

## **THE HEARTBURN AND REFLUX STUDY CENTER**

### **The STRETTA Procedure**

#### **Introduction**

The STRETTA procedure is an advanced state-of-the-art endoscopic technique for the correction of all forms of reflux disease including: 1) esophageal reflux, known as Gastro Esophageal Reflux Disease or GERD, and 2) respiratory reflux also known as Laryngopharyngeal Reflux or LPR.

The STRETTA catheter is a specially designed, FDA approved, device with a balloon and four needles. The catheter is connected to a control module, which delivers precisely monitored and controlled amounts of radio-frequency energy to the lower esophageal sphincter muscle or LES. Each needle has its own generator that carefully monitors and controls the energy so that only the correct temperature and energy is transmitted. The energy used is only 5 watts (like an LED light) and is carefully controlled between 65-85 degrees (temperature of a cup of coffee).

It is the LES that is responsible for reflux. Slowly over time this muscle weakens until it can no longer resist the normal pressure generated by the contraction of the stomach. When this happens you have reflux that occurs. The pressure of the LES may be normal or low, but the key is that it is relatively too weak to protect you against reflux of the stomach contents into your esophagus or throat.

The entire procedure consists of two parts. Initially, an upper endoscopy or EGD is performed while the patient is sedated. This allows the physician to take precise measurements of the distance from the mouth to the LES or sphincter muscle between the esophagus and stomach. After measuring the distance, the physician will then insert the STRETTA catheter, through the mouth, to the specifically measured distance. The balloon is then inflated, the needles pushed into the muscle of the sphincter, and radio-frequency energy is transmitted via the needles

#### **The Cause of GERD**

Reflux disease may exist as either a purely esophageal type or GERD, a purely respiratory type known as LPR, or a mixture of the two. The esophageal type of reflux is usually characterized by either burning or pain in the chest and/or upper abdomen and other symptoms such as difficulty swallowing, regurgitation or pressure in the chest. The respiratory type is more known for symptoms that include sore throat, increased mucus production, hoarseness, vocal pain or fatigue, sinus drainage, chronic cough, asthma, bronchitis, ear pain, and even sleep apnea.

The symptoms of all types of reflux have been shown to be caused by too many relaxations of the LES. These relaxations are known as transient lower esophageal relaxations or TLESR's. Normally, these relaxations occur only 2-3 times per hour. In patients with reflux, the transient relaxations may occur dozens of times in an hour, allowing the stomach contents to vent up into the esophagus or throat. The reflux associated with esophageal reflux is mostly a disease of the reflux of liquid acid, bile or digestive enzymes. The respiratory form of reflux is caused principally by aerosolized Pepsin (a digestive enzyme of the stomach) that adheres to the tissues and is reactivated by acid food or beverages in the diet. As such it is more difficult to control because it requires more LES pressure to hold back gas vs. a liquid. In the past it was felt that the abnormal number of TLESR's and therefore reflux, was due to excessive nerve impulses to the LES muscle, causing it to relax too often or lack of adequate contraction of the sphincter muscle. We now know that these increased relaxations are primarily due to weakening of the

LES due to progressive degeneration over time, to the point that LES is too weak to hold back the normal pressure of the stomach contents. This is why medications are largely ineffective and only help to control symptoms while the reflux continues and the LES degeneration continues to worsen over time until even the medications are ineffective.

### **How the STRETTA procedure corrects Reflux**

When the STRETTA procedure is performed, radio-frequency energy is transmitted via the needles in the STRETTA catheter. This creates pinpoint areas of irritation in the sphincter muscle, which in turn stimulates the muscle causing an increase in muscle bundles and muscle fibers in each bundle. The net effect is that the sphincter is remodeled and becomes thicker, stronger and longer (like the muscles of a weight lifter) and therefore relaxes less often. Over the course of 12 months after the procedure, it is expected that the sphincter muscle will roughly double in size. This remodeling of the LES will occur in a very individual manner and depends upon how rapidly each person will respond.

There are two predominant effects, which occur. The first effect is largely temporary and can be thought of as the *barrier effect*. There is an immediate swelling or edema of the tissue, which is followed by the body depositing a substance called collagen into the sphincter muscle. The thickened area helps to immediately reduce the reflux of stomach contents into the esophagus. This effect lasts for a short period of time. The swelling or edema will disappear within the first 2 weeks; however, much later most of the collagen is removed by the body, and some tissue thickening appears to remain. The reabsorption of the collagen usually takes 2-3 weeks.

The second or more permanent effect is known as the *remodeling or muscle hypertrophy effect*. This refers to the actual increase in the size and amount of muscle. Medical research has clearly demonstrated that as the result of the sphincter remodeling, the compliance (ability to stretch) of the muscle decreases and this results in a stiffer stronger sphincter, causing the number of TLESR's to be significantly reduced, and symptoms usually completely disappear.

### **Medical evidence of effectiveness**

In the past 10 years, many studies have been conducted with the STRETTA procedure in human subjects. The data reveals that, following the STRETTA procedure, the LES muscle is regenerated leading to a reduction in TLESR's and the symptoms of all forms of reflux.

The most recent literature has revealed that the STRETTA procedure is particularly effective in both respiratory reflux or LPR and esophageal reflux. It is considered the best method for the treatment of reflux that occurs after reflux surgery like a Nissen fundoplication or obesity surgery such as gastric bypass or gastric sleeve. In addition, it has been found to be effective regardless of the level of obesity or BMI index. Finally, STRETTA has found to be so effective in controlling reflux, that patients with Barrett's esophagus often see spontaneous regression or disappearance of the Barrett's tissue, and may even be protected against the development of cancer of the esophagus.

The procedure is successful in over 90% of patients. Currently, the longest results show that in a majority of patients 10-11 years after STRETTA, there is no significant return of symptoms in 72% of patients, and most patients remain either off of medications or on very reduced doses.

The procedure has also been demonstrated to reverse the problem of bloating and fullness, caused by delayed stomach emptying or abnormal gastric motility, a condition known as gastroparesis, which may be found in up to 45% of patients with GERD.

In patients who have had other anti-reflux procedures such as Nissen fundoplication, Hill procedure, TIF, Linx or Endostim, that have experienced either failure to control or recurrence of reflux or LPR symptoms, STRETTA has been found to be effective and safe in restoring the normal barrier function of the LES and controlling reflux and symptoms in both GERD and LPR.

## What to expect after the STRETTA procedure

Immediately after the procedure, due to the sedation, you may expect to feel very tired for the remainder of the day. Some patients have a sore throat or mild soreness in the chest area. You will be able to eat with some mild dietary restrictions and resume your normal medications immediately after the procedure. When eating you may experience a sensation of the food moving slowly down into your stomach.

You must continue your acid controlling medications, until instructed otherwise, by your physician for at least an additional 4-8 weeks.

Your reflux symptoms are *not* expected to improve immediately. The STRETTA procedure is a long-term correction for reflux, heartburn or LPR. The effects usually develop slowly over time. It is very important that you *do not expect immediate results*. **It may sometimes take as long as 8-12 months before the final improvements take place.**

### *Do's and Don'ts*

1. Do *not* eat any foods with hard or sharp edges for 4-5 days, such as chips, pretzels, nuts, popped corn, or bones. Chew your food well, and do not eat rapidly.
2. Do resume normal activities as tolerated, including exercise, the day following the STRETTA procedure.
3. Do *not* forget to take your acid lowering medication, such as Nexium, Prilosec, Prevacid, Protonix, Aciphex, Dexilant, or Zantac and Pepcid, for at least the first two months after your procedure. If you are not taking these medications you must immediately tell your doctor and restart the medications.
4. Do call your doctor immediately if you experience any of the following:
  - a. Severe chest or abdominal pain
  - b. Nausea or vomiting
  - c. Fever or chills
  - d. Vomiting of blood or coffee ground appearing material
  - e. Bloody or black tarry looking bowel movements
  - f. Difficulty swallowing
  - g. Difficulty breathing
5. If you are hospitalized or visit the ER within 2 weeks of your STRETTA procedure, *do not* allow any tubes or instruments to be introduced into your esophagus, unless the doctor who performed your STRETTA procedure is first notified.

## Side Effects and Complications

### Side Effects

The main side effect experienced after a STRETTA procedure is sore throat, which should last only 2-3 days. Other reported side effects include chest discomfort or pain. The discomfort ranges from a mild sensation of pressure or aching to intense pain. Up to 5% of patients experience chest discomfort and only 1% have significant pain. Your physician will supply you with detailed instructions on what medications to take for the pain and a prescription for a strong pain medication. The pain will normally only last 1-2 days, but rarely up to 1-2 weeks. If you have any questions at all contact your physician or nursing team member.

Another problem, which occurs in only 5-8% of patients, is dyspepsia presenting as bloating, or increased belching or passing excess gas rectally. This may occur for 1-2 days or up to 2 weeks after the procedure. It usually requires no treatment and will stop spontaneously. Some people report relief with either antacids or anti-gas medication like Phazyme or Gas-x.

### **Complications**

There have been some additional complications reported following the STRETTA procedure. Most of these complications were reported in the first six months of the year 2000, when the procedure was just being developed. These included: 1) perforation due to over distention of the STRETTA balloon catheter, 2) increased bleeding from the stomach or esophagus not requiring transfusion or medical intervention, and 3) gastroparesis or delayed emptying of the stomach, which occurred in four patients that resolved spontaneously at the end of eight months, and 4) aspiration pneumonia. Since that time, improvements were made to the device as well as the intra and post procedure care which have largely eliminated these complications.

Two rare but important potential complications are: 1) aspiration or the entry of either oral or stomach fluids into the trachea, bronchi or lungs and 2) gastrointestinal bleeding. With specific regard to aspiration, during your procedure many precautions are taken to prevent this from occurring, but because you are sedated and the STRETTA device uses water to keep the tissue cooled during the procedure, the risk is still present. This may occur in less than 0.1% of cases and is often silent and without notice. If you have this problem you will notice increased cough with mucus production and may experience shortness of breath and possibly even fever. If you do have these symptoms, notify your physician or nurse team immediately. You may be asked to have a chest x-ray to evaluate the degree of aspiration and may require antibiotics for complete recovery. Bleeding is rarer and almost never occurs, and has an incidence of 0.01%. For this reason you are asked to restart or remain on acid controlling medication for a minimum of 2 weeks after the STRETTA procedure and to take another medication, Carafate (sucralfate), for 2 weeks after the procedure to encourage healing and prevent bleeding.

Overall, the current complication rate of the STRETTA procedure in our center is officially noted to be less than 0.23% which is less than the complication rate of a standard upper G.I. endoscopy or EGD.

More recently, there have been some unusual occurrences reported which bear mention, which include the following: 1) the development of pericarditis or inflammation of the tissue surrounding the heart, 2) the development of cardiac tamponade, and 3) the development of fluid in the space between the lungs and the chest wall known as an effusion due to lymphatic fluid. In all three of these reported potential complications, following independent medical review, it was determined that there was *no direct relation*, other than timing, to the STRETTA procedure itself, but likely was associated with other underlying causes that were pre-existing or unknown at the time of the procedure.

The most important message with regard to possible side effects or complications is to remember to ***immediately*** call the physician or nursing triage center, which is available 24/7. This is especially important if you experience ***alert symptoms*** such as, but not restricted to: 1) fever, 2) chills, 3) nausea and/or vomiting, 4) difficult or painful breathing, 5) chest pain, 6) vomiting of blood, 7) black tarry or bloody bowel movements, 8) cough with increased mucus or sputum production, or 9) severe bloating or abdominal distention.

### **How fast will I get better?**

This is the both the most frequent and most important question. It is very important to *not* expect an immediate or instant improvement after the procedure. It takes at least 2 weeks for the tissue to begin to

replicate and grow, which is when up to 25% of patients may begin to experience some initial relief from their symptoms.

Everyone is different in their ability to heal and develop sphincter muscle enlargement and strength. It is only when the tissue heals and the sphincter muscle becomes stronger, that the reflux begins to improve. This process may take as long as 8-12 months to occur, but for many it occurs by 3-5 months. Patients with esophageal-type reflux symptoms or GERD may notice significant improvements at 8 weeks, while those with respiratory-type reflux or LPR may not see improvement for 6-10 months. There are many patients who report no improvement until month 11-12 and often continued improvement up to 13-15 months after the STRETTA procedure.

Do not set unrealistic expectations for when you will feel better. Otherwise you will be unnecessarily disappointed. The recovery and healing process is best described as "slow and steady wins the race." Look for small weekly improvements to occur over time. Also, be aware that occasionally, despite an initial rapid improvement, you may experience a return of your symptoms of heartburn and reflux. This usually occurs when there is a reduction or disappearance of the *barrier effect* of the procedure prior to the full onset of the *sphincter muscle hypertrophy effect*.

This period, known as a **lag phase**, which typically is seen 3 to 8 weeks after the procedure, is only a temporary setback, which responds to the reintroduction of medication. If this lag phase or recurrence of symptoms occur, it will usually pass in several weeks and continued improvement will resume. Only 25% of patients will experience the **lag phase**.

Once your heartburn and reflux symptoms begin to improve, your physician will start to decrease and eventually discontinue your medications.

## Summary

- The STRETTA procedure is an effective and safe means of correction of the chronic degeneration of the LES, which in turn controls the symptoms of heartburn and esophageal-GERD and respiratory-LPR reflux.
- It is the only therapy available that was developed specifically to treat the underlying root cause of all forms of reflux, namely the degeneration of the LES leading to abnormal amounts of transient lower esophageal sphincter relaxations. This is accomplished by administering radiofrequency energy, during a simple endoscopic procedure, which allows rapid recovery, without surgery.
- It is the only procedure in which results of the 10-year data after the procedure clearly demonstrate long term and continued effectiveness, for esophageal or LPR type reflux, in those patients who either initially or no longer respond to conservative measures or medical treatment or desire to be free of medication or have the inability to tolerate medication.
- There is a robust and consistent improvement in all reflux types and patient types.
- Recently it has also been shown to be very effective on those who have had prior failed anti-reflux procedures like LINX, TIF, Endostim, and Nissen.
- The procedure is repeatable and will not prevent other anti-reflux procedures from being performed later.
- The risks and potential side effects and complications are very low and make the STRETTA procedure the safest and best choice for initial correction of reflux related symptoms and disease.

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