

Excess Skin After Bariatric Surgery

**Patients' perspective and objective
measurements**

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To my family

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ABSTRACT

Most of the world's population lives in countries where overweight and obesity kills more people than underweight. The only effective treatment is found to be bariatric surgery. Excess skin is an undervalued, negative effect following the massive weight loss after the procedure.

Aim: The general aim of this thesis was to investigate the experience and the development of excess skin after massive weight loss following bariatric surgery.

Materials and method: Super obese patients filled in a questionnaire concerning experience and discomfort from excess skin after massive weight loss following bariatric surgery. Their experiences were correlated to circumference measurements of hip and waist. The questionnaire was developed further and test – retest was performed to test the reliability. Sahlgrenska Excess Skin Questionnaire, SESQ, aims to investigate excess skin on different body parts from the patients' perspective. In a longitudinal follow up, patients filled in SESQ and objective measurements of excess skin were made. Excess skin, ptosis and circumference were measured in a standardized way. Correlations were made between patients' subjective experiences and the objective measurements. The measuring protocol, designed to measure excess skin in massive weight loss patients, was evaluated regarding inter rater reliability by two testers.

Results: The SESQ consists of three different parts, I: demographic data, II: symptoms of excess skin and III: assessment and discomfort of excess skin on different body parts. The test-retest reliability of SESQ showed a kappa coefficient of 0.44 to 0.81 concerning parts I and II, and an ICC of 0.72 to 0.92 for part III. In addition, face validity was performed with ten post bariatric patients.

Weight loss after bariatric surgery in super obese and obese patients is associated with substantial experience and discomfort from excess skin. The excess skin is most commonly located on the abdomen, upper arms and thighs, and women experience more discomfort on several body parts than men. The excess skin causes intertriginous problems, such as fungus and eczema. It is heavy, which causes pain and hinders physical activity and is also a severe psychocosmetic problem.

Repeated, objective, measurements of obese patients demonstrate that all ptosis and excess skin measurements decreased after weight reduction due to surgery except for the ptosis on the thighs, which had increased significantly.

Comparison of objective measurements with the patients' subjective reports of experience and discomfort from excess skin gave little or low correlation for both obese and super obese patients.

The prediction analysis indicates that, for every centimeter of ptosis on the abdomen preoperatively, there is a twofold higher odds of having a postoperative ptosis on the abdomen > 3 cm (OR=2.32).

Measurements of ptosis and excess skin had high or good reliability even though the size of the ptosis varied by several centimetres and the majority of the measurements had an ICC > 0.9 despite the fact that the measurers were from different professions.

In summary: The SESQ is a reliable questionnaire for assessing excess skin from the patients' perspective and the measuring protocol represents a useful instrument for providing a consistent and objective assessment of excess skin. While the extent of excess skin that was measured is reduced in comparison with before the operation, patients seem to become more aware, inconvenienced and discomforted by it on several body parts after weight loss. Discomfort from excess skin correlates fairly well to the extent of excess skin or circumference measurements in super obese or obese patients.

Keywords: obesity, bariatric surgery, post bariatric plastic surgery, massive weight loss, excess skin, SESQ, discomfort from excess skin, objective measurements

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SAMMANFATTNING PÅ SVENSKA

Merparten av världens befolkning lever i länder där övervikt och fetma dödar fler människor än vad undervikt gör. Överviktskirurgi har visat sig vara den enda effektiva och långsiktiga behandlingen mot fetma. Efter den massiva viktminskningen är överskottshud en undervärderad negativ sidoeffekt.

Syfte: Det övergripande syftet med avhandlingen var att undersöka erfarenheter och utveckling av överskottshud vid massiv viktnedgång efter överviktskirurgi.

Material och metod: Superobesa patienter med ett BMI > 50 kg/m² fyllde i ett frågeformulär om sina erfarenheter och skattade sitt obehag från överskottshud efter överviktskirurgi. Deras erfarenheter korrelerades till omkretsmått av höft och midja. Frågeformuläret vidareutvecklades sedan och tillförlitligheten prövades. Sahlgrenska Excess Skin Questionnaire, SESQ, undersöker patientens upplevelser av överskottshud efter viktnedgång på olika kroppsdelar. Vid en långtidsuppföljning av patienter före och efter överviktskirurgi gjordes objektiva mätningar av överskottshuden på de kroppsdelar som ingår i SESQ och patienterna fyllde i frågeformuläret vid båda tillfällena. Överskottshud, ptos och omkrets mättes enligt en standardiserad mätmall. Korrelationer gjordes mellan patienternas subjektiva upplevelser av överskottshud och de objektiva mätningarna. Mätprotokollet, som har utformats för att mäta överskottshud på patienter efter massiv viktnedgång, utvärderades avseende tillförlitlighet av två olika testare.

Resultat: SESQ består av tre delar, I: demografiska data, II: skattning av symptom av överskottshud och III: skattning av mängd och obehag av överskottshud på olika kroppsdelar. Test- retest av SESQ visade att frågeformuläret hade god tillförlitlighet och ytterligare tio patienter som hade opererats för övervikt fick uttala sig om frågeformulärets utformning och användarvänlighet.

Både obesa och superobesa patienter upplevde mycket överskottshud och obehag av den samma efter viktminskning. Överskottshuden förekommer oftast på buken, överarmarna och låren och kvinnorna upplever större obehag än män på fler kroppsdelar. Överskottshuden orsakar ofta svamp och eksem och den upplevs som tung, vilket orsakar smärta och hindrar fysisk aktivitet. Den uppfattas också som ett stort kosmetiskt problem.

Upprepade mätningar av överskottshuden visade att alla ptosmått och mängden överskottshud hade minskat efter viktnedgången utom på låren, där ptosen istället hade ökat.

För både de obesa och superobesa patienterna var det låg samstämmighet mellan de objektiva mätningarna av överskottshud och patienternas egna, subjektiva upplevelser av mängd och obehag av överskottshud.

Prediktionsanalysen visar att för varje centimeter ptos på buken innan överviktsoperationen, dubblerades oddsen att få ptos på buken > 3 cm (OR = 2,32) efter viktnedgången.

Prövning av mätmallen visade att mätningarna av ptos och överskottshud hade hög eller mycket hög inter bedömar reliabilitet trots att storleken på ptosen varierade med flera centimeter på de olika kroppsdelarna. Majoriteten av mätningarna hade en ICC $> 0,9$ trots att mätningarna utfördes av personer ur två olika yrkeskategorier.

Sammanfattning: SESQ är ett tillförlitligt frågeformulär för bedömning av överskottshud ur patientens perspektiv och mätprotokollet är ett användbart instrument för konsekventa och objektiva mätningar av överskottshud.

Överskottshuden blev mindre i antal centimeter jämfört med före operationen, men patienterna tycktes bli mer medvetna, reagerade starkare och upplevde mer obehag av överskottshuden på flera kroppsdelar efter viktnedgången. Patientens obehag från överskottshuden var lågt korrelerade till graden av överskottshud och omkretsmått hos både obesa och superobesa patienter.

Nyckelord: övervikt, fetma, bariatrisk kirurgi, post bariatrisk plastikkirurgi, massiv viktnedgång, överskottshud, SESQ, obehag från överskottshud, objektiva mätningar

LIST OF PAPERS

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

- I. Börserud C, Olbers T, Søvik T, Mala T, Elander A, Fagevik Olsén M. *Experience of excess skin after gastric bypass or duodenal switch in patients with super obesity*. Surg Obes Relat Dis. 2014 Sep-Oct;10(5):891-6
- II. Börserud C, Nielsen C, Staalesen T, Elander A, Olbers T, Fagevik Olsén M. *Sahlgrenska Excess Skin Questionnaire, SESQ - A reliable questionnaire to assess the experience of excessive skin after weight loss*. J Plast Surg Hand Surg. 2013 Feb;47(1):50-9
- III. Börserud C, Olbers T, Staalesen T, Elander A, Fagevik Olsén M. *Understanding excess skin in post bariatric patients– objective measurements and subjective experiences*. In manuscript
- IV. Börserud C, Fagevik Olsén M, Elander A, Wiklund M. *Objective measurements of excess skin in post bariatric patients - inter rater reliability*. Submitted

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CONTENT

- ABBREVIATIONS V
- 1 INTRODUCTION 1
 - 1.1 Definition of obesity 1
 - 1.2 Epidemiology and etiology 2
 - 1.3 Stigmatization, quality of life and risk factors 4
 - 1.4 Treatment of obesity 5
 - 1.4.1 Operation methods 6
 - 1.5 Excess skin 8
 - 1.5.1 Previous research in the area of excess skin after bariatric surgery 8
 - 1.5.2 Consequences of excess skin 9
 - 1.5.3 Post bariatric plastic surgery 11
 - 1.5.4 Effects of post bariatric plastic surgery 13
 - 1.5.5 Complications after post bariatric plastic surgery 14
 - 1.5.6 Patient selection 14
 - 1.5.7 Questionnaires/classifications assessing excess skin in post bariatric patients 15
 - 1.6 Some important concepts in developing a questionnaire regarding health status 16
- 2 IMPORTANT CURRENT ISSUES RELATED TO EXCESS SKIN 17
- 3 AIM 19
 - 3.1 Specific aims 19
- 4 PATIENTS AND METHODS 20
 - 4.1 Overview of the research design and patient demographics 20
 - 4.1.1 Health Related Quality of Life 22
 - 4.2 Participants 22
 - 4.3 Methods of data collection 24
 - 4.4 Statistical methods 32
 - 4.5 Ethical considerations 33

5	RESULTS	34
5.1	Test – retest reliability in Paper II.....	34
5.2	Inter rater reliability in Paper IV	35
5.3	Patients’ experiences of excess skin in Papers I and III.....	38
5.3.1	Symptoms from excess skin	40
5.3.2	Amount of excess skin	40
5.3.3	Discomfort from excess skin.....	41
5.4	Objective measurements in paper III	43
5.5	Correlations.....	47
5.5.1	Experienced amount of excess skin versus discomfort in	
	Paper I	47
5.5.2	Objective measurements versus subjective experiences in	
	Paper I and III.....	48
5.5.3	Correlation between change in BMI versus experience	
	and discomfort in Paper I	49
5.5.4	Correlation between Δ BMI and Δ measurements in	
	Paper III.....	49
5.6	Prediction analysis in paper III	50
6	DISCUSSION	52
6.1	Methodological considerations	52
6.2	Discussion of the findings.....	56
7	CONCLUSIONS.....	63
8	FUTURE PERSPECTIVES	64
	ACKNOWLEDGEMENTS	66
	REFERENCES.....	69

ABBREVIATIONS

ASGARD	Aker Sahlgrenska Gastric bypass and Duodenal Switch study
BMI	Body Mass Index, kg/m ²
BPD/DS	Biliopancreatic Diversion with Duodenal Switch
EQ-5D	European Quality of Life- 5 Dimensions
HRQoL	Health Related Quality of Life
RYGBP	Roux-en-Y Gastric bypass
SESQ	Sahlgrenska Excess Skin Questionnaire
SF-36	Short- Form 36 Health Survey
VAS	Visual Analogue Scale
WHO	World Health Organization

1 INTRODUCTION

Most of the world's population live in countries where overweight and obesity kills more people than underweight¹. The only effective treatment is found to be bariatric surgery. Excess skin is an undervalued, negative effect following the massive weight loss after the procedure. There is a lack of knowledge in the area, however, and this thesis focuses on patients' subjective experiences and on objective measurements of excess skin.

1.1 Definition of obesity

Overweight and obesity are defined as abnormal or excessive fat accumulation that poses a risk to health. Body mass index, BMI, is normally used to measure overweight, and it is defined as the weight in kilograms divided by the square of height in meters (kg/m^2).

BMI classification according to the World Health Organization, WHO¹:

Classification	BMI kg/m^2
Underweight	< 18.5
Normal weight	18.5-24.9
Overweight	25.0- 29.9
Obesity class I	30.0 – 34.9
Obesity class II	35.0 – 39.9
Obesity class III	> 40.0

Further, classifications of obesity by the American Society for Bariatric surgery (ASBS) are: severe obesity (BMI 35-40 kg/m^2), morbid obesity (BMI 40-50 kg/m^2), super obesity (BMI 50-60 kg/m^2) and super - super obesity (BMI > 60 kg/m^2)². The BMI ranges are based on the effect that excessive body fat has on disease and death. BMI was developed as a risk indicator of disease; as BMI increases, so does the risk for some diseases¹.

1.2 Epidemiology and etiology

During the past decades the proportion of people who are overweight and obese has increased considerably³⁻⁵ and it is currently on a steady, high level⁶. There was almost a doubling of obesity worldwide between 1980 and 2008⁵ and the prevalence of overweight and obesity in 2013 was 37 % in men and 38 % in women⁷. Figure 1 illustrates worldwide prevalence of obesity in 2014¹. The proportion of persons who are overweight in Sweden has also nearly doubled in the last 20 years, and in 2014, 35 % of the adult population was overweight and 14 % were obese⁸. The incidence of obesity has been increasing in both men and women^{7, 9, 10} although there seems to have been a stabilization considering both adults and youths in the United States since 2003⁶ and there is also a declining trend among Swedish children^{11, 12}.

Overweight and obesity are developed through a combination of different factors. Heritage, lifestyle, social elements and environmental factors play important roles in the progress¹³. The central role of genetic influence has been well established in studies of twins and adopted children¹⁴. Regardless of whether identical twins grow up together or have been reared separately, they show great similarities in BMI as adults. Furthermore, obesity is more common in individuals with poor socioeconomic conditions and among those with a lower educational level¹³. It is also well accepted that children with obese parents develop overweight and obesity, and that this is related to genetic factors and to socioeconomic factors¹⁵⁻¹⁸.

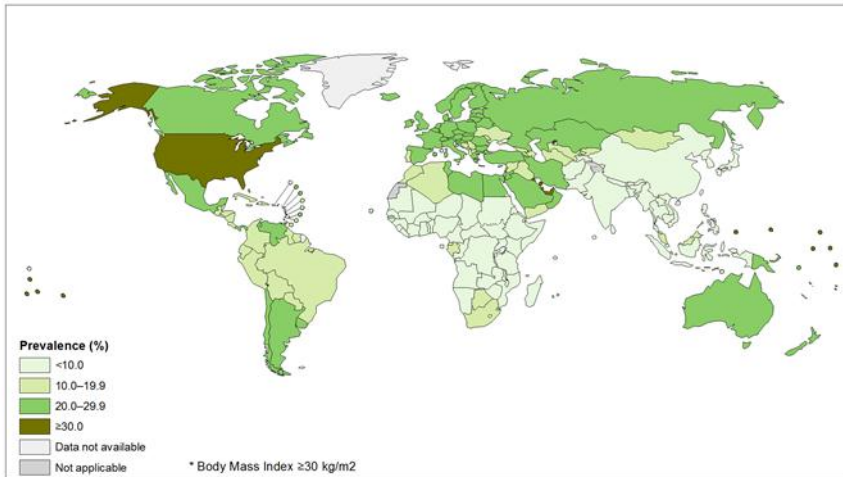
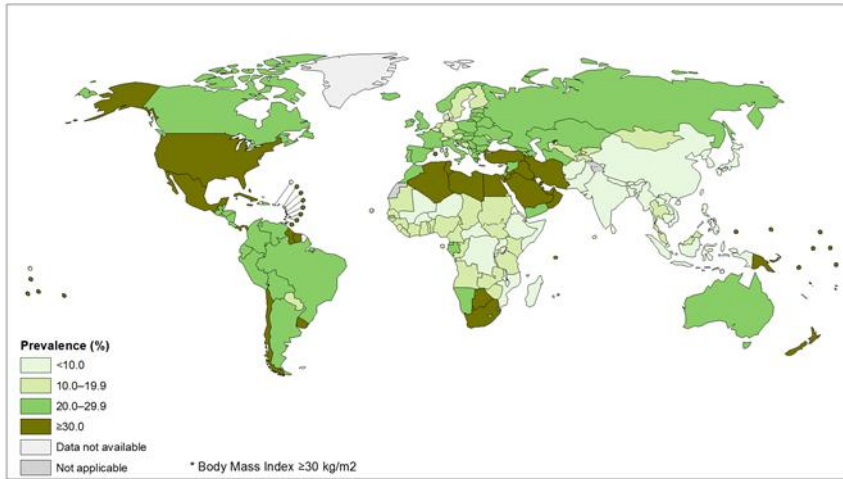


Figure 1. Worldwide prevalence of obesity in 2014 (WHO). Upper figure representing women, and lower figure representing men. Reproduced with permission of the WHO

1.3 Stigmatization, quality of life and risk factors

As early as in medieval times obesity was stigmatized in both the Buddhist and the Christian contexts¹⁹. Buddhists considered obesity to be a consequence of moral weakness in a former life. In present times, obesity is associated with failure, poor character, laziness, low intelligence, poor hygiene and social dysfunction²⁰⁻²². An American study demonstrated in the 1960s²³ that even six year old children have prejudices against obese counterparts, and this is further confirmed in a more recent Swedish study of ten-year-olds²⁴. Obesity was characterized by negative adjectives such as slow, lazy, lonely and different, but also by positive attributes such as kind and joyful. Latner et al.²⁵ demonstrate that children's stigma against obesity has not changed since the 1960s.

Obesity often has a negative impact on quality of life in both physical and psychical perspectives, and the prejudices against overweight and obesity can result in vast personal distress and feelings of shame^{20-22, 26}. Obese people have an explicit poorer quality of life compared to the general population, and obese people tend to estimate their quality of life as low as persons with spinal cord injuries, severe chronic pain or cancer survivors²⁷.

In 2010, overweight and obesity were estimated to cause 3.4 million deaths worldwide²⁸. Obesity is strongly associated with several major health risk factors such as diabetes, cardiovascular diseases,^{3, 29-31} certain cancers^{32, 33} and premature mortality^{30, 34-36}. For instance, in people with a BMI > 35 kg/m², excess weight is related to a substantial decrease in life expectancy^{37, 38}.

Obesity is also associated with infertility and, if a woman is pregnant, with a higher risk of adverse pregnancy outcomes^{39, 40}, sleep apnea⁴¹, gallbladder disease^{31, 42} and joint and muscular pain⁴³. The prevalence of having two or more health conditions increased with greater weight³¹.

1.4 Treatment of obesity

Compared to conventional therapy, bariatric surgery provides long-term weight loss in the treatment of severe obesity⁴⁴⁻⁴⁶. In the large Swedish Obese Subjects (SOS) trial, data concerning weight changes show that the average weight change in the non treated control group remained within $\pm 3\%$ over the entire observation period. Mean weight loss in the surgery subgroups was maximal after one to two years and the mean weight loss in patients who had had a GBP was 32%. Weight increased in all surgery subgroups, although the weight increase curves declined after eight to ten years⁴⁷.

Numerous studies present co morbidity resolution or improvements following bariatric surgery. Bariatric surgery results in improvements of type 2 diabetes and a majority of the patients obtain complete remission⁴⁸⁻⁵⁰. Surgery is furthermore associated with reduced numbers of cardiovascular deaths and lower incidence of cardiovascular events in obese adults^{51, 52}. The risk of cancer is reduced in obese women but not in obese men⁵³⁻⁵⁵, and bariatric surgery is associated with a reduction in overall mortality⁵⁶⁻⁵⁸.

A moderate but sustained weight reduction can prevent the progression and even cure sleep apnea in obese patients⁵⁹, and both joint and muscular pain is improved⁴³. Long-lasting weight reduction in the severely obese is furthermore associated with significant improvements in quality of life⁶⁰⁻⁶³, with peak improvements in the first year after surgery and the greater the weight loss, the better quality of life⁶⁰.

1.4.1 Operation methods

The first known surgical procedure aimed at reducing body weight was performed in Sweden in 1952 by Victor Henrikson. In 1954 the first real obesity surgery was performed in the United States and gastric restrictive procedures, such as Gastric bypass, were developed in 1967. In 1969 Sweden was the first country in Europe, and the fourth country in the world, to perform obesity surgery as a regular practice⁶⁴. The modern version of Gastric bypass is made with a laparoscopic technique and is often referred to as the “gold standard” in bariatric surgery⁶⁵. In 2011 almost 350,000 bariatric procedures were performed worldwide and the most commonly performed procedure was Roux-en-Y Gastric bypass (RYGBP), which accounted for 46.6 % of the procedures⁶⁶. Corresponding figures for Sweden in 2013 were 7700 bariatric procedures of which 92 % were RYGBP. During 2014, the proportion of RYGBP in Sweden somewhat declined while operations with Sleeve Gastrectomy (SG) increased. The total number of bariatric procedures in Sweden is also slightly decreasing⁶⁷.

Gastric bypass: The Roux-en-Y procedure induces partition of the upper part of the stomach using surgical staples to create a small pouch (50 ml or less) with a small outlet (gastroenterostomy stoma) to the intestine that is attached to the pouch⁴⁶. The mechanism of action in RYGBP is complex, and it includes changes in several systems regulating appetite and energy expenditure (Figure 2).

Duodenal Switch: The standard procedure involves the removal of part of the stomach (a limited horizontal gastrectomy) to limit oral intake and induce weight loss. Part of the small intestine is also bypassed (the malabsorptive component) by the construction of a long limb Roux-en-Y anastomosis with a short common ‘alimentary’ channel of 50 cm in length⁴⁶ (Figure 2).

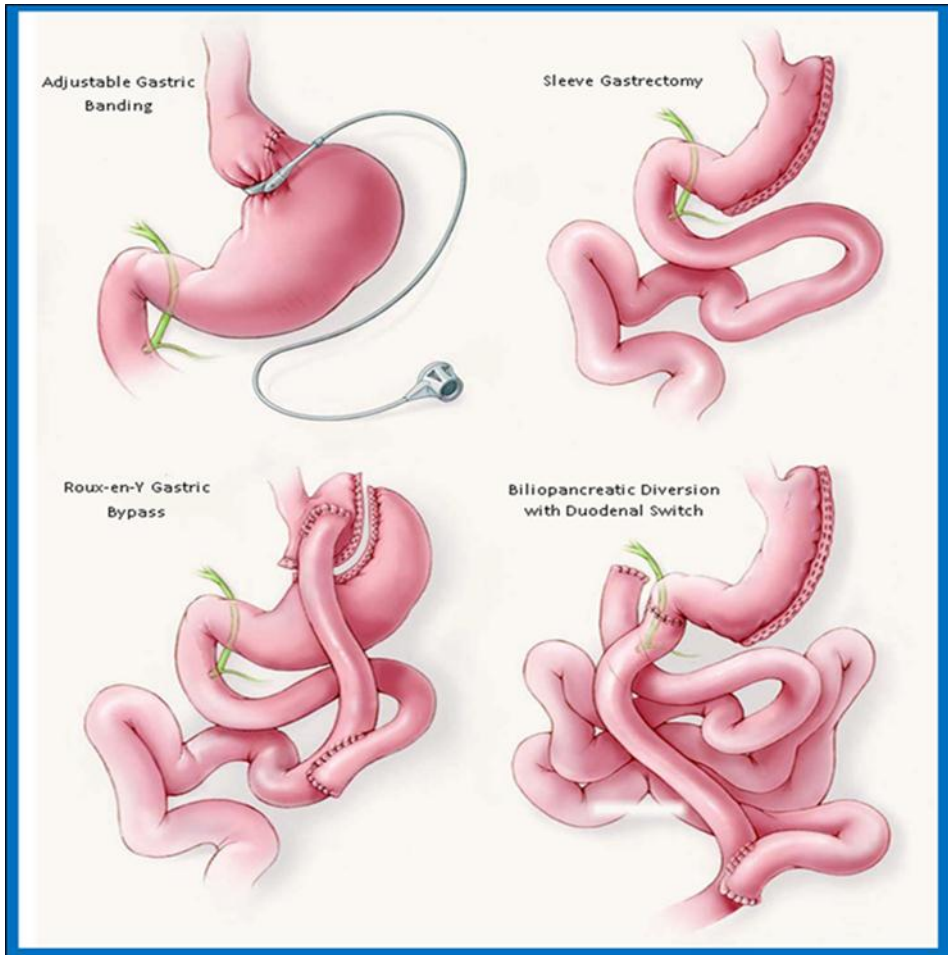


Figure 2. The most common bariatric surgery techniques. Reproduced with permission of the author⁶⁸ Copyright Massachusetts Medical Society⁶⁹

1.5 Excess skin

Excess skin is an undervalued negative effect of the massive weight loss following bariatric surgery. Even though there is prior knowledge, there is a lack of research in certain aspects of the complex problem of excess skin.

1.5.1 Previous research in the area of excess skin after bariatric surgery

In a historical perspective, abdominal lipectomy was first described and performed more than 100 years ago and was initially used for functional repairs. In 1910, Kelly⁷⁰ reported several benefits of abdominoplasty, such as improved wellbeing, reduction of back pain, increased level of physical activity and better personal hygiene. Later, in 1967, Pitanguy began to use abdominoplasty for cosmetic purposes⁷¹. When the number of bariatric procedures increased in the 1960s and '70s, research in post bariatric patients' experiences of excess skin became more common. In 1975, Palmer et al.⁷² described that "the loss of skin elasticity of the slimming patient leads to a 'redundant skin syndrome' creating dermatologic-cosmetic as well as psychiatric problems"⁷². In addition, in 1979, Shons⁷³ argued that patients who have sustained excess skin after massive weight loss should be informed of the possibilities of reconstructive plastic surgery and stated that the very real risks of the operative procedures, which are quite significant, must be understood⁷³. In 1987, Lanier⁷⁴ reported that 82 % of the patients who had undergone reconstructive surgery believed that the surgical results improved their self-esteem.

Various aspects of excess skin have been investigated during the last decade and some of the results are presented under the following themes:

- Consequences of excess skin
- Post bariatric plastic surgery
- Effects from post bariatric plastic surgery
- Complications from post bariatric plastic surgery
- Patient selection
- Questionnaires/Classifications assessing excess skin in post bariatric patients

1.5.2 Consequences of excess skin

Consistent studies have reported that excess skin is most commonly located on the abdomen, upper arms, inner thighs and breast⁷⁵⁻⁷⁹ but also on the cheeks, the back and over the knees⁷⁵ (Figure 3). Patients with a higher preoperative BMI and a greater weight loss are more likely to experience problems with excess skin⁸⁰ and women report discomfort from excess skin to a larger extent than men^{75, 76, 79, 80}. Furthermore, adolescent boys and girls who had undergone bariatric surgery also reported severe problems due to excess skin. Male adolescents reported significantly more problems than the male adult comparison group, while there was almost no difference between girls' and women's experiences⁷⁸.



Figure 3. Photo of a post bariatric patient illustrating excess skin. Forty- eight year old woman with a weight loss of 79 kg. Current BMI, 29.3 kg/m².

The excess skin is described in different terms as “wrinkly”, “hanging” and “loose” and the appearance caused by excess skin is described as “ugly” and “disgusting”⁸¹ and patients have likewise described being ashamed and embarrassed by their appearance⁷⁵. Insight into the magnitude of the problem for some patients is afforded by the qualitative exploration conducted by Klassen et al.⁸¹, wherein a number of participants stated that they actually preferred the appearance of their body before weight loss, when “at least the skin was smoothed out by fat”.

After weight loss, many participants were particularly concerned about the appearance of excess skin on the abdomen and upper arms and they chose clothing that would conceal the excess skin⁸¹. Some patients chose not to wear certain types of clothing, particularly bathing suits, short-sleeve shirts, and shorts, because it was difficult to hide the excess skin in such clothes^{75, 81}. Furthermore, many described how they had to buy clothes that were several sizes too large; for example the trousers had to be large around the waist because of the excess skin while the legs had become thinner. Many women described how they had to “roll” their breasts into the bra in order to get a good shape⁷⁵.

Patients have also described people staring and pointing at them, with several others reporting that having excess skin was more difficult and embarrassing than being obese had been⁷⁵. Gilmartin et al.⁸² concluded that post bariatric patients often feel like they are under investigation and do not fit into society’s normative rules, receiving constant reminders of their size and shape through the social environment and being marginalized in society. Furthermore, Groven et al.⁸³ described a huge contrast between patients’ experience of bad-smelling folds of skin that wobbled, sweated and irritated at the smallest movement, batwing arms, thick flabby thighs and sagging breasts and the positive response they received to their changed body shape when they had their clothes on.

About 40 % of post bariatric patients report that the excess skin causes problems with fungal infections, eczema and lesions below the abdomen, the breasts or chest, and/or in the groins, causing bad odor, itching, perspiration and problems with personal hygiene^{75, 84}.

Excess skin is further reported as being a hindrance, affecting intimacy and sexual relationships^{75, 81, 82}. Gilmartin⁸² reports that patients implied that sexual problems led to the breakdown of relationships, feelings of failure, depression and loneliness, with a consequential decline in quality of life. Groven⁸³ describes that women perceived the excess skin as something non-personal, something that no longer belonged to them. For most participants, the ugly body image impacted their self-esteem, promoting mood swings, severe body hatred and depression⁸².

Despite losing a massive amount of weight, patients are limited in their ability to participate in physical activities and the excess skin can further prevent them from engaging in certain interests and social events^{75, 81, 82, 84, 85}. According to results presented by Baillot et al.⁸⁵, 77 % of female post bariatric patients stated that they had mobility limitations due to excess skin when they were physically active or when they practiced sports. Excess skin on the abdomen was experienced as the most limiting, followed by excess skin on the upper arms and inner thighs. The movements that were most difficult to perform because of excess skin were walking (abdomen and thighs), running (abdomen) and bending (abdomen)⁸⁵.

1.5.3 Post bariatric plastic surgery

The vast majority of patients who have undergone bariatric surgery report excess skin. In a study by Björserud et al.⁷⁵, 84 % of the patients described problems with excess skin, and in other studies the corresponding figures are 90 % or more^{84, 86}. It is not possible to address the excess skin with exercise, diet or any creams. The only efficient intervention for removing this extra tissue is reconstructive plastic surgery⁸⁷. Various studies report that between 68 and 90 % of the post bariatric patients desired additional reconstructive surgery^{77, 84, 86, 88, 89}, and the equivalent figure for adolescents was 88 %⁷⁸.

Of the patients who had not previously undergone any reconstructive surgery, 62 % wanted body contouring surgery at two or more body parts⁷⁶ and further studies confirm that patients desire plastic surgery on more than just one body part^{78, 88, 90}. However, only about 20 % of the patients actually get the possibility to undergo these procedures^{79, 89}.

Information on body appearance and excess skin after massive weight loss probably varies quite a lot. In a study by Aldaqal et al.⁸⁴, about 80 % of the patients reported that they were aware of the possibility of getting excess skin before the weight loss surgery⁸⁴. Klassen et al.⁸¹ describe that the possibility of having loose, baggy skin after weight loss was of such concern to some patients that they would not have had the bariatric surgery if additional body contouring surgery was not possible.

Wagenblast et al.⁷⁷ have shown that the demand for reconstructive surgery has no correlation to age, gender or smoking habits. In contrast, Giordano et al.⁸⁸ demonstrate that patients > 50 years of age and > 3 years since surgery had a lesser desire for additional surgery. Furthermore, patients with a weight loss > 50 kg showed a significantly stronger overall desire for body contouring surgery compared to those with a minor weight loss.

The most common areas of concern for body contouring surgery were the abdomen/waist, breast, arms and thighs in both sexes^{76, 84, 88, 89}. Reconstructive surgery on the abdomen is the most common procedure followed by breast reductions and reconstructive surgery on thighs and arms^{84, 90, 91}. Improved appearance, improved self-confidence and improved quality of life are the most important expectations of the body contouring procedures^{77, 79, 81, 86}. Additional expectations were to be able to find better tailored clothes, better mobility and reduced rashes and itching. More women than men expected to achieve a better cosmetic appearance and to be able to find better tailored clothes after body contouring surgery⁷⁹.

1.5.4 Effects of post bariatric plastic surgery

At the beginning of the 20th century, Bolton et al.⁹² reported that body image dissatisfaction was improved after post bariatric plastic surgery and patients were more pleased with their weight after abdominoplasty even if it was the same as before the surgery.

In 2006, Song et al.⁹³ reported that post bariatric patients' self-perception of their current appearance improved significantly with body contouring procedures and, two years later, Cintra et al.⁹⁴ reported that 94 % of the patients were happy with their new body figure and silhouette, as concerns the abdomen and buttocks after plastic surgery. Further studies confirm these results. Post bariatric body contouring procedures generate improvements in self-esteem, social life, work ability, sexual activity and physical activity^{92, 93, 95-98}. These improvements in quality of life are furthermore presented to be stable over time^{95, 99}.

Post bariatric surgery patients who underwent body contouring surgery reported significantly better physical functioning compared to post bariatric surgery patients without this additional reconstructive surgery⁹⁸. Moreover, a higher maximum and pre body contouring BMI were significantly related to greater improvement in functional outcomes. A total of 76 % of the patients with a post bariatric BMI greater than 35 kg/m² had functional outcome improvements compared to 40 % of patients with a BMI less than 35 kg/m²¹⁰⁰. Patients operated with body contouring surgery have furthermore been shown to present better long-term weight control after RYGBP than patients without additional plastic surgery. Beyond the second year after bariatric surgery, patients without plastic surgery started to regain weight and the weight differences between the groups became even more significant over time. The weight difference remained at least seven years after surgery¹⁰¹.

Body contouring surgery made a huge difference in participants' psychological health. However, the dramatic change in appearance that often follows weight loss and body contouring surgery created some dissonance, and it took time to adjust to the new appearance⁸¹.

1.5.5 Complications after post bariatric plastic surgery

Reconstructive surgery is associated with satisfactory aesthetic results and content patients but also with prominent scars and an increased risk of serious complications^{102, 103}. Taylor et al.¹⁰⁴ reported in 2004 that the overall complication rate was 42 %. More recent data demonstrate that the complication rate after a single procedure is about 25 – 30 %, and corresponding figures for multiple procedures are 52 - 55 %^{102, 105}. The results of a recent meta-analysis show that there is a 60 – 87 % increased risk of having a postoperative complication if the patient had lost weight after bariatric surgery compared to if the patients had problems with excess skin after weight loss brought about by changes in dietary habits or exercise¹⁰⁶. The most common complication is dehiscence, followed by seroma and cellulitis¹⁰².

1.5.6 Patient selection

The most important risk factors in reconstructive plastic surgery are maximum BMI, BMI reduction after bariatric surgery and age of the patient^{102, 107}. However, smoking is also a well-documented cause of complications in patients undergoing plastic surgery as it gives an increased risk of both wound infection and wound dehiscence¹⁰⁸. A stable weight over a period of at least three months prior to body contouring surgery was associated with a significantly lower complication rate¹⁰³. Good candidates for body contouring procedures have achieved weight loss stability, are close to their goal weight and have adequate nutrition to heal the vast surgical excisions^{87, 108}.

1.5.7 Questionnaires/classifications assessing excess skin in post bariatric patients

A number of systems for assessing excess skin in post bariatric patients have been developed. An overview of these questionnaires is presented in Table 1.

Table 1. An overview of questionnaires/classifications assessing excess skin in post bariatric patients

Questionnaire	Body part	Whole body	Patient perspective	Professional evaluation
Sahlgrenska Excess Skin Questionnaire – SESQ ¹⁰⁹		x	x	
Pittsburg Rating Scale – PRS ¹¹⁰		x		x
“An anthropometric classification of body contour deformities after massive weight loss” ¹¹¹		x		x
Post Bariatric Satisfaction Questionnaire ⁸⁹		x	x	
Post Bariatric Surgery Appearance Questionnaire ^{90 112}		x	x	
Upper arms, by El Khatib ¹¹³	x			x
Mons pubis, by El Khatib ¹¹⁴	x			x
Abdomen, by Gurunluoglu et al. ¹¹⁵	x			x
Abdomen, by Nahas ¹¹⁶	x			x

1.6 Some important concepts in developing a questionnaire regarding health status

Several aspects must be considered in the development of a questionnaire. For example, test-retest reproducibility is the degree to which an instrument yields stable scores over time among respondents who are assumed not to have changed in the domains being assessed ¹¹⁷.

Some important concepts when developing health status and quality of life, QoL, are measurements according to the Scientific Advisory Committee, SAC ¹¹⁷:

- *Reliability*. The degree to which an instrument is free from random error
- *Validity*. The degree to which the instrument measures what it purports to measure
- *Burden*. The time, effort and other demands placed on those to whom the instrument is administered (respondent burden) or on those who administer the instrument (administrative burden)

2 IMPORTANT CURRENT ISSUES RELATED TO EXCESS SKIN

Excess skin following massive weight loss was acknowledged to be a consequence of bariatric surgery as early as in the late 1960s. The research is sparse, however, and comes mainly from the plastic surgeon's perspective – investigating and reporting on different operating techniques. Contemporary research focuses more on the patients' experiences, indicating that excess skin is a major problem for many patients. Still, important perspectives about excess skin are yet unknown. The following are some current issues concerning the understanding of excess skin.

- ✓ Patients with super obesity, BMI > 50 kg/m², are increasing. However, there was no research on excess skin that focused exclusively on this group of patients, who are most likely to have severe problems with excess skin after massive weight loss.
- ✓ There was no research investigating whether there is a difference in the experience of excess skin following different bariatric procedures. This knowledge might be useful in discussions of surgical procedure.
- ✓ To investigate the subjective experience of excess skin, it is important to have reliable questionnaires. No reliability tested questionnaires with a focus on excess skin from the patient's perspective were found in the literature when these studies were planned.
- ✓ Post bariatric patients are typically considered for additional plastic surgery 18 months after bariatric surgery. However, there is little information on how the average patient appears at this time. Today's knowledge about post bariatric patients' appearance is based on those patients seeking health care, preferably those who experience problems with excess skin. A longitudinal follow-up with objective measurements would provide valuable knowledge both to the patients and to public health care.

- ✓ A longitudinal follow-up, with objective measurements both before bariatric surgery and after the weight loss in a consecutive group of patients, would provide the opportunity to make predictions of which factors influence the development of excess skin. Does the age of the patients contribute? Are gender and preoperative BMI important factors?
- ✓ Additional plastic surgery after weight loss is considered to be most important to those patients who experience problems with excess skin. There is however a lack of knowledge about the agreement between patients' subjective experiences and objective measurements of excess skin. Such knowledge would be of help when discussing plastic surgery with patients after weight loss.
- ✓ To make objective and reliable quantifications of excess skin, measurements must be based on anatomical structures not affected by body weight or weight loss. Furthermore, to assess the development of excess skin following massive weight loss, the skin and ptosis should be measured in centimetres. However, no such protocol had been identified in the literature.

3 AIM

The general aim of this thesis was to investigate the experience and the development of excess skin after massive weight loss following bariatric surgery.

3.1 Specific aims

- I. An aim was to evaluate the experience of excess skin after laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) or laparoscopic Roux-en-Y gastric bypass (RYGBP) in super obese patients and to explore possible gender differences. Another aim was to analyze possible correlations between the reported experiences of excess skin with change in weight, body mass index (BMI), and hip and waist circumference after surgery.
- II. An aim was to describe the Sahlgrenska Excess Skin Questionnaire, SESQ, and report on its reliability.
- III. The primary aim of the study was to investigate the development and degree of excess skin after massive weight loss following RYGBP and to determine which body parts and which patient subgroups are most affected. Secondary aims were: (i) to determine the discomfort of excess skin at 18 months after surgery, when body habitus is expected to have completed most of its transformation and patients would typically be considered for reconstructive surgery; and (ii) to investigate the agreement between patients' experiences of excess skin as compared to professional, objective measurements.
- IV. The aim of this trial was to evaluate the inter rater reliability of ptosis and circumference measurements in patients with excess skin after bariatric surgery.

4 PATIENTS AND METHODS

It is important to have well-described and reliable measurements to assess the complexity of excess skin after weight loss. To respond to the general aim of this thesis, we needed to investigate excess skin from different perspectives, both the patient's subjective perspective and a professional perspective with objective and reliable measurements of excess skin.

4.1 Overview of the research design and patient demographics

In total, 341 patients participated in the studies in this thesis. Twenty-five patients were included in both Paper III and Paper IV, while others were included in only one study. All had undergone bariatric surgery procedures for obesity except six patients in Paper II who had lost weight through diet or medication. An overview of the research designs in the four Papers is given in Table 2. Demographic data of the patients whose results are included in the analyses in Papers I-IV are presented in Table 3.

Table 2. Overview of the research design in paper I-IV

	Paper I	Paper II	Paper III	Paper IV
Study design	Part of a randomized control trial	Test – retest reliability	Longitudinal	Inter rater reliability
Number of participants	60	46 (test-retest) 10 (face-validity)	200	25
Data collection	Self administered questionnaire and circumference measurements	Self administered questionnaire	Self administered questionnaires and measurements of excess skin	Measurements of excess skin

Table 3. Demographics of the patients whose results are included in the analyses in Papers I-IV

	Paper I n = 60	Paper II, test-retest n = 46	Paper III n = 200	Paper IV n = 25
Analyzed/lost to follow-up, n	57/3	38/8	149/51	25/0
Sex n (%)				
Female	42 (74)	29 (76)	109 (73)	18 (72)
Male	15 (26)	9 (24)	40 (27)	7 (28)
Age (years)	35.7 (6.3)	41.9 (9.3)	44.6 (11.5)	42.4 (10.2)
Height (m)	1.70 (0.10)	1.70 (0.10)	1.70 (0.09)	1.70 (0.09)
Weight (kg) Before weight loss	160.0 (19.8)	141.0 (31.0)	129.7 (22.6)	129.4 (20.4)
BMI (kg/m ²) Before weight loss	55.0 (3.4)	48.9 (9.4)	45.0 (5.6)	44.7 (4.8)
Weight (kg) After weight loss	98.8 (18.6)	88.0 (18.0)	89.0 (18.4)	84.8 (18.4)
BMI (kg/m ²) After weight loss	34.0 (5.2)	30.2 (5.4)	30.8 (5.3)	29.1 (4.5)

4.1.1 Health Related Quality of Life

In Paper III, as part of the patients' demographics, SF-36 and EQ-5D are given before surgery and after weight loss. There were significant improvements in the EQ-5D Index Score and EQ-5D VAS in both women and men between the pre operative assessment and the 18-month follow-up. However, there were no significant differences between the genders except that women scored significantly lower on the EQ-5D VAS before surgery as compared to the men.

There were also significant improvements concerning SF-36 in both women and men regarding the physical composite score after weight loss. However, no corresponding significant improvements were found for the mental composite score. Compared to the men, women scored significantly lower on the physical composite score before surgery.

4.2 Participants

Paper I

Paper I is part of a Scandinavian trial conducted in two different hospitals, Sahlgrenska University Hospital in Gothenburg, Sweden, and Oslo University Hospital Aker in Oslo, Norway^{118, 119}. It is a randomized control trial; the Aker Sahlgrenska Gastric Bypass and Duodenal Switch study, ASGARD, and inclusion criteria were BMI 50–60 kg/m², age 20–50 years and previous failed attempts at weight loss. In total, 60 patients were included in the trial, of whom 31 underwent laparoscopic Gastric Bypass, RYGBP, and 29 laparoscopic Biliopancreatic Diversion with Duodenal Switch, BPD/DS. The primary outcome was change in BMI two years after the bariatric procedure and secondary endpoints included changes in comorbidity, quality of life and gastrointestinal function. Another secondary endpoint was the patients' experience of excess skin after surgery, which is the focus of Paper I. Fifty-seven of the patients (30 RYGBP and 27 BPD/DS) were included in Paper I.

Paper II

Patients in Paper II were recruited from the Department of Surgery and the Department of Plastic Surgery at Sahlgrenska University Hospital. The questionnaire Sahlgrenska Excess Skin Questionnaire, SESQ, was sent to 46 patients and 38 (83 %) returned the questionnaire twice. Thirty-two patients had undergone bariatric surgery procedures and six patients were recruited from the waiting list for reconstructive surgery after major weight loss by diet or medication. In addition, ten other post bariatric patients, five Swedes and five Englishmen, did the face validity test of the SESQ.

Paper III

Two hundred patients were included in Paper III during May 2009 to December 2011. All were on the waiting list for RYGBP at Sahlgrenska University Hospital or at Carlanderska Hospital in Gothenburg, Sweden. During the inclusion period, a further 153 patients were operated with RYGBP at Sahlgrenska University Hospital but were not invited to participate for logistic reasons. No significant differences were observed between those included and those not included concerning gender ($p = 0.53$), age ($p = 0.65$) or preoperative BMI ($p = 0.19$). Inclusion criteria were BMI $> 35 \text{ kg/m}^2$, no untreated mental illness and no ongoing alcohol or drug abuse. Patients were furthermore required to understand and speak Swedish. Patients with any vertical scars on the abdomen were excluded.

Prior to surgery and approximately 18 months after surgery, the patients met a specialist nurse or a specialist physiotherapist who measured excess skin on body parts according to a standardized protocol.

Paper IV

Twenty-five of the patients who participated in the postoperative visit reported in Paper III were included in the evaluation of the inter rater reliability of the measuring protocol reported in Paper IV.

4.3 Methods of data collection

Paper I

At the follow-ups one and two years after surgery, patients were asked to fill out a specific questionnaire concerning the experience of excess skin in different body parts and how much discomfort it caused. The questionnaire covered the body parts previously identified⁷⁵ and known to be frequently troubled with excess skin. However, since the reliability tested version of SESQ was not complete, the questionnaire used in this study was an incomplete version that lacked part II, which assesses symptoms from excess skin.

For each specific body part, the patients were asked to score their experience of excess skin on a 5-grade Likert scale ranging from “no” (0) to “very much” (4) excess skin. In addition, they estimated the degree of discomfort of excess skin for each body part on a 100-mm visual analogue scale with the endpoints “no inconvenience at all” (0 mm) to “worst conceivable inconvenience” (100 mm). Open questions linked to each specific body parts examined what difficulties the excess skin caused and whether it involved any restrictions in daily life. Weight and hip/waist circumference were measured at the same occasions according to established standards¹²⁰.

Paper II

The Sahlgrenska Excess Skin Questionnaire, SESQ, aims to investigate excess skin on different body parts from the patients’ perspective. SESQ is based on previous knowledge⁷⁵ and clinical practice. A test – retest was performed to test the reliability of the questionnaire.

The SESQ was developed at Sahlgrenska University Hospital in Gothenburg, Sweden, during 2009- 2010. It consists of three different parts (Table 4). Part I comprises questions concerning general information and demographic data. Part II assesses symptoms caused by excess skin and part III includes questions on experience of amount and degree of discomfort caused by excess skin on different body parts. Part III furthermore asks about the desire for additional plastic surgery.

Part I and II is based on a questionnaire used in clinical practice at the Department of Plastic Surgery at Sahlgrenska University Hospital and part III is based on post bariatric patients' experiences of excess skin⁷⁵. Without the external influence of explicit response alternatives, patients were allowed to mark frontal and dorsal excess skin formation on a plain sketch (Figure 4).

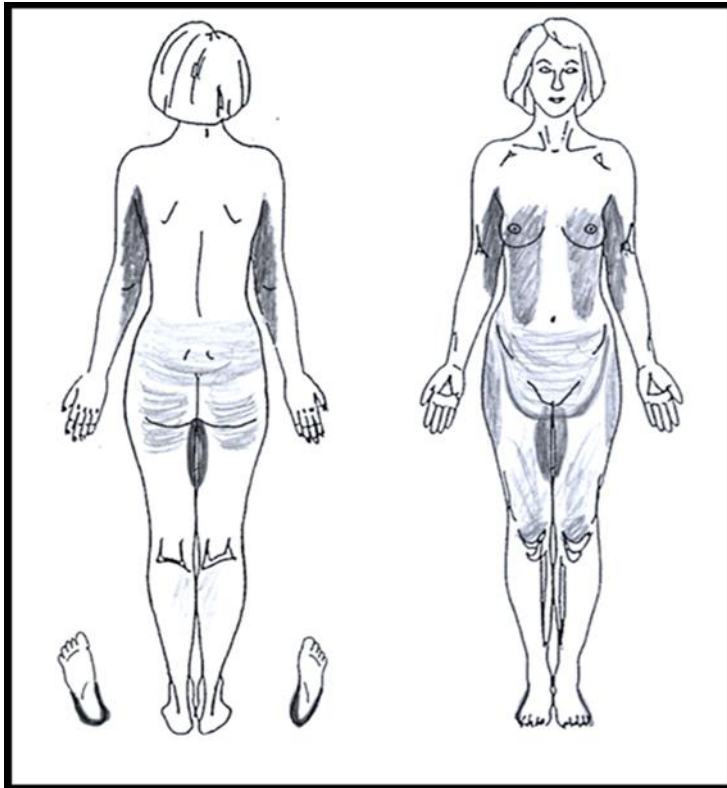


Figure 4. Representative schematic illustration of excess skin formation, following bariatric surgery

Table 4. Sahlgrenska Excess Skin Questionnaire, SESQ

Part	Number of questions	Type of questions/statements	Examples of questions/statements
I	7	General information/demographic data	<ul style="list-style-type: none"> - Age - Weight / Height - Time since bariatric surgery
II	10	Assessment of symptoms caused by excess skin. Rating on a 5-grade scale from “all the time” to “never”	<ul style="list-style-type: none"> - “I have itching and rash due to the excess skin” - “The excess skin makes it difficult for me to participate in sports” - “My body is unattractive because of the excess skin”
III	9	<p>Combined questions about the experience of excess skin on different body parts</p> <p>Amount is rated on a 5-grade scale from “no” to “very much”</p> <p>Degree of discomfort is rated on an 11-grade scale from “no problems” to “worst possible problems”</p>	<ul style="list-style-type: none"> - Upper arms - Stomach - Breasts/bust - Chin - Bottom - Back - Inside of the thigh - Outside of the thigh - Knees
	1	One summary question	<ul style="list-style-type: none"> - “Do you have excess skin on <u>one or more parts of your body</u>?”
	2	Desire for plastic surgery	<ul style="list-style-type: none"> - “If you are bothered by excess skin – have you considered plastic surgery?” - “<u>I</u>f you have considered plastic surgery, which part(s) of your body would you want operated?”

The SESQ was translated into English according to Principles of Good Practice (PGP) presented by Wild et al.¹²¹:

- *Forward translation*: Two professional interpreters, one born in England and the other born in Sweden, made the forward translation.
- *Reconciliation*: To resolve discrepancies, a pooled version was set together.
- *Back translation*: To demonstrate that the quality of translation was such that the same meaning was derived when the translation was moved back into the source language, a back translation into Swedish was performed.
- *Harmonization*: The Swedish version was compared with the English version, and minor adjustments were made to both versions.

Five Swedes and five Englishmen with excess skin answered the questionnaire and were asked face-to-face about the questions to confirm validity. Furthermore, face validity was performed with experienced plastic surgeons skilled in meetings with post bariatric patients and their desires. The questionnaire was then adjusted according to the suggestions and an additional language check was made.

A test – retest was carried out to test the reliability and reproducibility. Forty-six patients answered the questionnaire and received the SESQ once again after approximately two weeks. One reminder was sent out and 38 (83 %) patients answered the questionnaire twice.

Paper III

Two hundred patients were measured according to a standardized measuring protocol at their preoperative visit or when they were admitted for surgery at the Department of Surgery, Sahlgrenska University Hospital. Nine of the 200 patients were excluded from the study, eight patients did not undergo RYGBP and one patient was wrongly included as she had a vertical scar on the abdomen. An 18-month follow-up visit after surgery was completed in 149 patients (78 %) (Figure 5). There were no significant differences between patients who came to the follow-up visit and those lost to follow-up with regard to gender ($p = 0.59$), age ($p = 0.97$), preoperative BMI ($p = 0.36$), waist circumference ($p = 0.86$) or ptosis on the abdomen ($p = 0.92$).

At the pre operative visit and at the follow-up, the patients met a specialist nurse or a specialist physiotherapist who measured circumference and excess skin according to a standardized protocol. Objective measurements were performed with ruler, tape measure and plastic bowls in different sizes in the same body parts included in the SESQ. At both occasions, patients also filled in the SESQ, EQ- 5D and SF- 36.

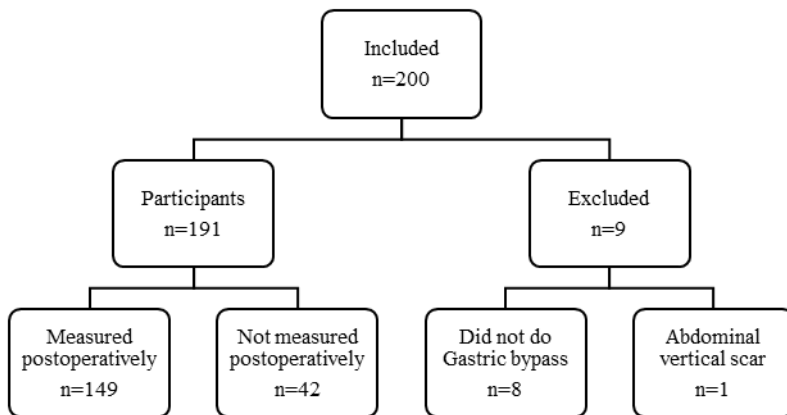


Figure 5. Flow chart of participants in Paper III

As changes in health related quality of life, HRQoL, are important aspects of the outcome from surgical procedures, the following questionnaires were added to demographics.

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

The EQ- 5D is a self-administered questionnaire, divided into two parts, that measures HRQoL. The first, descriptive, part comprises the following five dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The answers from the different dimensions can be converted into a summary index, the EQ-5D index. The second part, the EQ-5D VAS, records the patient's self-rated health on a vertical, visual analogue scale where the endpoints are labelled "best imaginable health state" (100) and "worst imaginable health state" (0)^{122, 123}.

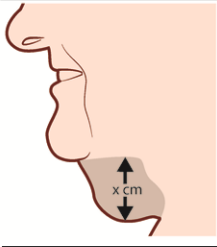
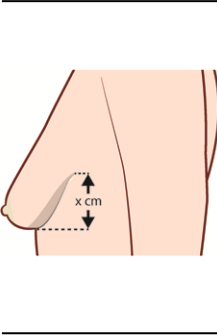
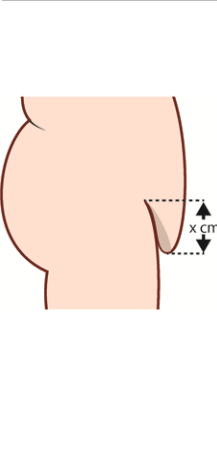
Short- Form 36 Health Survey (SF-36)

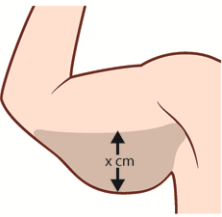
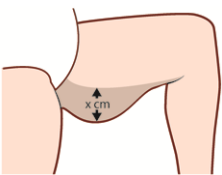
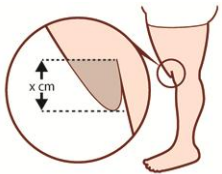
SF-36 is a self-administered questionnaire that includes 36 questions about HRQoL. It measures eight dimensions of health: physical and social functioning, physical and emotional problems (role limitations), mental health, vitality, pain and general health perception. Another aspect, not included in the previous eight dimensions, is change in health. The eight dimensions can be summarized into two comprehensive health indexes, physical health and mental health¹²⁴.

Paper IV

To evaluate the inter rater reliability of the measuring protocol used in Paper III, 25 patients were measured twice, by a specialist nurse and a specialist physiotherapist, at the postoperative assessment. Assessments were made in separate rooms and neither patient nor testers were permitted to discuss assessments or results during the test.

The following tests were undertaken with the patient standing upright, according to the standardized measuring protocol used in Papers III and IV:

	<ul style="list-style-type: none"> • <i>Chin:</i> <ul style="list-style-type: none"> - The circumference around the neck - The distance between the caudal edges of the underlying solid tissue and the caudal edge of the excess skin
	<ul style="list-style-type: none"> • <i>Breasts/chest:</i> <ul style="list-style-type: none"> - The distance between the jugulum and the mamilla (JM) - The ptosis from the submammary fold to the caudal limitation of the breast - In female participants the breast volume was measured using plastic bowls, with volumes ranging from 100 ml to 2000 ml, with the woman in a forward-leaning position
	<ul style="list-style-type: none"> • <i>Abdomen:</i> <ul style="list-style-type: none"> - Circumference at the waistline - A visual estimation of ptosis using six degrees of severity: 0 = no obvious ptosis or ptosis < 3 cm, 1 = skin hanging over the groins, 2 = skin hanging over the genitals, 3 = skin hanging part way down the thighs, 4 = skin hanging far down the thighs, 5 = skin hanging over the knees - The largest ptosis of the skin fold below the umbilicus in the midline in centimetres. If at another location, measured from the base of the fold to its caudal limitation

	<ul style="list-style-type: none"> • <i>Upper arm. With 90° arm and 90° elbow flexion:</i> <ul style="list-style-type: none"> - Loose circumference at the largest part of the arm - Firm circumference at the largest part of the arm using a measuring tape loaded with a weight of 0.5 kg - Largest amount of excess skin from the caudal edge of the muscle to the caudal edge of the skin
	<ul style="list-style-type: none"> • <i>Inner thigh. With 90° hip abduction and 90° knee flexion:</i> <ul style="list-style-type: none"> - Loose circumference at the largest part of the thigh - Firm circumference at the largest part of the thigh using a measuring tape loaded with a weight of 0.5 kg - Largest amount of excess skin from the caudal edge of the muscle to the caudal edge of the skin
	<ul style="list-style-type: none"> • <i>Buttocks:</i> <ul style="list-style-type: none"> - Distance between C7 and the caudal end of the skin fold of the buttocks
	<ul style="list-style-type: none"> • <i>Knees:</i> <ul style="list-style-type: none"> - The largest depth of the skin fold below the knee from the base of the fold to its caudal limitation - Circumference five centimetres above the patella

4.4 Statistical methods

An overview of the statistical methods used in Paper I – IV is given in Table 5.

Table 5. Statistical methods used in Papers I – IV

	Statistical methods	I	II	III	IV
Descriptive statistics	Mean, SD, median, minimum and maximum for continuous variables	x	x	x	x
	Number and (%) for categorical variables	x	x	x	x
Statistical analysis	For comparison between two groups: Mann-Whitney's U test for continuous variables	x		x	
	Mantel-Haenszel Chi Square Exact test for ordered categorical variables	x		x	
	Fisher's Exact test for dichotomous variables			x	
	For comparison within groups, over time: Wilcoxon Signed Rank test for continuous variables			x	x
	Sign test for ordered categorical variables			x	
	Percentage of Agreement, POA		x		
	Adjusted POA (± 1)		x		
	Weighted Kappa		x		
	Intra Class Correlation, ICC		x		x
	Spearman correlation coefficient	x		x	
	Regression	x		x	
	Bland - Altman plots				x

All significance tests were two-sided and conducted at the 5 % significance level.

Correlation was defined as: little, if any ($r_s < 0.25$), low (r_s 0.26-0.49), moderate (r_s 0.50-0.69), high (r_s 0.70-0.89) and very high (r_s 0.9-1.00) in Papers I and III¹²⁵. In Paper II, correlation was defined as: poor ($r_s > 0.20$), fair (r_s 0.21-0.40), moderate (r_s 0.41- 0.60), good (r_s 0.61- 0.80), and very good (r_s 0.81-1.00)¹²⁶. In Paper IV an ICC value ≥ 0.90 was regarded as high reliability, 0.80-0.89 good, 0.70-0.79 fair and ≤ 0.69 poor reliability¹²⁷.

4.5 Ethical considerations

For Paper I, the trial was approved by the local ethics committees in Sweden and Norway, and the trial was registered in Clinical Trials (NCT 00289705). In Paper II, the test - retest of the questionnaire was conducted in accordance with the ethical standards of the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. For Papers III and IV, the local ethics committee in Gothenburg, Sweden, approved the study (DNR 723-08).

Patients were provided with verbal and written information regarding the research projects. For Papers I, III and IV, each patient gave his or her written consent to participate.

5 RESULTS

The general aim of the thesis was to investigate the experience and the development of excess skin after massive weight loss following bariatric surgery. To obtain stable and consistent results, it is important to have reliable measurements. For this reason, the results of the test – retest of the SESQ (Paper II) and the inter rater reliability test of the measuring protocol (Paper IV) will be presented first. Thereafter follow the results of the patients' experiences of and discomfort caused by excess skin, the objective measurements in Paper I and Paper III and the results of the correlations and predictions.

5.1 Test – retest reliability in Paper II

The work reported in Paper II investigated the test – retest reliability of SESQ. The results are presented as the lowest and the highest Percentage Of Agreement (POA), Weighted Kappa and ICC (Table 6). SESQ is divided into three different parts. Part I comprises questions concerning demographic data. In part II, assessing symptoms from excess skin, the statement “Do you think your body is unattractive because of the excess skin?” had the highest POA (76 %) and the statement “The excess skin makes it difficult for me to find clothes that fit” had the lowest POA (46 %). In part III, investigating the experience of excess skin, the chin and abdomen had the highest POA (76 %) and the summary question about excess skin on the body as a whole had the lowest POA (50 %). In part III, which investigated discomfort from excess skin, the POA was found to be low for all body parts. Since these questions have additional response alternatives compared to the other parts of the questionnaire, an adjusted POA was used. The highest adjusted POA was found for the abdomen (87 %); the breasts had the lowest adjusted POA (63 %).

Table 6. Minimum and maximum POA, Weighted Kappa and ICC for the test- retest of SESQ

Part	POA (%)	Adjusted POA \pm 1 (%)	Weighted Kappa	ICC
II Symptoms	46-76	-	0.44-0.78	-
III Experience of excess skin	50-76	-	0.53-0.81	-
III Discomfort from excess skin	32-57	63-87		0.72-0.92

5.2 Inter rater reliability in Paper IV

No significant systematic differences between the two testers were found when testing the inter rater reliability of the measuring protocol except for measurements of the buttocks ($p = 0.0004$) and maximal knee circumference ($p = 0.0085$). Concerning the circumference measurements, the lowest mean difference between the testers was around the neck (0.07 cm) and the largest difference was around the knees (1.04 cm). For corresponding figures for the ptosis measurements, the lowest mean difference was in measuring ptosis on the chin (-0.06 cm) and the largest difference was in measuring thigh ptosis (0.58 cm).

All breast measurements in women had high reliability: maximum JM (ICC = 0.93), ptosis (ICC = 0.94) and volume (ICC = 0.97). A majority of 63 % of all the circumference and excess skin measurements had an ICC > 0.9. Except for measurements of excess skin on the chin and the buttocks, measurements had an ICC > 0.7. Table 7 presents the lowest and the highest mean differences between the two testers and the ICC for the circumference measurements, the ptosis measurements and the breast measurements.

Table 7. Minimum and maximum mean difference between Tester 1 and Tester 2 and ICC for the measuring protocol

	Difference between Tester 1 – Tester 2	ICC
Circumference measurements (cm)	0.07-1.04	0.82-0.98
Excess skin and ptosis measurements (cm)	-0.06-0.58	0.69-0.91
Breast measurements	-	0.93-0.97
Buttocks measurement (cm)	-2.50	0.60
Visual abdominal ptosis (cm)	-0.14	0.46

The inter rater differences in relation to the means of the measurements of the two testers are described as Bland - Altman plots for abdominal ptosis (I), visible abdominal ptosis (II), excess skin on upper arms (III) and excess skin on thighs (IV) (Figure 6).

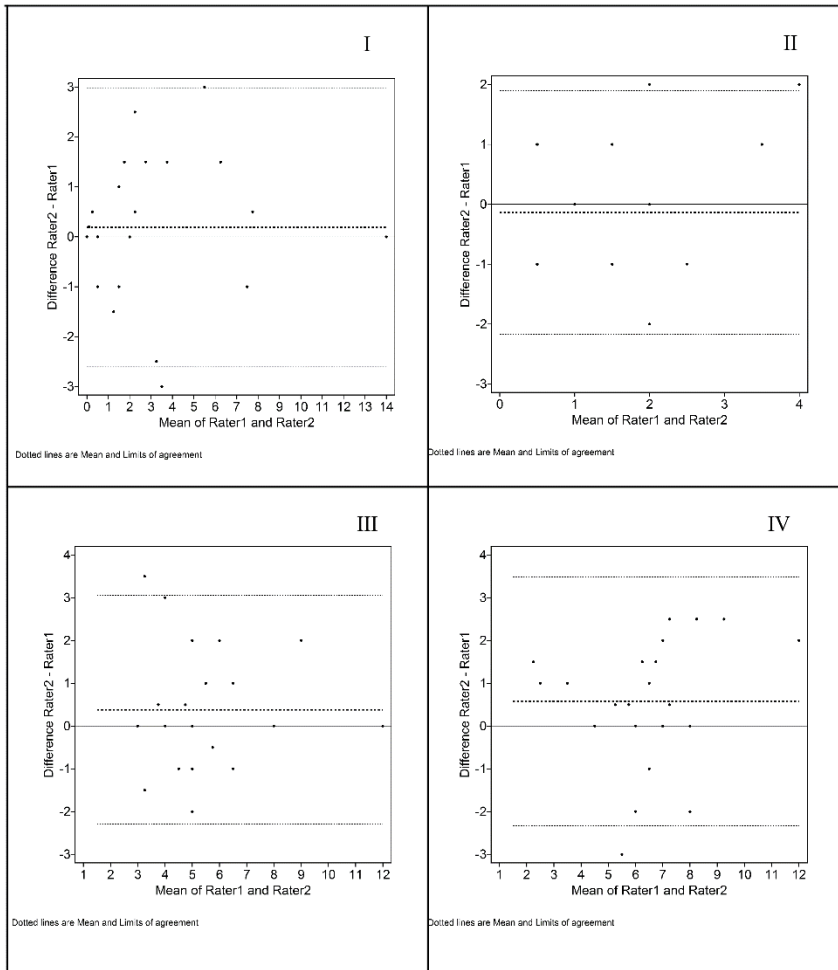


Figure 6. Bland - Altman plots. Dotted lines are mean and Limits of Agreement

5.3 Patients' experiences of excess skin in Papers I and III

The presentation and comparison of the experienced amount and discomfort from excess skin on the upper arms, abdomen and thighs between patients in Paper I and Paper III are presented in Table 8.

Table 8. Presentation and comparison of experienced amount and discomfort from excess skin in Paper I and Paper III

Variable		Paper I 1 yr post op (n=57)	Paper I 2 yr post op (n=57)	Paper III post op (n=149)	Paper I 1yr post op vs Paper III post op	Paper I 2yr post op vs Paper III post op
Upper arms						
Experience	No	3 (5.8%)	5 (10.0%)	7 (6.6%)	0.0067	0.0845
	A little	14 (26.9%)	12 (24.0%)	39 (36.8%)		
	Quite a lot	8 (15.4%)	9 (18.0%)	34 (32.1%)		
	A lot	11 (21.2%)	14 (28.0%)	12 (11.3%)		
	Very much	16 (30.8%)	10 (20.0%)	14 (13.2%)		
Discomfort	1-10	5.60 (3.21) 6 (0; 10)	5.04 (3.64) 5 (0; 10)	4.10 (3.11) 4 (0; 10)	0.0079	0.1327
Abdomen						
Experience	No	4 (7.7%)	1 (2.0%)	3 (2.9%)	0.0470	0.0014
	A little	6 (11.5%)	6 (12.0%)	19 (18.4%)		
	Quite a lot	9 (17.3%)	8 (16.0%)	32 (31.1%)		
	A lot	11 (21.2%)	12 (24.0%)	33 (32.0%)		
	Very much	22 (42.3%)	23 (46.0%)	16 (15.5%)		
Discomfort	1-10	6.35 (3.37) 8 (0; 10)	7.60 (2.72) 9 (0; 10)	6.11 (3.04) 7 (0; 10)	0.4077	0.0016
Inner thigh						
Experience	No	5 (9.6%)	2 (4.1%)	7 (6.8%)	0.0009	0.0007
	A little	7 (13.5%)	11 (22.4%)	41 (39.8%)		
	Quite a lot	13 (25.0%)	8 (16.3%)	28 (27.2%)		
	A lot	9 (17.3%)	15 (30.6%)	16 (15.5%)		
	Very much	18 (34.6%)	13 (26.5%)	11 (10.7%)		
Discomfort	1-10	5.59 (4.05) 6 (0; 10)	5.69 (3.87) 8 (0; 10)	4.31 (3.19) 4 (0; 10)	0.0561	0.0307

5.3.1 Symptoms from excess skin

Women and men reported symptoms from excess skin before bariatric surgery as well as after the weight loss. Paper III reported one significant difference between the genders concerning the evaluation of symptoms caused by excess skin after weight loss, i.e. men reported improvement for the statement “difficulties doing sports”. In addition, in terms of gender, women reported a significant deterioration for the statements “itching and rash” and “hindrance in intimate situation” due to excess skin after weight loss.

5.3.2 Amount of excess skin

Comparing the amount of excess skin experienced in the study reported in Paper I, the patients with the greatest weight loss, the BPD/DS group, experienced significantly more excess skin on several body parts. One year after surgery, those patients experienced more excess skin on the upper arms, the abdomen, the buttocks and the inside and outside of the thighs compared to patients in the RYGBP group. After two years, the only remaining significant difference was that the patients in the BPD/DS group experienced more excess skin on the buttocks. Similar results were obtained after adjustment for pre operative BMI and sex.

At the one-year follow up visit reported in Paper I women experienced significantly more excess skin on the upper arms, breast, thigh and buttocks compared to the men. At the two-year follow-up, the only significant difference between men and women was that women still experienced more excess skin on the upper arms. In contrast, there were no significant differences between the genders experience of excess skin in Paper III. However, women reported significantly more excess skin on the upper arms, breasts and on thighs, while the men reported significantly more excess skin on the upper arms in comparison to before weight loss.

5.3.3 Discomfort from excess skin

In Paper I, patients operated with RYGBP and BPD/DS experienced the most discomfort from excess skin on the same four body parts: the upper arms, abdomen, inside thighs and breasts (Figure 7). There were no significant differences between the groups, and the figures were approximately the same after two years. When assessing the difference in discomfort from excess skin on body parts pre and postoperatively in Paper III, there were no significant differences between the genders (Figure 8). However, there were significant differences from the preoperative assessment to the postoperative assessment within the genders.

Before surgery, the women investigated in Paper III reported significantly more discomfort from excess skin on the upper arms and abdomen than the men. At the one-year follow-up visit in Paper I and at the post operative visit in Paper III, women reported significantly more discomfort in the upper arms and the inside and outside thigh and knees as compared to the men. In addition, the women in Paper III also reported significantly more discomfort in the abdomen, buttocks and back compared to the men after weight loss. At the two-year follow-up in Paper I there remained a significant difference between the genders regarding the upper arms and inside thigh.

A summary of the open questions in Paper I revealed that excess skin caused intertriginous problems, such as fungus and eczema. The skin was heavy, which caused pain and hindered physical activity. It was also a psychocosmetic problem. Excess skin on the chin caused a wrinkled and elderly appearance. The overall comprehension was that excess skin made it complicated to find clothes. In general, excess skin was perceived as ugly and unattractive; the patients felt embarrassed and most of them preferred not to appear in public areas, such as public baths, or in certain clothes.

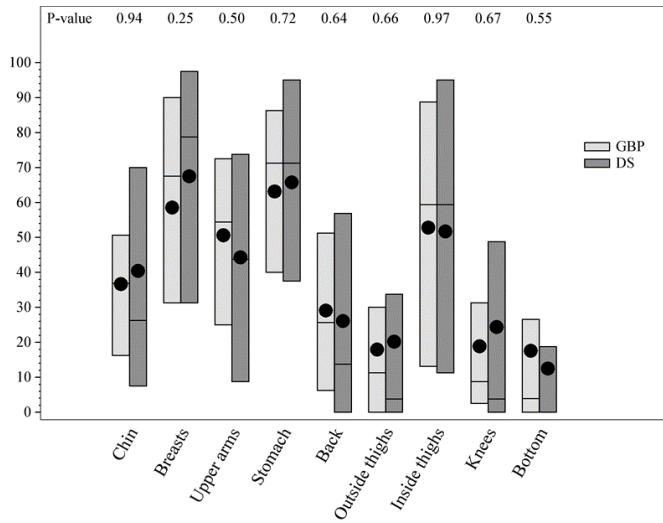


Figure 7. Assessment of discomfort from excess skin on body parts one year after gastric bypass or duodenal switch, Paper I. Box edges are Q1 and Q3, horizontal line is median and large dot is mean. P-values are given for analysis of difference between operation methods.

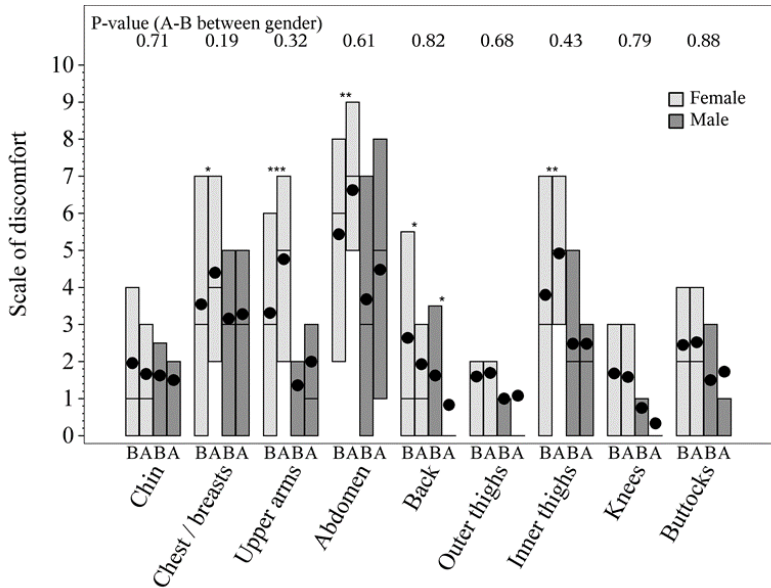


Figure 8. Assessment of difference in discomfort from excess skin on body parts pre (B) and postoperatively (A) by gender, Paper III. Box edges are Q1 and Q3, horizontal line is median and large dot is mean. P-values are given for analysis of change between genders.

5.4 Objective measurements in paper III

The differences in objective measurements from the preoperative visit to the 18-month follow-up are presented in Table 9. The table presents the mean difference for all patients, as well as the mean difference when the patients are divided into groups with $\Delta \text{BMI} < 20 \text{ kg/m}^2$ and $\Delta \text{BMI} > 20 \text{ kg/m}^2$.

The circumference measurements had decreased significantly between the two occasions in all patients. The only significant difference between the genders was that women showed a greater reduction in thigh circumference compared to the men (right thigh $p = 0.0002$, left thigh $p < 0.0001$). Furthermore, all ptosis measurements decreased after weight reduction due to surgery except for the ptosis on the thighs, which had increased significantly.

When the patients are divided into groups according to ΔBMI , the group with the greater weight loss had a significantly higher decrease in circumference measurements at the waist, arms and thighs, except for right thigh, where the difference was not significant. There was also a significant reduction in breast volume; the women with the largest weight loss had lost most, in average one litre of breast tissue from each breast. There were no significant differences concerning ptosis on any body part.

Table 9. Change in objective measurements from the preoperative visit to the 18 – month follow up

Variable	All		Delta BMI > 20		Delta BMI < 20		p-value between groups
	Change Pre-postop Mean (SD)/ Median(min; max)	p-value within group	Mean (SD)	p-value within group	Mean (SD)	p-value within group	
Chin/neck circumference (cm)	-5.05 (2.32) -5.0 (-12.0; 3.0)	<.0001	-6.50 (2.99)	<.0001	-4.82 (2.19)	<.0001	0.006
Chin ptosis (cm)	-0.058 (0.970) 0.0 (-3.0; 3.0)	0.31	0.156 (0.676)	0.36	-0.069 (1.013)	0.27	0.31
Waist, circumference (cm)	-25.9 (10.9) -26.0 (-63.0; 5.0)	<.0001	-37.6 (15.6)	<.0001	-24.5 (9.3)	<.0001	<.0001
Visible abdominal ptosis (0-5)	-0.347 (0.956) 0.0 (-2.0; 3.0)	<.0001	-0.563 (1.094)	0.073	-0.347 (0.893)	<.0001	0.34
Abdominal ptosis base (cm)	-2.69 (2.07) -3.00 (-8.0; 2.5)	<.0001	-3.78 (2.52)	<.0001	-2.62 (1.95)	<.0001	0.12
Abdominal ptosis max (cm)	-2.35 (2.21) -2.5 (-8.5; 4.0)	<.0001	-2.73 (2.34)	0.001	-2.37 (2.18)	<.0001	0.56
Breast, right JM (cm)	-2.60 (3.35) -3.0 (-12.0; 20.0)	<.0001	-3.29 (6.17)	0.010	-2.48 (2.92)	<.0001	0.034
Breast, left JM (cm)	-2.66 (3.39) -3.0 (-10.0; 20.0)	<.0001	-2.96 (5.92)	0.011	-2.58 (3.05)	<.0001	0.074
Breast, right ptosis (cm)	-2.44 (2.87) -2.0 (-27.0; 1.5)	<.0001	-3.21 (2.12)	0.001	-2.39 (3.03)	<.0001	0.085

Breast, left ptosis (cm)	-2.58 (2.97) -2.0 (-27.0; 1.0)	<.0001	-3.29 (1.97)	0.001	-2.56 (3.16)	<.0001	0.16
Breast, right volume (ml)	-540 (350) -500 (-1800; 50)	<.0001	-950 (507)	0.001	-477.6 (288.6)	<.0001	0.001
Breast, left volume (ml)	-540 (342) -500 (-1650; 50)	<.0001	-900 (495)	0.001	-487.1 (289.0)	<.0001	0.004
Arm, right ptosis (cm)	-0.044 (2.472) -0.5 (-15.0; 8.0)	0.56	0.250 (2.443)	0.81	-0.105 (2.528)	0.41	0.54
Arm, right circumference (cm)	-6.72 (3.88) -7.0 (-17.0; 5.0)	<.0001	-9.31 (4.56)	<.0001	-6.26 (3.71)	<.0001	0.004
Arm, left ptosis (cm)	0.090 (2.477) 0.0 (-15.0; 8.0)	0.67	0.656 (2.315)	0.32	0.004 (2.559)	0.98	0.39
Arm, left circumference (cm)	-7.17 (4.27) -7.0 (-21.0; 4.0)	<.0001	-9.69 (5.35)	<.0001	-6.76 (4.08)	<.0001	0.013
Thigh, right ptosis (cm)	0.959 (2.687) 1.0 (-17.0; 8.0)	<.0001	0.094 (5.132)	0.20	1.11 (2.26)	<.0001	0.97
Thigh, right circumference (cm)	-10.3 (5.2) -10.0 (-25.0; 6.0)	<.0001	-12.6 (7.2)	<.0001	-9.83 (4.94)	<.0001	0.053
Thigh, left ptosis (cm)	1.17 (2.59) 1.0 (-16.0; 7.0)	<.0001	0.156 (4.895)	0.27	1.30 (2.19)	<.0001	0.55
Thigh, left circumference (cm)	-10.2 (5.5) -10.0 (-29.0; 7.0)	<.0001	-13.4 (8.0)	<.0001	-9.69 (5.01)	<.0001	0.045

Mean weight loss for the patients in Paper III was 40.9 kg, corresponding to a decrease in BMI from 45.0 to 30.8 kg/m². Table 10 presents the postoperative ptosis measurements for abdomen, upper arm, thigh and breast volume. None of the patients had a visible abdominal ptosis estimated level 5, i.e. skin hanging to the knees. After bariatric surgery, the median abdominal ptosis was 3 cm and the maximum ptosis was 14 cm. The median ptosis on both the right and left arms and the thigh was 5 – 6 cm, with a maximum ptosis of 11 – 12 cm respectively. The median breast volume was 550 and 600 ml, with a maximum volume of about two liters.

Table 10. Postoperative ptosis and volume

Variable	Median (min; max)
Ptos	
Visible abdominal (0-5)	1.0 (0.0; 4.0)
Abdominal base (cm)	3.0 (0.0; 14.0)
Arm, right (cm)	5.0 (0.0; 11.0)
Arm, left (cm)	5.0 (0.0; 12.0)
Thigh, right (cm)	5.0 (0.0; 12.0)
Thigh, left (cm)	6.0 (0.0; 11.0)
Breast, right (cm)	6.0 (0.0; 15.0)
Breast, left (cm)	5.5 (0.0; 13.5)
Breast, right volume (ml)	600 (100; 1800)
Breast, left volume (ml)	550 (100; 1800)

According to Swedish National guidelines, abdominal ptosis must measure at least 3 cm to be approved for abdominoplasty¹²⁸. Table 11 presents the number and the percentage of patients that postoperatively had an abdominal ptosis < 3 cm or > 3 cm divided into different BMI groups.

Table 11. Postoperative abdominal ptosis < 3/> 3 cm by pre operative BMI

Abdominal ptosis	< 40 (n=25)	40 < 45 (n=58)	45 < 50 (n=33)	> = 50 (n=25)
< 3 cm	21 (87.5%)	38 (66.7%)	14 (43.8%)	5 (20.0%)
> 3 cm	3 (12.5%)	19 (33.3%)	18 (56.3%)	20 (80.0%)

5.5 Correlations

5.5.1 Experienced amount of excess skin versus discomfort in Paper I

One year after surgery, there was a high/very high correlation between the experienced amount of excess skin and the degree of discomfort for all body parts ($r_s > 0.810$, $p < 0.01$).

5.5.2 Objective measurements versus subjective experiences in Paper I and III

Comparing objective measurements of circumference or actual ptosis with the patients' subjective reports of their experience and discomfort from excess skin gave little or low correlation across most body parts in both Paper I and Paper III. The only measurement that reached a moderate correlation was patients' experience of excess skin on the abdomen ($r_s = -0.50$) in Paper I (Table 12). Corresponding moderate findings in Paper III were women's reported experience ($r_s = 0.51$) and discomfort ($r_s = 0.50$) of excess skin on the abdomen after bariatric surgery and men's experience of excess skin on the thigh preoperatively ($r_s = 0.54$) and discomfort of excess skin on the thigh both pre ($r_s = 0.53$) and postoperatively ($r_s = 0.52$) (Table 13).

Table 12. Correlation between experience and discomfort of excess skin on abdomen and buttocks versus objective circumference measurements, Paper I

Variable	Year 1 postoperative		Year 2 postoperative	
	Experience	Discomfort	Experience	Discomfort
	r_s		r_s	
Waist circumference	-0.50**	- 0.26	- 0.30*	- 0.30*
Hip circumference	- 0.34*	- 0.14	- 0.41**	- 0.34*

Table 13. Correlation between experience and discomfort of excess skin versus objective excess skin measurements, Paper III

Variable	Experience				Discomfort			
	Female		Male		Female		Male	
	Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop
	r_s		r_s		r_s		r_s	
Abdomen	0.43***	0.51***	0.12	0.42*	0.44***	0.50***	0.09	0.50
Chin	0.03	0.47***	0.07	0.11	0.05	0.39***	0.07	0.15
Breasts	0.37**	0.25**	Not measured		0.38***	0.23	Not measured	
Arms	0.33**	0.43***	0.47*	0.22	0.40***	0.43***	0.15	0.28
Thighs	0.23*	0.45***	0.54**	0.42*	0.24*	0.37**	0.53**	0.52**

5.5.3 Correlation between change in BMI versus experience and discomfort in Paper I

The correlations between changes in BMI, both one and two years after surgery, and the experience and discomfort of excess skin were all low. Moderate correlations were found for experience of excess skin on the abdomen one year after surgery ($r_s = 0.47$) and for the buttocks both one ($r_s = 0.47$) and two years after surgery ($r_s = 0.42$).

5.5.4 Correlation between Δ BMI and Δ measurements in Paper III

Comparing the Δ for each measured variable with Δ BMI showed significant correlations for all the circumference measurements. However, abdominal ptosis was the only ptosis measurement that was correlated to the weight loss.

5.6 Prediction analysis in paper III

Significant univariable predictors of postoperative ptosis on the abdomen > 3 cm were gender (OR 0.37, $p = 0.01$), preoperative BMI (OR 1.24, $p < 0.0001$), preoperative ptosis (OR 2.32, $p < 0.0001$) and circumference (OR 1.07, $p < 0.0001$), Table 14. After preoperative ptosis OR 2.32 (1.76-3.07) was entered into a stepwise logistic regression, no other variables were included.

Table 14. Factors predictive of abdominal ptosis > 3 cm. Univariable logistic regression

Variable	Value	n (%) of ptosis abdomen >3 cm postoperative	OR (95%CI)	p-value
Age group (years)	19-29	7 (43.8%)	0.96 (0.73-1.27)	0.77
	30-39	17 (48.6%)		
	40-49	21 (42.9%)		
	50-59	12 (44.4%)		
	60-71	8 (42.1%)		
Gender	Female	54 (50.9%)	0.37 (0.17-0.81)	0.01
	Male	11 (27.5%)		
Smoker	Non smoker	47 (43.9%)	1.28 (0.49-3.32)	0.61
	Smoker	10 (50.0%)		
Preoperative BMI (kg/m ²)	26.1-<41.8	10 (20.8%)	1.24 (1.14-1.35)	<0.0001
	41.8-<46.3	18 (37.5%)		
	46.3-64.2	35 (72.9%)		
Preoperative abdominal ptosis	0-<4	4 (8.7%)	2.32 (1.76-3.07)	<0.0001
	4-<7	15 (29.4%)		
	7-17	45 (93.8%)		
Preoperative waist circumference (cm)	99-<119	9 (19.1%)	1.07 (1.03-1.10)	<0.0001
	119-<130	22 (45.8%)		
	130-175	32 (65.3%)		

Significant univariable predictors of maximum JM after 18 months for women were preoperative age ($\beta = 0.07$, $p = 0.04$), BMI ($\beta = 0.32$, $p < 0.0001$), JM ($\beta = 0.57$, $p < 0.0001$) and breast volume in dl ($\beta = 0.56$, $p < 0.0001$). For both men and women, the equivalent significant univariable predictors of excess skin on upper arms were preoperative BMI ($\beta = 0.14$, $p < 0.0001$), ptos ($\beta = 0.36$, $p < 0.0001$) and circumference ($\beta = 0.21$, $p < 0.0001$). Corresponding significant univariable predictors of excess skin on thighs were preoperative age ($\beta = -0.06$, $p = 0.0001$), BMI ($\beta = 0.13$, $p < 0.0001$), ptos ($\beta = 0.31$, $p < 0.0001$) and circumference ($\beta = 0.15$, $p < 0.0001$).

Variables in the multivariable model were selected by stepwise linear regression of all variables with a univariable p-value < 0.05 . Table 15 presents the independent significant predictors of maximum JM for women and for excess skin on the upper arms and thighs for both men and women. The degree of explanation for excess skin on these body parts varied between 40 and 61 %.

Table 15. Independent significant predictors of maximum JM for women and for excess skin on upper arms and thighs for both men and women

Body part	Independent significant predictor	Beta (95 % CI)	p-value	R ²
Max JM (women)	BMI	0.15 (0.06; 0.24)	0.0023	0.61
	JM	0.40 (0.28; 0.52)	< 0.0001	
	Breast volume (dl)	0.23 (0.09; 0.36)	0.0019	
Upper arm	BMI	0.06 (0.01; 0.11)	0.0208	0.40
	Ptos	0.24 (0.15; 0.34)	< 0.0001	
	Circumference	0.12 (0.06; 0.18)	< 0.0001	
Inner thigh	Ptos	0.22 (0.13; 0.32)	< 0.0001	0.43
	Circumference	0.13 (0.10; 0.16)	< 0.0001	

6 DISCUSSION

This thesis focuses on patients' experiences of excess skin and on objective measurements of the same. The four studies contribute in various ways to highlight the subject, and different study designs were used to assess the different aims of the papers.

6.1 Methodological considerations

Paper I

Patients were measured for waist and hip circumference both one and two years after surgery and filled in the questionnaire concerning excess skin on both occasions. This repeated follow-up is a strength of the study since it captures the patients' experiences during the so-called honeymoon phase that occurs one year after bariatric surgery as well as their experiences two years after surgery, when they are expected to have reached weight stability.

A weakness of the study is that the questionnaire used to assess excess skin was neither validated nor reliability tested. Furthermore, the translation into Norwegian was made by our colleagues in Norway but not according to any standardized protocol or guidelines. Wild et al.¹²¹ stress that poorly translated instruments threaten the validity of research data and the safe aggregation of global data sets. There was thus a need for a reliable questionnaire assessing excess skin from the patients' perspective. A translation into English according to standardized practice would also facilitate future research.

Results presented in Paper I showed low correlations for the circumference measurements of the waist and the hip and patients' experiences and discomfort from excess skin. However, a weakness of the study is that only circumference measurements are made and that only two body parts were assessed. Would there be higher correlations if the patients' experiences were correlated to measurements of the actual excess skin or ptosis or if other body parts also were investigated.

Paper II

SESQ specifically addresses massive weight loss patients, and an obvious strength of the questionnaire is that it rates both the degree of common impairments related to excess skin and the discomfort caused by the excess skin on different body parts. Altogether, it provides a comprehensive estimation of excess skin from the patients' perspective.

A weakness however is that SESQ is not based on qualitative knowledge from interviews with post bariatric patients. Nevertheless, the selection and identification of body parts included in the questionnaire are based on patients' own experiences as it was a group of previous post bariatric patients that marked excess skin on a plain frontal and dorsal sketch of a body⁷⁵. One can assume that the SESQ covers the right body parts but that other dimensions of the complex problem might be missed. Another weakness of the study is the lack of validation against other questionnaires. Since we did not find any validated questionnaires assessing excess skin, the lack of validation was partly compensated by interviews with ten post bariatric patients with excess skin, five Swedes and five Englishmen. They answered the questionnaire and were asked about the questions. This gave us the patients' perspective and made it possible for them to influence the questionnaire if they felt that some aspects or questions were missing. In addition, face validity with skilled and experienced plastic surgeons was done to confirm the validity and usefulness of the SESQ.

Another strength of the SESQ is that the demographic data of the previous group of post bariatric patients⁷⁵ who originally marked excess skin on the frontal and dorsal sketch of a body is highly consistent with the demographics of the patients included in Paper II. The proportion of women that marked excess skin was slightly lower compared to the patients in Paper II (69 % compared to 76 %), and the patients were about three years older. In addition, the patients who marked excess skin had a somewhat lower preoperative BMI of 46.4 kg/m² as compared to 48.9 kg/m², although the mean postoperative BMI was 30 kg/m² in all patients. Since the body parts included in the SESQ are selected by patients with demographic data consistent with the demographics of those patients for whom the questionnaire is intended, it further suggests that the accurate body parts have been selected and included.

During the process of developing SESQ, the concept of burden was not taken into consideration. Respondent burden is defined as the time, effort and other demands placed on those to whom the instrument is administered. Administrative burden is defined as the demands placed on those who administer the instrument¹¹⁷. SESQ is a rather comprehensive questionnaire and takes approximately ten minutes to complete. Since it covers and includes all body parts that may be affected by excess skin, it is valuable in the context of research but it might be too complex in clinical practice.

Paper III

Two hundred patients were included in the study reported in Paper III. However, during the inclusion period, 153 additional obese patients undergoing RYGBP at Sahlgrenska University Hospital were not included in the trial for logistic reasons. There was nevertheless no systematic exclusion, and no significant differences were observed between those included and those not included. In addition, about 20 % of the patients were lost to follow-up. However, there were no significant differences between patients who came to the follow-up visit and those lost to follow-up. These patients could nevertheless have affected the result.

When analysing level of significance, there is always a risk for over-interpreting the results. The higher number of analyses, the higher risk of mass significance. The large number of analyses in Paper III increases the risk of mass significance, but since the differences in measured values between the measurements are large, the risk of over-interpretation seems minor.

As mentioned, it is important to have reliable questionnaires and the SF-36 and EQ- 5D were used to evaluate changes in HRQoL as part of patient demographics. The SF-36 is internationally well known and was originally constructed to survey health status, designed for use in clinical practice and research¹²⁴. The translation into Swedish, the construct validity and the applicability of SF-36 when investigating HRQoL in obese patients are well documented¹²⁹⁻¹³¹.

EQ- 5D is not frequently used to measure HRQoL in post bariatric patients, but a strength of the questionnaire is that the EQ- 5D Index Scores can be used for cost-effectiveness analyses. The SESQ was used to assess excess skin, and it is a reliable questionnaire for evaluating patients' experience of excess skin following massive weight loss¹⁰⁹. Patients completed the SESQ before the bariatric surgery and 18 months after, minimizing the risk of recall bias concerning experience of excess skin. Another valuable strength of the study is that the measuring protocol used had high inter rater reliability (in manuscript, 2015), indicating that the measurements of excess skin were consistent and objective.

Objective measurements of the breast/chest on male patients were inconsistent in the study. As a consequence of difficulties measuring breast volume with the plastic bowls and of misunderstanding between the two testers, the other breast measurements, JM and ptosis, were only measured intermittently. This large loss of data made us choose not to report the breast/chest figures for men. However, our clinical experience suggests that the male breast is an increasingly common problem for the post bariatric patients seeking help at the Department of Plastic Surgery. The loss of these data is therefore obviously important since they had been of great clinical importance.

Paper IV

The objective measurements in Paper III were made either by a specialist nurse or a specialist physiotherapist. When testing the inter rater reliability of the measuring protocol in Paper IV, the majority of the measurements had an ICC > 0.9 despite this difference. This result is a great strength of the measuring protocol since van der Beek et al.¹³² recently stated that different professions showed a rather different outcome in the evaluation of contour deformities using the Pittsburgh Rating Scale.

However, a potential limitation of the study was the absence of repeat measurements of patients before surgery.

6.2 Discussion of the findings

SESQ

The questions and statements assessing symptoms from excess skin (part II) of the SESQ cover the symptoms that have previously been reported in qualitative and quantitative research. Excess skin is known to cause medical complications, such as fungus and eczema, it can cause back pain in the back and it can be perceived as a hindrance in daily life. Furthermore, excess skin can complicate physical activity, make it difficult to find well-fitting clothes and greatly affect intimacy and sexual relationships by poor body image and feelings of shame over the excess skin^{75, 79, 81, 82, 85}. In addition, previous research has demonstrated that excess skin is most commonly located on the abdomen, inner thighs, breasts and upper arms^{75, 76, 79, 86}. Together with our experience, previous research enables us to conclude that there is a high probability that the right questions on symptoms from excess skin and that the right body parts are included in the SESQ.

Two other questionnaires assessing excess skin in post bariatric patients have been identified, the Post-Bariatric Satisfaction Questionnaire⁸⁹ and the Post-Bariatric Surgery Appearance Questionnaire (PBSAQ)^{90, 112}. Both questionnaires focus on the current degree of satisfaction with excess skin according to body region, cosmetic issues and level of desire for body contouring surgery. However, neither of the questionnaires have been reliability tested.

The SESQ is a reliable and valuable questionnaire assessing excess skin from the patients' perspective. However, the results of SESQ must be interpreted in combination with objective measurements when assessing excess skin in the research context as well as in clinical practice. Hence, the measuring protocol presented in Paper IV was developed in order to measure excess skin in a standardized way.

The measuring protocol

Results of the inter rater reliability test of the measuring protocol in Paper IV demonstrate that a majority of 63 % of the circumference and excess skin measurements had an ICC > 0.9. Except for measurements of excess skin on the chin and the buttocks, all other measurements had an ICC > 0.7. Furthermore, there were no significant systematic differences between the two testers except for measurements of the buttocks and maximal knee circumference. Fortunately, these two measurements seem to have less clinical relevance than other measurements.

Another strength of Paper IV is that measurements of ptosis and excess skin had high or good reliability even though the size of the ptosis varied by several centimetres. While the abdominal ptosis varied between 0 and 14 cm, the mean inter rater difference was 0.94 cm. Corresponding figures for the upper arm, with a variation of excess skin between 1.5 and 12 cm, was 0.38 cm, and of the thighs, with a variation of excess skin between 1.5 and 13 cm, was 0.58 cm.

A search of the literature identified two other classification systems designed for evaluation of excess skin on several body parts of the post bariatric patient: the Pittsburgh Rating Scale, PRS, based on evaluation of full-body photographs¹¹⁰ and “An anthropometric classification of body contour deformities after massive weight loss” based on fixed anatomical regions that comprises a grading of excess skin¹¹¹. The reliability test of the Pittsburgh Rating Scale presented by Song et al.¹¹⁰ in 2005 demonstrated good validity (Weighted Kappa > 0.6) for all anatomical categories examined. However, van der Beek et al.¹³² did not achieve as good results when they replicated the validation of the Pittsburgh Rating Scale and evaluated the usefulness of the scale in the treatment of massive weight loss patients in the Netherlands¹³². A part of the criticism of the usefulness was the absence of the patients’ perspective.

Patients' experience and discomfort from excess skin

The post bariatric patients' experiences and discomfort from excess skin should be interpreted and understood in the context of the average population's estimations of excess skin. A not yet published study by Ockell et al. (in manuscript, 2015) will present normal values of the SESQ. The results show that only a minority of the population experiences excess skin and that their discomfort of excess skin is low.

In a comparison of the patients' experiences and discomfort from excess skin on the upper arms, abdomen and inner thigh in Paper I and Paper III, it was noted that patients in Paper I experienced significantly more excess skin on all body parts both one and two years after surgery, except for excess skin on the upper arms two years after surgery, where the difference was not significant. For example, 42 % of the super obese patients rated "very much" excess skin on the abdomen the first year after surgery with corresponding percentage after two years of 46 %. In contrast, 16 % of the patients in the longitudinal study experienced "very much" excess skin on the abdomen. The super obese patients in Paper I also seem to rate their discomfort from excess skin to a higher extent, although the differences are only significant for upper arms in the first year after surgery and abdomen and inner thighs the second year after surgery. These differences between the studies is not unexpected since the patients in Paper I had a greater weight loss after bariatric surgery.

In Paper I, patients operated with BPD/DS experienced significantly more excess skin on several body parts as compared to the patients in the RYGBP group. They also had a significant decrease in BMI both one and two years after surgery. In contrast, Zammerilla et al.¹³³ reported that the type of bariatric procedure did not significantly affect the deformity grade of excess skin on the abdomen or change in BMI. However, the small number of patients in their study operated with Gastric Banding, compared with those operated with Gastric Bypass, might have influenced the analysis. On the other hand, Zammerilla et al.¹³³ demonstrated that patients with a greater change in BMI after massive weight loss were found to have a significantly higher deformity grade of excess skin on the abdomen. Further, Giordano et al.⁸⁰ stated that patients with a higher weight loss reported significantly more discomfort from excess skin and showed a significantly higher overall desire for post bariatric plastic surgery.

Concerning objective measurements, the patients in Paper III with a Δ BMI $> 20 \text{ kg/m}^2$ after bariatric surgery had a significantly higher decrease in circumference measurements at the waist, arms and thighs, except for the right thigh, where the difference was not significant, compared to the patients with minor weight loss. There were however no significant differences in ptosis measurements between patients with Δ BMI $>/< 20 \text{ kg/m}^2$.

Discomfort from excess skin in men and women

In Paper I and Paper III women experienced more discomfort on several body parts than men, and this difference between genders confirms previous findings^{75, 76, 79, 80}. It has been discussed earlier whether this difference depends on a difference in physical ideals among women and men⁷⁵. Studies have shown that women in the media have a significantly thinner body shape than women in the general population. However, in recent times, men are also indoctrinated with a muscular ideal¹³⁴⁻¹³⁶, and our clinical experience confirms that increasingly more men want post bariatric plastic surgery.

Objective measurements

Song et. al.¹¹⁰ established that the likelihood of individual patients suffering problematic excess skin, and which body part or parts may be affected, is at best only vaguely estimable. This unpredictability is often particularly distressing for patients. How does a body look after massive weight loss? Much of the knowledge today is based on the looks of the patients that seek health care, particularly of course those who experience problems with excess skin. There are no ideals, or even accurate estimations of normality, for the entire patient population. We thus saw a need to objectively examine a group of patients, irrespective of whether they reported excess skin. In addition, in a recent study by Zammerilla et al.¹³³, the authors identified and discussed the need for longitudinal and repeated measurements of excess skin in order to understand the process. The objective measurement of excess skin in Paper III gives us unique information on how the post bariatric patients' body habitus appears 18 months after RYGBP.

Because of the substantial weight loss, around 30 % of the total initial weight, all the circumference measurements decreased from the preoperative examination to the postoperative examination. Remarkably, most of the ptosis measurements decreased as well. Although the extent of the excess skin that is measured actually reduces in comparison with before the operation, patients seem to become more aware, inconvenienced and discomforted by it in several body parts after the weight loss.

A search of the literature found no studies with repeated measurements of obese patients for excess skin before bariatric surgery and after weight loss. However, the measuring protocol used in Papers III and IV was used earlier when measuring excess skin in post bariatric young adults, operated for obesity when they were adolescents⁷⁸. Comparison of the post bariatric measurements of the young adults and the patients in Paper III regarding the upper arms, abdomen and thighs shows that the median value for both boys and girls versus women and men is almost the same. However, the patients in Paper III had the maximum values of ptosis, which is several centimetres larger than the maximum values for the young adults on all body parts examined. The differences in maximum values were highest between girls and women and for both genders in terms of maximum values on the abdomen.

Correlations

One year after surgery, there was a high/very high correlation between the amount of excess skin experienced and the degree of discomfort in all body parts in Paper I. However, low correlations were found in comparisons of objective measurements of excess skin or circumference and patients' subjective experiences and discomfort of excess skin in Paper I and Paper III, indicating poor concurrence. In addition, Staalesen et al.⁷⁸ reported similar correlations between post operative objective measurements versus post bariatric adolescents' experiences and discomfort from excess skin. Thus there is a clear disagreement between reality and what is perceived.

Neither were the changes in BMI after surgery correlated to the reported experience and discomfort of excess skin in any body part in Paper I, and this is consistent with findings by Staalesen et al.⁷⁸. In Paper III, comparison of the Δ for each measured variable with Δ BMI showed significant correlations for all the circumference measurements. However, abdominal ptosis was the only ptosis measurement that correlated to the weight loss.

Predictions

There is a common belief about excess skin that younger patients do not experience excess skin to the same extent as older patients. However, Staalesen et al.⁷⁸ demonstrated that both adolescent boys and girls who had undergone bariatric surgery reported serious problems due to excess skin. Younger patients' experience of discomfort from excess skin is further demonstrated by Giordano et al.,⁸⁸ who reported a significant positive association between female sex, younger age and Δ BMI with desire for post bariatric plastic surgery. Nonetheless, Steffen et al.¹¹² report that age, gender, change in BMI and current BMI did not independently predict the desire for plastic surgery. In addition, when the preoperative objective measurements were used in Paper III for predictions of excess skin after bariatric surgery, preoperative age was a significant univariable predictor for maximum JM in the case of women and excess skin on the thigh. However, age did not become an independent significant predictor for any of the body parts examined.

Smoking and former smoking are known to increase laxity of the skin¹³⁷. Nevertheless, smoking was not found to be a predictor of excess skin on any body part after bariatric surgery. One explanation might be that we had a low response rate to the question that addressed smoking in SESQ. However, Wagenblast et al.⁷⁷ did not find any significant differences between smokers and non-smokers and their reported desire for post bariatric plastic surgery.

Furthermore, the prediction analysis indicated that, for every centimetre of ptosis on the abdomen preoperatively, there is a twofold higher odds of having a postoperative ptosis on the abdomen > 3 cm (OR=2.32). As mentioned in the results, abdominal ptosis must measure at least 3 cm to be approved for abdominoplasty according to Swedish National guidelines¹²⁸. The objective measurements in Paper III revealed that more than 50 % of the patients with a preoperative BMI between 45 and 50 kg/m² had a postoperative abdominal ptosis > 3 cm, and the corresponding percentage for the patients with a preoperative BMI > 50 kg/m² was 80 %. However, the National guidelines further require the patients to have a BMI < 30 kg/m² to be considered for plastic surgery and since the mean post operative BMI in Paper III was 30.8, it means that many patients who have an abdominal ptosis > 3 cm still weigh too much to have additional plastic surgery.

To summarize the results regarding experience of excess skin:

While the extent of excess skin that was measured is reduced in comparison with before the operation, patients seem to become more aware, inconvenienced and discomforted by it on several body parts after weight loss.

Discomfort from excess skin is fairly correlated to the extent of excess skin that was measured.

7 CONCLUSIONS

The following are the main conclusions drawn in the Papers:

- ✓ The SESQ is a reliable questionnaire for evaluating patients' experience of excess skin after massive weight loss.
- ✓ The measuring protocol presented in Paper IV has high reliability and therefore represents a useful instrument for providing a consistent and objective assessment of excess skin in the post bariatric patient.
- ✓ Weight loss after laparoscopic gastric bypass and duodenal switch in super obese patients is associated with substantial experience and discomfort from excess skin.
- ✓ Women experience more excess skin and more discomfort from massive weight loss, as compared to men, on several body parts.
- ✓ While the extent of excess skin measured actually decreased in comparison to before the operation, patients seem to become more aware, disturbed and discomforted by it on several body parts after weight loss.
- ✓ Comparison of objective measurements with the patients' subjective reports of their experience and discomfort from excess skin gave little or low correlation in women and men for most body parts.
- ✓ The prediction analysis indicates that, for every centimeter of ptosis on the abdomen preoperatively, there is a twofold higher odds of having a postoperative ptosis on the abdomen > 3 cm (OR=2.32).

8 FUTURE PERSPECTIVES

The intention of the work in this thesis was to obtain information on excess skin in order to help both patients and public health care to prepare for what can be expected with respect to excess skin after bariatric surgery. Results of the SESQ can give an indication of how excess skin is perceived after weight loss. Further, the objective measurements can hopefully serve as a start for setting up ideals and accurate estimations of normality for the whole patient population. Patients can form an idea of what to expect after weight loss, and public health care can be made prepared for the increasing demands for these post bariatric plastic surgeries. However, several new research questions have been raised during the work in this thesis.

- ✓ The results of the work reported in Paper I and Paper III show that patients with great weight loss experience serious problems and discomfort from excess skin on most body parts. Patients' demographics in this thesis demonstrate a mean postoperative BMI of around 30 kg/m² and a corresponding mean BMI 34 kg/m² for the super obese patients in Paper I. In Sweden, national guidelines imply that post bariatric patients have a BMI < 30 kg/m² to be considered for additional post bariatric plastic surgery. This means that many patients with serious problems from excess skin after massive weight loss nevertheless have too high a BMI to receive plastic surgery. As previously mentioned, post bariatric plastic surgery is associated with an increased risk of serious complications^{102, 103} and the most important risk factors are maximum BMI, BMI reduction after bariatric surgery and age of the patient^{102, 107}. However, as a contribution to the debate, Coriddi et al.¹⁰⁰ state that patients with a BMI greater than 35 had significantly improvements in functional outcomes after post bariatric plastic surgery as compared to patients with a BMI less than 35. It would therefore be of great interest to study these high risk patients and make comparisons between the risks of operation as opposed to the positive effects following post bariatric plastic surgery.

- ✓ The results reported in this thesis and consistent previous research show that excess skin is most commonly located on the abdomen, upper arms, inner thighs and breasts. The objective measurements reported in Paper III demonstrate for example that the maximum excess skin on the upper arms was 11-12 cm. The corresponding figures for the inner thigh were also 11-12 cm, with a median excess

skin for both body parts of 5-6 cm. These amounts of excess skin obviously cause great discomfort and functional and cosmetic problems. In Sweden, abdominoplasty is normally the only post bariatric plastic surgery procedure provided in the public health care system. It is also the most desired operation among patients. However, patients suffer from excess skin on several body parts, and some of the patients might wish for plastic surgery on other body parts as an alternative. It would be interesting to investigate whether patients may be even more satisfied with their plastic surgery if they were allowed to freely choose which body part that wanted to be operated. Furthermore, Song et al.⁹³ write that, even though quality of life improved after obesity surgery and was further enhanced by post bariatric plastic surgery, an unexpected result was the patients' dissatisfaction with other parts of the body. It would be of great interest to investigate patients who undergo additional plastic surgery and whether they are subsequently satisfied with their appearance or whether they notice excess skin on other parts of the body. In addition, it is not known whether the patients become more satisfied with their appearance if they operate more body parts.

- ✓ In daily clinical practice, it is important to have reliable instruments that are easy to use when assessing excess skin after massive weight loss. The results of this thesis have shown low correlations between patients' experiences of excess skin and objective measurements. It therefore seems highly relevant to create an assessment tool that covers both these aspects. A merged and revised version of the SESQ and the measurement protocol would meet these requirements. The questionnaire and the measuring protocol both have high reliability and are well suited for use in research. However, they are both rather extensive and time-consuming, and a merged and consolidated version would therefore be of great importance in everyday consultations with post bariatric patients.
- ✓ Qualitative studies assessing post bariatric patients experiences are few. Two have been published that focus on patients' body image concerns after massive weight loss^{82, 83} and one that focuses on satisfaction and quality of life factors in post bariatric plastic surgery patients⁸¹. There is a clear need for more qualitative studies to fill the knowledge gap regarding post bariatric patients' experiences of excess skin after massive weight loss.

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