

Surgery for Gastro-Oesophageal Reflux

- Fundoplication
- Magnetic Sphincter Augmentation

Introduction

The aim of this booklet is to explain what options are available for the treatment of gastro-oesophageal reflux with surgery. This includes what these operations involve; what to expect before and after surgery, and to answer some common questions. If after reading this you have any concerns or worries then please do not hesitate to contact your Specialist Consultant to clarify these before agreeing to undergo treatment.

Should you proceed with surgery, we would normally expect you to make a rapid recovery after your operation. However, it is important that you know about minor problems which are common after this operation, and also about more serious problems which can just occasionally occur. The sections of this booklet headed **“What problems can occur after the operation?”** and **“What are the specific risks of this operation?”** describe these, and we would particularly ask you to read them. The headings from this section will also be included in the consent form you will be asked to sign before your operation.

What is reflux disease?

Gastro-Oesophageal reflux disease (GORD, GERD) or simply, reflux is a common condition, where excessive amounts of fluid from the stomach come up into the oesophagus. This can cause troublesome symptoms and damage to the lining of the oesophagus.

The oesophagus (gullet) is a long, thin muscular tube that connects the back of the mouth to the stomach, travelling all the way from the neck, through the chest to get into the abdomen where it joins to the stomach. The function of the oesophagus is important in allowing us to swallow, drink and eat properly. It also acts as a vent to the stomach, allowing passage of gas (burping and belching) which are normal physiological functions, and occasionally vomiting to relieve to stomach of problematic contents, usually due to a gastro-intestinal illness.

There is a valve mechanism at the lower part of the oesophagus, where it joins to the stomach. The valve is made up of a combination of a circular muscles (sphincter) and a sling of fibres (crura) from the diaphragm, the muscle which separates the chest from the abdomen.

The valve is normally closed, but opens briefly to allow swallowed items to enter the stomach and keep them there for further digestion. It opens briefly to allow the stomach to vent, which for the functions of burping, belching and vomiting.

A small amount of fluid from the stomach enters the oesophagus during valve opening, and this is known as *physiological reflux* which is normal. However, if the valve-mechanism is weakened, then this can become abnormal and is known as *pathological reflux*.

What are the problems of abnormal reflux?

The lining of the oesophagus is sensitive, and not as resistant to damage as is that of the stomach. Reflux fluid from the stomach is a combination of digested material mixed with secretions including acid, bile and enzymes, which can be very corrosive to the oesophagus.

When reflux is excessive, symptoms which include heartburn, regurgitation of fluid (volume reflux) chest and upper abdominal pain, difficulty in swallowing can occur. In some cases, where this condition is severe other problems as the reflux travels further up the oesophagus towards the back of the mouth and throat may happen, including coughing, choking, sore throat, hoarse voice, fluid in the mouth and tooth decay. Some existing medical conditions such as asthma can be made worse by reflux.

Severe symptoms of reflux can have a very detrimental impact on individual's quality of life and well-being, particularly when this occurs at night, disturbing sleep and consequently affecting their normal day-time activities such as work and social life.

Reflux can cause damage to the lining of the oesophagus with inflammation (oesophagitis) and if this is not treated properly it can lead over years to scarring and the function of the oesophagus resulting in difficulty in swallowing (dysphagia).

Sometimes the cells in the lining of the oesophagus change and begin to look more like stomach cells. This is a condition known as Barrett's metaplasia. Once this has happened, the lining needs to be surveyed and regular intervals as there is a risk that these cells can later become cancerous.

Why does excessive reflux happen?

The valve-mechanism between the junction of the oesophagus and stomach, comprising of the sphincter and sling can become weakened. This means that the junction opens more easily, and can even be open all the time. As

a consequence, much more fluid than normal escapes from the stomach back up into the oesophagus. The oesophagus does try to push some of this fluid back into the stomach with its natural contractions (peristalsis), but this is not usually enough when the valve is defective, and eventually the oesophagus can become weaker due to reflux damage.

Either or both the sphincter and sling parts of the valve can be weak. When the sling becomes loose, some to the stomach can start to move up into the chest, alongside the oesophagus. This condition is known as a hiatus hernia (para-oesophageal hernia), and depending on the amount of stomach moving into the chest can make existing reflux symptoms worse or develop new ones.

How can reflux be treated?

Simple measures (conservative management) changing diet and lifestyle can be very helpful. Losing excess weight, changing meal times, avoiding certain foods and raising the head of the bed can certainly improve symptoms. For patients with mild symptoms, and particularly in those whom the amount of excess reflux is small, this is a very good first option. We can refer you on to our Specialist Dietician Service to help you.

Medication therapy is very commonly used to control reflux symptoms. The most commonly prescribed class of drugs are the proton-pump inhibitors (PPI's) including omeprazole, lansoprazole and rabeprazole. These drugs block the production of stomach acid production, so when reflux occurs, the fluid has less acid in it, which helps with many of the symptoms, particularly the heartburn and chest pain. It does not however improve the weakened valve-mechanism, and so some of the symptoms, particularly those relating to volume reflux, and damage to the lining of the oesophagus can still occur.

Drug therapy is successful in many patients with reflux symptoms, but needs to be continually prescribed and taken. Consequently, individuals can end up being dependent on drug-treatment for many years, and with time, the doses required to keep the symptoms under

control inevitably needs to be increased (dose escalation), and other drugs such as acid-neutralisers such as gaviscon, as well as another class of anti-secretory drugs, the H2-antagonists, may additionally have to be regularly taken. As a result, patient can end up taking many tablets a day (poly-pharmacy), but with less and less benefit.

Side-effects can occur with all of these medications and not everybody is able to tolerate taking them regularly or forever. Concern has been raised about the long-term use of medication to control reflux, particularly with the PPI's which are very commonly and widely prescribed. Whilst the evidence for an association between these drugs and the reported issues are weak, and these are regarded as very safe, it is worth considering and discussing with regards to the overall management of your condition. Sometimes, certain drugs are withdrawn from circulation by the manufacturers due to concern about adverse events, which may then also limit drug treatment options available.

Surgery for reflux (**anti-reflux surgery**) is focussed on improving the valve-mechanism by strengthening the sphincter and repairing the sling. The aim is to eliminate or significantly reduce reflux-related symptoms, stop or substantially reduce the need for drug therapy, and by physically preventing excessive reflux from occurring, limit further damage to the lining of the oesophagus.

The two options available for anti-reflux surgery are **fundoplication** and **magnetic sphincter augmentation**. In most cases these operations are performed by keyhole techniques through the abdomen and so are referred to as laparoscopic.

Endoscopic therapies, which involves improving the valve mechanism via an endoscope in a variety of ways are currently in development but remain unproven in their long-term efficacy. They cannot repair a hiatus hernia. These options are not currently available in Exeter, but you may wish to discuss these with your Reflux Specialist as an alternative to the above options.

Am I suitable for anti-reflux surgery?

You will need assessment by a Specialist Consultant in Reflux Surgery. This may be after referral from your GP or another specialist. The Specialist Consultant will evaluate your symptoms and then arrange for investigations which may include an endoscopy with biopsies, oesophageal physiology studies and barium studies of the oesophagus and stomach. Other investigations may also be necessary to assess for other conditions which may cause similar symptoms.

If it can be confirmed that a significant proportion of your symptoms are coming from reflux, and that improving the valve-mechanism may be beneficial, then you may be offered surgery as an alternative to the other options mentioned above.

What anti-reflux surgery operations are available?

Your reflux specialist surgeon will review your results and assess your suitability for surgery. The two options are fundoplication or magnetic sphincter augmentation. You may be suitable for either operation, in which case the benefits and risks of each procedure will be discussed and then you can decide which is best for you. If your Specialist thinks that one operation would be significantly better than the other, then they may recommend that option. Ultimately the choice is yours and you can decide whether to proceed with surgery or consider other alternatives including conservative and medical management.

■ Fundoplication

Fundoplication is where the upper part of the stomach (fundus) is used to wrap around your lower oesophagus to reconstruct the valve mechanism. This would aim to prevent reflux, whilst opening in response to contractions in the oesophagus after swallowing.

The wrap can go all the way around the oesophagus (total) or part way round (partial). Which option might be better for you, can be discussed with your specialist, but there is little proven difference between the two options.

The total wrap was considered to be more durable and effective and abolishing reflux, but is associated with greater side-effects than the partial wrap. More recent evidence suggests that the levels of durability and reflux control with the partial wrap are similar that of the total, along with fewer side effects and better functionality.

We usually keep you in overnight after surgery and perform a check X-ray swallow test to confirm the operation has been successful and then make sure you can swallow and have no reflux before discharging you.

You will then need to be on a modified diet for approximately six weeks after surgery after which you can return to a more normal diet. An information leaflet is available. You can stop your reflux medication immediately or in a staged manner as per your preference.

Some individuals can have side effects after the operation including difficulty or pain after swallowing, bloating and flatulence. Usually these settle down after a few months, but very rarely further intervention may be necessary. Some people find they are unable to belch, burp or vomit effectively after the operation.

■ **Magnetic Sphincter Augmentation (MSA, LINX procedure)**

Another option is magnetic sphincter augmentation. In this operation a small necklace of magnetic beads, sized to diameter of your oesophagus is implanted around its lower end at the junction with the stomach. The magnetic sphincter augmentation device consists of a ring of titanium beads, each with a magnetic core. This augments rather than reconstructs the valve mechanism and therefore is a less extensive procedure than fundoplication. The magnetic attraction of the beads provides a sustained force to keep the valve closed and prevent reflux. The device keeps the oesophagus closed, preventing reflux, but again opens in response to peristalsis, as well as to pass gas, enabling people to belch, burp and vomit more easily if necessary.

Most people are discharged home on the same day and a normal diet is encouraged, chewing your food well and drinking plenty of fluids with it, as well as taking soft snacks between meals for the first few weeks. This allows the capsule

which naturally forms around the device to be soft and flexible. Similar side effects can occur to a fundoplication, but these are reported to be much less severe or long lasting.

■ **For both procedures**

Any hiatus hernia found present is repaired using stitches to tighten the sling after the stomach is brought into the abdomen. If you have functional, motility, hypersensitivity or irritable bowel symptoms they may become worse after surgery. You may also develop these symptoms in the future with or without surgery. After full recovery, we would recommend a balanced diet and active lifestyle, aiming to keep your weight in a healthy range. This may prevent the development of further gastro-intestinal and general health problems.

What are the differences (and similarities) between fundoplication and magnetic sphincter augmentation?

- The traditional and standard accepted operation for reflux disease is fundoplication and uses the body's own tissues. It has been offered since the 1950's and became a laparoscopic operation from the 1990's. Magnetic sphincter augmentation is an alternative approach, using an implanted device. The procedure has been practiced for well over a decade now with growing World-Wide experience and good long-term results. Exeter offered MSA since 2012. The latest evidence is currently under review by NICE and updated recommendations for practice are anticipated to be released soon
- Both procedures are performed by keyhole (laparoscopic) surgery
- **Fundoplication** requires reconstruction of the upper gastro-intestinal anatomy so is a bit more complex. It is not reversible.
- **MSA** augments the existing structures but uses a mechanical manufactured surgically implanted device, which can be removed with further surgery if necessary. There is some restriction on the use of magnetic resonance

imaging (MRI) after MSA, but the device is resistant to magnetic fields of up to 1.5 Tesla, which means most investigations can still be done. If you have any doubts about this then you should discuss this with your Specialist Consultant before surgery. MSA is not suitable for you if you have a metal allergy. There should not be a problem with scanners at airport security devices, but you will be provided with an implant card stating you have had this procedure and relevant contact numbers.

- Fundoplication patients usually stay in overnight and have a check X-ray on the following day. MSA patients are usually allowed to go home on the same day
- Following **fundoplication** you are recommended to be on a soft diet for at least six weeks. With **MSA** you are encouraged to start a near-normal diet straight away

How are the operations carried out?

Both operations are carried out using the same sets of incisions, usually through two of approximately 1cm and three more of less than 0.5cm.

The operation is done under a general anaesthetic.

As with all laparoscopic procedures, the abdomen is inflated with gas to allow a good view, and a telescope and special instruments are used to carry out the procedure.

For a **fundoplication**, the upper stomach (fundus) is mobilised and usually freed from its attachments through blood vessels to the spleen. The oesophagus is also mobilised to make sure at least 3cm or more is within the abdomen. Stitches are placed in the diaphragm sling (crura) to repair any hiatus hernia and help keep the oesophagus in place. A small gap of around 0.5cm is left around the oesophagus so that swallowing function is not affected.

The stomach is then brought around the oesophagus to create a "wrap". This can be 360-degrees (total, full or Nissen), or 270 (partial

or Toupet) or other variations which may be advised to you by your Specialist Consultant. The operation usually takes about 120 – 150 minutes.

For **MSA**, the oesophagus is mobilised to allow at least 3cm to be within the abdomen, but stomach mobilisation is normally not necessary. The diaphragm and hiatus hernia are dealt with in the same way as with fundoplication.

Once mobilised, a sizing device is placed at the junction of the oesophagus and stomach. A LINX implant of the right size is chosen and then placed around the junction. The device is supplied as a chain, and its two ends are locked together using a clasp mechanism to create a ring. If a small hiatus hernia is present this is repaired with stitches. The operation usually takes about 30 – 60 minutes.

What happens before the operation?

A few weeks before your operation you may be called to a Pre-assessment clinic. Here you will see a nurse and sometimes a doctor who will assess your general health and ask you about illnesses, operations and medication you are taking. They will examine you, take some blood tests and may perform an ECG (a tracing of the heart). You will receive a letter telling you the date of your operation and where and what time to arrive. If you are unable to make this date for any reason, please ring the **Upper GI office (01392 406296 / 406297/ 402689)** to inform them and arrange another date. You should remain on your existing medicines (including anti-acid medication). You will also be offered the opportunity to see the Specialist Dietician if you have not already done so to help with advice about your eating after surgery.

What happens on the day of the operation?

On the day of the operation you should report to the ward specified in your letter. Bring an overnight bag if you are expected to stay in and your regular medicines with you. You will normally come into hospital on the morning of the operation. Do not have anything to eat for at

least six hours before coming in. You may drink clear liquids (water, black coffee or tea without milk) until two hours before you come in, but take nothing by mouth after that time.

You will see a nurse, one of the surgical team and the anaesthetist. They will be able to answer any other questions you have at this time and will ask you to sign a consent form if you have not already done so.

What happens after the operation?

Going home

Fundoplication patients are usually kept in overnight so that we can do a check X-ray (contrast swallow) the following morning to make sure the operation is satisfactory. The drainage tube (nasogastric) which is inserted into your stomach via your nose at the time of surgery is then removed and you can start drinking and a soft diet. If you are able to tolerate this and have not problems then you will be allowed to go home.

The **MSA operation** is usually carried out in the morning, and if you are well enough you can leave hospital in the late afternoon or early evening after you have been reviewed and checked that everything is satisfactory. The majority of patients are able to do this. If you are not quite ready, or have difficulties with transport or care at home, you will be able to stay overnight with a view to going home the next morning.

The incisions

The small incisions will be covered by water resistant dressings. Keep them dry (cover in bath or shower) for at least five days, and then simply remove the dressings. All the stitches dissolve and do not need to be removed.

Pain and sickness

You may experience some discomfort from the wounds: also from your abdomen, the back and shoulder tips as a result of the inflation during the operation. All this usually settles down

after 2-3 days. We will give you painkillers to take home: do take these so that you can get active and also rest with comfort. To reduce the risk of nausea and sickness (which might lead to vomiting) we will also give you a few days of anti-sickness tablets which you should take regularly for the first three days at least.

Eating and drinking

After **fundoplication**, you should continue with the soft diet for a further six weeks after your operation. We would also encourage you at all times to chew your food well, take time to eat and drink plenty of fluids. This helps strengthen and improve your oesophageal function. Very dry or hard foods should be avoided.

After **MSA**, try to get back to eating a normal diet as soon as possible including solid foods such as meat and vegetables. It is a good idea to take slightly smaller bites than usual, chew well, and drink plenty of water with your meals which strengthens and improves your oesophageal function. We also recommend taking some small snacks of soft food in between meals for the first six weeks after operation. This keeps the device active, opening and closing, and helps prevent the body forming a tight capsule around it which can sometimes restrict its opening.

Activities

You can return back to all your normal activities as soon as you feel able. Avoid heavy lifting or severe straining for at least six weeks to allow the internal tissues to heal to full strength. Drive when you feel easily able to control the car in an emergency.

Symptoms and medication

We hope that you will be free of symptoms immediately after the operation. You can stop your anti-acid medication straight away, or if you prefer gradually.

Follow-up

You will normally receive a follow up appointment in the outpatient clinic 6-8 weeks after your operation. Please do not hesitate to contact us (**Upper GI office 01392 406296/406297/402689**) if you are having problems before this. You may be contacted by a specialist nurse for more details.

What problems can occur after the operation?

Difficulty in swallowing

Some patients do experience at least some difficulty in swallowing after the both fundoplication and MSA operations. Usually this is already if you have swallowing problems before surgery and maybe because you have a weak or damaged oesophagus due to reflux.

Some people also complain of oesophageal spasm. This is just like a muscle cramp, but it occurs in the oesophagus which has to push against the new barrier. Because this has been weak for a long time before surgery, it sometimes finds this difficult and so spasms can occur. Although the pain can be intense, it usually only lasts a few seconds then disappears completely.

In most cases, these symptoms can get worse for up to about 6-weeks, but then goes away by about three months after the operation. By this time the oesophagus function improves and scarring around the surgery sites becomes softer.

If you experience difficulty in swallowing then we recommend that you take a few sips of water before your first bite of food, and in-between bites if necessary; take smaller bites of food so that they pass down your oesophagus and into your stomach more easily; chew your food well before swallowing; give sometime between swallows, identify any foods that seem to make swallowing more difficult for you, and avoid them.

With time, swallowing improves and spasms disappear. Rarely, if these fail to get better, an endoscopy (telescope examination of the oesophagus through the mouth) and stretching of the area of the fundoplication or MSA device

with a balloon (balloon dilatation) may be necessary. A short course of steroids may be prescribed which helps to soften the scar tissue.

Pain

This is described above. Usually pain can be well controlled with painkillers and it subsides after 2-3 days. Occasionally, pain is more severe and more prolonged. Sometimes stronger painkillers are needed and they may need to be taken for longer than 2-3 days. Oesophageal spasm, which can be intense, is usually very short-lived and we do not normally recommend taking any painkillers; it should settle down on its own.

Wound problems

The incisions used are very small, and rarely cause problems. However, there may be some bruising, swelling or inflammation in these areas afterwards. The larger wounds are sealed with a deep stitch but occasionally the deep layers of the wound can separate producing a weak area with a bulge (port-site hernia). If this happens an operation may be needed to repair the tissues and get rid of the hernia.

Burping, belching, vomiting, bloating and flatulence

Venting gas through burping and belching, and expelling stomach contents through vomiting are normal physiological functions. After anti-reflux surgery, some patients can report difficulty in these abilities and in some this may not be possible at all.

Bloating (swelling with discomfort of the abdomen) and flatulence (passage of rectal gas) may occasionally occur after anti-reflux surgery. This is because the gas that gets trapped in the stomach now passes on down the gut rather than back up through the oesophagus as it used to with reflux.

Functionality appears to be better and troublesome symptoms less problematic with partial fundoplication and MSA as compared to total fundoplication.

Functional and irritable bowel disorders

A proportion of patients with reflux disease also have functional bowel disorders (irritable bowel disease, IBS) as well. These may include bloating, flatulence and diarrhoea. Symptoms of functional bowel disorder will remain after the operation, which will only eliminate the reflux-related symptoms. In some patients, the functional/IBS symptoms become more noticeable because they are free of the more debilitating and serious reflux ones.

What are the serious risks of anti-reflux surgery?

Damage to internal organs and important structures

Any operation carried out by keyhole surgery does have the risk of damaging or injuring important organs or structures within the abdomen and chest. These include the bowel, stomach, oesophagus, liver, spleen, lungs and heart.

Damage to any of these is extremely rare, and it is usually recognised and dealt with at the time of surgery. It may be necessary to abandon a keyhole approach and “convert” to an open operation using a large, single incision to repair organ damage.

The recovery from this kind of surgery will take longer. Sometimes, injury to an organ only becomes apparent a few days after the operation and after going home. If you get any severe symptoms of abdominal pain, high fevers or sickness in the first few days after going home, you should contact the hospital or your GP immediately for advice.

The vagus nerves, which run along the oesophagus can sometimes become damaged or impaired after surgery. This may be more of a problem if this is not the first time you have had an anti-reflux operation. Symptoms after vagal nerve damage can be very variable but may include nausea, bloating and diarrhoea. In the majority of cases this settles down with time.

Hiatal herniation, wrap disruption and device intolerance erosion

In rare cases, the stitches in the diaphragm repairing the hiatus hernia can breakdown causing the hernia to recur or even be worse than the original hernia.

In rare cases, the stitches securing the **fundoplication** may become disrupted causing the fundoplication to breakdown.

In rare situations, some patients are unable to tolerate the **MSA** device. In rare cases, the **MSA** device may erode into the oesophagus (about 1 in 300).

These problems may cause recurrent reflux symptoms or other problems and may require further investigations and possible surgery. They can happen many years after the original operation.

Deep vein thrombosis (DVT)

This is a blood clot (thrombosis) in the leg. DVT is a possible problem after anti-reflux surgery, but is uncommon. You will be given a pair of stockings to wear during the operation to help reduce the risk and if staying overnight, and injection of drug to help abnormal clot prevention.

If you are at particular risk (having had a thrombosis before or if you are taking the contraceptive pill) then you should tell your surgeon about this so that special precautions can be taken to reduce the risk. Moving your legs and feet as soon as possible after the operation, and walking about early, all help to stop thrombosis occurring

The risks of a general anaesthetic

General anaesthetics have some risks, which may be increased if you have other medical conditions, but in general they are as follows:

Common temporary side-effects (risk of 1 in 10 to 1 in 100) include bruising or pain in the area of injections, blurred vision and sickness (these can usually be treated and pass off quickly).

Infrequent complications (risk of 1 in 100 to 1 in 10,000) include temporary breathing difficulties, muscle pains, headaches, damage to teeth, lip or tongue, sore throat and temporary difficulty speaking.

Extremely rare and serious complications (risk of less than 1 in 10,000). These include severe allergic reactions and death, brain damage, kidney and liver failure, lung damage, permanent nerve or blood vessel damage, eye injury and damage to the voice-box. These are very rare and may depend on whether you have other serious medical conditions.

What should I do if there is a problem?

If you have an acute problem such as severe and persisting abdominal pain, sickness and vomiting, fevers or an inflamed or discharging wound, then you should contact your family doctor first.

Your doctor may suggest that you see the surgeons at the hospital, and if this is necessary, he/she will make the arrangements. Should you be unable to get urgent medical attention from a General Practitioner, come to the Emergency Department of the Royal Devon & Exeter Hospital (Wonford). **RDE switchboard 01392 411611.**

The surgical team who did your operation will always be prepared to see you at the request of your own doctor, or the doctors who see you urgently in the hospital. If you attend the hospital urgently, you may be looked after by a different surgical team initially.

If you have had **MSA**, you will be provided with an implant card which will give anyone it might concern details of the operation you have had. Contact numbers and an address will be provided so that you or they can get in touch for advice easily.

Long-term results

Evidence from published studies and series of both fundoplication and MSA are equally successful at eliminating reflux-related symptoms and drug dependency for many years after surgery, resulting in significantly improved quality of life and well-being. The vast majority of patients are very satisfied after having undergone anti-reflux surgery. Damage to the oesophagus lining is reduced, but some of the changes that might have already occurred may not be reversible.

In Exeter we have a long-established Specialist Reflux Service. This incorporates Consultant Reflux Surgeons supported by our Regional Oesophageal Physiology, access to advanced endoscopy, specialist radiology, multi-disciplinary meetings and a dedicated dietician service and clinical nurse specialists. We carry out a high volume of anti-reflux and oesophageal functional operations each year and were the first Unit in the UK to offer MSA on the NHS in 2012.

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