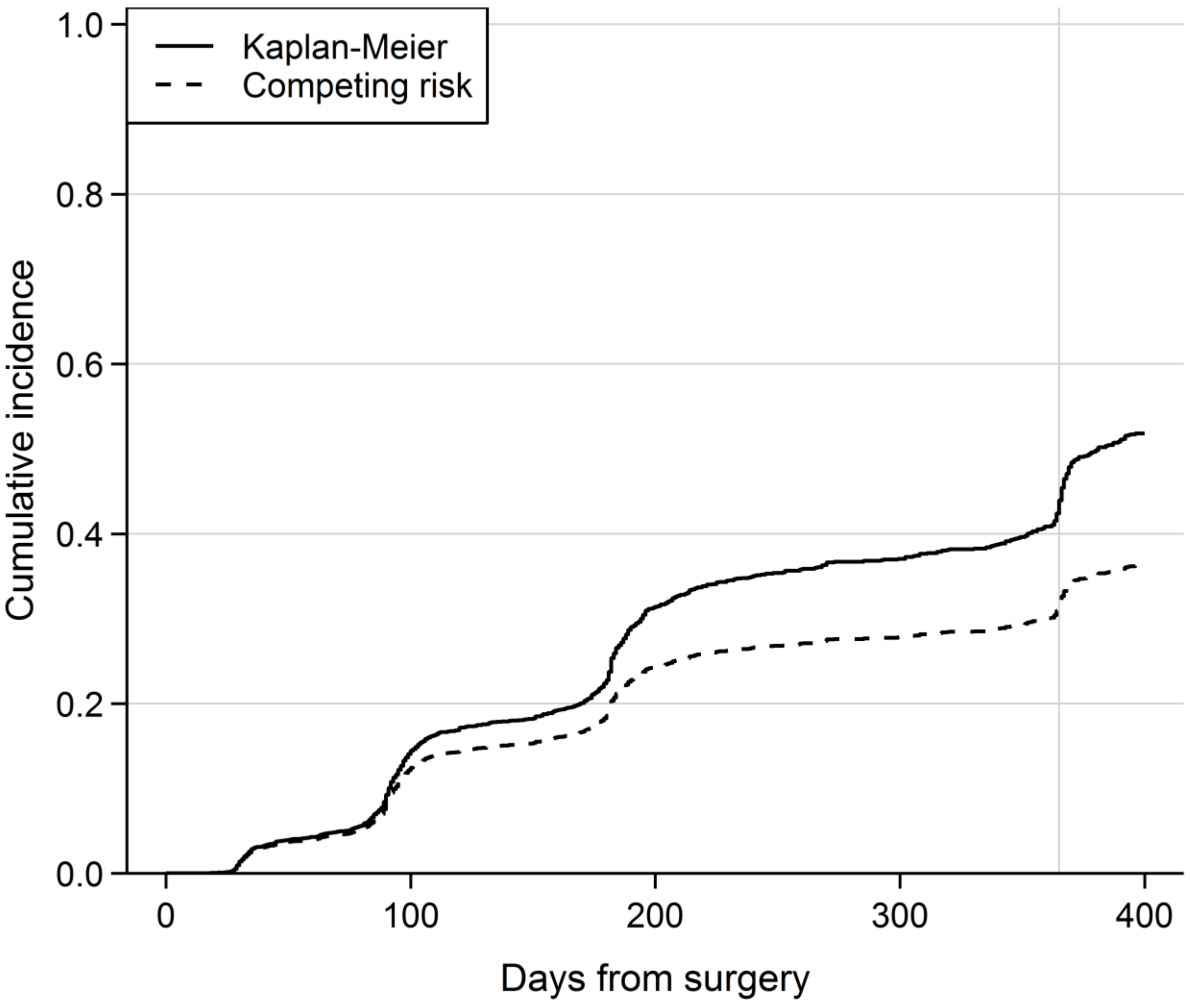


Figure 9. Cumulative incidence of parastomal bulging 400 days after stoma surgery. The unbroken line represents a standard Kaplan-Meier estimate; the dotted line is the estimate using death and stoma reversal as competing risks. (Figure from Paper I)

Table 3. Risk factors for parastomal bulging (Table modified from Paper I)

Variables	Adjusted hazard ratio (95% CI)
Age, years	1.02 (1.01; 1.02)
Male gender	1.6 (1.4; 1.9)
Diagnosis	
Cancer	1 (ref)
Inflammatory bowel disease	0.6 (0.4; 0.9)
Diverticulitis	1.4 (1.1; 1.8)
Other	1.1 (0.9; 1.3)
Body mass index	
<18.5	0.9 (0.7; 1.1)
18.5-24.99	1 (ref)
25.0-29.99	1.0 (0.9; 1.2)
30.0-34.99	0.9 (0.7; 1.2)
≥35.0	0.8 (0.5; 1.4)
ASA score	
I	1 (ref)
II	0.9 (0.8; 1.2)
III	1.0 (0.9; 1.2)
IV+	0.8 (0.5; 1.4)
Smoking status	
Smoker	1.0 (0.8; 1.6)
Non-smoker (including former smokers)	1 (ref)
Alcohol consumption	
0 Danish standard drinks per week	1 (ref)
1-21 Danish standard drinks per week	1.2 (1.0; 1.3)
>21 Danish standard drinks per week	1.4 (1.0; 1.7)
Mode of surgery	
Open surgery	1 (ref)
Laparoscopy	1.4 (1.2; 1.6)
Type of surgery	
Elective	1 (ref)
Emergency	1.1 (0.9; 1.3)

Table 3. (*continued*)

Variables	Adjusted hazard ratio (95% CI)
Type of stoma	
Ileostomy	1 (ref)
Colostomy	1.4 (1.2; 1.7)
Preoperative stoma marking	
Yes	1.1 (0.9; 1.3)
No	1 (ref)
Peristomal mesh placed (subgroup: sigmoid colostomies)	
Yes	0.7 (0.6;1.0)
No	1 (ref)
Stoma placed through separate incision (subgroup: laparoscopic surgery)	
Yes	1 (ref)
No	1.4 (1.1; 2.0)

CI = confidence interval, ref = reference, ASA = American Society of Anesthesiologists physical status classification system.

Study II

Thirty-seven participants were included in Study II (**Figure 8**), divided among the three groups with 12 in the Early group, 15 in the Intermediate group, and 10 in the Late group. The median age was 68 years across the three groups, and there were 18 (49%) female participants. Twenty-one participants (57%) had a colostomy, and 30 of the 37 participants (81%) had a cancer diagnosis.

Muscle activity

Figure 10 shows muscle activity for each muscle in each exercise, expressed as the percentage of participants with muscle activity reaching the onset criteria. The chart is color-coded so that red denotes a low percentage with muscle activity reaching onset criteria, and green denotes a high percentage. In the Early group, the muscle activity of the EO, IO, or TrA muscles was measured in up to half the participants in some exercises, but in some cases, only for a single muscle. The activity of the RA muscle was measured in less than 20% of the participants for all Early group exercises. In the Intermediate group, there were higher percentages with abdominal muscle activity than in the Early group, overall. For some exercises ("6. Diagonal isometric press" and "16. Ball squeeze," **Figure 6**), a high percentage with muscle activity was measured for all the muscles, including the RA muscles that were sparsely activated in the Early group. For Exercise 6 – performed in both the Early group and the Intermediate group – activity was measured in more participants in the Intermediate group. In the Late group, multiple exercises stood out positively with extremely high percentages of muscle activity across all muscles ("21. Diagonal sit-ups," "22. Legs from side to side," "25. Sit-ups on ball," and "31. Chair-plank, extend legs, ADIM," **Figure 7**).

EARLY GROUP

Ex.	RA-l	RA-r	EO-l	EO-r	IO/TrA-l	IO/TrA-r
1	0%	9%	33%	20%	25%	13%
2	0%	0%	17%	10%	17%	13%
3	0%	0%	0%	10%	17%	0%
4	0%	0%	17%	0%	42%	33%
5	0%	9%	8%	10%	25%	57%
6r	17%	9%	17%	50%	50%	14%
6l	9%	10%	45%	11%	18%	40%
7	0%	0%	42%	30%	42%	25%
8	17%	10%	42%	40%	17%	25%
9	0%	0%	18%	22%	60%	50%
10	18%	10%	27%	33%	11%	57%

INTERMEDIATE GROUP

Ex.	RA-l	RA-r	EO-l	EO-r	IO/TrA-l	IO/TrA-r
6r	69%	87%	85%	73%	92%	53%
6l	77%	67%	85%	53%	54%	87%
11	0%	9%	45%	36%	55%	73%
12	8%	20%	38%	7%	38%	36%
13	25%	29%	46%	36%	33%	64%
14	8%	7%	62%	43%	33%	46%
15	0%	0%	38%	15%	50%	36%
16	82%	92%	100%	100%	91%	83%
17	31%	29%	54%	31%	31%	36%
18	25%	14%	46%	38%	58%	50%
19	25%	14%	31%	23%	50%	21%
20	36%	46%	75%	67%	91%	69%

LATE GROUP

Ex.	RA-l	RA-r	EO-l	EO-r	IO/TrA-l	IO/TrA-r
21r	100%	100%	100%	100%	80%	56%
21l	100%	100%	100%	100%	80%	78%
22	100%	100%	100%	90%	70%	67%
23	30%	40%	50%	40%	50%	50%
24	30%	50%	30%	30%	30%	25%
25	100%	100%	100%	100%	100%	100%
26	44%	56%	78%	44%	44%	38%
27	38%	63%	50%	38%	63%	29%
28	29%	43%	71%	38%	57%	67%
29	40%	60%	70%	40%	40%	38%
30	40%	60%	60%	50%	80%	50%
31	100%	100%	100%	100%	80%	75%

Figure 10. For each exercise and muscle the percentage of participants with muscle activity meeting the onset criteria is presented. Ex. = exercise corresponding to Figures 5–7, RA-l = left side rectus abdominis, RA-r = right side rectus abdominis, EO-l = left side external oblique, EO-r = right side external oblique, IO/TrA-l = left side internal oblique and transversus abdominis, IO/TrA-r = right side internal oblique and transversus abdominis. (Figure from Paper II)

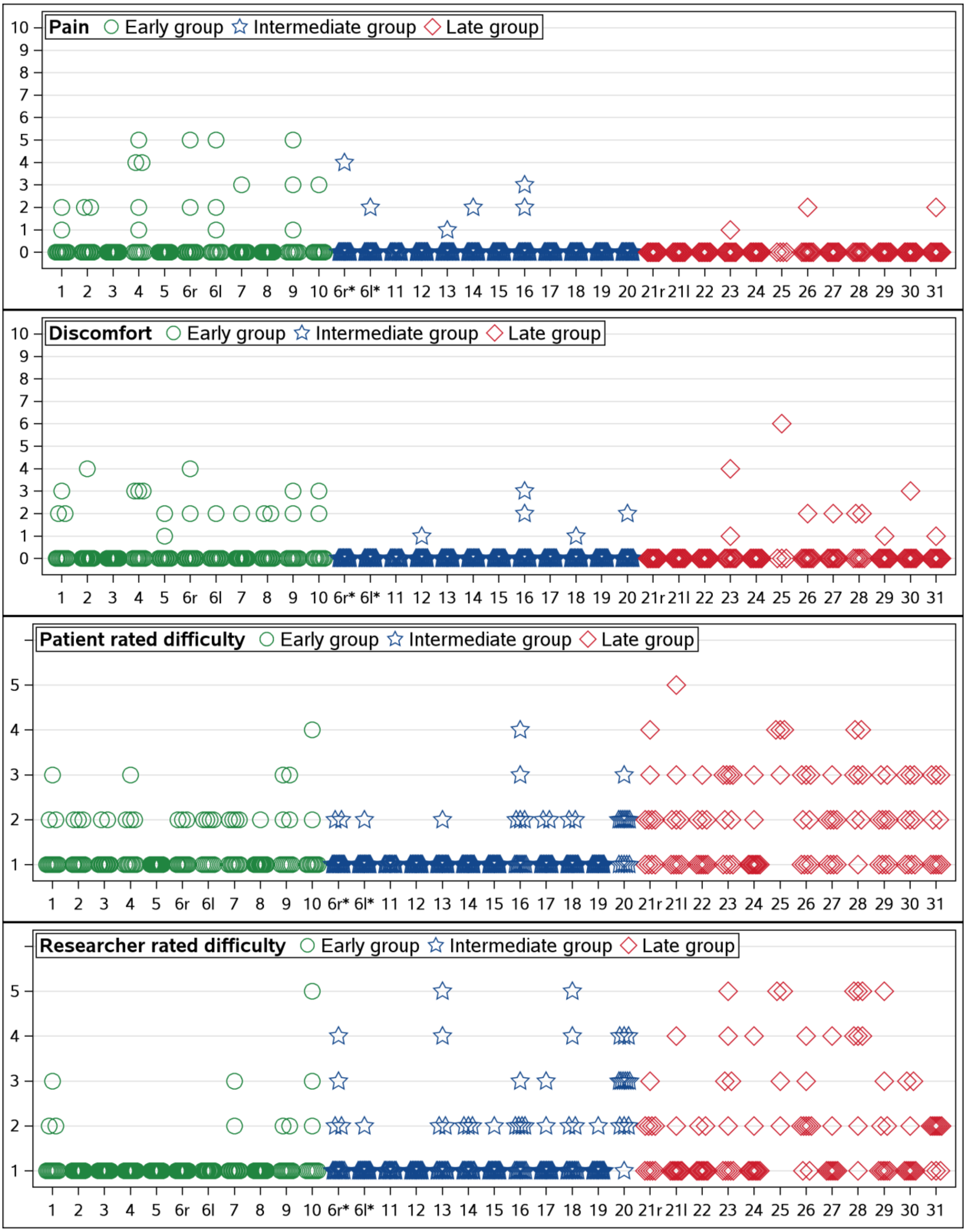


Figure 11. Ratings of pain, discomfort, patient-rated difficulty, and researcher-rated difficulty for each exercise. Numbers on x-axis correspond to the exercises shown in Figures 5–7. (Figure from Paper II)

Pain, discomfort, and difficulty

Figure 11 shows the ratings of pain, discomfort, patient-rated difficulty, and researcher-rated difficulty. The three groups are represented with different symbols and colors: Early group = green circles; Intermediate group = blue stars; and Late group = red diamonds. Pain and discomfort ratings were low. For exercises in all the groups, the median rating of both pain and discomfort was 0, meaning that for each exercise, most of the participants experienced no pain or discomfort. Pain and discomfort ratings above 0 appeared more frequently in the Early group than the other groups. The level of difficulty, as rated by both participants and the researcher, was highest in the Late group. Exercise 25 "Sit-ups on ball" (**Figure 7**) reached 100% with muscle activity for all muscles (**Figure 10**), but only 4 of 10 participants in the Late group were able to perform it, as the exercise was too difficult for the majority.

TrA thickness

Table 4 shows the resting thickness, active thickness, and contraction ratio of the stoma- and opposite-side TrA muscle. For each measure of TrA thickness, results were similar on the stoma and opposite side.

Table 4. Transversus abdominis thickness (Table modified from Paper II)

Outcome	Stoma side	Opposite side
Resting thickness (mm), median [IQR]	3.1 [2.7; 4.4]	3.3 [2.7; 5.1]
Active thickness (mm), median [IQR]	4.9 [3.7; 6.5]	4.8 [3.9; 6.8]
Contraction ratio, median [IQR]	1.35 [1.20; 1.53]	1.43 [1.26; 1.58]

mm = millimeters, IQR = interquartile range

Study III

Fourteen participants were included in Study III from the 21 participating in Study II during the recruitment period for Study III (**Figure 8**). Of the 14 participants, 2 had been in the Early group, 10 in the Intermediate group, and 2 in the Late group in Study II. The participants' median age was 67.5 years old (ranging 20–73 years), and the median interview duration was 24.5 minutes (ranging 15–37 minutes).

Findings

Inductive content analysis resulted in four categories (**Table 5**).

Table 5. Categories and subcategories

Categories	**Subcategories**
The attitude toward abdominal exercises is positive	
Treatment and illness form barriers to abdominal exercises	• Stoma surgery causes concern about doing abdominal exercises • Postoperative recovery and treatment pose challenges to abdominal exercises
Wish for help with abdominal exercises after stoma surgery	• A wish for guidance with abdominal exercises • Preferences for delivery of abdominal exercises vary
Abdominal exercises are experienced as being easy	

The attitude toward abdominal exercises is positive

Participants in Study III had a positive perception of the abdominal exercise and expected it to be beneficial for their physical function, physical appearance, and wellbeing. The participants mentioned being motivated for abdominal exercise by being able to measure and track their physical performance, and others were motivated to be prepared, physically, for another abdominal surgery. The documentation of an effect from abdominal exercises was important to the participants.

Treatment and illness form barriers to abdominal exercises

The participants described barriers to exercise as concerns regarding the stoma or intestines after surgery, as well as complications after surgery, chemotherapy, or practical issues.

> "The following week, I wasn't feeling very well, so I wouldn't have been able to do [abdominal exercises] … I was just lying there, waiting to throw up all the time. Then you don't start doing something like that."
> (*Male participant, 61*)

Wish for help with abdominal exercises after stoma surgery

Many expressed a need for guidance with abdominal exercises while having a stoma. Some needed help starting, while others had trouble identifying the exercises suitable for them. Occasionally, the need for help was tied to concerns or uncertainties over stoma or abdominal surgery. Participants had differing preferences on the delivery of abdominal exercises, particularly in relation to group-based exercise. Exercise starting 2–3 weeks after surgery was preferred, as it would allow surgical staples to be removed first.

Abdominal exercises are experienced as being easy

Overall, abdominal exercises were thought to be easy or sometimes boring.

> "I think that things like this [abdominal exercises] are such a drag, so boring you wouldn't believe it." *(Male participant, 67)*

A few participants questioned the possible benefit of doing abdominal exercises. The participants managed their stoma during exercises themselves, and the stoma was seldom in the way. Exercises sitting or lying on an exercise ball caused balance problems for some, making them unpleasant. Participants liked Exercises 6 "Diagonal isometric press" and 16 "Ball squeeze" (**Figures 5–6**), finding it positive if they were able to put force into the movement and feel the abdominal muscles being used.

Discussion

The overall objectives of the PhD project were to determine the incidence of parastomal bulges more precisely, qualify the choice of abdominal exercises, and explore the patients' perspectives of abdominal exercises after stoma surgery. Study I provided an estimate of the incidence of parastomal bulging, and Studies II and III offered informative observations on abdominal exercises and the participants' experience of performing them.

Discussion of key findings

Incidence of parastomal bulging

The finding of a 36.2% cumulative incidence of parastomal bulging 1 year after surgery was within the range of reported estimates (0% to 48%) on parastomal hernias (24-30). Aligned with expectations, parastomal bulges were found to be a common complication. The estimate from Study I should be tangible to patients and practitioners.

A more recent observational study reported a cumulative incidence of parastomal hernias of 7.7% over 5 years (90). This result is much lower than our finding, but there were major differences in how the outcome of interest was assessed. Patients in the Stoma Database were systematically assessed for parastomal bulging at scheduled follow-up visits. The study in question used parastomal hernia data from the Swedish National Patient Register (90). In this way, hernias were not systematically assessed, and a subset of asymptomatic hernias were omitted, leading to a lower number of detected events. As in prior studies focused on parastomal hernias, the recent study also omits bulges that are not considered real hernias (21). From a clinical perspective, parastomal bulges are important, as they affect the quality of life of patients (18) and lead to symptoms and problems like altered physical appearance, changing size of the bulge, and unpleasant sensations (91).

Abdominal exercises

Studies II and III touch on several overlapping aspects, and the findings agree in certain areas. The chosen abdominal exercises were perceived as being easy in both interviews and ratings. The increased difficulty in Late group exercises was not captured in interviews, which could have to do with only two interviewees being from the Late group. The findings on barriers to abdominal exercises from illness and adjuvant treatment, which was expressed in the interviews, nuance the clinical ratings by identifying other factors of importance for patients doing abdominal exercises after stoma surgery.

Another agreement between Study II and Study III was exercises with positive traits; exercises that allowed the participants to exert effort were highlighted in the interviews. These exercises, such as “6. Diagonal isometric press” and “16. Ball squeeze” (**Figure 6**), included an isometric contraction that allowed participants to adjust the load, making the exercise as intensive as they could tolerate. Exercises 6 and 16 stood out in the Intermediate group of Study II with high percentages of muscle activity compared to the other exercises performed by that group. It is to be expected that a higher exercise load leads to more muscle activity. In Study II, the high load and isometric nature were characteristics that consistently led to abdominal muscle activity. For the Late group, Exercises 21 “Diagonal sit-ups,” 22 “Legs from side to side,” and 25 “Sit-ups on ball” had high loads from movement of the entire upper or lower body against gravity. Exercise 31 “Chair-plank, extend legs, ADIM,” which also showed high percentages of muscle activity, was the most demanding of the three plank-style exercises (Exercises 29–31, **Figure 7**). Other exercises, such as those in a quadruped starting position (Exercises 13–15 and 23, **Figures 6–7**), were intended to activate the abdominal muscles keeping the trunk stable during the movement of the extremities. Exercise 6 was performed in both the Early and Intermediate group, but with fewer participants reaching the onset criteria in the Early group (**Figure 10**). This result indicates that the time after surgery is related to the ability to activate the abdominal muscles, and it is conceivable that participants in the Intermediate group could work at a higher load in Exercise 6 due to being further in their recovery from surgery.

A review of the three non-randomized trials on abdominal exercises (44-46) shows some similarities in the choice of exercises. The two studies of abdominal exercises after stoma surgery by Thompson and Trainor (44, 45) (**Table 1**) included three exercises starting 3 months after surgery: pelvic tilting, knee rolling, and sit-ups. The knee-rolling exercise is very similar to Exercise 2 “Knees from side to side” (**Figure 5**), which performed poorly in our measurements of muscle activity, but it may have other benefits, such as increased mobility in rotation of the columna. Like the Thompson and Trainor studies (44, 45), Study II included a form of sit-ups in “21. Diagonal sit-ups” (**Figure 7**), which showed positive results for activating the abdominal muscles. The main difference, however, was that exercises were performed beginning 3 months after surgery, which is a late start for an initiative to prevent parastomal bulging, as the cumulative incidence of parastomal bulging found in Study I was 12.4% after 100 days (**Figure 9**). The Association of Stoma Care Nurses UK recommends gentle abdominal exercise starting 3–4 days after surgery (43), and both “knee rolling” and “pelvic tilting” exercises (44, 45) are gentle enough to be considered earlier in the postoperative phase than 3 months.

A move toward the earlier initiation of abdominal exercises is seen in the study by North (46) with the following exercises starting at discharge: ADIM, pelvic tilting, and knee rolling. Both ADIM and knee rolling are similar to the Early group’s Exercises 1 “ADIM, crook lying” and 2 “Knees from side to side” (**Figure 5**). These are gentle exercises, and muscle activity was measured in few patients in the Early group within the first 2 weeks after surgery. Perhaps these exercises produce more muscle activity when performed at a later stage in the recovery, but by then, the Intermediate group exercises would be considered more suitable for activating abdominal muscles. Some studies (92, 93) question the notion (53) that the TrA muscle is active as a trunk stabilizer in movements of the extremities. Thus, less TrA muscle activity should be expected in movements where muscles other than the abdominal muscles are primarily responsible for generating the movement – for example, quadruped exercises (Exercises 13–15 and 23, **Figures 6–7**). The abdominal muscles are responsible for movements involving the flexion and rotation of the spine and torso.

Side differences in muscle measurements

Based on an existing study in patients with a stoma more than 9 months removed from surgery (55), we anticipated potential side differences in the thickness and function of the stoma- and opposite-side TrA muscle. The ultrasound measurements in Study II were performed in the first 12 weeks after surgery and did not show any difference between the stoma- and opposite-side in thickness, resting or active, or voluntary contraction with ADIM. From the ultrasound measurements in Study II, there is nothing to suggest that stoma surgery has a unilateral effect on the TrA muscle. To explore this further, I reviewed the EMG data for muscle activity and coded it as “stoma side”/“opposite side” rather than “left”/“right” (**Appendix Figure 1**). As with the ultrasound measurements, the EMG data showed no obvious signs of lower muscle activity on the stoma side for either of the three groups. The lack of side differences in TrA thickness and function suggests that the muscle is not further weakened from surgery on the stoma side than the opposite side. The hypothesized weakness in the abdominal wall muscles after stoma surgery (42) was not evident in our muscle measurements with an EMG and ultrasound. However, it is still possible that the abdominal muscles on both sides are equally weakened after abdominal surgery. Furthermore, stomas are placed within or lateral to the RA muscle (36), and thus, the other abdominal muscles – the EO, IO, and TrA – may not be markedly affected by surgery.

Limitations and strengths

Study designs

The aim of Study I was to provide a precise estimate of parastomal bulging in a broad sample that included both ileostomies and colostomies, as well as permanent and temporary stomas. The study design was apt for this objective, as the Stoma Database contains data on a high percentage of patients with a new stoma (7). Unfortunately, the Stoma Database has no information on the percentage of parastomal bulges that are actually parastomal hernias (21), and there was no feasible way of determining as such for the study sample in Study I. Parastomal bulging is an important outcome clinically and for patients, but most of the existing literature focuses on parastomal hernias. Knowledge of the number of respective bulges and hernias would have allowed us to better contextualize the findings through the existing studies.

The approach on risk factors was exploratory, and the results need support and confirmation from other studies. The design of this study – examining many variables at once – limited the ability to draw any hard conclusions on the specific risk factors of parastomal bulging. Many variables were included, and the same data sources and regression models were used for each risk estimate. A more specific approach to each variable would likely have reduced the risk of residual confounding bias, but it also would have required additional data sources. A focus on fewer variables and the use of causal inference methods (94) would likely have further advanced the knowledge on risk factors.

However, such an approach would have required one or more separate studies and was not possible for this PhD project.

The design of Study II fit its objective of using EMG to evaluate the muscle activity of individual exercises as well as the pain, discomfort, and difficulty of each exercise. The strengths and limitations of the chosen EMG measurements are discussed below. An investigation of abdominal exercises over a period of time – for example, 8–12 weeks of progressively harder exercises – would have been informative in terms of feasibility. Information on adherence, attrition, acceptability, harm, exercise dosage (frequency, repetitions, intensity), costs, time consumption, practical issues, and willingness to participate could have been gathered with a feasibility study. However, Study II was an important precursor to a feasibility study, as we needed knowledge of which abdominal exercises to investigate the feasibility of.

Semi-structured interviews were well suited for investigating the patients' experiences with the abdominal exercises. An investigation of a multi-week exercise program would have provided more experiences to interview the participants about, as many had only performed abdominal exercises on one occasion after stoma surgery. The qualitative approach adds unique and nuanced information to the patients' perspective, which can lack in recommendations (95). The number of interviewees (fourteen) was suitable and within expectations for Study III. Using a descriptive form of analysis, the study could have benefited from having up to 20 participants, and focus group interviews might have allowed participants to interact in the discussion of different topics (82). Due to convenience sampling, many interviews were held with participants from the Intermediate group in Study II. More participants from the Early group and Late group may have been more informative.

EMG measurements of muscle activity using onset criteria

The EMG measurements of muscle activity used predetermined onset criteria to evaluate if there was activity in each abdominal muscle during a given exercise. The use of onset criteria to dichotomize our outcome was a consequence of being unable to use maximum voluntary contractions (51, 79, 96) to normalize the EMG signals (express muscle activity as a percentage of a maximum). We feared that completing maximum abdominal muscle contractions as early as the first day after surgery would compromise the safety of the participants, many of whom had undergone open surgery. It would also undermine the caution implemented in the study design, using gentler exercises in the first 2 weeks and more challenging exercises in the groups after 2 and 6 weeks, respectively.

The onset criteria had the advantage of being objective, as opposed to the subjective judgment used in the visual inspection of EMG signals. The specific criteria for the onset (mean baseline activity plus six standard deviations for a duration of at least 0.2 seconds) were based on existing literature (80, 81) and the goal of certainty of muscle activity when measuring it. The criteria were conservative, as it was important that the measured signal exceeded uncertainty with a significant margin. This approach minimized the number of false positives (measurements of muscle activity when there was none) and was appropriate in identifying suitable exercises for activating the abdominal muscles. In other populations and types of analysis, there are examples of both more (97) and less strict (98, 99) onset criteria.

Selection bias

In Study II, a high number of screened patients (**Figure 8**) were excluded based on the study's eligibility criteria. Many excluded patients – around 54% – were intended for the Early group and were still hospitalized. There was a risk of selection bias, with the included sample primarily consisting of patients being well enough, physically and mentally, to undergo testing and exercise performance for 1–1.5 hours. The most likely effect of this selection is that pain, discomfort, and difficulty were skewed toward lower ratings. It may have also influenced the percentage of participants able to perform the exercises, with almost all the exercises being completed by most of the participants. The implications for the measurement of muscle activity are unclear, but it would be unlikely for muscle activity to be measured in a higher percentage among all new stoma patients. As participants for Study III were sampled from Study II participants, there could have been selection bias in Study III by extension. However, we managed to include a diverse sample, including participants that were still hospitalized, affected by mild symptoms and complications (e.g., nausea and edema), and experiencing the exercises as difficult.

Conclusions

Patients had a 36% risk of developing a parastomal bulge within the first year after the creation of an ileostomy or colostomy in the Capital Region of Denmark. Exploratory analysis showed an increased risk of parastomal bulging with a colostomy, advanced age, male gender, increased alcohol consumption, diverticulitis, and laparoscopic surgery. Inflammatory bowel disease, peristomal mesh, and stoma placement through a separate incision in laparoscopic surgery were associated with a reduced risk of bulging. The findings on risk factors should be interpreted with caution.

In the Early group of Study II, with patients 0–2 weeks after surgery, muscle activity was measured in a low percentage of the participants for most exercises. This finding was especially pronounced for the RA muscle. In the Intermediate (2–6 weeks after surgery) and Late groups (6–12 weeks after surgery), there were several exercises with muscle activity in a high percentage of the participants. Most of the exercises were feasible based on the evaluated clinical outcomes; pain and discomfort were low across all three groups, and the level of difficulty was moderate in the Late group, but low in the Early group and Intermediate group. A high number of patients were excluded, with their medical condition being the most common reason, but also for limited physical function and pain. It is likely that ratings of pain, discomfort, and difficulty would have been higher in a less strictly selected sample of participants. The following exercises were feasible based on the clinical outcomes and stood out positively in measurements of muscle activity: 6, 9, 16, 20–22, and 31 (**Figures 5–7**).

When interviewed about their experience, patients found abdominal exercises easy to perform and had a positive attitude toward them. However, illness and adjuvant treatment form barriers to exercise, and patients expressed a wish for guidance with abdominal exercises after having a stoma. Interviewees highlighted exercises that allowed them to exert an effort and provided a sense of the abdominal muscles being used. Exercises 6 and 16 (**Figures 5–6**) were specifically mentioned as positive.

Implications for clinical practice

Of the patients with an ileostomy or colostomy, 36% developed a parastomal bulge, and we should expect up to 1500 of the estimated 4000 Danes getting a stoma each year (7) to develop a parastomal bulge within the first year after surgery. Patients getting a surgical stoma should have access to information regarding this common complication and their options for stoma care and potential surgery if they develop a bulge. Age (26, 27, 32, 100-102) and a colostomy (20, 24, 27, 103) are risk factors commonly associated with parastomal bulging and hernias, including in Study I. As with other potential risk factors from Study I – for example, gender and diverticulitis – patients and health professionals can do nothing to change these factors. Laparoscopic surgery was associated with an increased risk of bulging in Study I, and while prior studies show diverging findings (102, 104-106), a recent study found the same for parastomal hernias (107). However, there is strong evidence of the benefits of a laparoscopic approach (58), which should outweigh the potential risk of parastomal bulging or hernias. Weight and obesity are commonly linked with an increased risk of parastomal hernias (43, 108, 109), but the cited evidence and similar studies are unclear and unconvincing (26, 32, 90, 101, 103-105, 110). In Study I, a high BMI was not associated with an increased risk of parastomal bulging. At this point, it is doubtful if weight or obesity should be considered risk factors for parastomal bulging.

As shown in the Background section (**Table 1**), the existing literature on abdominal exercises after stoma surgery is limited, and there is little to inform the choice of exercises in the first weeks after surgery, when patients are still hospitalized. Even if the findings from this PhD project are descriptive and lack evidence of the effect of abdominal exercises, they may still serve as guidance for clinical practice in the absence of such evidence. Abdominal exercises are being used after stoma surgery regardless of the lack of evidence, and our findings can qualify the choice of exercises if the intention is to train the abdominal muscles after stoma surgery. Study II showed muscle activity reaching the predetermined onset criteria for many participants in certain abdominal exercises. For clinical purposes, we were interested in exercises that stood out positively in measurements of muscle activity, as activation of the abdominal muscles is a prerequisite for exercising them. Qualitative data and the clinical outcomes of pain, discomfort, and difficulty are similarly important to consider when determining suitable exercises for clinical practice.

Based on the EMG measurements of muscle activity, there are no optimal options for activating the abdominal muscles the first 2 weeks after stoma surgery, especially not for the activation of RA muscles. However, if abdominal exercise in the first 2 weeks is the intention, Exercises 6 “Diagonal isometric press” and 9 “Knee lifts, sitting” (**Figure 5**) are the best recommendations for the activation and involvement of the oblique and deep abdominal muscles (the EO, IO, and TrA). It should be noted that Early group exercises may be beneficial for other reasons than abdominal muscle activity – for example, sit-to-stand exercises to improve leg strength and mobility and bridging exercises to improve hip extension. Several observations from this PhD project point to waiting 2–3 weeks after surgery before starting abdominal exercises. First, there was an overabundance of excluded patients in the first 2 weeks after surgery, with many patients intended for the Early group in Study II not meeting the eligibility criteria. Second, muscle activity was measured in only half the participants or less in the first 2 weeks. Last, participants in Study III thought 2–3 weeks after surgery was the best time to start doing abdominal exercises, with several mentioning the desirability of having surgical staples removed before starting.

For the period from 2 to 6 weeks after stoma surgery, Exercises 6 “Diagonal isometric press” and 16 “Ball squeeze” (**Figure 6**) activated all the abdominal muscles for most of the participants, and Exercise 20 “Knee lifts on ball” thoroughly involved the EO, IO, and TrA muscles. These were all exercises with low scores in pain and discomfort, but some had balance problems when sitting on an exercise ball. Poor balance after surgery is something health professionals should be mindful of when introducing ball exercises. Exercises 6 and 16 were well-liked in the interviews, specifically for the ability to exert effort and sense the abdominal muscles being used.

From 6 weeks after surgery and onwards, the following abdominal exercises appear suitable based on the outcomes measured in Study II: “21. Diagonal sit-ups,” “22. Legs from side to side,” and “31. Chair-plank, extend legs, ADIM” (**Figure 7**). Exercise 25 “Sit-ups on ball” could only be completed by 4 of the 10 Late-group participants and cannot be considered suitable in this population, regardless of the high measurements of muscle activity.

Based on the qualitative findings of Study III, help and guidance is important for patients if they are to do abdominal exercises after stoma surgery. If patients are given the necessary guidance, health professionals should not abstain from including abdominal exercises where patients can use and feel their abdominal muscles, such as those highlighted in this PhD thesis. It should still be within the local restrictions after surgery, whether that is a pain threshold or time duration. Caution should be used until future research projects provide more knowledge on the harms of abdominal exercises after stoma surgery. The interviews show some of the possible barriers to performing exercises, which are important for health professionals to screen for. On top of having abdominal surgery, a stoma adds an extra layer of potential concern and uncertainty to physical exercise. In their guidance, health professionals should navigate patients toward exercise activities that they feel comfortable in doing with their stoma.

Perspectives

The context of this PhD project was its placement between a handful of prior studies providing a low level of evidence and future studies on the benefit and harms of abdominal exercise after stoma surgery. The PhD project generated knowledge that can benefit both current practice and future research projects. Qualifying the choices regarding exercise delivery, timing, and choice of exercises can improve the odds of success for future abdominal exercise investigations. With so few studies on this subject, it is important that if/when an RCT study is conducted in the future, it is with as much prior knowledge as possible.

Perspectives for patients

Parastomal bulging is a frequent problem affecting the lives of many people with a stoma. The current options for treating or preventing parastomal bulges seem insufficient, with a peristomal mesh the most promising surgical option (23). Currently, newer systematic reviews point to peristomal mesh inlays reducing the incidence of parastomal hernias (111-113) – and, by extension, parastomal bulges – although with low-quality evidence per a Cochrane review (111). Peristomal mesh is typically only placed in elective surgeries during the creation of permanent colostomies, leaving many patients with a stoma who were not candidates for a mesh. Non-surgical preventive measures warrant continued research and investigation in search of solutions to reduce the problem of parastomal bulging.

If abdominal exercises were found to be an effective and safe way of preventing parastomal bulges after stoma surgery, it would open the possibilities for patients after stoma surgery. Patients with acute or temporary ileostomies would especially benefit, as they are rarely candidates for a peristomal mesh and may have no options for preventing a bulge. The avoidance of a parastomal bulge is important to the patients. An effective abdominal exercise intervention after stoma surgery would enable patients to actively improve their odds of preventing a parastomal bulge. Currently, fast track regimes (58, 114) try to help patients reach a higher mobility while they deal with the potential symptoms and complications following abdominal surgery (57). Abdominal exercises could serve as a compliment to this important mobilization (58, 115) and potentially improve the outcomes after surgery as part of physical rehabilitation. A knowledge of barriers and guidance in abdominal exercises can potentially lead to more patients completing abdominal exercises, which could then lead to overall improved recovery and, hypothetically, fewer parastomal bulges after surgery. Other potential benefits from an uptake in abdominal exercises after stoma surgery include the possibility for patients to be active and empowered to help themselves. Abdominal exercises may improve physical recovery and mobility during hospitalization after surgery. Finally, performing abdominal exercises after surgery may help patients eliminate their concerns and uncertainties related to their stoma, and it may break down the barriers to physical activity and exercise in general. This change could allow patients to live more active lives and return to activities from before their surgery and illness.

Perspectives for future research

Ultimately, an RCT study is needed to inform on the benefit and harms of abdominal exercise after stoma surgery. An RCT study on abdominal exercises after stoma surgery would add knowledge on the harms and potential secondary outcomes regarding physical function, performance, recovery, and more. Any new knowledge on the safety of abdominal exercises after stoma surgery is welcome. It would allow health professionals to better guide patients based on evidence. Secondary outcomes (e.g., physical function, recovery, postoperative days) would generate knowledge of the benefits. Abdominal exercises see use and are being advocated (43, 48, 109, 116) with the assumption that they are beneficial after stoma surgery. If they are shown to have no or minimal benefit, patients and health professionals could spend their time and effort in better ways and without the risk of potential harms.

A future RCT should be preceded by a systematic literature search or review (117). A literature review would be a natural inclusion in any plans for future research projects, justifying an RCT study (118). This review could be a systematic review of non-randomized studies on non-surgical interventions or a scoping review (119-121) on the benefit and harms of physical exercise after stoma surgery. Another requirement for the justification of an RCT study would be the conduct of a feasibility randomized trial or a pilot study (122-124) to investigate the feasibility of an abdominal exercise intervention.

In addition to the feasibility of the RCT design and intervention, a feasibility or pilot study could add valuable knowledge about the training load and dosage of abdominal exercises. Future RCT studies would have the potential to pave the way for the standardized use of abdominal exercise programs after stoma surgery to the benefit of future patients and society.

Perspectives for abdominal exercise interventions after stoma surgery

The findings of this PhD project can add perspectives to future abdominal exercise interventions after stoma surgery. In the following, the findings from the PhD project are contextualized in the Consensus on Exercise Reporting Template (CERT) (125). The findings allow me to comment on certain items in the CERT checklist on a scientific basis. Other CERT items require further research and planning, which should highlight the pieces of the puzzle already in place and those that still need addressed for planning an abdominal exercise intervention after stoma surgery. The following is the PhD student's recommendation for abdominal exercises after stoma surgery based on the findings of the PhD project, clinical experience, and the currently available knowledge.

CERT checklist items (125):

1. Detailed description of the type of exercise equipment

Exercise mats should be included for exercise starting in a prone or crook lying position. In a hospital setting, the hospital bed may be used. Exercise balls can be included in exercises starting 2 weeks after surgery. Sitting or lying on exercise balls should be restricted to supervised exercise or until safe use is demonstrated by the patient. Some patients may experience exercise balls to be unpleasant due to the unstable base of support.

2. Detailed description of the qualifications, expertise and/or training

Abdominal exercises should be handled by certified professionals qualified to supervise exercise in the surgical gastroenterological specialty – for example, physiotherapists.

3. Describe whether exercises are performed individually or in a group

Patients will likely have differing preferences for group-based or individually performed exercises, and it can be difficult for exercise interventions to meet the preferences of all patients. Practical, economic, or other issues should be considered when choosing group-based or individual exercises. Offering both and allowing the patients to choose may also be considered.

4. Describe whether exercises are supervised or unsupervised; how they are delivered

Abdominal exercises after stoma surgery should be supervised, at least partially, due to the concerns, uncertainty, and need for help and guidance that people with a stoma may experience in relation to abdominal exercises. Based on interviews, patients may not complete the exercise if the intervention is planned with unsupervised, home-based exercise.

5. Detailed description of how adherence to exercise is measured and reported

No recommendations. The PhD project did not touch upon the measurements of adherence to exercise.

6. Detailed description of motivation strategies

Patients scheduled for another abdominal surgery – for example, stoma reversal – may be motivated to heighten their level of physical fitness beforehand. Some patients may be motivated by having their physical performance measured at multiple times, allowing them to see their progress. Sending reminders to complete the exercises was suggested in patient interviews.

7a. Detailed description of the decision rule(s) for determining exercise progression

Abdominal exercises should start 2–3 weeks after surgery. The default for progression to more challenging exercises should be after 6 weeks. Patient and health professionals (physiotherapist, surgeon, etc.) may decide to accelerate or delay progression based on preferences, experience, and the judgment of the individual situation.

7b. Detailed description of how the exercise program was progressed

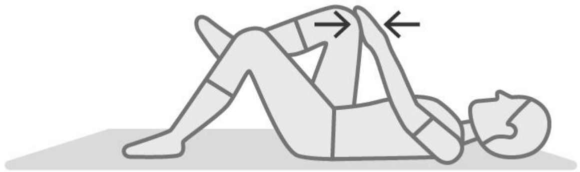
Not applicable.

8. Detailed description of each exercise to enable replication

Diagonal isometric press

Start in crook lying position.

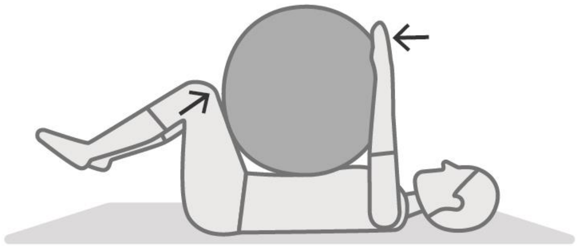
Lift one leg, press down against the knee with the opposite hand, and hold for 5 seconds.



Ball squeeze

Start in crook lying position.

Hold the ball between arms and legs, lift feet from the surface, press arms and legs toward each other, and hold for 5 seconds.

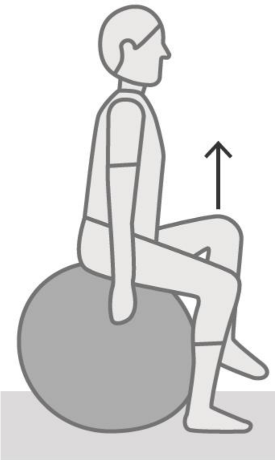


Knee lifts on ball

Start sitting on ball, hands resting on side.

Lift one knee while the rest of the body is kept steady.

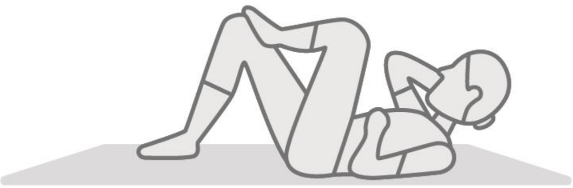
Lower knee slowly, then repeat with opposite knee.



Diagonal sit-ups

Start in crook lying position with one leg on opposite knee, opposite arm behind head.

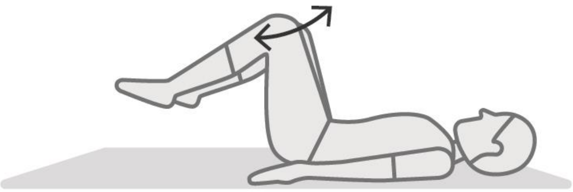
Lift upper body diagonally toward the upper leg so that the shoulder lifts from the surface, then lower the upper body slowly.



Legs from side to side

Start in crook lying position, arms down at the sides.

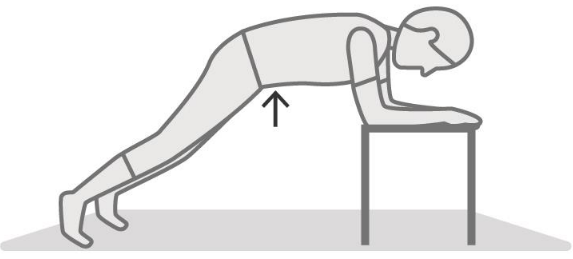
Lift both legs, keeping them together, and move them from side to side.



Chair-plank, extend legs, draw in

Start on knees, underarms resting on chair.

Extend legs, breathe in, then as you exhale, draw your stomach in (as if you were to put on a pair of tight jeans)



9. Detailed description of any home programme component

This PhD project investigated abdominal exercises in a supervised setting. It should be considered if supervised exercise should be supplemented with patients performing the exercises at home.

10. Describe whether there are any non-exercise components

Written material on the abdominal exercises should be provided and at least include an illustration or photograph and a description of the exercises. For optimal participation in exercise activities, patients should have access to stoma care. From stoma care nurses, patients receive help and learn to manage their stoma, which creates better conditions for doing the abdominal exercises.

11. Describe the type and number of adverse events that occur during exercise

We know little of the potential harms associated with abdominal exercises after stoma surgery. Two adverse events, leg cramps and nausea, occurred in Study II. For learning more about the harms of exercise, it is important to monitor adverse events routinely and, preferably, systematically as well as to thus report on them.

12. Describe the setting in which the exercises are performed

Travel distance, waiting, and a lack of flexibility are possible barriers to the abdominal exercises important to the setting. Exercise providers should be mindful that patients with a stoma may have multiple appointments with stoma care nurses and surgeons taking up their time. Many patients will seek to return to work at some point. The choice of setting may be important to the patients’ possibility to participate.

13. Detailed description of the exercise intervention

For postoperative Weeks 2–6, the exercises “Diagonal isometric press,” “Ball squeeze,” and “Knee lifts on ball” are performed. After postoperative Week 6, the exercises “Diagonal sit-ups,” “Legs from side to side,” and “Chair-plank, extend legs, draw in” are introduced and performed for the remainder of the intervention. Combining the abdominal exercises with other type of exercise – for example, cardiovascular exercise and general resistance training, should be considered.

14a. Describe whether the exercises are generic (one size fits all) or tailored

Based on patient interviews, it is of importance to the patients that exercises are tailored to the individual.

14b. Detailed description of how exercises are tailored to the individual

Tailoring should be made on a case-by-case basis and could include the continuous assessment of pain, difficulty/quality of the performance, and patient’s preferences.

Examples:

If balance problems from “Knee lifts on ball”: Perform sitting on chair or bed.

If “Legs from side to side” is too difficult: Perform with legs placed on exercises ball.

15. Describe the decision rule for determining the starting level

This PhD project did not address the training load or dosage of exercises. One suggestion based on experience would be four sets of 10 repetitions of each exercise, four times a week for 12 weeks.

16a. Describe how adherence or fidelity is assessed/measured

No recommendations. The PhD project did not touch upon the assessments of adherence or fidelity.

16b. Describe the extent to which the intervention was delivered as planned

Not applicable.

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Appendices

List of appendices:

Paper I

Paper II

Paper III

Appendix Figure 1. EMG muscle activity for stoma side/opposite side

Declarations of co-authorship

doi:10.1111/codi.13907

Incidence and risk factors for parastomal bulging in patients with ileostomy or colostomy: a register-based study using data from the Danish Stoma Database Capital Region

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Received 29 May 2017; accepted 4 September 2017; Accepted Article online 4 October 2017

Abstract

Aim The aim was to investigate the incidence and risk factors for parastomal bulging, a clinically important complication, in patients with an ileostomy or colostomy.

Method The Danish Stoma Database Capital Region prospectively collects data on patients with a stoma up to a year after surgery. Stoma care nurses clinically assessed the main outcome, parastomal bulging. We linked data from the Stoma Database to data from the Danish Anaesthesia Database. Cumulative incidence of parastomal bulging over the first year was calculated with death and stoma reversal as competing risks. Risk factors were investigated using an exploratory approach.

Results In a study population of 5019, the cumulative incidence (with competing risks) of parastomal bulging was 36.2% at 400 days after surgery. Age, colostomy, male gender, alcohol consumption and laparoscopy were associated with an increased risk of parastomal bulging. Compared with cancer, inflammatory bowel disease was associated with a lower risk of parastomal bulging, and diverticulitis was associated with a higher risk. Peristomal mesh and stomas placed through a separate incision were associated with a reduction in risk. There was neither increased nor decreased risk of parastomal bulging for body mass index, American Society of Anesthesiologists score, smoking status, emergency surgery and preoperative stoma site marking.

Conclusion Parastomal bulging is a common complication affecting one in three patients within 1 year of surgery. Along with previous findings, there is now considerable evidence for age and colostomy as being risk factors for parastomal bulging.

Keywords Parastomal bulging, hernia, ileostomy, colostomy, register, database

What does this paper add to the literature?

This paper adds a precise estimate (36%) of the incidence of parastomal bulging the first year after surgery. Risk factors for parastomal bulging are explored in a large clinical sample, adding to the body of evidence and introducing potential hypotheses for future research.

Introduction

Background/rationale

Parastomal bulging (PB) is a visible or palpable bulge at the site of a stoma and a common complication of stoma surgery [1,2]. It often leads to a feeling of heaviness, cosmetic problems and problems with stoma appliances, making patients more susceptible to leakage and skin irritation. PB is a clinical entity of importance to the patient and may reduce quality of life [1]. It includes both parastomal hernias [3] and 'pseudohernias', i.e. subcutaneous prolapse and a weak abdominal wall [4,5].

The literature on parastomal hernias provides rough estimates of the incidence of PB [6–10]. Depending on stoma type, the incidence varies from 20% to 40% [6,9]. For parastomal hernias, previous studies point to age [6,11–15], colostomy [4,6,10,16] and aperture size

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[6,13] as risk factors. Placement of a peristomal mesh at the time of stoma formation reduces the risk of PB [17–20]. Findings are inconsistent for other possible risk factors, e.g. high body mass index (BMI), cancer, laparoscopy and gender [11,13,14,16,21–23].

At present, the most common options for managing PB are conservative treatment or surgical repair [23,24]. Usually, surgical repair is only warranted if symptoms are severe, leaving many patients to live with PB.

The Danish Stoma Database Capital Region (DSDCR) is a clinical database established in 2007 [25]. Stoma care nurses (SCN) prospectively register clinical data, including data on PB, on patients with a stoma in the DSDCR at surgery and at scheduled visits up to 1 year after surgery.

Objectives

Our aim was to investigate the incidence of PB in patients with an ileostomy or colostomy at different periods of follow-up during the first year after surgery and to investigate the association between surgery-related and patient-related factors and the risk of PB.

Method

Study design

The incidence of PB in patients with an ileostomy or colostomy in the Capital Region of Denmark the first year after surgery was the primary outcome in this study. We used a register-based study design to evaluate prospectively collected data from the DSDCR [25]. In order to include relevant variables not collected in the DSDCR, the dataset was linked to data from the Danish Anaesthesia Database. The investigation of risk factors included several variables in an exploratory approach. We reported this study based on the guidelines of the STROBE statement [26] and the RECORD extension [27].

Setting

The Capital Region of Denmark is one of five Danish regions with a population of 1.8 million. After stoma surgery, all patients in the Capital Region of Denmark are seen by SCNs at one of five hospitals in the region. The DSDCR aims to include all regional patients undergoing stoma surgery and when checked against the Danish National Patient Register the database shows a data completeness of nearly 100% [25]. For this reason, the database population should relate well to the source population of patients with a stoma in the Capital Region of Denmark [25]. Since 2007, routinely collected health data on patients with a stoma have been registered in the DSDCR [25]. The Danish Anaesthesia Database is a national quality assurance database containing data on patients undergoing surgery [28].

Participants

All patients registered in the DSDCR with an ileostomy or colostomy were eligible for inclusion. From the DSDCR, eligible stoma types were jejunostomy, ileostomy, sigmoid colostomy and transverse colostomy. Patients without any follow-up data were excluded, as PB had not yet been assessed. We included patients with multiple records in the DSDCR from separate surgical procedures based on the following criteria: (i) multiple records with a difference in date of surgery of ≤ 30 days were treated as one case and the latest record was included for that patient; (ii) for multiple records with a difference in date of surgery of > 30 days, the latest record counted separately if the stoma type was different and the patient had not developed PB. If criterion (ii) was met, the previous records for that patient were censored. Also any records of a patient already included were excluded.

Variables

Danish stoma database capital region

PB was defined as a clinically assessed bulge at the site of the stoma. From the DSDCR, we also included variables of age, gender, diagnosis (primary cause for stoma creation), stoma type, BMI, type of surgery (emergency/elective), mode of surgery (open surgery/laparoscopy only), placement of a peristomal mesh, preoperative stoma site marking, and whether the stoma was placed through an incision separate from existing laparoscopic incisions. For the purposes of comprehensibility and interpretation, we grouped jejunostomy and ileostomy as 'ileostomy' and sigmoid and transverse colostomies as 'colostomy' in our analyses [25]. Diagnoses of Crohn's disease and ulcerative colitis were grouped as 'inflammatory bowel disease' (IBD).

Danish anaesthesia database

From the Danish Anaesthesia Database we included the American Society of Anesthesiologists (ASA) physical status classification system [29], smoking status and alcohol consumption. Disease severity, comorbidity and functional limitations are taken into account by the classification system. We retained the categorization of the variables of smoking status and alcohol consumption that were used in the Danish Anaesthesia Database. Alcohol consumption was measured in Danish standard drinks per week (equal to 12 g of pure alcohol).

Data sources/measurement

For both databases, data were extracted and delivered by the responsible data managers. Except for PB, all included variables were assessed at the time of surgery. PB was assessed clinically by SCNs at scheduled visits on postoperative day (POD) 30, 90, 182 and 365 (and at *ad hoc* visits in-between) [25]. Clinical assessments included visual inspection with the patient in different positions, interview about symptoms, measurement of the stoma diameter, digital examination of the stoma and the ostomy aperture, and observation of the stoma site during the Valsalva manoeuvre. SCNs in the Capital Region of Denmark use internal guidelines and training and a uniform definition of PB to standardize their assessments of PB.

The inter-rater reliability is reportedly low for clinical assessments when distinguishing three possible outcomes (bulge, parastomal hernia or neither) [30]. However, as SCNs assess whether PB (including parastomal hernias) is present or not, these findings are not entirely transferable and we would expect a higher agreement in assessments only distinguishing between its presence or not. The validity of the clinical assessment of PB has not been established. Some studies have detected parastomal hernias more frequently when assessed radiologically rather than clinically [13,31–33], while others found clinically assessed bulges or hernias not detected by CT scan [30,34].

Statistical methods

Entries with PB unknown were treated as the patient not having PB at that follow-up visit. In this way PB had to be positively confirmed. Missing data from patients failing to turn up were treated as not having PB at that follow-up point. If there were no later follow-up visits, the patient was treated as 'lost to follow-up' and censored. We expected this approach to provide a conservative estimate of the incidence of PB.

We calculated the cumulative incidence of PB using survival analysis. We used Kaplan–Meier plots to illustrate the cumulative incidence of PB after stoma formation up to 400 days after surgery. We used 400 days to account for POD 365 visit later than 365 days after surgery. Patients were censored in the Kaplan–Meier plots when patients were deceased, had their stoma reversed or were lost to follow-up. Additionally, we plotted the cumulative incidence using death or reversed stoma as competing risks [35] to provide a more conservative estimate, as patients who were deceased or had their stoma reversed were no longer at risk of developing PB. Estimates of cumulative incidence at POD 100, 200, 300 and 400 were calculated and presented with 95% confidence intervals.

We used Cox proportional hazards regression models to investigate risk associated factors. Crude estimates were calculated for the included variables, and multivariable models were used to calculate adjusted estimates. All variables except 'peristomal mesh' and 'stoma placed through separate incision' were included in the multivariable analyses. Additional models for multivariable analyses were constructed using backward selection, removing variables that were not statistically significant. The variable 'peristomal mesh' was analysed in a subgroup including only sigmoid colostomies as, historically, they are the preferred stoma type for mesh placement. Similarly, the variable 'stoma placed through separate incision' was analysed in a subgroup of laparoscopies only, as all open surgeries use a separate incision for the stoma [36]. For BMI, we applied the major category boundaries of the World Health Organization [37], also including a cut-off for obese class II+ at BMI ≥ 35. All analyses were done in R (version 3.2.3) software (R Foundation for Statistical Computing, Vienna, Austria).

Results

Participants

Data were delivered by the DSDCR on patients with eligible stoma types and did not include ineligible stoma types of urostomy or any types of intestinal neobladders. The delivered dataset included 8368 records on 7534 unique patients (Fig. 1). We excluded 2637 patients having no follow-up data. Reasons for missing follow-up data were unknown but were likely to include illness or visits to stoma care clinics outside the Capital Region. An additional 712 patient records were excluded due to already being included and not meeting the specified criteria. In total, we included a study population of 5019 patients, 102 of which were records of separate stoma procedures on the same patient. ASA was successfully linked for 4616 patients (92%), smoking status for 4089 patients (81%) and alcohol consumption for 4085 patients (81%).

Descriptive data

The characteristics of the study population are shown in Table 1. The majority (58%) of the study population

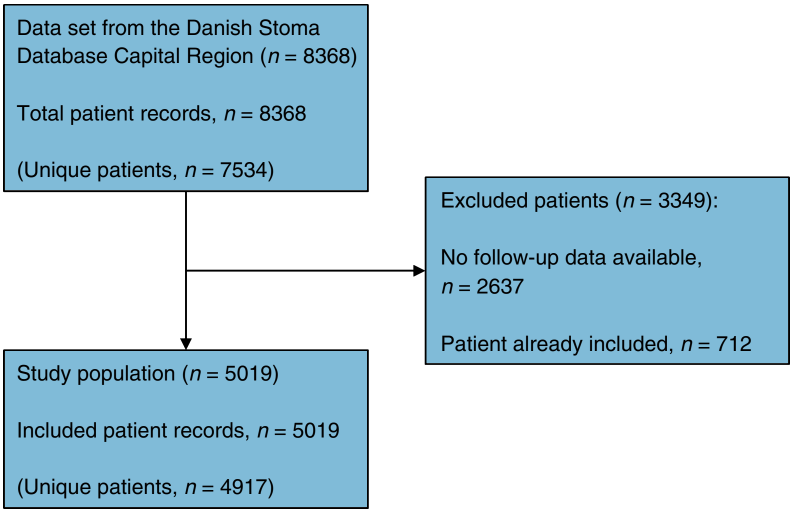

Figure 1 Flow diagram.

had a diagnosis of cancer, and the median age was 66 years. There were slightly fewer ileostomies (n = 2267) than colostomies (n = 2752). In 2013, the DSDCR added additional categories to the diagnosis variable that were formerly registered as 'other'. Many of the data are from before 2013, resulting in a high number (n = 646) of unknown 'other' diagnoses. Of the database population of 8368 patients, 2637 patients without any follow-up were not included in any analyses (Fig. 1). Patients without follow-up data differed from the study population in age, stoma type, diagnosis, type of surgery, mode of surgery and preoperative stoma marking. They were slightly older than the study population [median 68 years (interquartile range 55; 78) *vs* median 66 years (interquartile range 55; 74)]. The percentage of colostomies (47%) was significantly lower than in the study population (55%), and there were more 'other' diagnoses (30% *vs* 24%). Additionally, this group had significantly lower percentages of elective operations (48% *vs* 58%), 'laparoscopy only' (23% *vs* 34%) and preoperative stoma site marking (67% *vs* 76%).

Incidence

PB was identified in 1149 of the study population's 5019 patients. In the Kaplan–Meier plot, many patients were right-censored before possible completion of a POD 365 visit, and for this portion of the study population it is unknown if PB occurred within the first 400 days after surgery. A POD 365 visit without PB was registered for 538 of 5019 patients. 1377 patients were lost to follow-up due to death or stoma reversal, and 1955 patients were censored due to being lost to follow-up for other reasons. Reasons for right-censoring are shown in Fig. 2. Figure 3 shows Kaplan–Meier estimates of the incidence of PB. The dotted line represents an estimate using competing risks. Kaplan–Meier estimates were 14.4% (95% CI: 13.2%; 15.6%) at 100 days from surgery; 31.4% (95% CI: 29.6%; 33.2%) at 200 days; 37.0% (95% CI: 35.0%; 39.0%) at 300 days; and 51.8% (95% CI: 49.3%; 55.2%) at 400 days. With competing risks, the corresponding cumulative incidence was 12.4% (95% CI: 11.4%; 13.4%) at 100 days from surgery; 24.4% (95% CI: 22.9%; 25.8%) at 200 days; 27.8% (95% CI: 26.3%; 29.3%) at 300 days; and 36.2% (95% CI: 34.4%; 38.0%) at 400 days. Kaplan–Meier plots for subgroups of age, stoma type, diagnosis and 'peristomal mesh' are shown in Fig. 4. For the age variable in Fig. 4, we used a cutoff of 60 years as used in previous observational studies investigating age as a risk factor [11,14,15].

Risk factors

Table 2 shows risk factors for PB presented as hazard ratios with 95% confidence intervals. Male gender, age, colostomy, alcohol consumption and 'laparoscopy only' (also including robot-assisted procedures) were associated with an increased risk of PB after adjusting for other variables. Compared with cancer, IBD was associated with a lower risk of PB, and diverticulitis was associated with a higher risk. For the other variables, analyses showed neither increased nor decreased risk of PB. We included all variables in multivariable models with the exception of 'peristomal mesh' and 'stoma placed through separate incision', which were treated in subgroup analyses. Additional models with backward selection (data not shown) did not alter estimates significantly.

Table 1 Characteristics of the study population at the time of surgery.

Characteristics	Study population (*n* = 5019)
Age (years), median [IQR] (range)	66 [55; 74] (8–100)
Female, *n* (%)	2371 (47)
Diagnosis, *n* (%)	
Cancer	2924 (58)
Inflammatory bowel disease	525 (10)
Diverticulitis	383 (8)
Other*	1187 (24)
Body mass index, *n* (%), median [IQR] (range)	24.4 [21.6; 27.4] (12.6–57.8)
< 18.5	329 (7)
18.5–24.99	2310 (49)
25.0–29.99	1404 (30)
30.0–34.99	490 (10)
≥ 35.0	157 (3)
Missing	329
ASA classification, *n* (%)	
I	619 (13)
II	2510 (55)
III	1310 (29)
IV+	177 (4)
Missing	403
Smoking status, *n* (%)	
Smoker	1013 (25)
Non-smoker (including former smokers)	3076 (75)
Missing	930
Alcohol consumption, *n* (%)	
0 Danish standard drinks per week	2063 (51)
1–21 Danish standard drinks per week†	1697 (42)
> 21 Danish standard drinks per week‡	325 (8)
Missing	934
Mode of surgery, *n* (%)	
Open surgery	3300 (66)
Laparoscopy only	1709 (34)
Missing	10
Type of surgery, *n* (%)	
Elective	2927 (58)
Emergency/acute	2090 (42)
Missing	2
Type of stoma, *n* (%)	
Ileostomy	
Jejunostomy	89 (< 1)
Ileostomy	2178 (43)
Colostomy	
Transverse colostomy	340 (7)
Sigmoid colostomy	2412 (48)
Preoperative stoma marking, *n* (%)	
Yes	3713 (76)
No	1144 (24)
Missing	162
Peristomal mesh, *n* (%) (only sigmoid colostomies)	
Yes	254 (11)
No	2136 (89)
Missing	22
Stoma placed through separate incision, *n* (%) (only laparoscopies)	
Yes	1510 (89)
No	181 (11)
Missing	18

IQR, interquartile range; ASA, American Society of Anesthesiologists physical status classification system.
*Other diagnoses included: incontinence (71), ileus without other cause (201), fistula (57), constipation (27), anastomotic leakage (43), ischemia (64), necrotising fasciitis (5), trauma (70), pouch (3), and other (646).
†Corresponding to 1–252 g of alcohol per week.
‡Corresponding to > 252 g of alcohol per week.

Other analyses

Subgroup analyses for the variables 'peristomal mesh' and 'stoma placed through separate incision' are also shown in Table 2. In subgroup analyses, we adjusted for variables with a statistically significant risk of PB in the univariate models: gender, age, diagnosis, alcohol consumption and mode of surgery. Placement of a peristomal mesh was found to slightly reduce the risk of PB in sigmoid colostomies when adjusted for other variables. For laparoscopies only, a separate incision was associated with a decrease in the risk of PB, but only after adjusting for other variables. Figure 5 details the relationship between age and relative risk of PB, showing an increase in risk with increasing age.

Discussion

We used routinely collected health data from the DSDCR to investigate incidence and risk factors for PB in patients with ostomies based on a large study sample. We found a cumulative incidence of PB of 36.2% (competing risks) at 400 days after surgery; and the cumulative incidence was above 10% at 100 days from surgery. In our analyses, we found that age, male gender,

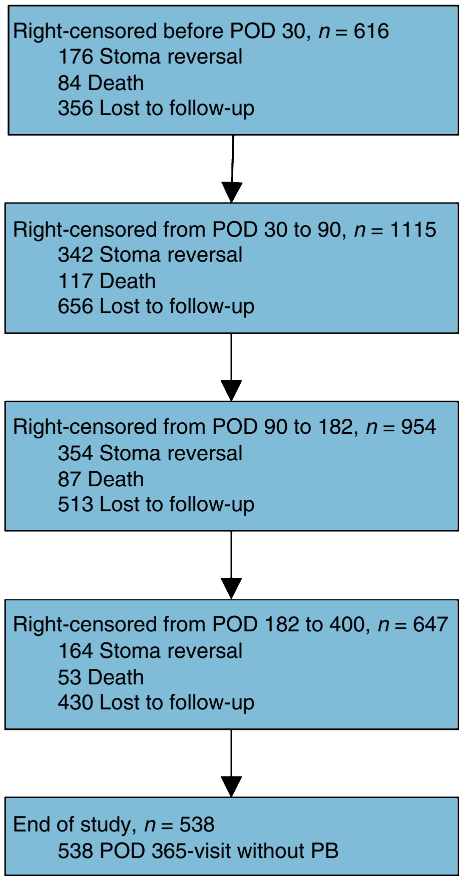

Figure 2 Reasons for right-censoring during the first 400 days after surgery for the study population (n = 5019). POD, post-operative day; PB, parastomal bulging.

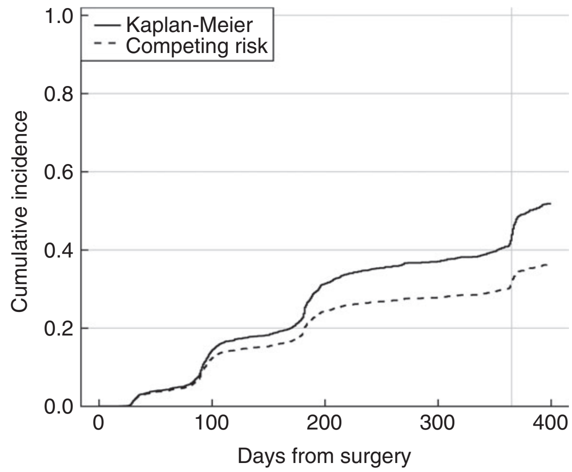

Figure 3 Kaplan–Meier plot showing the cumulative incidence of parastomal bulging the first 400 days after surgery. A more conservative estimate using competing risks was plotted with a dotted line.

diverticulitis, alcohol consumption, laparoscopy only and colostomy were associated with an increased risk of PB while IBD, peristomal mesh and stoma placement through a separate incision were associated with a reduced risk of PB.

The incidence of PB found in this study was at the higher end of the spectrum compared with other studies on parastomal hernias, where the incidence was 20–40% after 2 or more years [6–9,11]. With an incidence of more than 10% at 100 days and 36% at 400 days, effective preventative modalities would seem meaningful even in the short term. Peristomal mesh [38], surgical techniques [39–41] and non-surgical options, e.g. abdominal exercise, may warrant further attention [42–44].

In line with the findings of previous studies, age [6,11–15] and colostomy [4,6,10,16] were associated with an increased risk of PB. In unadjusted analysis patients with colostomies had twice the risk of PB compared with ileostomies. However, the hazard ratio for stoma type was 1.4 (95% CI: 1.2; 1.7) when adjusting for covariates. We have no plausible explanations for the increased risk of PB found after laparoscopic surgery; some observational studies have reported similar findings [21,36], while others found no difference [15,22]. The reduced risk of PB from placement of a peristomal mesh [hazard ratio 0.7 (95% CI: 0.6; 1.0), P = 0.019] was not as strong as reported in systematic reviews and randomized trials on parastomal hernias (odds ratios from 0.04 to 0.34, hazard ratio 0.134) [17,19,20,32]. Detailed information on mesh type and application was not available, which may have affected the internal validity of the estimate. Similar to our finding, another study suggested that stoma placement through a separate incision may reduce the risk of parastomal hernias [36]. Alcohol consumption was associated with an increased risk of PB, but the estimate for high intake was imprecise [hazard ratio 1.4 (95% CI: 1.0; 1.7)] and confidence intervals for both estimates contain values indicating little or no risk.

As routinely collected health data were used, we had no influence on the methods used for data collection, and there was a risk of misclassification bias [26,27,45]. However, as data were collected independently from this study, the risk of differential misclassification of variables should be limited [45]. Residual confounding bias, however, cannot be ruled out. For example the lack of data on aperture size, a possible risk factor for PB [6,13], or surgical technique could have affected the estimates.

Although the DSDCR attempts to include all patients with a stoma in the region, estimates could be at risk of bias due to the large number of excluded patients with no available follow-up data. Excluded patients had fewer colostomies and 'laparoscopy only' procedures than the study population, and based on

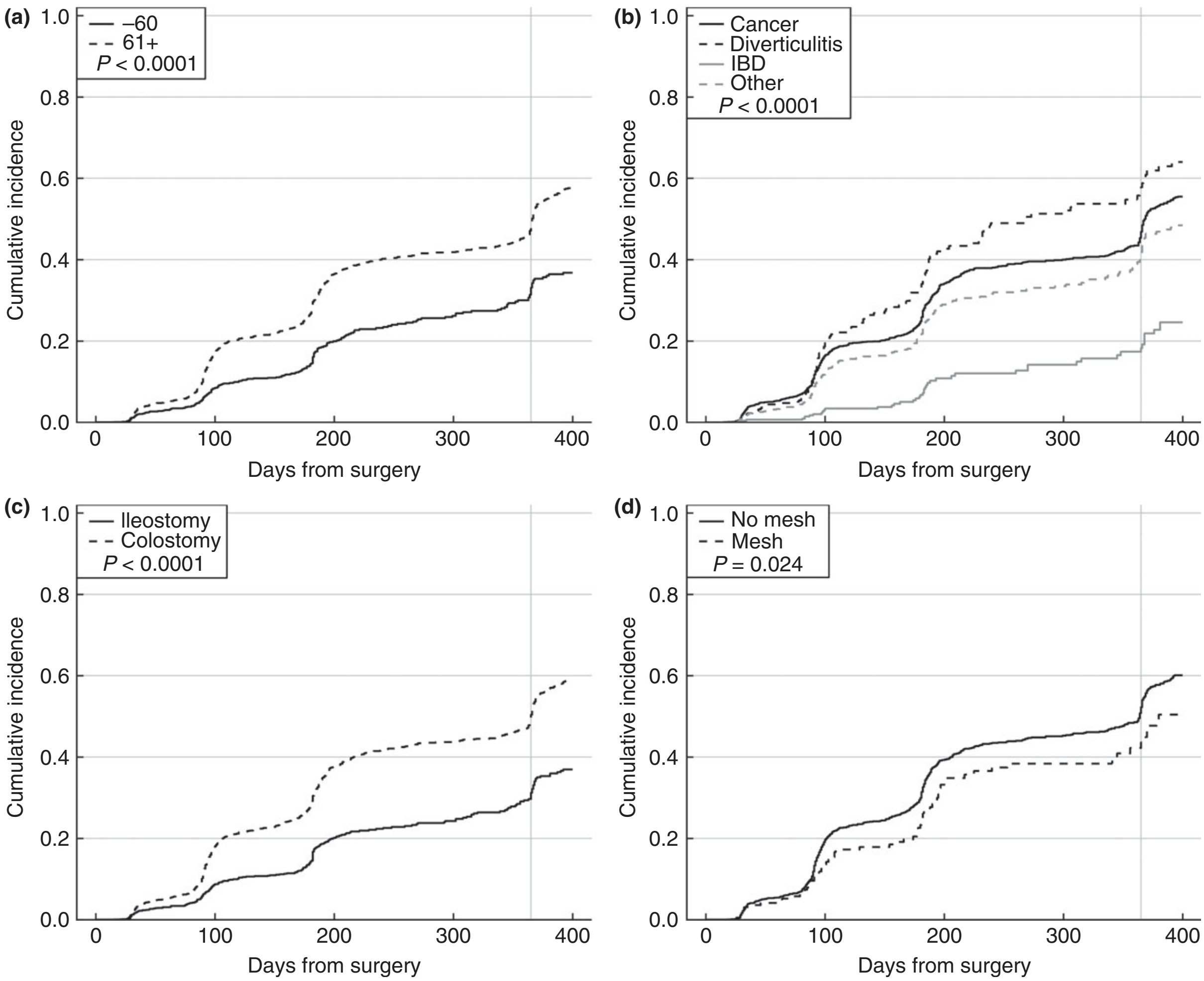

Figure 4 Kaplan–Meier plots of the cumulative incidence of parastomal bulging for subgroups of (a) age; (b) diagnosis; (c) stoma type; and (d) peristomal mesh (sigmoid colostomies only). IBD, inflammatory bowel disease. For b, the denoted *P*-value is an overall value for the entire variable.

our risk estimates we may have overestimated the incidence of PB. On the other hand, the study population was slightly younger, pointing toward a potential reduced estimation.

Parastomal hernias are considered potentially more dangerous than PB caused by subcutaneous prolapse and abdominal wall weakness. Unfortunately, we were not able to conduct separate analyses due to the lack of data distinguishing between the underlying causes of PB in the DSDCR. We argue, however, that PB can impact on quality of life regardless of the underlying cause [46]. For instance, although not potentially dangerous, appliance problems and an altered physical appearance matter to patients [46]. The uncertain reliability and validity of clinical assessments of PB could have biased the results. If true that fewer parastomal hernias are detected clinically than radiologically [13,31–33], we may have underestimated the incidence of PB.

This study has a high external validity representing a major portion of the source population. Despite the high percentage of patients without any follow-up data, we still consider that our findings contribute to the body of knowledge on incidence and risk factors of PB in this population. The findings should be fairly generalizable to a national level based on similarity in procedures due to national guidelines for surgery and standardized cancer procedures in Denmark. The results are likely to be generalizable to other countries with similar populations and surgical practices.

In conclusion, this study showed that one in three patients with a stoma developed PB in the first year after surgery. For risk factors, we found that age, male gender, diverticulitis, alcohol consumption, laparoscopy only and colostomy were associated with an increased risk of PB, while IBD and peristomal mesh and placement through a separate incision were associated with a

Table 2 Risk factors for parastomal bulging.

Factors	Univariate models Hazard ratio (95% CI)	Multivariable models Hazard ratio (95% CI)
Age (continuous, per year)	1.02 (1.02; 1.03)	1.02 (1.01; 1.02)¶
Male gender	1.6 (1.4; 1.8)	1.6 (1.4; 1.9)¶
Diagnosis		
Cancer	1 (ref)	1 (ref)
IBD	0.3 (0.2; 0.4)	0.6 (0.4; 0.9)¶
Diverticulitis	1.3 (1.1; 1.5)	1.4 (1.1; 1.8)¶
Other	0.8 (0.7; 0.9)	1.1 (0.9; 1.3)¶
BMI		
< 18.5	1.0 (0.8; 1.2)	0.9 (0.7; 1.1)¶
18.5–24.99	1 (ref)	1 (ref)
25.0–29.99	1.1 (0.9; 1.2)	1.0 (0.9; 1.2)¶
30.0–34.99	1.0 (0.8; 1.2)	0.9 (0.7; 1.2)¶
≥ 35.0	0.8 (0.6; 1.2)	0.8 (0.5; 1.4)¶
ASA		
I	1 (ref)	1 (ref)
II	1.0 (0.8; 1.2)	0.9 (0.8; 1.2)¶
III	1.1 (0.9; 1.3)	1.0 (0.9; 1.2)¶
IV+	0.7 (0.5; 1.1)	0.8 (0.5; 1.4)¶
Smoking status		
Smoker	1.0 (0.8; 1.1)	1.0 (0.8; 1.6)¶
Non-smoker (including former smokers)	1 (ref)	1 (ref)
Alcohol consumption		
0 Danish standard drinks per week	1 (ref)	1 (ref)
1–21 Danish standard drinks per week*	1.4 (1.2; 1.5)	1.2 (1.0; 1.3)¶
> 21 Danish standard drinks per week†	1.8 (1.5; 2.2)	1.4 (1.0; 1.7)¶
Mode of surgery		
Open surgery	1 (ref)	1 (ref)
Laparoscopy only	1.4 (1.3; 1.6)	1.4 (1.2; 1.6)¶
Type of surgery		
Elective	1 (ref)	1 (ref)
Emergency/acute	0.9 (0.8; 1.0)	1.1 (0.9; 1.3)¶
Type of stoma		
Ileostomy‡	1 (ref)	1 (ref)
Colostomy§	2.0 (1.7; 2.3)	1.4 (1.2; 1.7)¶
Preoperative stoma marking		
Yes	1.1 (1.0; 1.2)	1.1 (0.9; 1.3)¶
No	1 (ref)	1 (ref)
Peristomal mesh (only sigmoid colostomies)		
Yes	0.8 (0.6; 1.0)	0.7 (0.6;1.0)**
No	1 (ref)	1 (ref)
Stoma placed through separate incision (only laparoscopies)		
Yes	1 (ref)	1 (ref)
No	1.3 (1.0; 1.7)	1.4 (1.1; 2.0)**

CI, confidence interval; ref, reference; IBD, inflammatory bowel disease; BMI, body mass index; ASA, American Society of Anesthesiologists physical status classification system.

*Corresponding to 1–252 g of alcohol per week.

†Corresponding to > 252 g of alcohol per week.

‡Jejunostomy + ileostomy.

§Transvere colostomy + sigmoid colostomy.

¶Model included the following variables: age; gender; diagnosis; BMI; ASA; smoking status; alcohol consumption; mode of surgery; type of surgery; type of stoma; and preoperative stoma marking.

**Subgroup analysis model included the following variables: age; gender; diagnosis; alcohol consumption; type of stoma; and mode of surgery.

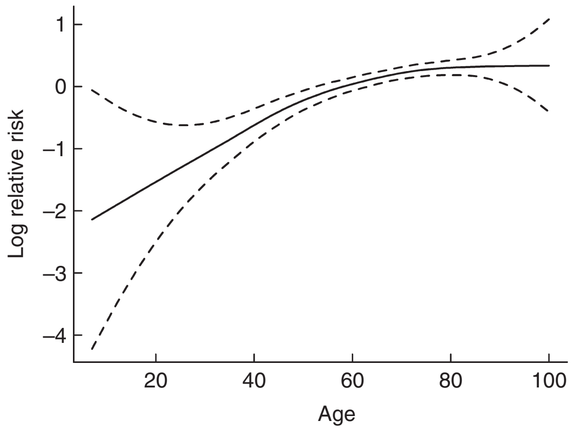

Figure 5 Relationship between age and the logarithm (log) of the adjusted hazard ratio of parastomal bulging. The risk was adjusted for gender, diagnosis, alcohol consumption, type of stoma, and mode of surgery. The median age of 66 years was set as reference corresponding to log hazard ratio of 0. The dotted lines illustrate 95% confidence intervals.

reduced risk of PB. Although it does not add causative data, the risk estimates found in this study add substantially to the body of evidence for PB.

Acknowledgements

The authors thank the funding sponsors for financial support. We are grateful for the help from stoma care nurses at Herlev Hospital and Rigshospitalet. The authors thank the Danish Stoma Database Capital Region and the Danish Anaesthesia Database.

This research received funding from The Research Foundation of the Capital Region of Denmark, Herlev and Gentofte Hospital, and Rigshospitalet, who were in no way involved in the study design or conduct, drafting of the manuscript, or any other aspects of the planning or conduct of this study.

Conflicts of interest

The authors have no conflicts of interest to disclose.

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Evaluation of abdominal exercises after stoma surgery: a descriptive study

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Implications for Rehabilitation

- The findings of this study can be used in clinical practice as guidance for choice of exercise at different time points after surgery
- This study identified useful exercises for activating the abdominal muscles in rehabilitation after stoma surgery from two weeks on
- Abdominal muscle activity was measured in a low percentage of participants in the first two postoperative weeks
- Most abdominal exercises were feasible after stoma surgery based on pain, discomfort, and difficulty

Evaluation of abdominal exercises after stoma surgery: a descriptive study

ABSTRACT

Purpose: To evaluate the feasibility of exercises for the abdominal muscles in patients after stoma formation on muscle activity, pain, discomfort, and difficulty.

Materials and methods: Patients with a new stoma were divided into groups based on time after surgery: Early group, 0-2 weeks (n=12); Inter-mediate group, 2-6 weeks (n=15); and Late group, 6-12 weeks (n=10). During a single individual test session, participants in each group performed a different set of 10 to 11 exercises. Activity of the abdominal muscles was measured with electromyography based on predetermined onset criteria. Pain, discomfort, and difficulty was rated for each exercise.

Results: For the Early group, muscle activity reaching the onset criteria was measured for half of the participants in a few exercises. In both the Intermediate group and the Late group, muscle activity reaching the onset criteria was measured for all muscles for a high percentage of participants in several exercises. Most exercises were feasible based on low ratings of pain, discomfort, and difficulty.

Conclusions: This study identified feasible exercises that activated the abdominal muscles at different time points after stoma formation. The observations can be used as guidance for the choice of exercises in clinical practice and future research.

Keywords: surgical stomas; ostomy; exercise; electromyography; ultrasonography

Word count (Introduction through Discussion, excl. table/figure indications): 2995

Introduction

The effect of abdominal surgery and stoma creation on the function of the abdominal wall muscles is unknown. The benefit or harms of abdominal exercise after stoma surgery has not been investigated in detail, but it is suggested to reduce the risk of parastomal hernias or bulging [1, 2, 3, 4, 5, 6]. Parastomal bulging is a common complication affecting one third of patients with a stoma 1 year after surgery, and more than 10% after 100 days [7]. Both parastomal bulging and hernias have a negative impact in the form of symptoms and affected quality of life [8, 9]. For parastomal hernias, surgical repair is associated with a risk of morbidity, mortality and recurrence of the hernia [10], and those not having hernia repair must learn to live with and manage their symptoms. There is no consensus on restrictions for postoperative physical activity after abdominal surgery [11]. The progression of the intensity of abdominal exercises must be carefully aligned with the patient's condition after surgery to ensure optimal outcome of the training. To qualify the choice of abdominal exercises, we need information on which abdominal exercises are feasible and if exercises activate the targeted abdominal muscles after stoma surgery. We therefore aimed to evaluate the feasibility of exercises for the abdominal muscles in patients after colostomy or ileostomy formation on the following parameters: muscle activity, pain, discomfort, and difficulty of performing the exercises.

Materials and methods

Study design

Patients with a new ileostomy or colostomy were recruited to participate in individual test sessions within 12 weeks after surgery. Participants were grouped based on time after surgery (**figure 1**): Early group, 0-2 weeks; Intermediate group, 2-6 weeks; and Late group, 6-12 weeks. Each group performed a different set of exercises (**figures 2-4**). Participants could only be included in one of the groups, and each participated in exactly one test session. Muscle activity was measured with electromyography (EMG) during exercises. Pain, discomfort, difficulty of exercises was rated by participants immediately after performing the exercises. We measured the transversus abdominis muscle (TrA) thickness and contraction bilaterally with ultrasound imaging at the beginning of test sessions.

[Figure 1 near here]

Setting

The study was conducted at inpatient wards and outpatient clinics at the Centre for Cancer and Organ Diseases, Copenhagen University Hospital, Rigshospitalet, Denmark, and the Department of Gastroenterology, Copenhagen University Hospital, Herlev and Gentofte, Denmark.

Participants

Eligibility criteria

Eligibility for each group was determined by the number of postoperative days at the time of participation: Early group, 1-14 days; Intermediate group, 15-42 days; Late group: 43-84 days. Eligible patients were 18 years of age or older, having undergone surgery with formation of a colostomy or an ileostomy. A colorectal surgeon at each site approved the patients' participation based on an overall assessment of the patient's health record including specific consideration of fascial dehiscence and wound complications. As participants for the Early group were recruited while still hospitalized after surgery, additional criteria were applied for that group based on the Danish Society of Anaesthesiology and Intensive Care

Medicine's recommended discharge criteria [12]: 10-30 respirations/minute; saturation >89%; systolic blood pressure 90-220mmHg; resting heart rate 50-120; the patient is awake and aware. Further, Early group-participants had to have resting pain scores below 3 on a 0-10 numeric rating scale [13] and no or mild nausea at the beginning of the test session (participant's subjective assessment). For the Intermediate and Late groups, pain or nausea had to be at a tolerable level (participant's subjective assessment) at the beginning of the test session. For all groups, patients were ineligible if either pregnant, breast feeding, medical condition prohibiting performance of any exercises (e.g. ICU stay), or cognitively unable to give informed consent. Patients were ineligible if exercises were prohibited due to complications or restrictions or if unable to get to a sitting position with minimal help from 1 person and sit without support.

Selection of participants

Potentially eligible patients were identified through stoma care nurses at each site. Patients were approached by a researcher (RMA), who assessed eligibility, gave oral and written information, and collected written informed consent. The study was approved by a regional research ethics committee (journal no. H-16032156).

[Figures 2 to 4 before or after 'Exercises']

Exercises

Within each of the groups, participants were asked to perform a distinct set of predetermined exercises (**figures 2-4**). The selection of exercises was inspired by previous studies on abdominal exercises after stoma formation [1, 2, 3, 4], studies on abdominal exercises for other conditions [14, 15, 16, 17, 18, 19, 20, 21, 22, 23], non-scientific literature (information pamphlets [24], websites [25]), physiotherapists with stoma experience, and from persons with a stoma. For the Early group, we aimed for abdominal muscle activation and exercises that could be performed in a hospital bed. For the Intermediate group, focus was on abdominal muscle activation and muscle strengthening. For the Late group, we chose exercises with a focus on abdominal muscle strengthening and coordination. The attempt was to align exercises for each group with the participants' presumed physical capabilities at the predefined times after surgery. At the test sessions, the researcher (RMA) demonstrated to the participant how to perform the exercises. The participant was asked to practice an exercise up to three times to ensure correct performance. Then the participant performed the exercise, while EMG was recorded during one or two repetitions. Subsequently, the participant rated pain, discomfort, and difficulty of the exercise before the next exercise was introduced.

[Figures 2 to 4 before or after 'Exercises']

Outcomes

Demographic data was collected, including American Society of Anesthesiologists physical status classification system (ASA) [26]. Any adverse events occurring during test sessions were registered.

Muscle activity

Activity of the abdominal muscles, rectus abdominis (RA), external oblique (EO), internal oblique (IO), and TrA, was measured during exercises using EMG. Surface electrodes were placed bilaterally on the skin at predetermined sites for electrode placement. Two surface electrodes were placed at each site in the direction of the muscle fibers of the corresponding muscles with an inter electrode distance of 2 cm [27, 28]. A single location was used for measurement of IO and TrA activity, as the muscles overlap, and signals cannot be discriminated with surface electrodes [29, 30, 31]. IO/TrA placement: 20 millimeters medial and inferior/caudal to the right anterior superior iliac spine [27, 29, 30, 31]. EO placement: slightly inferior to the eighth rib’s anterior angle, at the level of the umbilicus above and laterally to IO/TrA placement [27, 29, 30, 32]. RA placement: On the belly of the RA muscle above the umbilicus [27]. Reference electrode placement: On the tibial bone or the clavicle. If stoma appliances, bandages, or a surgical wound was blocking an electrode site, no electrode was placed, and the signals of the corresponding muscle were not recorded. Signal quality was inspected visually before testing. EMG signals were collected with an MQ-16 recording device (MarQ Medical, Farum, Denmark) and MathWorks MATLAB software (version 7.0 or newer). EMG signals were treated off-line. The signals were digitally high- and low-pass filtered (Butterworth fourth order zero-lag digital filter, cut-off frequencies 20 Hz and 500 Hz, respectively), full-wave rectified, and low-pass filtered at 15 Hz to create linear envelopes. From the linear envelopes, we determined the dichotomous outcome of whether muscle activity reached predetermined onset criteria of mean baseline activity (resting) plus six standard deviations for a minimum duration of 200ms [33, 34]. All signals were inspected visually for any artefacts or errors, and all data treatment was done in MathWorks MATLAB software (version 7 or newer).

Pain, discomfort, and difficulty

Immediately after each exercise, participants rated the amount of pain they experienced on a 0 to 10 numeric rating scale [13]. Discomfort was assessed in the same way. Participants were asked to rate the difficulty after each exercise on a five-point scale ranging from “1, very easy” to “5, very difficult”. The researcher (RMA) rated the difficulty on the same 1 to

5 scale based on an assessment of the participant's performance, understanding, and need for instructions.

Muscle thickness of the TrA

Thickness of the TrA muscle in millimeters was measured bilaterally at rest and during contraction using ultrasound imaging. Participants were asked to perform an abdominal drawing in maneuver (ADIM) to activate TrA. The following outcomes were calculated from ultrasound measurements: resting thickness of TrA; active thickness of TrA; and contraction ratio (active thickness divided by resting thickness) [35, 36]. A LOGIQ system (GE Healthcare) with a linear transducer and frequency of 9MHz was used for ultrasound measurements. Measurements were made in B-mode using the 'small parts' setting. Before measurement, participants were instructed in ADIM in a crook lying position [35, 37, 38] by inhaling and then exhaling while actively drawing the stomach toward the spine [35, 39]. Transducer placement was at the level of the umbilicus [39] with the anterior muscle-fascia junction at the medial edge of the screen [40]. Three freeze-frame images were taken during rest while exhaling and during ADIM on both the stoma side and opposite side of the abdomen. The mean thickness of each set of three images was used in the analysis. TrA thickness was measured with the built in measurement tool of the ultrasound system as the distance between the hyperechoic muscle fascia lines of the TrA [35] two centimeters from the anterior muscle-fascia junction (**figure 5**). Prior to participant recruitment, the researcher who performed measurements (RMA) was instructed by an experienced ultrasound physician and practiced the measurement protocol supervised and unsupervised until confident and familiar with the procedure.

Study size

No sample size calculations were performed for this descriptive study. The aim was to include at least 10 participants in each of the three groups in a given period.

[Figure 5 near hear]

Statistical methods

Descriptive statistics were used to present characteristics of each group and outcomes of pain, discomfort and difficulty. We calculated the percentage of participants with muscle activity reaching the threshold for each exercise and each muscle, bilaterally. Median TrA thickness (resting and active) and contraction ratio were calculated based on the mean of 3 measurements as described under ‘Outcomes’. All statistics were done in Microsoft Excel 2016 and SAS Enterprise Guide software (version 7.15).

Results

Participants

Participants were recruited between October 21, 2016, and July 24, 2018. Two hundred and forty-three patients were assessed for eligibility, 37 of whom were included in the study: 12 in the Early group; 15 in the Intermediate group; and 10 in the Late group (**Figure 6**). The majority of the excluded patients (n=157) did not meet the eligibility criteria. The most common reasons were medical condition prohibiting exercises (n=28, e.g. ICU stay, advanced disease), not having an ileostomy or colostomy (n=23, e.g. urostomy, not having a stoma, stoma reversal), and insufficient physical function to sit without support (n=21). Forty-two patients declined to participate: 19 were intended for the Early group, 17 for the Intermediate group, and 6 for the Late group. Of the 243 patients assessed (data on intended group missing for 19 of 243), most were intended for the Early group (120 of 224 with data, 54%), and fewer for the Intermediate group (69 of 224 with data, 31%) and Late group (35 of 224 with data, 16%).

[Figure 6 near here]

Descriptive data

Table 1 shows the characteristics of the Early group, Intermediate group, and Late group. For the entire study sample, there was an even gender and stoma type distribution, but an overweight of cancer diagnoses and participants having undergone elective surgery compared to the source population [7].

[Table 1 near here]

Outcome data

Muscle activity

The percentage of participants with muscle activity reaching the predetermined onset criteria is shown in **Figure 7**. For the Early group, less than 20% had RA-muscle activity reaching the onset criteria. In a few Early group exercises, muscle activity reaching the onset criteria was measured in oblique and transverse muscles for half the participants. For exercises 6 (left and right), more participants in the Intermediate group than in the Early group showed muscle activity reaching the onset criteria. For exercises 6 (left and right), 16, 21 (left and right), 22, 25 and 31, a high percentage of participants had muscle activity meeting the onset criteria across all muscles.

[Figure 7 near here]

Pain, discomfort, and difficulty

Pain, discomfort and difficulty ratings are shown in **figure 8**. Median pain was ’0’ for all exercises, meaning that for every exercise evaluated, more than half of the participants who performed them did not experience any pain. No participants rated pain higher than ‘5’ for any exercise. Pain above zero was rare in the Intermediate and Late groups, but a bit more common in the Early group. Six Early group-participants mentioned pain near the stoma in one or more exercises involving hip flexion. As with pain, the median discomfort was ‘0’ for all exercises (**figure 8**). Only one exercise, 25, received a discomfort rating above ‘4’. With respect to participant and researcher rated difficulty (**figure 8**), the exercises for the Late group were the most difficult to perform followed by those for the Intermediate group. The exercises were generally rated as easy for the Early group. For the Intermediate group and Late group, the researcher more frequently rated difficulty as ‘4’ or ‘5’ than did the participants (**figure 8**). For the Early group, participants rated difficulty above ‘1’ more frequently. Difficulty was observed in exercises sitting or lying on a ball, i.e. 18, 20, and 25-28 but not 19. Only 4 of 10 participants were able to perform and complete exercise 25.

[Figure 8 near here]

Muscle thickness

TrA thickness results for 33 of 37 participants are shown in **table 2**. Four participants had no ultrasound data (ultrasound device not working; no measurements; ultrasound device not available; not able to get clear image of TrA on either side). The resting thickness, active thickness, and contraction ratio of TrA were comparable on the stoma side and the opposite side.

[Table 2 near here]

Harms

Two participants belonging to the Early group experienced an adverse event during testing. One experienced known leg cramps that quickly passed, another became nauseated. Neither were serious adverse events [41] and both participants were able to continue.

Discussion

After colostomy or ileostomy formation, few patients in the Early group reached muscle activity according to onset criteria. Several exercises in the Intermediate and Late groups did well in activating the abdominal muscles after stoma formation. Pain and discomfort levels were low across the groups. The level of difficulty was low in the Early and the Intermediate groups and moderate in the Late group.

The limited ability of Early group participants to generate muscle activity meeting the onset criteria were likely related to the short time after surgery. This was illustrated by exercise 6 (left and right), which was performed in both the Early group and Intermediate group, but with more participants reaching the onset criteria for the same exercise in the Intermediate group. The chosen onset criteria were conservative [34], making us confident of actual muscle activity when measured. Early group exercises might have been too easy, as indicated by low ratings of difficulty, but the high number of excluded patients for the Early group makes it doubtful that more strenuous exercises should have been chosen. Pain, nausea, and fatigue are common clinical problems in the early postoperative period [42, 43]. Attempts at abdominal exercises in the first weeks after stoma surgery should include a plan for symptom-relief and perhaps facilitated exercises in attempt to increase exercise activities [44]. A previous study investigated abdominal exercises starting at hospital discharge [3], including exercises '1' and '2', indicating that initiation of gentle abdominal exercise is feasible from the time of discharge.

The more frequent difficulty ratings of '4' or '5' by the researcher in the Intermediate and Late groups was likely due to the researcher weighing the need for instructions, something the participants probably did not consider. The relatively low levels of difficulty, pain, and discomfort in the Intermediate group suggest, that health professionals should not underestimate the exercise capabilities of patients with a stoma in the weeks after hospital discharge.

We found no differences in TrA thickness or contraction ratio between stoma side and opposite side, giving no indication that TrA muscle function was impacted more on the stoma side after surgery. Another study [38] looked at people with an ileostomy (and low back pain) more than 9 months after surgery and reported on the difference in absolute contraction (active thickness minus resting thickness) between stoma side and opposite site [38]. The difference was small, stated as 1.21 millimeters on the stoma side and 1.38 millimeters on the opposite side with wide ranges, and does not appear meaningful.

Study limitations

There was likely selection bias from the high number of excluded patients, most of whom were intended for the Early group. The result was that we primarily included the patients who were most physically and mentally able to participate in test sessions. Pain, discomfort and difficulty levels were likely skewed towards lower values than if the exercises were evaluated in a broader population of patients with a new stoma. Another limitation was the low number of exercise repetitions in this study. Evaluations may have changed with more repetitions and if performed over a period of several weeks. Difficulty would likely be lower, and patients would presumably be able to generate more muscle activity with increasing familiarity with the exercises. This study was descriptive by design, and caution should be shown in not interpreting the findings as an effect of abdominal exercises after stoma formation.

Conclusions

The results suggest that most of the evaluated exercises were feasible based on levels of pain, discomfort, and difficulty. The observations in this study can be used as guidance for the choice of exercises in clinical practice and future research, e.g. of the effect of abdominal exercises on physical function and/or the incidence of parastomal hernias or bulging. Health professionals and researchers can choose exercises that activate the abdominal muscles after stoma formation and select exercises based on the time passed after surgery. Exercises 6, 9, 16, 20-22, and 31 led to activity of the abdominal muscles with low levels of pain, discomfort and difficulty in a high number of participants.

Acknowledgments

The authors would like to thank the stoma care nurses at Herlev Hospital and Rigshospitalet for assistance with patient recruitment; Team Danmark for help with electromyography equipment; physiotherapist Pia Espensen for input on exercises; and the ultrasound physicians at Herlev Hospital for supervision on ultrasound measurements.

The study was funded by grants from The Research Foundation of the Capital Region of Denmark; Toyota-Fonden, Denmark (KJ/BG-9092 H); Copenhagen University Hospital, Herlev and Gentofte, Denmark; and Copenhagen University Hospital, Rigshospitalet, Denmark.

Declaration of Interest

The authors report no conflicts of interest.

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Tables

Table 1. Characteristics of the study population

	EARLY GROUP (n=12)	INTERMEDIATE GROUP (n=15)	LATE GROUP (n=10)
Age, median [IQR*]	64.5 [52.5; 72.0]	69.0 [59.0; 72.0]	71.0 [55.0; 79.0]
Gender, n			
Female	7	8	3
Male	5	7	7
Stoma type, n			
Colostomy	3	7	6
Ileostomy	9	8	4
BMI†, median [IQR*]	23.7 [19.2; 25.9]	25.1 [21.3; 27.2]	24.4 [20.2; 27.1]
Days after surgery, median [IQR*]	10.0 [6.0; 12.0]	32.0 [27.0; 35.0]	70.0 [52.0; 82.0]
Diagnosis, n			
Cancer	9	14	7
Inflammatory bowel disease	1	1	2
Diverticulitis	1	0	0
Other	1	0	1
Type of surgery, n			
Elective	11	14	9
Emergency/acute	1	1	1
Mode of surgery, n			
Open surgery	6	6	4

Laparoscopy	1	6	3
Robot-assisted laparoscopy	5	3	3
Stoma prognosis, n			
Permanent	5	7	5
Temporary	7	8	5
Work status, n			
Working	1	3	2
Retired	6	9	6
Sick leave	5	3	2
ASA score‡, n			
I	1	1	0
II	9	11	8
III	1	2	2
Missing	1	1	0

*****IQR = interquartile range, †BMI = body mass index, ‡ASA = American Society of Anesthesiologists Physical Status Classification System

Table 2. Transversus abdominis thickness

Outcome	Stoma side	Opposite side
Resting thickness (mm*), median [IQR†] (range)	3.1 [2.7; 4.4] (1.6 – 5.8)	3.3 [2.7; 5.1] (1.2 – 6.7)
Active thickness (mm*), median [IQR†] (range)	4.9 [3.7; 6.5] (1.7 – 11.6)	4.8 [3.9; 6.8] (1.4 – 10.4)
Contraction ratio, median [IQR†] (range)	1.35 [1.20; 1.53] (1.01 – 2.39)	1.43 [1.26; 1.58] (1.03 – 2.41)

*mm = millimeters, †IQR = interquartile range

Figure captions

Figure 1. Overview of study design. Patients were grouped based on time after surgery at the day of participating in exercise evaluation. Evaluation of exercises included muscle activity as well as patient reported pain, discomfort, and difficulty during 1 or 2 repetitions of each exercise. Figures 2-4 show an overview of exercises for each group.

Figure 2. Overview of exercises for the Early group.

Figure 3. Overview of exercises for the Intermediate group.

Figure 4. Overview of exercises for the Late group.

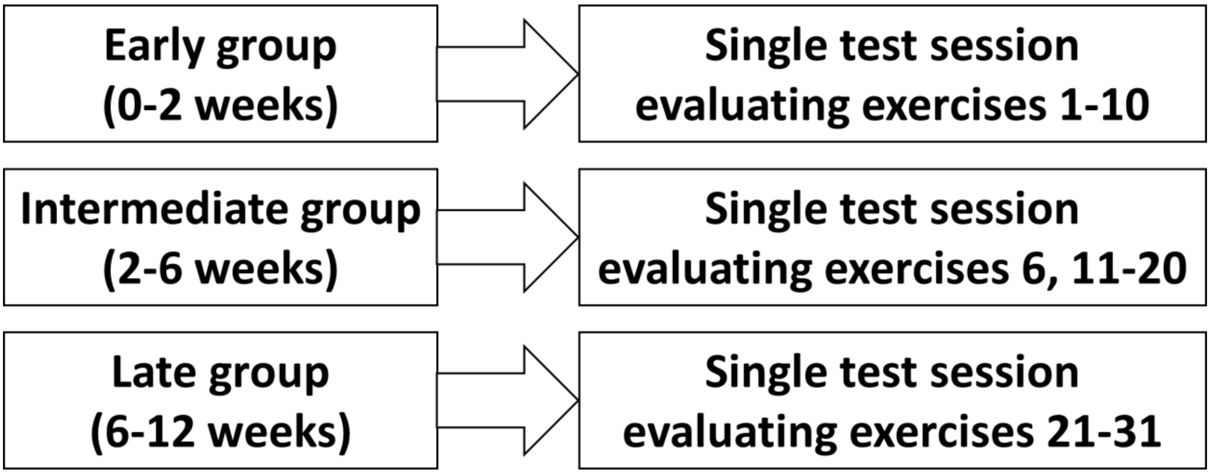
Figure 5. Example of ultrasound measurement of the transversus abdominis muscle. Left: Resting thickness. Right: Active thickness. EO = external oblique, IO = internal oblique, TrA = transversus abdominis. TrA thickness was measured as the distance between the hyperechoic muscle fascia lines two centimeters from the anterior muscle-fascia junction.

Figure 6. Flow diagram of patient screening and inclusion.

Figure 7. Percentage of participants with muscle activity meeting onset criteria for each muscle and for each exercise. Ex. = exercise, RA-l = left rectus abdominis muscle, RA-r = right rectus abdominis muscle, EO-l = left external oblique muscle, EO-r = right external oblique muscle, IO/TrA-l = left internal oblique and transversus abdominis muscles, IO/TrA-r = right internal oblique and transversus abdominis muscles. Red color denotes low

percentage of participants with muscle activity meeting onset criteria, green color denotes high percentage.

Figure 8. All ratings of pain (0-10), discomfort (0-10), patient rated difficulty (1-5), and assessor rated difficulty (1-5). Ratings are on the y-axes, and the numbers on x-axes denote exercises (see Figures 2-4). Early group ratings: green circles; Intermediate group ratings: blue stars; Late group ratings: red diamonds. *Exercises 6r and 6l were performed by participants in both the Early group and Intermediate group.



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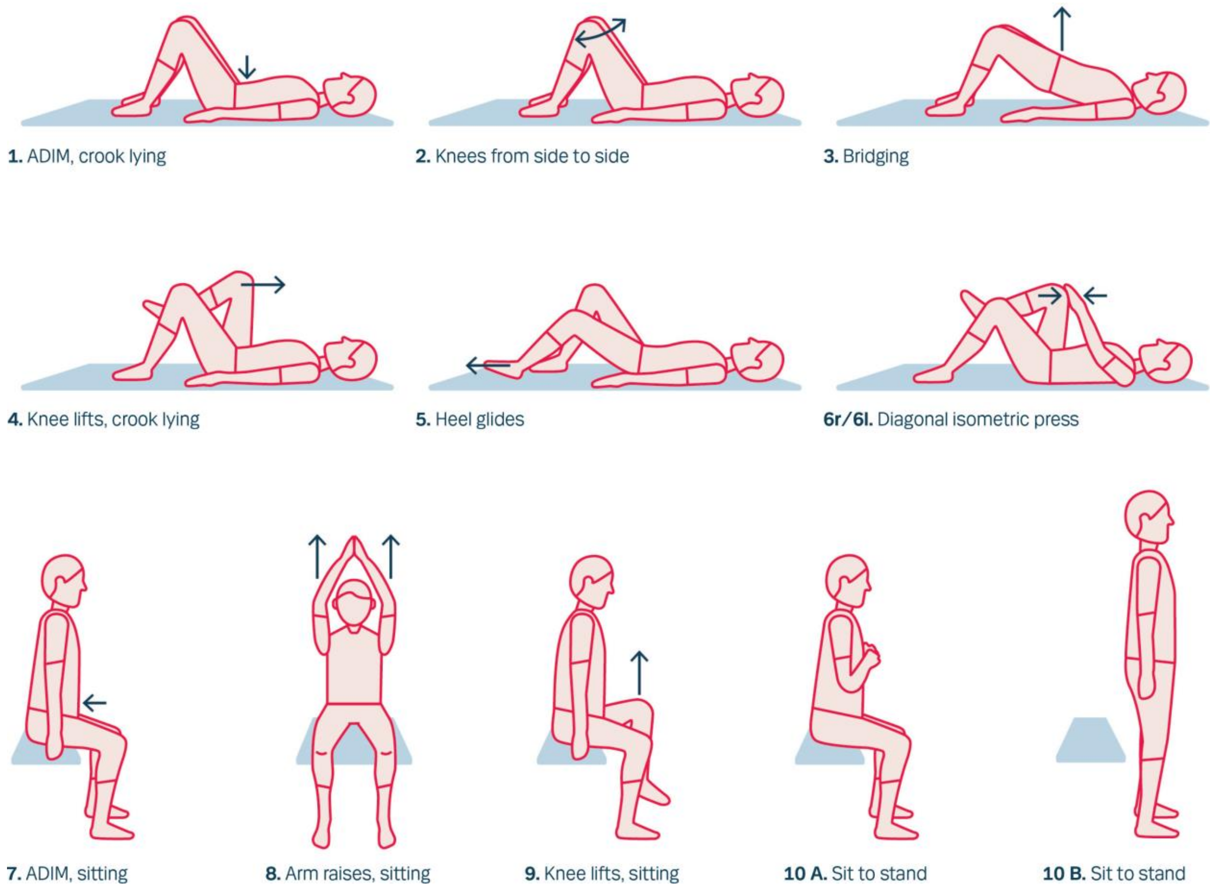

Figure 2. Overview of exercises for the Early group.

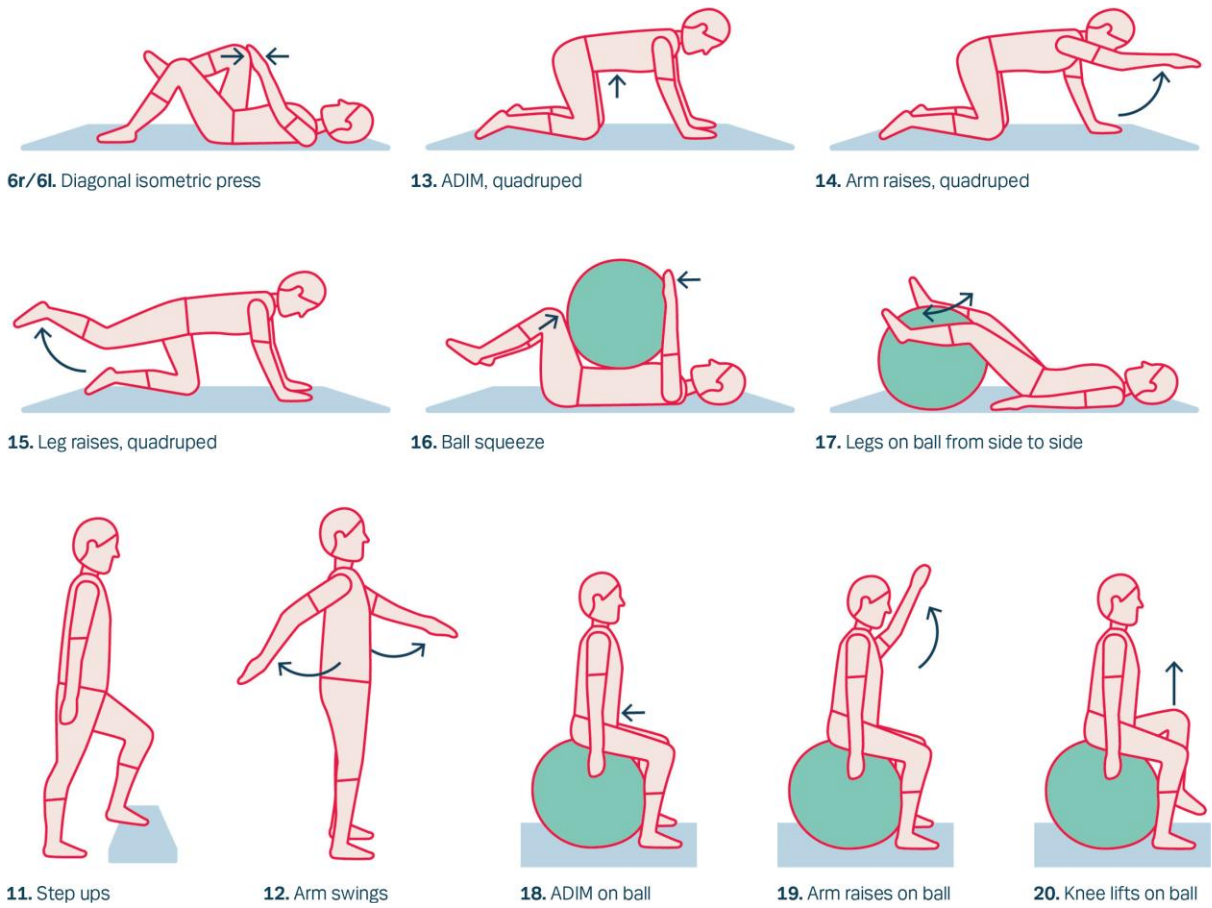

Figure 3. Overview of exercises for the Intermediate group.

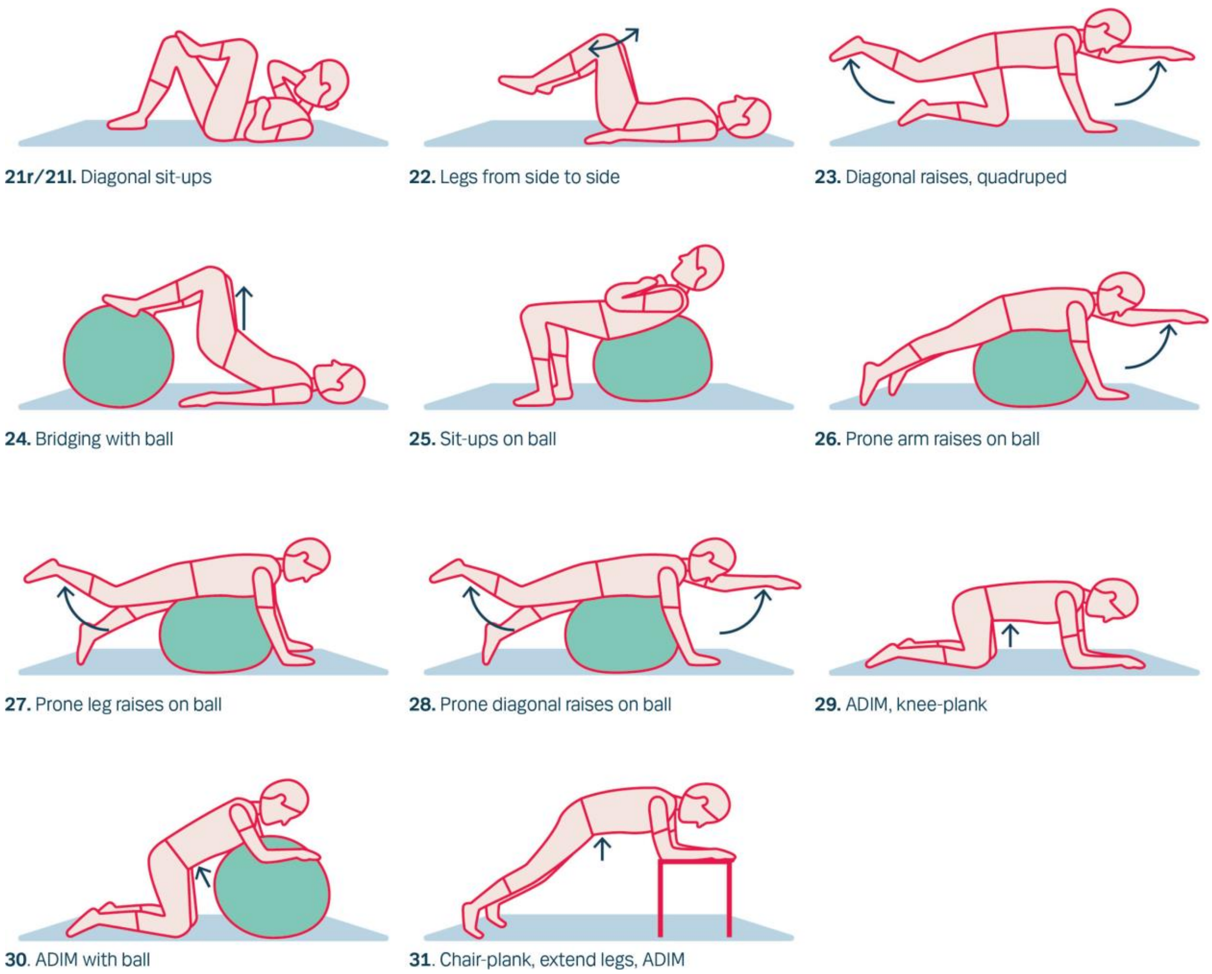

Figure 4. Overview of exercises for the Late group.

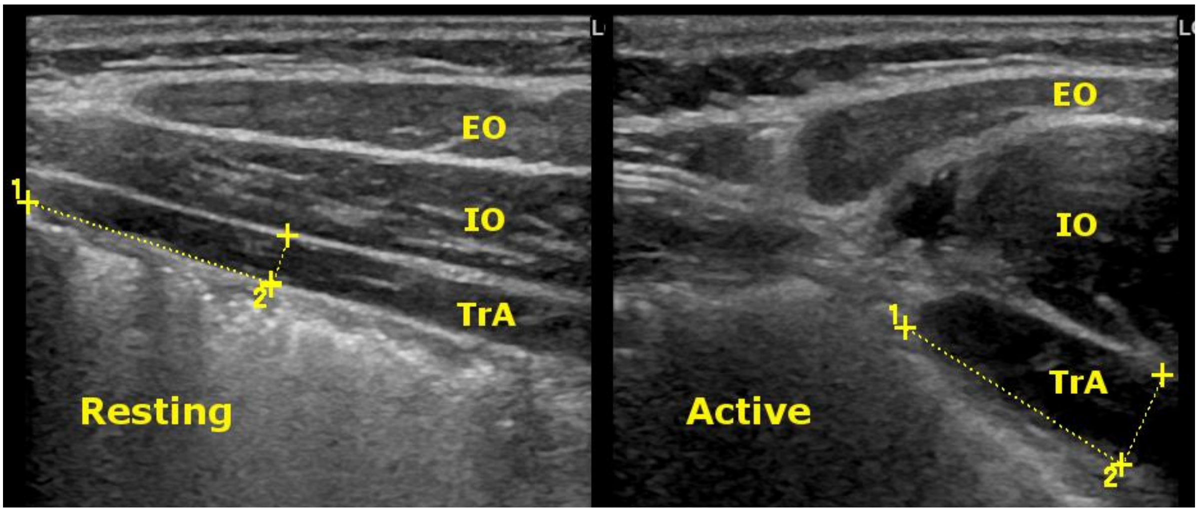

Figure 5. Example of ultrasound measurement of the transversus abdominis muscle. Left: Resting thickness. Right: Active thickness. EO = external oblique, IO = internal oblique, TrA = transversus abdominis. TrA thickness was measured as the distance between the hyperechoic muscle fascia lines two centimeters from the anterior muscle-fascia junction.

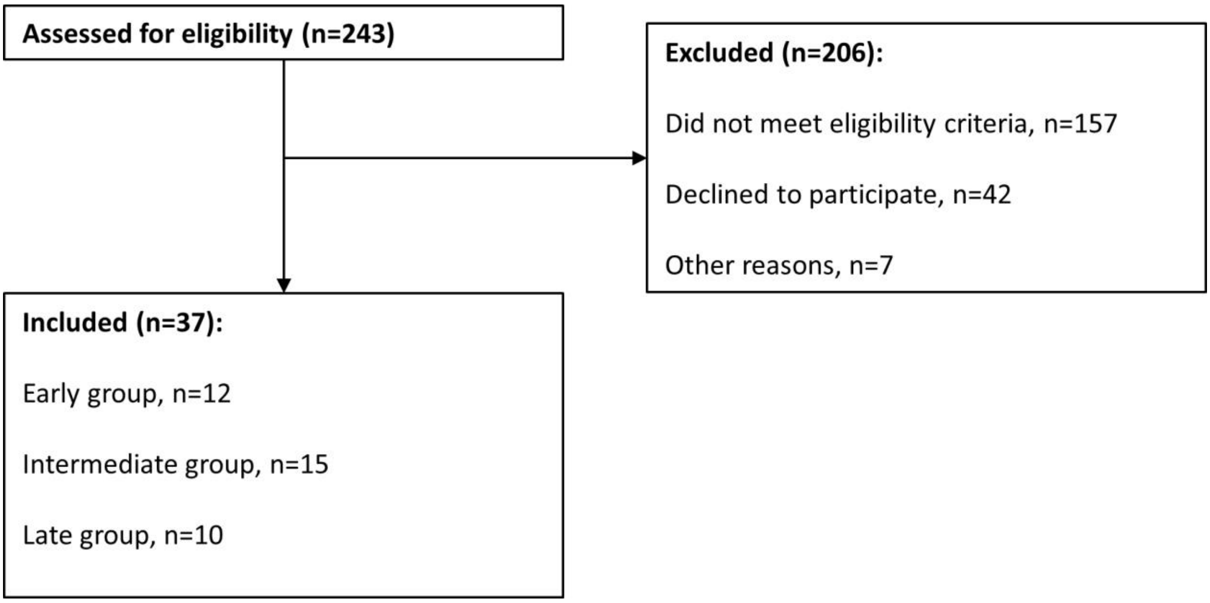

Figure 6. Flow diagram of patient screening and inclusion.

EARLY GROUP

Ex.	RA-l	RA-r	EO-l	EO-r	IO/TrA-l	IO/TrA-r
1	0%	9%	33%	20%	25%	13%
2	0%	0%	17%	10%	17%	13%
3	0%	0%	0%	10%	17%	0%
4	0%	0%	17%	0%	42%	33%
5	0%	9%	8%	10%	25%	57%
6r	17%	9%	17%	50%	50%	14%
6l	9%	10%	45%	11%	18%	40%
7	0%	0%	42%	30%	42%	25%
8	17%	10%	42%	40%	17%	25%
9	0%	0%	18%	22%	60%	50%
10	18%	10%	27%	33%	11%	57%

INTERMEDIATE GROUP

Ex.	RA-l	RA-r	EO-l	EO-r	IO/TrA-l	IO/TrA-r
6r	69%	87%	85%	73%	92%	53%
6l	77%	67%	85%	53%	54%	87%
11	0%	9%	45%	36%	55%	73%
12	8%	20%	38%	7%	38%	36%
13	25%	29%	46%	36%	33%	64%
14	8%	7%	62%	43%	33%	46%
15	0%	0%	38%	15%	50%	36%
16	82%	92%	100%	100%	91%	83%
17	31%	29%	54%	31%	31%	36%
18	25%	14%	46%	38%	58%	50%
19	25%	14%	31%	23%	50%	21%
20	36%	46%	75%	67%	91%	69%

LATE GROUP

Ex.	RA-l	RA-r	EO-l	EO-r	IO/TrA-l	IO/TrA-r
21r	100%	100%	100%	100%	80%	56%
21l	100%	100%	100%	100%	80%	78%
22	100%	100%	100%	90%	70%	67%
23	30%	40%	50%	40%	50%	50%
24	30%	50%	30%	30%	30%	25%
25	100%	100%	100%	100%	100%	100%
26	44%	56%	78%	44%	44%	38%
27	38%	63%	50%	38%	63%	29%
28	29%	43%	71%	38%	57%	67%
29	40%	60%	70%	40%	40%	38%
30	40%	60%	60%	50%	80%	50%
31	100%	100%	100%	100%	80%	75%

Figure 7. Percentage of participants with muscle activity meeting onset criteria for each muscle and for each exercise. Ex. = exercise, RA-l = left rectus abdominis muscle, RA-r = right rectus abdominis muscle, EO-l = left external oblique muscle, EO-r = right external oblique muscle, IO/TrA-l = left internal oblique and transversus abdominis muscles, IO/TrA-r = right internal oblique and transversus abdominis muscles. Red color denotes low percentage of participants with muscle activity meeting onset criteria, green color denotes high percentage.

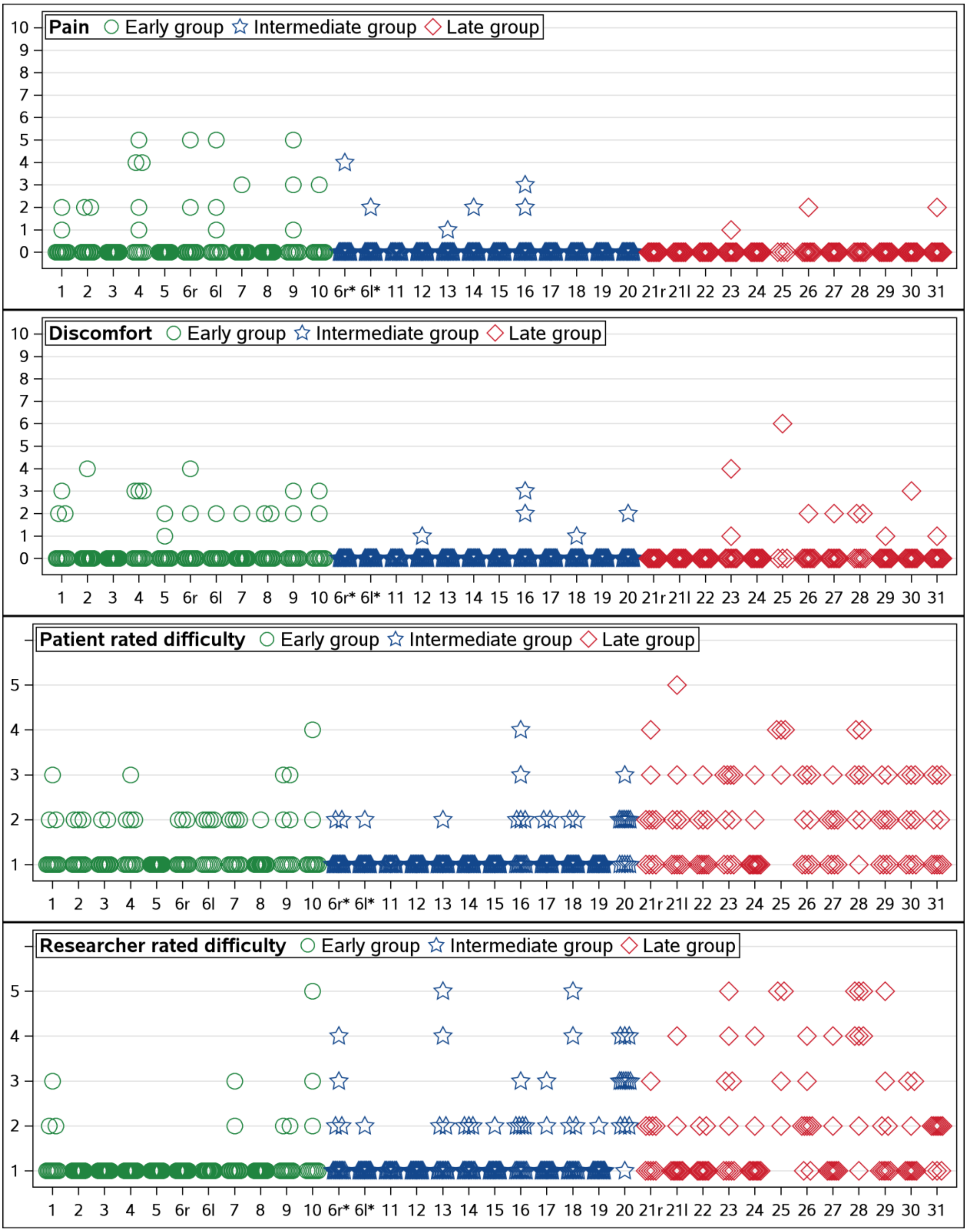

Figure 8. All ratings of pain (0-10), discomfort (0-10), patient rated difficulty (1-5), and assessor rated difficulty (1-5). Ratings are on the y-axes, and the numbers on x-axes denote exercises (see Figures 2-4). Early group ratings: green circles; Intermediate group ratings: blue stars; Late group ratings: red diamonds. *Exercises 6r and 6l were performed by participants in both the Early group and Intermediate group.

Patients' experiences of abdominal exercises after stoma surgery: a qualitative study

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Implications for Rehabilitation

- Participants were positive toward abdominal exercises, and the stoma was rarely in the way
- Help and guidance with abdominal exercises is important after stoma surgery
- Health professionals should consider possible barriers and concerns to exercise

Patients' experiences of abdominal exercises after stoma surgery: a qualitative study

ABSTRACT

Purpose: Abdominal exercises are being advocated after stoma surgery and investigated in clinical research. Little is known about the patients' perspective of doing abdominal exercises in the weeks or months after getting a stoma. The aim of this study was to explore patients' experiences with and attitude toward abdominal exercises after stoma surgery.

Materials and methods: Patients with a new ileostomy or colostomy were invited to participate in interviews after having performed abdominal exercises a single time as part of a preceding study. Semi-structured interviews were conducted at inpatient wards and outpatient clinics at two hospitals. Audio recordings were transcribed to text verbatim and analyzed with inductive content analysis.

Results: Analysis of 14 interviews resulted in 4 categories: 'The attitude toward abdominal exercises is positive'; 'Treatment and illness form barriers to abdominal exercises'; 'Wish for help with abdominal exercises after stoma surgery'; and 'Abdominal exercises are experienced as being easy'.

Conclusions: Participants with a new stoma wished for guidance to engage in abdominal exercises. Health professionals seeing participants with a stoma for abdominal exercises should be aware of possible barriers to participation in abdominal exercises. Abdominal exercises were easy to perform with a stoma.

Key words: surgical stomas; ostomy; exercise; qualitative research; rehabilitation

Word count: 3721

Introduction

Following surgery, the process of recovery begins for the patient with a new stoma [1]. Recovery continues after discharge, sometimes mediated by physical rehabilitation and visits to stoma care nurses and doctors at outpatient clinics, or perhaps halted or delayed by adjuvant oncological treatment. Physical exercise is important after stoma surgery and has long been viewed as an important part of rehabilitation [2], although concerns remain about what is appropriate. It is hypothesized that patients with a stoma should strengthen their abdominal muscles to prevent parastomal hernias [3, 4, 5, 6, 7, 8, 9], but the supporting evidence is weak and there is little knowledge of the potential harms. A UK survey of 2631 persons with a stoma found that few of the respondents had performed abdominal exercises after their surgery [3]. Abdominal exercises may facilitate physical rehabilitation after stoma surgery and have typically been applied in combination with other forms of exercise or mobilization [10, 11, 12]. We lack knowledge of the patients' perspectives on doing abdominal exercises following surgery. Health professionals working to help patients rehabilitate their abdominal wall and researchers looking to investigate abdominal exercises after stoma surgery would benefit from this insight, given that well-planned exercise interventions are worthless if patients do not accept or adhere to them. Addressing potential barriers to exercise should increase the odds of a higher adherence to abdominal exercises. A recent qualitative study looked into physical activity in cancer survivors with a stoma and identified reasons and deterrents for engaging in physical activity [13], but qualitative studies specifically looking at patient experiences of abdominal exercises in the immediate period after stoma surgery are to our knowledge absent in the existing literature. We therefore aimed to explore patients' experiences of and attitudes toward abdominal exercises after stoma surgery.

Materials and methods

Patients with a newly formed ileostomy or colostomy were invited to participate in a semi-structured interview after having tried abdominal exercises as part of a preceding study evaluating the feasibility of the exercises (described below under 'Participants'). Inductive content analysis [14, 15, 16] was used in a descriptive generic qualitative research approach [17, 18]. The Consolidated Criteria for Reporting Qualitative Studies (COREQ) checklist [19] was used in reporting the study.

Setting

Interviews took place at two university hospitals in the Capital Region of Denmark: Rigshospitalet, Blegdamsvej, Copenhagen, Denmark, and Herlev and Gentofte Hospital, Herlev, Denmark.

Participants

Participants were selected based on convenience sampling and were recruited consecutively from a preceding quantitative study in which abdominal exercises were performed (study under review in *Disability and Rehabilitation*). Participants were approached by the researcher, RMA, in person after having performed the abdominal exercises. Participants were eligible if they met the following criteria: participation in the preceding study evaluating abdominal exercises; willing to participate in an interview; Danish language skills; physically able to endure an interview of 30 minutes; and cognitively able to understand questions and respond meaningfully. To get nuanced information, we aimed for a representation of both genders, young and old, cancer and non-cancer diagnosis, and participants from all groups in the preceding study (described below). Therefore, we intended to recruit a minimum of 10 to 15 participants.

Abdominal exercises

Participants in the present study performed abdominal exercises in a preceding study of the feasibility of abdominal exercises after stoma surgery. Feasibility was assessed using electromyography, ultrasound imaging, and self-rated pain, discomfort and difficulty of the exercises. Participants in the feasibility study were grouped in three groups with different sets of exercises tailored to the time passed since stoma surgery (examples shown in figure 1). Each group performed a selection of up to 11 different exercises for the abdominal muscles during a single individual test session of 60 to 90 minutes duration. In the Early group, 0-2 weeks after surgery, exercises were relatively gentle, lying or sitting on a hospital bed. In the Intermediate group, 2-6 weeks after surgery, exercises were more demanding, and some involved sitting on an exercise ball. Finally, in the Late group, 6-12 weeks after surgery, exercises were more challenging.

[figure 1 near hear]

Data collection

All interviews were conducted by the same researcher, RMA, a male PhD student and physiotherapist with eight years of clinical experience in hematology, oncology, surgical gastroenterology, cardiac rehabilitation, respiratory physiotherapy, and falls prevention. RMA had limited experience in qualitative research and received training and supervision from the experienced members of the research team. RMA was interviewed to document his subjective preconceptions prior to commencing the study. The interviewer’s preconceptions included a positive view of exercises in general and as beneficial after major surgery; an expectation that participants might refrain from voicing negative views on the abdominal exercises; the anticipation of more worries and physical symptoms among participants who performed exercises shortly after surgery; and the belief that abdominal exercises were safe to perform, but that participants might not hold the same view. The interviewer's subjective preconceptions were considered throughout the study. RMA had already established relationships with the participants when evaluating abdominal exercises prior to the interviews. Participants were informed about the purpose of the study and that the interviewer was also researching the incidence of parastomal bulging after stoma surgery in addition to the study on abdominal exercises. Participants were offered to be interviewed at home, but all preferred being interviewed in an undisturbed room at the hospital and all interviews were conducted face-to-face.

An interview guide (table 1) was used to guide interviews and support the interviewer. The interview guide was based on the study purpose and also contained questions on prior exercise experiences and recommendations for future abdominal exercise programs inspired by the Consensus on Exercise Reporting Template [20]. A mock interview was done before study commencement to test the interview guide. The interview guide was adjusted during the study period as the interviewer, RMA, and another researcher, AKD, listened through the interviews. AKD also provided RMA feedback on interview technique throughout the study period. Interviews were audio recorded, and audio files were stored in compliance with data protection requirements. Field notes containing general notes and reflections on the context of the interview were taken after each interview.

[table 1 near hear]

Data analysis

Audio recordings were transcribed to text verbatim and analyzed with content analysis using the approach described by Graneheim and Lundman [14]. The content analysis approach was inductive, deriving codes, categories, and subcategories from the data [15]. After familiarization with the data, RMA coded the data on a manifest level [16] and went through the coding with other researchers, AV and MK, also familiarized with the data. When all interviews were coded, initial categories and subcategories were created in a group session (RMA, AV, MK, AKD, and TT). RMA and AV refined categories and subcategories and translated them to English. Investigator triangulation was used by having multiple researchers, with physiotherapist and nurse backgrounds, partake in the analysis [21]. REDCap through the Capital Region of Denmark and Microsoft Excel 2016 software was used for data management. QSR NVivo 12 software was used for analysis.

Ethical considerations

We contacted the regional committee on health research ethics in the Capital Region of Denmark and received written confirmation that the study was not subject to research ethics committee approval under Danish law (journal no. H-18001690). The study was approved by the Danish Data Protection Agency (journal no. RH-2018-31, I-Suite no. 6186). All participants received written and oral information and gave their written informed consent before being interviewed.

Results

Twenty-one patients performed abdominal exercises in the feasibility study during the recruitment period of the present qualitative study, from January to July 2018. Of these, 14 were included in the present study, 3 were ineligible, 1 declined to participate, and 3 could not be reached for an interview. Each group from the preceding study was represented with most participants from the Intermediate group performing exercises 2-6 weeks after surgery (n=10), and two participants from each of the Early and Late groups, 0-2 weeks and 6-12 after surgery, respectively (table 2). Participants had a median age of 67.5 years (range: 20-73) and 12 of them had cancer. All participants had undergone elective surgery. Interviews were conducted a median of 19.5 days (range 0-49 days) after abdominal exercises in the preceding study. Interviews lasted from 15 to 37 minutes. We identified 4 categories (figure 2): 'The attitude toward abdominal exercises is positive'; 'Treatment and illness form barriers to abdominal exercises'; 'Wish for help with abdominal exercises after stoma surgery'; and 'Abdominal exercises are experienced as being easy'.

[table 2 near hear]

The attitude toward abdominal exercises is positive

The participants overall agreed that exercise was a good thing. The perceived benefits of abdominal exercises included improved physical fitness and function; stronger abdominal muscles; shift of focus away from illness; tighter abdominal muscles; six-pack abs; flat belly; prevention of hernias; improved balance; and improved wellbeing. A documented effect was important for deciding to engage in abdominal exercises. A few participants anticipated that exercising would be painful but found that it was not. Others thought exercising after stoma surgery was wild and exciting:

> "I thought it was a bit wild, when I had just had abdominal surgery [laughs], but I thought it was exciting to see what I could endure" *(Female participant, 49)*

Some were motivated for exercise in general and wanted to improve their overall physical condition so as better to be able to go for runs, walks, or bike rides. A few who were scheduled for later stoma reversal or other abdominal surgery were motivated for abdominal exercises, as they wanted to be physically well-prepared for surgery. Having physical performance measured and being able to track progress was also a source of motivation. Not all participants were motivated to exercise. Some lacked strength or energy or needed help getting motivated, e.g. by committing to an exercise class. A few would rather pursue cardiovascular exercise or team sports and lacked the motivation for abdominal exercises.

[figure 2 near hear]

Treatment and illness form barriers to abdominal exercises

The participants described concerns and challenges that kept them from engaging in abdominal exercises. Some had to do with stoma surgery, others were related to illness, adjuvant treatment, or practical issues.

Stoma surgery causes concern about doing abdominal exercises

Some participants thought abdominal exercises to be unharmful, and others voiced concerns in relation to doing them. One concern was about something happening to the stoma, intestines or anastomosis. Participants worried that abdominal exercises could cause the stoma to rupture, separate from the skin, or be pushed in. For some it was difficult to articulate their concerns regarding their stoma other than a sense that something could happen. Stoma concerns were expressed by participants both weeks and months after surgery. A few participants were concerned that abdominal exercise could provoke a parastomal hernia and mentioned having heard that the incidence of hernias was high. Others thought exercises could help prevent a hernia.

Postoperative recovery and treatment pose challenges to abdominal exercises

Pain, surgical complications, a hunched posture, nausea, vomiting, stoma complications, discomfort when lying in a flat position, and leg edema made exercising difficult for some participants. A few experienced their illness preventing them from doing any kind of exercises. Chemotherapy was mentioned as a barrier to abdominal exercises due to low blood counts or catheters and pumps that limited or kept participants from doing exercises. Some participants struggled to overcome insecurity about being able to perform abdominal exercises. Being unable to engage in abdominal exercises like they were used to, was reported to affect participants mentally or emotionally. One participant mentioned noises from the stoma as a reason for not wanting to engage in exercise activities together with people without a stoma. Having to travel long distances, waiting time, frequent hospital appointments, competing (local) rehabilitation offers, return to work, and lack of flexibility were barriers to participating in an abdominal exercise program away from home. Group-based exercise away from home was also viewed as a way to establish a routine and to make sure that exercises were in fact done.

Wish for help with abdominal exercises after stoma surgery

Participants expressed a need for help and guidance on how to get started with abdominal exercises and assurance that it was safe to perform them. The participants had different preferences for how abdominal exercises should be offered.

A wish for guidance with abdominal exercises

Participants from all groups, 0-2, 2-6, and 6-12 weeks after surgery, expressed a wish for help with abdominal exercises, including the need for a "push" to get started. Participants with and without prior experience with abdominal exercises requested guidance in navigating exercises or assurance that it would be safe for them to perform abdominal exercises:

> "It would be nice just to get feedback that you don't have to worry about that [stoma separation from the skin], that never happens, [laughs] or something like that" *(Female participant, 70)*

Participants suggested that written material, i.e. a catalogue of exercises with descriptions or a detailed exercise plan, would be helpful. Exercises that were tailored to the individual patient were also suggested, as were follow-up on abdominal exercises and reminders. Participants thought it natural for physiotherapists to supervise the abdominal exercises or mainly wanted qualified health professionals with knowledge of their situation. Participants expressed confidence that abdominal exercises presented by their health professionals would be feasible and safe after stoma surgery.

Preferences for delivery of abdominal exercises vary

Few participants preferred individually supervised abdominal exercises, and they thought it a costly use of resources. The participants differed in their preferences as to how the exercises should be delivered. Some preferred group-based exercise and others individual sessions where they could set their own pace and not be confronted with the social element of exercising with other people. Stoma specific exercise classes and small groups with as few as 2-3 people per session were among the participants' suggestions. Several participants felt that they lacked the motivation for doing home-based exercise. Most participants considered 2-3 weeks after surgery the best time for starting abdominal exercises. Fatigue, wound healing, removal of surgical staples was cited as reasons for preferring to start later after surgery.

Abdominal exercises are experienced as being easy

In general, the participants perceived the abdominal exercises to be easy or even boring, leading some to question the benefit of the exercises. Ball exercises were challenging for participants' balance, but trying the abdominal exercises was a positive experience overall.

> "I have a hard time seeing how you can strengthen the abdominal muscles very much with something as calm as this." *(Female participant, 72)*

A few participants found the level of exercises to be fitting or even difficult. Participants liked the ball exercises even if sitting or lying on the ball could cause balance problems. Some viewed this as good balance training while others found it impractical for home-based exercise. Fear of nausea and an unstable base of support made ball exercises unpleasant. Most participants did not pay attention to their stomas during abdominal exercises and they rarely experienced that the stoma was in the way while doing exercises.

> "For me at least the stoma is not something that keeps me from doing exercises. It is solely a cosmetic thing, it is not something that is in the way or prevents me from performing." *(Male participant, 53)*

Participants gave examples of managing their stoma during exercises, including emptying the stoma bag, wearing a support belt, getting the necessary help and products through a stoma care nurse, or dressing in a way that fits the stoma.

To some, a prone position or a full stoma bag could be bothersome. For participants with an ileostomy, the fluid output and long stoma bag was impractical during exercises, hindered free movement, and was uncomfortable with the stoma bag being visible to others.

Few reported pain or nausea during exercises, but overall participants experienced few problems during and after performing the exercises. Certain abdominal exercises were highlighted by the participants as being good. Specifically, 'Diagonal isometric press' with one hand on opposite knee and ‘Ball squeeze’ between arms and legs (figure 1) were well-liked. Being able to put in effort and to sense that the abdominal muscles were activated was highlighted as positive.

Discussion

The aim of this study was to explore patients’ experiences with and attitude toward abdominal exercises after stoma surgery. The overall findings were that participants found abdominal exercises easy to perform with a stoma and had positive attitudes toward abdominal exercises. Illness, adjuvant treatment, and concerns kept participants from engaging in abdominal exercises, and they wished for help after stoma surgery.

Abdominal exercises were performed in a supervised setting with a health professional giving exercise instructions. This could make abdominal exercises appear easier to the participants, than if doing them on their own. Barriers relating to uncertainty about abdominal exercises were also negated in the supervised setting. The exercises that were highlighted in interviews (‘Diagonal isometric press’ and ‘Ball squeeze’) could be considered for future exercise interventions for the abdominal muscles after stoma surgery. Due to their isometric nature, both exercises allowed the participants to put in as much effort as they wanted. Any force added by the upper body and hand(s) could be countered by the lower body and leg(s). Thus, participants performing these exercises could adjust the intensity to fit what they were comfortable with without provoking pain or discomfort. Participants highlighted the ability to put in an effort and sense that their abdominal muscles were activated as positive. With participants finding other exercises too easy, this tells us that some patients prefer abdominal exercises with a high intensity. Many of the other abdominal exercises had a low load in general and no external load, which added to the impression of exercises being easy.

Measurements of performance and the ability to track their progress motivated some, and it is natural to implement these elements in an exercise intervention to evaluate the effect. Based on our interviews, it may be difficult to find a mode of exercise delivery, group-based or individually supervised, that fits the preferences of all patients. To accommodate different preferences, flexible forms of exercise delivery could be explored, e.g. with options for when, where, and with whom the patients could do abdominal exercises. Based on the participants' preferences, abdominal exercises should be initiated 2-3 weeks after surgery.

Concerns after stoma surgery, complications, and adjuvant treatment were among the barriers to abdominal exercises. A qualitative study on rectal cancer survivors with a stoma looked at reasons, deterrents, and practical implications for engaging in physical activity [13]. In keeping with our findings, side effects of cancer or treatment deterred engagement in physical activity. Similarly, concerns related to surgical wounds and the fear of parastomal hernias, which our participants also voiced, impeded physical activity. The study furthermore identified stoma-related issues, e.g. fear of odor or the stoma making others uncomfortable, as hindering factors for physical activity [13]. These factors were not voiced as predominant concerns by our participants, although one participant suggested an 'ostomates-only' exercise class as noises from the stoma discouraged exercise with others. Uncertainty about the most appropriate type and amount of physical activity was presented as an obstacle in the study [13]. Like in the present study, guidance was highlighted as important for overcoming barriers for physical activity [13]. Leakage (or fear of leakage) was not as big a concern for our participants as seen in prior reports [22].

If patients are to do abdominal exercises after stoma surgery, they will likely need help in doing so. This could be in the form of guidance, written material, or a "push" to get started, as mentioned in the interviews. The need for help aligns with a survey finding, that few people currently living with a stoma engaged in abdominal exercises after their surgery [3]. Most of the survey responders gave the reason that they did not know that abdominal exercises were important [3]. If patients are to perform abdominal exercises, it is important that health professionals consider potential barriers to exercise, like the concerns presented in this study, and help patients handle them. For example, a survey found a relation between concerns about the stoma and being less physically active [22], underlining the problems after stoma surgery with exercising or being physically active. Participants in the present study requested help navigating which exercises to do and assurance that abdominal exercises were safe for them to do. Core and abdominal muscle exercises are advocated for patients after stoma surgery [3, 4, 23], but systematic rehabilitation of the abdominal wall is currently not usual practice after stoma surgery. There is a need for high quality evidence from randomized controlled trials to substantiate the potential benefits and harms of abdominal exercises, which might increase the focus and resources devoted to abdominal exercises after stoma surgery. Currently, it is difficult for health professionals to give evidence-based recommendations regarding abdominal exercises, as the benefits and harms are largely uninvestigated and, consequently, restrictions on physical activity vary [24].

Strengths and limitations

Steps were taken to heighten the trustworthiness of the findings [25]. Investigator triangulation was used in the analysis to increase credibility [21]. We provided a transparent and thick description [21] of the study and its context, including reporting on items from the COREQ checklist [19]. The interviewer's subjective preconceptions were documented to ensure reflexivity throughout the conduct of the study [26].

With an already established relationship between interviewer and participants, a wish to please could have affected the answers. However, the participants had no problems saying that exercises were too easy or boring, and some participants were skeptical or even critical of the abdominal exercises. By establishing a safe atmosphere and expressing genuine interest in the opinion of the participants, we hoped participants felt comfortable sharing more than just their most positive views on abdominal exercises. With only 3 of 14 participants doing abdominal exercises while still hospitalized, the findings mostly relate to post-discharge exercise. Participants only performed abdominal exercises a single time as part of the feasibility study, and the basis for experience with abdominal exercises was limited. There may have been reduced recall in interviews taking place several weeks after exercises, as participants strongly preferred being interviewed at the hospital on days with an existing appointment.

Conclusions

Overall, participants were positive toward abdominal exercises and found them easy to perform in a supervised setting. However, adjuvant treatment and illness (e.g. chemotherapy, nausea, or complications) were barriers to exercise, and participants wished for help and guidance to do abdominal exercises after stoma surgery.

Acknowledgments

The study was funded by grants from The Research Foundation of the Capital Region of Denmark; Copenhagen University Hospital, Herlev and Gentofte, Denmark; and Copenhagen University Hospital, Rigshospitalet, Denmark.

Declaration of interest

The authors have no conflicts of interest to disclose.

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Tables

Table 1. Interview guide

Main questions	**Probes (optional)**
1. How have you been since doing the exercises?	*Have you felt anything different? Any changes? Have you done any abdominal exercises since last we saw?*
2. Would you describe for me your previous experience with exercise and sports?	*Have you done abdominal exercises before?*
3. What were your thoughts, when I presented the idea of doing abdominal exercises to you?	*Did it make sense to do abdominal exercises after your surgery? Did you feel excited? Worried?*
4. What were your expectations before doing the exercises with me?	*Positive? Negative?*
5. Thinking back, what were your experience of doing the abdominal exercises?	*What was easy/difficult? How difficult or challenging do you think it should be? Would it be demotivating if you can't feel if something is happening?*
6. How did your body react while doing the exercises?	*What did you feel in your stomach and stoma? Did you experience other sensations in your body?*
7. What have you thought of in relation to the abdominal exercises in the time since doing them?	*Do you feel like you have accomplished or overcome something by doing these exercises? Does it make sense for you to do abdominal exercises? Have you experienced any nuisances since? Have your opinion of abdominal exercises changed?*

8. What do you think could be gained from doing abdominal exercises after stoma formation?	*What do you think the beneficial effects could be? What do you think the negative or harmful effects could be?*
9. How soon after your own surgery should abdominal exercise have been offered, if you were to do it?	*What would you think of being asked to do exercises in the hospital bed? Would you do the exercises, if I told you, it was helpful?*
10. What qualifications do you think that health professionals handling abdominal exercise should have?	
11. What do you think of the exercise balls being part of the exercise?	*Have you tried lying on your belly?*
12. If you were to do abdominal exercises for a period of time, would you then prefer it to be home-based, group-based or 1-on-1 with a health professional?	
13. What do you think of doing abdominal exercises every day?	*Does it change your preference for home-based, group-based or 1-on-1 exercise?*

The interviewer sought to cover all the main questions. Probes were optional and a help for the interviewer.

Table 2. Participant characteristics

Characteristic	Participants (n=14)
Age in years, median (range)	67.5 (20-73)
Gender, n	
Female	7
Male	7
Stoma type, n	
Colostomy	6
Ileostomy	8
Body mass index, median (range)	25.0 (18.8-39.4)
Time from surgery to abdominal exercises, n	
0-2 weeks	2
2-6 weeks	10
6-12 weeks	2
Days from exercises to interview, median (range)	19.5 (0-49)
Diagnosis, n	
Cancer	12
Ulcerative colitis	1
Intestinal pseudo-obstruction	1
Elective surgery, n	14
Mode of surgery, n	
Open surgery	5
Laparoscopy	4
Robot-assisted laparoscopy	5
Stoma prognosis, n	

Permanent	7
Temporary	7
Work status, n	
Working	1
Retired	10
Sick leave	3
ASA score, n	
I	0
II	12
III	1
Missing	1
Interview duration (minutes), median (range)	24.5 (15-37)

ASA = American Society of Anesthesiologists Physical Status Classification System

Figure captions

Figure 1. Examples of the abdominal exercises that the participants performed at different time points after stoma surgery. Each group performed 10-11 different exercises. The diagonal isometric press-exercise was performed in both the Early group, 0-2 weeks after surgery, and in the Intermediate group, 2-6 weeks after surgery.

Figure 2. Categories and subcategories.

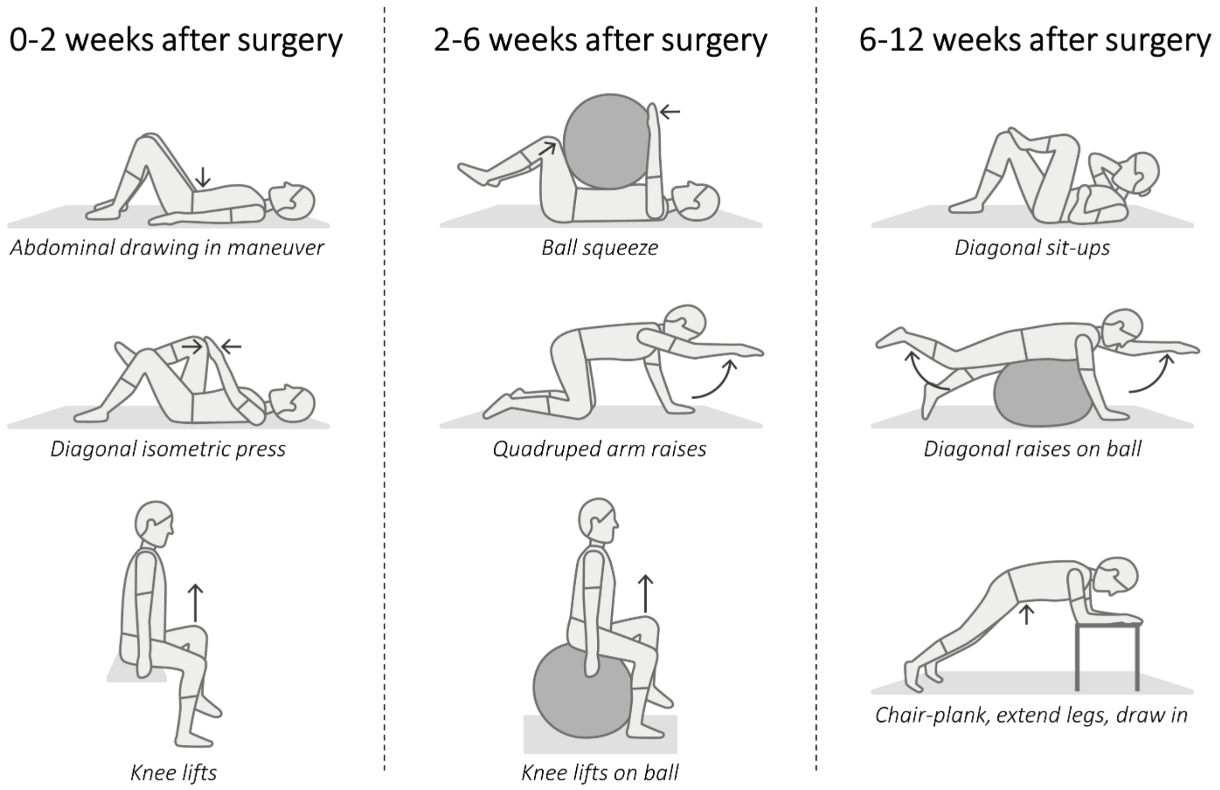

Figure 1. Examples of the abdominal exercises that the participants performed at different time points after stoma surgery. Each group performed 10-11 different exercises. The diagonal isometric press-exercise was performed in both the Early group, 0-2 weeks after surgery, and in the Intermediate group, 2-6 weeks after surgery.

The attitude toward abdominal exercises is positive
Treatment and illness form barriers to abdominal exercises *- Stoma surgery causes concern about doing abdominal exercises* *- Postoperative recovery and treatment pose challenges to abdominal exercises*
Wish for help with abdominal exercises after stoma surgery *- A wish for guidance with abdominal exercises* *- Preferences for delivery of abdominal exercises vary*
Abdominal exercises are experienced as being easy

Figure 2. Categories and subcategories.

Early group

	Rectus abdominis		External oblique		Internal oblique + Transversus abdominis	
Ex.	**SS**	**OS**	**SS**	**OS**	**SS**	**OS**
1	0%	9%	30%	25%	0%	36%
2	0%	0%	20%	8%	11%	18%
3	0%	0%	0%	8%	0%	20%
4	0%	0%	10%	8%	33%	44%
5	8%	0%	20%	0%	33%	40%
7	0%	0%	30%	42%	22%	45%
8	17%	10%	50%	33%	22%	18%
9	0%	0%	22%	18%	57%	55%
10	18%	10%	44%	18%	14%	44%

Intermediate group

	Rectus abdominis		External oblique		Internal oblique + Transversus abdominis	
Ex.	**SS**	**OS**	**SS**	**OS**	**SS**	**OS**
11	0%	10%	36%	45%	73%	55%
12	8%	21%	31%	14%	38%	36%
13	31%	23%	54%	29%	42%	57%
14	8%	8%	69%	36%	42%	38%
15	0%	0%	38%	15%	33%	50%
16	92%	83%	100%	100%	91%	83%
17	29%	31%	50%	33%	38%	29%
18	15%	23%	46%	38%	50%	57%
19	15%	23%	38%	15%	42%	29%
20	33%	50%	75%	67%	91%	69%

Late group

	Rectus abdominis		External oblique		Internal oblique + Transversus abdominis	
Ex.	**SS**	**OS**	**SS**	**OS**	**SS**	**OS**
22	100%	100%	100%	90%	78%	60%
23	30%	40%	50%	40%	67%	33%
24	30%	50%	30%	30%	33%	22%
25	100%	100%	100%	100%	100%	100%
26	44%	56%	67%	56%	63%	22%
27	50%	50%	38%	50%	71%	25%
28	57%	14%	43%	63%	67%	57%
29	50%	50%	60%	50%	44%	33%
30	50%	50%	60%	50%	78%	56%
31	100%	100%	100%	100%	78%	78%

Appendix Figure 1. Percentage of participants with muscle activity reaching onset threshold for each muscle and exercise. This figure shows the results for the stoma side (SS) and opposite side (OS). Ex. = exercise corresponding to Figures 5-7. Exercises 6 and 21 are not shown, as they were performed diagonally in one direction and cannot be interpreted with stoma side/opposite side coding.

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1. Declaration by	
Name of PhD student	Rune Martens Andersen
E-mail	runema8@gmail.com
Name of principal supervisor	Thordis Thomsen
Title of the PhD thesis	Abdominal exercises after stoma surgery: towards a rehabilitation effort with the intention of preventing parastomal bulges

2. The declaration applies to the following article	
Title of article	Incidence and risk factors for parastomal bulging in patients with ileostomy or colostomy: a register-based study using data from the Danish Stoma Database Capital Region
Article status	
Published ☒ Date: First published: 04 October 2017	Accepted for publication ☐ Date:
Manuscript submitted ☐ Date:	Manuscript not submitted ☐
If the article is published or accepted for publication, please state the name of journal, year, volume, page and DOI (if you have the information).	Colorectal Dis. 2018;20(4):331-40. doi:10.1111/codi.13907

3. The PhD student's contribution to the article ***(please use the scale A-F as benchmark)*** Benchmark scale of the PhD-student's contribution to the article **A.** Has essentially done all the work (> 90 %) **B.** Has done most of the work (60-90 %) **C.** Has contributed considerably (30-60 %) **D.** Has contributed (10-30 %) **E.** No or little contribution (<10 %) **F.** Not relevant	**A, B, C, D, E, F**
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2. Development of the key methods	B
3. Planning of the experiments and methodology design and development	A
4. Conducting the experimental work/clinical studies/data collection/obtaining access to data	A
5. Conducting the analysis of data	B
6. Interpretation of the results	A
7. Writing of the first draft of the manuscript	A
8. Finalisation of the manuscript and submission	A
Provide a short description of the PhD student's specific contribution to the article.[i] The PhD student, Rune Martens Andersen, planned the key methods in collaboration with coauthors. The PhD student was responsible for obtaining permissions and access to the data. The PhD student analyzed the data with help from a statistician. The PhD student wrote the first manuscript draft and finished the manuscript with input from the coauthors in accordance to the ICMJE authorship criteria.	

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If yes, please state name of the author and title of thesis / dissertation.	
If the article is part of another author's academic degree, please describe the PhD student's and the author's contributions to the article so that the individual contributions are clearly distinguishable from one another.	

5. Signatures of the co-authors[iii]				
	Date	Name	Title	Signature
1.	8/11-19	Thordis Thomsen	Associate professor, senior researcher	Thordis T
2.	8/11-2019	Anne Kjærgaard Danielsen	Senior researcher	Anne K Danielsen
3.	9/11-19	Ismail Gögenur	MD, DMSc, professor	[signature]
4.	8/11-19	Anders Vinther	Senior researcher	[signature]
5.	8/11-19	Tobias Wirenfeldt Klausen	Statistician, data manager	[signature]
6.				
7.				
8.				
9.				
10.				

6. Signature of the principal supervisor

I solemnly declare that the information provided in this declaration is accurate to the best of my knowledge.
Date: 8/11-19
Principal supervisor: Thordis Thomsen Thordis T

7. Signature of the PhD student

I solemnly declare that the information provided in this declaration is accurate to the best of my knowledge.
Date: 7/11-2019
PhD student: Rune Martens Andersen [signature]

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[i] This can be supplemented with an additional letter if needed.
[ii] Please see Ministerial Order on the PhD Programme at the Universities and Certain Higher Artistic Educational Institutions (PhD Order) § 12 (4):
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[iii] If more signatures are needed please add an extra sheet.

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1. Declaration by	
Name of PhD student	Rune Martens Andersen
E-mail	runema8@gmail.com
Name of principal supervisor	Thordis Thomsen
Title of the PhD thesis	Abdominal exercises after stoma surgery: towards a rehabilitation effort with the intention of preventing parastomal bulges

2. The declaration applies to the following article	
Title of article	Evaluation of abdominal exercises after stoma surgery: a descriptive study
Article status	
Published ☐ Date:	Accepted for publication ☐ Date:
Manuscript submitted ☒ Date: SEPTEMBER 13, 2019	Manuscript not submitted ☐
If the article is published or accepted for publication, please state the name of journal, year, volume, page and DOI (if you have the information).	

3. The PhD student's contribution to the article *(please use the scale A-F as benchmark)* Benchmark scale of the PhD-student's contribution to the article A. Has essentially done all the work (> 90 %) B. Has done most of the work (60-90 %) C. Has contributed considerably (30-60 %) D. Has contributed (10-30 %) E. No or little contribution (<10 %) F. Not relevant	**A, B, C, D, E, F**
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2. Development of the key methods	A
3. Planning of the experiments and methodology design and development	A
4. Conducting the experimental work/clinical studies/data collection/obtaining access to data	A
5. Conducting the analysis of data	A
6. Interpretation of the results	A
7. Writing of the first draft of the manuscript	A
8. Finalisation of the manuscript and submission	A

Provide a short description of the PhD student's specific contribution to the article.[i]
The PhD student, Rune Martens Andersen, received supervision throughout the planning, conduct, and reporting of this article. The PhD student collected all data and performed all analyses. Data collection and analysis was based on a protocol prepared with coauthors. The PhD student wrote the first manuscript draft and finished the manuscript with input from the coauthors in accordance to the ICMJE authorship criteria.

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If yes, please state name of the author and title of thesis / dissertation.	
If the article is part of another author's academic degree, please describe the PhD student's and the author's contributions to the article so that the individual contributions are clearly distinguishable from one another.	

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3.	19/11-19	Ismail Gögenur	MD, DMSc, professor	[signature]
4.	13/11-19	Tine Alkjær	Associate professor	[signature]
5.	8/11-19	Tyge Nordentoft	MD, PhD	[signature]
6.	7/11-19	Emma Possfelt-Møller	MD	[signature]
7.	8/11-19	Anders Vinther	Senior researcher	[signature]
8.				
9.				
10.				

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I solemnly declare that the information provided in this declaration is accurate to the best of my knowledge.

Date: 8/11-19

Principal supervisor: Thordis Thomsen [signature]

7. Signature of the PhD student

I solemnly declare that the information provided in this declaration is accurate to the best of my knowledge.

Date: 7/11-2019

PhD student: Rune Martens Andersen [signature]

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E-mail	runema8@gmail.com
Name of principal supervisor	Thordis Thomsen
Title of the PhD thesis	Abdominal exercises after stoma surgery: towards a rehabilitation effort with the intention of preventing parastomal bulges

2. The declaration applies to the following article	
Title of article	Patients' experiences of abdominal exercises after stoma surgery: a qualitative study
Article status	
Published ☐ Date:	Accepted for publication ☐ Date:
Manuscript submitted ☒ Date: NOVEMBER 20, 2019	Manuscript not submitted ☐
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5. Conducting the analysis of data	A
6. Interpretation of the results	A
7. Writing of the first draft of the manuscript	A
8. Finalisation of the manuscript and submission	A
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If yes, please state name of the author and title of thesis / dissertation.	
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2.	8/11-19	Anders Vinther	Senior researcher	[signature]
3.	7/11-19	Marianne Krogsgaard	PhD student	[signature]
4.	19/11-19	Ismail Gögenur	MD, DMSc, professor	[signature]
5.	8/11-19	Thordis Thomsen	Associate professor, senior researcher	[signature]
6.				
7.				
8.				
9.				
10.				

6. Signature of the principal supervisor

I solemnly declare that the information provided in this declaration is accurate to the best of my knowledge.
Date: 8/11-19
Principal supervisor: Thordis Thomsen [signature]

7. Signature of the PhD student

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