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LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING FOR MORBID OBESITY

PRIMARY, INTERMEDIATE, AND LONG-TERM RESULTS INCLUDING QUALITY OF LIFE STUDIES
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Primary, intermediate, and long-term results including quality of life studies

Academic dissertation to be presented, with the assent of the Faculty of Medicine of the University of Oulu, for public defence in the Auditorium Kurten of Vaasa University (Wolffintie 34, Vaasa), on September 19th, 2008, at 12 noon

OULUN YLIOPISTO, OULU 2008
Tolonen, Pekka, Laparoscopic adjustable gastric banding for morbid obesity. Primary, intermediate, and long-term results including quality of life studies
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Abstract
Morbid obesity is the most rapidly increasing health threat of developed countries, and the costs caused by it are already higher than those of smoking. In an increasing number of developing countries both starvation and morbid obesity are increasing simultaneously. Obesity in children and adolescents is also increasing rapidly. Conservative treatment almost invariably fails when treating morbid obesity. Results of pharmacotherapy have been disappointing after great expectations. Laparoscopic gastric banding has been used in the treatment of morbid obesity since 1993. The method was first used mostly in Europe. In the USA either an open or laparoscopic gastric bypass have been the most common methods of surgery.

The aim of this study was to investigate the operation results of 280 patients operated in Vaasa Central Hospital during the 11 years after March 1996. Of these patients, 123 have been followed at least 5 years. The results have been analyzed with BAROS that measures the quality of life.

Quality of life was measured prospectively 1 year after surgery with the 15D questionnaire that is validated in the Finnish population. The effect of gastric banding in esophageal motility and reflux was studied prospectively in 31 patients. Late results were analyzed in 123 patients 11 years after the first operation. Mean excess weight loss (EWL) was 56% in patients who had their band in place 7 years after surgery, and 46% in all patients.

There was no mortality related to the operation, and there was only one serious complication. Disease-specific quality of life improved in 78.8% of the patients in 28 months of follow-up. Health-related quality of life was significantly improved 12 months after surgery, but improvement was not connected to the amount of weight loss. The band inhibited reflux 19 months after surgery.

Complications, failures, and reoperations increase with longer follow-up. Weight loss is moderate 9 years after a gastric banding operation, and in carefully selected patients this operation is still a good option in the treatment of morbid obesity.

Keywords: 15D, 24-h pH measurement, bariatric surgery, BAROS, body mass index, co-morbidity, endoscopy, excess weight loss, follow-up, gastroesophageal reflux, GERD, health related quality of life, laparoscopic gastric banding, long-term, manometry, morbid obesity, quality of life, questionnaire
Acknowledgements

This study has been conducted at Vaasa Central Hospital gastroenterological unit between 1996 and 2007.

I thank the administrative leaders of Vaasa Central Hospital for open-mindedly accepting a new treatment method into clinical use.

I am grateful to Professor Jyrki Mäkelä for the support I have received during 20 years to pursue clinical studies and for accepting the study at Oulu University. I am grateful for the friendly advice and criticism I have received during the different phases of the study.

I am especially grateful to Docent Mikael Victorzon for supporting me into scientific thinking in clinical work, for helping in the arrangements of the study, for patiently assisting in the operations, and for a priceless help in planning and conducting the study and performing the statistical analysis.

I thank the reviewers Docent Jari Ovaska and Docent Marja Leivonen for constructive and well-informed critique.

I am grateful to my colleague Stig Bergkulla, M.D., who has helped me in the preoperative examinations of the patients at Vaasa Central Hospital medical outpatient clinic.

I thank the gastroenterological ward personnel at Vaasa Central Hospital for the help in the care of the patients.

Synnöve Liukku, Maija Huotari and Birgitta Korvo, nurses at the surgical outpatient clinic, and health nutritionist Johanna Niinikangas, have been a priceless help in supporting the patients pre- and postoperatively, in giving nutritional advice, and in interviewing the patients for the studies.

I thank Jaana Elberkennou, M.D., for the translation and language revision.

I am grateful to all members of my family for the support I have received to conduct a long study project. Especially my wife Ritva has always been supportive even on the bad moments and has also helped me in drawing the diagrams.

For my daughter-in-law Johanna I am grateful for the help I received at the end of the study in collecting the material.

My sons Tuomo, Timo, and Teemu and all my 9 grandchildren: Ilmari, Johannes, Tapio, Lauri, Markus, Helmi, Kerttu, Eeva, and Laura have given me plenty of more important things to think about than research.
Abbreviations

BAROS  Bariatric analysis and reporting outcome system
BIB  Bio Enteris Intragastric Balloon
BMI  Body mass index
BPD  Biliopancreatic diversion
BPD+DS  Biliopancreatic diversion with duodenal switch
BQL  Bariatric quality of life
EW  Excess weight
EW (kg)  Excess weight in kilograms
EW (%)  Excess weight (percentage)
EWL  Excess weight loss
EWL (kg)  Excess weight loss in kilograms
EWL (%)  Excess weight loss (percentage)
FDA  Food and Drug Administration
GB  Gastric banding
GIQLI  Gastrointestinal quality of life
HRQoL  Health-related quality of life
IFSO  International Federation for the Surgery of Obesity
IOTF  International Obesity Task Force
JIB  Jejunoileal bypass
LAGB  Laparoscopic gastric banding
LES  Lower esophageal sphincter
LRYGB  Laparoscopic gastric bypass
NASH  Non-alcoholic steatohepatitis
NIH  National Institute of Health
QoL  Quality of life
RDI  Respiratory disturbance index
RYGB  Gastric bypass
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<td>Swedish adjustable gastric banding</td>
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Original publications
1 Introduction

Only 5% of the world population had a body mass index (BMI) over 30 kg/m2 at the beginning of the 20th century. The number has now risen to 20%, and it is predicted that a third of the world population will be obese by 2025 (Kopelman 2000). The morbidity and costs of obesity are already reaching those of cancer and cardiovascular disease. Conservative treatments have so far given disappointing long-term results in most reliable studies. Pharmacotherapy provides only modest weight reduction at the cost of significant side effects (Yanovski & Yanovski 2002). The National Institutes of Health consensus development conference in 1991 concluded that "surgical therapy offers the best long-term approach to treat morbid obesity, and is probably the most effective therapy to cure type 2 diabetes" (NIH 1991). Since then, the safety and effectiveness of bariatric surgery have made a rapid increase in bariatric procedures possible. In the USA alone the number of operations for obesity has increased from 16,000 per year in the early 1990s to about 103,000 in 2003 (Steinbrook 2004). Any remaining doubts about the effectiveness of bariatric surgery on the recovery from co-morbid conditions were erased by the results of the Swedish Obese Subjects Study, in which 2- and 10-year recovery rates from diabetes, hypertriglyceridemia, hypertension and hyperuricemia were significantly higher in patients who had undergone surgery than in those managed conservatively (Sjöström et al. 2004).

In recent years laparoscopic adjustable gastric banding (LAGB) has gained increasing acceptance all over the world due to its relative simplicity, minimal invasiveness, safety, and efficacy (Belachew et al. 2002, Steffen et al. 2003). It has become the most common operation for morbid obesity in Europe.

Outcome analysis in bariatric surgery is complex because there are several different meaningful endpoints. The prejudice unfortunately still persists among many physicians and the public that bariatric surgery is performed for cosmetic purposes. Improved or resolved medical co-morbid conditions caused by obesity, and the possible changes in quality of life are, however, more important. As in other chronic diseases, quality-of-life (QoL) issues are important when analyzing the results of an intervention in obese patients.
2 Review of the literature

2.1 Epidemiology

2.1.1 Epidemiology worldwide

During the last decade obesity has become a global phenomenon especially in the developed countries, but increasingly also in the developing countries. Obesity is defined as the proportion of weight and the square of height from which a body mass index (BMI) may be calculated. World Health Organization (2000) defines obesity and overweight as follows: BMI 25.0–29.9 kg/m² pre-obese, BMI 30.0–34.9 obesity class I, BMI 35.0–39.9 obesity class II, and BMI more than 40 kg/m² obesity class III.

The consumption of high-energy food has tripled since the year 1980 in North America, England, Eastern Europe, Middle East, Pacific Islands, Australia and China. The number of obese people is increasing faster in developing countries where malnutrition is increasing simultaneously (WHO 2000). It is estimated that there are more than 1.7 billion preobese people in the world and 300 million of those can be classified as obese (Deitel 2003). The number of obese people will be as much as 700 million in the year 2015 (WHO 2006). Two extremes of obesity can be found in rural China, where 5% of the population is obese, and Samoa Islands, where the number is 75%. In the USA the number of overweight and obese people has increased rapidly during several decades. Between the years 1976 and 1980 and the years 1988 and 1991 the proportion of overweight adults increased by 8 % (Kuczynski et al. 1994). In the years 2003 and 2004 already 17.1% of the children and adolescents (2–19 years) were overweight, and 32.2% of the adults were obese (Ogden et al. 2006). Overweight in children and adolescents and obesity in adult males increased clearly during a follow-up period between 1999 and 2004, but no increase in the obesity of women was found.

A BMI over 40 kg/m² was found in 2.8% of men and 6.8% of women (Ogden et al. 2006). Obesity increases fast also in Europe. The average BMI 26.5kg/m² of the European population is one of the highest in the WHO areas. Today, about 400 million European adults are overweight and 130 million are obese (WHO 2005). According to a WHO estimate there will be 150 million obese people in Europe in 2010 if the numbers increase at the same rate as in the 1990s. Obesity in men increases especially fast in Finland, Germany, Greece, Sweden, and England. Women's obesity increases especially fast in Eastern Europe (WHO 2005). The
proportion of obese children increases also like an epidemic in Europe. IOTF (The International Obesity Task Force) has estimated that the numbers increased by 0.2% every year in the 1970s and as much as 2% after the year 2000 (WHO 2005).

2.1.2 Epidemiology in Finland

Obesity in the Finnish population has been studied since the 1960s in population studies. Obesity was common already in the 1960s. In 1997, 48% of working-age men and 32% of women were pre-obese (BMI 25–29.9 kg/m²) and 19% of both women and men were obese (BMI more than 30 kg/m²) (Lalhti-Koski et al. 1999).

According to the WHO 2005 statistics, about 22% of men in Finland are obese, which puts them on a second place after Croatia. Finnish obese women take the 5th place with a 13% obesity rate.

2.2 Costs of obesity

Obesity causes increased costs to the society because of increased health care costs and productivity losses caused by disability. It is estimated that in the USA obesity causes as much as 9.1% of the health care costs (Thompson & Wolf 2001; Salem et al. 2005). WHO has estimated that the costs caused by obesity in Europe are between 2% and 8% of the health care costs, but real costs are likely to be much higher, because all the costs of obesity have not been included in the calculations (WHO 2005).

Health care cost caused by obesity have been analyzed and published in Suomen Lääkärilehti (Pekurinen 2000). The results – using three different methods of analysis – showed that 1.4–7.0% of the health care costs are caused by obesity. That is more than the costs caused by smoking. Treatment of stroke caused most hospital costs, and treatment of hypertension most drug-related costs. It was estimated that obesity causes yearly an additional cost of 270–925 euros per one obese person. In Pekurinen's study only hospital ward costs and drug costs were included. It has been estimated that indirect costs caused by disability and sick leaves are tenfold (Sjöström et al. 1995). Two thirds of the costs caused for the society by obesity are related to type 2 diabetes, stroke and arthritis (Pekurinen 2006). Annual obesity-related costs for the society were 260 million euros (Pekurinen 2006). Obesity is a contributing factor for many diseases that cause disability, the most important groups being cardiovascular and musculoskeletal diseases.
In Finland obesity (BMI more than 25 kg/m²) could be regarded as the cause of one fourth of disability pensions paid for women for cardiovascular and musculoskeletal causes and half as many for men (Rissanen et al. 1990). Sampalis et al. (2004) have studied the effect of bariatric surgery for morbidly obese people in the health care costs in a Canadian patient material. Surgery resulted in higher health care costs in the first years after the surgery, but after 5 years the costs were 6 million Canadian dollars lower in a sample of 1000 patients. After the surgery the health care costs were equal with the control group at 3.5 years, but later than that the costs in the control group raised fast higher (Sampalis, et al. 2004).

2.3 Impact of obesity on public health

Obesity is connected to many important public health problems. According to WHO, 85% of diabetics are type 2, and 90% of those are either overweight or obese (WHO 2006). Obesity is the most important risk factor for type 2 diabetes (Chan et al. 1994, Colditz et al. 1995). It is estimated that between 60% and 80% of type 2 diabetics would not have got the disease if they were not obese [Current treatment recommendation 2002 (Käypää hoito-suositus 2002)]. Hypertension is strongly associated with obesity. An increased BMI value and hypertension have a clear linear correlation. Weight loss almost invariably reduces blood pressure and decreases the use of antihypertensive medication (Jousilahti et al. 1995, Bouldin et al. 2006). Metabolic syndrome, coronary artery disease, obstructive sleep apnea, gout, gall stones, fatty liver, knee arthritis, and asthma are also strongly associated with obesity (Dixon, et al. 2001, Griffin & Guilak 2005, Phillips & Cistulli 2006, Raman & Allard 2006, WHO 2006). Many cancer types are more common in obese people. The clearest connection has been found with cancers of the breast, uterine corpus, and colon (Bergström et al. 2001).

2.4 Effect of obesity on mortality

Study results about the effect of obesity on mortality are conflicting. In Rissanen's material body mass index was a weak predictor of mortality (Rissanen et al. 1990). Sjöström (1992) found a 40-fold increase in unexplained sudden deaths if BMI was over 35 kg/m². Mortality in cardiovascular diseases, diabetes, and certain cancer forms is also many times higher. Difference in mortality is offset after 55 years, and disappears for those over 80 years. In a material from Kuopio area cardiovascular deaths increased by 2.5–3 times, and all deaths by 1.9–2.1 times in
males between 42 and 60 years of age with metabolic syndrome (Lakka et al. 2002). In the USA in a material of over one million adults that were followed for 14 years the risk of death in white males was 2.5 higher if BMI was over 40 kg/m². The risk in women was two times higher. The risk of death by all causes in moderately and severely obese people was increased in all age groups (Calle et al. 1999). In a 55-year follow-up it was found that obesity in adolescence (13–18 years) increases the general risk of death by 1.8 times and the risk of cardiovascular death by 2.3 times in men, but not in women (Must, 1992).

Overweight increases also cancer deaths. Calle (2003) found in a sample of 90,000 adults that 14% of cancer deaths in men and 20% in women are connected to overweight. A clear connection was found in both sexes with cancers of esophagus, colon and rectum, liver, pancreas, gall bladder, and kidneys. In men a high body mass index was connected to increased mortality in gastric and prostate cancer. In women cancers of breast, uterine cervix and corpus, and ovarian cancer were the causes of increased mortality. The Framingham Study gave conflicting results. In a 20-year follow-up of 2500 men and women who were between 35 and 54 years old, the mortality was highest in those whose BMI decreased and whose BMI was the highest in the beginning. In men the mortality in cardiovascular and other diseases increased by 33–61% if they lost weight. In women both weight gain and weight loss increased the risk of cardiovascular and coronary artery diseases. Being thin and having a stable weight is the most profitable combination for preventing risk factors and the risk of death (Higgins et al. 1993). In the Swedish SOS (Swedish Obese Subjects) study the mortality decreased clearly in an average follow-up of 10.9 years. The mortality in the surgically treated group was 5.0%, and in the conservatively treated group 6.3% (Sjöström et al. 2007). In a German study of 6193 obese people (BMI 25–74 kg/m²) in 14 years of follow-up the risk of death was significantly increased in those with morbid obesity (BMI over 40 kg/m²). In men the risk was 3.05 times higher and in women 2.31 times higher. On the other hand, BMI between 32 kg/m² and 40 kg/m² resulted in a clearly lower risk of death than anticipated, and BMI between 25 and 30 did not have any impact on the risk of death (Bender et al. 1998). Long-term survival was studied in the USA between 1992 and 2002 after gastric bypass surgery in 7925 patients. They were compared to similar patients that had not been operated. Deaths of all causes were reduced by 40%, deaths due to diabetes by 92%, cardiovascular deaths by 56%, and cancer deaths by 60% (Adams et al. 2007).
2.5 Treatment of obesity

2.5.1 Conservative treatment

Nutrition

Obesity has increased to such extent in the world population that it causes a higher health risk than malnutrition and infectious diseases (Kopelman 2000). Genetic tendency, reduced physical activity, and increased energy value of food contribute to the global epidemic of obesity (Kopelman 2000). WHO has given recommendations for preventing and treating obesity. The main aims are that the society should make high-fiber food products available and support the possibilities for physical activity. WHO's Regional Committee for Europe gave an action plan for food and nutrition policy in Europe for the years 2000–2005 (WHO 2005). The aims in treating obesity are to prevent and treat diseases that are connected to obesity. A weight loss of 5–10% is remarkable, and a 5% weight loss is considered as a success in conservative treatment. The aims are to reduce the risks of co-morbidities and prevent further weight gain. Obtaining normal weight (BMI less than 25 kg/m²) is usually unrealistic [Current treatment recommendation 2007 (Käypä hoito-suositus 2007)].

Conservative treatment can be divided to basic treatment, VLCD (very-low calorie-diet) combined with basic treatment, and pharmacological treatment. Basic treatment consists of life-style modifications in diet, exercise, eating, and associated cognitive factors. VLCD treatment consists of a diet with less than 3.4 MJ of energy per day for 6 to 12 weeks. In a one-year follow-up the weight loss is between 8.6 kg and 14.2 kg (Wadden and Stunkard 1986). The result of VLCD treatment does not differ significantly from what is attained with a low-energy diet in one year, but in a five-year follow-up the result is significantly better [Current treatment recommendation 2007 (Käypä hoito-suositus 2007)]. In Finnish studies between 32% and 75% of those who went through a treatment program lost 5% of their weight in a two-year follow-up, and between 19% and 65% in a follow-up of 5 to 7 years (Karvetti and Hakala 1992). Pekkarinen's and Mustajoki's study compared VLCD treatment with treatment that consisted of similar basic treatment, but without the VLCD period of 6 to 8 weeks, in the treatment of obesity (BMI on an average 46 kg/m²). The drop-out rate was 56% in the VLCD-group and 28% in the other group. The groups were followed between 4.8 and 6.2 years. The weight loss in those who went through the whole treatment program
was 16.9 kg in the VLCD group, and 4.9 kg in the other group (Pekkarinen and Mustajoki 1997). In a 10-year follow-up of the Swedish SOS study (Swedish Obese Subjects), the weight of those that were treated conservatively increased by 1.6% (Sjöström et al. 2004, Sjöström et al. 2007).

**Pharmacological treatment**

In Finland 3 different drugs are used in the treatment of obesity: orlistat, sibutramine, and rimonabant.

Pharmacological treatment is not the primary treatment, but it can be used when BMI is more than 30 kg/m², or when it is more than 28 kg/m² and the patient has co-morbidities connected to obesity.

**Orlistat.** Orlistat inhibits the function of the lipase enzyme of pancreas and thus also absorption of fat. It helps weight loss and prevents weight gain after weight loss ((Sjostrom et al. 1998, Henness & Perry 2006, Richelsen et al. 2007). Orlistat reduces the cardiovascular risk factors and lowers the LDL cholesterol level in the blood (Sjöström et al. 1998). Orlistat improves glycemia and metabolic syndrome in obese patients with type 2 diabetes (Henness and Perry 2006). In a meta-analysis Padwal et al. (2003) found that it produced a weight loss of 2.7 kg, or 2.9%, during a follow-up of more than one year. The most common side effects are oily stools and fecal incontinence.

**Sibutramine.** Sibutramine affects via central nervous system by inhibiting the serotonin and norepinephrine reuptake. The effect comes via reduced food intake and feeling of fullness (Stock 1997). On the other hand, the reduced consumption connected to weight loss slows down. Weight loss with sibutramine is between 2.4 and 4.3 kg (Hansen et al. 1999, Padwal et al. 2003). Weight loss improves the blood lipid profiles (James et al. 2000). Sibutramine may cause hypertension and tachycardia. The most common side effects are insomnia, constipation, and dry mouth.

**Rimonabant.** Rimonabant is a selective cannabinoid-1 receptor blocker. It affects energy balance, weight, and metabolism of glucose and lipids. Rimonabant reduces weight about 5 kg compared to placebo, and it improves glucose balance and reduces the risk factors for cardiovascular diseases (Van Gaal et al. 2005, Pi-Sunyer et al. 2006). The most common side effects of rimonabant are connected to mood disorders.

The effect of all drugs used for the treatment of obesity is minor, and risks connected to long-term use are not known. Side effects are common and the drop-
out rate as high as 42% (James et al. 2000). It is important to develop new and more efficient drugs to fight the global obesity epidemic. The use of current drugs should be considered in the light of risk factors, efficacy, and costs (Padwal & Majumdar 2007).

Exercise. The importance of exercise in weight loss is minor. Increasing physical activity without diet changes reduces extra weight by a few kilograms. Physical activity combined with a low-energy diet does not increase weight loss significantly compared to a low-energy diet alone [Current treatment recommendation 2007 (Käypä hoito -suositus 2007)]. Physical activity reduces proportionally more the fat inside the abdominal cavity than diet even if the weight loss was minor. It also reduces the development of insulin resistance (Ross et al. 2000). Weight control after weight loss may require unexpectedly high additional energy consumption (6300–8400 kJ per week) to prevent weight gain (Fogelholm & Kukkonen-Harjula 2000, Saris et al. 2003). Even lesser exercise has beneficial effects on health irrespective of weight loss.

2.5.2 Operative treatment of obesity

Surgical indications: The NIH Conference recommendation from 1991 is usually used for surgical indications. BMI 40 kg/m² is recommended as a limit for surgical treatment as well as the patients' own will to lose weight and change their lives. BMI between 35 kg/m² and 40 kg/m² is also a surgical indication if obesity is connected to significant co-morbidities, such as diabetes, cardiovascular disease, arthritis, sleep apnea, and obesity-related cardiomyopathy (NIH 1991). Current treatment recommendation (Käypä hoito -suositus) 2007 follows similar guidelines. Age limit has been set to 20–60 years. In addition the patient should not have bulimia, and a low-calorie diet has not given any results. The explosive increase of obesity has lead, especially in the Western society, to a rapidly increasing need of surgical treatment. Conservative treatments have not given satisfactory long-term results. In a review-study Douketis et al. (2005) state that diet and lifestyle changes reduce weight less than 5 kg in 2–4 years, pharmacological treatments between 5 kg and 10 kg in 1–2 years, and operative treatment reduces weight between 25 kg and 75 kg in 2–4 years. At present surgical treatment is the only treatment for morbid obesity that results in a long-term weight loss and recovery from the co-morbid conditions (Karmali & Shaffer 2005).
Surgical treatment is divided into four types according to the principle of effect:

1. **Malabsorptive operations:** jejunoileal bypass (JIB) and biliopancreatic diversion (BPD), which has two variants: Scopinaro method and the so-called duodenal switch method.

2. **Malabsorptive/restrictive:** gastric bypass.

3. **Restrictive:** vertical banded gastroplasty (VBG), laparoscopic gastric banding (LAGB, SAGB), and sleeve gastrectomy.

4. **Experimental methods.**

**JIB (jejunoileal bypass)**

Bariatric surgery was developed in the 1950s from the jejunoileal bypass operation that is purely malabsorptive, and at the same time a maldigestive method (Buchwald & Buchwald 2002). A Swedish surgeon V. Henrikson performed the first operation for obesity in 1952 by removing 105 cm of the small intestine (Henrikson 1952). On the basis of his findings the idea of partially bypassing the small intestine for the treatment of obesity was born. In 1953 Varco from Minnesota performed the first jejunoileal bypass operation that included an end-to-end jejunoileostomy and a separate anastomosis of the bypassed intestine to cecum (Buchwald & Buchwald 2002). In 1963 Payne *et al.* published results of massive intestinal bypasses in morbidly obese patients. Almost the entire small intestine was bypassed in the surgery, and even colon to the middle of the transverse colon where 37.5 cm of proximal small intestine was anastomosed. This resulted in fast weight loss, diarrhea, liver damage, and disturbances in the electrolyte balance, and the anatomy had to be restored to normal (Payne *et al.* 1963). All the patients gained back their preoperative weight after the second operation (Payne & DeWind 1969). After several intermediary techniques (Lewisl *et al.* 1966), a specific technique was established in 1969, which became the standard jejunoileal technique: 35 cm of proximal jejunum was attached to terminal ileum 10 cm from the ileocecal valve (Payne & DeWind 1969). Jejunoileal bypass surgery is associated with metabolic disturbances that cause kidney stones, liver damage, and immunological joint symptoms. Because of the side effects the operation is no longer in use even though good long-term results have been achieved (Deitel 1993, Sylvan *et al.* 1995).
**BPD and BPD+DS (biliopancreatic diversion and biliopancreatic diversion with duodenal switch)**

Jejunoileal bypass surgery is no longer in use because of severe side effects, but malabsorptive biliopancreatic diversion (Figure 1), which was developed from jejunoileal bypass, is still widely used. It is the most efficient operative method that leads to a permanent 78% excess weight loss (Scopinaro 1996). The most important difference compared to the earlier bypass operations is the flow of food or bile and pancreatic fluids through all the segments of the bowels (Buchwald & Buchwald 2002). Scopinaro is known as the developer of the operation. He published the technique in 1979 first in canine experiments, and later during the same year in patients (Scopinaro et al. 1979). The current Scopinaro BPD operation consists of a partial gastrectomy (gastric volume about 250–500 ml), closing of the duodenum, a gastrojejunostomy with about 250 cm long Roux-en-Y jejunum loop, and an anastomosis of the biliopancreatic loop to ileum 50 cm above the ileocecal valve. Another modification of the method is the duodenal-switch technique where the stomach is reduced to a tube-like organ, a so-called "sleeve gastrectomy" is performed (Figure 2), and the pylorus is spared. The jejunum is attached to the proximal duodenal stump, and the biliopancreatic limb to the distal ileum as described by Scopinaro (Marceau 1993, Hess & Hess 1998). This operation has also been performed laparoscopically since 1999 (Ren et al. 2000). Even though this method has the most efficient effect on weight loss, it has not become very popular because of the associated metabolic risks. In many studies the risks do not differ significantly from those of the gastric bypass surgery. Anemia and vitamin D deficiency are the most common complication. Hypoproteinemia is rare; it is found in only 0.5% of the cases (Skroubis et al. 2002, Larrad-Jimenez et al. 2007).
Fig. 1. BPD.

Fig. 2. BPD+DS.
**LRYGB and RYGB (gastric bypass)**

In the combined restrictive and malabsorptive operation a small reservoir of the stomach is formed. It fills quickly and a sense of fullness results. The stomach empties slowly through a small opening into the jejunum the beginning of which is bypassed, which causes malabsorption (Figure 3). This operation was developed by Mason (Mason & Ito 1967). In the original Mason's and Ito's operation the stomach was cut transversely in its upper part. The volume of the upper part was between 100 ml and 150 ml. A proximal jejunum loop was attached to it with a 12 mm opening. Later the volume of the proximal pouch was reduced to 50 ml in order to increase the effect and reduce stomal ulcers. In the Alder technique (1977) the stomach was not cut, but the proximal pouch was formed by closing the stomach transversely with a stapler and attaching a Roux-en-Y anastomosis on it. Thus bile reflux could be avoided and tension in the anastomosis reduced (Alden 1977, Griffen et al. 1977). Several modifications were developed of this method. Torres used a horizontal pouch in the lesser curvature and a circular stapler for the gastrojejunal anastomosis (Torres et al. 1983). With the super obese (BMI more than 50 kg/m²) a long, between 150 and 200 cm long, jejunum bypass was adopted (Brolin 1992). Fobi added a silastic ring above the gastrojejunostomy to improve the restrictive effect (Fobi & Lee 1998). Laparoscopic technique entered bariatric surgery in 1994 when Wittgrove et al. published their first experiences of laparoscopic gastric bypass surgery. Higa et al. (2000) introduced anastomoses made with a suturing technique in the laparoscopic gastric bypass operation. This was considered to reduce anastomotic leakage. Laparoscopic gastric bypass in its different forms has become the most common of the techniques used today.
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Fig. 3. Gastric bypass.

VBG (vertical banded gastroplasty)

The development of restrictive methods began in 1971 when Mason and Printen divided the stomach horizontally into two parts leaving a small connective channel between the parts on the side of the greater curvature (Printen & Mason 1973). This operation gave only temporary benefit as well as the technique Pace introduced where the connection between the two parts of the stomach was formed by leaving a few staples out of the stapler (Pace et al. 1979). Fabito introduced a vertical gastroplasty (Fabito 1981), and Laws a silastic ring to support the opening (Laws & Piantadosi 1981). In 1980 Mason introduced the latest variation of gastroplasty, the vertical banded gastroplasty (VGB) (Figure 4) that is still in minor use today (Mason 1982, Buchwald & Williams 2004). Even the VGB operation has been performed laparoscopically (Hess & Hess 1994, Chua & Mendiola 1995). In the latest version a small tube-like pouch (about 20 ml) is created in the upper part of the stomach along the lesser curvature with a cutting stapler. This part of the stomach is completely isolated from the fundus area, and there is a small outlet, reinforced with a silastic ring, leading to the distal stomach.
GB (gastric banding)

Developments in laparoscopic surgery in the beginning of the 1990s made even laparoscopic bariatric surgery possible. There was a clear need for such operations to reduce the risks of open operations. A new band type was needed for laparoscopic surgery as well as animal experimentations to develop the technique. Developing the operational procedure took one year, and the first laparoscopic gastric banding was performed on September 1, 1993 (Belachew et al. 2001). The development of the procedure took place in Belgium in Centre Hopitalier Hutois. In 1994 Belachew published the results of four female patients whose BMI was 43, and in 1995 the results of 33 female and 4 male patients. No problems were encountered in their operations or recovery, and the initial results were similar to those of VBG (Belachew 1994, Belachew 1995). In 1994 an international workshop was held in Belgium for 30 laparoscopic surgeons, and more than 300 surgeons from different countries were trained to perform the operations using the same technique (Belachew et al. 2001). At the same time the laparoscopic banding technique was developed even in other centers (Broadbent et al. 1993, Catona et al. 1993, Forsell et al. 1993). In order to prevent pouch dilatation, Niville suggested placing the band close to the esophagogastric junction above the lesser sac and constructing a very small anterior pouch (Niville et al. 1998). In later studies it was found that using a similar, the so-called pars flaccida technique, the
most common complication, gastric prolapse through the band (slippage), could be reduced to about 2–3% (Ren & Fielding 2003, Fielding & Ren 2005, Weiner et al. 2003, Chevallier et al. 2004).

Fig. 5. Gastric banding.

Gastric banding is the least invasive method of bariatric surgery (Figure 5). This operation was preceded by Tretbar's fundoplication method (Tretbar et al. 1976). In Wilkinson's gastric wrapping technique the volume of the stomach was reduced by wrapping it inside a mesh (Wilkinson & Peloso 1981). Kolle and Molina developed a method where a pouch of 15–30 ml was formed of the upper part of the stomach by wrapping a Dacron® band around the stomach (Kolle 1982, Molina 1983). These methods were open operations and could not be adjusted. An adjustable band was developed simultaneously in two different centers. Professor Dag Hallberg developed an adjustable band in Huddinge hospital (Hallberg 1985). The first operation was performed in 1985 (Forsell et al. 1996). Dr. Lubomir Kuzmak registered a patent on his own band in the USA on June 3, 1986 (US patent 4,592,339 June 3, 1986). Both bands have the same basic idea. To a ring enforced with Dacron is attached an adjustable inner part to adjust individually the diameter of the ring. Hallberg's band became the so-called Swedish Band, and Kuzmak's band is known commercially as the Lap-Band, which is the only band that has been approved by FDA (June 5, 2001) in the USA. Both bands have the same basic idea of adjustment, but the Swedish band has a low pressure, is soft, and it can be adjusted on a larger scale.
**Sleeve gastrectomy**

Partial gastrectomy by forming a tube of the stomach has been used in connection with the biliopancreatic diversion (Figure 6). Sleeve gastrectomy alone is more efficient than gastric banding, at least in the short term (Himpens, et al. 2006). Sleeve gastrectomy is recommended as the initial operation in the super obese (BMI more than 50 kg/m^2). If needed, duodenal switch or gastric bypass can be performed after weight has been lost and operation risks reduced (Regan et al. 2003, Baltasar et al. 2005, Hamoui et al. 2006, Serra et al. 2006, Frezza 2007). Sleeve gastrectomy affects the volume of the stomach, but better effect compared to gastric banding may also be due to a hormonal effect. Removing the fundus area of the stomach decreases the ghrelin hormone level and reduces appetite. The advantages of sleeve gastrectomy include low complication rate, lack of malabsorption, and the possibility to continue with other surgical methods. However, long term results are still missing (Gumbs et al. 2007).

![Fig. 6. Sleeve gastrectomy.](image)

**Intragastric balloon (BiB)**

Intragastric balloon has been used in the treatment of obesity since the 1980s. The idea was to reduce the volume of the stomach with an artificial bezoar (Nieben & Harboe, 1982). In some patients the weight loss was promising, but the method was abandoned for more than 10 years because of frequent complications (Abri et
al. 1988, Brown et al. 1988, Mathus-Vliegen & Tytgat 1990). The balloon therapy was adopted again 10 years later as a simple primary therapy for the super obese and for those patients that are either unfit or unwilling to have an operation. The balloon is also recommended as a test before a restrictive operation. If the weight loss is more than 10 kg with the balloon therapy, a restrictive operation will most likely give a good result (Loffredo et al. 2001). With the design and material of the new BIB balloon complications (ulcers and intestinal obstructions caused by the balloon) related to the earlier model can be avoided. Balloon therapy is a solution for beginning the surgical treatment of obesity. The same balloon can be used for 6 months after which it has to be removed or changed, and the treatment has to be continued by other means. In the super obese a weight loss between 13 kg and 28 kg can be achieved in 3 months (Doldi et al. 2004, Genco et al 2005, Spyropoulos et al. 2007).

**Experimental operations**

Attempts to develop methods that interfere with appetite via the central nervous system date back to the 1970s. Quaade et al. (1974) published a stereotactic stimulation of the hypothalamus in five patients. Cigaina has developed the method first in animal experiments and later in patients (Cigaina et al. 1996). A gastroparesis and a feeling of fullness are initiated with the help of a pacemaker with electrodes attached on the wall of the stomach (Cigaina et al. 1996). The method affects the levels of gastrointestinal hormones, which might be the mediating mechanism (Cigaina & Hirschberg 2003). The method has initially given promising clinical results, and it is under the FDA investigation for clinical use (Greenstein & Belachew, 2002). A commercial version is expected to be released in 2008.

**Increase in bariatric operations worldwide**

Bariatric operations have increased worldwide with the rapidly increasing obesity epidemic. A survey made by IFSO (International Federation for the Surgery of Obesity) in its member countries and Sweden yielded a combined number of 146,301 operations in the year 2003. The most popular operations were laparoscopic gastric bypass 25.67 %, laparoscopic gastric banding 24.14 %, open gastric bypass 23.07 %, laparoscopic long-limb bypass 8.9 %, open long-limb bypass 7.45 %, and open vertical banded gastroplasty 4.25% (Buchwald &
In the USA gastric bypass has been the most popular operation, but after FDA approval also gastric banding operations have increased rapidly. The Lap-Band is the only FDA approved band since 2001, but approval is being applied also for the band called Swedish Band that is sold in Europe. A total of 177,000 bariatric operations were performed in the USA in 2006. According to commercial estimates, in 2007 the number will be 200,000 of which about 80% will be gastric bypass operations and 20% gastric banding operations. The proportion of gastric banding operations is expected to increase to about 50% by 2010 (Information given personally by Buchwald H. IFSO Meeting, Porto 2007).

2.6 Effect of surgery

2.6.1 Weight loss effect

A significant weight loss has beneficial effects on health by reducing or improving co-morbidities such as type 2 diabetes, hypertension, obstructive sleep-apnea, hypertriglyceridemia, non-alcoholic fatty liver and fertility in polycystic ovary syndrome. Also quality of life improves and life expectancy increases (O'Brien & Dixon 2003). It is difficult to compare different methods, because results of well conducted randomized trials have not been published and long-term results of gastric banding operations are not available (Colquitt et al. 2005). Two large literature reviews of bariatric surgery publications are available. The review by Chapman et al. (2004) includes gastric banding, gastric bypass, and vertical banded gastroplasty operations. Another large meta-analysis includes results of all the methods used in bariatric surgery (Buchwald et al. 2004). In Buchwald's analysis the mean excess weight loss (EWL) with all the methods of bariatric surgery was 61.2% in a sample of 10,172 patients at a time when all the co-morbidities had been examined. The results varied according to the method used: LAGB 47.5 %, RYGB 61.6 %, and BPD 70.1 %. The results were not significantly different in those followed 2 years or less compared to those followed more than 2 years. In Chapman's literature review LAGB is regarded as good as the compared methods at least until 4 years. The results varied greatly in different studies. The longest follow-up time was 48 months in O'Brien's study where EWL was 68% in LAGB patients. The corresponding RYGB results at 48 months varied between 50% and 74%, and those of VGB between 45% and 77% (Mason et al. 1995, Pories et al. 1995, O'Brien et al. 1999, DeMaria et al. 2001). The initial weight loss is faster after a bypass operation compared to gastric banding, but the
difference evens out after 4 years (48 months), and the result remains the same at 72 months (O'Brien et al. 2006). Biliopancreatic diversion (BPD) gives the most effective and lasting results. EWL remains in about 70% in 15 years of follow-up (Scopinaro et al. 1996, Miller 2004). In the Swedish SOS long-term study the weight loss after 10 years was 13.2% in the gastric banding group, 16.5% in the gastroplasty group, and 25% in the bypass group (Sjöström et al. 2004). The weight loss remained unchanged in 15 years of follow-up (Sjöström et al. 2007). Sleeve gastrectomy is an effective treatment for morbid obesity up to 2 years after surgery. Long term studies (> 5 years) are necessary to determine whether SG is a durable alternative in the treatment of morbid obesity. EWL at 6 and 12 months averages 49% and 56% respectively (Gumbs et al. 2007). Improvement in diabetes mellitus and hypertension has been reported in 60–100% of patients (Baltasar, 2005, Moon Han et al. 2005).

2.6.2 Effect on co-morbidities

Effect on diabetes

In the Swedish Obese Subjects (SOS) study diabetes was resolved in 72% of the patients 2 years after surgery, but in only 36% after 10 years. In this study the majority (94%) of the patients were gastric banding and gastroplasty patients who started to gain weight after 1 year and weight loss (WL) at 10 years was only 16.1%. Better weight loss also increases recovery from diabetes. Pories et al. (1995) showed in a study of 146 bypass patients that 83% recovered from type 2 diabetes in a 14-year follow-up. Even other co-morbidities such as hypertonia, sleep apnea, gout, infertility, and arthritis resolved or improved. The effect of bariatric surgery on glucose metabolism and insulin resistance is debated. All operations result in a reduced calorie intake and weight loss thus reducing the stimulation of the entero-insular axis. Bypass operations may even increase this effect by directing food away from the proximal part of the intestines. Long-term effect comes via reduction in fat mass and the release of adipocytokine (Faraj et al. 2003, Ballantyne et al. 2005, Gumbs 2005, Bouldin et al. 2006).

More than 95% of type 2 diabetes is connected to overweight. A clear connection exists between overweight and diabetes in both men and women (Chan et al. 1994, Colditz et al. 1995). All methods of bariatric surgery have been shown to improve diabetes. Pories et al. (1992) noticed recovery from type 2 diabetes after gastric bypass operation. Buchwald showed in a meta-analysis of 136
controlled studies recovery from diabetes in 76.8% of the patients. Different operating methods have different effects (Buchwald et al. 2004). According to the Buchwald's systematic review, 98.8% of the patients recover from type 2 diabetes after BPD, 83.7% after gastric bypass, 71.6% after gastroplasty, and 47.9% after gastric banding (Buchwald et al. 2004). Several other studies have given almost similar results (Schauer et al. 2003, Sugerman et al. 2003).

**Effect on hypertension**

Weight gain causes a linear rise in blood pressure (Jousilahti et al. 1995). In Sugerman's study of 1025 bypass patients hypertension was found in 75% of those who had diabetes. In a follow-up of 5 to 7 years, 86% of the patients recovered from diabetes and 66% from hypertension. Weight loss remained good, too: EWL was 59% (Sugerman et al. 2003). In the SOS-study in the 2- and 10-year follow-up the group of operated patients had less hypertension even though the weight loss at 10 years was only 16.1% (Sjöström et al. 2004). Recovery from hypertension seems to be connected to weight loss and not the final weight. Blood pressure may reduce to normal values even though ideal weight is not achieved (Carson et al. 1994, Bouldin et al. 2006). In Buchwald's meta-analysis blood pressure was reduced in 78.5%, and reduced to normal values in 61.7% of the patients who had had bariatric surgery (Buchwald et al. 2004). The effect of these operations on blood pressure is not as good as on diabetes. After BPD and BPD+DS blood pressure decreases to normal values in 83.4%, after VBG in 69.0%, after LRYGB in 67.5%, and after GB in 43.2% of the patients.

**Effect on hyperlipidemia**

Hypertriglyceridemia and hypercholesterolemia improve significantly with all methods of bariatric surgery. Total cholesterol values have reduced in several studies an average of 25%, and triglycerides 40% (Cowan & Buffington 1998, Bouldin et al. 2006). The proportion of patients whose blood lipid values improve varies, but is typically about 70 %. BPD and gastric bypass reduce hyperlipidemia most efficiently; 99.1% and 96.9% respectively (Buchwald et al. 2004). In the SOS study triglycerides and HDL cholesterol levels improved significantly in the surgically treated group in 2- and 10-year follow-ups. Even total cholesterol levels were significantly lower in the gastric bypass group (Sjöström et al. 2004). Buchwald et al. (2004) found improved HDL cholesterol levels after restrictive
operations (gastric banding and gastroplasty) even though total cholesterol levels did not improve. Brolin et al. (2000) found that an abnormal lipid profile may improve permanently after bariatric surgery even though EWL is less than 50% or less than 15% of the lost weight is regained.

**Effect on sleep apnea and obesity hypoventilation syndrome**

Obesity causes sleep disturbances and is the most important risk factor for sleep apnea (Dixon et al. 2001). Obstructive sleep apnea may cause hypertension and increase the risk for cardiovascular diseases (Phillips & Cistulli 2006). Between 45% and 60% of patients coming to bariatric surgery suffer from sleep apnea (Dixon et al. 2001, Rasheid et al. 2003, Haines et al. 2007). Surgical treatment of obesity is a very efficient way of treating sleep apnea. In Buchwald's study 85.7% were cured (Buchwald et al. 2004). In Haines's study RDI (respiratory disturbance index) decreased from the preoperative severe sleep apnea value of 51 to a value of 15, which reflects a mild disturbance. Preoperative BMI correlates with the severity of sleep apnea (Haines et al. 2007). The aim in treating obese patients with sleep apnea is a significant weight loss (Dixon et al. 2001). Weight loss improves or relieves obstructive sleep apnea, reduces day-time tiredness, and improves quality of life (Dixon et al. 2005).

**Effect on non-alcoholic steatohepatitis**

Fatty liver is the most common cause of elevated values in the liver function tests (Raman & Allard 2006). About 90% of the patients referred for bariatric surgery have fatty liver changes and between 30% and 50% have non-alcoholic steatohepatitis (NASH) (Liew et al. 2006, Machado et al. 2006). Fatty liver and NASH are connected to obesity, insulin resistance, and type 2 diabetes whereas advanced cirrhosis is connected to hypertension (Machado et al. 2006). A successful operative treatment of obesity with any method cures 90% of the patients from NASH. In Dixon's gastric banding patients the median weight loss was 31.5 kg (Dixon et al. 2006), and only 10% had NASH changes after surgery. In Baker's bypass patients weight loss was 52.4 kg and 89% recovered from NASH (Barker et al. 2006).
Effect on cardiovascular diseases

Bariatric surgery is the most effective means of reducing cardiovascular risk factors, such as hypertension, type 2 diabetes, and high LDL cholesterol, triglyceride, and total cholesterol levels, in severely obese people (Lara et al. 2005, Bouldin et al. 2006, Williams et al. 2007). Batsis et al. (2007) found that weight loss in gastric bypass patients was the defining factor in reducing cardiovascular events and deaths in class II and III obesity (BMI over 35 kg/m²) in a 10-year follow-up. According to a risk modeling 4 deaths and 16 cardiovascular events are prevented in 10 years per 100 patients that have undergone bariatric surgery compared to patients in a weight reduction program (Batsis et al. 2007). Apart from weight loss bariatric surgery also reduces the above mentioned risk factors for coronary artery disease, and especially the levels of the C-reactive protein (Williams et al. 2007). The risk factors decrease more than what could be expected based on the weight loss alone (Jazet et al. 2007). Left ventricular hypertrophy of the heart is reduced, aortic function returns to normal and the diastolic function improves after weight loss achieved by bariatric surgery (Ikonomidis et al. 2007). In the SOS study mortality was 5.0% in the surgical group and 6.3% in the conservatively treated group during 15 years of follow-up. The most common causes of death were myocardial infarction and disturbances in cerebral circulation (Sjöström et al. 2007).

Effect on degenerative joint diseases

Obesity is a risk factor for back pain, big joint degeneration and arthritis (Griffin & Guilak 2005, Bouldin et al. 2006, Brooks 2006, Wearing et al. 2006). Avoiding obesity is the most important factor in preventing the development and deterioration of osteoarthritis (Powell et al. 2005). In the age group between 30 and 39 years the mean BMI was 28.8 kg/m² in 53% of the patients with a total hip replacement (Marks & Allegrante 2002). BMI fulfilled the obesity criteria (more than 30 kg/m²) in those patients who were waiting for a reoperation because of joint replacement complications (Marks & Allegrante 2002). Total knee arthroplasty is associated with more complications and the functional result is worse in morbidly obese patients. Operative treatment for morbid obesity is recommended if overweight is regarded as a contraindication for arthroplasty (Winiarsky et al. 1998, Parvizi et al. 2000).
**Effect on urinary incontinence**

Obesity is an important etiological factor in urinary incontinence because of a raised intra-abdominal pressure (Bouldin *et al.* 2006). Urinary incontinence is common; between 61.2% and 66.9% of severely obese women suffer from it. Of the patients who have urinary incontinence, 32% have also anal incontinence. Bariatric surgery gives a good treatment effect when the excess weight is reduced by 50% (Deitel *et al.* 1988, Richter *et al.* 2005).

**Effect on pregnancy**

Morbidly obese women are often infertile (Deitel *et al.*1988, Wittgrove *et al.* 1998). Pregnancy and childbirth are associated with more complications, such as hypertension, diabetes, pre-eclampsia, and venous thrombosis, but complications are reduced after a bypass operation compared to the same patients’ earlier pregnancies (Deitel *et al.* 1988, Wittgrove *et al.* 1998). Gastric banding can be used to individually regulate the weight gain during pregnancy without obstetric complications (Dixon *et al.* 2001). Fertility improves after a gastric-by pass operation (Bouldin et.al.2006).

**Effect on asthma**


**Effect on quality of life**

Obesity is a chronic disease that is associated with important co-morbidities, reduced quality of life, and decreased life expectancy. Decreased quality of life can be compared with the impact stroke, myocardial infarction, or heart failure has in the ability to function. In estimating the result of surgery it is important to define how to measure patient's improved lifestyle (Livingston & Fink 2003, Nguyen *et al.* 2006). In estimating the results of bariatric surgery, quality-of-life
measurements have received less attention than postoperative morbidity. Quality of life can be measured with health-related scales or disease-specific scales. The most commonly used general scales are medical study 36-item short form (SF-36) and gastrointestinal quality of life (GIQLI) questionnaire. The 15D is a quality-of-life scale validated in the Finnish population (Sintonen 2001).

The NIH consensus conference (1991) found it difficult to compare the results of bariatric operations because of the lack of common scales (National Institute of Health consensus conference statement). The specialists were given a task to develop a common method for evaluation. The method was to include weight loss, improvement of co-morbidities, and changes in the quality of life with a disease-specific instrument developed by psychologists knowledgeable in the field (Oria & Moorehead 1998). BAROS (bariatric analysis and reporting outcome system) was developed as a simple scoring method with a five-degree scale: failure, fair, good, very good, and excellent. Moorehead-Ardelt questionnaire with its five QoL (quality of life) questions is used for estimating the quality of life: self-esteem, physical activity, social life, ability to work, and sexual activity (Oria & Moorehead 1998). In 2004 it was noticed that BAROS does not distinguish well enough the gastrointestinal side effects related to the operations, and that different operations have different side-effect profiles. A second version of the questionnaire was developed in 2004 where those events have been taken into account (Moorehead et al. 2003).

After bariatric surgery the QoL index improves as early as at 3 months. Nguyen et al. (2001) noticed in a randomized comparative study of open and laparoscopic gastric bypass operations that both SF-36 and Moorehead-Ardelt indexes were improved 3 and 6 months after surgery. Even Dymek et al. (2002) noticed a remarkable improvement in the SF-36 index 6 months after gastric bypass surgery. The result remained the same 12 months after surgery. A permanent improvement in both physical and mental SF-36 indexes has even been noticed after an average of 13.8 years following gastric bypass surgery (de Zwaan et al. 2002). Choban et al. (1999) noticed improvement in 7 of the 8 domains in SF-36 score when weight loss leveled out about 18 months after gastric bypass surgery. Obese people have abnormally low SF-36 scores, but the scores return to a normal level 1 year after Lap-Band operation. The beneficial effect lasts a minimum of 4 years after surgery. The improvement in the physical well-being had the highest impact on the improvement of the quality of life, and the effect of weight loss was less important in this respect (Dixon & O'Brien 2002, O'Brien & Dixon 2003). Weiner et al. (2005) presented a 30-item BQL (bariatric quality of
life) index for following the well-being of operated patients. It was found to comply with the BAROS scale, the SF-12 scale, and the GIQLI (gastrointestinal quality of life) scale, and it is ready for clinical use. Hell et al. (2000) compared the results of gastric bypass, VBG and LAGB operations using the BAROS scale. The operations were performed in the USA and Austria. Quality of life improved significantly in 75% of the patients in the operated group, and the gastric bypass was found to be superior to the restrictive operations.

The BAROS scale can be used to compare results from different countries, different surgeons, and different cultures (Hell et al. 2000). Weiner et al. (2003) followed the first 100 patients of a total of 984 for 8.24 years. Despite complications related to the initial method of surgery the quality-of-life index improved in 82% of the patients. QoL was measured 2 and 8 years after LAGB. The changes in the SF-36 scale were small, but the BAROS scale showed permanent improvement. Follow-up times with the GIQLI scale are short. Freys et al. (2001) followed 188 gastric banding patients for 2 years. One third had to go through revision surgery after which the patients gained the same QoL level as those without complications. Champault et al. (2006) found that 2 years after the surgery patients operated with gastric banding have the same quality of life as healthy people.

2.7 Complications of gastric banding

Complication rate related to gastric banding varies greatly in different patient materials.

Chapman et al. (2004) found in a systematic literature review that mortality was 0.05% and morbidity 11.3%. Morbidity varied between 0% and 68% in different publications. High complication rates have been reported by De Meria et al. (2001), Martikainen et al. (2004), and Gustavson and Westling (2002) who had a reoperation rate of more than 50% because of complications. Favretti et al. (2007) found in a 12-year follow-up, in a sample of 1791 patients, complications that necessitated a reoperation in 5.9% of the patients. The rate of small reoperations related to the port was 11.2%. Naef et al. (2007) found during a 5-year follow-up early complications in 6.25% and late complications in 10.9% of the patients. The number of complications has reduced noticeably since the so-called "pars flaccida technique" was established. In this technique the band is inserted higher, close to cardia, and above the lesser sac on the back side. The most common complication, slipping of the stomach through the band, became almost
non-existent. In Chevallier's 1000 patients slippage appeared in 24% of the patients operated with the so-called perigastric technique and in 2% with the pars flaccida technique (Chevallier et al. 2004).

2.7.1 Early complications

Early complications of gastric banding are rare. In Weiner's material of 984 patients 2 early complications were found: 1 perforation and 1 slippage (Weiner et al. 2003). In a material of 763 patients in a Belgian center the early complication rate was 2% in which was included the conversion rate to open surgery, 1.3% (Belachew et al. 2002).

Gastric prolapse

Gastric prolapse through the band may lead to necrosis and perforation of the stomach and immediate removal of the band is necessary. This may happen at any time after the initial operation (Chelala et al. 1997, Chevallier et al. 2004, Kriwanek et al. 2005).

Gastric perforation

Perforation of the stomach is a rare complication that can be found in 0.3–1% of the cases (Belachew et al. 2002, Chelala et al. 1997, Weiner et al. 2003, Chapman et al. 2004).

2.7.2 Late complications

Slippage

The most common problems related to gastric banding are the so-called slippage or dilatation of the stomach above the band (pouch dilatation). The incidence of slippage depends on the operation technique and follow-up time. The so-called "pars flaccida technique" has reduced complications from 24% to 2% (Chevallier et al. 2004), from 20.5% to 1.4 % (Ponce et al. 2005), and from 17% to 3.7 % (Weiner et al. 2003). In Martikainen's material the incidence of slippage or pouch dilatation was 21% (Martikainen et al. 2004). In Favretti's long-term follow-up slippage was found in 3.9 % (Favretti et al. 2007). Slippage and pouch dilatation
should be distinguished from each other. Slippage always requires an operation, but concentric pouch dilatation can be treated conservatively by adjusting the band (Moser et al. 2006). The model of the band may also have an effect on slippage. Peterli et al. (2002) and Wolnerhansen et al. (2005) found a reduced complications rate after the new 11-cm Lap-Band model became available.

**Erosion**

Erosion means that the band migrates through the stomach wall inside the stomach partially or in whole. Incidence varies between 0% and 9% (O'Brien & Dixon 2002, Martikainen et al. 2004). Changes in the operative technique and the band have reduced complications (O'Brien & Dixon 2002). In the longest published follow-up (12 years) the incidence of erosion was 0.9% (Favretti et al. 2007). Erosion can be treated by removing the band from inside the stomach or via laparoscopy and by converting the operation to LRYGB or BPD immediately during the same operation or after waiting for a few months (Ventienen et al. 2000, Regusci et al. 2003, Suter et al. 2004). Even a new band can be inserted in the same operation without any remarkable complications (Abu-Abeid et al. 2005).

**Leakage in the filling system of the band**

Technical problems related to the band are found in 2.5–11% of the operations (Belachew et al. 2002, O'Brien & Dixon 2002, Favretti et al. 2007). This can be managed by changing the leaking chamber or band. This complication has become less frequent after improvements have been made in the chamber, filling tube, and band (O'Brien & Dixon 2002).

**Gastroesophageal reflux**

The results of gastric banding on reflux are varied. The worst results have been published by Martikainen et al. (2004) and Gustavsson et al. (2002). In these materials the incidence of erosive esophagitis varied between 30% and 44%. On the other hand the reflux symptoms may improve after LAGB surgery as Dolan et al. (2003) showed in a material of 64 patients that had a hiatalplasty performed at the same time because of diaphragmatic hernia. Weiner et al. (2003) noticed in 68% of the patients preoperative reflux symptoms that disappeared after LAGB, but 4% of those who had no symptoms preoperatively developed symptoms after
the operation. The symptoms disappeared after the band was emptied. DeJong et al. (2004) noticed recovery from gastro-esophageal reflux if there was no pouch dilatation in the follow-up.

**Dilatation of esophagus**

It is difficult to define the incidence of esophageal dilatation, because in most large series it has not been studied. Chevallier et al. (2004) found 5 cases in a sample of 1000 patients. A band that was placed too high was considered to be the reason. Too tight a band or prolapse of the stomach may cause dilatation of the esophagus, but after the prolapse is repaired and the band emptied no symptomatic dysmotility of the esophagus can be found (O'Brien & Dixon 2002). Martikainen et al. (2004) found esophageal dilatation in 3% of the patients. Dargent (2005) found in a follow-up of 1232 patients 2 esophageal dilatations that necessitated band removal, and in addition 6 dilatations that contributed to band removal as additional reasons. During the follow-up a slight dilatation was found in 25% depending on how full the band was. A severe dilatation was found in 0.6%. Band removal and LRYGB were recommended as a treatment. Smaller dilatations can be treated by emptying the band. The pars flaccida technique has reduced slippage, but has not had any effect on esophageal dilatation (Dargent 2005). DeMaria et al. (2001) found esophageal dilatation in 71% of the patients in a 4-year follow-up. Of these patients 72% had dysphagia, vomiting, and reflux symptoms. Pseudoachalasia may be found after LAGB in patients whose band is in normal position and the diameter of the stomal opening is normal. In a material of 120 LAGB patients Wiesner et al. (2001) found 9 esophageal dilatations and dysmotilities. All 9 patients had LES insufficiency. Weight loss after 1 year was clearly worse in 7 patients. The same patients did not comply with the postoperative eating instructions and used esophagus as an extra storage for food. A manometry should be performed to find these patients and a critical approach should be taken to gastric banding operations (Wiesner et al. 2001).

### 2.8 Complications of the most common methods of bariatric surgery

Chapman found a large variation in the incidence of complications in a systematic literature review. Highest mortality was connected to RYGB; 0.5%. VGB was connected with 0.31% mortality, and LAGB with 0.05% (Chapman et al. 2004). In
Buchwald's meta-analysis of 85,048 patients' mortality in bariatric surgery less than 30 days from the operation was 0.28%, and mortality between 30 days and 2 years was 0.35%. Early mortality of open restrictive operations was 0.30% and that of laparoscopic operations 0.07%. The mortality of open and laparoscopic gastric bypass operations was 0.41% and 0.16% respectively. The mortality rates of malabsorptive operations (BDP) were 0.76% after open and 1.11% after laparoscopic operations. (Buchwald et al. 2007).

Laparoscopic gastric banding is the safest form of bariatric surgery. Parikh et al. (2006) compared bariatric operations performed in the same clinic. Complication rate ranged between 9% and 25%. Third or fourth grade complications that lead to death or a resection or an irreversible deficiency of an organ were found in 0.2% of LAGB, 2% of RYGB, and 5% of BPD operations (Parikh et al. 2006). In Scopinaro's (the developer of BPD) 15-year follow-up the operative mortality was 0.4%. The most common late complication was incisional hernia; 8.7%. Specific complications related to BPD were anemia 5%, stomal ulcer 2.5%, and protein deficiency 7% (Scopinaro et al. 1996). No significant difference in complications between BPD and RYGB were found (Parikh et al. 2006). Good results have been obtained after laparoscopic sleeve gastrectomy in some recent studies with no perioperative mortality. Perioperative complications occurred in 7.36% of the operations including 3.66% gastric fistulas. Esophageal reflux symptoms caused long-term morbidity in 11.80% of the cases (Nocca et al. 2008).

According to Buchwald and Williams (2004) the rates of open and laparoscopic bypass operations are almost the same, between 23.7% and 25.67%. There is no difference in mortality or 30-day reoperation rate between open and laparoscopic surgery, but wound infections are more common in the open operations (9.2%/1.7%) (Sekhar et al. 2007). The number of laparoscopic bariatric operations has increased by 470% in 5 years. Jones et al. (2006) estimated that open bypass surgery is better by comparing 25,759 open operations, performed by 16 experienced surgeons, to published materials of laparoscopic surgery. The incidence of the most common complication of open operations, incisional hernia, could be reduced from 6.4% to 0.3% by using the left subcostal incision. Ricciardi et al. (2006) found that hospital stay, mortality, and morbidity were significantly lower (p<0.001) after a laparoscopic approach. In a randomized study with a 3-year follow-up Puzziferri et al. (2006) found that the biggest advantage of the laparoscopic approach was the lower incidence of incisional hernia; 5% vs. 39%.
2.9 Metabolic complications

Vitamin, mineral, and trace mineral deficiencies are common after malabsorptive operations, but they can also be found after restrictive operations as a consequence of food intolerance and vomiting (Bloomberg et al. 2005). Significant deficiencies may lead to severe symptoms, such as Wernicke-Korsakoff syndrome and beriberi (thiamin deficiency), kwashiorkor (protein deficiency), night blindness, and corneconjunctival xerosis (vitamin A deficiency) (Bloomberg et al. 2005). Clinical symptoms suggestive of deficiencies (hair loss, dry skin, skin-muscle pains, and dental problems) could be found in 75% of the patients after LRYGB and in 45% after LAGB. Abdominal symptoms and food intolerance were more common after LAGB than LRYGB (80% vs. 37.5%) (Ledoux et al. 2006). Loss of bone mineral content has been described in small series after RYGB, but not after LAGB (Coates et al. 2004, von Mach et al. 2004).

Iron deficiency may be found especially in women before menopause (Brolin et al. 1998). The absorption of vitamin B12 is impaired after a bypass surgery. Vitamin B12 concentration is decreased in two thirds of the patients (Halverson 1986). Deficiencies in the fat soluble vitamins have been found in two thirds of the patients after BPD (Bloomberg et al. 2005). This deficiency is more common than generally expected even after LRYGB and should be taken into account (Ledoux et al. 2006). The commonly used multi-vitamin preparations, vitamin B12, and iron replacement after LRYGB, and in addition calcium, fat soluble vitamins and protein replacement after BPD are usually sufficient to replace any deficiencies. A European recommendation recommends additional vitamins and trace minerals even after restrictive operations to prevent deficiencies (Fried et al. 2007). The development of deficiencies should be monitored according to a fixed program with regular intervals (Fried et al. 2007).
3 Aims of the study

1. To analyze the primary results of the first 60 consecutive gastric banding operations performed at our hospital.

2. To re-evaluate the initial results by using the bariatric analysis and reporting outcome system (BAROS).

3. To analyze our intermediate results, after 5 years of experience and 110 consecutive LAGB operations, with a median follow-up time of 27 months.

4. To compare the QoL scores of a group of morbidly obese patients not yet operated with a group of operated patients and to compare our previous findings with the HRQoL outcome assessed by a 15-dimensional questionnaire (15D), a generic health-related QoL instrument well validated in the Finnish adult population. A prospective study of both QoL and HRQoL outcomes with a 1-year follow-up was included.

5. To investigate the effect of gastric banding on esophageal motility and GER.

6. To analyze our late failures after 11 years of experience and 280 consecutive LAGB operations with 123 patients followed at least 60 months and with a mean follow-up time of 86 months (range 60–132 months).
4 Methods and patient material

4.1 Methods

4.1.1 Laparoscopic operative technique

Five trocars were introduced; one 10 mm trocar for the camera above and to the left of the umbilicus, two additional 10 mm ports in the left upper abdomen, one 10 mm port near the xiphoid process and one 5 mm port in the upper right abdomen for the insertion of a liver retractor. A small fenestration was made through the fat along the lesser curvature near the caudate lobe of the liver using ultra-sound scissors. The avascular layer between the right crus and cardia was identified through this window. A similar fenestration was made on the other side, opening the phrenoesophageal ligament at the angle of His. An atraumatic endodissector (Goldfinger®, Ethicon Endo-Surgery) was introduced from the right window to the left by blunt dissection along the posterior wall of the gastroesophageal junction, well above the lesser sac. A loop suture was attached at the end of the band. The band was introduced through one of the port incisions and the loop was attached to the groove at the end of the endodissector. The endodissector, with the attached band following it, was drawn through the retrogastric channel. The band was closed in this position using the closing mechanism and secured with one suture according to the manufacture's recommendations. The fat and the vagus nerve of the lesser curvature were included within the loop of the band. A small proximal pouch, approximately only 2–4 ml in volume, was created above the band and secured anteriorly by 4–6 gastro-gastric sutures of nonabsorbable material. No calibration device was used. The catheter end of the band was brought out through one of the trocars, connected to the filling port, and the port was finally carefully fixed subcutaneously to the periosteum on the lower part of the sternum by 4 sutures. The band was left empty.

4.1.2 Postoperative course and band adjustment

The first postoperative visit was at 6 weeks after the operation followed by visits every 3 months during the first year. After one year patients are followed at least once every 6 months, indefinitely, because the operative treatment of morbid obesity is a lifelong commitment. The band was injected for the first time during the first postoperative visit, usually with 2–4 ml of radiopaque iopamidol
The injected fluid was later replaced with saline. Further injections were made only if weight reduction was unsatisfactory (< 0.5–1 kg/week). We never fill the port with more than 8 ml of fluid. Median volume used was 6 ml (range 2–8 ml) (III).

A total of 232 adjustments to the bands had been made at the time of the third study (III).

In 22 occasions the band volume was reduced (III). Gastroscopy was performed to all patients at their 3-year control visit.

4.1.3 Bariatric analysis and reporting outcome system (BAROS)

The bariatric analysis and reporting outcome system (BAROS), as introduced by Oria and Moorehead (Oria & Moorehead 1998), provides an evidence-based, simple, and patient-friendly analysis of outcomes of bariatric surgery. This system provides a simple scoring, evaluating mainly three areas [percentage of excess weight loss, changes in medical conditions, and assessment of quality of life (QoL)]. Points are reduced for complications and reoperations.

4.1.4 The Moorehead-Ardelt questionnaire

The Moorehead-Ardelt QoL questionnaire is a disease-specific, simple, and patient-friendly, one-page analysis that focuses on self-esteem, social, sexual, and physical activity, as well as working capacity (Oria & Moorehead 1998). It was created as a part of BAROS (see above), but it can be used independently as well.

4.1.5 The 15D questionnaire and health-related quality of life (HRQoL)

The 15D is a generic, comprehensive, 15-dimensional, standardized, self-administered measure of health-related quality of life (HRQoL) that can be used both as a profile and as a single index score measurement (Sintonen 2001). This instrument has been developed since the late 1970s in Finland to conform with the definition of health by the World Health Organisation (WHO), which states that health is composed of physical, mental and social well-being. The 15D includes the following 15 dimensions: breathing, mental function, speech (communication), vision, mobility, usual activities, vitality, hearing, eating, elimination, sleeping, distress, discomfort and symptoms, sexual activity, and depression. Each dimension is divided into 5 levels evaluating the dimension in more detail. The
15D score is counted using an application of the multiattribute utility theory (Sintonen 2001). A set of utility or preference weights, elicited from the Finnish adult population through a 3-stage valuation procedure, is used in an additive aggregation formula to generate the 15D score, which is a single index number. The maximum score is 1 (no problems in any dimension) and the minimum score is 0 (dead).

The basic values given by the patients were recoded twice to include the five different level values within each dimension (e.g. for drawing 15D profiles) and to include both the level values and the relative importance weights of the dimensions (e.g. for calculation of the total 15D index score).

The reliability, validity, sensitivity, discriminatory power, and responsiveness to change has been well tested in the Finnish population (Sintonen 1997, Sintonen 2001), and found to be very good. In many respects the properties of the 15D are considered superior to existing generally used profile and single index score quality-of-life instruments (Sintonen 2001).

4.2 Patients

4.2.1 Study I and II

Sixty consecutive patients (44 women, 16 men) were treated for morbid obesity between the years 1996 and 1999 by gastric banding using the Swedish adjustable gastric band (Obtech, Baar, Switzerland). All operations were performed by the authors. Inclusion criteria for this operation were in accordance with the guidelines issued by the International Federation for the Surgery of Obesity (IFSO) (BMI more than 40 kg/m² or BMI between 35 kg/m² and 40 kg/m² with a co-morbidity) (Hell 2000). Median age of the patients was 45 years (range 21–64 years). Median preoperative BMI was 45 kg/m² (range 35–55 kg/m²). The patients were referred to surgery by the hospital's endocrinologist after failed conservative treatment attempts. All patients suffered from obesity related co-morbidities or were at serious risk of developing one. None of the patients had previously had any surgical treatment attempts for their morbid obesity. The very first operation was performed by an open approach, and two additional operations had to be performed by an open approach due to a co-existing ventral hernia. The remaining 57 patients were treated by a five-trocar laparoscopic approach. Prophylactic antibiotics were administered to all patients. The initial results were reported after 12 months' follow-up.
After a minimum follow-up of 17 months (median 28 months, range 17–61 months) a postal questionnaire about the quality of life, medical condition, and excess weight loss (EWL) (BAROS) was sent to the patients. A second questionnaire was sent 3 weeks later to those who did not answer the first time. In addition, the patients’ opinion about the operation was evaluated using four alternatives: A: I am very satisfied with the operation, B: I am quite satisfied, C: I am somewhat disappointed, D: I regret that I had the operation (see Table 1). We also asked the patients about the most common adverse events by using the following questions: 1. Do you suffer from reflux (heartburn)? 2. Dysphagia? 3. Occasional vomiting? 4. Other (abdominal pain)? (see Table 2)

4.2.2 Study III

We have treated 110 morbidly obese patients (87 women, 23 men) with the Swedish adjustable gastric band (SAGB) between 1996 and 2001. Median follow-up time was 27 months, median age of the patients 42 years (range 21–64 years), and preoperative median BMI was 44 kg/m² (range 35–66 kg/m²). All patients suffered from obesity-related co-morbidities or were at serious risk of developing one.

4.2.3 Study IV

We compared the Moorehead-Ardelt QoL scores of the first 60 patients, operated at a median of 2 years earlier, with a group consisting of the following consecutive 65 operated patients, who answered the questionnaire preoperatively.

4.2.4 Study V

The Moorehead-Ardelt questionnaire was used for disease-specific QoL assessments in 95 patients preoperatively, in 52 patients prospectively followed up to 12 months, and cross-sectionally in 52 patients that had been operated at a median of 28 months before the assessment. A generic 15-dimensional questionnaire was used for HRQoL-measurements in 75 patients preoperatively. Of these patients, 34 have been followed for 12 months. HRQoL outcomes were compared cross-sectionally with the 52 patients operated at a median of 28 months earlier.
4.2.5 Study VI

The Lap-Band Van-Guard® (Inamed, Santa Barbara, CA, USA) or the Swedish Band (Obtech, Baar, Switzerland) were used for treating 61 consecutive patients for morbid obesity by LAGB between April 2003 and November 2004. Of these patients 31 (50.8%, 26 female, 5 male) agreed to participate in this study. The mean age of the patients was 44 years (SD 11 years). An upper GI-endoscopy was performed preoperatively on all 31 patients with a flexible endoscope. Findings of possible hiatal hernia and/or esophagitis were described in detail, and esophagitis graded according to the classification by Savary and Miller (Savary & Miller 1978). Six patients (19.3%) refused the same examination after a median follow-up time of 19 months (range 7–32 months) (lost to follow-up). Seven patients refused the postoperative 24-h pH monitoring and 6 patients refused the postoperative manometry examinations (lost to follow-up). Symptoms of GERD were assessed by questioning the patients at the time of the endoscopic examination both pre- and postoperatively. Possible use of PPI or other reflux medication was recorded. The patients had an ambulatory esophageal 24-hour pH monitoring performed preoperatively and postoperatively after a median follow-up of 19 months (range 7–31 months). Acid-reducing medication was discontinued a minimum of 5 days before the examination. The examinations and analyses were performed in the department of clinical physiology at Vaasa Central Hospital. The data were downloaded to a personal computer. The analyzed parameters included the percentage of time with an esophageal pH less than 4, the number of reflux episodes, the number of episodes lasting more than 5 minutes, and the duration of the longest episode. The DeMeester score was calculated for each patient. A score that was more than 14.75 was considered pathological (Johnson & DeMeester 1986). A conventional manometry was performed simultaneously with the 24-hour pH monitoring both preoperatively and postoperatively, after a median follow-up of 19 months. The measurements were performed in the supine position at the department of clinical physiology. Any medication with possible effect on esophageal motility was discontinued 5 days prior to the examinations. Analyzed parameters included upper and lower esophageal sphincter pressure, amplitude of peristaltic contractions, and sphincter relaxations.
4.2.6 Study VII

Prospective data have been collected on 280 patients operated since March 1996. By March 2002 (minimum follow-up time 5 years), 123 patients had been operated laparoscopically with the Swedish band. Major late complications, reoperations, EWL, and failure rates among these patients, with a mean follow-up time of 86 months (range 60–132 months), are reported. EWL less than 25% or a major reoperation was considered a failure. EWL that was more than 50% was considered a success.

4.3 Ethics

Studies II, IV, V, and VI were approved by the local Ethical Committee of Vaasa Central Hospital. Studies I, III and VII were follow-up investigations according to good clinical practice, and approval was not applied for.

4.4 Statistical analyses

The results were expressed as means or medians ± SD of the mean or median with the range in parenthesis (I–III, V, VII). Demographic data between groups were compared using the unpaired t-test or chi-square test and QoL scores were compared between groups using the unpaired t-test (IV, V). QoL and HRQoL scores were compared cross-sectionally between groups using the unpaired t-test. Preoperative 15D scores and their improvement in percentages at the 1-year follow-up were assessed for possible correlation, which was evaluated for significance within the 95% confidence interval. Significant differences between variables in univariate analysis were estimated by the chi-square test. In case data was missing in any dimension of the 15D questionnaire, a predicted value was calculated defining that dimension as a dependent variable, and the other dimensions, as well as age and gender, as explanatory variables in a regression model (V). Correlations between parameters were tested by calculating Spearman’s rank-order correlation coefficient (r) (V). Paired t-test or McNemar's test was used to compare data in the same patients pre- and postoperatively (VI). Fischer's exact test was used for testing the association between factors (VI). Statistical evaluations were performed using standardized software (StatView). A p-value of less than 0.05 was considered statistically significant.
5 Results

5.1 Study results in chronological order

5.1.1 Study I. Primary outcome
Operative time (from the incision to the last suture) ranged from 62 minutes to 206 minutes (median 97 minutes). Only one operation was converted to an open approach (1.8%), due to extensive adhesions. No intraoperative complications occurred. Median postoperative hospital stay was 3 days (range 2–53 days). Mean EWL at 1.5, 6, 12 and 24 months was 17.4%, 34.5%, 50.9%, and 50.6% respectively. Three patients were lost to follow-up. There was no mortality. Immediate (30 days) morbidity was 11.6%. Four re-operations (6.7%) have been required so far. Three bands have been removed; two because of band slippage and one because of band infection. Leakage of the filling system required a reoperation in one patient. Occasional dysphagia and vomiting was reported by 5 patients. In all cases this was due to overfilling of the system and managed successfully by reducing the volume in the band. No serious reflux disease was found, except in the patients with band slippage.

5.1.2 Study II. Outcomes according to BAROS
Of the 60 patients, 52 (87%) returned the questionnaire properly answered. Our reoperation rate has increased by 10 % with longer follow-up, from a previously reported 6.7% to 16.7%. Since our last report three more leakages, one slippage, and two band migrations (converted to gastric bypass) have occurred. Median excess weight loss at the time of the questionnaire (median follow-up 28 months) was 51 % (range 0–111%). Mean weight loss at this time was 30.1 kg [median 26.3 kg (range 0–75 kg)], and median BMI dropped from a preoperative value of 45 kg/m² (range 55–55 kg/m²) to 34 kg/m² (range 24–50 kg/m²). Co-morbidities, as measured only by changes in medication, were improved in 20 patients (38.5%), aggravated in 4 patients (7.7%), and were unchanged in the rest (28 patients, 53.8%). Quality-of-life scores ranged from -3 to 3 points, with 41 patients (78.8%) giving a positive score.
Table 1. Patient opinion regarding the outcome, n=52.

<table>
<thead>
<tr>
<th>Opinion</th>
<th>N  (%)</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>A= very satisfied</td>
<td>30 (57.7)</td>
<td>A + B = success 77%</td>
</tr>
<tr>
<td>B= quite satisfied</td>
<td>10 (19.2)</td>
<td></td>
</tr>
<tr>
<td>C= somewhat disappointed</td>
<td>11 (21.2)</td>
<td></td>
</tr>
<tr>
<td>D= regretting the operation</td>
<td>1 (1.9)</td>
<td>C + D = failure 23%</td>
</tr>
</tbody>
</table>

Table 2. Band-induced side effects reported by the patients, n=52.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heartburn</td>
<td>20 (38)</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>9 (17)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>26 (50)</td>
</tr>
<tr>
<td>Other</td>
<td>8 (15)</td>
</tr>
</tbody>
</table>

5.1.3 Study III. Intermediate results

Operative time ranged from 51 minutes to 206 minutes (median 88 minutes). Four operations (3.6%) were converted to an open approach due to a very big liver (2 patients), a large omentum (1 patient), and extensive adhesions (1 patient). No intraoperative complications occurred. Median postoperative hospital stay was 3 days (range 2–53 days). Mean weight loss (MWL), excess weight loss (EWL) and median BMI at 1.5, 6, 12, 24, and 36 months are shown in Table 3. Five patients with a preoperative BMI of more than 50 (super obese) have been followed for 24 months. EWL and median BMI among these patients at this time was 58% (range 42–84%) and 38 kg/m$^2$ (range 30–41 kg/m$^2$) respectively. Three patients have been lost to follow-up. There was no mortality. Immediate (30 days) morbidity has dropped to 9%. Three patients had raised body temperature (approximately 38°C) for 1–2 days without any signs of a focus of infection. The fevers subsided spontaneously without any treatment attempts. One patient was hospitalized one day after release due to severe constipation. This was successfully treated with an enema. Reoperations and their causes are listed in Table 4. We performed one correction of the band position laparoscopically because of slippage. As we found this difficult we did the following two corrections by an open approach. Rebandings for leaking bands were performed by open approaches. Two migrated bands were removed also by open approaches, and a gastric bypass was performed at the same operation. No patients needed reoperations because of a primary
intolerance to the band. So far routine endoscopy has been performed on 23 patients during their 3-year control visit, and the findings are listed in Table 5.

**Table 3. Weight losses during a 3-year follow-up.**

<table>
<thead>
<tr>
<th>Months</th>
<th>1.5</th>
<th>6</th>
<th>12</th>
<th>24</th>
<th>36</th>
</tr>
</thead>
<tbody>
<tr>
<td>MWL1 (kg)</td>
<td>10</td>
<td>19</td>
<td>26</td>
<td>30</td>
<td>31</td>
</tr>
<tr>
<td>EWL2 (%)</td>
<td>18</td>
<td>32</td>
<td>45</td>
<td>52</td>
<td>53</td>
</tr>
<tr>
<td>MBMI3</td>
<td>42</td>
<td>38</td>
<td>35</td>
<td>34</td>
<td>33</td>
</tr>
<tr>
<td>n</td>
<td>103</td>
<td>91</td>
<td>71</td>
<td>59</td>
<td>26</td>
</tr>
</tbody>
</table>

1. MWL = Mean Weight Loss. 2. EWL = Excess Weight Loss. 3. MBMI = Median Body Mass Index.

**Table 4. Reoperations during a 3-year follow-up.**

<table>
<thead>
<tr>
<th>Causes</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slippage</td>
<td>3 (2.7)</td>
</tr>
<tr>
<td>Leaking band or port</td>
<td>5 (4.5)</td>
</tr>
<tr>
<td>Band erosion</td>
<td>2 (1.8)</td>
</tr>
<tr>
<td>Infection</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>All</td>
<td>11 (10)</td>
</tr>
</tbody>
</table>

**Table 5. Findings during routine endoscopic follow-up 3 years after the operation.**

<table>
<thead>
<tr>
<th>Findings</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastritis</td>
<td>1 (4.3)</td>
</tr>
<tr>
<td>Reflux disease</td>
<td>12 (52.2)</td>
</tr>
<tr>
<td>Savary-Miller* grade 1</td>
<td>5</td>
</tr>
<tr>
<td>grade 2</td>
<td>6</td>
</tr>
<tr>
<td>grade 3</td>
<td>1</td>
</tr>
<tr>
<td>grade 4</td>
<td>0</td>
</tr>
<tr>
<td>Slippage</td>
<td>1 (4.3)</td>
</tr>
<tr>
<td>Pouch dilatation</td>
<td>2 (8.7)</td>
</tr>
<tr>
<td>Band erosion</td>
<td>1 (4.3)</td>
</tr>
<tr>
<td>Normal findings</td>
<td>6 (26.1)</td>
</tr>
<tr>
<td>All</td>
<td>23 (100)</td>
</tr>
</tbody>
</table>

*Savary & (1978)
5.1.4 Study IV. Disease-specific quality of life

Of the first 60 patients, 52 returned the questionnaire properly answered. No significant differences in demographic data were shown between that group and those who answered the questionnaire preoperatively. Assessment with the Moorehead-Ardelt QoL questionnaire prior to operation in one group, and at a median of 2 years postoperatively in another group of patients, is depicted in Table 6. The QoL scores among the operated patients were significantly better on all domains of the Moorehead-Ardelt questionnaire compared to those not yet operated (Table 6).

Table 6. Moorehead-Ardelt quality-of-life scores. Values are means (± SD). 95% CI.

<table>
<thead>
<tr>
<th>QoL categories</th>
<th>Score range</th>
<th>Preoperative group (n=65)</th>
<th>Postoperative group (n=52)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Self-Esteem</td>
<td>-1 to +1</td>
<td>-0.049 (0.413)</td>
<td>0.351 (0.462)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>2. Physical</td>
<td>-0.5 to +0.5</td>
<td>0.101 (0.212)</td>
<td>0.327 (0.213)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>3. Social</td>
<td>-0.5 to +0.5</td>
<td>-0.242 (0.223)</td>
<td>0.053 (0.290)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>4. Labor</td>
<td>-0.5 to +0.5</td>
<td>-0.074 (0.271)</td>
<td>0.173 (0.291)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>5. Sexual</td>
<td>-0.5 to +0.5</td>
<td>-0.070 (0.300)</td>
<td>0.130 (0.326)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total score</td>
<td>-3 to +3</td>
<td>-0.328 (1.106)</td>
<td>1.029 (1.355)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*Unpaired t-test.

5.1.5 Study V. Disease-specific and health-related quality of life

Changes in weight and co-morbidities. Percentages of excess weight loss (EWL) have been reported earlier (45% at 12 months, 52% at 24 months) (III) and they were not significantly different between the subgroups of patients in this study. Of the 52 prospectively assessed patients (by the Moorehead-Ardelt questionnaire), 41 (78.9%) suffered from at least one of the best recognized co-morbidities associated with morbid obesity, such as hypertension, diabetes, sleep apnea, joint disorders, or respiratory disorders (asthma). At 1 year, 24 (59%) patients showed improvement or resolution of their co-morbid condition(s), in 14 patients (34%) the co-morbid condition was regarded as unchanged, and in 3 patients (7%) as aggravated (Table 7).
Table 7. Changes in co-morbidities (hypertension, diabetes, sleep apnea, joint disorders, and/or respiratory disorders) in 41 patients 1 year after laparoscopic adjustable gastric banding.

<table>
<thead>
<tr>
<th>Co-morbidity change</th>
<th>n=41</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggravated</td>
<td>3</td>
<td>7.2</td>
</tr>
<tr>
<td>Unchanged</td>
<td>14</td>
<td>34.2</td>
</tr>
<tr>
<td>Improved</td>
<td>13</td>
<td>31.7</td>
</tr>
<tr>
<td>One major resolved</td>
<td>7</td>
<td>17.1</td>
</tr>
<tr>
<td>All major resolved</td>
<td>4</td>
<td>9.8</td>
</tr>
</tbody>
</table>

_Disease-specific QoL._ The QoL scores were significantly improved on all domains of the Moorehead-Ardelt questionnaire 1 year after surgical treatment. The QoL scores at a median of 28 months after surgery were very similar – with no significant differences – to the QoL scores at 12 months (Figure 7). There were no significant differences in the preoperative demographic data between these groups of patients.

![Fig. 7. Moorehead-Ardelt disease-specific QoL-profiles in 95 patients preoperatively compared to 52 prospectively assessed patients* 1 year later, and to 52 retrospectively assessed patients** at a median of 28 months postoperatively [p < 0.05 (*paired or **unpaired t-test)] on all dimensions, bars = standard error (SE).](image)
Health-related QoL. Significant improvements in HRQoL were seen in 6 of the 15 dimensions 1 year after surgery. Mobility, respiratory functioning, sleeping, performance of usual acts, vitality, and sexuality were all improved (Figure 8), leading to a significantly better HRQoL index. Significant worsening was seen on the dimension of eating. When comparing the unoperated group of patients cross-sectionally with the group of patients operated at a median of 28 months earlier, mobility and sleeping were not significantly improved in the operated group (Figure 8). HRQoL total scores at a median of 28 months were not significantly lower than the scores at 12 months (0.873 vs 0.892, p = 0.4074), but they were not significantly higher than the preoperative values, either (0.873 vs. 0.843, p = 0.1361). The group tested at a median of 28 months after surgery also performed worse on the dimension of eating, although this difference did not quite reach statistical significance (p = 0.0882).

Health-related quality of life compared to Finnish age norm. In 1995 the mean 15D score among 710 Finnish adult controls in the age group of 40–49 years was 0.933 (Sintonen 1997). This seems to be a significantly higher score compared to the preoperative (0.843) score, postoperative score (0.892) at 12 months, and postoperative score (0.873) at 28 months that were seen in this study.

![Fig. 8. 15D health-related profiles for 75 morbidly obese patients prior to operation compared to 34 prospectively assessed patients 12 months postoperatively, and to 52 retrospectively assessed patients at a median of 28 months postoperatively (bars=SE).](image)
5.1.6 Study VI. Gastric banding and reflux disease

There was a significant decrease in the total number of reflux episodes, total reflux time, and DeMeester score postoperatively (Table 8). A significant decrease in the number of symptomatic patients, in the use of proton pump inhibitors (PPI), and in the diagnosis of GERD, based on parameters of the 24-hour pH monitoring, could also be seen (Table 9). Only 64% of the patients had a normal postoperative manometry. The most common abnormality was incomplete relaxation of the lower esophageal sphincter (LES) (Table 10). There did not seem to be any association between the postoperative diagnosis of GERD and the amount of weight loss (Table 11). Of the 8 patients with findings of GERD on postoperative 24-h pH monitoring, 7 had similar findings preoperatively (Table 12). All of these patients were asymptomatic both pre- and postoperatively. Only one patient with normal preoperative findings had signs of GERD on postoperative recordings. This patient had symptoms and used PPI medication. There was no association between the presence of hiatal hernia preoperatively and the symptoms or findings of GERD postoperatively (Table 13).

Table 8. Reflux parameters pre- and postoperatively. Data given as mean (±SD), NS= not significant.

<table>
<thead>
<tr>
<th>24-h pH monitoring</th>
<th>Preoperatively</th>
<th>Postoperatively</th>
<th>p-values*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reflux episodes (n)</td>
<td>44.6 (23.7)</td>
<td>22.9 (17.1)</td>
<td>0.0006</td>
</tr>
<tr>
<td>Longest reflux episode (min)</td>
<td>60.3 (57.6)</td>
<td>35.1 (46.7)</td>
<td>0.12 (NS)</td>
</tr>
<tr>
<td>Reflux episodes &gt; 5 min (n)</td>
<td>8.3 (6.8)</td>
<td>8.6 (21.7)</td>
<td>0.74 (NS)</td>
</tr>
<tr>
<td>Total reflux time (%)</td>
<td>9.5 (6.2)</td>
<td>3.5 (3.7)</td>
<td>0.0009</td>
</tr>
<tr>
<td>DeMeester score</td>
<td>38.5 (24.9)</td>
<td>18.6 (20.4)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

*Paired t-test

Table 9. Symptoms, *proton pump inhibitor medication, and diagnose of GERD (gastroesophageal reflux disease) on 24-hour pH monitoring. Values in brackets are percentages.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Preoperatively n=31</th>
<th>Postoperatively n=25</th>
<th>p-values*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic patients</td>
<td>15 (48.4)</td>
<td>5 (16.1)</td>
<td>0.01</td>
</tr>
<tr>
<td>PPI*-medication</td>
<td>11 (35.5)</td>
<td>4 (12.9)</td>
<td>0.05</td>
</tr>
<tr>
<td>GERD (24-h pH recordings)</td>
<td>24/31 (77.4)</td>
<td>9/24 (37.5)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*Paired t-test
Table 10. Findings in manometry pre- (n=31) and postoperatively (n=25). *Data given as mean (± SD).

<table>
<thead>
<tr>
<th>Findings in manometry</th>
<th>Preoperatively</th>
<th>Postoperatively</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>LES-pressure* (mmHg)</td>
<td>22.0 (9.1)</td>
<td>21.4 (9.2)</td>
<td>&gt;0.5</td>
</tr>
<tr>
<td>Normal peristalsis</td>
<td>30 (96.8%)</td>
<td>23 (92.0%)</td>
<td>&gt;0.9</td>
</tr>
<tr>
<td>Normal manometry</td>
<td>29 (93.5%)</td>
<td>16 (64%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 11. Diagnosis of gastroesophageal reflux disease (GERD) in 24-h pH monitoring in relation to weight losses in 24 patients after a median follow-up of 19 months. Values in brackets are percentages.

<table>
<thead>
<tr>
<th>Excess weight loss (%)</th>
<th>Patients</th>
<th>GERD</th>
<th>p-values*</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10%</td>
<td>1 (4.2)</td>
<td>0 (0.0)</td>
<td>&gt;0.99 (NS)</td>
</tr>
<tr>
<td>&gt; 10%</td>
<td>23 (95.8)</td>
<td>8 (34.8)</td>
<td>&gt;0.99 (NS)</td>
</tr>
<tr>
<td>&lt; 20%</td>
<td>4 (16.7)</td>
<td>1 (25.0)</td>
<td>&gt;0.99 (NS)</td>
</tr>
<tr>
<td>&gt;20%</td>
<td>20 (83.3)</td>
<td>7 (35.0)</td>
<td>0.412 (NS)</td>
</tr>
<tr>
<td>&lt; 30%</td>
<td>9 (37.5)</td>
<td>4 (44.4)</td>
<td>0.388 (NS)</td>
</tr>
<tr>
<td>&gt;30%</td>
<td>15 (62.5)</td>
<td>4 (26.7)</td>
<td>&gt;0.99 (NS)</td>
</tr>
<tr>
<td>&lt; 40%</td>
<td>14 (58.3)</td>
<td>6 (42.9)</td>
<td>&gt;0.99 (NS)</td>
</tr>
<tr>
<td>&gt;40%</td>
<td>10 (41.7)</td>
<td>2 (20.0)</td>
<td>&gt;0.99 (NS)</td>
</tr>
<tr>
<td>&lt; 50%</td>
<td>19 (79.2)</td>
<td>6 (31.6)</td>
<td>&gt;0.99 (NS)</td>
</tr>
<tr>
<td>&gt; 50%</td>
<td>5 (20.8)</td>
<td>2 (40.0)</td>
<td>&gt;0.99 (NS)</td>
</tr>
</tbody>
</table>

*Fisher’ exact test

Table 12. Distribution of symptoms (31 patients) of GERD and findings in 24-h pH monitoring before (31 patients) and after (24 patients) laparoscopic adjustable gastric banding.

<table>
<thead>
<tr>
<th></th>
<th>Symptomatic patients preoperatively</th>
<th>Asymptomatic patients preoperatively</th>
<th>Normal findings in postoperative 24-h pH monitoring</th>
<th>GERD in postoperative 24-h pH monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic patients</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>postoperatively</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic patients</td>
<td>13</td>
<td>13</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>postoperatively</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GERD in preoperative 24-h</td>
<td>15</td>
<td>9</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>pH monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal findings in</td>
<td>0</td>
<td>7</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>preoperative 24-h pH</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of hiatal hernia</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>0*</td>
</tr>
<tr>
<td>in upper GI endoscopy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*One patient lost to follow-up, other 3 patients asymptomatic postoperatively.
Table 13. Findings in upper GI endoscopy pre- and postoperatively. Values in brackets are percentages. *According to the classification by Savary and Miller (Savary M 1978) NS= not significant. n=31 preoperatively, n=25 postoperatively.

<table>
<thead>
<tr>
<th>Upper GI endoscopy</th>
<th>Preoperatively</th>
<th>Postoperatively</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal findings</td>
<td>25 (80.6)</td>
<td>23 (92.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Esophagitis (grade I or II)*</td>
<td>6 (19.4)</td>
<td>2 (8.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Insufficient hiatus</td>
<td>6 (19.4)</td>
<td>0 (0.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Hiatal hernia (type I) or pouch enlargement (postop)</td>
<td>4 (12.9)</td>
<td>0 (0.0)</td>
<td>NS</td>
</tr>
</tbody>
</table>

5.1.7 Study VII. Long-term results

Median postoperative hospital stay is still 3 days (range 1–53 days) although, as a rule, the patients now leave the hospital on the first postoperative day. Excess weight loss (EWL) at 7 years was 56% among patients who had their band in place and 46% among all patients (intention-to-treat) (Table 14, Figure 9). Nearly 20% of the patients were lost to follow-up at 5 years, and 30% at 8 years. Band erosion occurred in 4 patients (3.3%), slippage in 8 patients (6.5%), and severe reflux symptoms were found in 4 patients (3.3%) (Table 15). Eight bands were removed due to slippage and two bands were repositioned due to pouch enlargement (Tables 15 and 16). Four bands were removed because of severe reflux symptoms/intolerance, one because of erosion, and one because of infection (Tables 15 and 16). Overall, 30 patients (24.4%) needed at least one reoperation (Table 16) and 36.7% of these reoperations were performed during the third year (Table 14). The failure rates increased steadily. They started from about 15% during the first to third years, increased to 25% during the fourth year, and further to about 30% during the years 5, 6, and 7. During the 8th and 9th postoperative years the failure rate increased to approximately 40% (Table 14, Figure 10). After 8 years the number of patients with EWL less than 25% exceeds the number of patients with EWL more than 50% (Figure 10). In other words, after 8 years there are more failures (44%) than there are successes (35%).
Fig. 9. Excess weight loss (EWL) in 123 consecutive patients operated with laparoscopic adjustable gastric banding at Vaasa Central Hospital between 1996 and 2002 [mean follow-up time 86 months (range 60–132 months)].

Fig. 10. Success and failure rates in 123 consecutive patients operated with laparoscopic adjustable gastric banding at Vaasa Central Hospital between 1996 and 2002 [mean follow-up time 86 months (range 60–132 months)]. Failure rates include patients lost to follow-up, patients with their bands removed, and/or patients with an excess weight loss less than 25%. 
Table 14. Eligible patients, available patients, patients lost to follow-up, and excess weight loss (EWL) percentages in 123 patients operated for morbid obesity with laparoscopic adjustable gastric banding, with at least 5 years of follow-up (mean follow-up time 86 months). *Success = more than 50% EWL. **Failure= less than 25% EWL. Failure rates include patients lost to follow-up. Reoperations n=30.

<table>
<thead>
<tr>
<th>Years</th>
<th>Eligible patients</th>
<th>Available patients</th>
<th>Lost to follow-up (%)</th>
<th>EWL (%)</th>
<th>Successes* (%)</th>
<th>Failures** (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>123</td>
<td>123</td>
<td>(1.6)</td>
<td>41.5</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>2</td>
<td>121</td>
<td>121</td>
<td>(2.4)</td>
<td>53.2</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>3</td>
<td>118</td>
<td>118</td>
<td>(4.1)</td>
<td>58.2</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>4</td>
<td>107</td>
<td>107</td>
<td>(13.0)</td>
<td>58.7</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>5</td>
<td>99</td>
<td>99</td>
<td>(19.5)</td>
<td>59.4</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>6</td>
<td>75</td>
<td>75</td>
<td>(19.4)</td>
<td>60.1</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>7</td>
<td>50</td>
<td>50</td>
<td>(18.0)</td>
<td>55.7</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>8</td>
<td>30</td>
<td>30</td>
<td>(30.2)</td>
<td>53.1</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>9</td>
<td>15</td>
<td>15</td>
<td>(34.8)</td>
<td>52.1</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
<tr>
<td>10</td>
<td>4</td>
<td>4</td>
<td>(42.9)</td>
<td>30.0</td>
<td>21 (17.0)</td>
<td>21 (17.0)</td>
</tr>
</tbody>
</table>

Table 15. Complications among 123 patients operated by laparoscopic adjustable gastric banding, with a mean follow-up of 86 months, n=123.

<table>
<thead>
<tr>
<th>Type of complication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Port infection</td>
<td>1</td>
<td>0.8</td>
</tr>
<tr>
<td>Band infection</td>
<td>1</td>
<td>0.8</td>
</tr>
<tr>
<td>Leaking port or catheter</td>
<td>2</td>
<td>1.6</td>
</tr>
<tr>
<td>Band erosion</td>
<td>4</td>
<td>3.3</td>
</tr>
<tr>
<td>Severe reflux symptoms</td>
<td>4</td>
<td>3.3</td>
</tr>
<tr>
<td>Slippage</td>
<td>8</td>
<td>6.5</td>
</tr>
<tr>
<td>Leaking band</td>
<td>10</td>
<td>8.1</td>
</tr>
<tr>
<td>Insufficient weight loss (EWL&lt;25% at 5 years)</td>
<td>36</td>
<td>29.3</td>
</tr>
</tbody>
</table>
Table 16. Reoperations among 123 patients operated by laparoscopic adjustable gastric banding, with a mean follow-up of 86 months.

<table>
<thead>
<tr>
<th>Type of reoperation</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Band removal alone</td>
<td>14</td>
<td>11.4</td>
</tr>
<tr>
<td>Band change</td>
<td>8</td>
<td>6.5</td>
</tr>
<tr>
<td>Conversion to RYGBP (one- or two-step)</td>
<td>3</td>
<td>2.4</td>
</tr>
<tr>
<td>Band repositioning</td>
<td>2</td>
<td>1.6</td>
</tr>
<tr>
<td>Port change</td>
<td>2</td>
<td>1.6</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0.8</td>
</tr>
<tr>
<td>Total number of patients with at least one reoperation</td>
<td>30</td>
<td>24.4</td>
</tr>
</tbody>
</table>
6 Discussion

6.1 The advantages of gastric banding

Laparoscopic gastric banding can be regarded as the least invasive choice of all the bariatric procedures available today (Cadiere et al. 1994). One advantage of this method is that it can be replaced with another method of bariatric surgery, should the band fail for any reason. Thus nothing is lost and therefore – in our opinion – this operation is a good "first choice." Other operations, such as gastric by-pass procedures, probably give a better long-term outcome, but have greater short-term risks (Lönroth & Lundell 2001).

6.2 Migrations of bands

Our results are fairly good and comparable to others (Catona et al. 1997, Forsell & Hellers 1997, Miller & Hell 1999). Five band migrations through the gastric wall have occurred (1.8%) (one of these was erosion, and was not among the first 123 patients). The incidence of this complication in our series is not much higher than the reported incidence in a systematic review of the literature (1.3%) (Oria 2000). Band migration is a serious complication that necessitates a reoperation. We removed the band in an open operation from two patients and performed a gastric by-pass at the same time. Both patients recovered well and their weight reduction continued (EWL 61% and 97% at 4 years). The other three patients had their bands removed via endoscopy with the aid of a gastroscope.

6.3 Endoscopic follow-up

A high incidence of esophagitis seems to be connected to the band. At the routine endoscopic follow-up 3 years after the operation more than half of the patients had signs of erosive reflux disease, although most of them were mild (Savary-Miller grade 1 and 2). However, we did not routinely perform an endoscopic examination preoperatively and, therefore, it is not clear if these findings are caused by the band or by the obesity itself. In one patient a band migration was found. This patient had no other symptoms than decreased weight loss. Routine endoscopic follow-up is mandatory, as this case proves. However, most reports on the outcomes of gastric banding do not clearly state whether there has been any endoscopic follow-up. Ignoring gastroscopy in the follow-up of banded patients may lead to impaired
interpretation of the results. The other patient with band migration was also diagnosed by endoscopy, but not during routine endoscopic follow-up.

It is not possible to distinguish pouch dilatation from slippage during endoscopic examinations. In our series the endoscopist assessed 2 patients as having pouch dilatations and one as having a slippage (Table 10) (see Table 5), but at the reoperations all three were found to have slippages. Even in the literature there exists some confusion about the definitions of pouch dilatation and slippage.

### 6.4 Technical problems

Technical problems with the band have caused us great frustration. Twelve of our reoperations so far have been performed because of a leaking band or port. Leakage may be the result of inappropriate handling and filling of the device. However, the manufacturer has admitted that there was a weak point in the early version of the band, and the quality of the band has since been improved.

### 6.5 Gastric banding and superobesity

It has been argued that the outcome of gastric banding operations for the super obese (BMI more than 50) may be less favorable (Michael Gagner, oral communication, 7th world congress of endoscopic surgery, Singapore 2000). Our data does not support this argument, although the number of super-obese patients in our series is low. Five patients of the 14 who had a preoperative BMI more than 50 have been followed for at least 2 years. The outcome among these patients has been even better than in the patients with a BMI less than 50.

### 6.6 Quality of life

Clearly, there are more variables involved in the success or failure of bariatric surgery than the degree of weight loss. QoL aspects, as well as changes in co-morbidities, are important variables that have to be taken into consideration when reporting the outcomes. BAROS is an evidence-based, unbiased, simple, patient- and surgeon-friendly method that standardizes the definition of success, thus permitting the comparison of results between different treatment modalities and different institutions (Oria & Moorehead 1998).

According to BAROS, 21% of our treatments were failures. It must be emphasized that this series represents the first 60 patients treated at our hospital.
The effect of the learning curve on these results is obvious. Favretti et al. (1998) reported a similar failure rate (24%) in their first 50 patients. Their failure rate dropped later to 4% in patients that were treated after the initial learning curve (patients 51–170) (Favretti et al. 1998). Wolf et al. (2000) reported an initial failure rate as high as 44%, which also improved with time. Of the 11 failures in our series, 7 were among the first 22 patients. These failures were probably due to the construction of too large a pouch above the band. We later modified our technique. We believe that better technique and patient selection will improve our results, and failure rates will reduce to acceptable levels, comparable with previously reported rates of 3–4% (Favretti et al. 1998, Hell et al. 2000). Nevertheless, 79% of the patients treated in this initial series can be regarded as successes.

The patients' own opinions about the operation seem to correlate with the BAROS score. Eleven patients where "somewhat disappointed" and one patient regretted having had the operation, giving a failure rate of 23% (21% by BAROS).

There seems to be an alarmingly high incidence of troublesome side effects connected to the band. Of our patients, 38% reported reflux symptoms, 50% suffered from occasional vomiting (III), and 17% claimed they suffered from dysphagia. However, what the patients really mean by these symptoms is not clear, and the symptoms are obviously interpreted differently by different patients. Despite these reported side effects, 77% of the patients said they were very satisfied with the operation. We think, however, that further research is necessary on the incidence of band induced side effects.

The methods used for studying changes in medical conditions have not been clearly stated in previous reports that have used the BAROS (Favretti et al. 1998, Hell et al. 2000, Wolf et al. 2000). By definition, medical disorders can be considered "resolved" when they are controlled without medication and "improved" when controlled by reduced doses of medication (Oria & Moorehead 1998). We relied entirely on patients' own reports when changes in medications were measured. In a postal questionnaire it is the only objective way to estimate changes in co-morbid conditions, but it probably underestimates the improvements. It is possible that the operation eliminates the risk of developing co-morbid conditions in patients who have a high risk of developing one, but who do not have any preoperative medication. How should these patients be scored? Clearer rules regarding the ways in which the changes in medical condition are to be studied and clearer definitions of improvements are urgently needed if the
BAROS is to be more widely adopted as a standardized way of reporting outcomes of bariatric surgery.

Nguyen et al. (2001) reported faster improvement of the Moorehead-Ardelt QoL scores in laparoscopic gastric bypass patients compared to those operated by open technique. Hell et al. (2000) used the BAROS, which incorporates the Moorehead-Ardelt questionnaire, to compare the outcomes of different bariatric procedures. Otherwise reports of QoL scores as an outcome measure for bariatric surgery are scarce.

The Moorehead-Ardelt QoL questionnaire was designed to detect changes compared to the situation prior to a medical event. This relies on the patients' memory, which may be unreliable. In our opinion, it is more reliable to use the questionnaire as a non-comparative measure of the QoL at a specific moment and to compare this outcome with the outcome at another moment, or with the outcome of another group of patients. We agree with Van Gemert et al. (2001) that it may be important to combine a general QoL instrument with a sickness-specific questionnaire, and we are currently using prospectively both the 15D questionnaire (Sintonen 2001), as a general QoL instrument, and the Moorehead-Ardelt questionnaire (Oria & Moorehead 1998), as a disease-specific instrument.

The decision to operate was always made before the patients answered the questionnaire. Therefore, the patients in the preoperative group did not have to fear their answers would affect their planned treatment. Had they had any doubt about it, the QoL scores might have been falsely low. On the other hand, the morbidly obese patients are possibly euphoric when they are finally admitted to undergo their operation after a long waiting period, and this could result in too high QoL scores. Whichever the case, the QoL scores of these not yet operated patients were significantly lower than the scores of the operated patients.

The drawbacks of the study number V are a relatively short follow-up period, mixing of prospective and cross-sectional comparisons, and a relatively small number of patients. A clearer picture of the possible changes in QoL and HRQoL over time would require a fully prospective study that compares outcomes at different, pre-set time points and includes long-term follow-up. Nevertheless, this is the first study that uses the 15D questionnaire (or any generic instrument) to assess the HRQoL in morbidly obese Finns before and after a surgical intervention.

A wide variety of disease-specific instruments have been developed for a number of medical conditions in order to assess particular clinically discernible impacts that the specific disease has on health. Because of the restricted and more
specialized content of disease-specific measures they are considered to be more sensitive to clinical change than generic measures. However, unexpected effects on health status are more likely detected by the latter (Patrick & Deyo 1989). Therefore, assessments of health status should include standardized, generic measures as well as more specific measures unique to diseases and treatments (Ware 1995). The Moorehead-Ardelt questionnaire (Oria & Moorehead 1998), used in this study for disease-specific measurements, showed significant improvements in QoL scores both 12 and 28 months after surgery. The 15D scores, however, were not as high 28 months after surgery as they were at 12 months. In addition, at 12 months the 15D scores were worse than the pre-operative scores in more than 20% of the patients. All these findings indicate that the Moorehead-Ardelt questionnaire is not as sensitive, or it may be less responsive to negative change, as the 15D instrument. The developers have since published an updated version of the Moorehead-Ardelt questionnaire, in order to improve the sensitivity and response differentiation (Moorehead et al. 2003). Another problem is the validation of QoL- and HRQoL instruments. There is no guarantee that an instrument is valid in a culture different from the one in which it has been validated. This is why we found it important to complement our previously published results, which were based only on a disease-specific instrument, with a generic and in Finnish circumstances well validated instrument.

Those who generally speak in favor of malabsorptive procedures, rather than restrictive, may argue that restrictive operations seem to disturb eating significantly. It is not surprising that patients with a gastric band are no longer able to eat as they used to. This is the main principle of the operation. Nevertheless, eating disturbances sometimes associated with banding operations, such as regurgitations, vomiting, and symptoms of reflux may have a negative impact on quality of life despite a good weight loss, as seen in this study. It is easy to understand that somebody who likes to eat does not enjoy the feeling of being constantly hungry. This feeling may impair the quality of life even without the disturbances mentioned above. Whether the impairment on the eating domain of 15D HRQoL questionnaire seen in this study is permanent will be answered after a longer follow-up.

The main findings of this study (V) were that patients treated laparoscopically for morbid obesity with a gastric restrictive operation sleep better, are able to move better, feel more energetic, breath better, can perform their daily, usual acts better, and have an improved sex life, but they have some problems with eating 12 months after surgery. In 60% of the patients co-morbidities were resolved or
improved. Interestingly, these improvements showed no correlation with the amount of weight reduction at this time. Other studies have reported similar findings (Karlsson et al. 1998, Dixon et al. 2001, Larsen et al. 2003). In the Swedish SOS study a similar weak relation between HRQoL change and excess weight loss was seen at 6 months (Karlsson et al. 1998). At 2 years the association was much stronger, and the authors speculated that early rise in HRQoL scores after surgery may be influenced by the patients’ general positive beliefs in treatment effects (Karlsson et al. 1998). A stronger association between lower BMI, higher BMI loss and better social, mental, and physical QoL was also noticed in patients followed more than 24 months (Larsen et al. 2003). The SOS study also showed a slight decline in HRQoL scores at 2 years (Karlsson et al. 1998). The HRQoL scores in our study were lower 28 months after surgery than at 12 months. As this was a cross-sectional comparison, the direct assumption that HRQoL scores will decline with time cannot be made.

A change of 0.02–0.03 in the 15D score has been observed to be enough so that the difference can be felt (Sintonen 2001). If this is true, 15D scores indicate a much worse quality of life in the operated patients compared to normal Finnish controls, and this difference is not completely restored even 28 months after surgery. However, these findings must be interpreted with caution since a more detailed comparison of the 15D profiles between patients and controls, carefully matched for age and sex, was not made in this study. These analyses will have to await longer follow-up and more patients. It is also of vital importance to ensure that improvements in health-related quality of life after surgery for morbid obesity are permanent.

6.7 Reflux symptoms

Conflicting effects on reflux symptoms have so far been published, in mostly small series. Some claim significant improvements, some no difference, and some worsening of the symptoms and findings of reflux disease after LAGB operations (Ovrebo et al. 1998, Westling et al. 1998, Dixon & O'Brien 1999, Korenkov et al. 2002, de Jong et al. 2006). The effect of the band on esophageal motility is also unclear. Band may increase resting lower esophageal sphincter (LES) pressure and lead to impairment of LES relaxation (Suter et al. 2005, de Jong et al. 2006). Other studies claim that the band makes no difference in esophageal motility disorders (Korenkov et al. 2002).
Our data indicate that, at least in the short term, the band itself may serve as an effective anti-reflux barrier, partly due to incomplete relaxation of the LES. Other effects on esophageal motility could not be shown in our study. Another explanation for the anti-reflux effect may be mechanical; a narrowing at the region of the gastroesophageal junction, as pointed out by Dixon and O'Brien (1999). Our results are in accordance with those presented by de Jong et al. (2004), de Jong et al. (2006), Dixon et al. (1999), and Korenkov et al. (2002), but in conflict with those presented by Ovrebo et al. (1998), Westling et al. (1998), and Suter et al. (2005). What could be the reason for this discrepancy in the literature?

The antireflux properties of the band seen in our study may be explained by the fact that no pouch enlargements were seen in endoscopy. De Jong et al. (2004) showed very clearly that the presence of a pouch enlargement was associated with esophagitis. One explanation for the reported increased incidence of reflux symptoms and findings following banding procedures may, therefore, be an enlarged pouch. With a sub-optimal operative technique the pouch may be too large from the very beginning. On the other hand, the initially correctly sized pouch may enlarge with time leading to increasing symptoms and findings of GERD with longer follow-up (Forsell et al. 1999). All the studies (including ours) claiming that the banding procedures have anti-reflux properties have fairly short follow-up times. Enlargement of the pouch with time may be difficult to prevent. If this happens the anti-reflux properties of the band are probably lost. This phenomenon may explain our earlier reported higher incidence of esophagitis (52%) in routine endoscopic follow-up at 3 years (III). These patients like to eat, and overeating will inevitably lead to enlargement of the pouch. We can think of no other reason for this discrepancy in the literature and between our observed short-term and long-term results. However, definitive conclusions about long-term results cannot be made yet. Whatever the case may be, it is very important to place and fix the band correctly, as high as possible, and to construct a very small pouch. We have made a very small pouch from the beginning, but nevertheless the incidence of large pouches seems to increase with time. It may therefore all come down to whether pouch enlargement can be permanently prevented, or if it is only a matter of time.

6.8 Long-term results of different operations

There is a lack of long-term data after gastric banding for morbid obesity, but an increasing number of reports claim higher complication and failure rates with
longer follow-up (Camerini et al. 2004, Chevallier et al. 2004, Martikainen et al. 2004, Gutschow et al. 2005, Suter et al. 2006). As the initial enthusiasm over gastric banding operations is fading, most European centers are now shifting to other procedures, mainly gastric bypass. In the USA the situation may paradoxically be the opposite, since the FDA approved the banding system as late as 2001. In both cases the boom of laparoscopic gastric banding and laparoscopic surgery has led to a renewed general interest in bariatric surgery.

Although gastric bypass has been performed since the 1960s as an open operation, long-term results (more than 10 years) are not very well documented. Biliopancreatic diversion is by far the most efficient operation in terms of weight loss with a 70% EWL after 2 years. Scopinaro reports that this weight reduction was sustained during 18 years of follow-up (2006). Concerns about deficiency problems due to malabsorption have, however, inhibited a widespread use of this operation.

Wound problems after open gastric bypass made this operation less popular in the 1980s, while in the 1990s the possibility to perform the operation by minimally invasive surgery led to a rapid increase in performed operations worldwide. However, there are specific problems connected to this operation, which is important to bear in mind when interpreting the results of other procedures. For instance, Capella et al. (2006) found a high incidence of obstructive bowel troubles requiring reoperation in nearly 12% of the patients during the first 2 to 3 years after surgery. Christou et al. (2006) reported a failure rate of 20% for morbidly obese patients and 35% for super-obese patients when all patients were followed for at least 10 years after gastric bypass. Our failure rates are comparable with a 30% failure rate at 7 years and 44% at 8 years. According to a systematic review of medium-term weight loss after bariatric operations, mean EWL % after standard gastric bypass was higher than after LAGB at the 1st and 2nd years, but there was no difference between 3 and 7 years (O'Brien et al. 2006). The mortality after gastric bypass is 10 times higher than after gastric banding, which also has to be kept in mind when deciding which operation to use for an individual patient (O'Brien & Dixon 2003). Only a well-conducted, prospective, randomized study could tell us how the long-term results of gastric bypass operations differ from those of gastric banding.

To our knowledge, there is only one study, with a rather small number of 45 patients, which has a longer follow-up (mean 105 months) than ours (mean 86 months). This study reported a 76% device-related long-term complication rate (Camerini et al. 2004). Another study, including 317 patients with a mean follow-
up of 74 months, reported very similar results to the results in our study (Suter et al. 2006). The writers reported an EWL of 50% to 60% after 7 years in patients with the band in place, a 37% failure rate, and a 43% success rate (Suter et al. 2006) compared to 56% EWL, a 30% failure rate, and a 44% success rate in our study. Belachew et al. (2002) showed somewhat better results but the follow-up was shorter. Suter et al. (2006) felt their results were not good enough and made the conclusion that gastric banding can no longer be considered as "the method of choice." We agree with that, but we would like to point out that there is no method of choice in bariatric surgery today! As no method is superior, the choice of operation should be tailor-made for each individual patient.

Our earlier results using BAROS showed at that point of time a failure rate of 21% (II). We were not able to use the BAROS in the long-term analysis as we did not have access to the quality-of-life data in all patients. In this study, we considered a major reoperation or an EWL less than 25% as a failure as did Suter et al. (Suter et al. 2006). Using these criteria, the failure rate has raised to 30–40% with longer follow-up. However, compared to conservative treatment results, even a 10–25% EWL is a good result and can have a positive impact on co-morbid conditions.

A problem in interpreting the results of any type of bariatric operation is patients that are lost to follow-up. Caution should be used when examining the results of any study with a significant loss to follow-up. Many reports do not even mention the number of patients lost. This will inevitably lead to a too optimistic an interpretation of the results. The results of patients who are not complying with the regular follow-ups are not known. However, Harper et al. found that patients who do not comply with regular follow-up care have a worse clinical outcome (i.e. less weight loss) (Harper et al. 2007). Follow-up is especially important after banding operations as the band has to be constantly calibrated. The need for indefinite and relatively frequent follow-up may be the Achilles's heel of gastric banding since the proportion of patients lost to follow-up will inevitably increase with time. In our study this proportion increased over the years to 30% at 8 years and 35% at 9 years. According to our experience, the patients who, despite repeated calls, do not comply with the regular visits are not doing well. Therefore, we made the frank conclusion that these patients have 0% EWL. This may not always be the case and the true EWL curve probably lies somewhere between the two curves shown in Figure 10. Thus the lower curve in Figure 10 represents the worst possible weight-loss curve.
Our results show a 25% complication and reoperation rate in the long term, which does not differ significantly from the rates (33% and 30% respectively) reported by Suter et al. (2006). Martikainen et al. (2004) reported a 52% reoperation rate and a 54% complication rate, but the results may not be comparable since the "pars flaccida" technique was not used in the operations. It is a well known fact that this technique yields better results than the initial technique with perigastric dissection through the lesser sac. So far, 11.4% of the bands in our series have been removed, compared to 33% of the bands reported by Martikainen et al. (2004), 22% of the bands reported by Suter et al. (2006), and 3.7% reported by Favretti et al. (2007). All of these studies had shorter follow-up times than ours.

6.9 Summary

Our results confirm those by others (Catona et al. 1997, Forsell & Hellers 1997, Miller & Hell 1999) claiming LAGB to be a fairly easy operation with few short-term complications and fast recovery. Those reporting disappointing results may have used a sub-optimal surgical technique (Morino et al. 1997, Westling et al. 1998). After an intermediate follow-up weight loss is good and the complications still few. However, the final outcome of this operation is not yet known. Our results using BAROS as a measure are comparable with other published results of initial series, including the initial learning curve. Laparoscopic gastric banding with the Swedish band seems to improve disease-specific quality of life scores significantly, at least compared to a group of morbidly obese patients not yet operated. The main findings of this study were that patients treated laparoscopically for morbid obesity with a gastric restrictive operation sleep better, are able to move better, feel more energetic, breath better, can perform their daily, usual acts better, and have an improved sex life, but they have some problems with eating 12 months after surgery. In 60% of the patients co-morbidities were resolved or improved. Laparoscopic adjustable gastric banding reduces gastroesophageal reflux in the short term. Reoperations, complications, and failures increase with time. Weight loss is fairly good even 9 years after laparoscopic adjustable gastric banding, and this operation can still be one of the tools of a bariatric center where detailed attention to patient selection is routine.
7 Conclusions

On the basis of this study the following conclusions may be drawn

1. On an average at least 50% excess weight loss (EWL) can be achieved in 1 to 3 years after laparoscopic adjustable gastric banding, and EWL is fairly good in the long term as well (9 years) (I, III, VII).

2. According to BAROS the failure rate after two years is 21% (II).

3. The intermediate mean EWL was 52% (mean follow-up time 27 months), and morbidity (less than 30 days) is 9%. In our series there was no mortality (III).

4. The operation improves significantly disease-specific and health-related quality of life, at least in the short term (IV, V). Sixty percent of co-morbidities will resolve or improve after the operation (V).

5. Laparoscopic adjustable gastric banding reduces gastroesophageal reflux in the short term (VI).

6. During medium-term follow-up (less than 5 years) 20% of banding operations will fail, but the failure rate increases to 40% at 9 years. About 25% of the patients will need one or more reoperations (VII).
8 References


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Appendix

FRÅGEFORMULÄR BETRÄFFANDE LIVSKVALITETEN HOS PATIENTER, VILKA KOMMER FÖR OPERATIV BEHANDLING AV SJUKLIG ÖVERVIKT

Må r Ni rent allmänt

Mycket dåligt  Dåligt  Ganska bra  Bra  Mycket bra

Hur klarar Ni er socialt

Mycket dåligt  Dåligt  Ganska bra  Bra  Mycket bra

Kan Ni delta i olika motionsaktiviteter

Mycket dåligt  Dåligt  Ganska Bra  Bra  Mycket bra

Hurudan är Er arbetsförmåga

Mycket dålig  Dålig  Ganska bra  Bra  Mycket bra

Hur är det med Ert intresse för sex

Mycket dåligt  Dåligt  Ganska bra  Bra  Mycket bra

Lider Ni av någon av följande sjukdomart:

- Förhöjt blodtryck
- Astma
- Diabetes
- Depression
- Belastningsrelaterade ledsmärtor
- Sömnapnea
- Någon annan sjukdom, vilken?_____________________________________________

Medicinerings, vilken?____________________________________________________
TERVEYTEEN LIITTYVÄN ELÄMÄNLAADUN KYSELYLOMAKE (15D©)


KYSYMYS 1. Liikuntakyky
1 ( ) Pystyn kävelemään normaalisti (vaikeuksitta) sisällä, ulkona ja portais.  
2 ( ) Pystyn kävelemään vaikeuksitta sisällä, mutta ulkona ja tai portaisa on pieniä vaikeuksia.  
3 ( ) Pystyn kävelemään ilman apua sisällä (apuvälinein tai ilman), mutta ulkona ja tai portaisa melkoisina vaikeuksina tai toisen avustamana.  
4 ( ) Pystyn kävelemään sisälläkin vain toisen avustamana.  
5 ( ) Olen täysin liikuntakyvytön ja vuoteenoma.

KYSYMYS 2. Näkö
1 ( ) Näen normaalisti eli näen lukea lehteä ja TV:n teksteitä vaikeuksitta (silmälaseilla tai ilman).  
2 ( ) Näen lukea lehteä ja tai TV:n teksteitä pienin vaikeuksin (silmälaseilla tai ilman).  
3 ( ) Näen lukea lehteä ja tai TV:n teksteitä huomattavina vaikeuksina (silmälaseilla tai ilman).  
4 ( ) En näe lukea lehteä enkä TV:n teksteitä ilman silmlaseja tai niiden kanssa, mutta näen kulkea ilman opasta.  
5 ( ) En näe kulkea oppaatta ei olen lähes tai täysin sokea.

KYSYMYS 3. Kuulo
1 ( ) Kuulen normaalisti eli kuulen hyvin normaalia puheääntää (kuulokojella tai ilman).
2 ( ) Kuulen normaalia puheääntä pienin vaikeuksin.

3 ( ) Minun on melko vaikea kuulla normaalia puheääntä, keskustelussa on käytettävä normaalia kovempaa puheääntä.

4 ( ) Kuulen kovaakin puheääntä heikosti; olen melkein kuuro.

5 ( ) Olen täysin kuuro.

KYSYMYS 4. Hengitys

1 ( ) Pystyn hengittämään normaalisti eli minulla ei ole hengenahdistusta eikä muita hengitysvaikeuksia.

2 ( ) Minulla on hengenahdistusta raskaassa työssä tai urheillessa, reippaassa kävelyssä tasamaalla tai lievässä ylämäessä.

3 ( ) Minulla on hengenahdistusta, kun kävelen tasamaalla samaa vauhtia kuin muut ikäiseni.

4 ( ) Minulla on hengenahdistusta pienenkin rasituksen jälkeen, esim. peseytyessä tai pukeutuessa.

5 ( ) Minulla on hengenahdistusta lähes koko ajan, myös levossa.

15D©/Harri Sintonen

KYSYMYS 5. Nukkuminen

1 ( ) Nukun normaalisti eli minulla ei ole mitään ongelmia unen suhteen.

2 ( ) Minulla on lieviä uniongelmia, esim. nukahtamisvaikeuksia tai satunnaista yöheräilyä.

3 ( ) Minulla on melkoisia uniongelmia, esim. nukun levottomasti tai uni ei tunnu riittävästi.

4 ( ) Minulla on suuria uniongelmia, esim. joudun käyttämään usein tai säännöllisesti unilääkettä, herään säännöllisesti yöllä ja/tai aamuisin liian varhain.

5 ( ) Käräsin vaikeasta unettomuudesta, esim. unilääkkeiden runsaasta käytöstä huolimatta nukkuminen on lähes mahdotonta, valvon suurimman osan yöstä.
KYSYMYS 6. Syöminen

1 ( ) Pystyn syömään normaalisti eli itse ilman mitään vaikeuksia.

2 ( ) Pystyn syömään itse pienin vaikeuksin (esim. hitaasti, kömpelösti, vavisten tai erityisapuneuvoin).

3 ( ) Tarvitsen hieman toisen apua syömisessä.

4 ( ) En pysty syömään itse lainkaan, vaan minua pitää syöttää.

5 ( ) En pysty syömään itse lainkaan, vaan minulle pitää antaa ravintoa letkun avulla tai suonensisäisestä.

KYSYMYS 7. Puhuminen

1 ( ) Pystyn puhumaan normaalisti eli selvästi, kuuluvasti ja sujuvasti.

2 ( ) Puhuminen tuottaa minulle pieniä vaikeuksia, esim. sanoja on etsittävä tai ääni ei ole riittävän kuuluvan tai se vaihtaa korkeutta.

3 ( ) Pystyn puhumaan ymmärrettävästi, mutta katkonaisesti, ääni vavisten, sammaltaen tai änyttäen.

4 ( ) Muilla on vaikeuksia ymmärtää puhettani.

5 ( ) Pystyn ilmaisemaan itseäni vain elein.

KYSYMYS 8. Eritystoiminta

1 ( ) Virtsarakkoni ja suolistoni toimivat normaalisti ja ongelmitta.

2 ( ) Virtsarakkoni ja/tai suolistoni toiminnassa on lieviä ongelmia, esim. minulla on virtsaamisvaikeuksia tai kova tai löysä vatsa

3 ( ) Virtsarakkoni ja/tai suolistoni toiminnassa on melkoisia ongelmia, esim. minulla on satunnaisia virtsanpidätysvaikeuksia tai vaikea ummetus tai ripuli.

4 ( ) Virtsarakkoni ja/tai suolistoni toiminnassa on suuria ongelmia, esim. minulla on säännöllisesti "vahinkoja" tai peräruiskeiden tai katetroinnin tarvetta.

5 ( ) En hallitse lainkaan virtsaamista ja/tai ulostamista.
KYSYMYS 9. Tavanomaiset toiminnot

1 ( ) Pystyn suoriutumaan normaalisti tavanomaisista toiminnoista (esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot).

2 ( ) Pystyn suoriutumaan tavanomaisista toiminnoista hieman alentuneella teholla tai pienin vaikeuksin.

3 ( ) Pystyn suoriutumaan tavanomaisista toiminnoista huomattavasti alentuneella teholla tai huomattavina vaikeuksina tai vain osaksi.

4 ( ) Pystyn suoriutumaan tavanomaisista toiminnoista vain pieneltä osin.

5 ( ) En pysty suoriutumaan lainkaan tavanomaisista toiminnoista.

KYSYMYS 10. Henkinen toiminta

1 ( ) Pystyn ajattelemaan selkeästi ja johdonmukaisesti ja muistini toimii täysin moitteettomasti.

2 ( ) Minulla on lieviä vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai muistini ei toimi täysin moitteettomasti

3 ( ) Minulla on melkoisia vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on jonkin verran muistinmenetystä

4 ( ) Minulla on suuria vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on huomattavaa muistinmenetystä

5 ( ) Olen koko ajan sekaisin ja vailla ajan tai paikan tajua

KYSYMYS 11. Vaivat ja oireet

1 ( ) Minulla ei ole mitään vaivoja tai oireita, esim. kipua, särkyä, pahoinvointia, kutinaa jne.

2 ( ) Minulla on lieviä vaivoja tai oireita, esim. lievää kipua, särkyä, pahoinvointia, kutinaa jne.

3 ( ) Minulla on melkoisia vaivoja tai oireita, esim. melkoista kipua, särkyä, pahoinvointia, kutinaa jne.
4 ( ) Minulla on voimakkaita vaivoja tai oireita, esim. voimakasta kipua, särkyä, pahoinvointia, kutinaa jne.

5 ( ) Minulla on sietämättömiä vaivoja ja oireita, esim. sietämätöntä kipua, särkyä, pahoinvointia, kutinaa jne.

**KYSYMYS 12. Masentuneisuus**

1 ( ) En tunne itseäni lainkaan surulliseksi, alakuloiseksi tai masentuneeksi.

2 ( ) Tunnen itseni hieman surulliseksi, alakuloiseksi tai masentuneeksi.

3 ( ) Tunnen itseni melko surulliseksi, alakuloiseksi tai masentuneeksi.

4 ( ) Tunnen itseni erittäin surulliseksi, alakuloiseksi tai masentuneeksi.

5 ( ) Tunnen itseni äärimmäisen surulliseksi, alakuloiseksi tai masentuneeksi.

**KYSYMYS 13. Ahdistuneisuus**

1 ( ) En tunne itseäni lainkaan ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

2 ( ) Tunnen itseni hieman ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

3 ( ) Tunnen itseni melko ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

4 ( ) Tunnen itseni erittäin ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

5 ( ) Tunnen itseni äärimmäisen ahdistuneeksi, jännittyneeksi tai hermostuneeksi.

**KYSYMYS 14. Energisyys**

1 ( ) Tunnen itseni terveeksi ja elinvoimaiseksi.

2 ( ) Tunnen itseni hieman uupuneeksi, väsyneeksi tai voimattomaksi.

3 ( ) Tunnen itseni melko uupuneeksi, väsyneeksi tai voimattomaksi.

4 ( ) Tunnen itseni erittäin uupuneeksi, väsyneeksi tai voimattomaksi, lähes "loppuun palaneeksi".
5 ( ) Tunnen itseni äärimmäisen uupuneeksi, väsyneeksi tai voimattomaksi, täysin "loppuun palaneeksi".

KYSYMYS 15. Sukupuolielämä

1 ( ) Terveydentilani ei vaikuta mitenkään sukupuolielämääni.

2 ( ) Terveydentilani vaikuttaa hieman sukupuolielämääni.

3 ( ) Terveydentilani vaikuttaa huomattavasti sukupuolielämääni.

4 ( ) Terveydentilani tekee sukupuolielämäni lähes mahdottomaksi.

5 ( ) Terveydentilani tekee sukupuolielämäni mahdottomaksi.
FRÅGOR ANGÄNDE LIVSKVALITET (15D©)

Läs först omsorgsfullt igenom svarsalternativen till varje fråga. Kryssa (x) därefter det alternativ som motsvarar ert nuvarande hälsotillstånd. Gör på samma sätt vid alla frågor, från 1 till 15. Vid varje fråga kryssas alltså endast ett alternativ.

1. Rörelseförmåga

1 ( ) Jag kan gå normalt (utan svårigheter) inomhus, utomhus och i trappor.

2 ( ) Jag kan gå utan svårigheter inomhus, men utomhus och/eller i trappor har jag lite svårigheter.

3 ( ) Jag kan gå utan svårigheter inomhus (med hjälpmedel eller utan), men utomhus och/eller i trappor har jag ganska mycket svårigheter eller behöver hjälp av en annan person.

4 ( ) Jag kan gå även inomhus endast med hjälp av en annan person.

5 ( ) Jag är helt rörelsehindrad och sängbunden.

2. Syn

1 ( ) Jag har normal syn, dvs. jag ser att läsa tidning och TV:s texter utan svårigheter (med glasögon eller utan).

2 ( ) Jag ser att läsa tidning och TV:s texter med lite svårigheter (med glasögon eller utan).

3 ( ) Jag ser att läsa tidning och/eller TV:s texter med betydande svårigheter (med glasögon eller utan).

4 ( ) Jag ser inte, varken med eller utan glasögon, att läsa tidning eller TV:s texter, men jag klarar mig (kunde klara mig) utan personlig assistent.

5 ( ) Jag klarar (skulle inte klara) mig inte utan assistent, dvs. jag är nästan eller helt blind.

3. Hörsel

1 ( ) Jag hör normalt, dvs. jag hör väl normal talröst (med hörapparat eller utan).
1 ( ) Jag hör normal talröst med små svårigheter.
2 ( ) Jag hör normal talröst med betydande svårigheter, under samtal krävs högre talröst än normalt.
3 ( ) Jag hör svagt även hög talröst; jag är nästan döv.
4 ( ) Jag är helt döv.

4. Andning

1 ( ) Jag andas normalt, dvs. jag har inte andnöd eller andra andningsbesvär.
2 ( ) Jag får andnöd under tungt arbete eller sport, rask gång på slät mark eller i lindrig uppförsbacke.
3 ( ) Jag har andnöd under gång tillsammans med jämnåriga på slät mark.
4 ( ) Jag får andnöd även under lindrig ansträngning, tex. under tvättning och påklädnings.
5 ( ) Jag har andnöd nästan hela tiden, även i vila.

15D©/Harri Sintonen

5. Sömn

1 ( ) Jag sover normalt, dvs. jag har inga problem med sömnen.
2 ( ) Jag har lindriga sömnproblem, tex. jag har svårt att somna eller jag vaknar sporadiskt under natten.
3 ( ) Jag har betydande sömnproblem, tex. jag sover oroligt, det känns att jag inte får tillräckligt sömn.
4 ( ) Jag har stora sömnproblem, tex. jag är tvungen att använda sömnmedicin ofta eller regelbundet, jag vaknar regelbundet under natten och/eller vaknar för tidigt på morgonen.
5 ( ) Jag lider av svår sömnlöshet, tex. trots rikligt användande av sömnmedicin är det nästan omöjligt att sova, jag vakar största delen av natten.
6. Ätande

1 ( ) Jag kan äta normalt, dvs. själv utan svårigheter.

2 ( ) Jag kan äta själv med små svårigheter (tex. långsamt, klumpigt, darrande eller med hjälp av specialhjälpmedel).

3 ( ) Jag behöver en aning hjälp av en annan person när jag åter.

4 ( ) Jag kan inte alls äta själv, någon måste mata mig.

5 ( ) Jag kan inte alls äta själv, jag måste matas med hjälp av slang eller med intravenös näring.

7. Tal

1 ( ) Jag kan tala normalt, dvs. klart, tydligt och flytande.

2 ( ) Jag har små svårigheter med tal, tex. jag måste söka orden eller rösten är inte tillräckligt tydlig eller den ändrar tonhöjd.

3 ( ) Jag kan tala förståeligt, men stapplande, darrande, läspande eller stammande.

4 ( ) Andra personer har svårt att förstå mitt tal.

5 ( ) Jag kan uttrycka mig endast med gester.

8. Utsöndring

1 ( ) Min urinblåsa och tarm fungerar problemfritt.

2 ( ) Jag har små problem med min urinblåsa- och eller tarmfunktion, tex. jag har urineringsproblem eller hård eller lös mage.

3 ( ) Jag har betydande problem med min urinblåsa- och eller tarmfunktion, tex. jag har sporadiska inkontinensbesvär eller svår förstoppning eller diarré.

4 ( ) Jag har stora problem med min urinblåsa- och eller tarmfunktion, tex. jag har regelbundet ”misstag” eller behov av lavemang eller katetrising.

5 ( ) Jag har ingen kontroll över min urinblåsa- och eller tarmfunktion.
9. Vanliga funktioner

1 ( ) Jag klarar mig normalt med vanliga funktioner (tex. arbete, studier, hemsysslor, fritidsintressen).

2 ( ) Jag klarar mina vanliga funktioner med en aning sänkt förmåga eller med små svårigheter.

3 ( ) Jag klarar mina vanliga funktioner med betydligt sänkt förmåga eller med betydande svårigheter eller endast delvis.

4 ( ) Jag klarar endast en liten del av mina vanliga funktioner.

5 ( ) Jag klarar inte alls mina vanliga funktioner.

10. Mental funktion

1 ( ) Jag kan tänka klart och konsekvent, mitt minne fungerar felfritt.

2 ( ) Jag har lindriga svårigheter att tänka klart och konsekvent, mitt minne fungerar inte helt felfritt.

3 ( ) Jag har betydande svårigheter att tänka klart och konsekvent, jag lider i någon mån av glömska.

4 ( ) Jag har stora svårigheter att tänka klart och konsekvent, jag lider av betydande glömska.

5 ( ) Jag är helt förvirrad och jag har inget begrepp om tid och rum.

11. Besvär och symptom

1 ( ) Jag lider inte av några besvär eller symptom, tex. smärta, värk, illamående, klåda osv.

2 ( ) Jag lider av lindriga besvär eller symptom, tex. lindrig smärta, värk, illamående, klåda osv.

3 ( ) Jag lider av betydande besvär eller symptom, tex. betydande smärta, värk, illamående, klåda osv.
4 ( ) Jag lider av svåra besvär eller symptom, tex. svår smärta, värk, illamående, klåda osv.

5 ( ) Jag lider av outhärdlig smärta, värk, illamående, klåda osv.

12. Depression

1 ( ) Jag känner mig inte alls sorgsen, nedstämd eller deprimerad.

2 ( ) Jag känner mig lite sorgsen, nedstämd eller deprimerad.

3 ( ) Jag känner mig betydligt sorgsen, nedstämd eller deprimerad.

4 ( ) Jag känner mig mycket sorgsen, nedstämd eller deprimerad.

5 ( ) Jag känner mig ytterst sorgsen, nedstämd eller deprimerad.

13. Ångest

1 ( ) Jag känner mig inte alls ångestfylld, spänd eller nervös.

2 ( ) Jag känner mig en aning ångestfylld, spänd eller nervös.

3 ( ) Jag känner mig betydligt ångestfylld, spänd eller nervös.

4 ( ) Jag känner mig mycket ångestfylld, spänd eller nervös.

5 ( ) Jag känner mig ytterst ångestfylld, spänd eller nervös.

14. Livskraft

1 ( ) Jag känner mig frisk och livskraftig.

2 ( ) Jag känner mig en aning utmattad, trött eller kraftlös.

3 ( ) Jag känner mig betydligt utmattad, trött eller kraftlös.

4 ( ) Jag känner mig mycket utmattad, trött eller kraftlös, nästan "slutkörd".

5 ( ) Jag känner mig ytterst utmattad, trött eller kraftlös, totalt "slutkörd".
15. Sexualliv

1 ( ) Mitt hälsotillstånd inverkar inte på något sätt på mitt sexualliv.
2 ( ) Mitt hälsotillstånd försvårar en aning mitt sexualliv.
3 ( ) Mitt hälsotillstånd försvårar betydligt mitt sexualliv.
4 ( ) Mitt hälsotillstånd gör mitt sexualliv nästan omöjligt.
5 ( ) Mitt hälsotillstånd gör mitt sexualliv omöjligt.
**LEIKKAUSHOITOON JA LEIKKAUKSEN JÄLKEISEEN SEURANTAAN TULEVIEN SAIRAALOISEN LIHAVIEN POTILAIDEN ELÄMÄNLÄATUA KARTOITTAVA KYSELYKAAVAKE**

**Voitteko yleisesti ottaen**

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<tr>
<th>Erittäin huonosti</th>
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<th>Aika hyvin</th>
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<th>Erittäin hyvin</th>
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**Tuletteko toimeen sosiaalisessa kanssakäymisessä**

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**Pystyttekö osallistumaan liikunnallisiiin tapahtumiin**

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**Onko työkykynne Teidän mielestä**

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**Onko Teidän kiinnostus seksiin**

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<th>Hyvä</th>
<th>Erittäin hyvä</th>
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</table>

**Onko Teillä jokin serauvista sairauksista**

- Verenpainetautia
- Astma
- Diabetes
- Masennusta
- Rasitusperäisiä nivelkipuja
- Uniapnea
- Jokin muu sairaus, mikä? _________________________________

**Lääkitys, mikä?** _________________________________

_______________________________________________
Original publications


The permission of Springer (I–II, IV–VII), and KargerAG (III) to reprint the original papers is gratefully acknowledged.

Original publications are not included in the electronic version of the dissertation.
967. Huilaja, Laura (2008) Collagen XVII and pathomechanisms of junctional epidermolysis bullosa and gestational pemphigoid
969. Juntti, Hanna (2008) Association of respiratory syncytial virus infection with asthma and atopic allergy
972. Liljeroos, Mari (2008) Toll-like receptor 2 (TLR2) and TLR4 signaling in the innate response against bacterial components
973. Vierimaa, Outi (2008) Multiple Endocrine Neoplasia Type 1 ( MEN1 ) and Pituitary Adenoma Predisposition ( PAP ) in Northern Finland
980. Palosari, Kari (2008) Quantity and semi-quantitative imaging techniques in detecting joint inflammation in patients with rheumatoid arthritis. Phase-shift water-fat MRI method for fat suppression at 0.23 T, contrast-enhanced dynamic and static MRI, and quantitative 99mTc-nanocolloid scintigraphy
981. Perkiömäki, Marja Riitta (2008) Craniofacial shape and dimensions as indicators of orofacial clefting and palatal form. A study on cleft lip and palate and Turner syndrome families
Pekka Tolonen

LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING FOR MORBID OBESITY

PRIMARY, INTERMEDIATE, AND LONG-TERM RESULTS INCLUDING QUALITY OF LIFE STUDIES