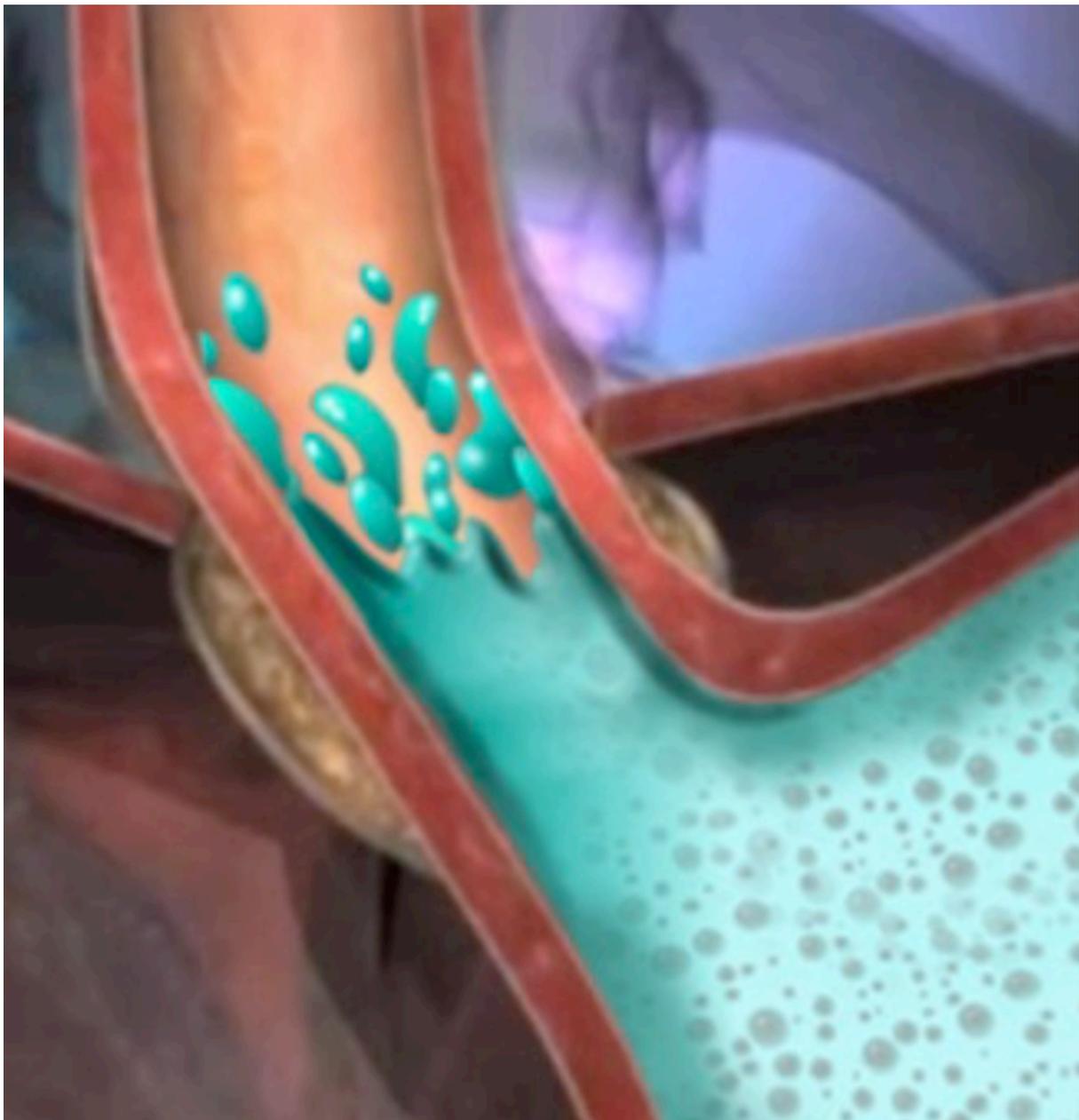


What is Gastro-Oesophageal Reflux Disease (GORD)?

When the muscle between your stomach and oesophagus is weak, stomach contents like acid or bile can reflux up into your oesophagus causing GORD symptoms.



What are the treatment options for GORD?

Treatment options for GORD often depend on the severity of the condition and may include the following:

Lifestyle Modifications

Changes in lifestyle may relieve GORD symptoms in some patients.

- Eliminate coffee, alcohol, smoking
- Avoid eating close to bedtime
- Sleep with the head of the bed elevated
- Eliminate spicy or fatty foods, and citrus or tomato products

Prescription Medications

These medications provide symptomatic relief but are generally required for the lifetime of the patient.

The following drugs work by decreasing acid production:

- Proton-Pump Inhibitors (PPIs)
- H₂-receptor antagonists

Anti-Reflux Surgery

This surgery involves wrapping the stomach around the oesophagus to improve the barrier function of the lower oesophageal sphincter.

- 2-4 hour procedure
- General Anaesthesia
- 1-4 day hospital stay
- 1-3 weeks back to work

The Stretta Procedure

Stretta is an effective outpatient procedure for patients who prefer a non-surgical, minimally invasive option:

- 45-minute procedure
- Outpatient treatment, no hospital stay
- 1-2 days back to work

For those who suffer from chronic heartburn and are considering a surgical intervention, Stretta may be an optimal and less invasive option.

PATIENT SELECTION CRITERIA - THE SPECTRUM OF GORD TREATMENTS

Medications (PPIs)

stretta[®]

ANTI-REFLUX SURGERY:

- Transoral Fundoplication
- Surgically Implanted Devices
- Laparoscopic Fundoplication

70% Respond to Meds

- Mild GORD symptoms
- Functioning LOS
- Highly motivated patient
- Compliant to routine
- Tolerant of medication
 - No side effects
 - No drug interactions

25-30% Refractory GORD

- Mild to moderate GORD
- <2 cm hiatal hernia
- Partial response to meds
- Non-compliant to med routine
- Intolerant of long-term use of medication
 - Side effects
 - Drug interactions
- Post bariatric surgery with GORD symptoms
- Non-erosive reflux disease
- Post anti-reflux surgery with GORD symptoms
- Extra-oesophageal symptoms of GORD

5% Have Anti-Reflux Surgery

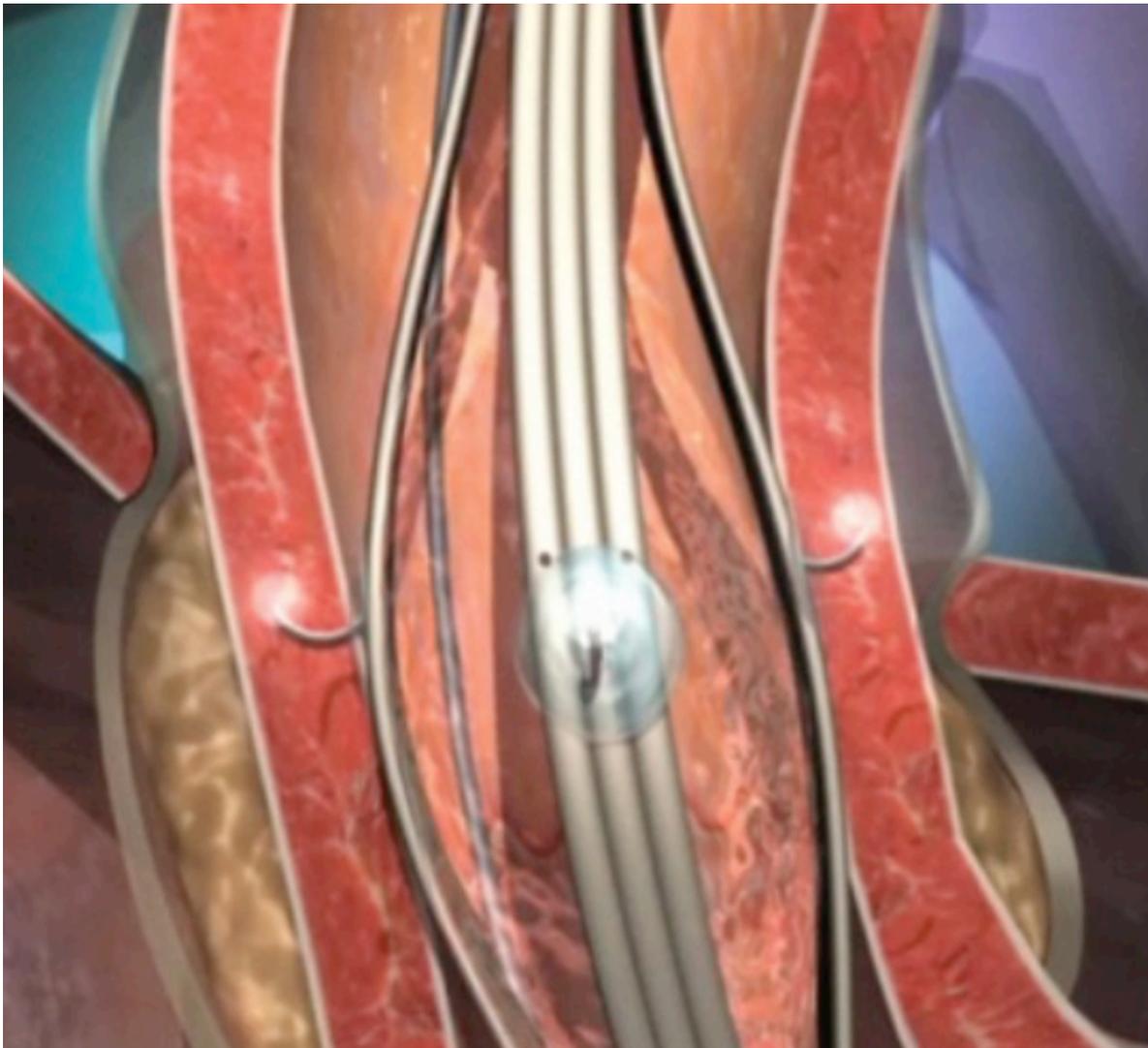
- Severe GORD
- Intolerant of long-term use of medication
 - Side effects
 - Drug interactions
- Post-Stretta procedure with GORD symptoms
- Erosive oesophagitis
- > 2 cm hiatal hernia (ARS)
- **SPECIAL INDICATIONS TRANSORAL FUNDOPLICATION**
- <2cm hiatal hernia
- <35 Body mass index
- **SPECIAL CONSIDERATIONS IMPLANTED DEVICES**
- Magnetic implants are not considered safe for MRI

What is Stretta Therapy?

Stretta is a non-surgical, outpatient procedure that treats the underlying cause of GORD – a weak muscle between the stomach and oesophagus.

Stretta has been shown to:

- Significantly reduce GORD symptoms
- Eliminate or decrease medications
- Decrease acid exposure
- Improve quality of life



The Stretta Procedure

Stretta Therapy is a non-surgical, minimally invasive outpatient procedure that takes approximately 45-minutes to perform. Patients are sedated and the Stretta catheter is passed through the mouth so there are no visible cuts or scars as a result of the procedure. Patients typically can go home 1 – 2 hours after the procedure. Most patients are able to return to work and their normal activities the day after treatment so there is minimal interruption to everyday life.

What anaesthetic will I be given?

You could be presented with the option for 2 types of anaesthesia:

- General Anaesthesia
- Conscious sedation

How Stretta Works

A specially designed, flexible catheter is passed through the mouth into the oesophagus and is positioned at the LOS valve near the stomach. The catheter places 4 small needles into the muscle of the LOS and delivers Radiofrequency energy to the muscle, thereby warming the tissue to 85 Celcius (185 Fahrenheit). Several areas in the region of the LOS and stomach are treated.

Getting ready for your procedure

Do not have anything to eat or drink for at least six hours before your test. This is to make sure that we can have a clear view of your stomach. You must tell the nurse if you have any loose teeth, caps, crowns or veneers as there is a risk they could become dislodged.

You will be asked to remove any tight clothing, ties, dentures, spectacles and contact lenses. Please do not bring large amounts of money or valuables with you, as the Trust cannot be held responsible for them. When you come to the department, please tell the doctor or nurse about any medicines you are taking, any possible allergies or bad reactions you may have had in the past or any heart valve problems that may require antibiotics before your procedure.

How Stretta Works

The Physician places the Stretta catheter through patient's mouth and into the valve between the stomach and oesophagus. Radiofrequency energy is delivered at multiple levels to the muscle of the lower oesophageal sphincter and stimulates the muscle to grow over time* resulting in a thicker muscle, improved barrier function and prevention of all types of reflux events (acid, bile, etc.)

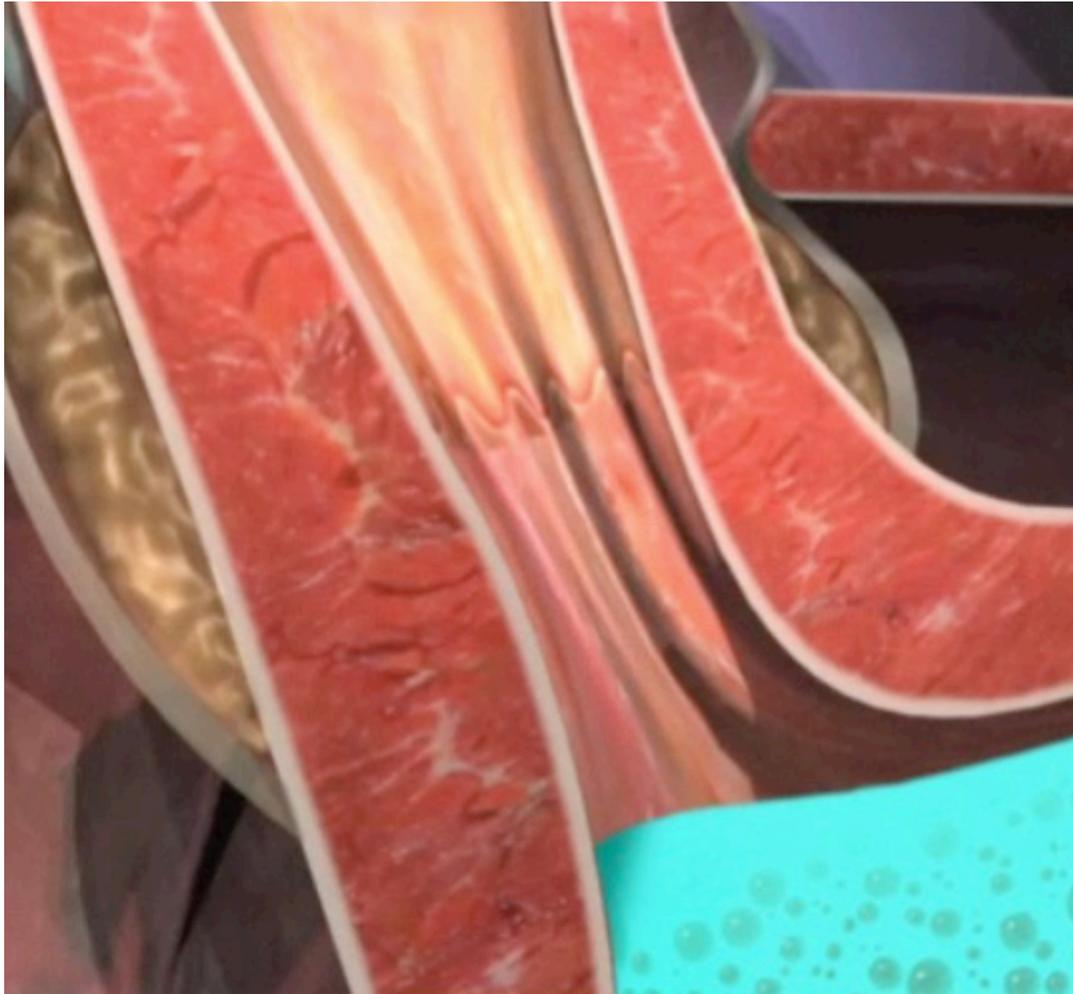


*Herman, et al. *Colorectal Disease*: May 2015 – 17:433-440

The Healing Power of Radiofrequency

Radiofrequency energy is widely used in healthcare:

- Cardiologists use RF to treat atrial fibrillation
- Urologists use RF for treating prostate enlargement
- ENTs use RF to eliminate snoring and sleep apnea
- RF is used in cosmetic procedures for body contouring, skin rejuvenation and tightening



*Animal studies show that the technology used in Stretta may increase smooth muscle and improve collagen in the treatment zone.**

*Herman, et al. *Colorectal Disease*: May 2015 – 17:433-440

What are the advantages of Stretta

- Middle option fits between medications and surgery
- Non-surgical and outpatient procedure
- Low complication rate
- Does not alter patient anatomy
- Widely studied with long-term follow-up
- Cost effective when compared to long-term medications or surgery



Long-Term Outcomes of Stretta Therapy

Stretta treatment has been widely studied:

- More than 20,000 Stretta procedures performed
- 40 clinical studies conclude Stretta safe and effective
- Low complication rate <1% (similar to EGD)
- 93% patient satisfaction after Stretta

Long term data

- 4-year follow-up 86% of patients off daily PPIs
- 8-year follow-up 72% of patients off daily PPIs
- 10-year follow-up 64-72% of patients off PPIs
- 15-year data concludes Stretta Safe and Effective

Perry et al. *Surgical Endoscopy* 27: 2658-2672 Noar, et al August 2014.

Surgical Endoscopy 28, 2323-2333

What to Expect After Stretta

- Expect to feel very tired for rest of the day
- Most common side effect is a sore throat or mild chest soreness
(may continue for 1-5 days)
- Some patients feel bloated with increased belching and gas
- Resume normal activities as tolerated the next day
- Follow all post-procedure instructions provided

Continue taking your acid controlling medications until instructed by your physician (at least 2-months after Stretta)

- Do not expect symptoms to improve immediately
- The effects develop slowly over time
- Some patients improve faster than others
- Your physician will begin to wean you off of your PPI medications
approximately 2-months after Stretta
- Most patients start to see improvements in 2-4 months but
sometimes it may take as long as 8-12 months

Post Stretta Patient Instructions

- Avoid instrumentation of the oesophagus for at least one month after treatment, specifically the passage of a nasogastric tube.
- Refrain from use of oral NSAIDS for 14-days after Stretta.
- Use liquid acetaminophen, with or without codeine or equivalent preparation, for post treatment analgesia.
- Crush all medications or use liquid preparations of all medications, for at least one month after treatment.
- Modify diet post Stretta: full liquids for 24 hrs, soft diet for 2-weeks.
- Continue previous GORD medication regimen for 2-months after the Stretta procedure. Notify the physician if any of the following symptoms occur: Fever, chest pain, nausea, vomiting, bleeding, shortness of breath, increasing abdominal discomfort, difficulty swallowing, tachycardia.