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**ALTERNATIVES IN THE TREATMENT
OF ABDOMINAL RECTUS MUSCLE DIASTASIS
AN EVALUATION**

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To my beloved family and
my two brightest shining stars

Genom att försöka med det omöjliga
når man högsta graden av det möjliga.

AUGUST STRINDBERG

ABSTRACT

Introduction

Abdominal rectus diastasis (ARD) is defined as a widening of the distance between the two rectus muscles located on either side of the Linea Alba (LA). A width of more than 3 cm is, in this thesis, considered as pathological. There are several reasons why ARD occurs, where pregnancy is one of the most common. Genetic variations in collagen composition, massive weight loss, and previous abdominal surgery are others.

Patients with ARD usually perceive no pain at rest whereas discomfort, pain, corset instability and bulging of the abdominal wall are symptoms appearing during physical activity. Conclusive data regarding the most appropriate treatment of ARD are sparse, and studies with focus on abdominal wall function and quality of life after repair are lacking. Furthermore, no reliable data exist regarding evaluation of patients with ARD prior to surgery and the relevance of specific symptoms, width of ARD and abdominal wall strength.

The overall aim of the present thesis was to evaluate the outcome of two surgical methods with regard to relapse of ARD; repair with a retromuscular mesh or double row self-retaining suture. Quality-of-life, pain and abdominal muscle strength were important secondary endpoints in the outcome of repair. Secondary aims were to evaluate: the effects of a dedicated training programme on symptoms and complaints from ARD; imaging and measurements of the ARD width prior to surgery; and to develop a reliable method for evaluation of abdominal wall strength.

Material and methods

Study I

The validity and reliability of the Biodex System-4, was tested in ten healthy volunteers and ten patients with ARD \geq 3 cm. The reliability of isokinetic and isometric muscle strength was assessed by test-retest with one week in between. Validity was tested by IPAQ (International Physical Activity Questionnaire) and VAS-assessment of patient-perceived muscle strength.

Study II

The width of ARD was evaluated clinically, with CT-scan and intra-operatively in 55 patients. Agreement between these modalities was evaluated to determine the most relevant measurement.

Study III

Early complications during the initial three postoperative months were monitored in 56 patients of whom 29 were randomised to repair with a retromuscular mesh and 27 to the Quill™ suture technique. All patients presented with an ARD wider than 3 cm.

Study IV

The same 56 patients randomised to surgery as in Study III were compared to 30 patients assigned to a training programme. Follow-up for the operated patients was at 1 year while training outcome was studied after the stated period of 3 months.

Results

The reliability of the Biodex System-4 was excellent as shown by ICC (Intra Class Correlation) statistics. The internal validity was excellent when compared to VAS using Spearman's test. The external validity showed no correlation between IPAQ and isometric muscle strength using the Kendall-Tau test (Study I). Evaluation of the three methods to assess ARD showed a strong agreement (high CCC; Concordance Correlation Coefficient) between the clinical and intraoperative measurements whereas CT-scan and intraoperative measurements did not show agreement (low CCC). CT measurements underestimated the width of the ARD (Study II). Minor complications were observed three months after surgery. No significant difference between the two surgical groups in terms of early complication and perceived pain was observed. Patients in the mesh group experienced greater improvement in abdominal muscle strength (Study III). One year after surgery one recurrence was documented in the Quill group and five encapsulated seromas were distributed with no difference between the two surgical groups. Biodex System-4 showed significant improvement in all muscle strength modalities with the three methods. Quality-of-life (SF-36) domains were all significantly improved one year after surgery ($p < 0.001$) with the exception of bodily pain (BP) in the physiotherapy group after three months of training (Study IV).

Conclusions

The prospective randomised trial has shown that patients with an ARD wider than 3 cm have physical symptoms and poorer quality of life than an age-matched Swedish population. Surgical intervention improves patient comfort and

improves quality of life. There is no difference between the Quill technique and retromuscular mesh in the effect on abdominal wall stability, with a similar complication rate one year after surgery. Dedicated training strengthens abdominal muscles objectively but does not improve perceived muscle strength or pain in the abdominal wall.

LIST OF PUBLICATIONS

This thesis is based on the following papers, which are referred to in the text by Roman numerals as indicated below (I–IV):

- I. Stark B, Emanuelsson P, Gunnarsson U, Strigård K. Validation of Biodex System-4 for measuring the strength of muscles in patients with rectus diastasis. *Journal of plastic surgery and hand surgery*. 2012 Apr; 46(2):102-5.
- II. Emanuelsson P, Dahlstrand U, Strömsten U, Gunnarsson U, Strigård K, Stark B. Analysis of the abdominal musculo-aponeurotic anatomy in rectus diastasis: comparison of CT scanning and preoperative clinical assessment with direct measurement intraoperatively. *Hernia*. 2014 Aug; 18 (4):465-71.
- III. Emanuelsson P, Gunnarsson U, Strigård K, Stark B. Early complications, pain and quality of life after reconstructive surgery for abdominal rectus muscle diastasis: a three-month follow-up. *Journal of Plastic, Reconstructive & Aesthetic Surgery*. 2014 Aug; 67(8):1082-8.
- IV. Emanuelsson P, Gunnarsson U, Dahlstrand U, Strigård K, Stark B. Surgical correction of abdominal rectus diastasis (ARD) reduces pain and improves abdominal wall muscle strength; a randomised prospective trial comparing retromuscular mesh repair to double-row self-retaining sutures. In manuscript.

LIST OF ABBREVIATIONS

ARD	Abdominal Rectus Muscle Diastasis
AW	Abdominal Wall
BMI	Body Mass Index
BP	Bodily Pain
CCC	Concordance Correlation Coefficient
GH	General Health
HTP	Home Training Programme
ICC	Interclass Correlation Coefficient
IPAQ	International Physical Activity Questionnaire
LA	Linea Alba
LBP	Low Back Pain
MET	Metabolic Equivalent of Task
MH	Mental Health
OCCC	Overall Concordance Correlation Coefficient
PF	Physical Functioning
RE	Emotional Role Functioning
RP	Physical Role Functioning
SF-36	Short form health survey with 36-Items
SF	Social Functioning
SPSS	Statistical Package for the Social Sciences
VAS	Visual Analogue Scale
VHPQ	Ventral Hernia Pain Questionnaire
IV	Intravenous Injection
VT	Vitality

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1 INTRODUCTION

1.1 Background

Abdominal rectus muscle diastasis (ARD) is defined as the widening of the Linea Alba (LA) width or as an increased distance between the rectus muscle sheaths. ARD is a neglected diagnosis worldwide and commonly affects women after childbirth. Considering an annual occurrence of 110 700 childbirths in Sweden, more emphasis should be placed on the topic of ARD in the literature (1). Why only certain women develop a persistent abdominal wall (AW) weakness during pregnancy is unclear. Fluctuation in weight during pregnancy, increased intra-abdominal pressure, hormonal changes combined with uterine growth, as well as caesarean section are all reasons to be considered as a cause of ARD (2–5). A possible change in anatomical morphology of the abdominal wall after caesarean section is one possible reason for the occurrence of ARD (5). These women with ARD are usually not offered treatment through the public general healthcare system in Sweden, as ARD is often not considered a pathological entity. Physiotherapy is the only available treatment that has the potential to give relief from symptoms related to ARD for these patients. Furthermore, it is not clear whether conservative physiotherapy really is the most effective method to prevent and/or improve ARD-related complaints (3).

The abdominal rectus muscles have functional importance for trunk stability and posture. An increase in the distance between the anterior borders of the rectus muscles causes imbalance of the pelvic-lumbar muscular girdle and may influence the strength of the abdominal wall musculature (6, 7). There is an ongoing debate whether ARD directly or indirectly causes discomfort and/or back pain as a consequence of the above-mentioned imbalance. Other reported complaints associated with ARD are bulging of the abdominal wall, swelling after food intake, abdominal wall weakness, and limitations during physical activity.

Other aetiological factors associated with ARD and worthwhile considering are: age; massive weight loss occurring spontaneously or after bariatric surgery; previous abdominal surgery; and hereditary disorders (8–10). Interestingly, the width of the LA seems to be more dependent on age than on BMI. Furthermore, the impact of BMI is dependent on whether or not there is an increase in the amount of intra- or extra-abdominal fat (11, 12). A common denominator for the above-mentioned aetiologies is that the patients' symptoms are multifaceted. Until now, there are no available data for objective evaluation of these complaints. Consensus concerning diagnosis, treatment and follow-up is lacking.

1.2 Epidemiology

In the general- and plastic surgery literature, the topic of ARD and its repair has had low priority. There are no present data on functional impairment and symptoms related to ARD. The incidence of ARD and its association with age is unknown.

Rectus diastasis is primarily prevalent in women with multiple pregnancies. Between 66 and 100% of women are reported to develop ARD in the third trimester of pregnancy (3, 4). The exact aetiology and pathogenesis of ARD related to pregnancy is unknown. The prevalence of pregnancy-related low-back pain (LBP) is highest during the third trimester with an incidence of 60–70% (13–15). Increased separation of the anterior borders of the rectus muscles might lead to poor postural stability and LBP. In a retrospective chart review of patients presenting with uro-gynaecological disorders, it was found that 52% of the patients also had ARD (16). There is currently no data in the literature on the incidence of ARD in men. ARD in the upper midline of the abdomen occurring in over-weight men that does not appear to affect their daily life is often detected *en passant* while investigating other surgical complaints.

1.3 Anatomy

The anterior aspect of the abdominal wall includes the paired rectus muscles and the aponeurosis of the external, internal and transverse muscles that run antero-laterally on the abdominal wall. The rectus muscle extends caudally on each side of the umbilicus from the xiphoid process to the crest of the pubis. Data in the literature indicate that the rectus muscles show variations in their insertion to the costal cartilage of the ribs 5–7 (17). The rectus sheath consists of two layers (laminae), the anterior and posterior sheath. The anterior rectus sheath joins the aponeurosis of the external oblique muscle and completely covers the abdominal wall. The posterior sheath joins the aponeurosis of the transverse muscle and does not extend below the arcuate line (17).

The blood supply to the rectus muscles mainly originates from the inferior epigastric artery and vein in the posterior region of the abdominal wall. This vascular pedicle enters the rectus fascia at the arcuate line and supplies the lower part of the abdominal wall. The superior epigastric vessels originate from the internal thoracic vessels and supply the upper part of the rectus muscles. Superior and inferior epigastric vessels anastomose and provide collateral circulation to the abdominal wall (18). The muscles are innervated by the thoraco-abdominal nerves and by subcostal ilio-hypogastric, and ilio-inguinal nerves. The role of the rectus muscles is complex; maintaining intra-abdominal pressure, protecting the viscera, assisting breathing excursions and flexion of the

lumbar spine. They have an overall role to preserve posture (19). The linea alba is defined as the midline fibrous structure that separates and connects the rectus muscles to the aponeurotic system. The LA consists of collagen and elastin and is structurally similar to tendons and ligaments in other parts of the human body. These midline fibres are in continuity with the rectus aponeurotic sheath. The LA together with rectus muscles should be considered as a functional unit located on the anterior part of the abdominal wall. Two types of forces act on the LA, intra-abdominal pressure and linear traction exerted by the three muscles of the flank (20).

1.4 Classification

Until now, consensus has not existed regarding the normal width of the LA. There are just a few studies in the literature presenting data on definition and classification of ARD (12, 20–22). A comparative study in 2009 measured the width of LA in 150 nulliparous women. The general definition of a “normal” LA is a width of 15 mm at the xiphoid process, 22 mm at 3 cm above the umbilicus, and 16 mm at 2 cm below the umbilicus (21). Another study including 40 cadavers and 40 abdominal-pelvic scans suggested that the width of the LA is age dependent. Furthermore, data indicated that in women younger than 45 years the LA was 10 mm at the supra-umbilical level, 27 mm at the umbilicus, and 9 mm between the pubic symphysis and umbilicus. Corresponding values in women older than 45 years were 15, 27 and 14 mm (20).

Several aetiological factors may lead to protrusion of the anterior abdominal wall. It has not been studied whether ARD is an entity in itself or should be seen as part of a complex aponeurotic system of the entire anterior and lateral abdominal wall. A specific classification based on different myoaponeurotic deformities has been introduced. Nahas defines myoaponeurotic deformities as follows: Type A – women presenting with ARD after pregnancy; Type B – laxity of the lateral and inferior parts of the anterior abdominal wall; Type C – lateral insertion of the rectus muscles to lateral costal cartilages; and Type D – a poor waistline (22). Nahas’ classification is a general description of anterior abdominal wall weakness without specific focus on ARD. Despite this it has gained some popularity amongst clinicians.

2 AIMS OF THE THESIS

The overall aim of the thesis was to evaluate the outcome of two surgical techniques and compare these to physical training in patients with abdominal rectus diastasis. Secondary aims were: to evaluate the effects of a dedicated training programme on symptoms and complaints arising from ARD; to compare imaging and clinical assessment of ARD width prior to surgery with direct measurement intra-operatively; and to develop a reliable method for the measurement of abdominal wall strength.

The specific aims were:

1. To investigate the validity and reliability of the Biodex System-4 for measurement of abdominal muscle strength in patients with rectus diastasis.
2. To compare the correlation and reliability of preoperative CT-scanning with pre- and intra-operative clinical assessment of ARD.
3. To assess early complications, pain and quality-of-life three months after repair of rectus diastasis comparing two surgical techniques; retro muscular mesh or double-row plication.
4. To evaluate the risk for recurrence one year after repair of ARD and outcomes in terms of pain, muscle strength and quality-of-life with two surgical techniques, and to compare these outcomes with the results of physical training.

3 HYPOTHESES

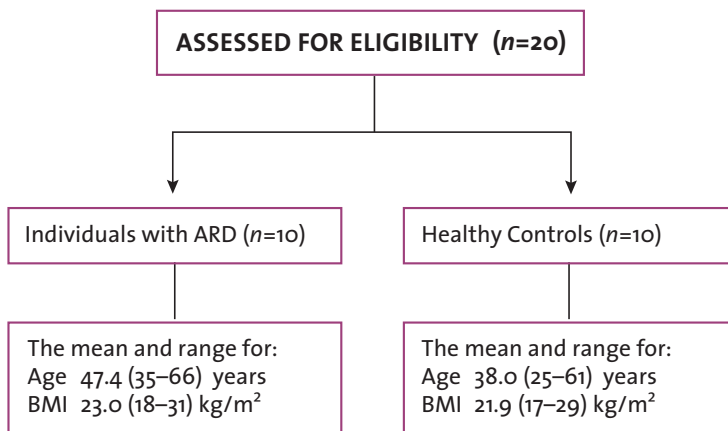
- Study I: The Biodex System-4 is an appropriate tool to measure abdominal wall muscle strength in rectus diastasis.
- Study II: Preoperative clinical assessment of ARD has a higher correlation to intraoperative measurement than CT-scanning.
- Study III: Reconstruction with Quill plication has fewer post-operative complications but less pronounced improvement in abdominal wall stability compared to reconstruction with a retromuscular mesh.
- Study IV: Patients operated with Quill technology have a higher incidence of recurrence compared to patients repaired with a retromuscular mesh for rectus diastasis.

4 PATIENTS

PAPER I

In order to assess the reliability and validity of the Biodex Multi-Joint System-4, two groups of volunteers were recruited; ten active healthy individuals and ten persons with an ARD ≥ 3 cm after pregnancy (Fig. 1). These healthy volunteers had not undergone prior abdominal surgery. Both groups were matched for age and BMI.

FIG. 1 Flow chart for patients in Study I.

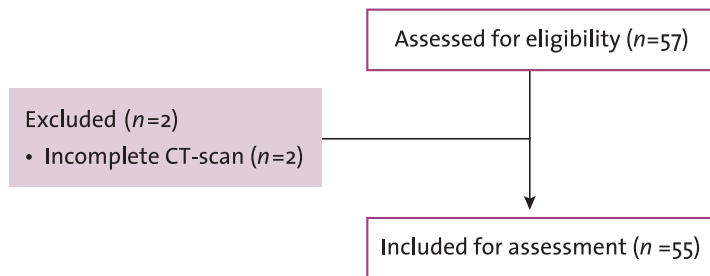


PAPER II

From the prospective randomised trial (Papers III, IV) evaluating two surgical techniques for the repair of ARD, all operated patients ($n=57$; 55 women, 2 men) were included in this study. Inclusion and exclusion criteria are listed in Papers III and IV. All patients underwent CT-scanning preoperatively to exclude any pathology prior to randomisation.

Two patients had an incomplete CT-scan leaving 55 patients for assessment (Fig. 2).

FIG. 2 Flow chart for all patients in Study II.



PAPER III

In order to compare two different surgical methods for repair of ARD, a prospective randomised trial was designed. The power calculation was based on the one-year follow-up study (Paper IV), the primary endpoint assuming that there is a difference in recurrence rates between the two surgical techniques after one year. Therefore, no power estimation was performed for this part of the study, which was an evaluation of early complications at a 3-month follow-up.

Of the 64 patients (62 women and 2 men) finally eligible, 57 were allocated to surgery and evaluated, while 7 patients were excluded (Fig. 3). The median age at surgery was 40 (range 25–60) years and the median BMI 23 kg/m² (range 18–31).

All female participants had an abdominal wall deformity Type A (22) and fulfilled the inclusion criteria (Table 1).

FIG. 3 Flow chart for all patients in Study III.

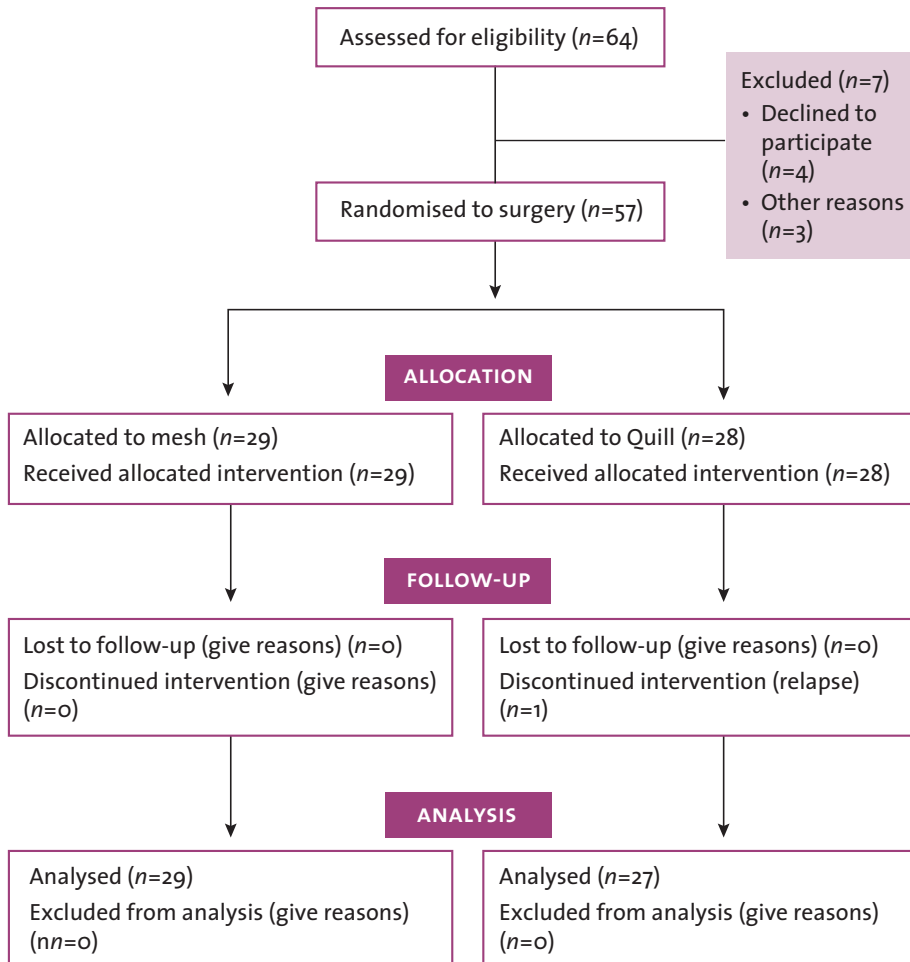


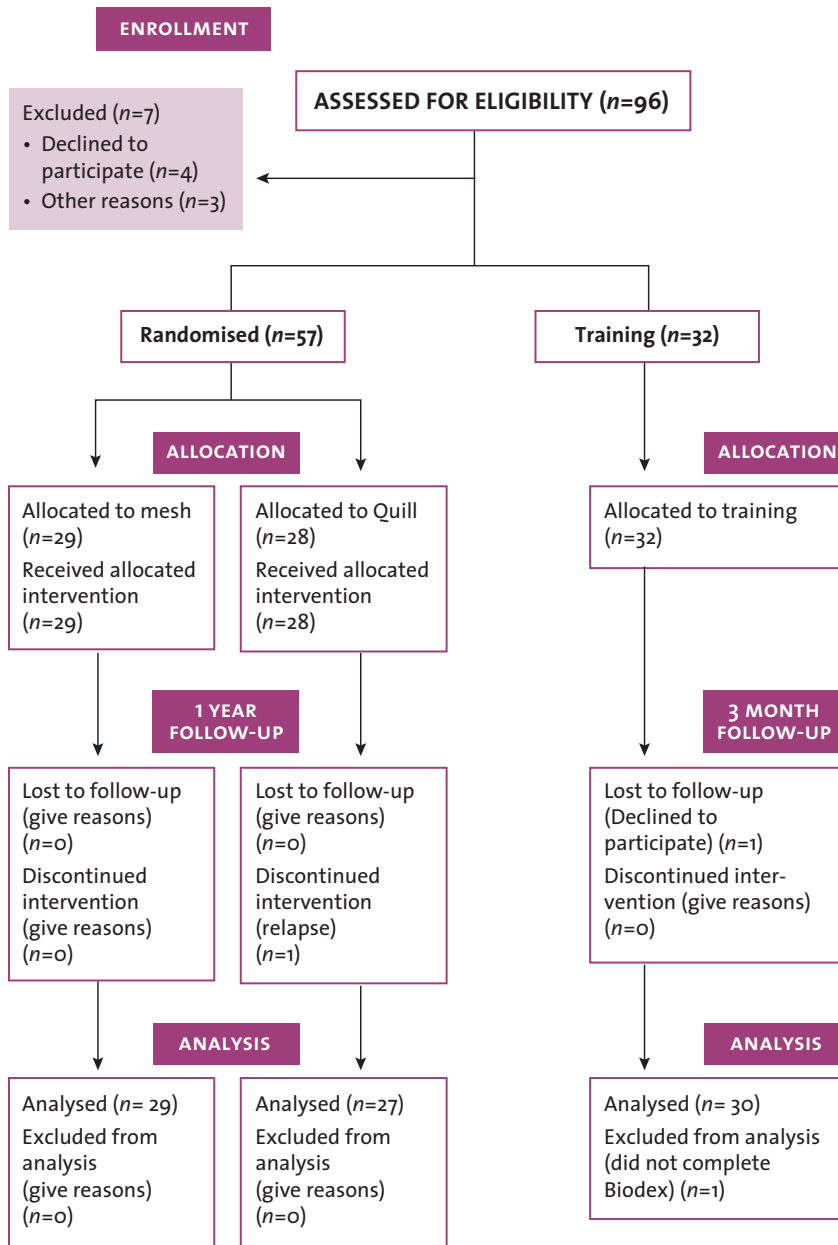
TABLE 1 Inclusion/exclusion criteria.

INCLUSION CRITERIA	EXCLUSION CRITERIA
<ul style="list-style-type: none">• Rectus diastasis ≥ 3 cm• For women: at least 1 pregnancy• Older than 18 years• Discomfort or tenderness in the abdominal wall• Wish to have abdominal wall reconstruction	<ul style="list-style-type: none">• Ongoing pregnancy• Breastfeeding• Immunosuppressive therapy• Smoking

PAPER IV

This 3-armed prospective randomised controlled study comprises two surgically treated and one conservative group treated with physiotherapy. A total of 75 patients, 25 in each arm were included from the beginning. For each randomised patient, lost after randomisation or with violation of the protocol, 3 new patients were included in order to maintain power. Finally, a total of 96 participants were included (Fig. 4). Median age for the Quill group was 40 (29–60) years and the median BMI 23 kg/m² (18–31). Median age for the mesh group was 42 (27–62) and BMI 23 kg/m² (18–30), and in the conservative physiotherapy group 39 (24–63) years and 22.5 kg/m² (18–30). The study assumed an 80% power with 95% significance, based on 30% recurrence in the Quill arm and 5% in the mesh arm at one-year follow-up (23, 24). Ethics approval was on condition that patients not satisfied with the outcome of physical training were offered surgical repair. The study was approved by the Regional Ethics Review Board in Stockholm (D.nr. 2009/227-31, 2011/1186-32). The study was registered at ClinicalTrial.gov with the number 2009/227-31/37PE/96.

FIG. 4 Consort flow chart for all patients included in this thesis.



5 METHODS

The clinical assessment of ARD at the first visit was performed with the patient in the erect and supine positions. All measurements were performed three times by the same investigator using a tape-measure at two fixed landmarks, halfway between the xiphoid process and the umbilicus, and halfway between the umbilicus and the pubic symphysis. A complete medical history was taken before randomisation. A normal CT-scan without any abdominal pathology was a prerequisite for inclusion in the study and randomisation. The first eight patients were randomised before they had a CT- scan, but patient number 8 was diagnosed as having myeloma. We therefore decided to postpone randomisation until after CT-scan investigation. Patients fulfilling the inclusion criteria were then randomised by a research nurse to either surgery or training (2:1 ratios) using sealed envelopes. Participants were then photographed with views in frontal, side, and forward-bending positions. Abdominal wall muscle strength was measured using the Biodex System-4 in all cases.

5.1 Surgery

Twenty-nine patients were randomised to retromuscular inlay of a lightweight polypropylene mesh (BARD™ Soft Mesh) and twenty-eight patients to double layer plication of the anterior rectus sheath using an absorbable self-retaining barbed suture (Quill™ SRS) (25, 26). All procedures were performed by a plastic and a colon-rectal surgeon in collaboration. Surgery was performed under general anesthesia and muscular relaxation with Rocuronium 0.5 mg/kg body weight followed by maintenance doses as required. It was necessary to perform a wide dissection from the pubic symphysis to the xiphoid process for technical reasons. This was done via a lower abdominal transverse incision above the pubic symphysis. When a retromuscular mesh was used, it was not sutured to surrounding tissues. Previous data have shown that mesh sutures can cause postoperative pain (27). At the time of dissection, the width of the ARD was measured with a tape measure at the two previously described landmarks (Fig. 5). All measurements were repeated three times. No drains were used to avoid potential infection, and metronidazole (Flagyl® 5 mg/ml) 1.5g i.v. and cefuroxim (Zinacef®) 1.5g i.v were given preoperatively as single dose prophylaxis. A girdle was worn for 3 months postoperatively, 6 weeks throughout the day and 6 weeks daytime only.

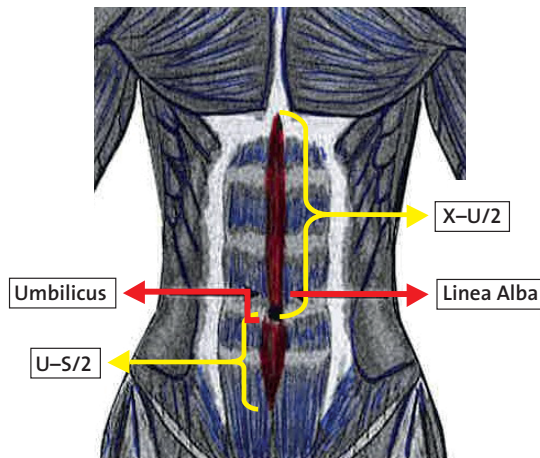


FIG. 5 Illustration of the two landmarks halfway between the xiphoid and the umbilicus (X-U) and halfway between the umbilicus and the pubic symphysis (U-S), where the ARD width was measured.

5.2 Training programme

Thirty-two patients were eligible for physical training, corresponding to the conservative arm of Study IV. Two patients were excluded, one because of unwillingness to complete the training programme and one because of not participating in the follow-up Biodex System-4 measurements. Finally, thirty patients performed a home training programme (HTP) over a period of three months. Certain general abdominal wall muscle training exercises were selected, which included rectus, oblique and transversus abdominal muscles (28, 29). A detailed training scheme was specifically constructed for that purpose by a physiotherapist at the Physiotherapy Unit, Karolinska University Hospital, Huddinge (30). Patients were given personal and written instruction by the physiotherapist (Fig. 6). During the course of the physical training programme there was a change in the exercise protocol. Several patients complained of difficulty in performing the exercises and/or pain perceived during training. The patients were followed up at 1.5 and 3 months. Patients not satisfied with their clinical ARD improvement were offered surgical repair after completion of the Biodex System-4 investigation and a clinical examination at least three months after onset of the training programme.

FIG. 6 Training programme.

TRAINING PROGRAMME I



Lie on your back with your arms crossed over your chest. Tighten your tummy muscles and lift your head and shoulders off the floor.



Bend both legs against the abdomen. Stretch your legs straight and lift from them off the floor. It is important to have the upper body stable.



With your hands behind your head and knees bent, lift the upper body by tightening your tummy muscles, and put your chin on your chest. Turn one elbow towards the opposite knee and lift the knee a little. Repeat with the other elbow.



Keep upper body stable and bend your knees. Shift your weight from side to side.

Train three times a week. Repeat the exercises 10–20 times and vary the sequence.

TRAINING PROGRAMME II – PART I



Warm-up: stand on all fours. Arch the back by tightening the backside muscles with the neck bent, looking at your tummy. Relax and then repeat 6–8 times.

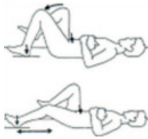


Lie the back or on one side. Tense the pelvis muscles more and more in 3–4 stages then hold 5 secs. Relax. Repeat 10 times three times a day.



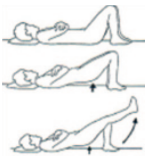
Start position: lie on your back with knees bent and feet together.

Exercise: tighten the tummy muscles then lift one leg and push the knee against the opposite hand. Hold 7 secs. then relax. Repeat 10 times. Change sides and do the same.



Start position: lie on your back with hips bent 90 degrees and knees in the air.

Exercise: tighten the tummy and backside muscles so that your back is flat on the floor. Lower one knee slowly till the heel touches the floor then roll the foot forwards. Hold 5 secs. then lift the leg back again. Repeat 10 times. Change sides.



Start position: lie on your back with knees bent and feet together.

Exercise: tighten the tummy and backside muscles so that your back is flat on the floor. Slowly lift your pelvis off the floor. Hold 10 secs. then back again. Repeat 8 times. Advancer variant: as above but shift your weight onto one side and stretch out the other leg keeping the back straight and knees together. Hold 5 secs. Repeat 10 times and change sides.

TRAINING PROGRAMME II – PART II



Start position: lie on one side as in the picture.

Tighten the tummy muscles and stretch your back.

Exercise: with your feet together lift the upper knee by rotating the hip keeping the pelvis still. Return slowly to the start position. Repeat 15 times.

Change sides.



Lie on one side with your weight on the knee and forearm. Tighten the tummy muscles keeping the neck and back straight. Repeat 10 times. Change sides.



Start position: stand on all fours with knees below the hips.

Exercise: lift one arm and the opposite leg to the horizontal position, keeping the back and pelvis perfectly still. Hold 5–10 secs. Slowly lower them back. Repeat 10 times. Change sides.



Start position: sit up straight with knees bent and arms relaxed.

Exercise: Lift one knee up slowly 10 degrees without bending the back or pelvis, or tipping backwards. Hold 10 secs. Slowly lower it again. Repeat 5 times. Change sides.



Stand straight on one leg then slowly lift the knee to 90 degrees (if possible) without bending the back or pelvis. Return the knee slowly and repeat 10 times. Change sides.

Advanced variant: standing perfectly straight on one leg with the weight on the outside of the foot. Perform a curtsy slowly keeping the back straight – work with your tummy muscles. Repeat 10 times. Change sides.

5.3 Clinical follow-up

Patients randomised to surgery were clinically followed-up 3 months and 1 year after their operation. Patients and observer were blinded to the method used. Patients randomised to the conservative arm were followed-up at 1.5 and 3 months after beginning their training programme. The examination included questions on general health, BMI, medical history, assessment of the width of the ARD by a senior general surgeon. ARD was measured as described above. All patients completed SF-36 (31) and VHPQ questionnaires (32). A VAS (visual analogue scale) was used for self-assessment of improvement in abdominal muscle strength (33, 34). Measurement of abdominal muscular strength was performed using the Biodex System-4 prior to surgery or physical training, after the training period, and at 3 months and one year after surgery.

5.4 The Biodex System-4

The Biodex System-4 has gained widespread popularity for the orthopaedic assessment of range of motion and muscular strength of extremities. It is also used to evaluate outcome after trauma rehabilitation (35). It has a specific unit for the evaluation of back muscle strength. Isokinetic muscle strength is measured, which means that measurements are taken at a constant rate of motion. To explore the possibility of using the system for abdominal muscle strength our patients were placed in a defined seated position (Fig. 7), with the iliac crest as fixed landmark and centre of motion. The chest, thighs and knees



were held still and geometric positions were stored to allow for reproducibility. The protocol consisted of five sub-tests; four isokinetic tests and one static test. The isokinetic tests were performed at two speeds. Tests 1 and 2 were performed at 30° per second. Tests 3 and 4 were performed at a speed of 60° per second. The fifth test was a static test where the dynamometer was locked at -20° from zero reference. Before each sub-test there was a warm-up and training phase under the

FIG. 7 Biodex System-4 with the back abdomen unit.

supervision of the physiotherapist, to ensure that the subject had understood how to perform the test. Each sub-test was repeated five times. Between sub-tests was a preset pause of 90 seconds. The physiotherapist kept a neutral tone of voice during the test to avoid affecting the outcome (36). Test and retests were performed with and without a girdle.

5.5 Radiographic evaluation

All patients included in the prospective randomised study underwent preoperative CT-scanning to evaluate the width of the ARD. Axial sections were used at the aforementioned levels of investigation. Accuracy of measurement was at the millimeter level. The examination was performed by the same radiologist with the patient in the supine position and at the end of a deep breath. Two independent radiologists estimated ARD width. Measurements were expressed in centimeters. The majority of patients were investigated with a Siemens Definition AS machine while the rest were examined with CT machines of equivalent performance. Patients allocated to surgery had a new CT investigation at the one-year follow-up. The Ethics Committee decided that patients allocated to the training group should not be subjected to CT-scanning because of unnecessary radiation. In general a CT-scan exposes a patient to approximately 8 mSv (millisivert) compared to the annual background radiation of 5 mSv.

5.6 Short Form-36 (SF-36) and Ventral Hernia Pain Questionnaire VHPQ

To assess health-related quality-of-life, the validated Short Form-36 (Standard Swedish Version 1.0) health survey was used, consisting of 36 items divided among eight domains (31). The physical functioning (PF), physical role functioning (RF), bodily pain (BP) domains are associated with physical well-being, the general health (GH) and vitality (VT) domains are associated with both physical and emotional dimensions, and the social functioning (SF), emotional role functioning (RE) and mental health (MH) domains are associated with emotional well-being.

The mean score for each of the domains was transformed to a 100-point scale where 100 points represented maximum function. The results were compared with normative data (i.e. country-specific data for healthy individuals with same sex and age) for the Swedish population. Participating patients subjected to surgery completed the SF-36 questionnaire preoperatively as well as at a 3-month and 1-year follow-up. Patients following the training programme completed the SF-36 before starting training and at the 3-month follow-up.

Ventral Hernia Pain Questionnaire (VHPQ)

The VHPQ is a comprehensive and validated instrument for the assessment of pain. Initially the IPQ (Inguinal Pain Questionnaire) was constructed to assess postoperative chronic pain in patients operated for inguinal hernia (37). This validated instrument was further developed to allow evaluation of pain in patients with ventral hernia and it takes approximately 5 minutes to complete (32). The first six questions investigate the level and duration of pain. The following seven questions relate to the impact of pain on daily activities, and the final seven questions address the patient's satisfaction and to what extent pain interferes with his/her professional activities. A 7-stage scale was used to assess pain intensity (Fig. 8).

FIG. 8 VHPQ, Ventral Hernia Pain Questionnaire

VHPQ

Questionnaire for pain before/ after surgery of the abdominal wall

1. Date of completion
2. Grade the pain experienced from hernia/diastasis prior to operation.
 - a. No pain
 - b. Pain easily ignored
 - c. Pain that cannot be ignored, but does not affect everyday activities
 - d. Pain that cannot be ignored and affects concentration and activities
 - e. Pain that inhibits most activities
 - f. Pain that requires rest
 - g. Pain that is so great that medical help is required
3. Grade the pain presently experienced in your tummy after surgery.
 - a. No pain
 - b. Pain easily ignored
 - c. Pain that cannot be ignored, but does not affect everyday activities
 - d. Pain that cannot be ignored and affects concentration and activities
 - e. Pain that inhibits most activities
 - f. Pain that requires rest
 - g. Pain that is so great that medical help is required
4. Grade the pain in your tummy when it was at its worst this last week.
 - a. No pain
 - b. Pain easily ignored
 - c. Pain that could not be ignored, but did not affect everyday activities
 - d. Pain that could not be ignored and affected concentration and activities
 - e. Pain that inhibited most activities
 - f. Pain that required rest
 - g. Pain that was so great that medical help had to be summoned
5. If no more pain is felt in the operated area, try to remember when the pain stopped. Then go to point 16.
 - a. I still have pain in the abdomen
 - b. Pain in the operated area was gone after 1 month following surgery
 - c. Pain in the operated area was gone after 3 months following surgery
 - d. Pain in the operated area was gone after 6 months following surgery
 - e. Pain in the operated area was gone after 1 year following surgery
 - f. Pain in the operated area was gone after 2 years following surgery
 - g. Pain in the operated area disappeared recently

If you have experienced some form of pain in your tummy during the last week, please answer the rest of the questionnaire:

6. How often have you felt pain in the operated area in the last week?
 - a. A few times
 - b. Several times
 - c. Every day
 - d. Every day and night
 - e. All the time, day and night

7. How long were periods of pain that you have experienced last week?
 - a. Few minutes
 - b. Several hours
 - c. All day
 - d. Throughout the day
 - e. Had pain all the time, day and night

8. Have you had problems getting up from a low chair because of pain in the operated area?
 - a. No
 - b. Yes
 - c. Don't know
 - d. Not applicable

9. Have you had problems sitting down longer periods as a result of pain (more than 30 minutes)?
 - a. No
 - b. Yes
 - c. Don't know
 - d. Not applicable

10. Have you had problems standing upright longer periods as a result of pain (more than 30 minutes)?
 - a. No
 - b. Yes
 - c. Don't know
 - d. Not applicable

11. Have you had problems climbing stairs as a result of pain?
 - a. No
 - b. Yes
 - c. Don't know
 - e. Not applicable

12. Have you had problems driving car as a result of pain?
 - a. No
 - b. Yes
 - c. Don't know
 - d. Not applicable
13. Have you had pain problems that have inhibited physical activities?
 - a. No
 - b. Yes
 - c. Don't know
 - d. Not applicable
14. Have you at any point during the last week taken some sort of painkiller for pain in the tummy?
 - a. No
 - b. Yes
15. To what degree has pain in the tummy inhibited your ability to work the last 2 months?
 - a. Nothing
 - b. I've been off-sick for 1–7 days
 - c. I've been off-sick for 1–4 weeks
 - d. I've been off-sick all the time
 - e. I've received temporary disability
 - f. I'm not employed
16. Have you been operated for hernia/diastasis or some other abdomen operation, since your distasis operation?
 - a. No
 - b. Yes
17. Do you experience any stiffness in the tummy wall after the operation?
 - a. No
 - b. Yes
18. Are you pleased with the result of the operation?
 - a. No
 - b. Yes
19. Would you go through the operation again should it be necessary?
 - a. No
 - b. Yes
20. How would you describe your work?
 - a. Heavy physical work
 - b. Light physical work
 - c. White-collar work

5.7 Statistical methods

Reliability

To investigate test-retest reliability in Study I, the same investigator conducted all tests using identical instructions every time to avoid a positive or negative influence due to the investigator. We were obliged to test reliability as the Biodex System-4 had not been used for evaluation of abdominal muscle strength before. All volunteers performed two exercise series separated by 5 minutes of rest, with and without an abdominal girdle. Each series consisted of 5 tests repeated 5 times with 90 seconds of rest in between. All participants were requested not to change their degree of physical activity during the week between the test and retest. Reliability was tested by comparison of results from specific time intervals and identical settings.

External validity

The IPAQ and the VAS were used in Study I. These results were compared with isometric strength measurements from the Biodex System-4. The agreement between these data reflects the external validity. IPAQ is an instrument for measurement of daily activity. In this study the short Swedish version was used and contains 11 questions about daily activity over the previous 7 days (37–39). With METs (Metabolic Equivalent of Task) the extent of physical activity can be calculated in relation to energy requirements defined in MET-minutes, and classified as low, moderate and high activity. The VAS-scale is an instrument for assessing subjective characteristics or attitudes that cannot be measured directly. It is widely used for clinical and scientific purposes. In this study it was used to estimate the patient's self-assessment of their muscle strength as a score ranging from 0 to 10 where 0 = extremely weak and 10 = extremely strong (33, 40).

Statistical Analyses

PAPER I

Statistical analyses were performed using Statistica® (Statsoft, Tulsa, USA). The interclass correlation coefficient (ICC) was used to study reliability of the Biodex system for measurement of muscle strength (41). Correlations were calculated using the Statistical Package for the Social Sciences (SPSS) and values higher than 0.75 were considered excellent, 0.40–0.75 fair to good, and < 0.40 poor reliability. To find out if there was any difference in the test and retest results using a girdle or not, the Wilcoxon sign rank test was used. Internal validity, comparing isometric strength with VAS, was estimated by the Spearman's test. The external validity, the correlation between isometric

strength and IPAQ, was estimated by the Kendall-Tau test. The patients' demographic data were expressed as median and ranges.

PAPER II

Stata/IC 12.1 for Windows (StataCorp. College Station, TX, USA) was used for statistical analyses. All data from the patients were recorded in a Microsoft Access database. Standard descriptive statistics were used to aggregate the variables.

LCCC (Lin's Concordance Correlation Coefficient) is used to measure the strength of coherence between two methods or measurements designed to measure the same thing. The coefficient can have values between -1 and 1 where the value 1 means total coherence. CCC together with corresponding 95% confidence interval was used to quantify the absolute agreement between the modalities of measurement. CCC was also applied to calculate the agreement between the independent measurements of two radiologists.

The agreement between methods used for measurement was assessed using the method described by Bland and Altman (42) BA-plot (Bland Altman Plot). It is a visual tool to determine the consistency between two methods.

PAPER III

Statistical analyses were performed using Statistica® (Statsoft, Tulsa, USA). The intended sample size was based on the assumption of 30% recurrence in the Quill group compared to 5% in the mesh group at the one-year follow-up (based on experience with umbilical and inguinal hernia repairs). To obtain 80% power with a significance level of 95%, each surgically treated group needed 25 patients. Continuous variables were assigned as median and range.

Self-perceived improvement in muscle strength was expressed in median and rated by VAS, and correlated with VHPQ. Fisher's exact test was used for dichotomous variables and the Mann-Whitney U-test for continuous and ordered variables.

PAPER IV

Statistical analyses were performed using Statistica® (Statsoft, Tulsa, USA). The sample size of patients was the same as in Study 3, except that a training group of 25 patients was added, requiring a study total of 75 patients. Non-parametric statistics were generally used. The Mann Whitney U test was used to compare the continuous variables whereas the Chi-square test was used for dichotomous data. The Wilcoxon sign rank test was used to analyse the dependent variables. To compare the effects on muscle strength between the two surgical techniques and conservative training treatment, ANOVA with repeated measure design was used to compare the relative changes.

6 RESULTS

PAPER I

All twenty patients included in the study completed the test-retests. The demographic data for the two groups are shown in Table 1. The two groups did not significantly differ regarding BMI (body mass index). Variation in physical activity was not considered to be a confounding factor.

Reliability

No statistically significant differences between the study groups were found. There was excellent test-retest stability calculated by ICC as our results ranged between 0.77 and 0.97 in the 30°/s and 60°/s extension /flexion sessions (Table 2). The lowest value for ICC was observed in the ARD group for 60°/s extension with and without a girdle, even though it was still excellent (higher than 0.75). Biodex performance improved when a girdle was worn in the ARD group (Table 3). The Biodex System-4 showed acceptable consistency in test-retests.

TABLE 2 Reliability for test retest events expressed in ICC (G = test done with girdle).

Tests	ICC	95 % KI	P value
30° flexion	0.93	0.74–0.98	<0.001
30° flexion G	0.85	0.50–0.96	0.001
60° flexion	0.97	0.88–0.99	<0.001
60° flexion G	0.96	0.83–0.99	<0.001
30° extension	0.91	0.69–0.98	<0.001
30° ext. G	0.82	0.44–0.95	0.001
60° extension	0.77	0.31–0.94	0.003
60° ext. G	0.81	0.40–0.95	0.001

TABLE 3 Wilcoxon rank tests with and without use of girdle (G stands for test performed with girdle).

Test	Mean (range)	P value
30° flexion	78,52 (39,1–114,7)	0,114
30° flexion G	81,085 (43,75–120,35)	
60° flexion	84,685 (40–120,4)	0,203
60° flexion G	88,59 (51,75–125,1)	
30° extension	90,235 (74,15–125,5)	0,508
30° extension G	92,15 (68,75–133,9)	
60° extension	95,86 (60,6–137,05)	0,025
60° extension G	104,21 (75,85–137,05)	
Maximal Isometric Muscular Contracture	70,21 (49,6–89)	0,203
Maximal Isometric Muscular Contracture G	68,045 (45,65–88,95)	

Validity

To assess validity, isometric strength data were compared to results of self-assessment of abdominal wall strength VAS (internal validity) and to the results of IPAQ (external validity). There was a strong correlation between isometric muscular strength and VAS ($R = 0.78$, $p = 0.0077$). The present data indicate that the Biodex System-4 can be considered an appropriate tool to study abdominal muscle strength. It should be noted, however, that there was no correlation between isometric muscular strength and IPAQ ($\tau = 0.30$, $p = 0.22$).

PAPER II

Demographic data of patients included in Study II were retrieved from the group assigned to surgery. The median width and ranges of ARD for the different methods are presented in Table 4. CT investigation of ARD underestimated the width of ARD compared to clinical findings. A measurement of ARD under direct view during surgery was considered the gold standard. LCCC showed highest strength of coherence between the clinical and intra-operative measurements both in the upper midline (0.370) and in the lower midline (0.479). Poor agreement was obtained between CT-scans and intra-operative

examination both in the upper midline (0.162) and in the lower midline (-0.002). Agreement between the two independent radiologists was excellent (upper midline = 0.86, lower midline = 0.98).

BA-plot (Bland Altman Plot) showed a smaller difference in mean values of the ARD width in the upper and lower midline between the clinical and intra-operative measurements than the agreement between intra-operative and CT-scans. The CT-scans underestimated the ARD width by more than 0.5 cm in 83% of all patients compared to the values from direct intra-operative measurement. In 87% of all cases, CT-scans underestimated the ARD by more than 0.5 cm compared to preoperative clinical assessment. Finally, the study showed that pre-operative clinical assessment overestimated the width of the ARD by more than 0.5 cm compared to the intra-operative measurements in 35% of cases (Table 5).

TABLE 4 Abdominal rectus diastasis (ARD) measures; median and range in centimetres. X-U: xiphoid-umbilicus (upper midline measurement), U-S: umbilicus-pubic symphysis (lower midline measurement).

	X-U		U-S	
	Median (cm)	Range (cm)	Median (cm)	Range (cm)
Clinical	4.0	0.0 to 7.0	3.5	0.0 to 6.0
CT	2.6	0.8 to 6.1	0.0	0.0 to 3.4
Intraoperative	4.0	2.0 to 7.0	3.0	1.0 to 6.5

TABLE 5 Differences between types of measurement. Differences (in centimetres) between indicated modalities are divided into three categories and the number of patients in each category is shown. X-U: xiphoid-umbilicus (upper midline measurement), U-S: umbilicus-pubic symphysis (lower midline measurement).

	X-U (n = 55)			U-S (n = 55)		
	<-0.5 cm (n)	-0.5-0.5 cm (n)	>0.5 cm (n)	<-0.5 cm (n)	-0.5-0.5 cm (n)	>0.5 cm (n)
CT-intraoperative	41	10	4	49	3	3
Clinical-intraoperative	14	27	14	8	23	24
CT-clinical	45	6	4	50	3	2

PAPER III

The results are based on the 57 operated out of 64 patients allocated to surgery. Assessments were made three months after surgery. All patients underwent a clinical investigation by an independent senior general surgeon. No major complications such as deep venous thrombosis or pulmonary embolism were reported. Only minor complications occurred such as superficial wound infection and seromas. Eight out of 57 patients developed postoperative seroma, and 6 patients were subjected to syringe aspiration. There was no difference between the two surgical groups regarding the complication rate (Table 6). One early recurrence occurred in the Quill group within one month, which was repaired immediately. This patient completed the investigation at 3-month follow-up. All participants reported less pain three months postoperatively compared to pain perceived prior to surgery as assessed with the VHPQ. No difference in terms of pain sensation was detected between the two surgical groups.

According to the VAS, the patients operated with the mesh technique rated their postoperative improvement in abdominal wall strength as being significantly better (mean 6.9, range 0–10) than the Quill group (mean 4.8, range 0–10).

A total, 55 patients completed the SF-36 questionnaire (two were excluded because of missing data). Both surgical groups showed a significant enhancement in 4 out of 8 quality-of-life domains in the SF-36 (Fig. 9). BP, GH, VT and SF were the domains used to show overall significant improvement. However, the physical role functioning (RP) was the only domain not significantly improved in both groups, compared to a normal population ($p < 0.05$). Preoperatively, the mesh group has consistently better values compared to the Quill group. When considering the difference between the groups prior to surgery and at the 3-month follow-up, only vitality and mental health scales were significantly different (Fig. 10, 11).

TABLE 6 Number of patients with early complications in both surgical groups.

Early complications	Quill (<i>n</i> = 28)	Mesh (<i>n</i> = 29)	Total (<i>n</i> = 57)	<i>P</i> value
Wound infection	5 (18%)	9 (31%)	14 (25%)	0.25
Seroma	4 (14%)	5 (17%)	9 (16%)	0.76
Haematoma	0	2 (7%)	2 (4%)	0.16
Relapse of ARD	1 (4%)	0	1 (2%)	0.30
Any complication	9	13	-	0.33

FIG. 9 Health profile comparing pre-and postoperative results from both Quill and mesh groups with an age-matched normal population. PF = physical function, RP = physical role functioning, BP = bodily pain, GH = general health, VT = vitality, SF = social functioning, RE = emotional role functioning, MH = mental health.

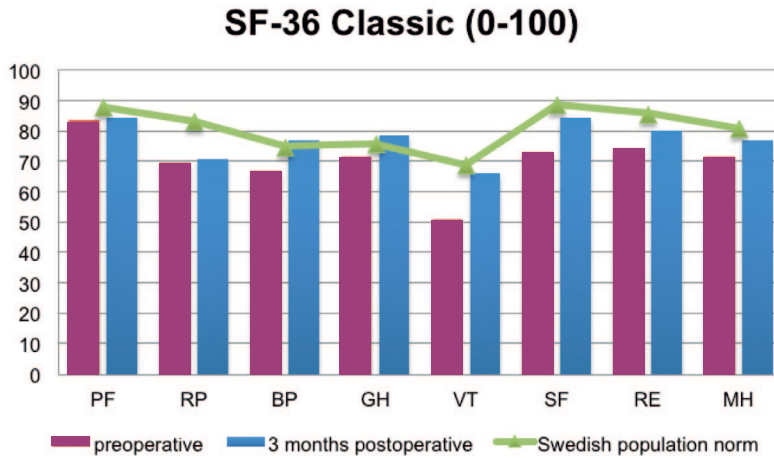


FIG. 10 Preoperative SF-36 in the Quill and mesh group.

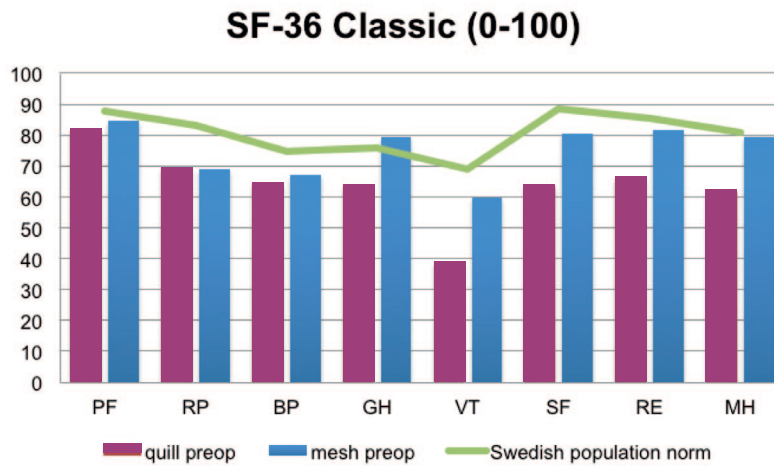
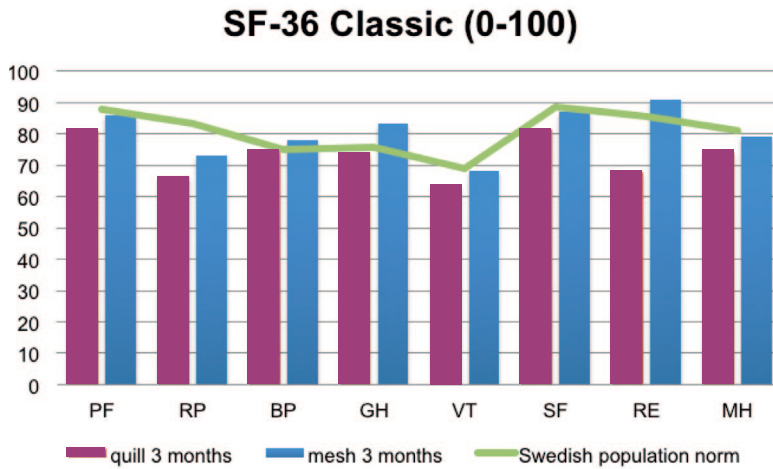


FIG. 11 Quill and mesh group three months after surgery.



PAPER IV

The thirty patients in the training group were followed-up after three months. Twenty-six of these were not satisfied with the outcome of the training programme and were offered surgery. The self-estimated improvement in abdominal wall strength (VAS) was significantly lower in the training group compared to the surgical groups ($p < 0.001$). Bodily pain (BP) was found to be unaffected by physical exercise at the 3-month follow-up. No recurrence of ARD was found in the surgical groups at one year follow-up. Five out of totally 54 patients analysed were diagnosed with encapsulated seroma in the 1-year follow-up CT-scan. All were corrected with surgery. For all patients the SF-36 questionnaire showed significantly lower values for all eight domains compared to the normal Swedish population. One year after surgical repair, there was a significant improvement ($p > 0.05$) in all domains. PF, RP and BP even exceeded the normative population values. The VHPQ results indicated that surgical intervention markedly reduced abdominal wall pain and associated impairment of daily activities. However, the training patient group still experienced pain.

7 DISCUSSIONS

7.1 Discussion on materials

PAPER I

The main purpose of this thesis was to evaluate which of two surgical repair methods are most effective in improving symptoms in patients with ARD and to compare those outcomes with the effect of a physical training programme. An objective tool was needed to assess abdominal wall strength. The Biodex System-4, a widely used instrument in orthopaedic surgery had not previously been validated for the purposes of the present study. The prerequisite for tests of reliability and validity were made possible using the back unit to measure abdominal muscle strength. The test persons in the ARD group and healthy volunteers were similar in age and BMI to make comparisons between the groups as reliable as possible. One could argue that each patient could be considered her own control, as should be the case in the test-retest situation. However, it is also important to evaluate cases from each diagnostic entity that is to be evaluated and compared with healthy subjects. One important reason for this is that each diagnosis has its own abdominal muscle aberrations (43). Ten healthy persons were chosen as controls to avoid bias due to potential interference by poor physical health and outcomes.

PAPER II

CT-scans are considered the gold standard when intra-abdominal pathology requires investigation (44). It had not previously been evaluated or validated whether clinical assessment of ARD could be as reliable or comparable to data from CT-scanning, and thus, of course, their relationship to direct intra-operative measurement of ARD. We therefore decided to compare these data in a comparative study the results of which could then be used as a basis for Papers III and IV. The number of patients included in Study II seems acceptable to test the three different methods for assessing width of ARD. Patients had comparable demographic data and the study group was homogenous.

PAPER III

The study population was the same as that in Paper II. For inclusion all patients were required to have an ARD ≥ 3 cm width considered pathological and, for women, a history of at least one pregnancy. A prerequisite for participation was pain or any kind of discomfort arising from the abdominal wall. In clinical practice ARD is a more frequently complained of by women than men.

PAPER IV

A total of 75 patients were allocated to provide 80% power with the assumption a 30% difference in recurrence between the surgical groups. Drop-outs were compensated by recruiting three new cases to maintain power this resulted in a total of 96 patients (Fig. 4). Demographic data of the three study groups were comparable. All participants apart from the two men presented with a deformity Type A (22).

7.2 Discussion on methods and results

PAPER I

Why did we choose test-retesting with and without a girdle? At the time of the study there were no available data concerning the impact of a girdle on muscle strength of the abdominal wall. The function of a girdle is to support and exert some external compression on the abdominal wall. It helps to maintain intra-abdominal pressure when the myoaponeurotic structures are transposed toward the midline. This effect might have a positive impact upon muscular strength and seemed worth investigation. Results from the present study indicate that tests at 60°/sec. of extension is a large elongated movement and might not represent the coherent muscular activity being performed. An abnormal anatomical position of the rectus muscles seems to decrease strength expressed as lower ICC values. This may explain why healthy volunteers having a normal anatomical abdominal muscle configuration performed equally with or without a girdle. An equivalent study for patients with giant hernias reported similar conclusions to ours; that the Biodex System-4 is a valid and reliable tool (43).

The VAS was used as a validated tool for measuring the patients' self-experience of strength of specific muscle groups, as opposed to the IPAQ that reflects general level of physical activity without referral to specific muscle groups (38, 39). We decided to compare results from isometric strength measurement with VAS and IPAQ scores. To reduce bias, a comprehensive simple instruction was given before performing the Biodex test. During an isokinetic range of movement one could suspect that small differences in instructions or in performance could interfere with the outcome. Despite the fact that we used isometric data, no correlation was found between IPAQ and isometric strength indicating that IPAQ should be considered being too general a tool for this cohort of patients.

PAPER II

CT-scanning was used to exclude intra-abdominal pathology but also to provide a radiologic assessment of the width of the ARD. Ultrasound investigation is another method described in the literature but it is highly dependent on the skills of the examiner (11). The ultrasound transducer is available with a 4–6 cm field width, which limits the field of view during measurement and may have impact on the accuracy of the examination.

Data from Study II showed that agreement between independent radiologists was excellent. It appeared that CT-scanning underestimates the width of ARD and that preoperative clinical measurement is the most effective way of measuring ARD width prior to clinical decision making. CT-scanning, a highly specific method, will identify the most medially located muscle fibres of the rectus muscles that have no relevance for muscular activity, thus leading to underestimation of ARD width. CT-scanning is time-consuming, expensive and exposes patients to radiation, but was considered the gold standard for assessment of ARD at the beginning of this study (11, 45).

PAPER III

When designing the study it was unknown which surgical technique gave the best ARD repair. The self-retaining double-row technology is thought to improve the repair by vertical anchoring of the rectus aponeurosis. These anchors might reduce the risk of cutting through the fibres of the rectus aponeurosis compared to conventional polydioxanone sutures. To our knowledge, the Quill technology has not been tested in a randomised setting. General surgeons repair ARD and incisional hernias using a retromuscular mesh, widely undermining the rectus muscles. The wide dissection required when inserting a mesh could result in higher risks for bleeding, postoperative pain, injury of supporting nerves to the rectus muscles as well as postoperative seroma, compared to the Quill technique. On the other hand, one would expect mesh repair to provide more long-lasting stability of the abdominal wall. The present randomised study revealed no statistical difference in terms of early complications between the two surgical techniques. Seroma occurred equally in both groups despite the extent of undermining and implantation of foreign material in the mesh group. The very first patient repaired with the Quill technique developed a recurrence within one month but this must be considered a technical failure.

Patients gave higher scores for abdominal stability and subjective improvement in muscular strength (VAS) in the mesh group. This was in line with our hypothesis prior to surgery. Both techniques offer sufficient support to the abdominal wall, but also provide some sensation of tightness and stiffness as reported at the 3-month follow-up. The groups did not differ in perception of pain at follow-up as shown with the VHPQ, but some persisting pain was reported in 13 patients, persistent stiffness and pain might be expected as early as 3 months after extensive surgery (Tables 7a–b).

Our data showed that an overall improvement in quality-of-life was achieved through surgery apart from the domain physical role functioning (RP) when compared with a normal Swedish population. It should be mentioned that the number of participants in each group was small and it may be that a larger cohort of patients in each group could have provided even more convincing results. Participants in the present study well matched the normal population (18–75 years) in terms of age. At the 3-month follow-up the only significant differences persisting between the surgical groups were in two of the eight domains; patients operated with mesh had better vitality (VT) and mental health (MH) than those operated with Quill.

TABLE 7A The clinical assessment of the patients symptoms motivating surgery.

Preoperative parameters	Total (<i>n</i> =57)
Discomfort in the abdomen	57
Back pain	19
Abdominal wall weakness	20
Bulging of the abdomen	25
Swollen after food intake	6
Preventing physical activity	6
Palpation tenderness of the abdomen	24

TABLE 7B Pre- and postoperative assessment using the VHPQ, comparing the two surgical groups. Answers from VHPQ. Pain right now ≤ 1 is the same as no pain or pain easy to ignore. The other categories are the numbers for yes.

	Quill	Mesh	Quill	Mesh
Pain right now ≤ 1	21	22	20	24
Pain right now > 1	7	6	8	5
Difficulty rising from chair	3	1	3	1
Difficulty sitting	7	2	4	2
Difficulty standing	6	1	3	0
Difficulty climbing the stairs	6	2	3	0
Difficulty driving a car	0	1	1	1
Difficulty performing sports	13	12	9	8

PAPER IV

This study was designed and power-calculated to assess the rate of recurrence one year after surgical correction. The data at one-year follow-up revealed that the two surgical techniques were equally effective for ARD repair. Interestingly, five patients needed revision surgery because of the occurrence of encapsulated midline seromas. CT-scanning at one year also verified these clinical findings. That there is a higher incidence of seromas in patients operated with mesh could not be verified. Data in the literature concerning this complication are sparse (23, 46–48). A relationship between encapsulated seroma and recurrence was not observed, neither clinically nor with CT-scanning. The hypothesised higher risk for complications in the mesh group was not confirmed in the present study.

Muscular strength of the abdominal wall was improved both after surgery and physical training as assessed by VAS and the Biodex System-4. Interestingly, 26 patients participating in the physical training programme were not satisfied with the outcome because of persistent bulging of the midline and functional symptoms such as bodily pain (Fig. 12). SF-36 data before and 3 months after onset of training show that patients with ARD still suffer more BP compared to controls. Consequently, these data indicate that physical training does not seem to meet patients' expectations as they continue to have pain and bulging of the abdominal wall. We further conclude that muscular strength is improved by physical training but that constant physical training is required to maintain a long-lasting result.

Patients in both surgical groups did not perceive more pain than the normal population at twelve months. One could speculate that operated patients were so happy with the outcome that pain was not reported as having an impact on quality-of-life. All 8 domains were significantly improved at 1-year follow-up compared to scores prior to surgery (fig. 13). The VHPQ also demonstrated that pain was significantly decreased at one year. These findings indicate that it takes time to recover from these surgical procedures.

Biodex System-4 results showed no significant difference between the two surgical techniques.

FIG. 12 Physical training pre- and 3 month SF-36.

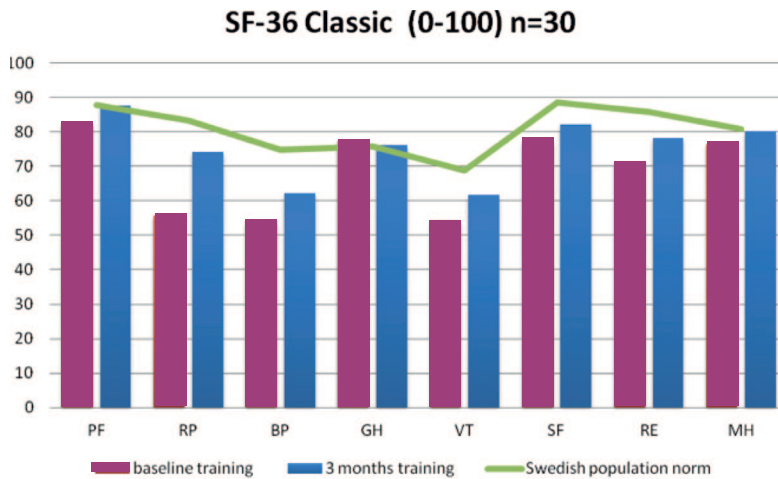
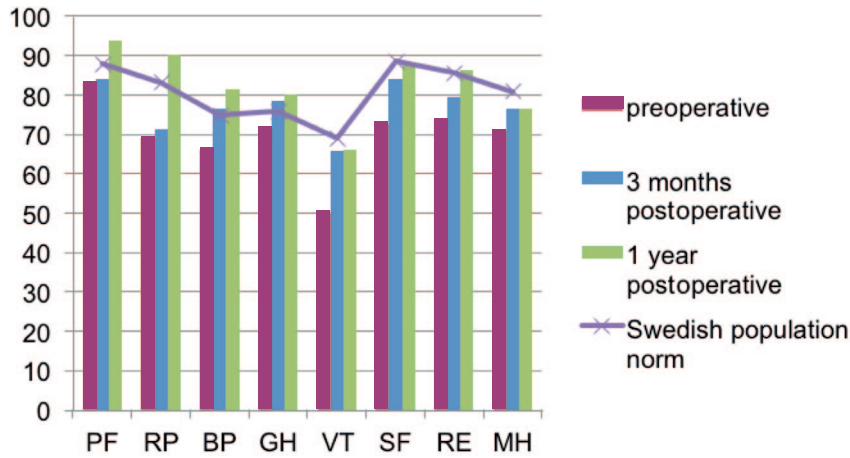


FIG. 13 Total surgery group pre-, three- month and one-year post-operative SF-36.



7.3 Methodological considerations, strengths and limitations

PAPER I

One limitation is that men were not included. One could speculate that gender leads to bias for Biodex System-4 reliability. The investigation is based on a standardised programme making gender as a bias more improbable. The tests are time-consuming and the device is expensive. It is questionable if the Biodex System-4 can be applied in daily clinical practice. Our data indicate that the Biodex System-4 can be considered a valid and reliable method to study abdominal wall muscular strength. In Study 1 all measurements were performed by a physiotherapist. We don't know at present whether or not similar reliability can be obtained by other groups of investigators but there is no reason to suspect this. The system provides objective data that have been evaluated in the fields of rehabilitation and sports medicine (49–52). Previous studies have shown that the amount of force generated from one or several muscles exerted on the dynamometer is inversely proportional to the distance between a joint axis and the point of application of the force. Even small deviations from the original sensor placement might introduce errors of 2–5% in the recordings, with serious consequences on the reproducibility of test findings (53). These errors were not seen in the present study.

In order to set up a prospective randomised trial comparing two different techniques for surgical ARD repair with physical training, we required an objective tool for measuring abdominal wall muscle strength. To our knowledge, no previous study evaluating the reliability and validity of Biodex System-4 in patients with ARD existed prior to this one.

The strength is that the results of Study 1 provide a reliable tool for the analysis of muscle strength and function before surgery or physical training are undertaken.

PAPER II

CCC was used in agreement with the statistical methods of how to calculate the agreement between the three different methods used to measure ARD width. One could discuss whether ICC would not better fit our clinical study since both methods are correlation measurements. CCC is a better-suited instrument for measuring coherence than ICC when quantifying the coherence around a regression line at 45°. Furthermore, OCCC (overall concordance correlation coefficient) could be taken into consideration when there are more than two methods and repeated measurements compared in the study. OCCC can be used to calculate the degree of repeatability of the measurement methods. It may prove to be a limitation that we decided not to calculate and report OCCC in Study 2.

PAPER III

This is the first randomised study comparing two different surgical methods for the correction of ARD, assessing pain and discomfort prior to and after surgery. The strength of the study is that the surgical techniques were compared in a prospective randomised manner and an independent, blinded surgeon performed the postoperative investigations. Validated questionnaires (VHPQ, SF-36) were used to assess patient perception of muscular strength and quality-of-life. It is possible that the frequency of postoperative seromas could have been reduced by the use of drains. We decided not to use drains throughout the study for reasons of comparison, as drains are considered to increase the risk for infection in the presence of foreign material (mesh) (54).

The present study was designed and power-calculated to answer the question on recurrence. From the quality-of-life perspective (SF-36) we estimate that the number of patients included might be somewhat low for definitive conclusions to be drawn for all modalities.

PAPER IV

To our knowledge, no other randomised study has been published that investigates two different surgical methods in comparison to physical training in patients with ARD.

Drop-outs were compensated by three new randomised patients before onset of treatment. Statistical power could thus be maintained throughout the study. All participants completed validated surveys and questionnaires. Statistical analyses were appropriate to answer the hypothesis of the study. The SF-36 assessment showed that all physical scales were improved for both surgical groups at the 1-year follow-up. It would have been interesting to compare the results of the conservative training group at one year to those of the surgical groups. This, however, would have been impossible since most patients allocated to the training group were dissatisfied and operated after the three-month training period.

A limitation of the present study is that two different training programmes were recommended and unevenly distributed among the patients in that group. The outcome of physical training, however, was not significantly different between the programmes (36) although it must be mentioned that the numbers of participants in Programmes I and II were small and uneven. The Training programme was practiced at home or at a private gym without any supervisor to check for compliance. No CT-scanning was performed after completion of the training programme since the Ethics Committee did not approve CT-scan investigation because of radiation risk in a group of patients where CT was considered unnecessary.

7.4 General discussion and implications for future research

The exact incidence of ARD after pregnancy is unknown. The reported incidence of ARD ranges from 30–60% of women during the postpartum period in western countries (2, 3, 7). Other reasons for ARD include caesarean section, multiparity, obesity, genetic factors, post-bariatric conditions as well as repeated abdominal surgery. Physicians may not take ARD seriously as the functional impact on health is not understood. ARD does not lead to emergency conditions such as herniation of abdominal contents, but symptoms can develop in the long-term perspective due to weakening of the abdominal wall and the pelvic girdle. To the best of our knowledge, the incidence rate of ARD in men is also an unknown factor. The present study has shown that patients with ARD present with major complaints; low quality of life, pain and/or discomfort as well as reduced muscular abdominal strength. We further demonstrated that surgical

repair of ARD has improved these symptoms and general health at the 1-year follow-up. Training can improve several of these parameters, but residual pain and patient perception of an instable abdominal wall remain resulting in dissatisfaction. Should all patients suffering complaints associated with ARD be offered surgical repair? To be able to answer this question there must be consensus on how ARD width is assessed and the critical width that indicates surgical repair. This must be achieved in the near future, the primary aim being to avoid long-term pain and improve health-related quality-of-life in these patients. This group of patients suffering from ARD is under-reported in the literature and are usually not offered any help by the public healthcare system. Our findings confirm that ARD should be considered a pathologic entity and not just a question of aesthetics. To strengthen these observations, we aim to follow up the surgical groups three years postoperatively. Items to be studied will be recurrence rate, muscle strength, functional disorders and quality-of-life. It would also be interesting to compare the self-retaining absorbable Quill™ suture with PDS™ monofilament absorbable suture in a double-row plication, for the reconstruction of ARD. The theoretical advantage of Quill self-retaining sutures is that the anchors do not damage the fibres of the aponeurotic system as opposed to PDS sutures. Studies in the literature report on long-term recurrence rates ranging from 0 to 40 % when monofilament sutures are used (55, 56). Further studies are needed to objectively evaluate these techniques. A wide dissection is required to be able to place a retromuscular mesh and the medial borders of the rectus muscles are then sutured with running PDS™. One could question whether stability of the abdominal wall is obtained through the mesh or through the plication sutures. This study focused on the importance of mesh in the outcome of repair regarding recurrence and stability of the abdominal wall. The present studies show that patients with an ARD wider than 3 cm have physical symptoms and a reduced quality of life. Surgical repair has been shown to improve the patient's symptoms and to increase their quality of life. No significant difference between the two surgical techniques was observed. Physical training despite leading to an improvement in muscular strength, was not able to meet patient expectations, gave lower quality-of-life scores and did not improve the ARD.

8 SUMMARY IN SWEDISH SAMMANFATTNING PÅ SVENSKA

Bakgrund

En försvagning i bukens medellinje, rektusdiastas, kan beskrivas som vidgning mellan de två raka bukmusklerna och sträcker sig från revbensbågen ner till blygdbenet. Det finns flera orsaker till att man kan drabbas av en rektusdiastas. Vanligen ser man detta efter graviditet men även efter kraftig viktnedgång. Ärftlighet, ålder och tidigare bukkirurgi kan vara bidragande orsaker. I samband med graviditet är rektusdiastasen mest uttalad i den sista tredjedelen av graviditeten. Hos majoriteten av kvinnorna återgår medellinjen till sin ursprungliga vidd. Har den inte normaliserats inom 6 månader blir den oftast bestående. Förekomsten hos män är okänd. Diagnosen rektusdiastas är en negligerad patientgrupp. Det finns få tillgängliga data i litteraturen. En obesvarad fråga är om patienterna med rektusdiastas har funktionella besvär och hur man i så fall kan förbättra besvären. En viktig frågeställning är om en kirurgisk behandling är överlägsen ett riktat träningsprogram. Kunskap baserad på forskning saknas gällande optimal behandling. Det är oklart när rektusdiastas ger kliniska besvär och bör repareras. Patienter med rektusdiastas upplever vanligen ingen smärta i vila däremot vid fysisk aktivitet. Obehag, smärta, nedsatt muskelstyrka i bukväggen samt minskad livskvalitet kan vara konsekvenser av icke återhämtad bukväggförsvagning. Patienterna rapporterar att obehag och smärta kan uppstå i samband med matintag, medan ryggvärk kan uppstå p.g.a. obalans och försvagning av rygg- och bäckenregionen.

Det övergripande syftet med studien är att jämföra två olika kirurgiska metoder med en icke kirurgisk behandling med sjukgymnastisk träning för att återställa normala förhållanden i bukväggen. Delmålen består av att utvärdera ett instrument för att objektivet mäta bukmuskelstyrka, avgöra bästa sätt att mäta diastasen och att analysera tidiga komplikationer. Risken för återfall efter kirurgi samt förbättringen i muskelstyrka och smärta utvärderas efter ett år.

Metod och resultat

Studie I syftar till att utvärdera tillförlitligheten av Biodex System-4 vid mätning av bukmuskelstyrka. I studien deltog 10 friska och 10 testpersoner med en rektusdiastas bredare än 3 cm. Undersökningarna gällande reproducerbarhet utfördes vid 2 mättillfällen varvid patienterna var sina egna kontroller. Överensstämmelse med andra sätt att mäta styrka utvärderades dels med en

skattningsskala och dels med ett internationellt etablerat frågeformulär som värderar fysisk aktivitet (IPAQ). Biodex System-4 visade sig vara ett tillförlitligt instrument.

I studie II deltog 55 patienter (53 kvinnor, 2 män). Syftet var att utvärdera överensstämmelsen mellan mätning av diastas med datortomografi (CT) undersökning och kliniska mätningar före och under operation. En signifikant samstämmighet mellan klinisk mätning med måttband före operation och det faktiska värdet uppmätt under operation förelåg. CT underskattade bredden av rektusdiastaser.

Studie III–IV belyser komplikationsrisken av två olika operationsmetoder i en lottad studie. Värdet av sjukgymnastisk träning utvärderas. Vid 3 månaders uppföljning (studie III) analyseras utfall av tidiga komplikationer hos 57 patienter, 29 patienter rekonstruerade med inläggning av syntetiskt nät och 28 patienter med en teknik då vävnaden enbart sys ihop. Ett återfall uppkom 4 veckor i den hopsydda gruppen. Mindre komplikationer uppstod i lika stor utsträckning i båda de kirurgiskt behandlade grupperna i form av ytliga infektioner och inkapslade vätskefyllda hålrum. Muskelstyrkan (Biodex System-4) förbättrades efter bägge operationsmetoderna. Patienter opererade med nät upplevde en förbättrad stabilitet i bukväggen 3 månader efter operationen jämfört med patienter opererade med ihopsyning. Denna skillnad kvarstod inte efter 1 år. En tydlig förbättring av livskvaliteten konstaterades 1 år efter operationen (studie IV). Trettio patienter med diastas lottades till sjukgymnastisk träning och vid 1 års uppföljning redovisades inga flera återfall av bukväggsdiastasen i de opererade grupperna. Inkapslade vätskefyllda hålrum krävde operation i fem fall och uppkom lika ofta i båda de kirurgiskt behandlade grupperna. Samtliga tre grupper blev signifikant förbättrade avseende livskvalitet och bukmuskelstyrka. Det fanns inga signifikanta skillnader mellan operationsmetoderna. Patienterna i träningsgruppen upplevde inte en signifikant förbättring och majoriteten erbjöds kirurgisk behandling.

Konklusion

Den lottade studien har visat att personer med en rektusdiastas över 3 cm har fysiska besvär och sämre livskvalitet. Kirurgisk åtgärd förbättrar patientens besvär och ökar livskvaliteten. Det finns ingen skillnad mellan de två utvärderade kirurgiska metoderna vid 1 års uppföljning. Träning förstärker muskelstyrkan i bukväggen men patienterna upplever fortfarande sina besvär väsentligen oförändrade.

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