SAFE | EFFECTIVE | DURABLE

stretta®

Stretta therapy is a safe, effective and minimally invasive procedure that significantly reduces GERD symptoms and esophageal acid exposure, and improves quality of life for patients suffering from chronic reflux.

STRETTA - THE PATIENT

Stretta fills a significant unmet need in:

- Patients who don't respond to, or are intolerant of PPIs
- Patients who don't wish to have surgery or an implant
- Non-erosive reflux (NERD) patients
- Laryngopharyngeal reflux (LPR) patients
- Post-nissen patients with recurring reflux
- Post-gastric bypass/sleeve patients

Because Stretta doesn't alter the anatomy or introduce foreign substances, it can be utilized in a variety of patient groups, and doesn't preclude other treatment options. Stretta is by far the most widely studied of any minimally invasive treatment option for GERD, with studies showing a high rate of effectiveness and durability without the higher complication rates of surgery, or the higher costs.

META-ANALYSIS - 18 STUDIES

Outcome Variable	Studies (n)	Patients (n)	Mean Follow-up (mo)	Pre-Stretta	Post-Stretta	P-value
GERD-HRQL score	9	433	19.8	26.11	9.25	0.0001
QOLRAD score	4	250	25.2	3.30	4.97	0.0010
SF-36 physical	6	299	9.5	36.45	46.12	0.0001
SF-36 mental	5	264	10.0	46.79	55.16	0.0010
Heartburn score	9	525	24.1	3.55	1.19	0.0001
Satisfaction score	5	366	21.9	1.43	4.07	0.0006
Esophageal Acid Exposure (% Ph<4)	11	364	11.9	10.29	6.51	0.0003
Demeester score	7	267	13.1	44.37	28.53	0.0074
LES pressure	7	263	8.7	16.54	20.24	0.0302

Surg Lap, Endo & Perc Tech: August 2012; 22(4) 283-288.

HOW STRETTA WORKS

CONCENTRATED RF ENERGY DELIVERED TO TISSUE

MULTI-LEVEL THERMAL TREATMENT REMODELS LES AND GASTRIC CARDIA

LES BARRIER AND FUNCTION IS SIGNIFICANTLY IMPROVED

Stretta therapy is an endoscopically-guided, minimally invasive, outpatient procedure performed by a doctor in approximately 60 minutes. The Stretta Catheter, powered by the MDRF1 Generator, is an innovative design for precise and safe delivery of radiofrequency energy to the lower esophageal sphincter (LES), and gastric cardia. There is no hospital stay involved with Stretta therapy and patients are typically able to return to normal activities the following day.

STRETTA - THE NUMBERS

86%
PATIENTS OFF MEDS

4-10
YEARS DURABLE SYMPTOM RELIEF

<1%
COMPLICATION RATE

33+
STUDIES

20,000+
PROCEDURES

NEW!

10-Year Data
SHOWS LASTING RESULTS!

- Normalization of GERD HRQL scores in 72% of patients
- PPI use reduced by ≥50% in 64% of patients
- 41% remained off PPIs entirely
- Pre-existing Barrett's regressed

SAGES CLINICAL SPOTLIGHT REVIEW GUIDELINE GIVES STRETTA STRONGEST RECOMMENDATION.
Quality of Evidence: (++++)
Grade Recommendation: Strong

stretta®
Instrumedsurgical.com

MEDERI

Clinical studies on file.

173-5024P

STRETTA FOR GERD | RF MECHANISMS OF ACTION

DECREASED ACID EXPOSURE

"Analyses of symptom improvement vs. acid exposure suggested that symptom improvement was associated with decreased esophageal acid exposure... A comparison of patients before vs. after treatment indicated that acid exposure decreased significantly (median decrease, -2.4%; P=0.01) between baseline and 12 months for all treated patients (both initial active treatment and crossed-over patients)."

Improvement of Gastroesophageal Reflux Symptoms After Radiofrequency Energy: A Randomized, Sham-Controlled Trial. Corley D, Katz P, Wo J, Stefan A, Patti M, Rothstein R, Edmundowicz S, Kline M, Mason R, and Wolfe MM. *Gastroenterology* 2003;125:668–676

" 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 daily dose consumption were significantly improved..."

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.

DECREASED TISSUE COMPLIANCE-NO FIBROSIS

" Stretta improved GERD symptoms and decreased GEJ compliance. Decreased GEJ compliance, which reflects altered LES neuromuscular function, may contribute to symptomatic benefit by decreasing refluxate volume."

A Double-Blind Sham-Controlled Study of the Effect of Radiofrequency Energy on Symptoms and Distensibility of the Gastro-Esophageal Junction in GERD. Arts J, Bisschops R, Blondeau K, Farré R, Vos R, Holvoet L, Caenepeel P, Lerut A, Tack J, *Am J Gast*, advance online publication, 22 November 2011; doi: 10.1038/ajg.2011.395

INCREASED WALL THICKNESS

" EUS demonstrates that LES muscle is significantly thickened after RF delivery...thickening may result in reduced compliance of the GE junction and contribute to its mechanism of action."

Endoscopic ultrasound (EUS) in-vivo assessment of radiofrequency (RF) energy delivery to the gastroesophageal (GE) junction in a porcine model. Chang KJ, Utley DS. *Gastrointest Endosc* 2001;53:AB4191.

DECREASED TLESRs-INCREASED LES PRESSURE

" RFe reduced the rate of postprandial transient LOS relaxations from 6.8 (5.7–8.1) (median (interquartile range) per hour to 5.2 (4.2–5.8) per hour (p<0.01), and increased mean basal LOS pressure from 5.2 (SEM 0.3) mm Hg to 8.0 (SEM 0.4) mm Hg (p<0.01)."

Delivery of radiofrequency energy to the lower oesophageal sphincter and gastric cardia inhibits transient lower oesophageal sphincter relaxations and gastro-oesophageal reflux in patients with reflux disease. Tam WCE, Schoeman MN, Zhang Q, Dent J, Ridga R, Utley D, Holloway RH. *Gut* 2003;52:479-285.

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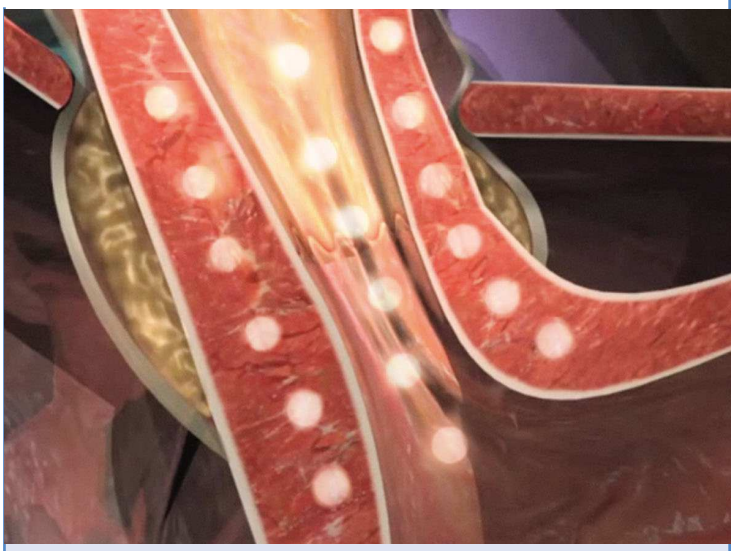
MEDERI THERAPEUTICS INC



Reduction in esophageal acid exposure

Perry et al. 2012 – Surg Lap, Endo & Perc Tech
Aziz et al 2010 – Curr Opin Gastroenterol - RCT
Arts et al 2007 – Digestive Disease Science - RCT
Mattar et al. 2006 – Surg Endosc
Lufti et al. 2005 – Surg Endosc
Cipoletta et al. 2005 – Surg Endosc
Torquati et al. 2004 – Surg Endosc
Triadafilopoulos et al. 2004 – Surg Endosc
Houston et al. 2003 – Surg Endosc
Richards et al. 2003 – Annals of Surgery
Triadafilopoulos et al. 2002 – Gastrointest Endosc
Corley et al. 2003 – Gastroenterology - RCT

Reduction in transient LES relaxations

Arts et al. 2012 – Am Journal of Gastroenterol - RCT
Tam et al. 2003 – Gut
Kim et al. 2003 – Gastrointestinal Endosc

Decreased tissue compliance without fibrosis

Arts et al. 2012 – Am Journal of Gastroenterol - RCT

Increase in LES wall thickness

DiBaise et al. 2002 – Am Journal of Gastroenterol
Chang et al. 2001 – Gastrointestinal Endosc
Kim et al. 2003 – Gastrointestinal Endosc

Increased LES pressure

Aziz et al. 2009 – Curr Opin Gastroenterol
Meier et al. 2007 – Scandinavian Journal of Gastro
Tam et al. 2003 – Gut
Utley et al. 2000 – Gastrointest Endosc