

Patient agreement to investigation or treatment

Laparoscopic Nissen Fundoplication for Gastro-oesophageal reflux

Authors: Cambridge Oesophago-gastric Centre

Brief description:

- This operation is an operation to treat gastro-oesophageal reflux (acid reflux). The aim of the surgery is to stop reflux occurring.
- Here, we explain some of the aims, benefits, risks and alternatives to this operation. We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website: <http://www.addenbrookes.org.uk/consent>
- Remember, you can change your mind about having the procedure at any time.

For staff use:

Does the patient have any special requirements? (For example: requires an interpreter or other additional communication method)

.....
.....

What is gastro-oesophageal reflux disease?

- Gastro-oesophageal reflux disease (GORD) occurs when the acidic contents of the stomach flow backwards into the oesophagus causing inflammation of the lower oesophagus (oesophagitis). This may lead to a number of symptoms including heartburn, regurgitation of semi-digested food, difficulty swallowing and pain on swallowing. In addition, you may also experience welling up of a foul tasting fluid into the back of your mouth; you might also notice fluid welling up when you bend over to tie your shoes or to lift something up. Rarely, GORD may be associated with chest conditions such as asthma and may also lead to problems with tooth decay.
- GORD occurs when there is a failure of the valve (sphincter) at the lower end of your oesophagus (gullet). This valve should prevent fluid from the stomach passing back up your oesophagus, but in patients with GORD this is not the case and fluid from the stomach can pass freely into the oesophagus. Although not the cause, patients with GORD frequently also have a hiatus hernia. This occurs when the upper part of the stomach and valve in the lower part of the oesophagus sit in the chest cavity, rather than the abdominal cavity.

What are the options for treating gastro-oesophageal reflux?

- The majority of patients who have gastro-oesophageal reflux treat their condition with simple over the counter medicines, (for example: Rennie's), and other medications that can be brought from the chemist that reduce the acidity in the stomach.
- If these simple measures do not work then patients are commonly prescribed tablets that reduce the acid levels in the stomach. These drugs are collectively known as Proton Pump Inhibitors (PPIs, for example: Lansoprazole, Omeprazole, Esomeprazole, Pantoprazole and Rabeprazole). These drugs are highly effective at relieving the symptoms of gastro-oesophageal reflux; they do not do anything to the sphincter at the lower end of the oesophagus.
- Sometimes patients notice that an improvement in their symptoms if they loose weight or by giving up alcohol and smoking. We therefore generally advise people, who have severe reflux disease, to follow these measures and also to avoid eating large meals late at night and drinking large amounts of caffeine containing drinks and loosing weight.

What is the aim of surgery?

- Surgical operations for reflux disease aim to prevent acid reflux by reinforcing the valve mechanism at the lower end of the oesophagus so that the fluid cannot reflux into the oesophagus from the stomach. The sphincter mechanism itself cannot be directly repaired. Instead it is reinforced by buttressing the valve mechanism with the upper stomach.

- Surgical treatment for acid reflux disease has been around for many years but has become more popular in recent times as key hole methods (laparoscopic) for carrying out the surgery have been developed and it is also related to the increased number of patients who suffer with GORD.

Who is suitable for surgery?

- Surgery can potentially benefit the majority of patients who have troublesome acid reflux disease. However, it is important that you are fully aware of the different options for treating your reflux disease before going through an operation.
- It is critical that a precise diagnosis of gastro-oesophageal reflux disease is made prior to surgery. It is most important to be certain that reflux is causing your symptoms. There are many other conditions of the oesophagus and stomach that can cause symptoms which may be interpreted as reflux. These other conditions are not helped by surgery and may be made worse. Therefore, your surgeon will carefully decide whether surgery is likely to help your symptoms.
- The majority of patients who wish to explore the possibility of surgical treatment are those who have severe reflux symptoms that are inadequately relieved by taking medication. Some patients have the desire not to stay on long-term medication, or have had side effects from the PPI medications they have been prescribed.

What tests do I need before the operation?

- Before you have a surgical treatment for your gastro-oesophageal reflux, it is important that we confirm that this is the problem that you have as other conditions can mimic GORD and they would not be helped by this type of surgery. You will undergo an endoscopy test to have a look to see if you have oesophagitis, (inflammation of your gullet), or a hiatus hernia.
- You will also be asked to undergo some tests of your oesophagus to make sure that the muscles within the oesophagus work properly and strongly when you swallow. You will also be asked to undergo a test where a fine catheter tube is placed down your nose for a 24 hour period; this catheter tube measures the acid (pH level) in your lower oesophagus and allows us to confirm that you have an abnormal degree of acid reflux.
- We will also ask you about your response to acid reducing medications as frequently patients who respond well to these medications do well after surgery.

Who makes the final decision regarding surgery?

When we have all the information available from your pre-operative tests we will discuss with you the pros and cons of surgery. If we feel you will benefit from the surgery then it will be your decision as to whether you wish to go ahead with surgery.

Before your procedure

- You will be asked to attend a pre-admission clinic where you will be seen by a member of the surgical team that will be looking after you in hospital.
- You will be asked details of your medical history and undergo a physical examination. We will arrange for any further investigations you may require to prepare you for your operation. We encourage you at this time to ask any questions about the procedure or any other concerns you might have.
- You will be asked if you are taking any tablets or other types of medication; these might be ones prescribed by your doctor or bought over the counter in a pharmacy. It helps us if you bring details with you of anything that you are taking: (i.e. bring the packaging with you or a full list of your medications).
- You will be asked if you are allergic to anything and details of operations you have had in the past.
- A member of the surgical team will discuss any issues you have and you will be given a consent form to take away with you at this time and to bring back to hospital when you are admitted.
- At the time of your pre-admission you will receive information regarding the details of your admission.
- Usually you will be admitted to hospital on the morning of your operation.
- You will be advised about what you can eat and drink before the operation and from what time you will need to be starved

What happens when I am admitted?

- When you are admitted, you will be seen by the anaesthetist. They will review your medical history and information from the preclerking clinic and investigations. They will also want to know details of any previous anaesthetics you have had. The anaesthetist may examine you and will want to look in your mouth.
- You will also meet the surgical team who will be looking after you. If you have not already signed your consent form, you will be asked to do so.
- Before you go for your operation, you will be asked to change into a gown.

During the procedure (operation/treatment) itself

- Before your operation you will be taken to the operating theatre and the anaesthetist will insert a plastic tube (drip) in your hand or arm through which you will be given an injection which will make you sleepy.
- During the operation the anaesthetist will stay with you at all times and you are closely monitored. Monitoring machines will measure your heart rate, blood pressure and oxygen levels within your blood.
- While you are asleep a fine tube will be passed through your nose into your stomach to drain the air off the stomach; this will be removed at the end of the procedure.
- We perform this type of surgery using a keyhole (laparoscopic) approach. This allows us to use long thin instruments and cameras to work inside your abdomen, using small incisions rather than through a traditional large incision.
- There is always a small chance (5%) that a larger incision will be made on the abdomen. This is done if the operation is unable to be completed using the key hole technique or if there is a complication such as bleeding that cannot be controlled using a key hole technique.
- This approach means that you experience much less pain after the operation and thus, able to recover more quickly.
- When the special keyhole (laparoscopic) instruments have been inserted the liver is lifted out of the way with a special instrument allowing us to identify the lower oesophagus and stomach, where we will do the actual operation. This area is freed up preserving the nerves that lie around this area that control your intestine. The upper part of the stomach (fundus) is then freed from its attachments. This involves dividing some small blood vessels that run between the fundus and the spleen.
- Once the fundus of the stomach and the oesophagus are completely mobile the stomach is manipulated around the back of the oesophagus and stitched over the front of the oesophagus and back to the stomach (this is called a fundoplication). If you have had a hiatus hernia the diaphragm through which the hernia was extending will also be repaired using some stitches.
- The incisions will be closed with dissolving sutures and injected with local anaesthetic so that you are comfortable when you wake up.
- Your wounds will be closed with waterproof dressings, which means that you can shower. We ask you to remove the dressings yourself at home five days after the operation.

Who will perform my procedure?

- Your operation will be performed by a consultant surgeon or by a senior surgeon in training under the direct supervision of the consultant surgeon.

After the procedure

- You will wake up in the recovery room after your operation. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.
- After the operation, you will have a small, plastic tube in one of the veins of their arm. This will be attached to a bag of fluid (called a drip), which provides your body with fluid until you are well enough to eat and drink by yourself.
- While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to a ward.
- It is very important that you are not sick and you will be given a number of anti-sickness medications while you are asleep.
- If, after the operation you feel at all sick, you must immediately inform the nurses looking after you.
 - After your operation, on the day of your operation, you will be allowed to drink water and then progress onto other fluids during the day as you feel able and are not feeling sick.
 - You will be monitored carefully and given regular painkillers and anti-sickness medications to prevent sickness occurring.
 - The day after your operation, you will be seen by the surgical team and provided you are well you will be allowed to start eating soups and simple soft food.
 - We advise you during this period to avoid liquids that are either particularly hot or cold, but generally take tepid fluids. We would also caution against taking fizzy drinks.
 - We would expect you to be discharged home one to two days after your operation.

Serious or frequently occurring risks:

- Keyhole (laparoscopic) surgery for acid reflux disease is a safe procedure. However, there are potential risks involved in any form of surgery and we believe that it is important that you are aware of these.

- **Damage to the spleen.** During the part of the operation discussed earlier, the small blood vessels between the spleen and the upper part of the stomach (fundus) are cut using special instruments that seal the blood vessels before they are divided. However, sometimes damage to the spleen can occur. Frequently this can be controlled simply using the keyhole method, however, if the spleen were to sustain more severe injury this may require conversion to an open cut operation with the potential of removal of the spleen.
- **Damage to the oesophagus.** When the oesophagus is being freed up inside your abdomen there is a risk that it can be damaged. If this is seen at the time of the operation it can be repaired simply and the operation will be completed using the keyhole method, or it may mean you need to stay in hospital for a slightly longer period of time to ensure that it heals up well.
- **Severe swallowing difficulty.** While we expect you to notice things go down more slowly after your operation, a few patients experience severe problems with swallowing in the first few days after their operation. If this occurs, it may be necessary to perform a second keyhole operation to loosen or remove some of the stitches we have put in.
- **Wound infection.** These are rare with keyhole surgery and if they do occur can be treated simply with antibiotics.
- **Damage to other organs inside your abdomen.** This is a rare complication of keyhole surgery but it has been recognised that during the insertion of instruments into the abdominal cavity damage can occur to any other intra-abdominal organs, including the intestine, liver and blood vessels. If this were to occur then it is likely that the approach to the operation would have to be changed from a keyhole approach to an open approach.
- **Chest infection.** Because you are relatively comfortable and able to easily mobilise after the operation, chest infections are rare. If a chest infection did occur it could be treated with antibiotics.
- **Deep vein thrombosis (DVT) and pulmonary embolus** - All surgery carries varying degrees of risks of thrombosis (clots) in the deep veins of your leg. In the worst case a clot in the leg can break off and travel to the lung (pulmonary embolism). This can significantly impair your breathing. To prevent these problems around the time of your operation and following your operation we give you some special injections to 'thin' the blood. We also ask you to wear compression stockings on your legs before and after surgery and also use a special device to massage the calves during the surgery. Moving about as much as you can, including pumping your calf muscles in bed or sitting out of bed as soon as possible reduce the risk of these complications.
- **Conversion to an open operation.** We always warn people who are undergoing a keyhole procedure that there is a small risk that if the operation is technically not possible to complete through a keyhole technique we will make an open cut. If this is necessary, it will result in a larger scar and more post-operative discomfort and, inevitably, a longer stay in hospital.

- **Scarring** – Any surgical procedure that involves making a skin incision carries a risk of scar formation. A scar is the body's way of healing and sealing the cut. It is highly variable between different people. All surgical incisions are closed with the utmost care, usually involving several layers of sutures. The sutures are almost always dissolvable and do not have to be removed. The larger an incision the more prominent it will be. Despite our best intentions, there is no guarantee that any incision (even those only 1-2 cm in length) will not cause a scar that is somewhat unsightly or prominent. Scars are usually most prominent in the first few months following surgery, however, tend to fade in colour and become less noticeable after a year or so.
- **Requirement for re-operation** – It is unlikely (5%), although possible, that some time after the operation you may need a further procedure related to the fundoplication. This is because it possible for things to move slightly inside or for sutures to give way. If this is the case this may need to be corrected with another operation to revise the fundoplication. In very rare cases coughing, heaving or vomiting in the first few days after the operation can cause things to move or a suture to give way. This then may require another operation to correct things.
- **Other complications** – We have tried to describe the most common and serious complications that may occur following this surgery. It is not possible to detail every possible complication that may occur following any operation. If another complication that you have not been warned about occurs, we will treat it as required and inform you as best we can at the time. If there is anything that is unclear or risks that you are particularly concerned about, please ask.
- **Following discharge** – You will be given a copy of your discharge summary. If you experience any concerns requiring urgent medical advice please contact:

Nurse Specialist (Monday – Friday 09:00-17:00) on 01223 596383 or through switchboard 01223 245151 and ask for pager 154-348

Or

Ward D7 (Evenings/Weekends) on 01223 217303

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on; whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and soreness, confusion or memory loss.

- Uncommon side effects and complications (1 in 1000 people)
Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.

After the procedure

- The operation aims to increase the pressure of the valve mechanism at the lower end of your oesophagus
- You will, therefore, notice that in the first few weeks after your operation it is more difficult to swallow food than it was before your operation. This is entirely normal and advice is given later on in this information sheet as to the type of food you should be eating during this period.
- You need to be very careful about eating foods of a coarser texture, such as bread or red meat. If these are eaten too quickly or too large a mouthful is swallowed they may become stuck in the lower end of the oesophagus.
- Because the valve has been tightened it is difficult for patients to belch and this can lead to painful trapped wind. In a similar manner, it is also difficult for patients to be sick. All these symptoms do improve with time, but it is important that you avoid precipitating these symptoms as much as possible in the early post-operative period.
- Approximately 50% of the patients who have this operation notice that they pass more wind through their bottom after the operation. Simple medications that absorb gas can be obtained over the counter at a chemist.

Eating and drinking

- We advise you to eat food that is soft, sloppy and easy to swallow. This means avoiding foods that contain large pieces (for example, bread or red meat).
- Always take your time eating and chew your food very well.
- If you are having difficulties swallowing initially, we advise you to only take foods of a consistency that are able to be sucked up a straw. After about two weeks you should be able to increase this to sloppy foods such as mashed or vitamised foods for another two weeks.
- Foods like soups, pasta, mashed vegetables and mince are suitable.
- You should avoid fizzy or gassy drinks that might make you feel bloated. This is because you are generally less able to belch or burp due to the surgery.

When you can resume normal activities including work

- After your operation we would expect you to make a quick recovery from your surgery. You are able to resume normal activities as you feel comfortable. In general, you can resume driving a week or so after your operation. We would advise against extreme physical activity (weight lifting or heavy lifting), for about a month after the operation so that all the swelling and post-operative effects have settled down.

Follow up

- You will be seen in the surgical clinic six weeks after your operation to assess your progress. During the first six weeks after your operation we would expect you to experience some difficulty with your swallowing and will advise you regarding the diet you should stick to. In general, you should avoid eating chunky food (for example, pieces of meat) and dry foods (for example, bread) for the first six weeks after your operation.
- We believe that it is important that we monitor the effects of your operation over a long period of time to ensure that the good results of the surgery are maintained. We will see you in outpatients in early post-operative period but after this will continue to follow-up with a telephone questionnaire. The details of this will be discussed with you while you are in hospital.

Information and support

- You might be given some additional patient information before or after the procedure, for example: leaflets that explain what to do after the procedure and what problems to look out for. If you have any questions or anxieties, please feel free to ask a member of staff including your surgeon or one of the senior trainees.

Mr Richard Hardwick	Consultant Upper GI Surgeon	Tel: 01223 217421
Mr Peter Safranek	Consultant Upper GI Surgeon	Tel: 01223 217421
Mr Chris Collins	Consultant Upper GI Surgeon	Tel: 01223 358024



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

Help with this leaflet:



If you would like this information in another language, large print or audio format, please ask the department to contact Patient Information: 01223 216032 or

patient.information@addenbrookes.nhs.uk



Document history

Authors	Cambridge Upper Gastro-intestinal Unit
Department	Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ www.cuh.org.uk
Contact number	01223 245151
Publish/Review date	April 2011/April 2014
File name	Lap_nissen_fundoplication.doc
Version number/Ref	4/CF147

Consent form 1

Patient agreement to investigation or treatment

For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)

Special requirements
 (For example, other language/other communication method)

Name of proposed procedure or course of treatment

Laparoscopic Nissen fundoplication

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefits of the procedure
 To prevent acid reflux.....
 - Any serious or frequently occurring risks from the procedures including those specific to the patient
 Damage to the spleen, oesophagus and other organs in the abdomen; Severe swallowing difficulty; Wound infection; Chest infection; DVT; Conversion to open operation.....
 - Any extra procedures that might become necessary during the procedure
- Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following information leaflet has been provided: Laparoscopic Nissen Fundoplication for Gastro-oesophageal reflux; Version/Date/Ref: 4/April 2011/CF147

This procedure will involve:

- General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature:Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature..... Date:

Name (PRINT):

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will (eg Jehovah's Witness form)

Copy accepted by patient: yes / no (please circle)

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.** Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. Yes No

- I agree** that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research. If you wish** to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.
- I agree** to the use of photography for the purpose of diagnosis and treatment.
- I agree** to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature: Date:

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: Date:

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature Date:

Name (PRINT): Job Title:

