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**THE EVALUATION, PREOPERATIVE AND OPERATIVE
ASPECTS OF ABDOMINAL WALL RECONSTRUCTION FOR
GIANT VENTRAL HERNIA**

Leonard Clay



**Karolinska
Institutet**

Stockholm 2016

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Published by Karolinska Institutet.

Printed by E-Print AB 2016

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ISBN 978-91-7676-461-9

The evaluation, preoperative and operative aspects of abdominal wall construction for giant ventral hernia

THESIS FOR DOCTORAL DEGREE (Ph.D.)

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ABSTRACT

BACKGROUND:

The optimal method for surgical repair of giant ventral hernia remains to be determined. Different concepts for reinforcement have been used, which have decreased the risk for recurrence. However, the use of foreign material has shown potential adverse effects such as pain, enterocutaneous fistula and decreased comfort of the corset caused by stiffness and pain. In an attempt to explore ways to decrease surgical complications in giant ventral hernia repair, a randomized study comparing synthetic material with autologous full thickness skin transplantation was planned and executed. In order to conduct such a study and detect any differences, it was first necessary to develop instruments for the evaluation of patient related outcome measurements. This included assessment of pain which is known to be an outcome in inguinal hernia surgery. Also, the effect on abdominal strength after medialization of the rectus muscles is something that has been previously discussed but not explored in randomized studies. Similarly, the effectiveness of using a post-operative elastic girdle in connection with abdominal surgery and abdominal wall reconstruction has not been previously studied in detail. Giant ventral hernia affect the integrity of the abdominal wall. Abdominal rectus diastasis (ARD) elicit a similar affect on abdominal wall integrity. This being the case, the effectiveness of ARD repair could shed some light on the repair of giant ventral hernia.

METHODS:

A questionnaire was tailored to evaluate hernia related pain and its interference with the daily activities of a patient's life. This questionnaire was validated compared to the existing BPI questionnaire assessing general pain. For validation purposes, focus groups with patients operated for ventral hernia were utilized. Test retest reliability was assessed by distributing the VHPQ and BPI to patients who had previously undergone ventral hernia repair. In total, 225 patients were involved in this study.

To be able to evaluate the effect of surgical reconstruction of ARD where the abdominal muscles are brought together, 57 patients underwent evaluation with the VHPQ and their results were compared with abdominal wall strength measured with the Biodex pre- and postoperatively.

A randomized trial evaluating the effect of wearing an elastic abdominal girdle was conducted with 48 patients after midline laparotomy. Postoperative cough-PEF, spirometry, pain and wound healing were evaluated.

Ultimately, as planned, the randomized study of abdominal wall reconstruction in patients with giant ventral hernia was designed and initiated, including 52 patients. Randomization was performed to create parallel groups for reconstruction using synthetic mesh or autologous full-thickness skin transplant. The primary outcome was surgical complications after 3 months. Post-operative evaluation was performed by a surgical

specialist not otherwise involved in the study and blinded to the reconstruction method used.

RESULTS:

The VHPQ showed good validity and reliability when compared to the BPI and evaluation of test-retest stability. A relationship between preoperative ratings on VHPQ questions regarding performing sports and sitting for more than 30 minutes and the effect of surgical repair in terms of improved muscle strength was revealed for patients with ARD. The use of a post-operative elastic abdominal girdle following laparotomy did not impair respiratory function but seemed to decrease post-operative pain.

Abdominal wall reconstruction using full-thickness skin grafts instead of synthetic mesh for abdominal wall reinforcement showed a similar complication profile at 3 month follow-up. Patients reconstructed with full-thickness skin grafts experienced less post-operative pain at 3-month follow-up.

DISCUSSION:

This thesis evaluated the effect of autologous full thickness skin grafts as onlay reinforcement in the surgical repair of giant ventral hernia. Our hypothesis that the use of skin grafts would give less surgical complications was not confirmed but patients with full thickness skin grafts suffered less abdominal wall discomfort compared to those reconstructed using synthetic mesh. In the future, these patients will also be evaluated for recurrence, abdominal muscle force and adverse events at 12 and 36 months after surgery.

As a precursor to embarking upon a study to evaluate abdominal wall reconstruction, a useful tool for evaluation of pain in the abdominal wall after ventral hernia surgery was generated. This instrument makes it possible to compare different surgical techniques with regard to patient experience. It may also provide a possible tool for the selection of patients with ARD who might benefit most from surgical repair. The use of an individually fitted girdle does not hinder respiratory function or wound healing. Nor does it provide a supportive effect for cough-PEF. One positive effect from wearing a girdle postoperatively is that it seems to reduce postoperative pain.

LIST OF PUBLICATIONS

This thesis is based upon the following articles, which will be referred to by their Roman numerals as indicated below (I-IV):

I

Clay L, Fränneby U, Sandblom G, Gunnarsson U, Strigård K. Validation of a questionnaire for the assessment of pain following ventral hernia repair - the VHPQ. *Langenbeck's archives of surgery* 2012;397(8): 1219-1224.

II

Strigård K, Clay L, Stark B, Gunnarsson, U. Predictive factors in the outcome of surgical repair of abdominal rectus diastasis. *Plastic and Reconstructive Surgery Global Open*: May 2016 Volume 4 Issue 5 p e702.

III

Clay L, Gunnarsson U, Franklin KA, Strigård K. Effect of an elastic girdle on lung function, intra-abdominal pressure, and pain after midline laparotomy: a randomized controlled trial. *Int J Colorectal Dis*. 2014;29:715-721.

IV

Clay L, Stark B, Gunnarsson U, Strigård K. Full-thickness skin graft vs synthetic mesh in the repair of giant incisional hernia – a randomized controlled multicenter study. Submitted.

LIST OF ABBREVIATIONS

AD – Anno Domini

ARD – Abdominal Rectus Diastasis

BC – Before Christ

BioDex – BioDex Multi-Joint System-4

BMI – Body Mass Index

BPI – Brief Pain Inventory

CCS – Carolina Comfort Scale

CRF – Case Report Form

EDA – EpiDural Analgesia

EMG – Electro Myography

FEV – Forced Expiratory Volume

FVC – Forced Vital Capacity

HRQoL – Health Related Quality of Life

ICU – Intensive Care Unit

IPOM – IntraPeritoneal Onlay Mesh

IPQ – Inguinal Hernia Pain Questionnaire

IV – IntraVenous

MMP – Matrix MetalloProteinases

PEF – Peak Expiratory Flow

PO – Per Oral

PREM – Patient Reported Experience Measures

PROM – Patient Reported Outcome Measures

QoL – Quality of Life

TIMP – Tissue Inhibitor of MetalloProteinase

VAS – Visual Analog Scale

VHPQ – Ventral Hernia Pain Questionnaire

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1. INTRODUCTION

Hernia and their treatment have been described as early as the 16th century BC. The scrolls of the Egyptian papyrus of Ebers contain descriptions of hernia (Fig 1).

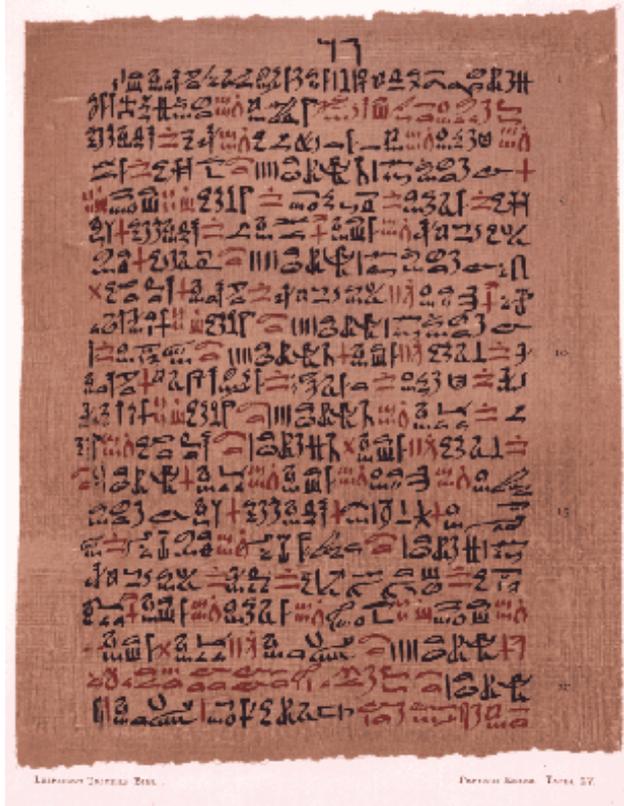


Fig. 1 Papyrus of Ebers

part of a general encyclopedia covering various subjects, *De Medicina* was the only portion that dealt with medical content. It contains detailed descriptions of surgical procedures and pre- and post-operative care but was ignored for centuries. It was rediscovered after the 10th century and its content regained significance. Many of the practices described in *De Medicina* (written in Latin) form the basis of, or are still used in, surgical procedures today. Celsus described tying off blood vessels with string before cutting between the two knots. He also described fasting the day prior to surgery and the use of enema before procedures involving the intestines. Though surgery was an accepted practice by Celsus' time, he acknowledged the

In the centuries that followed, there are numerous descriptions of hernia and the importance of its treatment. More than a thousand years later, the first known documentation describing the surgical treatment of hernia was written by Cornelius Celsus. Celsus, who lived between approximately 25 BC and AD 50 wrote an eight volume compendium called "*De Medicina*", *Medicine*. As



Fig. 2 Ancient portrait of umbilical hernia



Fig. 3. First randomized patient in study IV with giant ventral hernia.

importance of the work done by those who came before him like Philoxenus from Egypt, Heron, the Alexandrians and others.

Though hernia have been described since before Antiquity (Fig 2) and surgically treated since the time of Celsus, much remains to be achieved in order to help the hundreds of thousands of individuals currently suffering from this condition. A variety of different methods have been used to repair ventral hernia but none have produced completely desirable results. The fact of the matter is that ventral hernia is a very complex condition requiring a multidisciplinary and multi-professional approach in order to achieve a good treatment outcome (Fig 3).

One might think that a good treatment outcome means the effective repair of a hernia which prevents its return but there are several other aspects that are important to consider. These issues have likely been important as long as people have suffered from hernia. Aside from patients that require emergency surgery due to sudden incarceration of their hernia, the majority of hernia sufferers endure long-term pain, discomfort and functional limitation. Hernia pain can be so severe that it interferes with normal activities of daily living and even management of daily hygiene. Because most focus in the past was concerned with preventing the return of the hernia, the other important questions like pain and function have been comparatively neglected. Only recently has more interest been

directed to addressing hernia pain, abdominal wall function and quality of life for hernia sufferers.

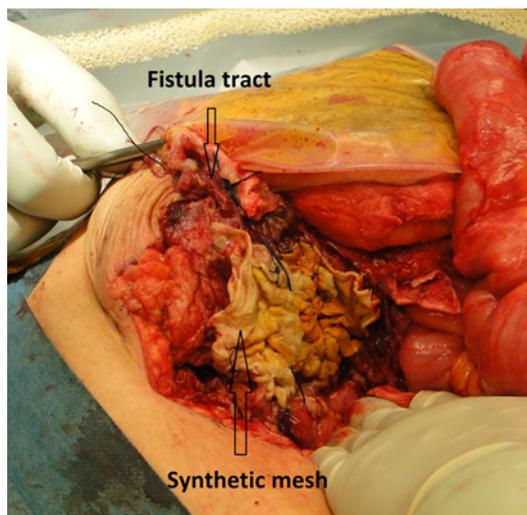


Fig. 4. Synthetic mesh with fistula and infection.

Surgical closure of a ventral hernia larger than 2 cm in diameter using suture alone risks resulting in recurrence in up to 70% of cases (1, 2). This being the case, other methods have been tried in efforts to reduce the risk of recurrence. The current standard of surgical treatment of ventral hernia larger than 2 cm involves the use of a synthetic mesh to reinforce the abdominal wall. Unfortunately, implantation of synthetic mesh into the abdominal wall opens the door to several serious complications, like the formation of enterocutaneous fistula (Fig 4). If a patient who has undergone abdominal

wall reconstruction using mesh develops a wound infection and that infection spreads to the underlying mesh, the result will likely be a serious mesh infection that either requires months of antibiotic treatment or ultimately removal of the mesh leaving a larger hernia than the patient started out with. On the other hand, if the mesh avoids bacterial colonization and heals in place, it forms a hard inflexible “plate” that stiffly impairs abdominal wall flexion, extension and movement (3). Synthetic mesh does not contribute to abdominal wall function in any way, as it has no inherent capacity for movement. The mesh has no or little elasticity so it has a tendency to cause strain and pain with movement of the abdomen. Mesh can also cause chronic pain without the initiation of movement (4). Besides correcting an abdominal defect, the purpose of hernia surgery is also to improve and regain good abdominal wall function. The abdominal wall is responsible for a large part of maintaining upright posture and avoiding overexertion of the back muscles. Until recently, there has been no objective method available for evaluating this aspect of post-operative surgical recovery. Perhaps not much has been done in this area because all focus has been placed on reducing the risk of recurrence.

An alternative to using a “synthetic” mesh is a “biological” mesh grown or cultured from porcine cells, for example. While this alternative may eliminate the problem of an inflexible obstructive structure covering the abdomen, it comes with an extremely high monetary cost (up to 30,000 Euro/Dollars) (5). Biologic meshes are either cross-linked or not and may give different immunological reactions. When used as bridging, the biologic material is degraded over time and after a while the hernia may become evident again (6). This process is most obvious for non-crosslinked materials. The cost of a synthetic mesh used for abdominal wall reconstruction is cheaper than biologics at 300 Euro/dollars (6). Considering these exorbitant prices makes one realize that it is extremely important to avoid the occurrence of ventral hernia in the first place.

Both ARD and incisional hernia are conditions of varying magnitude that affect the integrity of the abdominal wall and its function. When it comes to ventral hernia, how much discomfort, pain and disability a person experiences depends upon the size of the defect in the abdominal wall and is very individual. In ARD, it is not known whether it's the size in relation to the umbilicus or width in general that is of most importance. However, an ARD with a width of more than 3 cm producing symptoms could be relieved by surgical correction (7, 8). Some people may not even know they have a hernia or an ARD because it causes them no pain or change in bodily appearance, while others may experience debilitating pain and difficulties performing daily activities. While a hernia can become life threatening if a portion of the intestines become trapped and suffer a loss of blood flow, there is no danger of this occurring in cases of ARD. Though this fact exemplifies the structural difference between ventral hernia and ARD, it does not negate the similarities in symptomatology and functional impairment. Ventral hernia and ARD are two conditions that affect the same area of the body, sometimes with similar symptoms and other times with vastly different deficits and dangers. Since these conditions have such a large range of presentations, it is not always easy to decide when

surgical repair is indicated. To further complicate matters, some patients may experience no improvement following hernia or ABD corrective surgery. Naturally, this calls into question the very decision to perform the surgery in the first place, potentially subjecting the patient to unnecessary risk. All things considered, any tools that might assist in identifying which patients would benefit from abdominal wall reconstruction could be of great value.

It has been postulated that the use of an abdominal girdle following surgical correction of a hernia can reduce the risk of hernia recurrence (9, 10). Opponents of this theory suggest that the use of a girdle post-operatively could actually do the patient more harm than good by impairing the circulation to the area surrounding the surgical closure and impairing the patient's ability to breathe adequately, thereby increasing the risk of pneumonia and other respiratory complications. However, there are no randomized studies supporting this. Two review articles were published 2014, both with the conclusion that abdominal binders might affect postoperative pain and that there are diverging results from studies on respiratory effects (11, 12). One reason for the incongruous findings regarding pulmonary effects may be that only few studies include dynamic spirometry. No other effects were seen and there was a call for further randomized studies.

Otherwise, when evaluating the surgical result, history has shown a primary interest in preventing recurrence but the ultimate goal should be to have a patient that feels better without pain and has an improved quality of life. This is yet another aspect of incisional hernia surgery that has been neglected, but more extensively studied in inguinal hernia repair (13, 14). There is an obvious deficit of studies evaluating patient perception of pain, objective evaluation of abdominal wall function and quality of life following surgery for incisional hernia. Do patients experience improvement of their abdominal wall function? Can they perform regular daily activities more actively following surgery for incisional hernia? Previously, there have been no tools available to address these questions. Surprisingly, in the past, few articles have focused on clarifying this issue. Instruments for abdominal wall function have been poorly validated and those for measuring muscle strength have shown low reproducibility. Again, the sparsity of research regarding quality of life and functional ability following surgery for ventral hernia is likely a reflection of the difficulty involved when evaluating these issues without adequate PROMS and PREMS.

Quality of life and function are generally subjective parameters because the focus is on how an individual feels or perceives their own existence. Evaluating these parameters, when assessing a specific diagnosis under controlled circumstances, requires a standardized approach and compilation of questions that are both applicable and understandable to all individuals being evaluated.

The next challenge involves how to convert subjective responses into quantifiable data. To this end, surveys have been used. The usefulness of a survey depends upon its

appropriateness to the subject at hand. Quality of life and function following surgery for ventral hernia is a complex issue and, as such, assemblage of questions focusing on these subjects presents unique challenges. When discussing surgery for incisional hernia, much of the focus has been on reducing the risk of recurrence. The operative word here is “reduce” because reinforcement with mesh does not eliminate the risk of recurrence. It merely reduces that risk from approximately 35 to 10% (2).

Incisional or ventral hernia arise as a result of defective tissue remodeling and repair of the abdominal wall following abdominal surgery or a traumatic injury. MMPs may play a role in determining who develops a hernia and who doesn't. Antoniou et al demonstrated in 2011 that local tissue levels of MMP-2 and -9 were increased in the surgical area compared to decreased levels of the same MMPs found systemically when patients with inguinal hernia were investigated (15). Moreover, an imbalance between collagen I/III and MMP 1 has been shown to predispose for hernia (16). Surgical technique when closing the abdominal wall after laparotomy is an obvious factor that can influence the risk for incisional hernia (17).

Whether the eventual imbalance between MMPs and collagen I/III also form the biological basis for ARD is not known. Since a diastasis of the abdominal muscles is typical during pregnancy this might be true. The ARD usually diminishes after delivery and cessation of breast feeding but a proportion of women retain a residual ARD. This condition is also common after massive weight loss. Persons with ARD may have complaints related to a weak abdominal core but these symptoms are often poorly defined.

The surgical repair of incisional hernia has made significant advances with the advent of synthetic and biological materials that may be used to reinforce the abdominal wall and reduce the risk of recurrence. While synthetic and biological materials may reduce the risk of hernia recurrence, they may contribute to the occurrence of several undesirable complications.

Therefore, the successful result of hernia repair does not only depend upon the lack of recurrence of the hernia but also the well-being of the patient following surgery. It is important to minimize the risk of chronic post-operative pain and complications while maximizing the possibility of good abdominal wall function following surgery. Aspects of post-operative pain following incisional hernia surgery have been difficult to objectify, as is also the case with abdominal wall function. There is an obvious need for more objective tools to evaluate outcome as well as for development of methods for surgical repair with focus on decreasing the risk for adverse effects.

2. AIMS OF THE THESIS

The overall aim of the thesis was to improve and individualize patient oriented outcome measurements and the methodology for surgical repair of giant ventral hernia.

More specific the aims are

1. To construct and validate a questionnaire for the assessment of pain and quantification of the impact on ordinary life activities for patients with ventral hernia.
2. To determine the relationship between preoperative VHPQ ratings and abdominal muscle strength following the surgical repair of ARD as a model for further evaluation of outcome following ventral hernia repair.
3. To evaluate the effect of using an elastic abdominal girdle after midline laparotomy on respiratory function, pain and specifically cough support.
4. To compare abdominal wall reinforcement using autologous full-thickness skin grafts with synthetic mesh in the repair of giant ventral hernia conducting a randomized controlled study with surgical complications at three months as main outcome.

3. HYPOTHESIS

- Study 1: VHPQ can be used as a standardized instrument for the assessment of pain and its impact on regular daily activities in patients with ventral hernia.
- Study 2: Preoperative VHPQ ratings in specific items are predictive for the effect of surgical repair of ARD and may aid selection of patients who will benefit most from surgery.
- Study 3: Abdominal support, using a prefabricated elastic girdle with a broad attachment area around the abdomen, provides cough support and reduces pain without concurrent negative effects on pulmonary function.
- Study 4: The use of autologous full thickness skin grafts for reinforcement in repair of giant ventral hernia decreases the risk for surgical complications compared to the use of synthetic mesh.

4. MATERIAL AND METHODS

Study I

Ventral Hernia Pain Questionnaire (VHPQ)

As a result of the lack of studies evaluating pain following inguinal hernia repair, the IPQ was devised and validated (18). It was developed from a questionnaire used by Kehlet et al. (19). The IPQ is now widely accepted as a valid instrument for the evaluation of pain in individuals undergoing surgery for inguinal hernia (20-22).

Just as there was an absence of studies focusing on pain and quality of life following inguinal surgery, there was a similar deficiency with respect to incisional hernia repair. While these surgical conditions have structural similarities, ventral hernia and abdominal wall reconstruction pose new difficulties regarding the effect on abdominal wall function and consequent ability to execute daily activities. Considering these substantial differences, there was a need to develop an instrument for addressing these topics in ventral hernia patients. Because of the similarities in outcome aspects and surgical intention, the IPQ was chosen to serve as the foundation for the development of the VHPQ after some fundamental adjustments. Approval was obtained from the regional board of ethics at the Karolinska Institutet (D.nr. 2009/670-31/3).

Focus groups

While the basic focus of the questions in the IPQ were used as a framework, the derivation and finalization of the VHPQ questions was quite different. The questions used in the IPQ were written independently by its authors, without input from patients (18). In contrast, the VHPQ uses questions initially composed by the research group and subsequently honed by the use of repeated focus groups. Patients of both genders, at least 18 years of age were selected based upon their initial diagnosis of ventral hernia greater than 3 cm in diameter and recently completed ventral hernia repair with implanted mesh. The questions proposed for the VHPQ were then presented to groups of 10-15 patients that had previously undergone surgery for incisional hernia. These patients were asked to evaluate the questions and give feedback on whether the questions addressed issues that were relevant to their experience following surgery for incisional hernia. Patients were also asked to suggest modifications in order to make the questions more applicable and appropriate. Upon making the suggested modifications, the questions were then presented to the next focus group that contributed with the same evaluation. This process continued until the focus group had no suggestions for modification and the questions for the VHPQ were deemed suitable for presentation to current patients. A total of 90 patients evaluated and contributed to the fine-tuning of the VHPQ over a period of 1 month.

The responses to the first six questions in the VHPQ are based on a 7-step scale addressing the level and duration of pain. The next 7 questions address the effect of pain

on the execution of various daily activities. The final questions ask about the patients' occupation.

Validation

In order to evaluate the VHPQ, it was presented to three groups of patients. As a test of validity, a total of 74 patients received the VHPQ and BPI one and four weeks following surgical repair of a ventral hernia measuring at least 3 cm in transverse size. These patients were at least 18 years of age and received both verbal and written information about the study and what would be expected of them after inclusion. It was made clear that participation was entirely voluntary and their decision would not in any way affect their surgical care should they choose not to participate. All hernia were repaired utilizing a synthetic mesh to reinforce the abdominal wall as either a sublay or onlay. The BPI is a previously validated instrument for evaluating pain in general (23). In order to address validity, the patient responses to the VHPQ were compared to their responses to the BPI.

Test-retest reliability was assessed by distributing the VHPQ and BPI, on two occasions, to 104 patients who had previously undergone ventral hernia repair (within the last 3 years). This time frame was chosen in order to select patients likely to remember how they felt prior to and just after surgery and also reached stabilization of their postoperative recovery. The surgical record was reviewed to determine the size of the hernia the patient had repaired. If their hernia was at least 3 cm and repaired using a synthetic mesh they were offered inclusion in the study. The VHPQ was sent to these patients in the mail, along with an informational letter explaining that the VHPQ was part of a study to assess pain and function following surgery for incisional hernia. It was stated clearly in the letter that participation in the study was completely voluntary and that there would be no consequences if they chose not to participate. The VHPQ was sent to this group of patients on two occasions separated by one month. This group was expected to give similar responses on both occasions.

Baseline calibration

When addressing abdominal pain following surgery, consideration must be given to the fact that some people experience abdominal pain for other reasons and this pain can also be chronic in nature. It was important to try to identify and exclude any non-surgically related pain from the responses to the VHPQ. To establish if a baseline level of abdominal discomfort is present in the general population, 100 individuals whom had never undergone abdominal surgery were asked to complete the VHPQ. This group was obtained from the general population without anything in common but a lack of previous abdominal surgery. These subjects were comprised of a diverse group of healthcare workers and relatives coming to visit patients on the surgical wards. These people were asked if they had undergone any abdominal surgery. If they responded that they had not, they were provided a written and verbal explanation of the study and asked if they would like to participate. Upon accepting, they were provided with a VHPQ and asked to complete it during their visit or prior to the end of their workday.

Study II

The VHPQ and BioDex were utilized to determine if there are any pre-operative factors that could predict potential improvement in abdominal muscle strength following surgical repair of ARD (Fig. 5). Experience from this, and other studies of muscle strength using the BioDex system will be implemented in the design of outcome measurements following repair of the much more complex group of patients with giant ventral hernia.

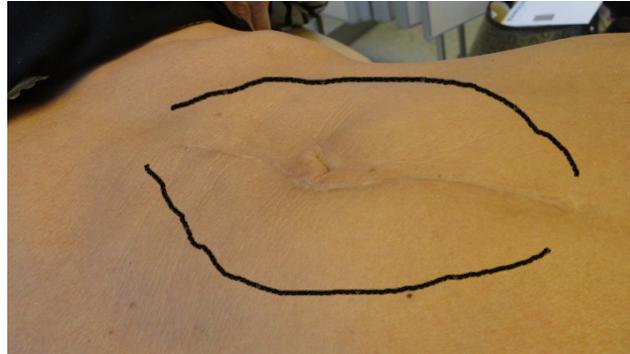


Fig. 5. Patient with ARD. The inner borders of m. rectus abdominis are marked.

ARD

Significant weight loss and childbirth contribute to the development of ARD, which can also be found in men. People suffering from ARD can experience similar symptoms seen with giant ventral hernia in the form of pain, discomfort, weakness of the abdominal core and decreased quality of life (24, 25). Just as the size of a ventral hernia influences the array of symptoms a patient experiences, the width of ARD also affects abdominal muscle strength (26). This begs the question of how to determine which patients will benefit from hernia or ARD corrective surgery. Are there any pre-operative indicators that can be used to determine which patients are more likely to experience an improvement in abdominal wall function following hernia repair?

Because of the similarities between ventral hernia and the simpler ARD, a study was devised to ascertain if there are any factors that can predict post-surgical improvement following surgery for ARD. In order to accomplish this, it was necessary to be able to evaluate and quantify a person's pre-operative state as well as measure their post-operative abilities in terms of abdominal core function and strength. The validated VHPQ could be used to quantify the patient's subjective pain and function. In order to compare the subjective experience of the post-surgical condition and any actual differences in core strength and function a method for objective measurement of abdominal wall strength was also necessary.

Patient and study procedure

The study was comprised of 55 women and 2 men for a total of 57 patients, all of whom had an ARD of 3 cm or larger. All of these patients were part of a previous randomized controlled study to compare the surgical correction of ARD using suture plication with that of reinforcement with synthetic mesh (7). For the 57 patients used in this study, no distinction was made with respect to which surgical procedure was performed as they were all randomized in the initial controlled study. Written informed consent was obtained and the study was ethically approved from the regional board of ethics at the Karolinska

Institutet (D.nr. 2009/227-31/3) and the study was registered on ClinicalTrial.gov (number 2009/227-31/3/PE/96).

To compare the pre-operative condition with the post-operative state, all patients underwent pre-operative evaluation with the VHPQ and BioDex. A VAS scale was used postoperatively and numbered 0 to 10. Using this instrument the patients' subjective improvement was estimated from 0 = no improvement to 10 = more improvement than they thought possible. Post-operative follow-up was performed at 3 and 12 months. 12-month follow-up included completion of the VHPQ, assessment of subjective muscle strength improvement shown with the VAS scale and objective evaluation of abdominal wall muscle strength using the BioDex.

BioDex

The BioDex (BioDex Corp., Shirley, NY), is a device initially designed for exercising and testing specific muscle groups in the back. Further development of the BioDex system expanded its capabilities so that it is now validated for the testing and evaluation of abdominal muscles and abdominal wall function in cases of ARD (26) and giant ventral hernia (27). To accomplish this, patients sit in the BioDex with their position fixed by Velcro straps at the shoulder, crossed in front of the chest and Velcro straps across the pelvis and legs at the thigh and calves (Fig. 6). The seat is adjusted in order to achieve the optimal position for measurement. These particulars were determined by a specially trained physical therapist, certified for BioDex usage. All adjustable parameters were recorded for later use to eliminate variation upon repeated testing. Once positioned in the seat of the BioDex, the patients performed a passive isokinetic test for both concentric and eccentric movements. There were two different speeds, 30



Fig. 6 Test patient in the BioDex

degrees/second and 60 degrees/second. An isometric static test was also performed. All three different tests were done 5 times and repeated twice. Measurement was in newton meters (Nm) measuring abdominal muscle core strength.

Study III

Abdominal girdle

Every day patients undergo abdominal surgery for a variety of reasons, all of which create a risk for developing an incisional hernia. Along with, and perhaps because of, abdominal pain, respiratory function can also be affected (28, 29). This has been one of the key issues of concern surrounding the usage of a post-operative elastic abdominal girdle (30-32).

Previous studies have indicated that the length of abdominal midline incision impacts the risk of experiencing post-operative pain and affecting post-operative recovery (28, 33). Critics for the use of post-operative girdle also warned of the risk of compromising proper wound healing due to compression of the circulation around the incision. The use of an elastic abdominal girdle is of importance in the study of giant ventral hernia as its use could be beneficial. On the other hand, it's important to determine if girdle usage could be detrimental. Does an elastic abdominal girdle affect lung function measured with cough-PEF or not? To address this question in a more standardized setting, patients scheduled to undergo planned laparotomies were chosen for the study.

Cough PEF was used as the primary effect variable. A normal cough PEF for a subject without a girdle was defined as 360 l/min based on previous measurements. In patients having muscular weakness, for example Duchenne's dystrophy, this value is 138 l/min. However, in these patients, cough PEF can be increased to 204 l/min, with the help of abdominal thrust (34).

The significance level was set to 95% and the power level to 80%. Postulated that the standard deviation is 40 l/min and that the girdle would lead to an improvement in performance by 10%, 21 patients were required in each group for the study (42 patients in total).

Patients and study procedure

To evaluate these issues, a diverse group of patients was assembled without any bias for diagnosis. The effect of a post-operative elastic abdominal girdle was evaluated in a randomized study comparing girdle with no girdle. Patients who were planned to undergo a midline laparotomy with an incision length of 12 cm or more, to provide an incision going around the umbilicus, were offered inclusion in the study. A specially trained research nurse handled the randomization process whereby 50 opaque envelopes were filled with a piece of paper with either the word "girdle" or "no girdle" printed on it, 25 for each. These patients were to undergo surgery for both benign and malignant colorectal conditions ranging from reversal of stoma to hemicolectomy due to tumor or cancer. All patients were provided detailed oral and written information describing the study in all its detail and given the option to participate. They were assured that their medical treatment would not be affected if they chose not to participate. Approval was obtained from the regional board of ethics at the Karolinska Institutet (D.nr. 2010/1589-31/1) and the study was registered at ClinicalTrials.gov (number NCT01517217). From former observations a normal value for cough PEF is assumed to be 360 l/min, without a girdle. If standard deviation is 40 l/min and the girdle is expected to increase cough PEF by 10%, then 21 patients are needed in each group for 95% significance and 80% power. In case of dropout, the number of envelopes prepared were 50. Due to the fact that there were no dropouts, 48 patients were included. The patients were randomized to 2 groups – one of which would wear an elastic abdominal girdle for the first 5 days post-operatively (n=23) and the other who would not use any post-operative abdominal support (n=25). The elastic

abdominal girdle, produced by NordiCare©, has a broad Velcro attachment strip which spans the width of the girdle and offers optimal adjustment for various abdominal forms and ease of attachment. It is also possible to make an orifice for a stoma without compromising the function (Fig. 7).



Fig. 7. The elastic girdle used in study III.

A specially trained nurse was responsible for fitting each patient in the girdle group with the most suitable girdle size prior to surgery. Particular effort was taken to optimize and define the correct amount of tension to be created and proper positioning upon application of the girdle. A marking was placed on the girdle to assist with proper tensioning. Except for the girdle fitting and usage, all patients in both groups were treated identically in all other respects pre- and post-operatively.

Respiratory measurements

In order to assess the respiratory effects of a post-operative elastic abdominal girdle, all patients underwent pre-operative cough peak expiratory flow and spirometry testing. Pulmonary function was evaluated the day before surgery and daily postoperatively day 1-5, unless discharged earlier, using a portable spirometer, (Care Fusion Spiro USB, Micro Medical Limited, UK). The portable spirometer was connected to a laptop computer and



Fig. 8. Person demonstrating the portable spirometer.

taken to the patient's bedside. All patients were asked to sit up at the bedside with both feet on the floor. They received a detailed verbal explanation of how to perform the spirometry exercises; taking as large a breath as possible, placing the disposable mouthpiece in their mouth and exhaling as forcefully and completely as possible (Fig. 8). They were all asked to perform this exercise 3 times. Measurements for forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1) and peak expiratory flow (PEF) were recorded

on the laptop computer. Measurements for all patients were taken by 1 of 3 individuals trained to use the portable spirometer. The best of the 3 measurements was used for subsequent calculation.



Fig. 9. Person demonstrating the Mini Wright cough-PEF.

This was also the case for the cough-PEF measurements. All patients were evaluated for cough peak expiratory flow (cough-PEF) using the Mini Wright (Clermont Clarke International Limited, UK) meter. The patients were asked to take as deep a breath as possible and cough as forcefully as possible. The flow as indicated by the pointer on the Mini Wright meter was recorded and the exercise was repeated a total of 3 times (Fig. 9).

Pain measurements

Patients in both the girdle and non-girdle group were evaluated to assess their level of pulmonary function and pre-operative pain using various methods. Preoperative pain was evaluated the day before surgery using the VHPQ and VAS (35). Patients were presented with a VAS scale and asked to slide the indicator to the point on the scale which best approximated the amount of abdominal pain they were experiencing at that point, pre-operatively. The chosen position on the VAS scale was assigned the corresponding number from one to ten shown on the scale on the back of the VAS instrument.

Patients in both groups were also asked to complete the VHPQ preoperatively. Subsequently, all patients were assessed for pain using the VAS scale twice daily for the first five days following surgery unless they were discharged sooner. They also all completed the VHPQ on day 5 post-operatively or sooner if discharged earlier.

The amount of iv and po pain medication was assessed for each patient as well as the use of EDA for postoperative pain treatment.

Intraabdominal pressure and wound healing

Intraabdominal pressure was measured daily using an indwelling urinary catheter (catheter a demur) for patients receiving epidural anesthesia. The column of urine extending above the abdominal wall was measured and this value was used for later comparison to the patients perceived pain, mobilization and bowel function.

Wound healing was assessed by photographic analysis of the abdominal incision on post-operative day five or earlier if discharged sooner. The photos were evaluated for redness, swelling, discoloration, discharge or wound dehiscence by an independent observer who had no knowledge of the patient's prior girdle status.

Study IV

For this study patients with giant hernia (>10 cm transverse) were chosen. Reasons for this were that these patients have a considerably higher risk for surgical complications (36) and would benefit most from a method reducing this risk and thus also provide a reasonable number to include in a study with complications as the endpoint while achieving enough power. The decision for surgery was made after thorough workup, often including spirometry, ergometry, echocardiography and assessment by a specialized anesthesiologist. When the patient was judged unable to perform enough work load because of the hernia, ergometry was exchanged with echocardiography during administration of dobutamine.

The primary endpoint was surgical complications during the first three months after the operation. A secondary endpoint was patient comfort.

Surgical procedure

An alternative surgical method for the repair of giant ventral hernia was compared to the standard method of abdominal wall reinforcement using synthetic mesh. In a prospective randomized controlled setting, 53 patients were randomized to 2 groups with one group undergoing abdominal wall reconstruction reinforced using an autotransplant of the patient's own full-thickness skin (Fig. 10).

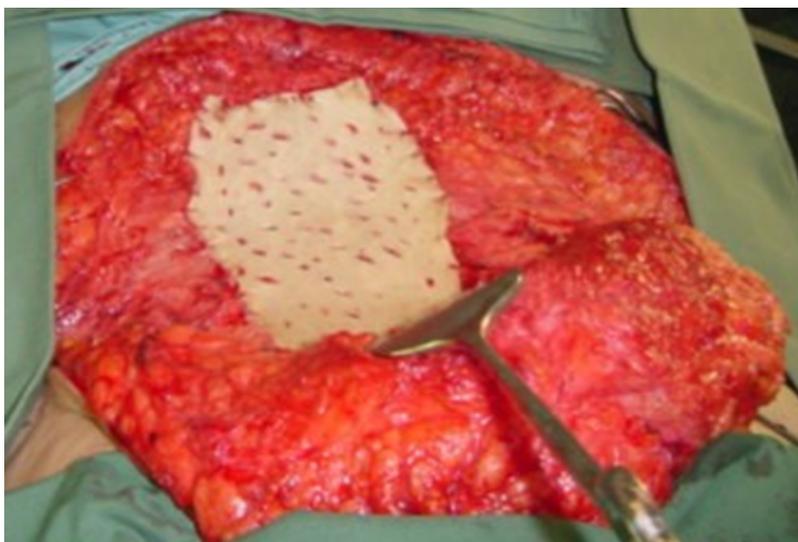


Fig. 10. Abdominal wall reconstruction with autologous, meshed full-thickness skin transplant as an onlay reinforcement.

The other group had hernia repair using the standard method of mesh reinforcement (Fig. 11, 12).

The patients were evaluated at 3-month short-term follow-up by a surgeon blinded to the surgical method used.

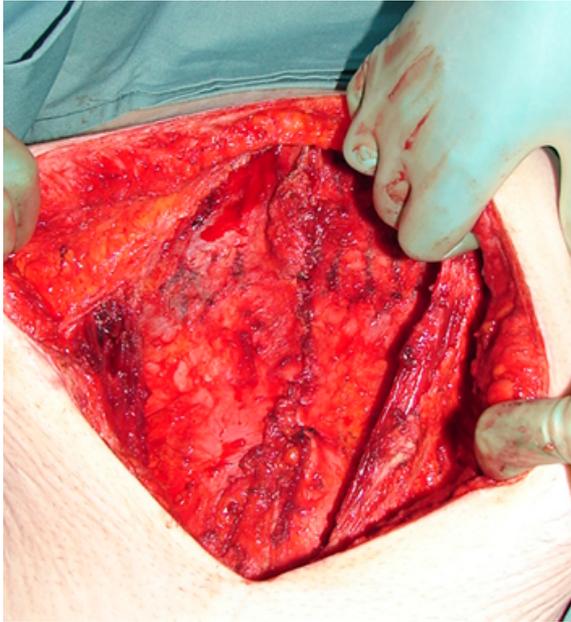


Fig. 11. The sublay space dissected.



Fig. 12. The retromuscular space has been made accessible and a synthetic mesh placed for sublay reinforcement.

Giant ventral hernia

A ventral hernia measuring 10 cm or more in diameter is classified as “giant”. Accordingly, a ventral hernia can be extremely large and classified as a giant hernia at the time of its initial presentation. These large hernia are much more complex and difficult to surgically correct than small to normal hernia. There is a greater risk of complication following surgery for giant ventral hernia compared to smaller defects (36). One reason for this is loss of domain where a large proportion of the content of the abdominal cavity is placed back in the abdomen and may cause pulmonary insufficiency following surgery (37). Considering the fact that many people suffering from giant ventral hernia have other health problems like; obesity, diabetes and advanced age, the risk for surgical complications is even higher (38). For this reason, many giant ventral hernia are left untreated. However, although the giant hernia per se does not pose an immediate threat to an individual’s life, it may cause serious impairment of their quality of life and ability to manage activities of daily living. The standard surgical reconstruction involving reinforcement of the abdominal wall with synthetic mesh, in many cases, makes surgery not worth the risk in terms of morbidity and even mortality. The risk of recurrence following surgery for a giant ventral hernia can be up to 30% (36), while the risk for wound complications is even higher at approximately 40-50% (39).

Study design

This study was designed to compare standard hernia repair using synthetic mesh to reinforce the abdominal wall with an alternative method using the patient’s own full-thickness skin as an onlay reinforce-

ment. Approval was obtained from the regional board of ethics at the Karolinska Institutet (D.nr. 2009/227-31/3) and the study was registered with ClinicalTrials.gov (number NCT01413412).

Full-thickness skin as a means of repairing defects in the abdominal wall was tried as early as the 1950s when it was used as a reinforcement in inguinal hernia surgery (40). In the 1960s the use was further extended as reinforcement of the abdominal wall (41). Almost 40 years later, a feasibility study using full-thickness skin grafts to reinforce the abdominal wall in repair of large ventral hernia in a group of high-risk patients was performed. That study showed a favorable outcome (42) although the study design and complicated patients included did not allow for a control group using synthetic material for reconstruction. Initial design was set for 2 groups of patients with 25 in each group for a total of 50.

Assuming the complication rate for hernia repair with synthetic mesh would be 50% and 20% for patients operated with full-thickness skin, a total of 50 patients would be needed to obtain a power of 80% and 95% significance. Patients with pain and discomfort due to their ventral hernia were offered inclusion in the study if their hernia measured at least 10 cm transversely by clinical exam or with computerized tomography (CT). All patients were given detailed oral and written information regarding what the project would entail and how inclusion would vary from the standard treatment and follow-up. Informed consent was obtained for all those interested with the assurance that they would not be treated any differently from the standard patient if they chose not to participate.

Randomization

A specially trained research nurse handled the randomization process whereby 50 opaque envelopes were filled with a piece of paper with either the word “skin” or “mesh” printed on it, 25 for each. These envelopes were sealed and mixed up in a container. Just prior to surgery, the research nurse would select an envelope from the container and upon opening it reveal the surgical method for that patient and assign the patient the next randomization-number. After randomization, one person was excluded due to rapid weight progression and other health problems making it too dangerous to proceed with surgery. In order to replace this patient, 10 additional envelopes were filled in the same fashion used in the initial randomization and 3 were selected for randomization. All 3 of these were randomized to the mesh group making the final numbers 24 in the skin group and 28 in the mesh group.

Patients

Patients of both genders at least 18 years of age and non-smoking for at least 3 months prior to surgery were offered participation. Individuals requiring supplemental oxygen or immunosuppressive therapy were not considered for participation because of the additional risk for pulmonary and infective complications. In study number III of this thesis, an elastic abdominal girdle used post-operatively showed no impairment of

pulmonary function and offered improved pain-relief on day 5 following planned abdominal surgery. This parameter was therefore included in this study whereby all patients were required to wear an elastic abdominal girdle 24-hours-a-day for 3 months leading up to the surgery and 6 weeks post-operatively. Following this, the girdle would be worn for 6 more weeks during the day when the patient was active and could be removed during the night time hours for sleep.

Pre-operative workup

Patients in both groups were examined with computerized tomography in order to verify and document the dimensions of their hernia. In selected cases workup also included cardiac evaluation with ergometry and/or echocardiography. Most patients were seen by a specialized anesthesiologist. All patients received pre-operative antibiotics approximately 30 minutes before surgery. The patients in the mesh group received Bactrim 800 mg (Sulfamethoxazole 800 mg/Trimethoprim 160 mg), 2 tablet and Metronidazole 400 mg, 3 tablets. Patients in the skin group received the same, with the addition of Clindamycin 300mg, 2 tablets pre-operatively and Clindamycin 300 mg, 1 tablet, 3 times per day for 10 days. This variation was chosen as it was used in the previous feasibility study (42). Epidural anesthesia was inserted prior to intubation. Demographic data for gender, age, weight, body mass index (BMI) (weight (kg)/height (meter) squared), blood pressure, heart rate and medications was registered on the CRF.

Synthetic mesh

On the operating table, after intubation, all patients underwent abdominal palpation to assess the clinical dimensions of their hernia under muscle relaxation. A midline incision was made and electrocautery was then used to expose and delineate the hernia sac. Great care was taken not to enter the abdominal cavity. In the event that the peritoneum was perforated during dissection, the opening was sutured closed using absorbable monofilament suture. Once the fascia boundaries of the hernia were exposed, the decision was made for the optimal placement of the mesh, sublay being the ultimate goal. The retromuscular space was made accessible with 5 cm in all directions using electrocautery. Light weight polypropylene mesh of suitable size was then trimmed to fit and placed in the retromuscular space according to Reeves Stoppa (43, 44). The anterior rectus fascia was then closed using size 0, non-absorbable polypropylene monofilament suture, knotting the suture every 6th stitch. If it wasn't possible to close the hernia without undue tension, relaxing incisions were made according to Chevrel (45). The pulmonary pressures for all patients were recorded after intubation and after closure of the hernia defect. The skin was then closed in 3 layers using absorbable monofilament suture. In case the sublay space was unable to be used, the fascia was closed after dissection and reduction of the hernia and a mesh was placed onlay according to Chevrel. In these cases a full-weight mesh was used. According to the protocol IPOM was also allowed.

Autologous skin graft

An area of skin overlying the hernia was demarcated with a surgical marker. An elliptical incision was made along the demarcation using the needle pointed cautery and the skin for autotransplant was then excised by separating it from the underlying subcutaneous tissue. Once removed, the autotransplant was taken to a separate table for preparation with complete removal of all subcutaneous adipose tissue. It was then meshed with a scalpel to create ca. 8-15 mm holes throughout the entire transplant, rolled in cotton gauze soaked in 0.9% sodium chloride until time for autotransplantation. The anterior rectus fascia was exposed using cautery and scalpel in order to obtain a minimum of 5 cm margin from all edges of the hernia. This typically required dissection from the xiphoid process and costal margins down to the pubic symphysis and laterally to the external oblique muscles. Great care was taken to stop all bleeding. The hernia edges were then cleaned to expose the fascial edges. The hernia was closed using slowly absorbable polydioxanone monofilament suture, size 0 in a continuous fashion, knotting the suture after every 6th stitch. The autotransplant was then brought to the operating table and sutured over the hernia closure as an onlay, using absorbable monofilament suture, size 4.0. Stitches were placed along the perimeter of the autotransplant under tension. After fixation, the area under the autotransplant was flushed with 60 ml hydrogen peroxide using a plastic peripheral vein catheter. Two drains were placed; one in the upper and lower operative areas. The incision was closed in 3 layers with interrupted stitches of monofilament, absorbable suture, size 4.0 to close the subcutaneous adipose layer, 3.0 monofilament interrupted suture subdermally and continuous intracutaneous 4.0 monofilament to the dermis.

Postoperative care

The specially fitted elastic abdominal girdle that the patient used pre-operatively was reapplied before reversal of the anesthesia and was to be worn 24-hours daily for the first 6 weeks post-operatively and a further 6 weeks during daytime hours, after which it could be removed before sleeping.

Patients in both groups were mobilized upon return to the surgical ward. Abdominal drains were removed when their daily drainage was 40 ml or less.

Follow-up

Patients in both groups returned for follow-up 3 months following surgery. This follow-up visit was conducted by a specially trained abdominal surgeon with no knowledge of the surgical method

Question	Answer	Comment
Discomfort in the abdominal wall?	Yes/no	Comment
Experienced improvement	VAS 1-10	
Pain	VAS 1-10	
Healing of the scar	Yes/no	Comment
Excess of skin	Yes/no	Comment
Uneven distribution	Yes/no	Comment

Table 1. Questions asked at three month follow up.

used for respective patients. After clinical examination, the patients were asked a predetermined sequence of questions regarding their impression of the surgical results and their wellbeing (table 1).

5. STATISTICS

In general, non-parametric statistics were used in all studies. Although some parameters may fit into the normal distribution, sub-groups and other parameters might not. In the randomized trials as simple statistics as possible were used. This was the case because the study designs were judged to assure that patients randomized to each group had comparable characteristics.

Statistica® version 10 (Statsoft, Tulsa USA) was used for all the statistical analysis in study 1-3 except for the intra-class correlation test (ICC). The ICC test was made in SPSS. Statistics in study 4 were analyzed using Statistica® version 12 (Statsoft, Tulsa, USA).

Study I

Construct validity of the VHPQ, or the degree to which the questionnaire measures what it claims to be measuring, was tested using two different models.

In the first model it was presupposed that pain following ventral hernia repair abates between week one and four postoperatively. Thus, a decline in recorded pain intensity in group A between week one and four would be proof of the questionnaire's construct validity. This was tested using the chi-square test for dichotomous responses and a Wilcoxon signed-rank test for ordinal scale responses.

The second model tested internal consistency, which can also be seen as a proof of construct validity. Data was taken from group B. Cronbach's alpha coefficient (a lower bound estimate of the reliability) was used to compare items concerning interference with daily activities with items concerning pain intensity. Furthermore, the responses were evaluated regarding logical coherence. For example, pain combinations such as 'Pain right now' described as worse than 'Worst pain past week' for group A were regarded as illogical.

Concurrent validity was assessed using data from group B. Responses for item 'Pain right now' in the VHPQ was compared with corresponding pain measurement in the BPI using the Spearman's rank correlation test. Moreover, the reliability of the questionnaire was also tested using responses from group B. Pain levels were expected to be stable three years following ventral hernia repair. The concordance between pain ratings by the same patient was tested. For ordinal variables the intra-class correlation test (ICC) was used and for dichotomous variables Kappa statistics were used.

The specificity of the questionnaire was assessed using data regarding pain from group C. It was postulated that pain in patients having had ventral hernia repair would be greater

than in the normal non-operated population. For comparison, the Mann–Whitney U test was used for ordinal scale and the chi-square test for dichotomous variables.

Study II

VAS for abdominal muscle strength improvement was compared with relative improvement in muscle strength, measured by BioDex, using Spearman Rank Order. The BioDex measurements included flexion 30°, 60° and isometric force.

VHPQ ratings and relative improvement in muscle strength was compared using the Kendall Tau test since the VHPQ ratings were considered as classes rather than scales. The same test was used when analyzing the relationship between improvement in VHPQ ratings preoperatively and VAS.

Study III

Change in respiratory physiologic parameters was defined as a proportion of the baseline value.

Comparisons between two measurements were made using Wilcoxon sign rank test, whereas between groups the Mann–Whitney U test was used. When comparing groups with repeated measurements ANOVA with repeated measure design was used until discharge. For dichotomous variables the Chi Square test was used.

ANOVA with repeated measure design was used in order to keep the statistics as simple and understandable as possible. However, that means only subjects staying in hospital until day five were included in the analysis, resulting in data loss. An alternative statistical method would have been ANOVA mixed effects. Using this method, patients discharged before day 5 or patients with missing measurements could also have been included. Nonetheless, the backside of this method is its complexity. It is more challenging to correctly interpret the results, leading to a higher risk of misinterpretation. The more missing values, the bigger risk for misleading results. Furthermore, it is difficult to assure that patients randomized to each group have comparable characteristic. Therefore, it was decided ANOVA with repeated measure design would be used in this study, in spite of the method's drawbacks.

Study IV

The hernia area was defined as $\pi \times \text{hernia length} / 2 \times \text{hernia width} / 2$.

For comparisons, the chi-square test was used for dichotomous variables.

6. RESULTS

Study I

Two hundred twenty five people were included in the study; fifty-one patients in the validity group A, seventy four in the reliability group B and one hundred non operated people. Pain not related to surgery was examined in the non-operated group. Group A responded to VHPQ (Fig 13) and BPI one and four weeks following surgery. Group B received the VHPQ and BPI on two separate occasions three years after surgery. The non-operated group responded to VHPQ on one occasion.

The VHPQ showed good validity and reliability when compared to the BPI and evaluated for test-retest stability.

In group A, 51/70 (72.9%) patients responded week one as well as week four. A significant decrease for pain intensity items was seen from week 1 to week 4 postoperatively, as anticipated (Table 2).

Similarly, questions connected to pain-provoking activities declined (all $p < 0.05$ except for performing sports). Patient memory of postoperative ventral abdominal wall pain was consistent (one week postoperatively median score=3, four weeks postoperatively median score=2, $p=0.122$). Tested 1 week postoperatively, Spearman rank correlations were significant when comparing pain intensity items of the VHPQ and the BPI ($p < 0.05$).

In group B, 74/104 (71.2%) patients responded two times. Kappa levels for interference with daily activities were above 0.5 for all items with the exception of driving a car (Table 3).

Intra-class correlation was significant for pain intensity items ($p < 0.05$). Furthermore, the pain intensity items correlated well with responses regarding behavior after pain; 11/11 of the patients stating not having pain also reported no intake of analgesics and 10/11 no limitations in

Group A	p
Pain right now	0.001
Worst pain last week	<0.001
Pain frequency last week	<0.001
Attack duration last week	<0.001
Sick leave	0.436

Table 2. 1 week vs 4 weeks postoperatively (Wilcoxon signed-rank test).

Group B	Kappa
Difficulty rising from chair	0.830
Difficulty sitting	0.684
Difficulty standing	0.609
Difficulty climbing the stairs	0.570
Difficulty driving a car	-0.040
Difficulties performing sports	0.598
Taken analgesics last week	0.578
Stiffness or rigidity	0.586
Satisfied with surgery	0.738
Prepared to repeat surgery	0.716

Table 3. Test-retest, dichotomous variables (Kappa values).

Group B vs Non-operated group	p
Pain right now	<0.001
Worst pain last week	0.003
Pain frequency last week	0.004
Attack duration last week	0.288
Sick leave	<0.001

daily activities.

When comparing group B to the non-operated group, the operated group stated more interference with daily activities ($p < 0.05$) and more pain in the pain intensity items (Table 4).

Table 4. Responses three years postoperatively compared with matched non-operated controls. (Mann-Whitney U-test).



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Questionnaire regarding pain after surgery for ventral hernia

Choose the alternative which best describes your pain following surgery for ventral hernia. Choose only one alternative for each question.

1. **Date**

2. **Describe the pain you experienced from your hernia prior to surgery.**
 - a. No pain
 - b. Pain that could easily be ignored
 - c. Pain that could not be ignored but did not influence daily activities
 - d. Pain that could not be ignored, which affected concentration and performance of daily activities
 - e. Pain that inhibited most daily activities
 - f. Pain that required rest or bed rest
 - g. Pain so severe that you were forced to seek medical attention

3. **Describe the abdominal pain you experience right now following surgery.**
 - a. No pain
 - b. Pain that can easily be ignored
 - c. Pain that cannot be ignored, but does not affect your daily activities
 - d. Pain that cannot be ignored, which affects concentration and daily activities
 - e. Pain that inhibits most daily activities
 - f. Pain that requires rest or bed rest
 - g. Pain so severe that you are forced to seek medical attention

4. **Describe your abdominal pain when most intense during the last week.**
 - a. No pain
 - b. Pain that could easily be ignored
 - c. Pain that could not be ignored but did not influence daily activities
 - d. Pain that could not be ignored, which affected concentration and performance of daily activities
 - e. Pain that inhibited most daily activities
 - f. Pain that required rest or bed rest
 - g. Pain so severe that you were forced to seek medical attention

- 5. If you no longer have pain in the operated area, try to recall when your abdominal pain stopped. After answering this question, go skip to question 16.**
- a. I still have abdominal pain
 - b. Pain in the operated area stopped within 1 month following surgery
 - c. Pain in the operated area stopped within 3 months following surgery
 - d. Pain in the operated area stopped within 6 months following surgery
 - e. Pain in the operated area stopped within 1 year following surgery
 - f. Pain in the operated area stopped within 2 years following surgery
 - g. Pain in the operated area stopped recently

If you have reported some form of abdominal pain during the last week, please answer the remainder of the questionnaire.

- 6. How often have you felt abdominal pain in the operated area in the last week?**
- a. A few times during the last week
 - b. Several times during the last week
 - c. Every day
 - d. Every day and night
 - e. Constant pain during the last week (day and night)
- 7. How long does the pain persist when experienced this last week?**
- a. A few minutes
 - b. Several minutes
 - c. Most of the day
 - d. All day
 - e. Constant pain during the last week (day and night)
- 8. Do you find it difficult to rise from a low-sitting chair as a result of your abdominal pain?**
- a. No
 - b. Yes
 - c. Not sure
 - d. Never perform this activity
- 9. Do you find it difficult to sit for an extended period (over 30 minutes) as a result of your abdominal pain?**
- a. No
 - b. Yes
 - c. Not sure
 - d. Never perform this activity
- 10. Do you find it difficult to stand for an extended period (over 30 minutes) as a result of your abdominal pain?**
- a. No
 - b. Yes
 - c. Not sure
 - d. Never perform this activity
- 11. Do you find it difficult to climb stairs as a result of your abdominal pain?**
- a. No
 - b. Yes
 - c. Not sure
 - d. Never perform this activity
- 12. Do you find it difficult to drive a car as a result of your abdominal pain?**
- a. No
 - b. Yes
 - c. Not sure

d. Never perform this activity

13. Has abdominal pain limited your ability to perform sports activities?

- a. No
- b. Yes
- c. Not sure
- d. Never perform this activity

14. Have you taken any pain medication during the last week for abdominal pain?

- a. No
- b. Yes

If yes, which medication?

15. To what extent has abdominal pain limited your ability to work during the last two months?

- a. I have not needed any sick-leave as a result of abdominal pain
- b. Abdominal pain has caused 1-7 days of sick-leave during the last 2 months
- c. Abdominal pain has caused 1-4 weeks of sick-leave during the last 2 months
- d. Abdominal pain has caused constant sick-leave during the last 2 months
- e. Abdominal pain has caused me to seek disability income
- f. I am unemployed or retired

16. Have you had hernia or any other type of abdominal surgery after your initial surgery?

- a. No
- b. Yes

17. Do you feel any abdominal stiffness or rigidity after surgery?

- a. No
- b. Yes

18. Are you satisfied with your operation?

- a. No
- b. Yes

19. Would you repeat the operation if necessary?

- a. No
- b. Yes

20. How would you describe your work?

- a. Heavy physical work
- b. Light physical work
- c. Office work

Fig. 13 The VHPQ questionnaire

Study II

Fifty seven patients undergoing surgery for ARD were included in the study. All patients completed the VHPQ prior to surgery. Muscle strength was measured using the BioDex. One person did not complete the BioDex postoperatively and in one case data was not possible to interpret due to a technical failure.

Comparison of the preoperative and postoperative results using the VHPQ and BioDex following surgical repair was shown to be a reliable method for the evaluation of

Pair of Variables	p-value
Flex30prop & Last week (1)	0,53
Flex30prop & Rise (2)	0,27
Flex30prop & Sit (3)	0,046
Flex30prop & Stand (4)	0,83
Flex30prop & Stairs (5)	0,98
Flex30prop & Drive (6)	0,92
Flex30prop & Perform sports (7)	0,022
Flex60prop Last week (1)	0,64
Flex60prop & Rise (2)	0,4
Flex60prop & Sit (3)	0,0044
Flex60prop & Stand (4)	0,99
Flex60prop & Stairs (5)	0,98
Flex60prop & Drive (6)	0,34
Flex60prop & Perform sports (7)	0,06
Ext30prop & Last week (1)	0,53
Ext30prop & Rise (2)	0,86
Ext30prop & Sit (3)	0,68
Ext30prop & Stand (4)	0,96
Ext30prop & Stairs (5)	0,95
Ext30prop & Drive (6)	0,34
Ext30prop & Perform sports (7)	0,12
Ext60prop & Last week (1)	0,4
Ext60prop & Rise (2)	0,36
Ext60prop & Sit (3)	0,71
Ext60prop & Stand (4)	0,36
Ext60prop & Stairs (5)	0,41
Ext60prop & Drive (6)	0,33
Ext60prop & Perform sports (7)	0,55
Isoprop & Last week (1)	0,53
Isoprop & Rise (2)	0,27
Isoprop & Sit (3)	0,71
Isoprop & Stand (4)	0,67
Isoprop & Stairs (5)	0,76
Isoprop & Drive (6)	0,85
Isoprop & Perform sports (7)	0,038

abdominal wall function/strength following surgery for abdominal wall diastasis. A significant correlation was observed between the relative improvement in muscle strength measured by the BioDex for flexion 30° (p = 0,046) and 60°/s (p = 0,004) and the preoperative question “Do you find it painful to sit more than 30 minutes?”. Furthermore, there was a correlation between BioDex improvement for flexion 30° (p = 0,022) as well as for isometric test (p = 0,038) and score for the question “Has abdominal pain limited your ability to perform sports activities?”. There was a non-significant trend with all BioDex modalities except extension 60° and the question about performing sports. No other correlations were seen (table 5).

Table 5. Correlation between delta-BioDex and the various VHPQ parameters. 1. Have you experienced pain last week. Do you have pain - 2. When rising from a low chair. 3. When sitting more than 30 minutes. 4. When standing more than 30 minutes. 5. When climbing the stairs. 6. When driving your car. 7. When performing sports.

Calculations are made with Kendall Tau. Number of patients 55.

	Kendall Tau	Z	p-value
VAS & Last week (1)	-0,006	-0,063	0,95
VAS & Rise (2)	0,013	1,4	0,16
VAS & Sit (3)	0,19	2,05	0,04
VAS & Stand (4)	0,19	1,98	0,047
VAS & Stairs (5)	0,085	0,91	0,36
VAS & Drive (6)	0,073	0,78	0,44
VAS & Perform sports (7)	0,051	0,54	0,59

There was also a significant correlation between VAS score and preoperative VHPQ ratings for the question “Do you find it difficult to sit more than 30 minutes” (p = 0.04) and “Do you find it difficult to stand more than 30 minutes” (p = 0.05). No other correlation between Bio-Dex improvement for

Table 6. Correlation between delta-BioDex and VAS. 1. Have you experienced pain last week. The other questions are; Do you have pain; 2. When rising from a low chair. 3. When sitting more than 30 minutes. 4. When standing more than 30 minutes. 5. When climbing the stairs. 6. When driving the car. 7. When performing sports. Calculations are made with Kendall Tau. Number of patients 55.

extension, flexion or isometric measurements and subjective postoperative improvement measured on a VAS was seen (table 6).

Study III

Forty-eight patients were included in the study; twenty-three were randomized to wearing a post-operative elastic abdominal girdle and twenty-five to not wearing a girdle. In both groups, respiratory function was evaluated using FVC, FEV1, PEF and cough PEF. Pain was measured using the VAS. Wound healing was assessed using photographs. Intra-abdominal pressure was measured via an indwelling urinary catheter. The VHPQ was completed by all patients before surgery and at the end of the study.

	ANOVA day 0 to 2	ANOVA day 0 to 4
VC girdle/ VC no girdle	p = 0,095 F = 2,95 n = 37	P = 0,23 F = 1,52 n = 23
FEV girdle/ FEV no girdle	p = 0,066 F = 3,59 n = 41	p = 0,11 F = 2,75 n = 27
PEF girdle/ PEF no girdle	P = 0,30 F = 1,08 n = 42	P = 0,43 F = 0,64 n = 27
Cough PEF girdle/ Cough PEF no girdle	P = 0,76 F = 0,096 n = 43	P = 0,49 F = 0,49 n = 28

Table 7. Postoperative lung function (ANOVA)

For the primary outcome variable, cough PEF, no improvement was seen with girdle usage. On the other hand, there was no impairment of respiratory function due to the use of a post-operative girdle. FVC, FEV1, PEF and cough PEF were reduced after surgery in both groups, but there was no significant difference in decrease between the girdle and the non-girdle group (Table 7).

Values for calculation were taken day two and four postoperatively and compared to preoperative baseline values.

Mean intra-abdominal pressure in the girdle group was 13.4 cm H₂O (range 6–26 cm H₂O) and in the non-girdle group 9.3 cm H₂O (range 5–24 cm H₂O). No significant difference in pressure between the groups was observed.



Fig. 14. Typical wound where a girdle was used, postoperative day 5.



Fig. 15. Typical wound where no girdle was used, postoperative day 5.

Evaluation of the photographs showed no differences in healing in terms of redness, swelling, and purulence at time of discharge (Fig. 14, 15).

The results showed significantly lower pain on the day of discharge or day five postoperatively in the girdle group compared to the non-girdle group when using the VAS ($p=0.004$). When performing an ANOVA analysis day 1-5, $p=0.003$. On day five, 30 people were still in hospital. Since complete repeated measurements for the entire period were used, only the 30 remaining patients were included in this analysis. Both groups experienced more pain post-operative day two

compared to preoperatively ($p<0.001$). Responses regarding perceived pain and its effect on the performance of daily activities in the VHPQ were not significantly different for the girdle and non-girdle groups pre or postoperatively. Even though not reaching statistical significance, patients in the non-girdle group stated greater difficulty in daily activities compared to the girdle group.

Study IV

Fifty-two non-smoking patients with a ventral hernia >10 cm across were included in the study; twenty-four patients were randomized to the full-thickness skin graft group and twenty eight to the synthetic mesh group. There was a small imbalance in the number of participants between the groups. This was due to necessary exclusions shown in a CONSORT diagram in Fig 16.

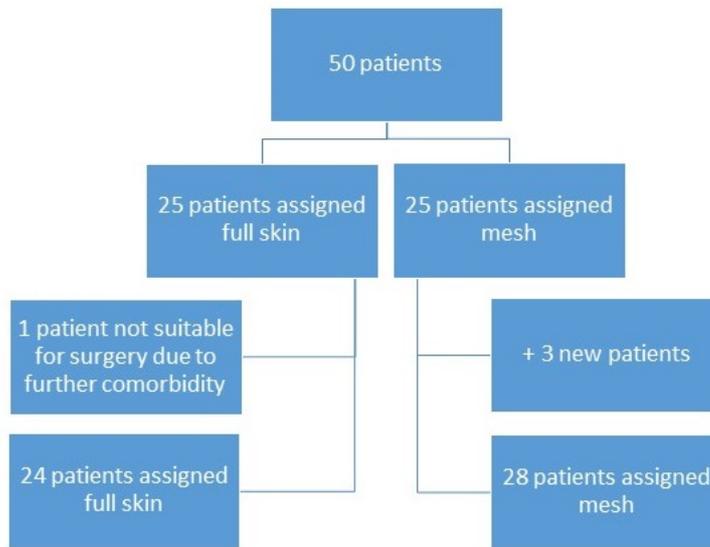


Fig. 16. CONSORT diagram of the study comparing reinforcement with full thickness skin graft against mesh implantation.

Only onlay (eight patients) and sublay (twenty patients) mesh placements were used in the study.

The results showed that utilization of full-thickness skin, instead of synthetic mesh, for the reinforcement of the abdominal wall produces a comparable complication profile at short-term three month follow-up. This compared to abdominal wall reconstruction using synthetic mesh. For complications overall, no differences were seen. There were 16 complications in 24 patients in the full-thickness skin transplant group and 17 complications in the synthetic mesh group. There was no difference for the surgical complication of seroma (13/28 in the skin graft group and 13/24 in the mesh group) or subcutaneous wound infections (5/28 in the skin graft group and 7/24 in the mesh group). Superficial sinuses were equally common. There was one hernia recurrence in each group. Two patients in the synthetic mesh group and three in the full-thickness skin graft group required care in the Intensive Care Unit (ICU).

Patients undergoing abdominal wall reconstruction reinforced with full-thickness skin experienced less postoperative pain and a better general improvement at 3-month follow-up. Three (12%) of the patients in the skin graft group reported discomfort compared to 12 (43%) in the mesh group ($p = 0.016$) (Fig 17). Although not significant, a larger proportion from the mesh group stated postoperative pain compared to the skin group and those with pain in the mesh group rated more severe pain.

Basic patient characteristics including BMI were similar in the two groups (Table 8). The area of the hernia was slightly larger in the full-thickness skin graft group.

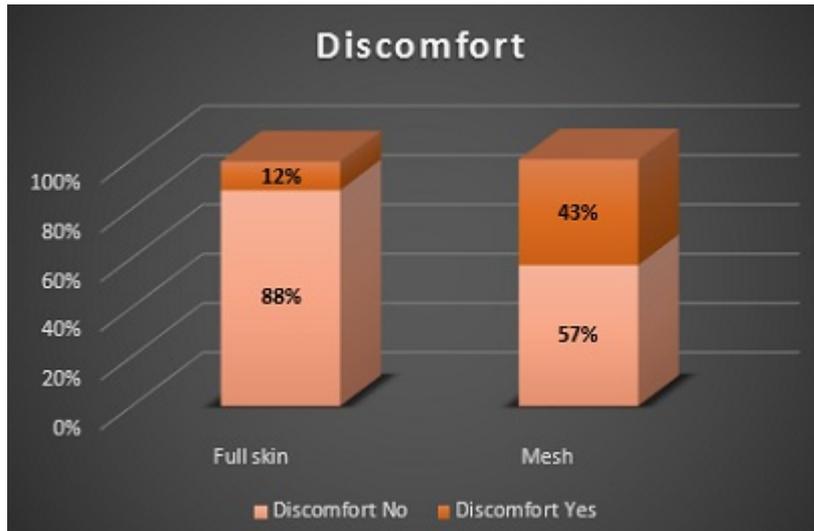


Fig. 17. Number of patients replying “yes” or “no” when asked if they have postoperative discomfort at the 3-month follow-up.

	Full-thickness skin	Mesh
BMI	31.8 (22.0-41.5)	31.4 (23.0-46.0)
Age	63 (42-77)	63 (35-76)
Gender (M/F)	12/12	15/13
Width of hernia	14.0 (8.0-26.0)	13.7 (4.5-37.0)
Area of hernia	181.4 (78.5-433.3)	153.2 (21.2-357.2)

Table 8. Basic data showing mean and range. For gender, the actual number of males and females are provided. The width of the hernia is in cm and area in cm^2 .

7. DISCUSSION

In spite of more than 3500 years' experience of hernia treatment some of the most important problems remain unsolved. The motivation for writing this thesis was to address the enormous problem of treating giant hernia and find a solution that may lead to fewer complications and improved functional ability for the patient. Key aspects of this solution must include the restoration of the abdominal wall and a decreased level of pain compared to preoperative measurements.

Giant hernia create a unique dilemma not only regarding perioperative care but also regarding the surgical technique and choice of reinforcement material. Many patients have several risk factors making implantation of large pieces of synthetic material as an onlay, sublay or IPOM reinforcement very risky. Reading historical papers from the beginning of the 20th century (46, 47) indicating the possibility of using a patients' own skin for reinforcement, the idea arose to develop a modern and reliable method using autologous material in giant ventral hernia surgery. Full-thickness skin grafts have been tested in modern time as a shoelace repair of hernia (48), so why not use it as a type of "mesh"? A proof of concept study was performed using autologous skin including eight patients where usage of foreign material was contraindicated. In this study, autologous full-thickness skin transplant gave a good result (27, 42) without material-related adverse effects. When this thesis project began, biologics as reinforcement were new, poorly evaluated and extremely expensive. The idea of one's "own" tissue material seemed more appropriate and worth investigating.

Chapter I

During planning of the randomized study comparing reinforcement using full thickness skin with synthetic mesh in patients with giant ventral hernia, several issues came up. Recurrence is still an important outcome measurement but with decreasing frequencies achieved by the use of modern techniques, other outcomes have become more important. A patients' own experience from surgery and the possibility to rate improvement are also important topics to explore.

We know from inguinal hernia surgery that a considerable proportion of patients suffer from pain after surgery, some of whom also had severe pain before surgery. Persons with pain before surgery are also more prone to develop pain during the postoperative course. This relationship has also been shown in ventral hernia (49, 50).

A questionnaire like the VHPQ, focused on abdominal pain following surgery for incisional hernia does not exclude the possibility that some responses may be influenced by pain and/or discomfort caused by reasons not related to the hernia or the repair procedure.

One obvious weakness of this study is that not all situations related to daily life are covered by a questionnaire and that the questionnaire may include activities not relevant for each specific patient. As an example, all patients do not drive a car. Another weakness of the VHPQ is that, so far, it is still only available in Swedish and English. Further validated translations as is the case for the IPQ will hopefully strengthen the usefulness of the VHPQ.

During validation of the VHPQ, the BPI (23) was used. This seemed appropriate since the IPQ used the BPI for validation and it is considered to be a world-wide validated questionnaire used for pain analysis. However, while the BPI measures general pain and patients provide a mark on a sketch indicating where the pain is located and its nature, it is not focused on daily activities and how those can deteriorate as a result of pain.

On the other hand, an important strength of the VHPQ questionnaire is the use of focus groups during the construction process, comprised of patients who have experienced ventral hernia. This step was taken to further assure that relevant topics were covered and that all questions were relevant, consistently interpreted and easy to understand. Another advantage with the VHPQ compared to many alternative instruments is its 7-step scale making it possible for the patient to grade complaints when performing a specific activity, for example “rising up from a low chair”.

Other methods to evaluate a patient’s experience of the effect of surgery is the use of a VAS scale for response to questions like “if less pain, how much better”, “are you satisfied with the result”. This kind of question is however more hazardous in terms of reproducibility. Christoffersen et al (51) used a validated questionnaire (52) to evaluate pain after umbilical hernia. However, it turns out that this questionnaire is only validated for the question of recurrence and not for pain. It constitutes a four grade scale for pain, ranging from no pain to severe pain in the operated region.

Another commonly used scale is the CCS which is a QoL questionnaire evaluating pain in relation to mesh implantation. It is a development of the Likert scale where pain sensation and activity limits are noted from 0 to 115. CCS has been validated against SF-36 and was presented in 2007 at American Hernia Society with no peer-reviewed publication of the validity (53).

Several other questionnaires have been tailored to measure the outcome of hernia surgery, for example HerQles. In contrast to that instrument, VHPQ seems more reliable due to the fact that no focus groups were used in constructing the HerQles and no validation procedure against established instruments was undertaken.

In which aspects can the VHPQ be further improved? Eventhough it constitutes only twenty questions, there are still three pages for the patient to read. It may be that some of

the questions could be omitted and a shorter version can be constructed for easier use in routine clinical practice.

So, why is it important with PROM? They include both symptoms from the disease or intervention, function and HRQoL. Thus such instruments can provide systematic information about patient self-reported experience. With today's active and information seeking patients it is important for them to use their experience to further improve surgical technique and provide a satisfactory result from intervention. In Sweden, there is also a new law that gives patients an extended right to be actively involved in medical decisions.

Chapter II

One way to objectify the effect of surgery is by use of the BioDex. This system has been frequently used in sports medicine, particularly for rehabilitation (54). Before BioDex, the Kin Com system was used. Unfortunately, no dedicated device was provided for measurement of abdominal wall muscle strength in the BioDex system, but there was a device designed for assessment of the back. Using the back attachment, we standardized and validated a method for measurement of abdominal wall muscle strength in healthy volunteers, patients with giant ventral hernia and ARD (26, 27). Many patients with giant ventral hernia are overweight and the question was raised whether this utility designed for sports medicine could actually provide reliable measurements for the intended purpose. This question was answered when the back attachment was used to measure abdominal muscle strength, showing validity and reliability. When operating ventral hernias with open surgery, the Linea Alba is restored giving the anatomical basis for normalized muscular function. One small study has shown improved core physiology after surgery with reconstruction of the midline and also improved quality of life (55). To determine if this medialization of the abdominal rectus muscles is important for the abdominal corset function it must be tested in randomized studies both in open and laparoscopic surgery. In our test environment, the patients are their own controls at pre and post-surgery examinations.

In ARD our research group has revealed that abdominal muscle strength measured with BioDex improves after surgical repair in all modalities (24). Whether this improvement of muscle strength measured by the BioDex is a result of restoration of the Linea Alba, or a result of an improved ability for the patient to perform exercises after surgery, remains undetermined. If we were able to identify preoperative symptoms clearly related to ARD and an improvement in such symptoms after surgery, we would be able to offer surgery to those who would benefit. One way to achieve this could be to see if the improvement in muscle force measured with the BioDex is related to symptoms and pain as measured with the VHPQ. The results of this study did not provide ONE single determining item. However, there was a correlation between the relative improvement of muscle strength measured with the BioDex and the questions "Do you find it painful to sit more than 30

minutes?” and “Has abdominal pain limited your ability to perform sports activities?”. The relationship between preoperative VHPQ ratings and improvement of muscle strength formed a pattern where these two questions manifested as the most interesting preoperative indicators. The correlation between patient-estimated improvement measured with the VAS and the question about sitting on the VHPQ may aid in deciding if surgery should be offered or not. A positive answer to these questions should be regarded as a sign that ARD is the etiology of the patient’s symptoms. The abdominal muscles are involved in everyday life including walking, running and other necessary activities. Although the VHPQ was designed for ventral hernia, it may be that further use of focus groups could reduce the number of questions leaving those that can be useful in cases of ARD. In a thesis work about ARD, preoperative VHPQ values were reduced or eliminated one year after surgery independent of surgical method used with the exception of pain when driving a car (24). This is strong evidence supporting the possibility of also using the VHPQ in the evaluation of ARD. On the other hand, a weakness of the study is that VHPQ is not validated explicitly for ARD.

In a recent study, we have also shown an inverse relationship between the area of a giant ventral hernia and BioDex performance in all modalities (56). The inverse correlation between BioDex abdominal muscle strength and clinically assessed hernia area, seen in all modalities, was so robust that it seems safe to conclude that the area of the hernia is an important determinant of the degree of loss of abdominal muscle strength. Results using hernia area calculated from the CT scan showed no such correlation and this would seem to concur with the results from a previous study by our group on patients with abdominal rectus diastasis. In that study, defect size assessed clinically, but not that measured by CT scan, was in agreement with the size of the diastasis measured intra-operatively.

The BioDex system will also be used in the giant hernia study at one year follow-up to evaluate the relationship with preoperative symptoms and the eventual improvement in abdominal muscle force.

EMG studies in athletes have described how different abdominal muscles interact while walking (57, 58). Using EMG makes it possible to isolate a specific muscle, which is not possible with the BioDex when evaluating abdominal exercise. In contrast to EMG, the measurement from BioDex represents a composite force from several involved muscles. However, in a clinical setting a method necessitating the application of needles into muscles is often too complex whereas the standardized use of a dynamometer seems more applicable. There are also alternative methods for measurement of abdominal muscle strength, for example by lifting the legs (59). Even if it is possible to reproduce such measurements by test - retest measurements, standardization of this kind of method still remains a challenge.

Additional knowledge about the dynamics of abdominal wall muscles may be provided by a dynamometer specifically developed to evaluate the strength of the oblique muscles

(isolated from the rectus muscles) with the primary purpose to be used for ski athletes. Such a machine has been used in sports medicine and training but no data on patients with abdominal wall complaints have been published.

Chapter III

Upon creating instruments to evaluate how we influence a patient's daily life with surgical intervention, it became important to address how to prepare the patients for postoperative exercise. Every breath we take involves the activation and movement of muscles of the thorax and abdomen. This being the case, pain caused by movement of the abdominal wall will inherently be felt with every breath taken. Consequently, deeper breathing will likely result in more nociceptive stimulation and the experience of more pain. Knowledge about dynamic spirometry after laparotomy is limited.

Lack of adequate respiration and prolonged sedentary positioning, as during bed rest, contribute to the development of atelectasis (28, 29). The combination of these occurrences create a situation conducive to the development of pulmonary infection and decreased pulmonary function. An effective method to decrease the experience of post-operative pain following abdominal surgery could also possibly decrease the likelihood of developing post-operative pulmonary complications/pulmonary impairment. The post-operative condition usually involves the need for analgesia with the risk of further impairment of ventilation.

The pilot study using full thickness skin grafts for reinforcement of the abdominal wall was performed on heavily overweight patients. These patients wore a girdle before and after surgery. Our experience was that these patients received an effective abdominal support before surgery and were therefore able to be more physically active resulting in an improvement in working capacity and pulmonary function. Reciprocally, their use of a girdle also postoperatively enhanced their recovery and working capacity. It has been speculated that this could also be related to a faster ingrowth of the reinforcement material. To the contrary, negative effects have also been claimed.

It has been speculated that a girdle can give rise to increased abdominal pressure and restricted lung capacity, side effects that have the potential to make giant ventral hernia repair even more hazardous. Many of the studies investigating effects of wearing a girdle pre and/or post-operatively are old, non-randomized and with a divergent and badly defined study population (12). In order to address objections about girdle usage from our anesthesiologists, we decided to conduct a randomized study on lung function after laparotomy with and without a girdle. To obtain a well-defined population with as much conformity as possible to ventral hernia surgery, patients undergoing laparotomy for colorectal resections was used. This study did not reveal any negative effects on lung function caused by the use of a girdle. The reduced respiratory capacity appeared to be caused by the laparotomy per se which has also been indicated in some previous studies

(28, 30). In a recent review from Denmark (12), no negative effect on lung function was found, but only two of the studies included static spirometry and of these two, one favored abdominal girdle and one did not. Interestingly, this review also listed a paper that found increased intraabdominal pressure in the group of patients who used girdles (60). Does the intraabdominal pressure relate to patients experience of pain? This was not seen in our study and may be explained by an additive effect of the girdle and reduction of the hernia per se causing a change in the intraabdominal pressure. It's also important to note that there are always inherent difficulties when performing studies using newly operated patients. In this study there was always the uncertainty of whether the patients were doing their best performing the cough PEF or if they were being careful - afraid of breaking their stitches or afraid of causing pain. Can one perform spirometry a day after abdominal surgery in the presence of nausea? While there is no way to conclusively answer these questions, we expect randomization to make the two investigated groups equal in these respects and thereby remove these aspects from the equation.

In our patients undergoing laparotomy, both pain relief and mobilization were improved in the girdle group. These findings are encouraging but large randomized trials may be difficult to conduct in patients with giant ventral hernia due to differences both in hernia configuration and comorbidity. Many patients testify that they feel safer and that mobilization from the bed is facilitated by a girdle. They also use it when initiating active physical training after surgery. We have all seen patients in bed with a pillow over their abdomen when coughing, trying to support the abdominal muscles with counter pressure. An abdominal girdle suited for the patient will give the same effect but in a more effective and comfortable way.

Wearing a girdle preoperatively has been studied even less. It is import that the patients actually use their personal abdominal binder. A study from our group based on patient interviews showed that although it was sometimes troublesome wearing a girdle, they still chose to continue using them even after the recommended period was over. The most frequent complaints mentioned were discomfort and problems applying it in the appropriate manner (61).

It is a scientific challenge to show that it is possible to slowly reduce the loss of abdominal domain by use of a girdle before surgery for giant ventral hernia. The abdominal content should not be "stuck" and the reduction must be made over a long period of time, which in turn must be emphasized to the patient to motivate them to continue the girdle treatment while waiting for surgery. Delivering appropriate information to these patients about what to expect before and after surgery and also regarding cosmetic results is of great importance.

Due to the effect on pain, treatment with a personally fitted girdle in the ICU after abdominal surgery may have potentially beneficial effects. Studies concerning ICU patients during ventilator treatment must be performed before starting such treatments.

Today, the choice of when to wear a girdle, how long before and after surgery and how hard it should be fitted is most up to the surgeons personal preference.

Finally

With new and objective PROMS and patient oriented outcome measures in our arsenal, we were prepared to complete a randomized study where autologous full-thickness skin grafts were compared to the best possible method for implantation of synthetic mesh. The use of biological material in ventral hernia surgery has increased during the past 10 years. Opinions amongst hernia surgeons regarding biological mesh diverges between “believers” and “non-believers”. Biological material has been marketed as safe and recommended for use in “clean contaminated” and “contaminated” fields during abdominal wall reconstruction. Biologics have also been used to bridge large defects.

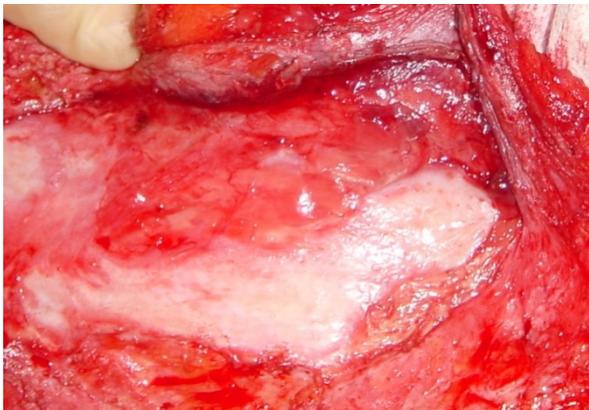


Fig. 18. Full-thickness skin which has been remodeled to fascia, detected upon reoperation after three years.

Under these circumstances, healing can be tenuous at best. Unfortunately, biologics for the repair of hernia are very expensive.

Alternatively, full-thickness skin grafts have been used as “shoelace” reinforcement in hernia surgery (40) and as an onlay mesh (48). The theory behind the use of full-thickness skin grafts is that the skin will be remodeled into fascia when the cells regress to a more stem cell like stage. Several reported cases where a specimen of implanted skin graft has been taken during reoperation for different reasons confirm this theory (fig. 18).

This biological behavior is similar to that intended from non-cross linked biologic reinforcement materials. However, using biological implants from other species activates degradation from immunological cascades. To prevent this, the most immunogenic epitopes have been either encapsulated or inactivated. Despite these measures, several observations (62) imply a successive degradation despite a concurrent infiltration of fibroblasts, in-growth of fibrin as well as angiogenesis. The use of autologous material should slow this process if not alleviate it all together.

If the main reason for hernia formation is alterations in the balance between the expression of MMP and TIMP after surgery, autologous skin grafts may not seem to be a favorable material to use for reinforcement. If, on the contrary, hernia are caused by poor surgery or an emergency operation with temporary alterations, the full-thickness skin transplant appears to be a more attractive alternative. Another possible scenario could be an alteration in MMP/TIMP balance at the time of the index operation due to malnutrition,

cancer or infections. If this is the case, patients suffering from ventral hernia in the absence of these conditions would potentially benefit from autologous full- thickness skin transplants when treating giant ventral hernia.

Our hypothesis that full-thickness skin graft should significantly decrease the risk for surgical complications could not be proven. However, the fact that patients operated with skin grafts expressed markedly better comfort after 3 months is a positive sign. One reason for this may be a less pronounced inflammatory response resulting in a more adaptive adnominal wall compared to the dense plate often formed after reconstruction with synthetic mesh.

Further follow up of the study patients is scheduled at 12 and 36 months following surgery. At the one year follow-up, muscle force will be measured using the BioDex system and pain and its effects on daily activities will be evaluated with the VHPQ. At the three year follow-up, the secondary endpoint of hernia recurrence will be eventually determined.

In this study the full-thickness skin transplants have been used as an onlay mesh. It may be that the complication rate can be further reduced applying the full-thickness skin graft as an IPOM or sublay implant. Before such studies can be performed, experimental animal models should be used to determine the extent of tissue integration to the peritoneum as well as possible tissue reactions including adhesions to the intestine.

8. SUMMARY

	+	-
Chapter one VHPQ	Validated questionnaire	Many questions
	Focus groups	Limited international translations
	Patients as their own control	
Chapter two ARD, Biodex, VHPQ	Indicators for surgery of ARD	Diseases or discomfort
	Randomized	No validation – VHPQ – ARD
	PROM and PREM	
Chapter three Girdle	Girdle safe postoperative	Not ventral hernia surgery
	Pain relief	No positive lung effect
Chapter four Full-thickness skin transplant	No negative side effects	Surg. complications not better
	Randomized	
	Better comfort	

9. SUMMARY IN SWEDISH

Bakgrund:

Ännu är inte den optimala metoden för att operera gigantiska ärrbräck fastställd. Syntetiska nät har använts som förstärkning vilket har minskat risken för återfall. Dock kan dessa material ge upphov till smärta, fistlar mellan tarm och hud samt stelhet i bukväggen. För att minska de kirurgiska komplikationerna planerades en randomiserad studie där syntetiskt nät jämförs med full hudstransplantat av egen hud. För att genomföra studien behövde patient-orienterade instrument utvecklas för mätning av flera viktiga utfall. Ett sådant viktigt utfall är smärta efter operation. När det gäller ljumskbräck har man sett att ca 6% av befolkningen har smärta som man ej kan bortse från efter kirurgi, mätt med IPQ, en enkät utarbetad i gruppen. Ett liknande verktyg för bukväggsbräck är viktigt för utvärdering av effekt efter olika typer av kirurgi. I den randomiserade studien ingår att gördel används före och efter operation. Då klinisk erfarenhet talar för en positiv effekt av att använda gördel efter bräckkirurgi men även negativa röster har höjts med rädsla för minskad andningsvolym bör detta testas i en grupp patienter som laparotomas. Effekten av att föra samman muskelbukarna vid kirurgi för ARD och bukväggsbräck är inte studerad gällande muskelkraften före och efter kirurgi och inte heller i jämförelse med smärtupplevelsen.

Metod:

En enkät för att utvärdera smärta och se hur denna påverkade patientens vardag utformades med hjälp av fokusgrupper. Validering skedde mot en enkät som mäter generell smärta, BPI. Reliabilitet testades genom att sända enkäten till personer som tidigare genomgått ärrbräcksoperationer. Sammanlagt var 225 personer involverade i studien.

Hos 57 patienter med rektusdiastas jämfördes den relativa förbättringen av muskelstyrka mätt med BioDex med preoperativa svar i smärtenkäten VHPQ.

En randomiserad studie genomfördes där 48 patienter postoperativt efter medellinjelaparotomi hade eller inte hade gördel. Lungfunktionen utvärderades med host-PEF och spirometri. Sekundärt studerades smärta och sårhäkning.

Slutligen genomfördes den planerade randomiserade studien mellan syntetiskt nät och eget fullhudstransplantat där 52 patienter inkluderades. Primärt utfall var kirurgiska komplikationer efter 3 månader. Klinisk utvärdering gjordes av oberoende kirurgspecialist som ej kände till vilken operationsmetod som använts.

Resultat:

VHPQ uppvisade god validitet och reliabilitet vid jämförelse med BPI och vid test retest. En relativ förbättring av muskelstyrka efter operation av rektusdiastas var kopplat till de preoperativa frågorna gällande att sitta mer än 30 minuter och att utföra sportaktiviteter.

Vid användande av elastisk postoperativ gördel påverkades inte lungfunktionen mer i gördelgruppen än i icke gördelgruppen. Sår läkningen påverkades inte. Patienterna i gördelgruppen upplevde mindre postoperativ smärta.

De kirurgiska komplikationerna vid 3 månaders uppföljning skilde inte i grupperna fullhuds transplantat och syntetiskt nät. De med egen hud upplevde mindre smärta än de som opererats med nät.

Diskussion:

Resultaten i denna avhandling har gett ett verktyg att utvärdera smärta i bukväggen efter bräckkirurgi. Detta möjliggör utvärdering av olika kirurgiska tekniker vid bräckkirurgi och kan hjälpa oss att selektera patienter som kan ha nytta av operation vid rektusdiastas.

Gördel efter operation påverkade inte host-PEF positivt som hypotesen föreslog men påverkar inte heller resultaten vid spirometri eller sår läkningen negativt. Däremot reduceras den postoperativa smärtan.

Avslutningsvis kunde inte hypotesen bekräftas att fullhuds transplantat minskar kirurgiska komplikationer. Dock uppvisade gruppen med egen fullhud mindre obehag i bukväggen vid 3 månaders uppföljning. Patienterna kommer att följas upp vid 12 och 36 månader gällande återfall av bråcket och andra eventuella komplikationer.

10. ACKNOWLEDGEMENTS

This thesis would not have been possible without the help and guidance of many individuals, to all of whom I owe a great deal of gratitude. Though I may have missed listing your name below, I would like to say Thank You! Additionally, I would like to extend a special thanks to:

Karin Strigård, principal supervisor, for your input, encouragement, relentless determination and drive to help things move forward with this thesis. You were always available for assistance and consultation despite the geographical distance between us. Your culinary contributions to the research meetings were superb! I could not have done it without you!

Ulf Gunnarsson, co-supervisor, for your assistance and steady support throughout this process. Your guidance through the statistical maze has been invaluable. The research group you envisioned has become a reality and made a real impact on my doctoral endeavors.

Birgit Stark, co-supervisor, for your invaluable counseling, feedback and support. Your perspective has given my work an extra level of insight. Thanks also to André Stark for a great meal, interesting conversation and great questions!

Ulf Fränneby, co-author of paper I, for allowing me to base the VHPQ on your IPQ. Your knowledge on the subject area was invaluable.

Gabriel Sandblom, co-author paper I, for your super help with the sea of statistics!

Karl Franklin, co-author of paper III, for your valuable perspective and input.

Peter Emanuelsson, for taking care of all of my patient follow-ups, your support and encouragement. We started our thesis projects at the same time, I was super happy for you when you finished and I can't tell you how happy I am to now say the same!

Jörgen Larsson, Johan Permert, Magnus Nilsson, Annika Bergkvist, Ralf Segersvärd, former and current department heads of gastrointestinal surgery, for approving my projects.

Ursula Dahlstrand, Per Nilsson, section heads of acute and trauma surgery, for allowing me time for research.

Thyra Löwenmark, for all your help with the VHPQ database and statistics.

Margareta (Maggan) Michanek, research nurse, for your enormous help with all randomizations, organization, patient follow-up, logistics and general participation during all projects.

Eva Köhn, research secretary, for the great help with administrative details, data input, organization and support.

Linda Olsson, research administrator, for invaluable assistance in organizing the paperwork, arranging all meetings and keeping things on track.

Jessica Björklund Lehto, research administrator, for all your help with patient follow-up, data input and with the book layout.

Colleagues (present and former) at the Karolinska Gastrocentrum Surgery: Kajsa Anderin, Olle Bernell, Monika Egenvall, Annika Sjövall, Caroline Nordenvall, Lovisa Strömmer, Cristian Buchli, Anna Märtling, Björn Törnqvist, Gabriella Jansson Palmer, Ulrik Lindfors, Thorhallur Agustsson, Henrik Iversen, Torbjörn Holm, Peter Elbe, Mari Hult, David Edler, Malin Mörner, Petri Rantanen, Magnus Falkén, Naseer Baloch, Patrik Lundström, Johannes Blom, Folke Hammarqvist, Leif Törkvist, Christoph Ansorge, Urban Arnelo, Lars Lundell, Marco Del Chiaro, Gona Jaafar, Rozh Noel, Mahbobe Merhabi, Martin Sundelöf, Jon Tsai, Ioannis Rouvelas, Matthias Löhr, Bengt Isaksson, Anders Jansson, Anders Hansson-Elliot, Ernesto Sparrelid, Peter Elbe, Johan Erlandsson, Madelene Olsson, Ann Kjellin, Mats Lindblad, Eduard Jonas, Cecilia Strömberg, Mikael Wirén, Björn Bolmstrand, Louis Riddez, Rebecka Ahl, Hannes Wållgren.

Mats Johansson, Anna Skowonius, physiotherapists, for expertly doing all the BioDex measurements.

Hélène Jansson, CLINTEC administrator, for your expert knowledge and guidance through the doctoral process.

Christina Albäck, clinic administrator, for your constant kindness and assistance.

Karl Anton Harms, for helping with article acquisition and compilation.

Simona Magnusson, nurse, for meticulously sizing appropriate girdles for all patients in paper IV.

Research Group, for taking the time to share valuable insight and suggestions that have aided me in my research despite your own busy schedules.

Deborah Saraste, Frida Ledel, Mirna Abraham Nordling, Kristina Stenstedt, Helena Sackey Ickonomidis for always giving kind words of support and encouragement.

Ulrika Hjorth, Kicki Edberg, Liselotte Stenalm, amazing secretaries, for never hesitating to help when needed and really trying to help solve my dilemma of finding a room!

Robert Brännström, for encouragement throughout and our fun morning discussions!

Karin Isaksson, for our many debriefing sessions, your support, encouragement, feedback and friendship.

Hughes and Ruta, for always being there with encouragement and support. Now it's time to do all the things we've been talking about!!

All of my friends and their families, none mentioned, none forgotten, for all your support and encouragement.

Mats, for being there and understanding all the times when I couldn't participate and helping me focus despite distractions.

Gudmundsson, Eliasson and Edfeldt families, for being there and supporting me throughout this process.

My beautiful, wonderful, loving and always supportive sisters; Patricia, Rosalind, Brittee and Sabrina; my brother Calvin and all of your families. Thank you for always being there and helping me with everything whenever I've needed it. Love you.

My beloved mother; beautiful, courageous, strong, sweet and loving. Ma' you are my everything. When I'm having a tough day, I only need to think of your beautiful smile to make me feel better. Your unquestionable love, guidance, encouragement and support have given me the strength to achieve all that I have thus far in life and it will be my fuel for the future. I love you!

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