Assessment of Excess Skin and Outcome of Body Contouring Surgery in Post Bariatric Patients

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Gothenburg 2014

Cover illustration: Renoir, Pierre Auguste (1841-1919)

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ISBN: 978-91-628- 9139-8 (print)
ISBN: 978-91-628-9185-5 (e-pub)
http://hdl.handle.net/2077/36740
Printed in Gothenburg, Sweden 2014
By INEKO

Life is so much better when you stop caring what others think, and start to actually live for yourself

-Anonymous

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Abstract

Aim: A negative effect of massive weight loss is the development of excess skin. Excess skin causes both physical and psychological problems for those affected and their families. The overall aim of this thesis was to improve the knowledge of the prevalence and associated problems of excess skin in post bariatric patients and to evaluate the outcome of abdominoplasty regarding HRQL.

Patients and methods: A literature search was performed to evaluate the quality of evidence for health benefits of abdominoplasty. Thereafter, adult post bariatric patients were sent the Sahlgrenska Excess Skin Questionnaire (SESQ) together with a study specific questionnaire to evaluate their experience with excess skin regarding physical, functional and psychosocial impairments, amount and discomfort regarding the same and requested and undergone body contouring surgery. Further, post bariatric adolescents answered the same questionnaires as the adults, and measurements of excess skin were performed. Finally, post bariatric patients undergoing abdominoplasty answered the Short Form-36 (SF-36), a modified version of SESQ and the EuroQol-5D (EQ-5D) before and one year after abdominoplasty. Prior to the surgery, all study participants were randomly assigned to either undergo or not undergo rectus fascia plication, and measurement of the amount of abdominal excess skin was performed.

Results: The quality of evidence of positive health effects for patients undergoing abdominoplasty was very low regarding HRQL. Most of the post bariatric patients, including both adolescents and adults of both genders, reported that they suffered from excess skin in several body parts. The majority of the post bariatric patients also requested body contouring surgery. Abdominoplasty increased the physical function subscale of the SF-36 and all 10 items regarding physical, functional and psychosocial impairments of the SESQ. However, plication did not influence the outcome of abdominoplasty regarding HRQL. In addition, low correlations were found between the measured amount of abdominal excess skin and discomfort with the same or change in the physical function subscale of SF-36 following abdominoplasty.

Conclusions: Most of the post bariatric patients seem to suffer greatly from excess skin independent of sex or age, and a majority request body contouring surgery at several body sites. Abdominoplasty appears to improve physical and psychosocial dimensions of HRQL. However, the impact of the preoperative measured amount of abdominal excess skin on the improvements in HRQL is low.

Keywords: Post bariatric patients, massive weight loss, excess skin, body contouring surgery, health related quality of life, plication, abdominal rectus fascia

ISBN: 978-91-628- 9139-8 (tryckt)
ISBN: 978-91-628-9185-5 (e-pub)
http://hdl.handle.net/2077/36740

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Staalesen T, Elander A, Strandell A, Bergh C. A systematic review of outcomes of abdominoplasty. J Plast Surg Hand Surg 2012; 46:139-144.

II. Staalesen T, Fagevik Olsén M, Elander A. Experience of Excess Skin and Desire for Body Contouring Surgery in Post-bariatric Patients. Obes Surg 2013; 23:1632-1644.

III. Staalesen T, Olbers T, Dahlgren J, Fagevik Olsén M, Flodmark CE, Marcus C, Elander A. Development of Excess Skin and Request for Body-Contouring Surgery in Post-bariatric Adolescents. Plast Reconstr Surg. 2014;134: 627-636.

IV. Staalesen T, Fagevik Olsén, Elander A. The effect of abdominoplasty and outcome of rectus fascia plication on health related quality of life (HRQL) in post bariatric patients. Submitted 2014.

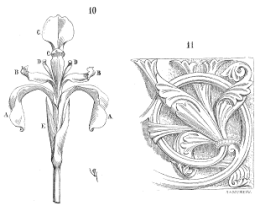
CONTENT

ABBREVIATIONS

AMED	The Allied and Complementary Medicine Database
ASA	American Society of Anesthesiologists
BMI	Body Mass Index (kg/m^2)
CINAHL	Cumulative Index to Nursing and Allied Health Literature
EQ-5D	European Quality of Life-5 Dimensions
GRADE	Grading Recommendation Assessment Development and Evaluation
HRQL	Health Related Quality of Life
HTA	Health Technology Assessment
PICO	Patient Intervention Comparison Outcome
QUALY	Quality Adjusted Life Years
SBU	Swedish Council on Health Technology Assessment
SESQ	Sahlgrenska Excess Skin Questionnaire
STEER	Succinct and Timely Evaluated Evidence Review
WHO	World Health Organization

DEFINITIONS IN SHORT

Body contouring surgery	This expression is used for all surgical procedures that involve removing abdominal excess skin, including different variations of abdominoplasty and panniculectomy. Pure liposuction is not included.
Fleur-de-Lis	The fleur-de-lis is a stylized lily (in French, *fleur* means *flower*, and *lis* means *lily*) as illustrated in the figure below



Fleur-de-lis

GRADE-system	GRADE is a system for rating the quality of evidence in systematic reviews and guidelines. It is also used for grading the strength of recommendations in guidelines. The system is designed for reviews and guidelines that examine alternative management strategies or interventions, which may include no intervention or best management (1). GRADE is approved by WHO, and SBU has so far adapted the first part of the GRADE-system concerning grading of the strength of evidence.

HRQL	Health-related quality of life (HRQL) describes the impact of health status on quality of life. It is a multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning.
Linea alba	The term *linea alba* originates from Latin and means *white line*. It is a fibrous structure that runs down the midline of the abdomen in humans and other vertebrates. It separates the left and right rectus abdominal muscles.
Obesity	According to WHO, BMI(kg/m²) greater than or equal to 30 is defined as obesity
Overweight	According to WHO, BMI(kg/m²) greater than or equal to 25 is defined as overweight
PICO	A "well-built" question includes four parts, referred to as PICO that identify the problem of the patient or the population (P), intervention (I), comparison (C) and outcome(s) (O) (2).
Quality of Life; QoL	The definition according to WHO is as follows: An individuals´ perception of their position in life in the context of the culture and the value systems in which they live and in relation to their goals, expectations, standards and concerns.

1 INTRODUCTION

1.1 Facts about overweight, obesity and associated co-morbidity

The World Health Organization (WHO) reports that global overweight and obesity have more than doubled since 1980. In 2008, more than 1.4 billion adults were overweight or obese, and in 2012, more than 40 million children under the age of 5 were overweight or obese (3). The probability of obesity into adulthood is higher in obese children compared to non-obese children, and the risk of adult obesity is increased if one parent is obese (4, 5).

Sweden follows the global trend of a dramatic increase in overweight and obesity since the 80s (6, 7). According to statistics of the Swedish population, more than 50% of all men and close to 40% of all women over 16 were overweight or obese 2010. Of these, 12% and 11%, respectively, were obese.

A Swedish study on 6- to 10-year-old children conducted from 2003 to 2005 showed that 18-24% of the boys were overweight or obese, of whom 3-7% were obese. The corresponding figures for girls were 16-22% and 3-5%. These figures show a dramatic increase of overweight in 20 years (6, 8, 9).

According to figures from 1984/85 for 10-year-old children, the proportion of overweight or obese was close to 9%. Of these 1% were obese (6).

According to WHO, overweight or obesity kills more than 3 million adults each year. Furthermore, more than 40% of all diabetes, 40% of certain cancers and more than 20% of all ischemic heart disease is related to overweight and obesity (3). Obesity in children is associated with several comorbidities such as type 2 diabetes, hypertension, sleep apnea, hyperlipidemia, hepatic steatosis, and orthopedic complications (10).

1.2 Treatment of obesity

Diet has not been shown to be effective in achieving a sustained weight loss either in children or in adults (11, 12), and there are no available drugs for the effective treatment of obesity (12). The most successful way to achieve a substantial weight loss is bariatric surgery. In addition to the often dramatic weight loss that occurs during the first year after surgery, follow-up of post bariatric patients have shown a permanent weight reduction of an average

16% even after 10 years (13). Bariatric surgery has a number of other health benefits both in terms of reduced co-morbidity (14-16), and improved health related quality of life (HRQL) (17-22).

It is difficult to predict the future need for obesity surgery. Worldwide, the number of weight-reducing surgical interventions increased dramatically during the years 1998-2010. Thereafter, the curve has leveled off to approximately 340,000 procedures (23). The same trend can be observed in Sweden. In 2013, approximately 7700 weight-reducing interventions were performed, which was slightly lower than that performed in the previous year (24) and lower than that estimated in 2009 by the Expert Group on National Indications for Bariatric Surgery in Sweden. At that time, they estimated that between 10,000 and 15,000 bariatric procedures would need to be performed annually to achieve a balance between those who need surgery and those who may be offered surgery (25).

1.3 Bariatric surgery in adolescents

As childhood obesity is increasing, the focus on bariatric surgery as a potential treatment also for adolescents has received increasing attention. Bariatric surgery is not commonly performed in adolescents, and it constitutes less than 1% of all bariatric operations (26). Therefore, limited evidence exists concerning the long-term outcomes and safety in adolescents. However, prospective controlled trials on a limited amount of adolescents with follow-up 2 years after bariatric surgery show a mean weight loss of 30% and improved cardiovascular risk factors and quality of life (27, 28). To determine whether bariatric surgery should be implemented in the treatment of obesity in youths in the future, larger prospective studies including long-term follow-up are needed.

1.4 Excess skin after massive weight loss

One significant sequelae of massive weight loss is the development of excess skin, and 70-96% of the patients who have undergone bariatric surgery report that they are bothered by excess skin (29, 30). In a study of patients who underwent either gastric bypass or duodenal switch, 85% or 77%, respectively, reported that they had "a lot of" or "very much" excess skin on one or more body parts (31). The corresponding figures for the number of people who suffer from excess skin after dieting or pregnancy have not been identified in the literature. However, most of the patients who seek public health care because of excess skin have undergone bariatric surgery, which indicates that this group of patients suffers more from excess skin than the other two groups. According to patient reported data, the three most frequent sites of excess skin were the abdomen, the upper arms and the inner thighs. Other common localizations for excess skin were the outside of the thighs, the chest, the back, the buttocks and the knees (31, 32). All body parts can be affected by excess skin, and there is no way to predict which body parts will be affected. Below are some photos of post bariatric patients illustrating varying degrees of excess skin in different parts of the body (figure 1-4). These figures illustrate how massive weight loss affects the body, leaving an oversized “costume” of skin involving the whole body.

Figure 1: Post bariatric female, 36 years of age, who lost 82 kg. Excess skin is located on the upper arms, breasts, buttocks, abdomen, flanks and thighs.

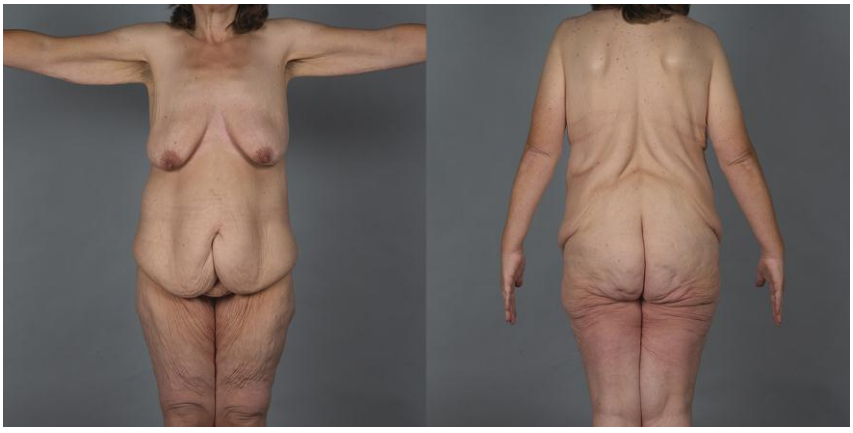


Figure 2: Post bariatric female, 42 years of age, who lost 70 kg. Excess skin is most pronounced on breast, back, buttocks, abdomen, flanks and thighs.

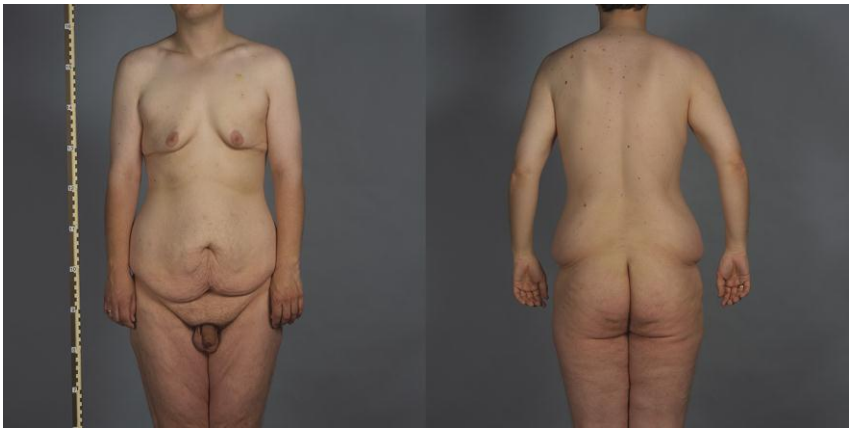


Figure 3: Post bariatric male, 31 years of age, who lost 61 kg. Excess skin is located mainly on the chest, abdomen and flanks. The patient also has a smaller amount of excess skin on the thighs.

Figure 4: Post bariatric male, 35 years of age, who lost 50 kg. Excess skin is mainly located on the chest, abdomen and flanks. He also has a smaller amount of excess skin on the thighs.

Based on clinical experience, the skin is tighter and more elastic in younger individuals compared to older individuals and is often considered to have a better ability to retract after stretching. However, this is more of a public opinion, and no published studies describing the occurrence or perception of excess skin in younger individuals after massive weight loss were identified. However, due to the focus on "looks" in society today, the younger generation is likely to have higher demand on appearance and functionality, which most likely affects their perception of excess skin.

1.5 Symptoms of excess skin

A majority of the post bariatric patients rate specific body areas such as the upper arm or the abdomen as neutral or unattractive or express that the weight loss has had negative effects on their body primarily due to the excess skin (30, 33). Other common psychological problems caused by excess skin are feelings of disgust, embarrassment and shame (29, 32).

The psychological problems caused by excess skin often have major consequences for the way of life for those affected and their families. Many post bariatric patients express that they have difficulties finding suitable clothing and avoid wearing short-sleeves or shorts. They also avoid going to the beach or undressing in front of their partner, or they do not dare to begin

new relationships due to the above problems. In addition, excess skin also causes physical concerns such as fungal infections, itching, difficulties in mobility and difficulties participating in sports. (29, 32).

1.6 Requesting and undergoing body contouring surgery

According to the literature, 73-85% of post bariatric patient's request body contouring surgery (29, 33-36). Request for correction of abdominal excess skin was most commonly followed by thighs, chest and arms (33). Several studies have shown that there is a large discrepancy between the number of post bariatric patients requesting body contouring surgery and the number undergoing such surgery (14, 15, 18, 19). The proportion of post bariatric patients who have undergone one or more body contouring procedures vary from 14-47%, of which abdominoplasty is by far the most common procedure (33, 36, 37). Corresponding figures describing the relationship between requested and performed body contouring surgery for Sweden are lacking.

1.7 Biological mechanisms leading to the development of excess skin

The biological mechanisms causing development of excess skin after weight loss is not clear. The connective tissue of the skin is made up mainly of collagen and elastic fibers. Elastic fibers are complex extracellular matrix protein polymers consisting mainly of the protein elastin. Collagen also consists of long protein polymers. Collagen fibers are inelastic, with a tensile strength greater than steal. Collagen gives the skin mechanical and structural strength, while the elastic fibers are responsible for the elastic properties of the skin (38, 39). One possible approach to try to understand the mechanisms behind the development of excess skin is to study some already known genetic disorders such as *cutis laxa*, Marfans Syndrome and Ehlers-Danlos Syndrome, which all are characterized by sagging and inelastic skin (40). The natural aging of the skin, which resembles the appearance of skin after massive weight loss, is also worth studying to increase the understanding of the biology behind the development of excess skin. During aging, the synthesis of collagen and elastin decrease and the skin becomes thinner and less elastic (39). Mutations in the genes encoding collagen or of the proteins that make up the elastic fibers can result in a number of disorders of connective tissue including the skin. Both *cutis laxa* and Marfans Syndrome

are caused by mutations in the elastic fibers (40), whereas Ehler-Danlos Syndrome is caused by defects in the collagen synthesis (41).

Studies in a limited number of post bariatric patients have shown histological changes in the dermis including degradation of collagen and elastin (42, 43). It has earlier been shown that the density of collagen of the skin of obese individuals does not differ from the skin of those who are non-obese (38). Animal studies have demonstrated reduced collagen production following weight loss (44). These findings indicate that there may be some similarities regarding the impaired quality of the skin after weight loss and the changes caused by natural aging as well as the hereditary disorders of collagen and elastic fibers. Whether the above findings are of clinical importance for the development of excess skin after weight loss remains to be investigated.

1.8 Objective classifications and subjective assessments of excess skin

A number of systems for the objective classification of body contouring deformities have been developed, including the classifications of the abdominal wall and skin laxity (45-47) and classification of brachial excess skin (48). The Pittsburgh rating scale is a classification system directed at multiple body sites, addressing the amount of excess skin at 10 different body sites grading the deformity at each region from 0-3, where grade 0 indicates a normal appearance and grade 3 the most severe deformity (49). The main purpose of the above classifications has been to serve as a guideline to facilitate selecting the most appropriate surgical procedure for the individual patient.

Some studies on patients` self-reported data regarding their experience of excess skin have been published (29-31). However, only one reliability-tested questionnaire addressing patients` subjective assessment of excess skin has been identified: The Sahlgrenska Excess Skin Questionnaire (SESQ). The SESQ was developed by our research group to improve the state of knowledge regarding excess skin in massive weight loss patients. It measures how the patients assess the physical, functional and psychosocial impairments caused by excess skin in addition to their experience of the amount and discomfort of excess skin in different body parts (50). SESQ has so far not been used in clinical trials.

1.9 Indications for body contouring surgery

The first Swedish National guidelines for body contouring surgery was published in 2008, describing the medical indications for abdominoplasty and other body contouring procedures based on clinical experience and the existing scientific knowledge at that time.(51)

According to these Swedish National Indications, the medical indication for abdominoplasty is based on objective measurements and subjective complaints (Fig. 5). A higher BMI than 25 kg/m² may be accepted depending on the severity of the other symptoms. Regarding indications for rectus fascia plication, no specific requirements are stated. Contraindications for abdominoplasty are reported in figure 6. Indications for the removal of excess skin on body parts other than the abdomen are the same as those for abdominoplasty, except for the specific requirement of a skin fold of ≥3 cm, which is lacking in other body parts. Objective requirements for other body parts are lacking.

INDICATIONS FOR ABDOMINOPLASTY

An abdominal skin fold measuring ≥3 cm causing one or several of the symptoms below

- Trouble with personal hygiene
- Wound / rash in skin folds
- Trouble urinating
- Psychosocial problems
- Sexual problems
- Difficulty finding suitable clothes
- Low quality of life
- Pain from the lumbar spine
- Impaired mobility
- Rectus diastasis
- Appearance related handicaps
- Increased sick leave

Stable body mass index (BMI) ≤ 25 is desirable but not required

Figure 5: Indications for abdominoplasty in public health care taken from "National Indications of body contouring surgery" published 2008 (51).

CONTRAINDICATIONS TO ABDOMINOPLASTY

Absolute contraindications

- ASA* ≥ 3
- Advanced cardiovascular disease
- BMI > 35
- Unstable weight
- Active psychosis or other comparable non-optimally treated mental conditions
- Currently smoking

Relative contraindications

- Unrealistic expectations
- Diabetes mellitus
- Increased risk of venous thromboembolism
- High age
- Previous open abdominal surgery
- Planned pregnancy

Figure 6: Contraindications for abdominoplasty in public health care taken from "National Indications for body contouring surgery" published 2008 (51).

1.10 Need for body contouring surgery in Sweden

The medical need for body contouring surgery has not been defined. To determine the volume of body contouring procedures that it is reasonable to perform within public health care, many factors have to be taken into consideration: patient requests, priorities of other interventions and available resources.

The recorded number of patients who had undergone abdominal contouring surgery between 1998 and 2008 is 400, as registered by the Swedish National Board of Health and Welfare (52) (fig. 7). The majority of the operated patients were women. During the same period, the number of bariatric interventions increased dramatically. Thus, the proportion of the performed

abdominal contouring surgeries in relation to bariatric procedures decreased during this period. According to the expert group that devised the national indications for body contouring surgery, this discrepancy was most likely due to priorities other than body contouring surgery in public health care (51). However, from 2008, the number of patients undergoing abdominal contouring surgery annually in public health care more than doubled, exceeding 1000 operated individuals in 2012. Regarding the surgical removal of the excess skin from the extremities, the total number of patients remained low between 1998 and 2012 with approximately 30 patients undergoing such procedures each year (52) (Fig. 8). The number of unrecorded cases performed is most likely higher (51).

The expert group that devised the national indications for body contouring surgery estimated that just over 30% of those who had undergone bariatric surgery were in need of abdominoplasty (51). This indicates that the need for abdominoplasty would at least be double the number performed during 2012, i.e., approximately 2300 abdominoplasties, based on current figures for weight reducing surgery as described earlier. Furthermore, it was estimated that the need for body contouring surgery procedures of other body parts would be approximately 10% of the number of abdominoplasties, representing approximately 230 interventions per year.

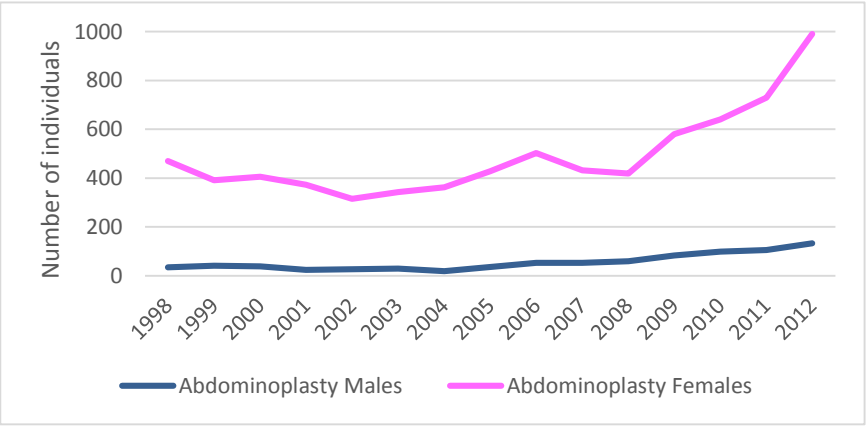


Figure 7: Swedish figures regarding the number of patients undergoing abdominoplasty according to the National Board of Health and Welfare .

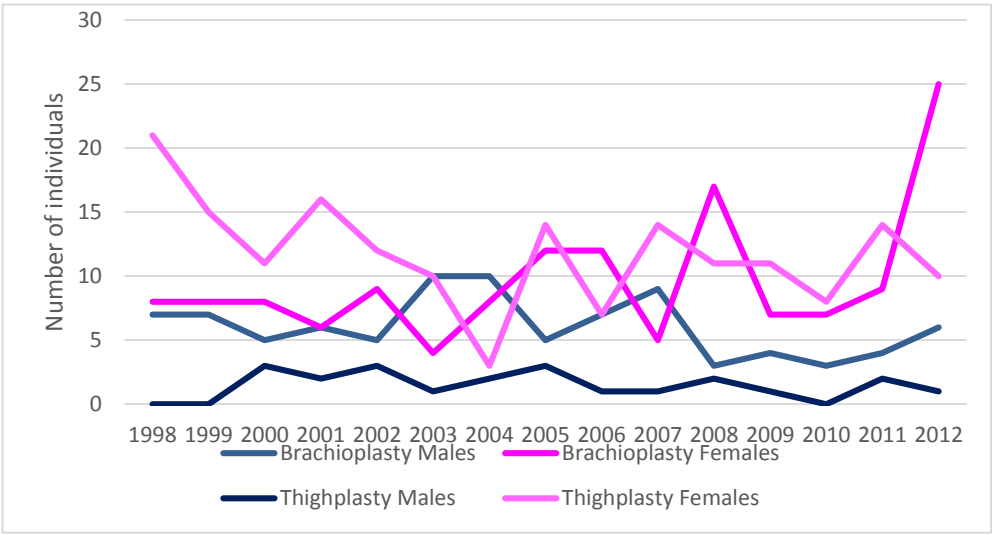


Figure 8: Swedish figures of patients undergoing brachioplasty and thighplasty according to the National Board of Health and Welfare.

1.11 Treatment of excess skin

To date, surgery is the only known effective treatment for excess skin. Such surgery, referred to as body contouring surgery, aims to normalize the anatomy and improve functionality. The main principle of all body contouring procedures is to stretch the skin and resect excess skin, while creating as few visible scars as possible. The most requested procedures are those that provide both symptom relief and an improved cosmetic appearance such as the removal of excess skin on the abdomen, the upper arms, the inner thighs and the breasts. The removal of excess skin from other body parts is usually performed for cosmetic reasons only. Massive weight loss patients usually suffer from a greater amount of excess skin, distributed on more body parts than the typical cosmetic patient.

To address a larger amount of excess skin in several parts of the body, combined body contouring surgical procedures involving several procedures are performed. These surgical techniques are well established worldwide. The following is a description of the approach to different body parts.

Approach to the abdomen

Abdominoplasty, which aims to remove excess skin from the abdomen, is the most common body contouring procedure. An abdominoplasty involves an incision made across the lower abdomen. The umbilicus is cut out separately, while maintaining its blood circulation. The excess skin is then removed, and the size of the resection is customized to the individual (Fig. 9A). In the typical massive weight loss patient, with larger amounts of excess skin localized centrally on the abdomen or in the flanks, additionally excess skin has to be removed through a wedge-shaped incision in the midline (Fig. 9B, fig 10). This technique is referred to as a "fleur-de-lis" abdominoplasty in the literature.

In certain cases with pronounced comorbidity or with other contraindications for abdominoplasty, such as an unacceptable high BMI, removal of the infraumbilical excess skin without undermining the skin above the umbilicus and without cutting out the umbilicus is performed, minimizing the size of the dead space and wound to reduce the risk of severe postoperative wound complications. This procedure is referred to as panniculectomy, which may not normalize the anatomy, but dramatically improves the functionality as several kilograms of excess skin and underlying subcutaneous fat can be removed.

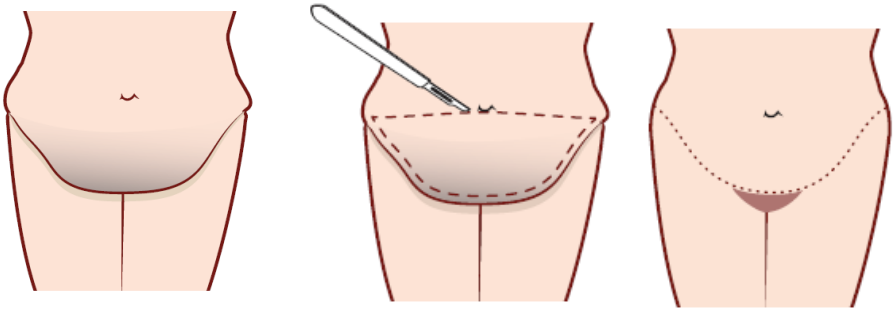


Figure 9A: Operating technique for traditional abdominoplasty.

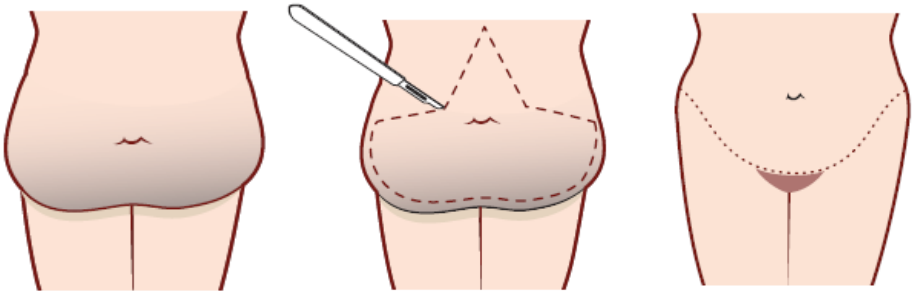


Figure 9 B. Operating technique for "fleur-de-lis" abdominoplasty.

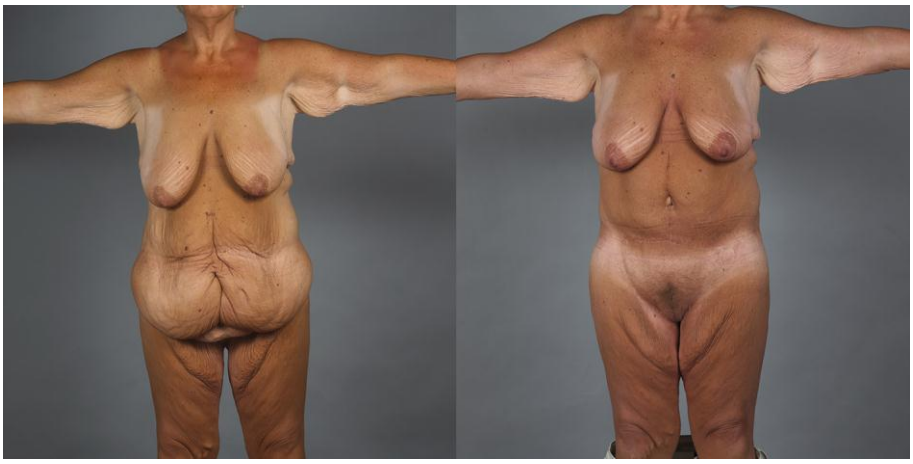


Figure 10: Post bariatric female, 36 years of age, before (A) and at one year follow up (B) after undergoing a "fleur de lis" abdominoplasty.

Approach to the breast/chest

Weight loss also dramatically affects the shape and size of the female breast, leading to a decrease in size and sagging of the breast skin. Volume and shape can be restored with a breast lift. In some cases, it is also necessary to insert breast implants or to increase the breast volume with local flaps to obtain an acceptable esthetic result. In addition, the male breast and chest wall can be affected by massive weight loss. Excision of excess skin of the male chest wall usually leaves long, visible scars, making the intervention less efficient regarding cosmetic outcome.

Approach to the arms

In the typical massive weight loss patient, the excess skin begins at the elbow, or slightly below and continues into the axilla, which requires modified surgical techniques with extended excisions.

Approach to the medial thighs

In routine patients with lower amounts of excess skin located proximally on the medial thigh, a crescent-shaped excision of the excess skin adjacent to the external genitalia is usually sufficient obtain a good result. In massive weight loss patients, an extended vertical excision to the knees is often needed.

Combined procedures

By performing combined procedures, a more complete treatment of the upper and lower body may be achieved, which is referred to as an upper and lower body lift in the literature. The total upper body lift includes brachioplasty, breast lift and resection of excess skin lateral to the breasts and on the back. The combination of thigh and buttock lifts and abdominoplasty is referred to as a total lower body lift. In some cases with more extensive deformities, both a total upper and lower body lift are indicated, which is often performed in several steps. In other cases, more limited procedures are indicated depending on the location and amount of excess skin. The location of scars after total upper and lower body lifts in a typical massive weight loss patient is illustrated in figure 11.

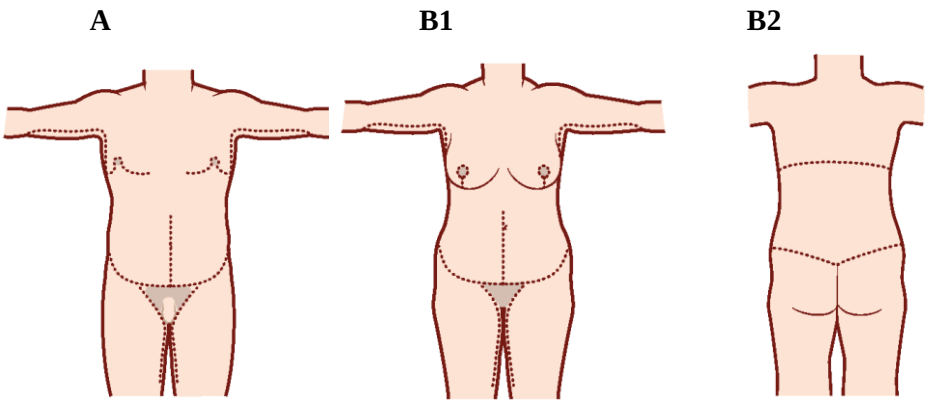


Figure 11 Location of scars after total upper and lower body lift in the typical male (A) and female (B1, B2) massive weight loss patient.

1.12 Complications of body contouring surgery

The risk of post bariatric patients suffering from complications following body contouring surgery vary between 27 and 52% (53-55). The corresponding data for patients who have not undergone bariatric surgery tends to be lower (22-29%) (54, 55). There are data indicating that the complication rates are higher in post bariatric patients compared to patients who have lost weight following dieting, despite similar preoperative BMI in both groups (55). It has been suggested that malnutrition in post bariatric patients may be a possible explanation of these findings (54). The risk of complications also tends to be higher with combined procedures compared to

single procedures (53) and with cases involving a higher preoperative BMI (56, 57).

The most common complications following body contouring surgery are local wound complications such as wound dehiscence, seroma and local infections. Serious complications such as thromboembolism or severe infections occur in a small percent of the cases (55, 57, 58).

1.13 Rectus diastasis and health benefits of rectus fascia plication

The rectus abdominal muscle is a paired muscle running vertically on each side of the midline of the abdominal wall. The fascia of the two rectus muscular components are joined in the midline in a band of connective tissue called the *linea alba* (Figure 12A). Laterally, the rectus fascia is fused to the lateral abdominal muscle fascia. The lateral abdominal muscle fascia is further fused to the lumbar fascia, which is attached to the lumbar spine. Through its mechanical connections to the spine, it is believed that contraction of the abdominal muscles adds passive support to the spine. Pregnancy or severe abdominal obesity leads to tension of the abdominal wall that leads to stretching and weakening of the abdominal muscles. In some of these cases the abdominal rectus muscles are separated in the midline. This condition is referred to as rectus diastasis (Figure 12B).

The width of the *linea alba* is normally between 5-23 mm (59), but with rectus diastasis, the width can increase by several centimeters. In some cases, rectus diastasis may persist even after weight loss. Individuals with a pronounced rectus diastasis may experience symptoms in the form of a cosmetically disturbing bulge in the abdomen located in the midline. There are also a few studies that indicate that there is a connection between chronic back pain and rectus diastasis (60, 61). Any laxity of the abdominal wall with or without rectus diastasis can be corrected by a surgical plication of the rectus fascia, which is performed during abdominoplasty. Plication means that the rectus muscle fascia is sutured in the midline (Figure 12C). The purpose of a plication is to restore the original position of the muscles and thereby the abdominal muscle function.

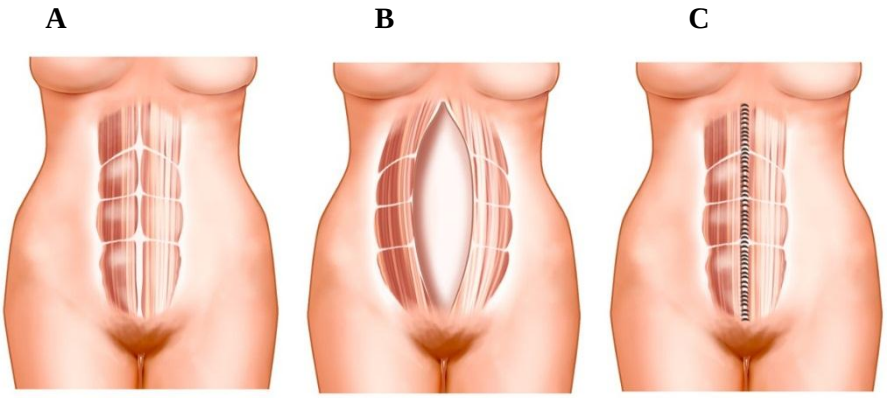


Figure 12: Plication of rectus fascia

According to the prevailing clinical view, plication of the rectus fascia as an additional procedure to abdominoplasty improves the cosmetic appearance by achieving a more defined waist and a flatter abdomen. However, the positive effect of plication on HRQL is rarely evaluated. One study reported that plication had no effect on the physical aspects of HRQL (62). A few non-randomized studies in a small number of patients indicated that a wide plication relieves severe back pain (60, 61). A study of 14 patients from 2002 indicates that plication also can lead to better lung function (63). Abdominal muscles are among our most important breathing muscles, and it is believed that plication may improve the contractility of the abdominal rectus muscles, which leads to better lung function.

1.14 Effects of body contouring surgery on HRQL

The health benefits of body contouring surgery have been incompletely studied. In a systematic review from 2003, it was concluded that the scientific evidence of the effectiveness of abdominoplasty on HRQL was insufficient. The reason was a lack of well-designed studies. Most of the reviewed studies were small with methodological limitations (64). Over the last few years, numerous studies have been published indicating improved HRQL among post-bariatric patients following body contouring surgery (65-68). However, the results from these studies are not conclusive, and sparse prospective data exist. In addition, most of the published studies that have evaluated the effects of body contouring surgery are based on general investigations, without specifying which body parts were reconstructed or whether the surgery was performed as a single procedure or combined procedures. These results are therefore difficult to interpret and are less reliable with regard to the specific effects of different body contouring procedures.

Data on the potential health economic benefits of body contouring surgery would be greatly beneficial but has so far not been identified in the literature.

2 IMPORTANT CURRENT ISSUES RELATED TO EXCESS SKIN

The following are some important current issues concerning excess skin and outcome of body contouring surgery in post bariatric patients:

- Patient-reported data in the literature indicate that a majority of post bariatric patients suffer from excess skin. However, data on how patients rate their discomfort and how the amount of excess skin is related to discomfort, are lacking. Information about the severity of the symptoms is important to estimate the proportion of the post bariatric patients who are in need of surgical correction of excess skin. At the individual level, the above information is important to identify which patients benefit most from body contouring surgery concerning health related effects.

- Whether age or sex is important for the development of excess skin is poorly investigated. It is believed that younger individuals develop less excess skin than older patients based on the clinical experience that the skin is tighter and more elastic in younger subjects compared with older. However, this has not been scientifically evaluated.

- According to the Swedish National Indications for body contouring surgery, the ptosis of the abdominal excess skin must measure at least 3 cm to be approved for surgery. However, this requirement has been established on a non-scientific basis. No published scientific data describing the relationship between objective measurements and experience of excess skin have been identified. Knowledge of how the objective amount of the excess of skin correlates to the experience of the same is important information to take into account to optimize requirements for surgery.

- According to the current clinical opinion, body contouring surgery in post bariatric patients has positive health effects. However, insufficient scientific evidence supporting this opinion exists. Most of the published studies that have evaluated the effects of body contouring surgery involve general evaluations, without specifying which body parts were reconstructed, how much skin that was removed or whether the surgery was performed as a single procedure or as combined procedures. Thus, these results are difficult to

interpret and are less reliable with regard to the effects of different body contouring procedures.

- According to the prevailing clinical view, plication of the rectus fascia as an additional procedure with the abdominoplasty improves the cosmetic appearance by achieving a more defined waist and a flatter abdomen. However, the positive effects of plication on HRQL have been insufficiently evaluated.

3 AIMS

The overall aim of this thesis was to improve the level of knowledge regarding excess skin in post bariatric patients and to evaluate the outcome of abdominoplasty regarding HRQL.

Specific objectives were:

- To evaluate the quality of evidence on health benefits for patients undergoing abdominoplasty subsequent to massive weight loss or childbirth.

- To analyze the frequency, distribution and degree of problems associated with excess skin.

- To evaluate the frequency of requested and undergone body contouring surgery in post bariatric patients.

- To compare the subjective experience of excess skin, requested and undergone body contouring surgery in post bariatric adolescents and in post bariatric adults.

- To correlate objective measurements of excess skin to the subjective experience of the same in post bariatric patients.

- To evaluate the health effect of abdominoplasty on HRQL, with or without plication of the rectus fascia.

- To determine whether the objectively measured amount of abdominal excess skin is related to a possible improvement in HRQL following abdominoplasty.

4 PATIENTS AND METHODS

4.1 Overview of the research design and patient demographics

An overview of the research design of the four papers included in this thesis is reported in table 1. Patient demographics from paper II-IV is presented in table 2.

Table 1. Overview of the research design in paper I-IV.

Paper	**I**	**II**	**III**		**IV**
Study design	Systematic review	Cross sectional study	Case control study		Prospective randomized parallel group study
			Participants	Adult comparison group	
Material/ number of participants	16 articles	484	47	94	94
Inclusion criteria	Controlled studies of ≥ 30 patients, Case series ≥ 100 patients undergone abdominoplasty, panniculectomy or beltlipectomy	Undergone bariatric surgery between 1999 and 2008 at Sahlgrenska University Hospital(SU)	Adolescents undergone bariatric surgery	Post bariatric adults >30 years of age matched to the study participants	Post bariatric patients accepted for abdominoplasty at SU between 2008 and 2012
Intervention	–	–	–		Abdominoplasty
Randomization	–	–	–	-	Plication or no plication of abdominal rectus fascia
Data collection	Literature search	Self administered questionnaires	Self administered questionnaires, measurements of excess skin	Self administered questionnaires	Self administered questionnaires measurements of excess skin
Outcome measures	QOL, respiratory function, back pain, complications	HRQL, patient reported amount of and discomfort of excess skin, body contouring surgery	HRQL, patient reported discomfort of excess skin amount of and discomfort of excess skin, requested and undergone body contouring surgery	HRQL, patient reported discomfort of excess skin amount of and discomfort of excess skin, requested and undergone body contouring surgery	Effect of abdominoplasty on HRQL with or without plication, subjective and objective amount of and discomfort of abdominal excess skin

Table 2. Patient demographics in paper II-IV.

	Paper II	Paper III		Paper IV	
	(n=484)	Participants (n=47)	Adult comparison group (n=94)	Plication (n=38)	No plication (n=56)
Sex n(%)					
Female	353(72.9%)	29(61.7%)	58(62%)	33(86.8%)	47(83.9%)
Male	131(27.1%)	18(38.3%)	36(38%)	5(13.2%)	9(16.1%)
Actual age(yr)	46.3(13.3)	19.8(1.8)	50.4(10.5)	–	–
Age at preoperative Assessment(yr)	–	–	–	44.4(9.5)	42.7(9.9)
Actual BMI (kg/m²)	31.1(8.1)	Female 31.4(4.8) Male 30.7(6.1)	_	–	–
BMI at preoperative assessment visit(kg/m²)	–	–	–	26.4(2.2)	26.4(2.4)
Highest lifetime BMI (II,IV), BMI prior to bariatric surgery (III) (kg/m²)	47.9(10.0)	46.6(6.3)	46,8(6.1)	45.4(6.5)	46.0(5.5)
BMI reduction from highest lifetime BMI to current BMI (II)/ BMI at preoperative assessment (IV)	-	-	-15.6(7.0)	-19.1(6.0)	-19.8(5.3)
Reduction in BMI from prior to bariatric surgery to study assessment	-	-15.4(7.3)	-	-	-
Time elapsed from bariatric surgery to study assessment visit / preoperative assessment(yr)	–	Female 3.3(1.07) Male 3.2(0.9)	–	2.3(1.1)	3.3(3.2)

n(%) is presented for categorical variables, mean (SD) is presented for continuous variables.

4.2 Practical implementation of the studies

Study I

A literature search was performed in 2009 in association with the regional Health Technology Assessment (HTA) Centre in Region Västra Götaland, Sweden to evaluate the quality of evidence for the risks and benefits of abdominoplasty. This literature search resulted in a report published by the HTA center (69). A complementary literature search was performed later, including all articles published after the primary search until October 2011, using the same search strategy as in the primary search. The results from both literature searches were pooled and further analyzed in a systematic review.

Study II

All patients who underwent bariatric surgery at the Department of Surgery at Sahlgrenska University Hospital between 1999 and 2008 were identified. The patients with an available address were mailed two questionnaires in the fall of 2010. One reminder was sent out to patients who did not respond to the first letter.

Study III

Study participants

A total of 86 adolescents who had undergone gastric bypass surgery were invited by mail to participate in the study, of which 47 (55%) agreed to participate. Two self-instructing questionnaires were sent to the adolescents with the study invitation. At an assessment visit at the study center's outpatient facilities during the spring or autumn of 2011, the questionnaires were collected, and weighing and objective measurements of excess skin were performed. To determine whether the adolescents who agreed to participate in the study were representative of all the invited post bariatric adolescents regarding the volume of body contouring surgery, data from the adolescents who refused to respond (non-responders) were obtained from preexisting data and supplemented with phone calls to obtain information regarding eventual body contouring surgeries.

Matched adult comparison group

Data from a matched adult cohort of patients at Sahlgrenska University Hospital who underwent bariatric surgery between 1999 and 2008 (paper II in this thesis) were used for the comparison group. The adults were matched to the adolescents 2 to 1 regarding gender, BMI before bariatric surgery (+/- 4 units) and change in BMI before bariatric surgery to current BMI (+/- 4 units). Individuals below the age of 30 years were excluded.

Study IV

All patients who were accepted for abdominoplasty because of excess abdominal skin between April 2008 and September 2012 were potential candidates for inclusion in this study. The selection criteria for abdominoplasty were based on the amount of excess abdominal skin and symptoms of the same. The participants were invited to volunteer for the study when they were accepted for abdominoplasty. Randomization to undergo rectus fascia plication or not was performed at a preoperative medical assessment 4-6 weeks prior to surgery. At the same time, the participants completed three questionnaires, and demographic data, BMI data and the measurements of excess skin were collected. The study participants who attended the one-year follow-up assessment completed the same questionnaires as at the preoperative assessment; in addition, their weights were recorded a second time.

4.3 Methods of data collection

Paper I

Search strategy

PubMed, the Cochrane Library, CINAHL, AMED, PsycInfo and a number of other databases (SBU, Kunskapssenteret and Sundhetsstyrelsen) were searched for articles published until November 2011. The following search strategy was used: (body lift or body lifts or body-lift) or (body contouring or body-contouring) or plastic bariatric surgery or plastic bariatric surgeries) or (abdominal skin reduction or abdominal skin reductions) or (belt-lipectomy or belt lipectomy or belt-lipectomies or belt lipectomies) or (abdominoplasty or abdominoplasties) or (panniculectomy or panniculectomies) or (diastasis recti or rectus diastasis) and (post-bariatric or postbariatric) or (post-obese or postobese) or (weight loss) or (weight-reduction) or (pregnancy or pregnancies or pregnant) or (post-pregnancy or post-pregnancies or post-pregnant) or (postpregnancy or postpregnancies or postpregnant).

PICO ((Patient, Intervention, Comparison, Outcome)
The included articles had to meet the pre-defined criteria specified in a PICO (2);

P1: Women and men at all ages with abdominal tissue excess after massive weight loss

P2: Women with abdominal tissue excess after childbirth

I: Full/partial abdominoplasty, panniculectomy or beltlipectomy

C: No surgical intervention

O: Quality of life, respiratory function, back pain, complications

Included articles

Sixteen relevant articles were included, of which 15 were case series and one was a controlled observational study. No randomized studies were identified.

Validity assessment and grading of evidence

The study quality was evaluated using the checklists of the Swedish council on health technology assessment (SBU) (70). Quality ratings were given for each study according to SBUs criteria, i.e., high, moderate or low. The quality of evidence was evaluated using the GRADE-system (Grading Recommendation Assessment Development and Evaluation) (1, 71). The definitions of the grades of quality of evidence according to the GRADE system are shown in table 3.

Table 3. Definitions of quality of evidence according to the GRADE system (1).

Grade of evidence	**Description**
High	Further research is unlikely to change our confidence in the estimated effect.
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

Paper II-IV

Questionnaires

The Sahlgrenska Excess Skin Questionnaire (SESQ)

The SESQ consists of 29 questions/statements and is divided into three parts. Part one contains questions concerning general information and demographic data. Part two measures physical, functional and psychosocial impairments related to excess skin. Part three includes questions regarding the experienced amount and degree of discomfort from excess skin on specific body sites and one question regarding requests of body contouring surgery (50).

SESQ –modified version (SESQ-modified)

A modified version of SESQ (SESQ-modified) addressing only abdominal excess skin concerning statements regarding physical, functional and psychosocial impairments of excess skin was used in paper IV.

Short-Form-36 (SF-36)

The SF-36 is a self-instructing questionnaire that includes 36 questions. It measures HRQL in eight multi-item dimensions, covering functional status, well-being and overall evaluation of health (table 4) (72, 73). The eight dimensions of the SF-36 can be summarized into two comprehensive health indexes named physical health and mental health, respectively.

Table 4. Dimensions of SF-36.

Area	**Dimensions**	**Number of questions**
Functional status	Physical functioning	10
	Social functioning	2
	Role limitations (physical problems)	4
	Role limitations (emotional problems)	3
Well being	Mental health	5
	Vitality	4
	Pain	2
Overall evaluation of health	General health perception	5
	Change in health*	1
Total number of questions		36

*Not included in the eight dimensions

European Quality of Life-5 Dimensions (EQ-5D)

The EQ-5D is a self-instructive questionnaire with two parts measuring HRQL. It contains five questions that measure self-perceived health based on five dimensions - physical functioning, social skills, pain and psychological disorders. Each dimension is divided into three levels: no problem, some problems and extreme problems. The answers from the different dimensions can be converted into a single summary index (EQ-5D index). The second part of the EQ-5D consists of a Likert scale graded from 0 to 100 were 100 is the best possible health and 0 is the worst possible health (74, 75).

Study specific questionnaire for paper II

This questionnaire includes nine statements regarding body contouring surgery performed on specific body sites and eight statements regarding requests for body contouring surgery on the same body sites.

Measurements of amount of excess skin

Measurements of excess skin at different body sites were performed according to the standardized clinical practice at our clinic (Fig. 13A-F). The amount of excess skin on the chin was evaluated by measuring the distance between the caudal edge of the underlying solid tissue to the caudal edge of the excess skin. Breast ptosis was measured from the sub mammary fold to the caudal limitation of the breast. The ptosis of the excess skin on the upper arm and thigh was measured with 90° arm/hip abduction and 90° elbow flexion. The largest ptosis was measured from the caudal edge of the muscle to the caudal edge of the skin. The largest ptosis of the skin fold below the umbilicus, not necessary in the midline, was measured from the base of the fold to its caudal limitation. The largest ptosis of the skin fold below the knee was measured from the base of the fold to its caudal limitation.

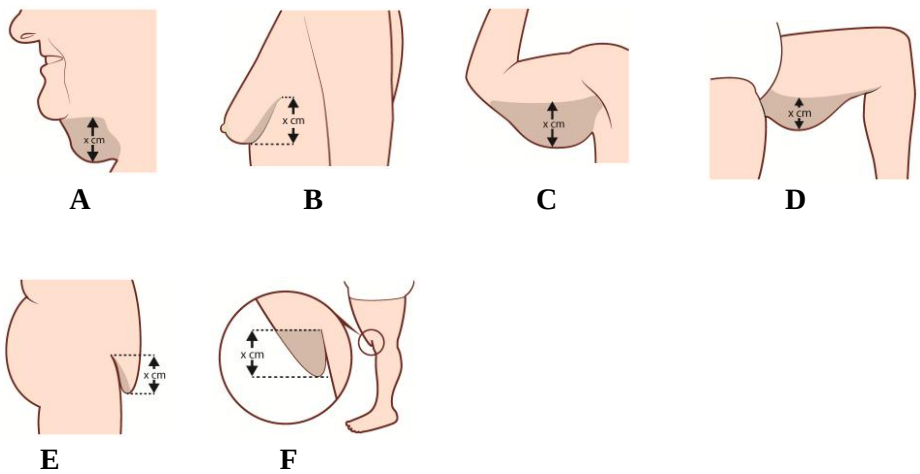


Figure 13: Measurements of excess skin at different body parts.

4.4 Statistical methods

An overview of the statistical methods used in paper II-IV is presented in table 5.

Table 5. Statistical methods used in paper II-IV.

Overview Statistical Methods	**Paper**			
	I	**II**	**III**	**IV**
Descriptiv Statistics Mean, SD, median, minimum and maximum for continuous variables.		X	X	X
Number and % for categorical variables		X	X	X
Statistical Analysis For comparison between two groups: - Mann-Whitney U-test for continuous variables		X	X	X
- Mantel-Haenzsel Chi-Square test for ordered categorical variables		X	X	X
- Fisher's exact test for dichotomous variables			X	X
Changes over time for continuous variables: Wilcoxon Signed Rank Test				X
Changes over time for ordered categorical variables: Sign test				X
Spearman's rank correlation coefficient for analysis of correlations		X	X	X
For comparison between two randomized groups with adjustment for difference in baseline variables using multiple logistic regression with group as dependent variable and main variable and covariate as independent variables.				X
For comparison of dichotomized variables between study population and Swedish population, age adjusted p-values was calculated using Mantel-Haenszel's pooling technique over age groups.				X
For comparison of continuous variables between the study population and Swedish population, z-scores were first calculated based on mean and SD within each subgroup. These z-scores were then analyzed with Wilcoxon Signed Rank test.				X

5 RESULTS

5.1 Review of outcome of abdominal contouring surgery (I)

Selection process

A total of 796 potentially relevant abstracts were identified, of which 780 did not meet the inclusion criteria and were excluded. Sixteen relevant articles were included. Fifteen of the articles were case series reporting complications following either single or combined body contouring procedures. Abdominoplasty constituted the majority of all interventions in all the included case series. The last article was a controlled observational study assessing psychosocial parameters in patients undergoing abdominoplasty. Regarding the effect of abdominal contouring surgery on respiratory function and back pain, no studies that fulfilled PICO was identified.

Complications

In the only study with a prospective design, including 449 massive weight loss patients, the total complication rate was 25% for single procedures and 52% following combined procedures (53).

HRQL

In the only controlled study included, patients reported a significant improvement in the subscale attractiveness/self-esteem for body image after abdominoplasty in comparison to a control group. Study quality was assessed as low. Based on the result of this study, the scientific level of evidence of a positive effect of abdominal contouring surgery on HRQL according to the GRADE system was assessed as very low.

5.2 Subjective experience of excess skin (II, III)

Amount of excess skin in adults (II)

The three most common locations of excess skin in adult females were the upper arms (91%), inside of the thighs (89%) and the abdomen (85%). In adult men, corresponding figures were abdomen (78%), chest (64%) and inside of the thighs (63%).

Amount of excess skin in adolescents and the matched adult comparison group (III)

The amounts of excess skin on different body parts in adolescents of both genders and the matched adult comparison group are illustrated in figure 14.

Adolescents

The three most common reported locations of excess skin in adolescent females were upper arms (93%), inside of the thighs (93%) and breasts (86%). Corresponding figures for adolescent males were abdomen (94%), chest (89%) and upper arms (79%). The female adolescents reported significantly more excess skin on the upper arms compared to the males ($p= 0.037$)

Comparison between adolescents and the matched adult controls

The female adolescents reported significantly more excess skin then the female adult comparison group in the following three locations: upper arms, breasts and inside of thighs ($p<0.05$). The male adolescents reported significantly more excess skin than the adult comparison group at the following six locations: upper arms, abdomen, chest, inside and outside of thighs and knees ($p<0.05$-$p<0.001$).

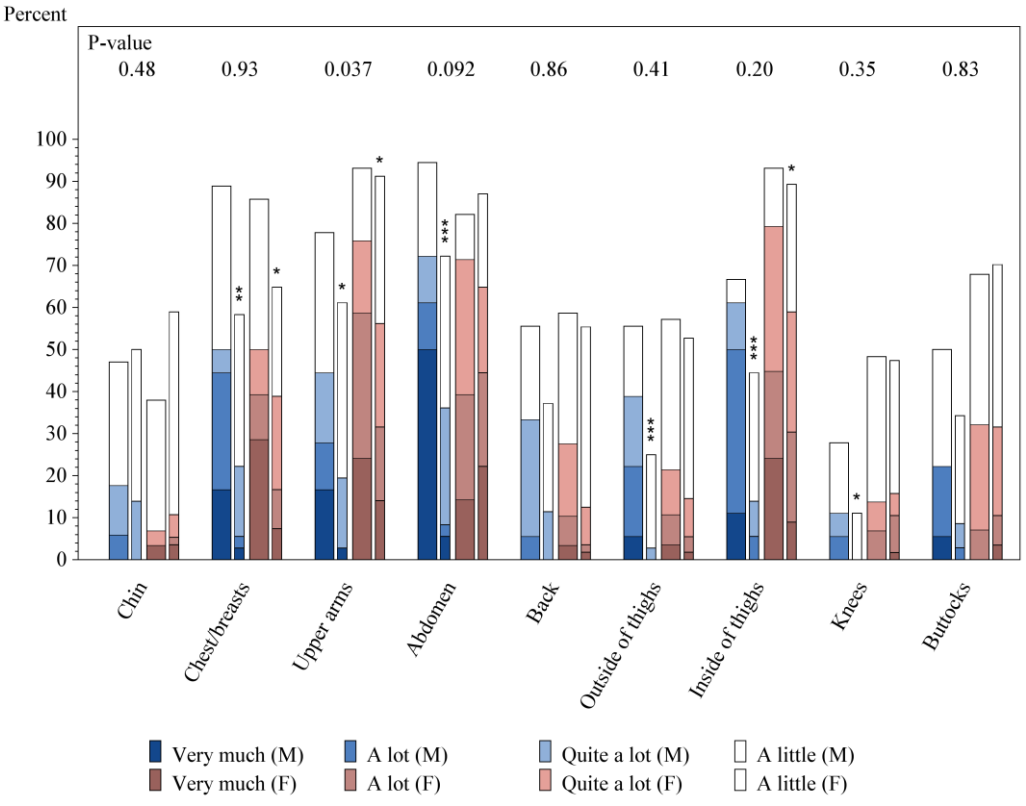


Figure 14 Experienced amount of excess skin at different body sites in adolescents and matched adult comparison group by gender. F=Female, M=Male. Wide bars illustrate adolescents and narrow bars illustrate adult comparison group. The y axis represents the percent of the individuals, and P values refer to differences between female and male adolescents. Asterisks represent significant differences between adolescents and matched adults:
**refers to P<0.05, **refers to p<0.01 and ***refers to p<0.001*

Discomfort of excess skin in adults (II)

Excess skin on the abdomen was reported to cause the most discomfort in both genders with a median of 7 in females and 3 in males on a ten-point scale.

Discomfort of excess skin in adolescents and the matched adult comparison group (III)

The experienced discomfort of excess skin at different body parts in adolescents of both genders and matched adult comparison group are illustrated in figure 15.

Adolescents

The location reported by adolescent females to have the highest degree of discomfort was the inner thighs (median 7.5), and the corresponding figure for male adolescents was the abdomen (median of 9).

Comparison between adolescents and matched adult controls

The female adolescents reported significantly higher discomfort ($p<0.05$-$p<0.001$) compared to the matched adult comparison group at the following three body sites: upper arms, breasts, and inside of the thighs

The male adolescents reported significantly more discomfort ($p=0.05$-$p<0.001$) compared to the matched adult comparison group at the following body sites: upper arms, abdomen, back, chest, inside and outside of thighs, knees and buttocks.

To summarize the results above regarding experience of excess skin, a majority of the post bariatric patients regardless of age and sex, report that they suffer from excess skin on several body parts.

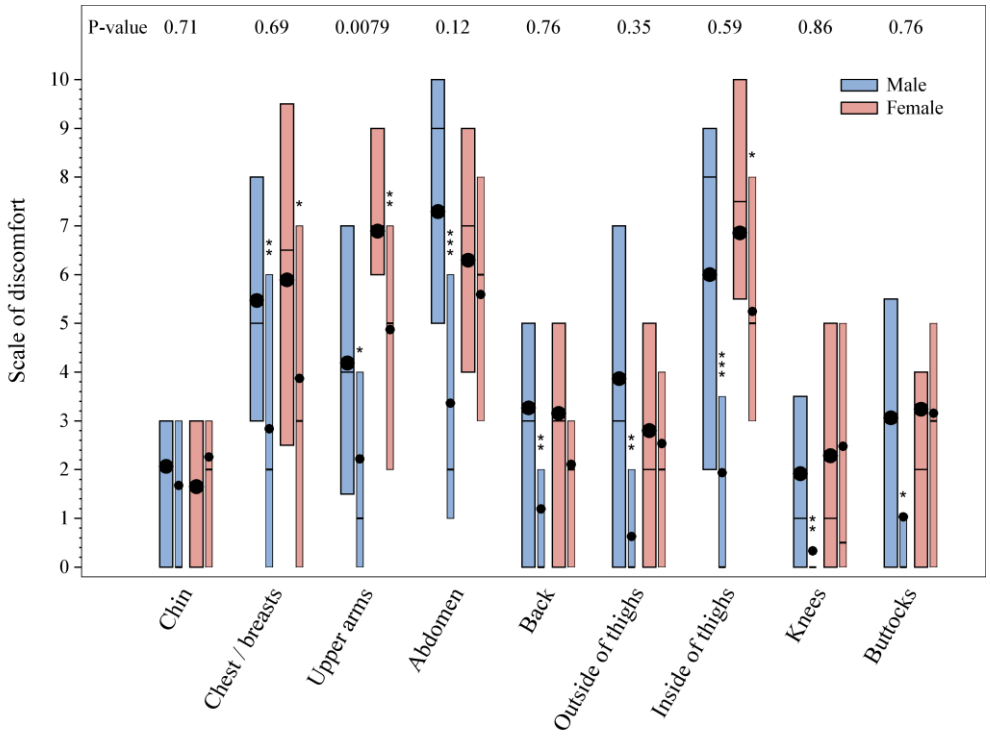


Figure 15: Discomfort of excess skin in adolescents and the matched adult comparison group by gender. The y axis represents the degree of discomfort of excess skin. Wide bars illustrate adolescents and narrow bars illustrate adult comparison group. P values refer values refer to differences between male and female adolescents. Asterisks represent significant differences between adolescents and matched adults:
**refers to P<0.05, **refers to p<0.01 and ***refers to p<0.001*

5.3 Requested and undergone body contouring surgery (II, III)

Requested and undergone body contouring surgery in adults (II)

Requested body contouring surgery

The requested number of body contouring procedures by gender among the adults who had not previously undergone body contouring surgery is illustrated in figure 16. Of the adult males, 25% requested one body contouring procedure, and 40% requested more than one such procedure. Among females, corresponding figures were 11% and 74%. The requested body contouring surgery on different parts of the body is illustrated in figure 17. When specifying the body sites where the study participants requested body contouring surgery, the abdomen was the most common site in females (77%) as well as men (59%).

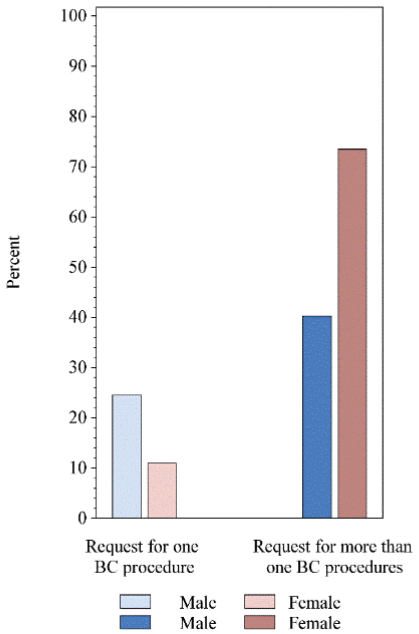


Figure 16: The request of body contouring procedure(s), one or more, in adults by gender. BC= body contouring surgery. The y axis represents the percent of the study participants. Study participants who underwent body contouring surgery were excluded.

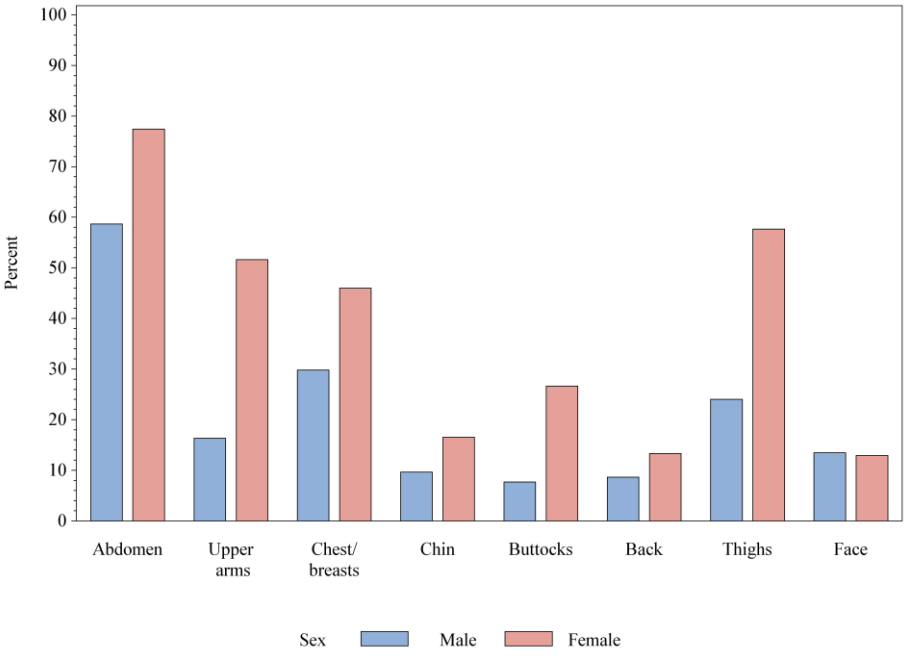


Figure 17: Requested body contouring surgery on different parts of the body in adults by gender. BC= body contouring surgery. The y axis represents the percent of the study participants. Study participants who underwent body contouring surgery were excluded.

Undergone body contouring surgery

The percentage of the adults who had undergone one or several body contouring procedures prior to the study is illustrated in figure 18. Of the adult males, 16% had undergone one body contouring procedure and 2% had undergone operations at two or more sites. Among the females, the corresponding figures were 19% and 7%.

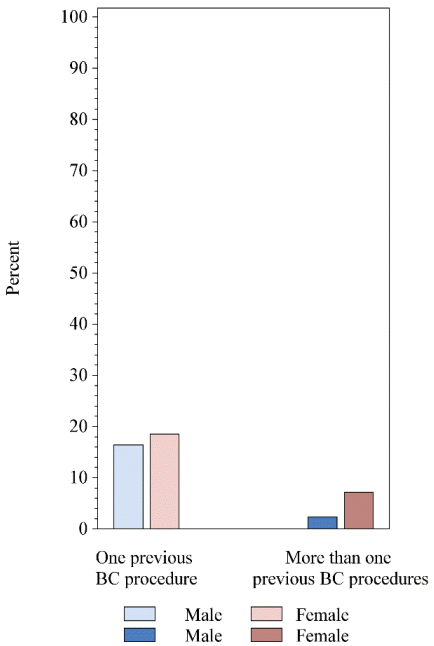


Figure 18: Undergone body contouring surgery in adults by gender. BC= body contouring surgery. The y axis represents the percent of the study participants

Requested and undergone body contouring surgery in adolescents and the matched adult comparison group (III)

Requested body contouring surgery

The requested number of body contouring procedures among the adolescents and matched adult comparison group by gender is illustrated in figure 19. When specifying the body sites where the male adolescents wanted body contouring surgery, the abdomen was the most common in both male (77%) and female (96%) adolescents. Significantly more female than male adolescents requested body contouring surgery of the upper arms ($p<0.036$). Significantly more male adolescents requested surgery of the thighs compared to the male adult comparison group ($p<0.05$), while significantly more female adolescents requested surgery of abdomen ($p<0.05$) and breasts ($p<0.05$) compared to the female adult comparison group.

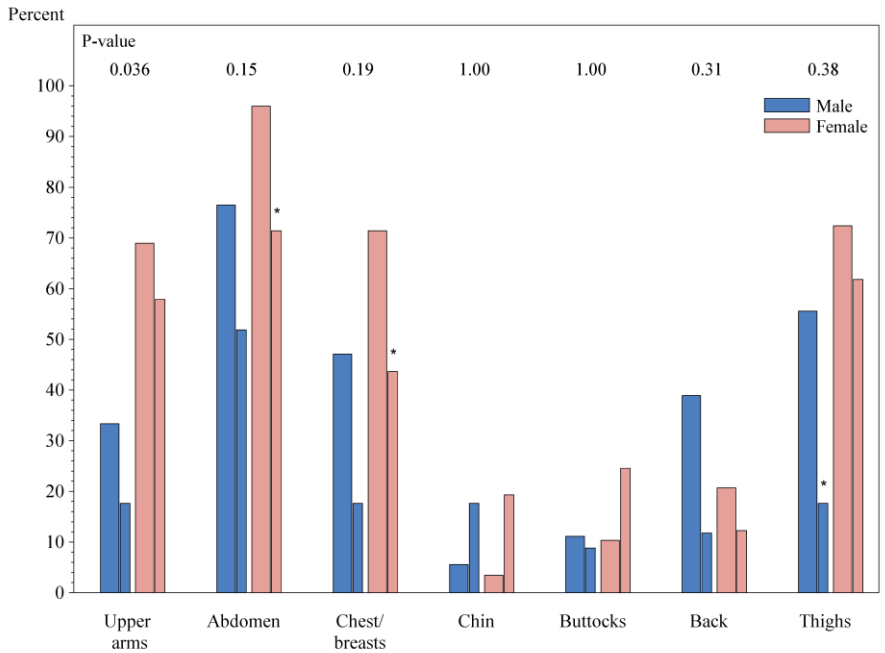


*Figure 19: Requested number of body contouring procedures by gender among the adolescents and the matched adult comparison group. The y axis represents the percent of the study participants. Wide bars illustrate adolescents, and narrow bars illustrate the adult comparison The patients who had undergone body contouring surgery previously were excluded. P values refer to differences between male and female adolescents. Asterisks represent significant differences between adolescents and matched adults:*refers to P<0.05*

Undergone body contouring surgery

Five (11%) of the adolescents had undergone post-bariatric body contouring surgery. No significant differences between the adult comparison group and the adolescents concerning previous body contouring surgery were found.

5.4 Impairment of excess skin assessed with the SESQ (II, III)

Adults (II)

The most frequently reported impairment was a feeling of having an unattractive body, in both males (67%) and females (91%), followed by difficulties finding clothes that fit, in 58% of the males and in 83% of the females, respectively. The third most frequently reported problem was hindrance in intimate situations, in males 52% and females 72%.

Adolescents and matched adult comparison group (III)

Impairment of excess skin in adolescents and the adult matched control group is shown in figure 20. As in the adults of paper II, problems that can be classified as psychosocial impairments dominated both in adolescents and in the matched adult comparison group.

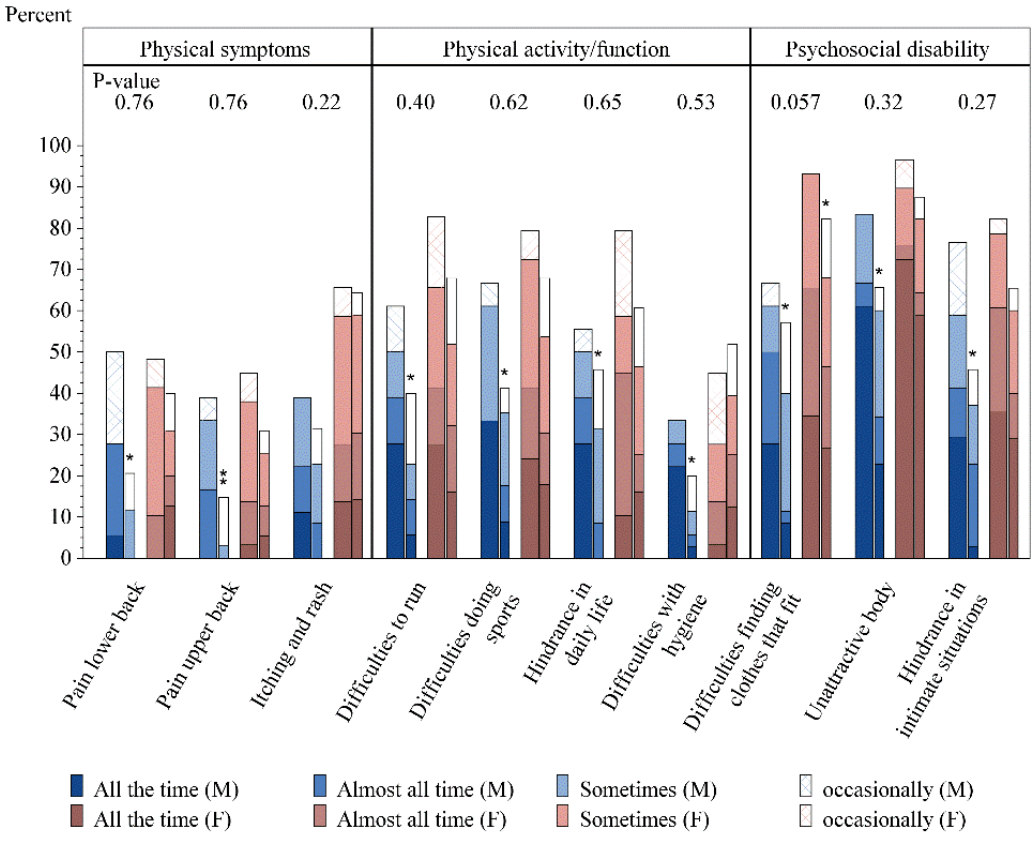


*Figure 19: Impairment of excess skin in adolescents and the adult matched control group. The y axis represents the percent of the study participants. Wide bars illustrate adolescents, and narrow bars illustrate adult comparison group. P values refer to difference between male and female adolescents. Asterisks represent significant differences between adolescents and matched adults: *refers to p<0.05 and ** refers to p=0.01*

5.5 Outcome of abdominoplasty regarding HRQL (IV)

Changes in impairments assessed by SESQ

At follow up, significant ($p < 0.001$) improvements were recorded for all 10 items concerning impairment in both the plicated and non-plicated group.

Changes in the SF-36

A significant increase in the SF-36 physical function subscale was observed at follow up for both plicated ($p=0.022$) and non-plicated ($p=0.031$) groups. For the non-plicated group, significant decreases were found regarding general health ($p=0.039$) and mental composite ($p=0.008$).

Changes in the EQ-5D

No significant changes in the EQ-5D dimension or scores were observed in either the plicated or in the non-plicated groups at follow up.

5.6 Effect of plication as measured by the SESQ, SF-36 and EQ-5D (IV)

No significant differences were observed between the plicated and the non-plicated patients when comparing the results of the SF-36, SESQ or EQ-5D at follow up.

5.7 Correlations (III, IV)

Measured excess skin and discomfort

Adolescents (III)

Significant correlations were found between the measured excess skin and discomfort, regarding the same, for the abdomen (r=0.39), breast/chest (rs=0.56), upper arms (rs=0.51) and chin (rs=0.43).

Adults (IV)

A significant correlation was found between the objectively measured abdominal excess skin and subjectively experienced discomfort from the same (r_s=0.26, p=0.018).

Measured excess skin and experienced amount of the same

Adolescents (III)

Significant correlations were found between the measured excess skin and the experienced amount of excess skin for the abdomen (r_s=0.6), breast/chest (r_s=0.56), upper arms (r_s=0.42) and chin (r_s=0.39).

Adults (IV)

A no significant correlation (r_s=0.15, p=0.16) was found between measured abdominal excess skin and experienced amount of the same.

Measured excess skin and change in SF-36 (IV)

A significant correlation (r_s =0.26, p=0.033) between preoperatively measured abdominal excess skin and improvement of SF-36 physical function subscale at follow up was identified.

6 DISCUSSION

6.1 Discussion of the findings

When initiating the research that resulted in this thesis, a number of current issues regarding excess skin and body contouring surgery in post bariatric patients were identified, as reported in the introduction. It was also concluded that reliable instruments to answer the above questions were lacking.

The first work of this thesis is a systematic literature review on the state of knowledge concerning outcomes of abdominal contouring surgery. This study focuses on the question of scientific evidence to support the current clinical opinion that the surgical outcome of abdominal contouring surgery is positive regarding HRQL. In the same study, effects of abdominoplasty on respiration and back pain were also evaluated in addition to postoperative complications; however, the results of these assessments are not highlighted in this thesis.

In paper II, the experience of excess skin from the patient's perspective, as well as that of requested and undergone body contouring surgery in a larger group of adult post bariatric patients is determined. SESQ made it possible to evaluate the degree of discomfort caused by excess skin on different body parts in a standardized manner, providing new valuable data. By adding corresponding data from post bariatric adolescents in paper III, possible differences in the experience of excess skin between adults and adolescents were evaluated.

In paper III and IV, objective measurements of excess skin were added and allowed an objective evaluation of excess skin. However, the main focus of paper IV was to study the outcome of abdominoplasty with or without plication of the abdominal rectus fascia regarding the experience of excess skin and HRQL. Abdominoplasty is a well-established surgical procedure that has been performed for more than 100 years. Interestingly though, the patient benefits of this procedure are still incompletely studied, as verified by the systematic review of paper I in this thesis. The number of post bariatric patients requesting abdominal contouring surgery in public health care is constantly increasing, and consequently, there is an increasing need to improve the state of knowledge concerning the outcomes of this procedure. According to the general clinical perception, plication of the rectus fascia, which is usually included as a part of an abdominoplasty, improves the cosmetic result of abdominoplasty. This perception is, however, based mainly

on results from cosmetic patients, who request abdominal contouring surgery because of aesthetic reasons, such as a residual bulging belly after pregnancy. The knowledge of the effect of plication in post bariatric patients is low however, and no data in the literature describing the effect of plication on HRQL in post bariatric patients were identified.

Paper I represents an update of a STEER report from 2003, which concluded that the scientific evidence of the effectiveness of abdominoplasty on HRQL was insufficient, mainly because of the lack of well-designed studies. Our literature search showed that the number of relevant studies was still limited concerning health outcome. Although one small controlled study was identified reporting improved HRQL after abdominoplasty, the quality of evidence of the outcome measures as evaluated according to the Grade system was still very low. After the systematic review was published, additional studies have been published, indicating improved quality of life after body contouring surgery (67, 68). However, sparse prospective randomized data still exist. In addition, most of the published studies that have evaluated the effects of body contouring surgery involved general investigations, without specifying which body parts were reconstructed or whether the surgery was performed as a single procedure or combined procedures. Thus, these results are difficult to interpret and are less reliable with regard to the effects of different body contouring procedures.

The results of the SESQ from paper II and III showed that the majority of the post bariatric patients, both the adults and adolescents, suffered from excess skin in many aspects of daily life. Regarding post bariatric adults, this result is consistent with the results of other studies (29, 30, 32). Concerning reported findings of excess skin in adolescents, no preexisting data exist. The most common sites of excess skin were the upper arms in adult women and the abdomen in adult men. The other most frequently reported sites of excess skin were the inside of the thighs and the breasts/chest. This result is consistent with the literature (29). The same results were recorded for adolescents, indicating that adolescents are affected by excess skin on the same body parts as adults.

We found in paper II that in adults of both genders, abdominal excess skin caused the most discomfort, with a median of 3 in males and 7 in females on a ten-point scale. A similar result with an even higher discomfort of abdominal excess skin of a median of 9 was achieved in adolescent males, while in the adolescent females, the inside of the thighs had the highest discomfort with a value of more than 7 on a ten point scale, closely followed by the abdomen and upper arms. According to our results, 88% of

adolescents who had not previously undergone body contouring surgery requested such surgery, whereas the corresponding figures in adults of paper II was 75%, which corresponds well with the literature (29). In summary, our results suggest that the degree of discomfort of excess skin is high among post bariatric patients and that abdominal excess skin seems to cause the biggest discomfort. Given the high degree of discomfort of abdominal excess skin, it is not surprising that abdominal contouring surgery was the most common procedure desired among both adults and adolescents. However, one can conclude that there is a large discrepancy between the amount of body contouring surgery requested and that performed within public health care in Sweden, according to the national database. A similar discrepancy has been described in the literature. Two studies from the USA have shown that a vast majority of post bariatric patients request body contouring surgery, but only a small number actually undergo such surgeries (15, 19). This difference is explained by the lack of coverage by third party payers in the USA. The same discrepancy is reported in Austria (18) and Saudi Arabia (14), but is attributed to other factors such as fear of complications and scarring, a low level of knowledge of body contouring surgery among the patients and incongruity between the number of patients and the number of plastic surgeons in governmental hospitals. In Sweden, one reasonable explanation for this discrepancy is that body contouring surgery has not been prioritized in the public health care system, and since it is not common to have private health insurance, most patients have to rely on what public health care can provide.

According to our findings, adolescents of paper III reported more impairment, higher amounts of excess skin and greater discomfort compared to the adult comparison group. No measurements of excess skin were conducted in the adult comparison group, which precluded comparisons between the measured amount of excess skin in adolescents and the adult comparison group. However, the adolescents proved to have a substantial amount of abdominal excess skin, which was somewhat smaller than in the adults of paper IV, which is reasonable because the patients of study IV represented a selected group of patients with larger amounts of abdominal excess skin qualifying for abdominoplasty according to the Swedish guidelines. Our results suggest that adolescents are bothered by excess skin just as much or more than adults. Thus, the commonly held belief that young people do not develop excess skin to the same extent as adults is strongly questioned.

The majority of the post bariatric patients of paper II, III and IV experienced problems related to excess skin including physical, functional and

psychosocial impairment. This result is consistent with previously published data (33). According to our findings in paper II and III, when applied to both adults and adolescents, psychosocial impairments such as the feeling of having an unattractive body and difficulties finding clothes that fit occurred more often than both the physical and functional impairments. The same result was achieved in paper IV. All patients included in this paper had clinically documented large amounts of abdominal excess skin. In this patient group, major physical and functional concerns such as itching and rash and physical limitations related to the size and weight of the excess skin were expected. However, according to our findings, psychosocial impairments dominated even in these patients, which is a somewhat an unexpected result. This suggests that psychosocial impairments of abdominal excess skin possibly cause more problems than the physical and functional impairments, even in patients with a documented high amount of excess skin.

According to Swedish National guidelines, abdominal excess skin must measure at least 3 cm to be approved for abdominoplasty (51). Because the objective amount of excess skin is crucial in the determination of whether a patient is offered abdominal body contouring surgery in public health care, it is important to understand the relationship between the patients experienced symptoms of excess skin and the objective amount of excess skin to optimize requirements for surgery. The correlation between objective measures and the patients' experience of excess skin was investigated for the first time in paper III, where moderate correlations were found between the measured excess skin and experienced amount and discomfort of the same concerning the abdomen, breasts / chest, upper arms and chin. In paper IV, a low correlation was found between the measured abdominal excess skin and discomfort of the same. More prospective good-quality studies are needed to determine whether the achieved correlations above have a clinical significance. However, this result indicates that other factors in addition to the measured amount of excess skin affect the patient’s discomfort of the same.

According to the results of SESQ-modified in paper IV, significant improvements were found following abdominoplasty with regard to all items concerning the physical, functional and psychosocial impairments related to abdominal excess skin. Experienced amount and the discomfort associated with abdominal excess skin also improved. These results indicate that abdominoplasty has a number of positive effects related to impairments of abdominal excess skin and the experience of amount and discomfort of the same. Paper IV also showed a significant increase in the SF-36 physical function dimension of HRQL one year after surgery, while no other

improvements in any of the other dimensions was achieved. A conflicting result was that no significant improvement in EQ-5D scores was noted, which could be explained by the feature of EQ-5D. The questions of this instrument have only three alternatives. Therefore, the specificity is rather low and the instrument might not be able to detect changes after abdominoplasty. The results in the literature on the effects of body contouring surgery on HRQL are inconclusive. Data in the literature support our findings regarding improvement in physical functioning following either abdominal contouring surgery (62) or body contouring surgery in general. There are also data that deny any positive effect of body contouring on HRQL concerning all dimensions of the SF-36 (65). However, the results of paper IV and the existent literature indicate that body contouring surgery has positive health effects, primarily with regard to the physical and psychosocial dimensions of HRQL.

There are several possible explanations for the lack of a positive effect on mental health dimensions of HRQL. According to our clinical experience, post bariatric patients are generally very satisfied with the result of an abdominoplasty; however, they often complain of remaining excess skin on the thighs, chest and upper arms, which could have a negative impact on their mental health. In addition, some patients also express disappointment that the abdominoplasty did not have an effect on the excess of skin in the pubic area, the flanks and on the back. This may indicate a lack of information or, alternatively, lack of ability to perceive the preoperative information on the results that can be expected from the planned surgery. Moreover, in some cases, it may also inform refining of the operation techniques to optimize the surgical outcome according to the patient's requests.

No effect of plication of the rectus fascia on any area of HRQL was found. A similar result concerning effect of plication on functional outcome in massive weight loss patients undergoing abdominoplasty was previously reported (62). There are data in the literature indicating that a wide plication relieves severe back pain (60, 61). However, in these studies, a much wider plication than performed in usual practice was described, which together with the methodological limitations restrict the value of the results from these studies. To clarify the possible relationships between plication and HRQL, additional prospective randomized studies that account for the size of the rectus diastasis and the width of the plication must be performed, which might influence the study outcomes.

A weak correlation was identified between the change in physical function subscale of SF-36 after abdominoplasty and the measured preoperative

amount of abdominal excess skin, indicating that improvements of abdominoplasty in terms of physical parameters are not strictly related to the preoperative amount of abdominal excess skin. This might indicate that the degree of abdominal excess skin is of limited importance regarding the outcome of abdominoplasty. The correlation between the measured abdominal excess skin and discomfort was also low, indicating that the measured amount of abdominal excess skin excess skin is less important also in terms of discomfort.

A decrease in the general health dimension of SF-36 in the non-plicated group was detected at follow up, whereas no significant corresponding decrease was found in the plicated group. A possible explanation for this result is that the outcome of the procedure was not as satisfying as expected in the non-plicated group regarding the cosmetic appearance of the stomach, which may have negatively affected the general health dimension of the SF-36.

6.2 Methodological considerations

General methodological considerations

In paper I, the internationally developed GRADE system for the classification of the quality of evidence was used. One difficulty with this system is that randomized, preferably blinded studies are required to produce high-quality evidence. In clinical research, it is often impossible to conduct blinded randomized studies that automatically result in a lower quality of evidence. An obvious risk using this system is that the potential clinical value of the results from other types of studies are not valued, which could be the case regarding the studies included in paper I.

SF-36 and EQ-5D was chosen for evaluation of HRQL because both of these questionnaires are internationally accepted standardized assessment tools for estimating HRLQ. Additionally, the SF-36 is a well-used questionnaire for post bariatric patients (66 63) (76 84) (77 85). Regarding the EQ-5D, this questionnaire is not frequently used to measure HRQL in post bariatric patients, but a strength of this questionnaire is that the EQ-5D Index scores can be used for cost-effectiveness analyses.

To improve the state of knowledge on excess skin in massive weight loss patients both in general and from a surgical point of view, our research group

developed the SESQ, which specifically addresses massive weight loss patients. The questionnaire has been in use for the first time in paper II of this thesis and plays a central role in paper III and IV. An obvious strength of the SESQ is that it rates both the degree of common impairments related to excess skin and the discomfort of the same on different body sites in a standardized way. To our knowledge, there are no other questionnaires that report similar information. However, some improvements regarding the SESQ are still required: the questionnaire has still not been validated. Furthermore, SESQ data from the general Swedish population need to be collected to produce normal values. There is also scope for linguistic and structural improvements.

Study specific limitations

Paper II

One obvious limitation of paper II is that the results are based only on the patient`s own perceptions and not on objective measurements, which makes the findings concerning amount of excess skin less reliable. Another limitation is the lack of data from non-responders. In the case of a higher response rate from those with minor problems, there is a risk of over-interpretation of the results or vice versa.

Paper III

Only 47 of 86 adolescents participated in the study. Information regarding extent of excess skin in the non-responders and the prevalence figures regarding excess skin in adolescents are therefore unknown. It can also be assumed that patients with more substantial requests for body contouring surgery would be likely to participate. Another limitation is that our assessments were not performed at the same time point after bariatric surgery, which may affect the experience and the measured amount of excess skin.

Paper IV

The patient attrition rate was high. However, the drop out was not systematically distributed.

7 CONCLUSIONS

- The scientific level of evidence of positive health effects of abdominal contouring surgery is still low, mainly because of the lack of well-designed studies.

- The majority of the post bariatric patients regardless of age and sex report that they suffer from excess skin at several body parts.

- The majority of the post bariatric patients experience physical, functional and psychosocial impairments related to excess skin.

- Abdominal excess skin causes the largest discomfort, and abdominal contouring surgery is also the most common procedure requested.

- Adolescents suffer just as much or more of excess skin than adults both regarding subjective experience and objective measurements of excess skin.

- The correlations between discomfort or impairments and objective measurements of excess skin are moderate or low, which may indicate that factors other than the measured amounts of excess skin affect the patient's experience of the same.

- Abdominoplasty improves the physical and psychosocial dimensions of HRQL.

- Plication does not seem to affect the outcome of abdominoplasty regarding HRQL.

8 FUTURE PERSPECTIVES

With this thesis, we have expanded the understanding of the problems associated with excess skin and outcomes of body contouring surgery in post bariatric patients. However, one must note that there are still many remaining knowledge gaps regarding the knowledge of excess skin.

Despite a lack of knowledge concerning excess skin, we think that with the support of our results, it is reasonable to question the importance of objective measurements of the amount of excess abdominal skin concerning the assessment of the need for abdominoplasty. Whether the health benefits of an isolated abdominoplasty in post bariatric patients is sufficiently large to justify that this procedure is performed as a single procedure can also be questioned. It is also relevant to discuss whether it is reasonable that the figures for body contouring surgery regarding other body sites besides the abdomen is so much lower than the corresponding figures for abdominoplasty.

We believe that a first natural step in improving our care of post bariatric patients from a surgical point of view is to consider patients with excess skin from a holistic perspective with a greater focus on the patient's symptoms of excess skin on various body parts instead of mainly focusing on the measured amount of excess skin on any individual body site. We also need to be more responsive to patient requests for body contouring surgery with respect to which body parts the individual patient is most anxious undergo operations on. Surgical treatment should be adjusted accordingly, based on what is reasonable both from a medical point of view and from a cost perspective. A patient who is experiencing the greatest difficulty from the abdomen, flanks and thighs could be a good candidate for a lower body lift, for example, whereas a patient who has the greatest difficulties with the arms and chest may be suitable for an upper body lift. Knowing that there are still major gaps in the knowledge concerning the outcome of body contouring surgery in post bariatric patients, it is of great importance that all body contouring patients undergo operations within the framework of prospective, well designed studies by skilled plastic surgeons to ensure that this group of patients receive an optimal and effective care within the public health system in the future based on scientific facts rather than opinions.

In a broader perspective, regarding the selection of patients for body contouring surgery, the patient's age is a parameter that is frequently discussed especially concerning younger patients. According to Swedish law, it is forbidden to give priority to age in health care. According to the Swedish national indications for body contouring surgery, younger patients do not prefer surgery compared to older patients, which means that the same indications for acceptance of surgery applies to everyone, regardless of age. This may be perceived as unfair to the younger population. When young people do not meet the requirements for body contouring surgery, the young patients themselves and their relatives often express great frustration and anger that the requirements for surgery are not lower for adolescents compared to older people given the motivation that the adolescents "are at the beginning of their lives".

The term "age normalized appearance" can be used to defend the above perception. This term describes the clinical perception that you have to accept a greater degree of excess skin in an elderly individual compared to a younger individual. This view is based on the notion that a certain amount of excess skin in an older individual is part of a natural aging of the skin. However, there is no scientific support for what is considered "normal appearance" related to age. It seems difficult to use scientific methods to determine what an "age normalized appearance" is. Despite the lack of scientific evidence, we think it is still important to address the issue of a possible priority on the age, where younger individuals receives priority over older even though Swedish law forbids us to give priority to age in health care.

9 ACKNOWLEDGEMENTS

I would like to express my gratitude to everyone who in various ways contributed to the completion of this thesis. I particularly wish to thank the following:

The Institute of Clinical Sciences/Department of Plastic Surgery for providing the opportunity to complete the thesis.

All study participants who participated in the studies in paper I-IV in this thesis.

Anna Elander, my main supervisor for support at any time, day or night, for her wisdom, knowledge, positive energy and creative ideas.

Monika Fagevik Olsén, my co-supervisor who provided support, knowledge and amazing motivation to maintain focus.

Åsa Jalhed Sahlin, study coordinator for her enthusiasm, great ability to create good relationships with our patients and for being such a friendly and warm hearted person.

Nils-Gunnar Pehrsson and Anders Pehrsson for excellent statistical support.

My colleagues who accepted a higher clinical workload so that I could write my thesis.

Torsten Olbers, Annika Strandell, Christina Bergh, Carl-Erik Flodmark, Jovanna Dahlgren and Claude Marcus for the fruitful collaboration resulting in the papers of this thesis.

Finally, I would like to thank my family, Paul, Sara, Josef and Julla for endless patience and positive thinking.

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