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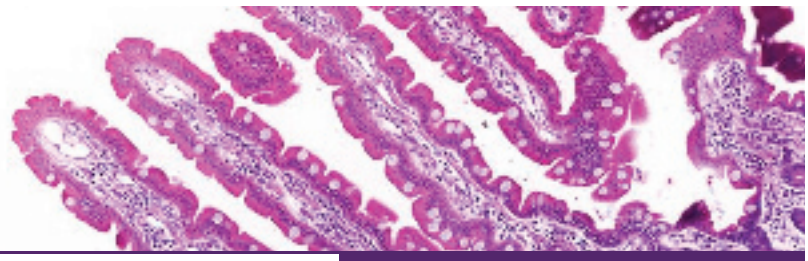


PATIENT INFORMATION

Fundoplication - Informed Consent

Informed Consent of Fundoplication surgery for gastroesophageal reflux disease (GERD)

1. What is a fundoplication surgery?

During fundoplication surgery, the upper curve of the stomach (the fundus) is wrapped around the esophagus and sewn into place so that the lower portion of the esophagus passes through a small tunnel of stomach muscle. This surgery strengthens the valve between the esophagus and stomach (lower esophageal sphincter), which stops acid from backing up into the esophagus as easily. This allows the esophagus to heal. This procedure can be done through the abdomen or the chest. The chest approach is often used if a person is overweight or has a short esophagus.

This procedure is often done using a laparoscopic surgical technique. Outcomes of the laparoscopic technique are best when the surgery is done by a surgeon with experience using this procedure.

If a person has a hiatal hernia, which can cause gastroesophageal reflux disease (GERD) symptoms, it will also be repaired during this surgery.

2. What to expect after surgery?

If ***open surgery*** (which requires a large incision) is done, you will most likely spend several days in the hospital. A general anesthetic is used, which means you sleep through the operation. After open surgery, you may need 4 to 6 weeks to get back to work or your normal routine.

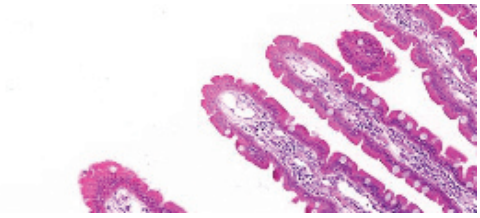
If the ***laparoscopic*** method is used, you will most likely be in the hospital for only 1 or 2 days. A general anesthetic is used. You will have less pain after surgery because there is no large incision to heal. After laparoscopic surgery, most people can go back to work or their normal routine in about 2 to 3 weeks, depending on their work.

After either surgery, you may need to change the way you eat. You may need to eat only soft foods until the surgery heals, and you should chew food thoroughly and eat more slowly to give the food time to go down the esophagus.

3. Why is it done?

Fundoplication surgery is most often used to treat GERD symptoms that are likely to be caused in part by a hiatal hernia and that have not been well controlled by medicines. The surgery may also be used for some people who do not have a hiatal hernia. Surgery also may be an option when:

- Treatment with medicines does not completely relieve your symptoms, and the remaining symptoms are proved to be caused by reflux of stomach juices.
- You do not want or, because of side effects, you are unable to take medicines over an extended period of time to control your GERD symptoms, and you are willing to accept the risks of surgery.



You have symptoms that do not adequately improve when treated with medicines. Examples of these symptoms are asthma, hoarseness, or cough along with reflux.

4. How well it works

Studies show that laparoscopic fundoplication improves GERD symptoms in about 6 to 9 out of 10 people who have the surgery (depending on how experienced the surgeon is). But no studies have proven that laparoscopic fundoplication surgery is effective in maintaining healing of the esophagus over the long term. [1] A successful surgery does not guarantee that you will never have symptoms again. Some studies show that only about 1 out of 10 people who have fundoplication surgery done by an experienced surgeon have symptoms come back in the 2 years after surgery. [2] But there isn't much research on how many people have symptoms come back after more than 2 years.

But compared to people who do not have surgery, people who do have surgery are less likely to need medicine every day and have less severe symptoms when they stop taking medicine. Also, people who have surgery for GERD seem to be happy with the results, even if their symptoms do come back and they have to take medicine again. [3]

About 2 or 3 out of 10 people who have surgery to relieve GERD symptoms have new problems (such as difficulty swallowing, intestinal gas, or bloating) after the surgery. [2] These new symptoms may or may not respond to treatment with medicines.

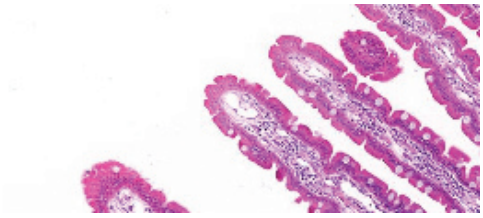
5. Risks

Risks or complications following fundoplication surgery include:

- Difficulty swallowing because the stomach is wrapped too high on the esophagus or is wrapped too tightly. This complication may be more likely to occur in people who receive fundoplication surgery using a laparoscopic surgical technique. [4]
- The esophagus sliding out of the wrapped portion of the stomach so that the valve (lower esophageal sphincter) is no longer supported.
- Heartburn that comes back.
- Bloating and discomfort from gas buildup because the person is not able to burp.
- Excess gas.
- Risks of anesthesia.
- Risks of major surgery (infection or bleeding).
- Damage to the vagus nerve which leads to dumping syndrome which is characterized by early stomach emptying with nausea, sweating, diarrhoea and weight loss after meals.

For some people, the side effects of surgery-bloating caused by gas buildup, swallowing problems, pain at the surgical site and dumping syndrome are as bothersome as GERD symptoms. The fundoplication procedure cannot be reversed, and in some cases it may not be possible to relieve the symptoms of these complications, even with a second surgery.

Patients must consider these potential side effects and complications prior to deciding on surgery.



What to think about

When fundoplication surgery is successful, it may eliminate the need for long-term treatment with medicine. When trying to decide between surgery and treatment with medicine, weigh the cost, risks, and potential complications of the surgery and the possible risk of complications against the cost and inconvenience of long-term, often lifetime, medication therapy.

Before surgery, additional tests will usually be done to be certain surgery is likely to help cure GERD symptoms and to diagnose problems that could be made worse by surgery.

Second surgeries are more difficult to do, are less successful, and are more risky. So, it is extremely important that the first procedure be considered carefully and be done by an experienced surgeon who is more likely to be successful the first time.

Surgery to treat GERD is rarely done on people who:

- Are older adults, especially if they have other health problems in addition to GERD.
- Have weak squeezing motions (peristalsis) in the esophagus. These motions are important to move food down the esophagus to the stomach. Surgery may make this problem worse, causing food to get stuck in the esophagus.
- Have unusual symptoms that might be made worse by surgery.
- In special cases, other surgeries such as partial fundoplication or gastropexy may be done instead of fundoplication surgery.

Complete the surgery information form to help you prepare for this surgery

Signed ----------

Date ----------

Witnessed ----------

Date ----------

Citations

1. Kahrilas PJ (2001). Management of GERD: Medical versus surgical. Seminars in Gastrointestinal Disease, 12(1): 3–15
2. Richter JE (2006). Gastroesophageal reflux disease and its complications. In M Feldman et al., eds., Sleisenger and Fordtran's Gastrointestinal and Liver Disease, 8th ed., vol. 1, pp. 905–936. Philadelphia: Saunders Elsevier.
3. Spechler SJ (2003). Gastroesophageal reflux disease and its complications. In SL Friedman et al., eds., Current Diagnosis and Treatment in Gastroenterology, 2nd ed., pp. 266–282. New York: McGraw-Hill.
4. Bais JE, et al. (2000). Laparoscopic or conventional Nissen fundoplication for gastroesophageal reflux disease: Randomised clinical trial. Lancet, 355(9199): 170–174.