Is it time for surgery?

You've long-lived with the symptoms of chronic GERD. You have either:

- Tried diet and lifestyle changes, without consistent improvement or symptom resolution
- Taken medicines for your GERD symptoms, without adequate relief
- Become frustrated with progressively increasing dosages/costs of these medicines
- Said that you're concerned about adverse long-term effects from taking these medicines and would like to come off them
- "Atypical" symptoms of GERD from regurgitation (e.g. asthma, hoarseness, cough, chest pain, aspiration, etc.) which medicines haven't been very effective in treating
- Certain complications of GERD (e.g. Barrett's esophagus, narrowing of the inside space of the esophagus)
- Considered surgical intervention, but have been concerned about the complication rate, mortality and potential side effects (e.g. gas bloat, difficulty swallowing, inability to burp or vomit) of antireflux surgery

I think it's time we discussed the surgical options for treating your GERD and the TIF Procedure—TIF is an acronym for Transoral Incisionless Fundoplication.

What is the TIF Procedure?

The goal of antireflux surgery is to restore the normal functions of the junction between the esophagus and the stomach by creating a new antireflux valve. This is carried out by wrapping the upper portion of the stomach (the fundus) around the esophagus, either partially or totally. Both the TIF procedure and traditional antireflux surgery have the same goal. Benefits of the TIF procedure include:

- No scars, due to incisionless approach
- Faster recovery, since there is no internal cutting of the natural anatomy
- Fewer adverse events and complications than conventional surgery
- Can be revised if required (doesn't limit any of your future treatment options)

The purpose of the surgery is to:

- Reduce a small hiatal hernia (2cm or smaller if present). If you have a larger hiatal hernia (greater than 2 cm) we can laparoscopically repair the enlarged opening in the diaphragm prior to performing the TIF procedure all in the same anesthesia session.
- Ensure proper positioning of the stomach and esophagus below the diaphragm
- Restore the angle at which the esophagus enters the stomach
- Increase the pressure of the LES (lower esophageal sphincter) to prevent reflux and restore one-way valve operation
**How is the New Valve Created?**
The EsophyX device and an endoscope are introduced together through your mouth (transorally) and advanced into the esophagus. With visualization provided by the endoscope, fasteners will be placed in specific locations to reconstruct and form a new gastroesophageal valve – fixing GERD symptoms at the source of the problem.

**Are fasteners staying permanently in my body? Does this create any short term or long-term risk?**
The fasteners stay permanently in the body, but they are too small to be noticed and do not disrupt any bodily functions. The fasteners are very small and are made of the same material that surgeons have used for decades to sew tissue inside the body. Once in place, the body acclimates to the fasteners and often grows tissue around them.

A simple way to describe how the fasteners are applied is to imagine how a plastic price tag attaches to a piece of clothing. The fasteners are like that, but a much smaller version. The fastener rides along a very small needle that glides through two layers of tissue—stomach and esophagus. The fastener opens forming an “H” shape on either side of the two layers. The center of the “H” holds the tissue together while the body knits the two layers together. The knitting process is known as serosal fusion. The body needs about 6-8 weeks to complete this process. To help the body heal, we instruct you to eat foods with graduating texture from clear liquids, full liquids, soft foods up to normal texture foods.

**How Long Does the Procedure Take?**
The TIF procedure (exclusive of any hiatal hernia repair) is performed under general anesthesia and usually takes less than an hour to perform, but may vary from patient to patient. If a hiatal hernia repair is performed immediately before the TIF procedure, it adds more time; however, you are still under general anesthesia for a relatively short time overall.

**What Should I Expect After the Procedure?**
Please know that long-term side effects with the TIF Procedure are virtually nonexistent. Immediately post procedure, you should expect to experience some discomfort in your stomach, chest, nose and throat for three to seven days after your procedure. Patients will also be given dietary guidelines to help maximize success while tissue heals. You will also be asked to restrict physical activity for the first weeks (e.g. lifting) because your body uses many muscles including those in your abdomen. Walking is fine.

**Why Do I Have to Go on a Special Diet?**
The strength of the new antireflux valve is largely determined by how well it heals; to aid healing patients are asked to be on a short-term liquid diet followed by a mashed and soft food diet as the valve heals.

**How Soon Can I Go Back to Work?**
Assuming your work doesn’t involve physical activity, due to the unique approach of the TIF procedure, you will most likely be able to return to work and normal activities within a few days after your TIF procedure. This lets you get back to your life sooner, free of the distraction and discomfort of GERD.
Is the TIF Procedure Effective / How Long Does the TIF Procedure Last?

Yes! The TIF procedure offers patients who require an anatomical repair an effective treatment option to correct the underlying cause of GERD. In a 2016 U.S. study, 90% of patients experienced elimination of their regurgitation and 88% of patients experienced elimination of their troublesome atypical symptoms. And 71% of patients were able to completely stop taking their PPIs after the procedure. A study in Europe also showed excellent results with durability seen out to 6 years.

Is the TIF Procedure Safe?

The TIF Procedure has an excellent safety profile. To date, the TIF procedure has been performed on more than 20,000 cases worldwide with minimal complications and a serious adverse event rate under 0.5%. Clinical studies demonstrate that properly selected TIF patients rarely experience long-term side effects commonly associated with traditional antireflux surgery, such as chronic trouble swallowing, gas bloat syndrome, and increased flatulence.

Why TIF Procedure and Why Not Nissen / Other Fundoplications? OR I thought I initially was going to get a Nissen – Why Change to this?

Among the treatments available to people with severe GERD-related symptoms, the more advanced options are the TIF procedure and traditional antireflux surgery. Traditional, or conventional, antireflux surgery has been long considered an effective solution for treating GERD. However, the surgery involves several abdominal incisions and typically includes side effects such as difficulty swallowing (26%), bloating (36%), and increased flatulence (65%).

I want to give you the option of the TIF procedure for chronic acid reflux because it features:

No Incisions: Conventional antireflux surgery involves accessing the anatomy via 3-5 abdominal incisions. The TIF procedure does not require any incisions as it is performed through the patient’s mouth. This difference leads to less patient discomfort.

Excellent Safety Profile: To date, more than 20,000 TIF procedures have been performed with far fewer complications than conventional antireflux surgery.

No Dissection: Certain antireflux surgeries require the surgeon to cut around anatomy, which can increase the risk of complications and adhesions and can prolong recovery time. The TIF procedure does not require cutting.

Similar Results: It follows the well-established principles of conventional antireflux surgery, rebuilding the antireflux valve and restoring the body’s natural protection against reflux, and delivers similar results in an innovative way.

All doors remain open: Because GERD is a progressive disease, there’s no permanent cure. The treatments are designed to be as effective as possible for as long as possible. However, if symptoms return because anatomy has deteriorated, and you previously had a TIF procedure, all treatment options are open to you including a repeat TIF procedure if it clinically makes sense.

What are my Options after the TIF Procedure, Should my Symptoms Ever Return?

One of the best things about the TIF procedure is that it doesn’t preclude any future treatment options. Patients may opt to adjunct their TIF Procedure with occasional use of medications frequently at reduced doses, may opt for another TIF Procedure in the future, or for other types of antireflux surgeries.
I DON’T WANT TO BE A “GUINEA PIG” / GET A “NEW” TREATMENT.

Surgeons have performed fundoplication surgery for over 50 years and it has proven successful at managing GERD symptoms. By mechanically reconstructing the antireflux barrier, the technique aims to naturally reduce troublesome reflux by restoring the body’s normal defense.

Rest assured, the TIF Procedure is definitely not a “new” procedure! This is a more advanced, transoral approach to fundoplication that has been out for over 10 years and has been performed over 20,000 times. Over 60 centers have published more than 80 peer-reviewed papers on the well-established TIF procedure.

CAN THE TIF PROCEDURE BE REVERSED (UNDONE)?

There should not be a need to undo the TIF procedure. Most patients experience positive outcomes and can eliminate or reduce their need for therapy. If your symptoms recur, we will work at that time to identify additional treatment options to help manage your GERD.

WHY DO I HAVE TO UNDERGO MORE TESTING – DON’T WE KNOW I ALREADY HAVE REFLUX?

Additional testing is often required by insurance companies to provide objective evidence of GERD to pre-authorize surgery. These tests can help examine the esophagus for erosive esophagitis, pre-cancerous conditions, motility, and to spot any anatomic abnormalities such as a hiatal hernia, blockages, inflammation of the esophagus or stomach and free reflux.

WILL MY INSURANCE COVER THE TIF PROCEDURE?

All Medicare Recipients have the TIF procedure as a covered benefit. However, some private health insurance companies do not initially cover the procedure for their members. In this case, EndoGastric Solutions (the manufacturer of the Esophyx device for the TIF procedure) has partnered with PRIA Healthcare to work directly with you, my office and your insurance company to obtain an approval for the procedure or appeal any service denials until a final decision is determined. The majority of TIF Procedures become covered upon appeal with insurance companies, and I’d like to give PRIA a chance to see if we can get the TIF procedure covered for you before discussing other options.

I HAVE BEEN TOLD THAT I HAVE A HIATAL HERNIA; CAN I STILL UNDERGO A TIF PROCEDURE?

Yes. The Esophyx device used in the TIF procedure is indicated for use on a hiatal hernia under 2cm. The product has FDA clearance allowing patients with hiatal hernias larger than 2cm to have their hiatal hernias repaired surgically to less than 2cm. This is performed in a separate surgery followed immediately by a TIF procedure, all under the same anesthesia session.

WILL THE TIF PROCEDURE ALTER ANY OF MY BODILY FUNCTIONS?

No. Clinical research demonstrates that TIF patients maintain normal functions such as the ability to belch and vomit. The TIF procedure is a partial fundoplication, which more closely mimics the body’s normal anatomy.

In contrast, a traditional fundoplication such as the laparoscopic Nissen procedure creates a full 360-degree wrap around the esophagus that results in a “supra-physiologic” (literally translated: “more than is natural”) antireflux valve. Because the wrap is tighter than in normal anatomy, functions such as normal amounts of reflux, belching, and vomiting may be limited.

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