
Patient information - morbid obesity

Adjustable gastric band

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This brochure is about the adjustable gastric band, a device that enables the effective treatment of severely overweight people (morbid obesity).

Why bariatric surgery?

People who exceed their normal weight by more than 45 kg are considered morbidly obese. Morbid obesity is an illness in its own right as this condition significantly reduces life expectancy. Obesity is also commonly associated with other illnesses, such as diabetes, blood clotting, joint pain, heart failure, gallstones and psychological problems. These conditions can be greatly reduced with weight loss.

Most patients who suffer from obesity have repeatedly tried to lose weight either in applying diets, exercising, psychotherapy, hypnosis or even group therapy. Unfortunately, the improvement has been of short duration, and weight is regained rapidly as soon as the method is stopped. Surgery is an effective alternative for the treatment of morbid obesity, which presents excellent long-term results.

Facts:

- BMI (Body Mass Index) > 40 kg/m² - The National Institute of Health (NIH) recommends surgical treatment - Consensus Conference 1991
- Mortality for patients with a BMI (Body Mass Index) > 40 kg/m² is 12 times greater than for normal weight people! Drenick EJ, et al. JAMA 1980; 243: 443-445
- Studies have also shown that drug therapies, diets or behaviour therapies are unsuccessful in the long term. Council on Scientific Affairs. JAMA 1988; 260: 2547-2551.

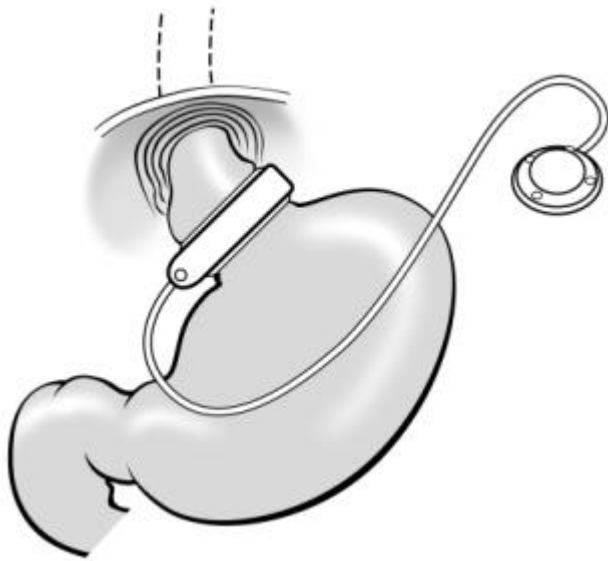
Aim of the surgical intervention

The aim of surgery performed on the stomach is to reduce food intake and/or to create malabsorption of food by removing, shortening or repositioning sections of the stomach or intestines.

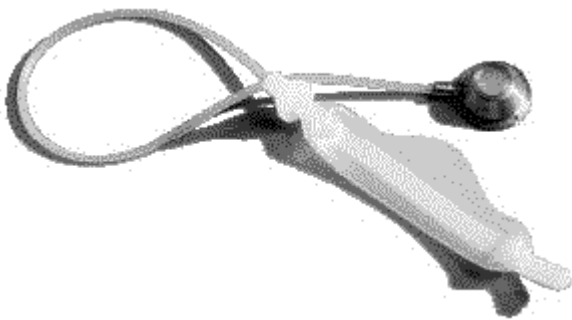
The most common surgical methods used for the treatment of obesity involve removing and/or resectioning of the stomach or intestines. These techniques are therefore dependent on carrying out dramatic anatomical alterations to the digestive tract.

Adjustable gastric banding is an operation method which achieves restricting food intake simply by surrounding the top part of the stomach with a band

The Adjustable Gastric Band (AGB) System



So-called adjustable gastric banding has become popular since 1985 as a mean of achieving gastric restriction and treating morbid obesity. Adjustable gastric banding (AGB) as described by Kuzmak and the Swedish adjustable gastric band (SAGB) proposed by Hallberg permits regulation of gastric restriction.



The adjustable band is placed around the top part of the stomach, leaving a small section of stomach (about 25 ml) above the band; the main part of the stomach lies below the band. A small passage is left open through the section of stomach surrounded by the band, so that liquids and food can still flow through from the upper to the lower part of the stomach. This small opening is called the stoma.

The adjustable gastric band allows the surgeon to modify the width of the opening of the stoma (through which food passes), by injecting or removing liquid from the inflatable balloon which is fixed to the inside of the band. The balloon of the band is attached to a long tube that plugs into an injection port. The injection port is fixed to the stomach muscle during the operation, and can be localised by X-ray later.

The surgeon can remove or add liquid into the balloon of the band via the injection port, thus altering the inner diameter of the closed band: more liquid in the balloon will reduce the opening of the stoma, whereas by removing liquid from the balloon, the opening will increase, enabling more food to pass through into the stomach.

This procedure is ideal because adjustments can be made as frequently as necessary and according to each patient's need without a further surgery.

What are the advantages of the adjustable gastric band?

This method is:

1. the less invasive surgical intervention actually available for the treatment of morbid obesity, as no alterations are made to the anatomy of the stomach or intestines.
2. the only method which enables a perfect calibration of the stoma diameter and pouch size (small part of the stomach which remains above the band).
3. the only method where the width of the stoma can be modified postoperatively without further surgery.
4. the only totally reversible method in obesity surgery, in which the anatomy of the stomach is entirely restored to its original form, after the band is removed.

About weightloss

Average weightloss obtained with the laparoscopic adjustable gastric band is comparable to traditional surgical methods.

The percentages listed below represent average excess body weight loss over a period of 5 years.

3 months: 20% (excess body weight loss)

6 months: 20-40%

1 year: 58%

4 years: 65%.

It is of course essential that you comply with:

- medical advices
- dietary instructions
- follow-up controls
- exercising

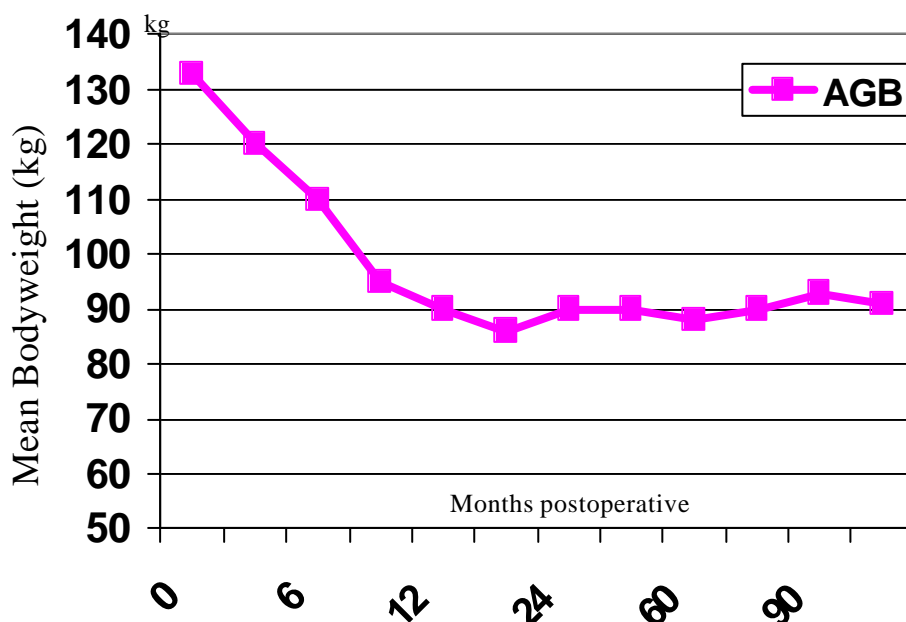


Fig. 3. Long term weight loss with the Adjustable Gastric Band (AGB) [Miller K. et al. Obesity Surgery 1998; 8:359 and Miller K et al. Zentralbl Chir 2002; 127]

Who is suitable for a gastric band operation?

You must fulfill the following items :

1. You are at least 80% above your ideal weight (equivalent to approx. 45 kg excess body weight or a Body Mass Index above 40%).
2. You do not suffer from any other illness that causes obesity.
3. You are prepared to modify your lifestyle and attend follow-ups regularly.

These are the basic criterias, but other requirements can be considered too, according to the results of the individual consultation.

The operation – the adjustable gastric band

You will be admitted to the hospital a couple of days before your operation. The actual operation is performed under full anaesthetic. The band is placed around the stomach and the injection port is fixed to the stomach muscle or on the breast bone. Immediately after your operation you will be given new eating rules and be asked to introduce as much exercise into your daily routine as possible. The length of your hospital stay will depend upon your progress, approximately 3-4 days after the operation. After leaving the hospital it is important that you follow the instructions given to you by your doctor very carefully.

DIETARY INSTRUCTIONS

The Adjustable Gastric Band (AGB) operation is the first step towards a major readjustment in the patient's lifestyle. The patient has to learn a new eating behaviour and a new eating practice.

The following 6 rules are very important for the new eating habit.

1. **Only eat small quantities:** The capacity of the stomach has changed. Also the amount of food intake has to change. Nevertheless it is not always easy to stop eating at the right time.
What does we mean, if we say small quantities? For example one slice of bread for breakfast or 2 potatoes and a small piece of fish for lunch.
2. **Chew well and swallow food only completely mashed:** You need more time for chewing and also not all food is possible to chew well. The list with "unsuitable food" will show you the products which are usually not easy to chew.
3. **Never eat and drink at the same time:** The reduced capacity of the first part of the stomach will no longer permit to take in both: liquid and food at the same time. The usual amount of beverage, 2-3 litre liquid per day, are desirable. You drink it better between or before meals.
4. **Do not lay down or rest after eating:** because in a horizontal position reflux is easier to take place. The food also remains longer in the prestomach and leads to a very uncomfortable accumulation of mucus.
5. **Eat five times a day:** This is important, because if you only eat 2-3 times a day, it is not possible to have a great variety of food. Consequently, as you can only eat small amounts, you do not get enough proteins, minerals and vitamins. In addition, when eating 5 times daily, it is less likely that you are overpowered by sudden hunger attacks where you probably forget the new eating habits.
6. **Watch for beverages rich in calories:** We experienced, that many people take in a lot of their calories with soft drinks, hot chocolate and milk shakes. At this is certain

possible after operation, be carefully. The type of liquid should be varied and include tea or coffee, diluted fruit- or vegetable juice, light drink with artificial sugar, low fat variants of sour milk, mineral water without gas.

Certain food are not easily tolerated and should be avoided unless they can be broken down into easily digestible alternatives. These are food, that generally get stuck in the opening of the stomach and are therefore likely to cause obstruction, and thereby vomiting and fluid depletion.

Unsuitable food are:

- tough meet, especially beef
- pastas and noodles
- vegetables with shell or skin (beans, corn, peas, asparagus)
- mushrooms
- sausages and bacon
- fruit with peel or skin e.g. grapes
- carbonic acid

It is, therefore, advisable to abstain from eating meat in the beginning and only introduce this progressively into the diet. Much depends on how much fluid is injected into the AGB`s balloon as this affects the size of the aperture between the upper und lower part of the stomach. A small hole will allow greater weight loss, but will also require from patients that they be more careful about what they eat. With the balloon totally empty, the patient will be able to eat almost normally.

Eating program in the hospital:

1. on the operation day, you get only tea in little sips. The remaining need of liquids is given by infusion
2. on the first day after the operation you get tee, as much as you want, and for lunch and dinner a soup.
3. on the second day you get your first breakfast with tea or coffee, crisp bread with butter and jam. For lunch we serve mashed potatoes, mashed vegetables and mashed meat – only small portions. Please eat with a tea-spoon to enforce slow eating. Between

breakfast und lunch and between lunch and dinner you get a snack – pureed fruits or yoghurt. For dinner you can choose between every kind of porridge with applesauce or a sandwich with cream.

Possible beverages are: coffee, tea, mineral water without gas, diluted orange or apple juice.

4. after the third day, if you responds well to this diet, you get solid food like: potatoes, vegetables, fish, minced meat, dumplings e.g. – well done cooked but not mashed.

After the time in the hospital, you can start to make up your own menus. It is still important, that you eat little, often and chew the food thoroughly.

If you comply with all advices given on your diet, you should have no problems with the healing process. You should not lift any heavy objects for two weeks after your operation, as this may cause abdominal pain.

You must not take aspirin or any other drug such as non-steroid anti-rheumatic drugs, that may irritate your stomach, without gastric protection. Therefore you must inform your doctor of this advice (gastric mucosal prophylactic).

When is it necessary to adjust the diameter of the gastric band?

The great advantage of gastric banding is that the band's width can be altered postoperatively. The stoma (the small passage through the stomach where it is surrounded by the band and through which food passes from the upper to the lower part of the stomach) diameter can be adjusted if weight loss has slowed down too much or if you find you are able to eat a lot of food in a small period of time. The stoma diameter is widened if you are only able to swallow liquids or if you frequently need to vomit.

What are the risks associated with gastric banding?

As with any important surgical intervention, the normal risks encountered with surgery also apply to gastric banding. It is not always possible to perform gastric banding by keyhole surgery, in this case the intervention is converted to traditional open surgery.

The risk of postoperative complications average out between 3-5%. This includes infections, pneumonia or bleeding. Severely overweight patients run a higher risk of incurring operative complications. The risk of mortality is, according to literature, below 0.3%.

It is also possible to regain weight after some time, because snacks and high calorie food could make the band ineffective.

The main goal is to make radical changes in your lifestyle after gastric banding. You must learn to have five meals a day and no snacks in between. Also, high calorie drinks such as coca cola, icetea or any other soft drink must be avoided.

Possible risks specific to gastric banding and their frequency according to statistical data found in the literature and in our series:

- Stomach mucus irritation and swelling due to pressure of the band onto the stomach and migration of the band through the stomach wall: 0.6%
- Leakage from the tube and balloon: 1.8%
- Wound infection in the area of the injection port: 0.3%
- The need to reoperate: 6%

The first 500 patients had following results:

Laparoscopic AGB is performed since 1994, 99 % of the patients had a gastric band fitted by keyhole surgery in our hospital (3 patients had a laparotomy). Significant longterm weightloss is achieved in 90 % of all patients (Zentr.Chir.2002). The only early postoperative complications noted were linked to the removal of the gallbladder in one patient (0,2%), two pulmonary embolism and one pneumonia. Late complications have included six pouch dilatations and seven band leakages which necessitated the replacement of the band with a new operation. One patient died due to pulmonary embolism (mortality rate also in literature 0,3 %).

Our average complication rate is therefore 6% (pouch dilation, band leakage, etc).

But – patients between 20 and 30 years with morbid obesity without any treatment have a 12 times higher mortalit rate than people with normal weight. (Drenick EJ, et al. Jama 1980; 243: 443-445).

Possible complications

INFECTION AND MIGRATION

An infection may develop either in the port area or in the abdomen, and in some instances this may cause the band to migrate into the stomach. In such a case, reoperation may be necessary. Most of the complications linked to migrations have occurred as a result of too much fluid being injected into the AGB (Adjustable Gastric Band), which then causes too much pressure onto the stomach wall. The balloon must therefore be filled with no more than 9 ml of fluid, as recommended by Obtech Medical and no more than 4 ml in the Bioenterics LAP-Band. In nearly all of the reported cases of migration, the balloon had a fluid content above 11 ml. This is 2 ml more than the recommended maximum volume. This problem has now mostly been solved. The rate of migration will be kept low by avoiding overfilling the system. Migration can also be caused by a subclinical infection.

LEAKAGE

Leakage from the AGB or from the connecting tube between the balloon and the port may require reoperation. The balloon is made of fragile material, and leakage can occur either shortly after surgery or many years later. In the event of leakage, the AGB can normally be replaced with a new one. Nowadays this is a rare complication but you must be aware that experience using the SAGB dates back to 1985 only and therefore there is a possibility that in the very long term the band may need to be replaced with a new one.

SLIPPAGE OF THE BAND AND POUCH DILATATION

The band may slip, and the pouch (the part of the stomach above the band) may become too enlarged, and a reoperation may be necessary. This is nowadays a rare complication due to a better operating technique.

PUNCTURES IN THE SILICONE TUBE AND PORT DISLOCATION

The injection port may dislocate. When injecting into the port, there is always the risk of puncturing the silicone tube. Post dislocations can be corrected with a small operation under local anaesthesia.

OTHER COMPLICATIONS

There may be other rare, unspecified complications. You should ask your doctor for more detailed information. There is no guarantee that the AGB will work without fault for the rest of your life, however, extensive use of the AGB since 1985 has led to a method where failure is rare. In most patients, the AGB works well and provides an essentially complication-free and long-term weight loss. You must understand that the possibility of reoperation is an integral

part of the procedure. The overall rate of reoperation following the placement of an AGB is low (3-9 %) and problems can usually be corrected and patients are generally rapidly back on track after such treatment.

General advice and possible minor side-effects

VOMITING

Patients occasionally vomit or feel pain after food intake. This can be caused either by a poor eating behaviour, or by the narrow passage of the AGB following the injection of fluid into the balloon. By eating slowly and calmly, you will learn to listen to the signals from your stomach. Regular vomiting is definitely a warning sign. In such cases, the amount of liquid in your AGB may need to be readjusted.

VITAMINS

During the phase of rapid weight reduction, vitamin supplements are advisable. A liquid vitamin mixture containing multivitamins, in particular the vitamin B complex, is recommended for at least the first 6 months following surgery.

PREGNANCY

The period between surgery and weight stabilisation is considered as a period of starvation. It is not advisable to become pregnant during starvation, because the foetus needs a well provided food supply. Should you nevertheless get pregnant it is advisable to remove all the fluid from the band. Pregnancy is never a risk in patients with AGB but follow-ups and controls are necessary.

MEDICATION

Tablets must be broken down into small pieces or crushed before they are taken. It is common that medication for conditions such as hypertension, diabetes or asthma may need to be altered (reduced) after this operation. Patients should consult their doctors in this matter.

CONSTIPATION

Many patients feel constipated after surgery. This is mainly due to the fact that the reduced food intake leads to less faeces and thus to fewer bowel movements. If laxatives become necessary, it is advisable to abstain from so-called bulking agents and instead use liquid laxatives, such as lactulose.

DOCTOR APPOINTMENTS

After surgery you must undergo regular outpatient check-ups. Initially, these check-ups will be carried out monthly, but soon visits will become less frequent. The AGB will gradually be filled via the injection port during the first 18 months following surgery. During this period, your weight loss and level of well-being will be monitored. Once your weight has stabilised, check-ups will be necessary on an annual basis.

PHYSICAL ACTIVITY

It will be important to alter not only your eating habits, but also your level of physical activity. Patients are generally recommended to start exercising slowly. As weight loss is achieved, physical activities will gradually become easier.

Weight loss:

BMI = (weight) / (height m * height m)

BMI = ____ kg / ____ m * ____ m

Preoperative weight: _____ kg _____ lbs

	30 days after operation	60 days after operation	90 days after operation	4 months after operation	5 months after operation
Weight					
Weight reduction					

	6 months after operation	7 months after operation	8 months after operation	9 months after operation	1 year after operation
Weight					
Weight reduction					

	1,5 years after operation	2 years after operation	2,5 years after operation	3 years after operation	3,5 years after operation
Weight					
Weight reduction					

	4 years after operation	5 years after operation	6 years after operation	8 years after operation	10 years after operation
Weight					
Weight reduction					

Notes for follow-up procedures:

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Patient Consent Form

By signing this document you are confirming that you understand and accept the possible complications linked to the laparoscopic adjustable gastric band operation, and that you are aware that there is no full guarantee that the operation will be successful. No third party, be it the manufacturer or distributor of the Adjustable Gastric Band (AGB) or your team of doctors, can be held responsible for the complications.

Name

.....

Address

.....

.....
Date

.....
Signature

.....
Dr. Miller Karl Associate Professor of Surgery

Agreement of operation

ADJUSTABLE GASTRIC-BAND

Patientlabel

I explain explicitly to be informed in detail by Prof. Dr. Karl Miller about the kind of treatment, the aim and the kind of the following therapeutic or special

diagnostic measures and the possible typical risks of the adjustable gastric-band:

The information conversation took place on _____ and concerned especially:

- kind of illness
- kind of operation of the adjustable gastric-band (operation method)
- alternatives of treatment, present treatment
- usual healing process, consequential of operation
- typical risks, possible complications
- atypical, unusual risks
- possible further measures
- duty of co-operation (self-discipline, change of eating habits)

I confirm the receipt of the brochure "patient information – operation of the adjustable gastric-band". All my questions have been answered to my full satisfaction during the information conversation. After the medical conversation I explain explicitly to agree with the planned medical treatment.

If a complication or a new medical problem should arise during the operation, I give my authorisation - according to the information about aim and kind of operation - to use all possible and reasonable measures to improve my medical recovery and condition.

Hallein, on

(Personal signature of the patient,
Personal signature of the legal representative of the patient till the accomplished age of 18 or of incapacitate patients.)

Miller K, MD, PhD