

Operative correction of abdominal rectus diastasis (ARD) reduces pain and improves abdominal wall muscle strength: A randomized, prospective trial comparing retromuscular mesh repair to double-row, self-retaining sutures



Peter Emanuelsson, MD, PhD,^a Ulf Gunnarsson, MD, PhD,^c Ursula Dahlstrand, MD, PhD,^b Karin Strigård, MD, PhD,^c and Birgit Stark, PhD,^a Solna and Umeå, Sweden

Background. The primary aim of this prospective, randomized, clinical, 2-armed trial was to evaluate the risk for recurrence using 2 different operative techniques for repair of abdominal rectus diastasis. Secondary aims were comparison of pain, abdominal muscle strength, and quality of life and to compare those outcomes to a control group receiving physical training only.

Methods. Eighty-six patients were enrolled. Twenty-nine patients were allocated to retromuscular polypropylene mesh and 27 to double-row plication with Quill technology. Thirty-two patients participated in a 3-month training program. Diastasis was evaluated with computed tomography scan and clinically. Pain was assessed using the ventral hernia pain questionnaire, a quality-of-life survey, SF-36, and abdominal muscle strength using the Biodex System-4.

Results. One early recurrence occurred in the Quill group, 2 encapsulated seromas in the mesh group, and 3 in the suture group. Significant improvements in perceived pain, the ventral hernia pain questionnaire, and quality of life appeared at the 1-year follow-up with no difference between the 2 operative groups. Significant muscular improvement was obtained in all groups (Biodex System-4). Patient perceived gain in muscle strength assessed with a visual analog scale improved similarly in both operative groups. This improvement was significantly greater than that seen in the training group. Patients in the training group still experienced bodily pain at follow-up.

Conclusion. There was no difference between the Quill technique and retromuscular mesh in the effect on abdominal wall stability, with a similar complication rate 1 year after operation. An operation improves functional ability and quality of life. Training strengthens the abdominal muscles, but patients still experience discomfort and pain. (Surgery 2016;160:1367-75.)

From the Department of Molecular Medicine and Surgery,^a and the Department of Surgery, CLINTEC,^b Karolinska Institutet, Solna, Sweden, and the Department of Surgical and Perioperative Sciences,^c Umeå University, Umeå, Sweden

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Reprint requests: Karin Strigård, MD, PhD, Centre of Surgery, Umeå University Hospital, Umeå, Sweden. E-mail: karin.strigard@umu.se.

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FUNCTIONAL DISABILITY RELATED TO MIDLINE BULGING of the abdominal wall is a common complaint in women after childbirth. Abdominal rectus diastasis (ARD) is a sequela of the expansion of the abdominal contents during pregnancy. Massive weight loss and/or congenital disproportion of the collagen III/I ratio may also result in ARD. The most common operative procedures for repair include the use of a retromuscular mesh or double row of sutures with resorbable/nonresorbable

suture material. There is still no consensus on whether ARD should be considered a pathologic condition requiring operative attention.¹⁻³

The topic is addressed poorly and conclusive data on the benefit of ARD repair are sparse in the literature. Consensus is also lacking regarding the most appropriate method of repair regarding recurrence of ARD, muscular strength, and pain. It is not known whether ARD repair enhances the functional outcome of abdominoplasty. Neither has the impact of abdominal muscle training on ARD been explored fully.⁴ Our own data indicate that operative repair of ARD improves abdominal wall function.⁵ We have not found any studies indicating whether ARD repair provides long-term relief of symptoms (eg, pain) and improvement of function or improves abdominal wall muscle strength.

The primary aim of this prospective, randomized trial was to assess the risk for relapse of ARD wider than 2 cm within 1 year after an operation, using 2 operative techniques: implantation of a retromuscular, lightweight mesh or double-row suture of the anterior rectus sheath with Quill sutures (Quill SRS [self-retaining system] with polydioxanone [PDO 2]; Angiotech, Stenlose, Denmark). Secondary aims were to assess the outcomes of abdominal wall muscle strength, pain, and quality of life using these 2 techniques 1 year after an operation. The results of surgical care were compared to those achieved in a control group of patients undergoing a 3-month, specific training program only.

MATERIALS AND METHODS

Study design and participants. In the period between December 2009 and December 2012, study participants were recruited among patients referred to either the Department of Reconstructive Plastic Surgery or the Centre for Digestive Diseases at Karolinska University Hospital, Stockholm, Sweden, with a diagnosis of ARD and a history of functional disabilities, such as back pain, discomfort, and pain from the abdomen, or symptoms of weakness of the abdominal girdle. Inclusion criteria are listed in [Table I](#). Patients grading <1 for the ventral hernia pain questionnaire (VHPQ) question “pain right now” had symptoms such as discomfort of the abdominal wall and swelling after meals. Back pain and impairment of physical exercise were also symptoms reported. Patients scoring >1 experienced pain that could not be ignored during daily activities.

Table I. Inclusion and exclusion criteria

Inclusion criteria
ARD width ≥ 3 cm
>18 yr old
Abdominal wall discomfort or tenderness
Wants abdominal wall reconstruction
For women; ≥ 1 pregnancy, 1 yr after childbirth
Exclusion criteria
Ongoing pregnancy
Ongoing breastfeeding
Immunosuppressive therapy
Smoking

Eligible patients were randomized to either 1 of 2 operative procedures or a 3-month, dedicated training program serving as a control group ([Fig 1](#)). A physiotherapist instructed the patients on the specific training program. Follow-up was completed 1 year after the operation and 3 months after starting the training program. A short-term follow-up was conducted at 3 months in the patients who had surgical care.⁵

The study was approved by the Regional Ethics Review Board in Stockholm (D.nr. 2009/227-31, 2011/1186-32). Approval included a clause that patients in the training arm who were not satisfied with the outcome in terms of functional improvement would be offered operative correction. Written informed consent was obtained prior to inclusion. The trial was registered on ClinicalTrials.gov with the number 2009/227-31/3/PE/96.

The present study received grants from Stockholm County Council. The sponsors had no role in study design, data collection, data analysis, data interpretation, or in the writing of the report. This study was run solely as an academic trial. There was no support from manufacturers or distributors. The ethical standard followed the principles of the Declaration of Helsinki.

Randomization. Patients who met all inclusion criteria were first randomized in a 2:1 ratio to either operative repair or training, respectively. Patients in the group assigned to operative repair were further randomized at the day of operation to either repair with a retromuscular, lightweight polypropylene mesh (BARD Soft Mesh, Davol Inc., A Bard Company, Warwick, RI; standard mesh according to procurement by the county council) or to double-row plication of the anterior rectus fascia with Quill SRS suture, PDO 2/0.^{6,7} This logistic procedure was chosen to minimize the risk for imbalance between the 2 operative

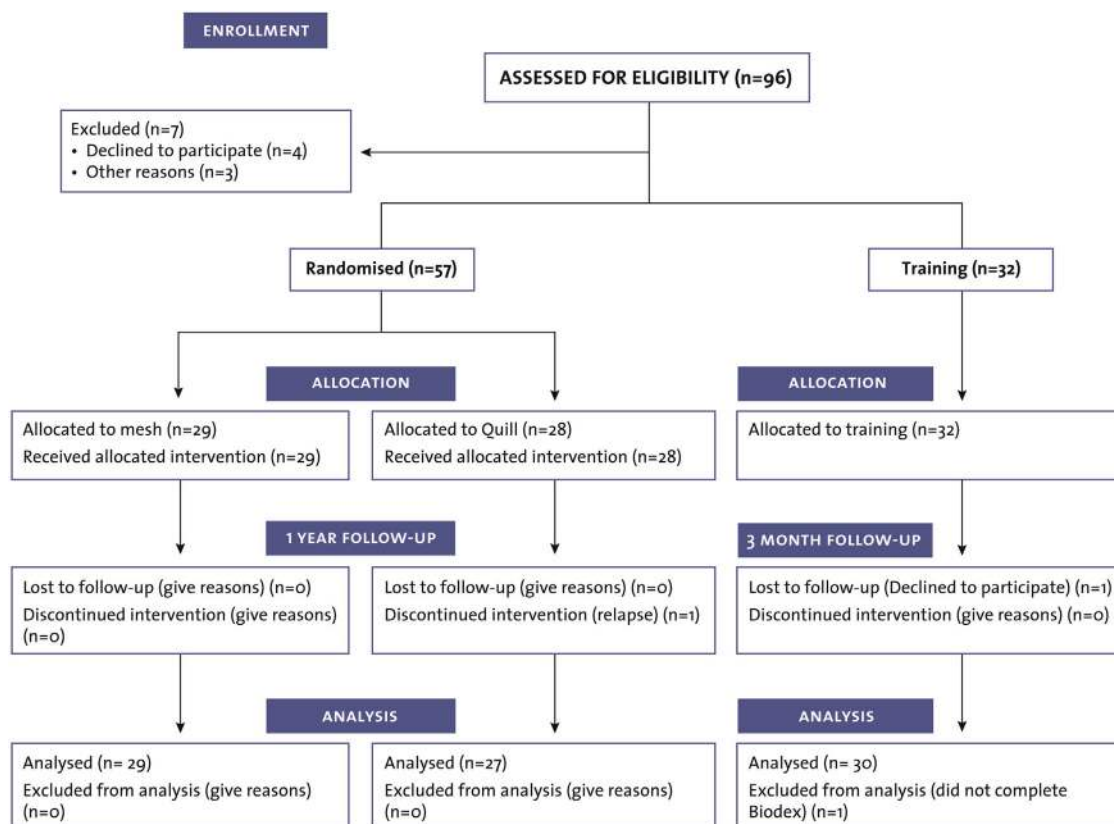


Fig 1. Consort diagram.

study arms. A research nurse, using sealed envelopes, performed the randomization procedures. Patients who were randomized to surgical care were blinded to the type of abdominal wall repair throughout the study period. At follow-up, the examining surgeon was blinded as to which operative procedure had been performed.

Procedures. ARD width was assessed clinically and with computed tomography scanning (CT) in all patients prior to randomization. CT scanning was used to exclude intra-abdominal pathology prior to inclusion. Clinical measurements of ARD were performed in the supine position, halfway between the xiphoid process and the umbilicus and halfway between the umbilicus and the pubic symphysis. Measurements were taken 3 times by the same investigator using a tape measure. Mean values were calculated and expressed in centimeters.⁸

Description of the anesthesiology and operative procedures has been published elsewhere.⁵ In the mesh group, the anterior rectus fascia was incised along the medial border of the rectus muscle bilaterally. The retromuscular space was prepared from

the xiphoid process to mons pubis, and a lightweight, polypropylene mesh (BARD Soft Mesh 30.5 cm × 30.5 cm) was applied and adjusted to cover the dissected space to the lateral border of the rectus muscle without lateral suture fixation. The anterior rectus fascia was closed using a slowly absorbable (PDS 2/0; Ethicon, Somerville, NJ) running suture.

In the suture group, repair of the ARD was performed with dual closure of the anterior rectus fascia using Quill SRS sutures.⁹ The Quill sutures started at the umbilicus and proceeded upward to the xiphoid process and downward to the mons pubis in a double-row layer. No drains were used. The same surgeon performed all operations.

The group randomized to training took part in a program targeting mainly the rectus, oblique, and transverse abdominal muscles.^{10,11} Participants were instructed to perform the exercises 3 times a week over a period of 3 months.

Outcomes. The primary end point was relapse of the ARD at the 1-year follow-up, assessed clinically and by CT scan. Secondary end points were perception of long-term pain, restriction of

daily activities, quality of life, patient-perceived improvement in muscle strength, and objective measurement of muscle strength. Perceptions of pain and restriction of daily activities were evaluated using a validated questionnaire for pain assessment, the VHPQ.¹² Scoring for the question “pain perceived last week” was used for the measurement of long-term pain at the follow-up.

Quality of life was evaluated with the SF-36 (short form, including 36 questions, 8-scale profile). The 8 domains addressed were physical functioning (PF); physical role functioning (RP); bodily pain (BP); general health perceptions (GH); vitality (VT); social role functioning (SF); emotional role functioning (RE); and mental health (MH). Data were matched with reference data from an age-matched, Swedish population.¹³

Patient perceived postoperative improvement in abdominal muscle strength was assessed using a visual analog scale (VAS) (0 = no improvement in muscle strength, 10 = maximal muscle strength).^{14,15} Abdominal wall muscle strength was assessed objectively using the Biodex System-4, validated previously for this purpose by our group.¹⁶ All participants underwent dynamometric testing prior to and after the intervention. Muscle strength measured by the Biodex system in all patients, regardless of randomization arm, correlated well to the intraoperatively measured width of ARD as shown in a previous publication.¹⁷ For the groups that were treated operatively, postoperative testing was performed 1 year after the operation. In the training group, this was performed 3 months after starting the training program. There was one isokinetic test and tests for flexion and extension performed in 2 ranges of motion, 30° and 60°, respectively. In the static test, the dynamometer was locked 10° from zero.¹⁶

Statistical methods. Statistical analyses were calculated using Statistica software (Version 12; Statsoft Inc, Tulsa, OK). Sample size was based on the assumption that there would be 30% recurrence in the Quill group compared to 5% in the mesh group at the 1-year follow-up (from experience with umbilical and incisional hernia repair) and no subjective improvement of abdominal wall strength (as assessed by VAS) in the conservative group. To obtain 80% power with a significance level of 95%, each group treated operatively required 25 patients. A training group of 25 patients as control was added, requiring a study total of 75 patients. Each case of protocol violation or dropout after randomization but before start of assigned treatment was replaced by 3 new cases to maintain power.

Nonparametric statistics were used. Comparisons of continuous variables were made by the Mann-Whitney *U* test, whereas dichotomous data were compared using the χ^2 test. Dependent variables were analyzed using the Wilcoxon signed rank test. The difference between the 3 treatment arms in terms of effect on muscle strength was evaluated by comparison of relative changes using analysis of variance with repeated measure design.

RESULTS

A total of 89 patients were enrolled into the study (87 women, 2 men); 86 patients completed follow-up (Fig 1). Demographics were comparable between groups (Table II). There were no patients with diabetes or patients using immune-suppressive drugs. Fifteen patients had undergone cesarean section in the Quill group and 14 in the mesh group. Five patients in each group had undergone other types of abdominal operations, where 1 man in the Quill group was operated due to testicular cancer. Two patients in the training group and 2 in the Quill group were operated with gastric bypass.

Recurrence of ARD and other complications.

The first patient in the Quill group had an early total relapse of ARD and was revised within 3 months. She was thus excluded from the 1-year follow-up. No further relapse was seen in either group. Five patients (3 with a Quill repair, 2 with mesh repair) complained of midline swelling, discomfort, and pain. CT scanning revealed a large, encapsulated seroma. These patients were revised operatively due to lack of spontaneous improvement. In the training group, 26 of 32 patients were dissatisfied and reported discomfort due to continued bulging of the abdominal wall and functional disability at the 3-month follow-up. They were all offered and received operative repair in accordance with the ethics approval clause.

Perception of pain and restriction of activities.

The VHPQ results are shown in Table III. Operated patients were improved in terms of abdominal wall pain at follow-up compared to preoperative data (VHPQ). There was no difference between the operative groups. Even though improvement of the ARD was seen at 3 months, discomfort and pain was still perceived during sports and daily activities according to the VHPQ (Table IV). Patients in the training group improved in all VHPQ modalities except “pain right now.” There was a slight but nonsignificant improvement in “pain last week” in the training group ($P = .19$).

Table II. Patient demographic data

	Operation with Quill (n = 27)		Operation with mesh (n = 29)		Training group (n = 30)	
	Median	Range	Median	Range	Median	Range
Age (yr)	39.6	29.0–61.0	42.0	27.0–62.0	44.2	28.9–66.9
BMI (kg/m ²)	23.0	18.0–31.0	23.0	18.0–30.0	22.8	18.0–30.0
Parity (n)	2.0	2.0–4.0	2.0	1.0–7.0	2.4	1.0–5.0
Pregnancy (n)	3.0	2.0–7.0	3.0	2.0–9.0	3.4	1.0–11.0
ARD at X-U/2 (cm)	4.0	2.0–6.0	4.0	0–7.0	4.3	1.5–9.0
ARD at U-P/2 (cm)	4.0	0–5.5	3.2	0.5–6.0	3.6	1.5–7.0

BMI, Body mass index; U-P/2, halfway between umbilicus and pubic symphysis; X-U/2, halfway between xiphoid and umbilicus.

Quality of life. Results from the SF-36 are shown in Fig 2, A and B. All groups demonstrated significantly lower scores for all 8 domains compared to a Swedish general population data prior to intervention. In the groups treated operatively, all 8 domains reached the Swedish population norm at the 1-year follow-up ($P < .001$).⁵ Data from patients operated with retromuscular mesh showed significantly higher scores for GH, VT, and MH compared to Quill repairs. Patients allocated to Quill, however, had initially significantly lower preoperative scores. For the training patients, PF, RP, BP, and VT domains were significantly improved 3 months after starting the program ($P < .05$), but BP, as the only domain, was still significantly lower than the population norm (Fig 2, B).

Self-perceived improvement in abdominal strength. No difference was seen between the 2 operative groups regarding perceived improvement in abdominal wall strength according to the VAS scale. The median improvement in the sutured group was 7 (range 0–10); in the group with mesh repair, improvement was 8 (range 0–10, $P = .86$). Improvement was rated significantly lower in the training group (median 3, range 0–10, $P < .001$) than in both operative groups (Table IV).

Objective abdominal muscular strength. Both training and operative repair improved abdominal wall muscle strength compared to preoperative values (Fig 3, A–C). The largest effect was seen for isometric strength and flexion strength at 30° in all groups. The type of intervention (Quill repair/mesh repair/training) did not influence the magnitude of improvement in terms of flexion at 30° ($F [2, 83] = 2.346$, $P = .102$), extension at 30° ($F [2, 83] = 1.950$, $P = .149$) or isokinetic testing ($F [2, 83] = 0.362$, $P = .697$). Improvement in abdominal wall strength was lower after training compared to operative repair (Fig 3, C).

DISCUSSION

This study has shown that there is no difference in the relapse rate of ARD in patients undergoing repair with either mesh reinforcement or Quill sutures. We expected a significantly higher incidence of failure for the Quill technique in patients with ARD wider than 3 cm based on experience from repair of incisional and umbilical hernias.^{18,19} This hypothesis was not confirmed, because only 1 patient was reoperated for early recurrence after Quill repair. This failure was due to technical reasons. In contrast, 56 patients were successfully repaired.

Interestingly, the recurrence rate in the suture group was lower than that expected after repair of umbilical hernia. One reason may be that several umbilical hernias are combined with an ARD and that a reliable reconstruction requires repair of the entire ARD, including the umbilical hernia. This theory is supported by results from a study of laparoscopic extrafascial repair, where a plication of the ARD was done concurrently with a mesh repair of the hernia without any recurrence in 21 patients after a mean of 22 months.²⁰ The present data have socioeconomic significance for future clinical practice, because mesh is more expensive than Quill.

Although there were no exclusion criteria for very low or high body mass index, the present study came to include a limited span. Whether our results are valid also for obese persons or male persons with diastasis only above the umbilicus and how the results and symptoms appear after a bariatric operation is not known and must be further studied.

The use of retromuscular mesh (larger foreign body and wider dissection) could theoretically involve a higher risk for complications. Data from the present trial did not confirm this hypothesis. Five of 57 (9%) patients were reoperated within

Table III. The VHPQ results for preoperative and 1-year follow-up after the operation, pretraining, and 3 months after completion of the training program

VHPQ	Preop		Postop 1 yr		Pretraining	Training 3 mo
	Quill (n = 28)	Mesh (n = 29)	Quill (n = 27)	Mesh (n = 29)	(n = 30)	(n = 29)
Pain right now ≤ 1	21	22	26	24	19	16
Pain right now > 1	7	6	1	5	11	12
Pain last week > 1	12	11	1	4	20	15
Difficulty rising from chair	3	1	1	0	6	4
Difficulty sitting	7	2	0	2	6	3
Difficulty standing	6	1	0	2	13	3
Difficulty climbing stairs	6	2	0	0	13	0
Difficulty driving a car	0	1	0	2	2	1
Difficulty performing sports and physical activity	13	12	3	6	15	6

Table IV. Patients' self-perceived improvement of abdominal wall strength 1 year after operation and 3 months after starting the training program

VAS	Quill (n = 27)	Mesh (n = 29)	Training (n = 30)
Median (0–10)	7	8	3
Std dev	2.62	2.08	2.76

Std dev, Standard deviation.

1 year for persistent swelling and discomfort of the abdominal wall due to an encapsulated seroma. This major complication appeared in both operative groups. Interestingly, these patients had no recurrence of their ARD. The overall occurrence of seroma is reported to range between 10% and 30%.^{21–27} This major complication could be reduced potentially by the use of drains.²⁸ We did not use drains because of the increased risk of infection when mesh is used.²⁹

Operated patients reported significant improvement in abdominal wall strength at the 1-year follow-up. Biodex System-4 measurements also confirmed that operative repair had an important impact. One might speculate that a large retro-muscular mesh would be more appropriate to provide stability of the abdominal wall compared to a simple, double-row, suture technique. Our data do not support this hypothesis. The relative improvement in muscular strength in Newton/meter at 1-year follow-up did not significantly differ between the 2 operative groups. The slightly better values for abdominal muscle strength using a VAS scale seen in the mesh group at the 3-month follow-up could not be confirmed at the 1-year follow-up.⁵

There is little in the literature on the topic of postpartum abdominal wall dysfunction. Functional impairment and pain related to ARD, regardless of cause, is underreported in the literature.^{30–32} VHPQ results preoperatively and 1 year after surgical care showed clearly that operative repair of ARD significantly improved function regardless of operative technique employed. In light of these findings, it may be said that operative repair of ARD has a clear impact on abdominal wall function and should be considered when an ARD is wider than 3 cm. A study using a laparoscopic intervention supports this, because back pain was significantly reduced 1 year after an operation.²⁰

Most participants in the training group were not satisfied with the outcome regarding abdominal wall strength (as assessed by VAS). The majority was therefore offered and received operative repair. The knowledge in this group of patients that there was an option for an operation if they were not satisfied may have affected their scorings, thus introducing a possible bias in outcome. Since the scoring for the different parameters improved in all cases except for “bodily pain,” this eventual bias seems unintentional.

A randomized trial, including a training program for ARD, has not been reported. Only 4 of 30 patients were satisfied with the improvement in symptoms and abdominal wall stability at the end of the training period. This is in contrast to our findings using the Biodex System-4, which showed an increase in muscle strength. VHPQ and VAS ratings in the training group appeared to be significantly lower compared to those who underwent an operation. Responses to the question

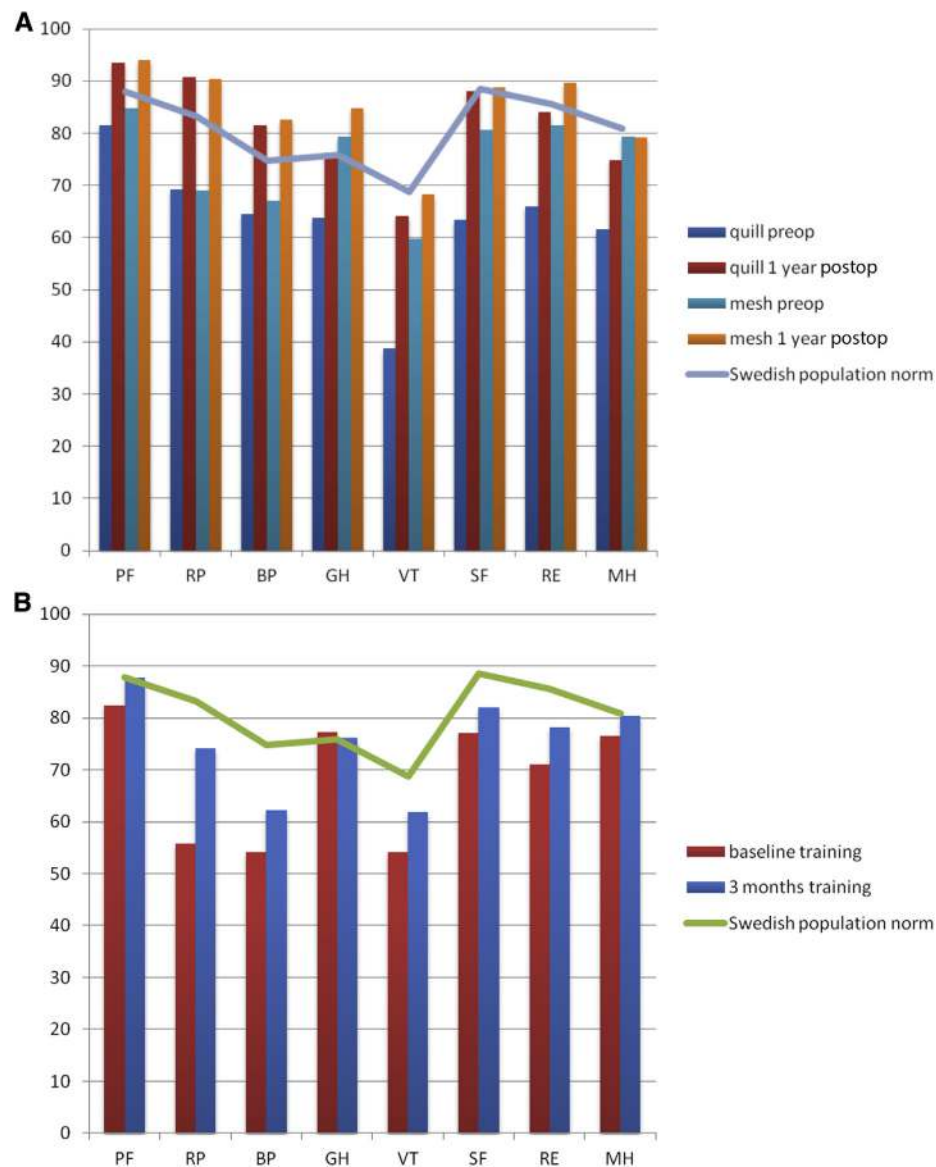


Fig 2. (A) SF-36 preoperative and 1-year follow-up after the operation. *PF*, physical function; *RP*, physical role functioning; *BP*, bodily pain; *GH*, general health; *VT*, vitality; *SF*, social functioning; *RE*, emotional role functioning; *MH*, mental health. (B) SF-36 baseline and after 3 months training.

“pain last week” at the end of the training period did not differ significantly from responses before onset of training. A comparison between outcome and predictive factors estimated by VHPQ has been published recently showing that complaints when sitting in a low chair and performing sport is predictive for operative outcome regardless of operative method used.³³

Since the present study was power calculated for the main outcome recurrence, interpretations of the secondary outcomes must be done with caution. There was no calculation of power for any of the secondary outcomes prior to the

operation and thus not for the patients receiving physical training only. Such a power calculation also would have been difficult to perform because of the aforementioned lack of knowledge regarding these outcomes. Thus, for these outcomes, there may still be a possibility of a type 1 error.

There is also an interindividual variability in, for example, baseline values for muscle strength that may interfere with calculation of the effects from an operation. Since patients are their own controls in ratings and muscle strength measurements, the effects of such variability decreases but may still

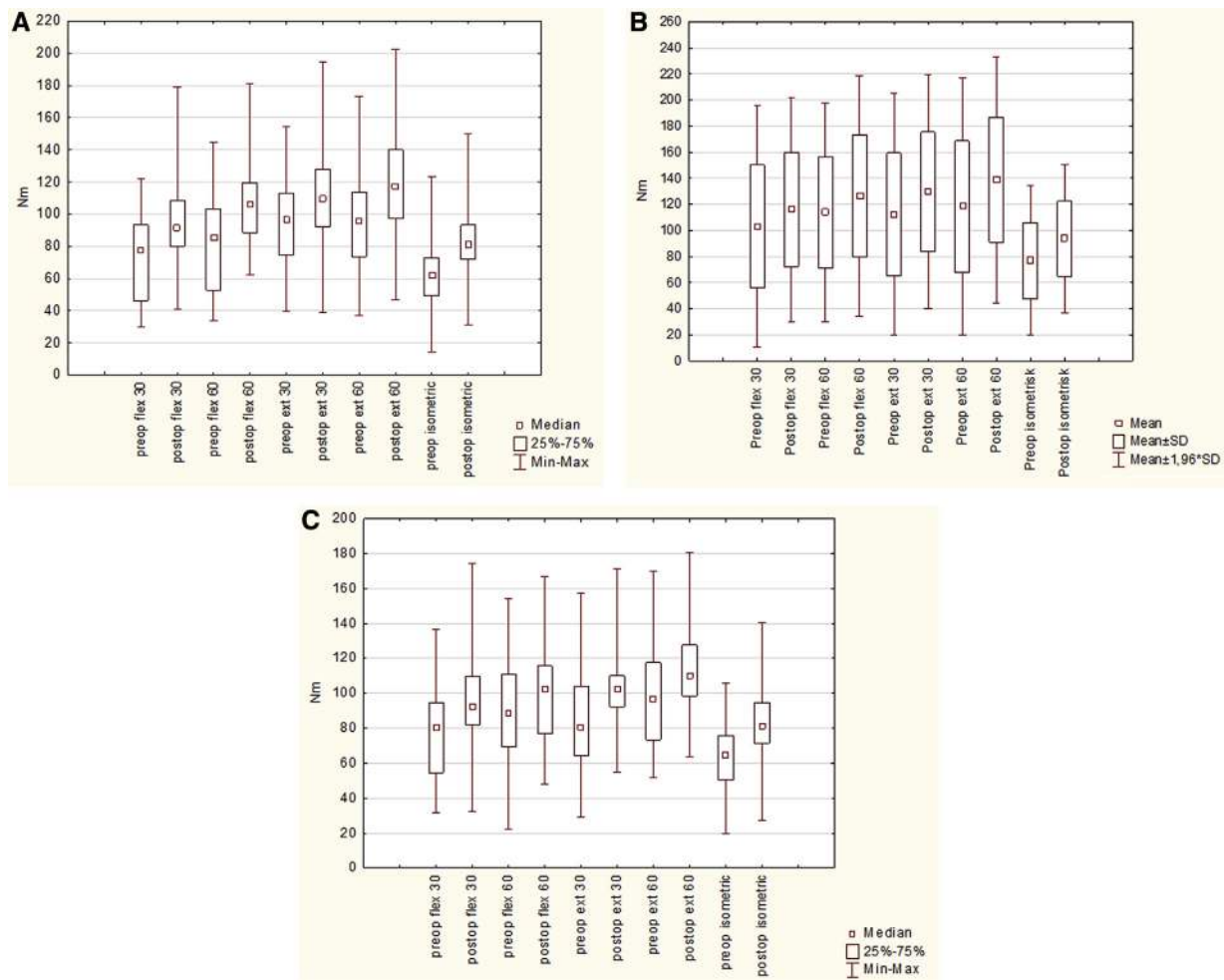


Fig 3. (A) Biodex-4 data before and 1 year after Quill ARD repair. (B) Biodex-4 before and 1 year after mesh ARD repair. (C) Biodex-4 before and after a 3-month training program.

interfere. The ratings of subjective improvement and satisfaction, however, seem conclusive, while comparison against the patients treated operatively regarding muscle strength and quality of life is more uncertain. To optimize the potential to compare the secondary outcomes, the reference group was randomized to a number of patients equal to those in the groups receiving operative treatment, which is a strength compared to using nonrandomized patients.

In conclusion, patients with an ARD wider than 3 cm have functional disability as indicated by improvement in SF-36 for bodily pain and physical parameters. Operative repair using Quill suture or mesh techniques is able to provide stability of the abdominal wall equally, improve quality of life, and reduce functional disability. Training improves objective muscular strength but does not lead to subjective improvement. Abdominal wall repair

should be considered in patients with an ARD wider than 3 cm who present with symptoms.

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