Treatment Options for an Inguinal Hernia

INSIGHTRA® MEDICAL

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If you have received the diagnosis of an inguinal hernia, it is important to know your options. The good news is that there are a variety of treatment alternatives, including non-surgical. Determining the best course will depend on your health and the clinical conditions of your hernia, your physician's recommendations, as well as your own needs and wishes. On rare occasions an inguinal hernia can lead to a life-threatening situation. Contact your surgeon or seek emergency treatment if your hernia becomes painful.

Inguinal hernia operations generally fall into two categories: open surgery and laparoscopic surgery. Each method offers different benefits and risks.

1. Open Surgery

Open surgery is still the most common approach for inguinal hernia repair. It requires only one small incision above the hernia so the surgeon can repair the defect from the outside. It takes about 30 minutes under local or regional anesthesia.

2. Laparoscopic Surgery

Instead of an incision above the hernia, small incisions for trocars (ports used to access the abdominal cavity) are made in your abdomen, usually three. Using a video camera and surgical instruments, the hernia is repaired from the inside of the groin, usually in about one hour. This method is considered more technically challenging, and carries certain inherent risks.

Laparoscopic procedures are nearly always carried out under general anesthesia in a laparoscopic center. It is considered an excellent option for patients with groin hernia defects on both sides (bilateral) or for patients undergoing a revision surgery for a groin hernia that has come back.

Consult with your doctor about all the available options, and which is more suited to your clinical condition and personal needs.

The Freedom ProFlor™ Inguinal Hernia Repair System

One of the newer options for open inguinal hernia repair, this procedure consists of the Freedom ProFlor™ synthetic implant (made from polypropylene), which fills the hernia space, and a unique surgical delivery device that assists with placement during open inguinal hernia surgery.

The device is used to perform a "tension-free" repair of certain types of inguinal hernia. The synthetic implant is permanent, so choose carefully after consulting with your doctor. There are alternatives to Freedom ProFlor, and your physician will help choose the right procedure based upon your needs.

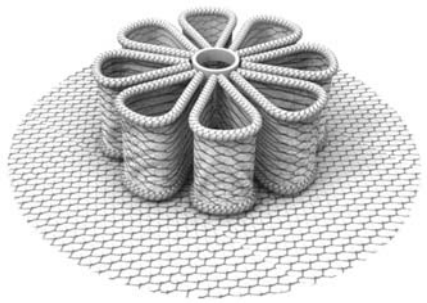
What's Different About the Freedom ProFlor?

Freedom ProFlor is built differently, even though it's made from polypropylene, the most common synthetic material used in hernia repair.

Freedom ProFlor has a flat mesh component that covers under the hernia hole plus a flower-shaped core that sits within the hernia hole. The core creates a frame into which tissue will become incorporated.

The key difference is that the Freedom ProFlor implant is built like a "spring" so it can compress and spring back. The surgeon inserts the implant into the hernia hole in a compressed state, then when released, the implant springs open and is wedged within the hernia hole. Because the tissues surrounding the hernia hole compress the flower-shaped core, the surgeon doesn't always need to stitch the implant in place, thereby minimizing a potential source of post-operative pain.

Clinical results with Freedom ProFlor to date have shown very low levels of pain, immediately after surgery and more than one year after the operation. (1)



Freedom ProFlor™

Freedom ProFlor is a 3-D dynamic implant made from lightweight, large porous polypropylene that is fixation-free, does not have an onlay mesh component, and fills the hernia space. A unique delivery device assists the surgeon in placing the device during an open inguinal hernia surgery procedure. (1)

1. Amato G, Agrusa A, Romano G, Cocorullo G, Di Buono G, Mularo S, Gulotta G. Modified fixation free plug technique using a new 3D multilamellar implant for inguinal hernia repair: A retrospective study of a single operator case series. Hernia. 2013 May 8. Epub ahead of print

Surgery

The surgeon makes a two-inch (5cm) incision above the hernia to dissect out the hernia sac. Once free, the hernia sac is returned to the abdomen. The surgeon then prepares the area to insert the mesh device. Once the area is prepared, the Freedom ProFlor device is inserted into the hernia hole. The core springs open and fills the hole. The rear disk is then deployed beneath the defect.

A procedure with Freedom ProFlor can be performed under general, local, or regional anesthesia by a trained doctor in about 30 minutes. Most patients return home a few hours afterwards.

After Surgery

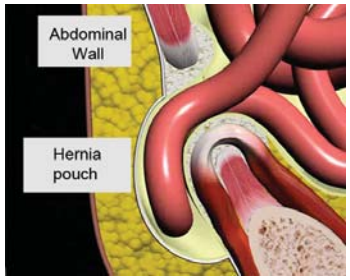
Complications with the Freedom ProFlor Hernia Repair System have been studied and are shown to be very rare. Common problems such as swelling, fluid collection, and bruising are similar to any hernia operation performed in the groin.

Studies also show after-surgery pain to be very low. (Normal pain medications are given for the first week or two.) Follow your physician's recovery recommendations, such as not lifting or straining for the first few days to avoid dislodging the implant or causing pain. Most patients return to normal activity within a few weeks.

See your physician immediately if you have excessive pain, swelling, discomfort or other problems.

Is the Freedom ProFlor Right For You?

No one implant is right for everyone. It depends on your condition, type of inguinal hernia, health status, and needs, as well as whether your clinician is trained with the Freedom ProFlor system.



Side view showing the hernia pouch (or hernia sac)

Side view of the Freedom ProFlor

Top view of the Freedom ProFlor

Ultimately, you're the patient, so you need to be satisfied with the outcome of your surgery. A good consultation with your doctor on all the options available — surgical and non-surgical — will help you to make an informed decision.

Common Surgery Risks

All surgeries carry risks. While hernia surgery is common and generally considered very safe, it also carries risks. These would include, but are not limited to:

1) **Excessive bleeding**
2) **Adverse reaction to medications or anesthesia**
3) **Injury to the intestines**
4) **Infection**
5) **Testicular atrophy**
6) **Sexual dysfunction**
7) **Chronic groin pain**
8) **Recurrence of the hernia**
9) **Problems with your heart, lungs and/or kidneys**
10) **Death**

What is a Hernia Mesh?

The most common option with either laparoscopic or open surgery is to use a "hernia mesh" or "hernia implant".

When herniated tissues are sewn back together, they're not very strong. So surgeons sought to reduce the tension by reinforcing the groin area with a synthetic mesh patch, or hernia mesh.

In a laparoscopic repair the mesh is generally placed below the hernia hole (underlay); in open surgery it is placed above (onlay or Lichtenstein). The mesh can also be formed into a "plug," which can be placed to fill the hernia hole.

Hernia Mesh Benefits and Risks

The benefit of using a hernia mesh is that it reduces tension and reinforces the inguinal wall. Clinical literature indicates the advantages of reducing pain, discomfort, and recurrence in most patients when using a mesh.

Mesh also carries certain risks, including a higher risk of infection, plus the risk of a foreign-body reaction, which can include pain, fever, discomfort, sensation of the foreign body, rejection, and other side effects.

Mesh can have a "shrinkage" reaction where the natural scarring becomes aggressive and causes a contraction of the mesh, producing pain or discomfort or a sensation of feeling the mesh. Should such a problem arise, ask your doctor about removing the mesh.

Mesh may also need to be surgically removed or replaced if the nerves become "entrapped" in it.

Although these problems are rare, be sure to discuss potential risks and benefits fully with your doctor before deciding to go forward with any surgery.

From the FDA

Please read this advice from the FDA and consult fully with your doctor.

Information on Surgical Mesh for Hernia Repairs

The FDA wants to inform you about complications that may occur with the surgical mesh that is sometimes used to repair hernias, and provide questions you may want to ask your surgeon before having this procedure.

Hundreds of thousands of hernia repair operations are performed each year, both with and without surgical mesh, and patients generally recover quickly and do well after surgery.

However, the FDA has received reports of complications associated with mesh, including adverse reactions, adhesions (when loops of the intestines adhere to each other or the mesh), and injuries to nearby organs, nerves or blood vessels. Other hernia repair complications can occur with or without mesh, including infection, chronic pain and hernia recurrence.

Most complications reported so far have been associated with mesh products that have been recalled and are no longer on the market. For more information on recalled products, please visit:
http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm

Talk to Your Doctor

Before having a hernia operation, let the surgeon know if you've had a past reaction to surgical mesh or suture materials, such as polypropylene.

Questions to ask your surgeon:

- What are the pros and cons of using surgical mesh in my particular case?
- Is there patient information on surgical mesh that I can have?
- What's your experience with surgical mesh, and with treating potential complications?
- What can I expect to feel after surgery and for how long?

Reporting Complications to the FDA

Help the FDA learn more about possible problems by reporting any complications that may be associated with surgical mesh. Use postage-paid FDA form 3500, available online at: MedWatch Forms Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD. 20852-9787. Fax: 1-800-FDA-0178