stretta®

AN EFFECTIVE SOLUTION TO GASTRIC REFLUX IN WELL SELECTED PATIENTS

Stretta therapy is an effective and minimally invasive procedure that improves the function of the LES barrier.

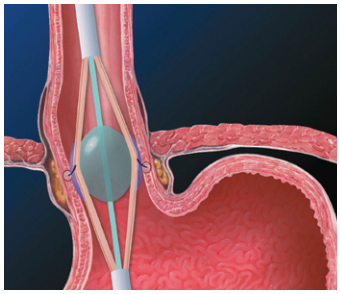
- An excellent option for patients that have failed or are intolerant of drug therapy
- Significantly lower costs and complication rates compared to surgery
- An effective stand alone treatment or augmentation to other GERD therapies

A recent clinical study in a large group of patients documents important long-term durability of beneficial symptomatic effects and elimination of medication usage effects of the Stretta procedure in patients who have failed escalated PPI therapy — the patients in this study had statistically significant improvement and sustained effect in all parameters for up to 4 years.

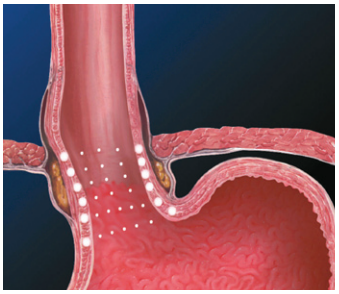
Treats the disease, not just the symptoms

- Minimally invasive
- Documented long-term effectiveness
- 90% patient satisfaction
- Safe and well tolerated

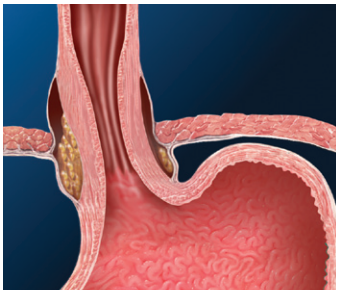
HOW STRETTA WORKS



CONCENTRATED RF ENERGY DELIVERED TO TISSUE



MULTI-LEVEL DENATURED COLLAGEN LESIONS CREATED



LES BARRIER FUNCTION IS SIGNIFICANTLY IMPROVED

Stretta therapy is an endoscopically-guided, minimally invasive, outpatient procedure performed by a doctor in 60 minutes or less. The Stretta Catheter, powered by the Stretta Generator, is an innovative design for precise and safe delivery of radiofrequency energy to the lower esophageal sphincter (LES), muscle and gastric cardia. As treated areas heal, the barrier function of the LES is augmented, reducing the frequency and severity of reflux events. There is no hospital stay involved with Stretta therapy and patients are typically able to return to normal activities the following day.

stretta-therapy.com

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PROVEN EFFECTIVE CLINICAL STUDY SUMMARIES

Gastroesophageal Reflux Disease – Clinical Practice Guidelines

Grzegorz Wallner, Michał Solecki, Wiesław Tarnowski, Tadeusz Wróblewski, Edward Stanowski, Andrzej Budzyński, Maciej Michalik , *Videosurgery and other miniinvasive techniques* 2009; 4 (Suppl 1)

SUMMARY: Reflux disease is a serious problem of not only medical, but also economic significance. The costs of long-term pharmacological treatment are tremendous. Surgical treatment for the majority of these patients seems justified. Such therapy ought to be undertaken in a centre with the volume exceeding 50 anti-reflux procedures per year. The procedure performed by an experienced surgeon gives a chance for remission of symptoms for over 5 years in more than 90% of patients. Application of laparoscopic techniques has made this method of treatment much more attractive.

Endoluminal Full-Thickness Plication and Radiofrequency Treatments for GERD. An Outcomes Comparison

Louis O. Jeansonne IV, MD; Brent C. White, MD; Vien Nguyen, MD; Syed M. Jafri, BS; Vickie Swafford, RN; Mina Katchooi, DDS; Leena Khaitan, MD, PhD; S. Scott Davis, MD; C. Daniel Smith, MD; Shahriar Sedghi, MD; Edward Lin, DO. *Arch Surg.* 2009;144(1):19-24

RESULTS: In the RF group, patients with moderate to severe heartburn decreased from 55% to 22% (P=.01), and proton pump inhibitor (PPI) use decreased from 84% to 50% (P=.01). Decreases were also seen for dysphagia, voice symptoms, and cough. Percentage of time the pH was less than 4 was unchanged. In the FTP group, patients with moderate to severe heartburn decreased from 53% to 43% (P=.3), and PPI use decreased from 95% to 43% (P=.01). Percentage of time the pH was less than 4 decreased from 10.0% to 6.1% (P=.05). Decreases were also seen for regurgitation, voice symptoms, and dysphagia. There was no change in scores for chest pain or asthma in either group.

CONCLUSIONS: For patients with GERD, RF and FTP both resulted in a decrease in both PPI use and in scores for voice symptoms and dysphagia. In addition, RF resulted in decreased heartburn and cough, while FTP resulted in the most dramatic reduction in regurgitation. Our experience indicates that both procedures are effective, providing symptomatic relief and reduction in PPI use. For patients whose chief complaint is regurgitation, FTP may be the preferred procedure.

A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease.

Abdel Aziz AM, El-Khayat HR, Sadek A, Mattar SG, McNulty G, Kongkam P, Guda MF, Lehman GA. *Curr Opin Gastroenterol.* 2009 Jul;25(4):352-7.

RESULTS: The Stretta procedure was completed successfully for all the patients in both active treatment groups. At 12 months, the mean HRQL scores of those off medications, the LES basal pressure, the 24-h pH scores, and the proton pump inhibitor (PPI) daily dose consumption were significantly improved from baseline in both Stretta groups ($p < 0.01$). The double Stretta was numerically but not significantly better than the single Stretta for mean HRQL, mean 24 h pH, mean LES pressure, and PPI use. Seven patients in the double Stretta treatment group had normalized their HRQL at 12 months compared with 2 patients in the single-treatment group ($p = 0.035$). The sham patients had a small but statistically significant decrease in their daily PPI dosages ($p < 0.05$) and mean HRQL scores ($p < 0.05$). No serious complications (bleeding, perforation, or death) occurred. However, two patients experienced significant delayed gastric emptying after the second Stretta treatment.

CONCLUSIONS: The Stretta procedure significantly reduced GERD HRQL, use of PPI drugs, esophageal acid exposure, LES pressure, and grade of esophagitis compared with the sham procedure. The double Stretta therapy had numerically superior outcomes for most parameters and a significantly more frequent normalization of HRQL scores compared with the single Stretta.

Gastroparesis associated with gastroesophageal reflux disease and corresponding reflux symptoms may be corrected by radiofrequency ablation of the cardia and esophagogastric junction.

Noar MD, Noar E. *Surg Endosc.* 2008 Nov;22(11):2440-4.

RESULTS: At baseline, 31 patients were classified as abnormal. At 6 months after the procedure, emptying scores had improved significantly, with the percentage of solid food emptied at 90 min improved from 41% to 66% ($p < 0.0001$) and at 120 minutes from 55% to 84%. Significant improvements were seen at all intervals. Overall, 23 patients (74%) experienced normalization of gastric emptying, and 4 patients were improved but remained abnormal. Four patients showed no improvement on their gastric emptying scans, with one patient electing to undergo a Nissen procedure. All the patients had a 1-year symptom follow-up assessment, which showed significant improvements in GERD health-related quality of life, dyspepsia, and heartburn scores.

CONCLUSIONS: Radiofrequency treatment has been demonstrated to correct gastroparesis. Patients' symptoms improved significantly. The mechanism of action is unknown but may be related to reduction in transient lower esophageal sphincter relaxations (TLESRs), increased esophagogastric junction barrier, decreased esophageal venting, alteration of the gastric pacemaker function in the region of radiofrequency therapy administration, removal of medications for symptoms, or a combination of all these.

Clinical trial: radiofrequency energy delivery in proton pump inhibitor-dependent gastro-oesophageal reflux disease patients

J. P. GALMICHE, E. CORON, V. SEBILLE, G. CADIOT, F. ZERBIB, P. DUCROTTE, F. DUCROT, P. POUDEROUX, J. ARTS, M. LE RHUN, T. PICHE, S. BRULEY DES VARANNES. *Aliment Pharmacol Ther* 28, July 2008 1147-1158

RESULTS: In the RF group, 1820 patients stopped (n = 3) or decreased (n = 15) PPI use as compared to eight of 16 in the PPI group (P = 0.01). None of the control patients could stop PPI. Health-related quality of life scores were not different between groups. No significant change in oesophageal acid exposure (OAE) was noted between baseline and 6-months after RF. No severe complication was reported.

CONCLUSIONS: Radiofrequency energy delivery is a safe and effective therapeutic option, allowing reduction in or discontinuation of PPI therapy in patients with PPI-dependent symptoms, without loss of quality of life. However, in a majority of patients, PPI therapy cannot be completely stopped. The efficacy of RF does not seem to be related to a decrease in OAE.

Long-term results of radiofrequency energy delivery for the treatment of GERD: sustained improvements in symptoms, quality of life, and drug use at 4-year follow-up.

Reymunde A, Santiago N. *Gastrointest Endosc.* 2007 Mar;65(3):361-6.

RESULTS: We performed the Stretta procedure in 83 consecutive patients with persistent GERD symptoms. Complete matched data for follow-up evaluations are reported at 12, 36, and 48 months. The mean GERD QOL score was 2.4 (baseline), 4.6 (36 months), and 4.3 (48 months, $P < .001$). The mean GERD symptom score was 2.7 (baseline), 0.3 (36 months), and 0.6 (48 months $P < .001$). Daily medication usage was 100% (baseline) and 13.6% (48 months, $P < .001$). LIMITATIONS: Nonrandomized study design, lack of control arm, and lack of 24-hour pH.

CONCLUSIONS: For these GERD patients followed to 4 years, the Stretta procedure was a safe, effective, and durable treatment, with significant and sustained improvements in GERD symptoms, QOL, and PPI elimination.