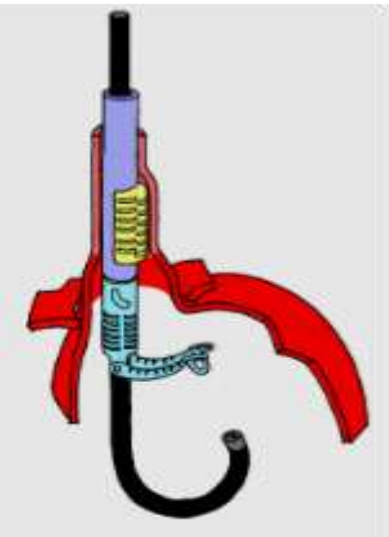


Que reste-t-il du traitement endoscopique du RGO ?

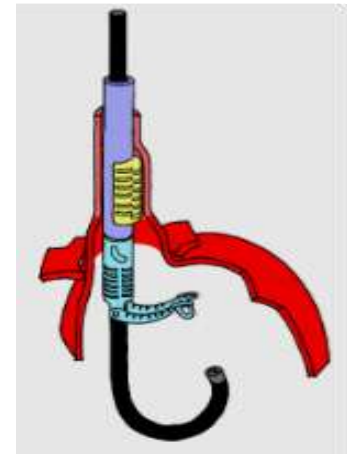
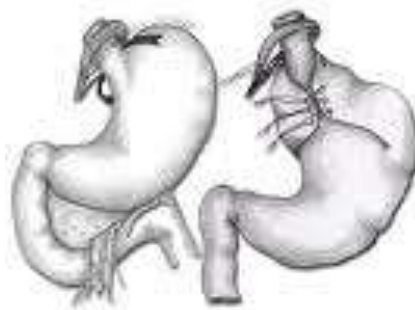


Dr BOUMAHDJ
Dr BALAMANE



3 Catégories de traitement

1. Traitement médical IPP (Référence)
2. Traitement chirurgical Fundoplicature laparoscopique de Nissen
3. Traitement endoscopique mal codifié



2000 à 2003 : Age d'or !



2000

Endocinch

2001

Endocinch

Stretta

Enteryx

2002

Endocinch

Stretta

Enteryx

Plicator

Gatekeeper

2003

Endocinch

Stretta

Enteryx

Plicator

Gatekeeper

ESD

2004 – 2005 : Age de glace ...



Endocinch



Stretta

ESD



Plicator

Enteryx



Gatekeeper



3 catégories

- Sutures ou plicatures endoluminales

Endocinch

ESD

Plicator

Esophyx

- Radiofréquence

Stretta

- Injections de matériel synthétique inerte

Enteryx

Gatekeeper

Systemes de suture ou plicature

Endocinch

Etapes de la suture ou plicature gastrique avec le système Endocinch TM (Bard)

A. La paroi cardiaque est aspirée dans la fenêtre prévue à cet effet;

B. Passage du fil de suture

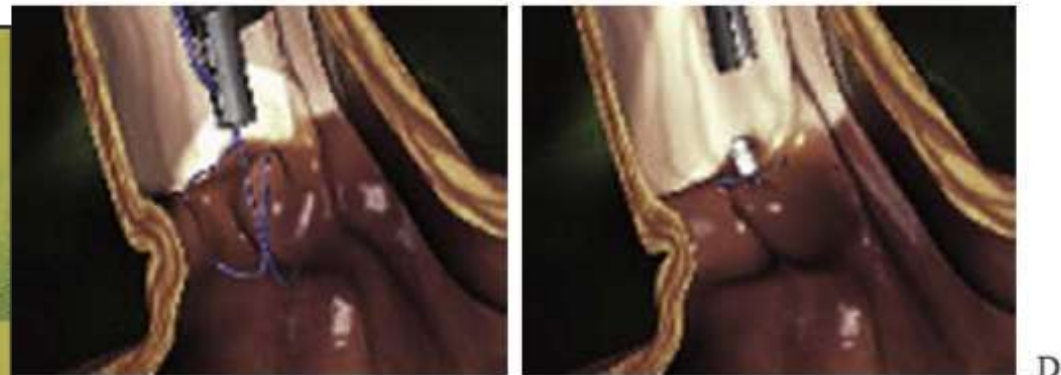
C. Suture aboutissant à la plicature pariétale

D. Serrage du noeud à l'aide du rivet

E. 2 sutures ont été réalisées, 2 à 4 nécessaires

Systemes de suture ou plicature

Endocinch



Systèmes de suture ou plicature

Long term failure of endoscopic gastroplication (EndoCinch)

I Schiefke, A Zabel-Langhennig, S Neumann, J Feisthammel, J Moessner, K Caca

Gut 2005;54:752–758. doi: 10.1136/gut.2004.058354

Introduction: Endoluminal gastroplication (EndoCinch; Bard) has been introduced as an endoscopic treatment option in gastro-oesophageal reflux disease (GORD) patients with promising short term results. However, little is known about the long term efficacy of endoscopic suturing. The aim of this study was to evaluate prospectively the long term outcome after EndoCinch.

Patients and methods: A total of 70 patients treated with EndoCinch at a single referral centre were studied prospectively. All patients were interviewed using a standardised questionnaire regarding their symptoms and medication prior to and 18 months after EndoCinch. In addition, follow up included endoscopy, 24 hour pH monitoring, and oesophageal manometry.

Results: The procedure was well tolerated without major short or long term complications. Eighteen months after EndoCinch, 56/70 patients (80%) were considered treatment failures as their heartburn symptoms did not improve or proton pump inhibitor medication exceeded 50% of the initial dose. Endoscopy showed all sutures in situ in 12/70 (17%) patients while no remaining sutures could be detected in 18/70 (26%). In 54 and 50 patients examined, respectively, no significant changes in 24 hour pH monitoring (median pH <4/24 hours, 9.1% v 8.5%; $p=0.82$) or lower oesophageal sphincter (LOS) pressure (7.7 v 10.3 mm Hg; $p=0.051$) were observed while median LOS length slightly increased (3.0 to 3.2 cm; $p<0.05$).

Conclusion: Endoscopic gastroplication (EndoCinch) is a safe and minimally invasive endoscopic treatment for GORD with reasonable short term results. In contrast, long term outcome is disappointing, probably due to suture loss in the majority of patients. Therefore, technical improvements to ensure suture durability are mandatory before endoscopic suturing can evolve as a therapeutic option for GORD treatment.

Systemes de suture ou plicature

ESD

Cook Endoscopic Suture Device ESD™

SR•5™ Device Operation



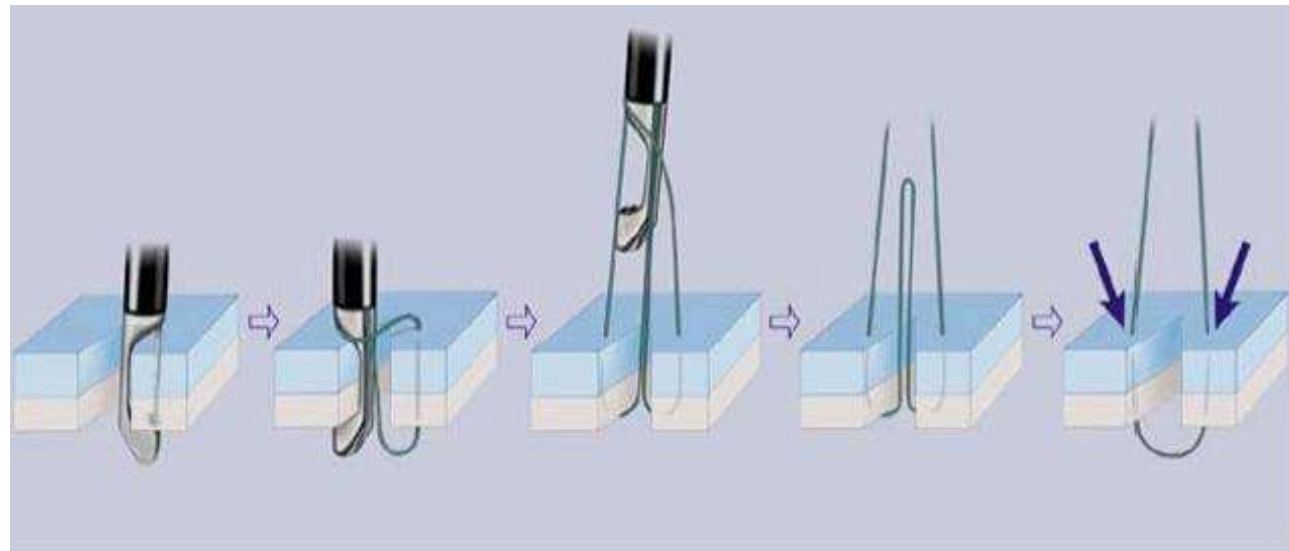
With a (single) squeeze of the lever the first needle passes through the tissue.



The needle automatically captures the suture and pulls it back through the tissue.

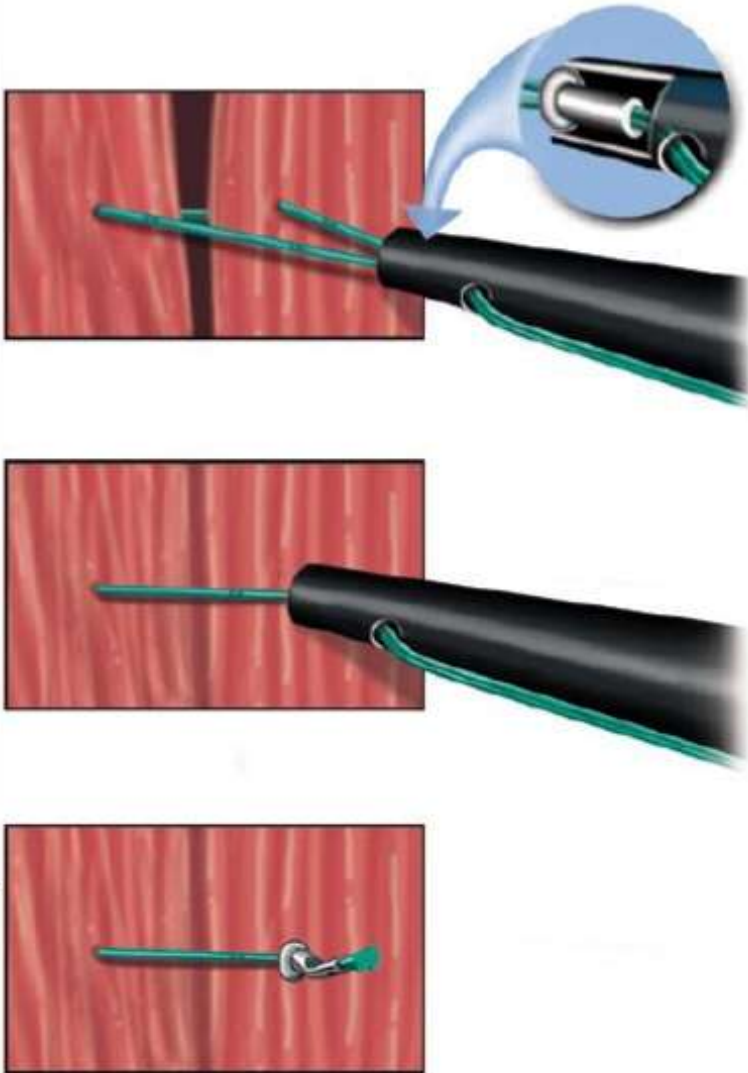
Systemes de suture ou plicature

ESD



Systemes de suture ou plicature

ESD



ESD

Systemes de suture ou plicature

Endoscopy. 2005 Aug;37(8):700-5.

Use of an endoscopic suturing device (the "ESD") to treat patients with gastroesophageal reflux disease, after unsuccessful EndoCinch endoluminal gastroplication: another failure.

Schiefke I, Neumann S, Zabel-Langhennig A, Moessner J, Caca K.

Department of Internal Medicine II, University of Leipzig, Leipzig, Germany.

Abstract

BACKGROUND: Endoluminal gastroplication, using the EndoCinch procedure, has emerged as a potential endoscopic antireflux therapy. Although initial results have been promising, the long-term durability of the treatment is uncertain due to suture loss. A new endoscopic suturing device, the "ESD," has been developed that promises excellent visibility and endoscopic control. The aim of this study was to evaluate prospectively the feasibility and efficacy of the ESD method after EndoCinch failure.

METHODS: The study involved 20 patients with gastroesophageal reflux disease (GERD), who had been initially treated with an EndoCinch procedure, but had relapsed after a median of 7.5 months, with lost or dysfunctional sutures and with reflux symptoms that required proton pump inhibitor (PPI) treatment. Using the ESD, at least three plications were created at the gastroesophageal junction. Patients underwent endoscopy, 24-hour pH monitoring and esophageal manometry before treatment and 6 months afterwards. In addition, reflux symptoms as well as quality-of-life scores were assessed (using the SF-6 and GERD-HRQL scales). **RESULTS:** The ESD procedure (median procedure time 45 min) was performed successfully in all patients without major complications. After 6 months only one patient (5 %) still had all sutures in situ, while no remaining sutures could be detected in 3/20 (15 %). No significant changes in reflux esophagitis; 24-hour pH monitoring results (median pH < 4/24 h 9.9 % vs. 12.3 %; P = 0.60); manometry findings (median lower esophageal sphincter pressure 7.2 mm Hg vs. 9.9 mm Hg; P = 0.22); PPI use; or reflux esophagitis could be detected after 6 months. While reflux symptoms improved (heartburn severity score 30 vs. 48, P < 0,05), no changes in quality-of-life scores were detected. **CONCLUSIONS:** Endoluminal gastroplication using the ESD is an easy and safe, but unfortunately ineffective procedure for endoscopic GERD treatment. Endoluminal gastroplication techniques clearly need refinements before these therapies can evolve as a treatment option for GERD patients.

Suture : problème de tenue dans le temps !



- ESDTM : 12% encore en place à 3 mois

Schilling et al. GI endos 2005

- EndocichTM :

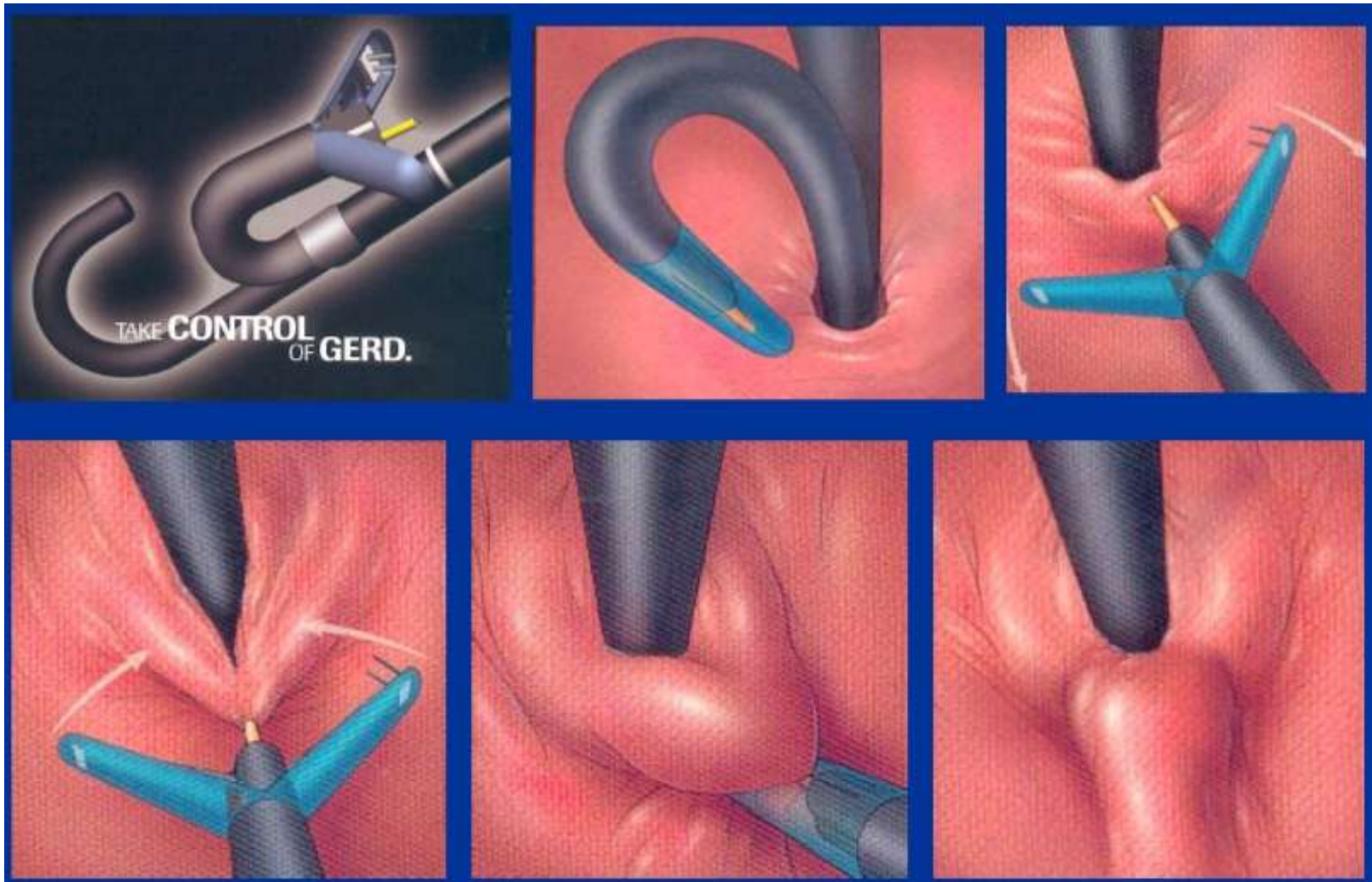
- 38 patients, 0 avec suture en place à 1 an
- 90% de sutures perdues

Abou Rebyeh Endoscopy 2005

Systemes de suture ou plicature

Plicator

Ethicon Endosurgery, Sommerville, NJ, USA



Systemes de suture ou plicature

Plicator

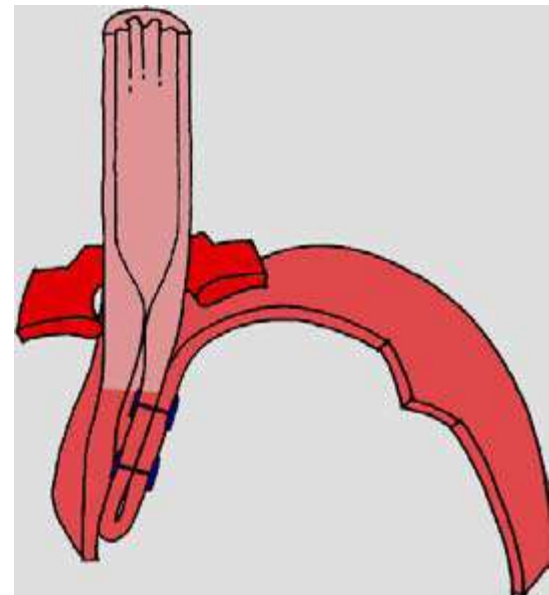
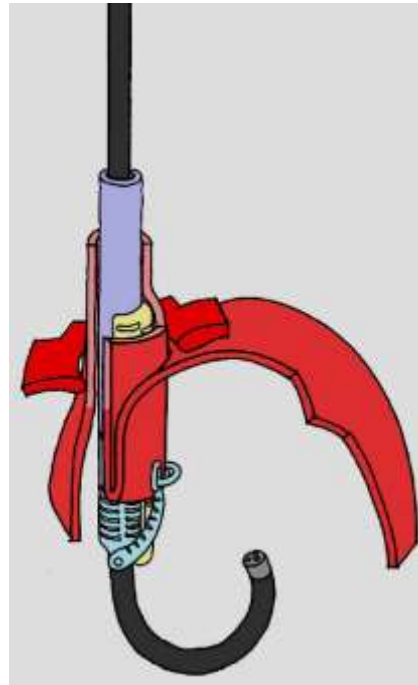
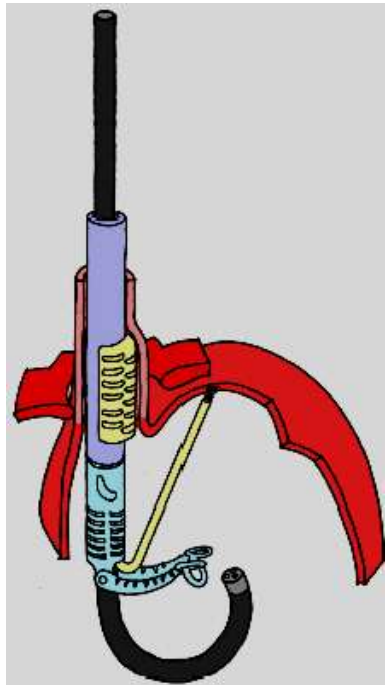
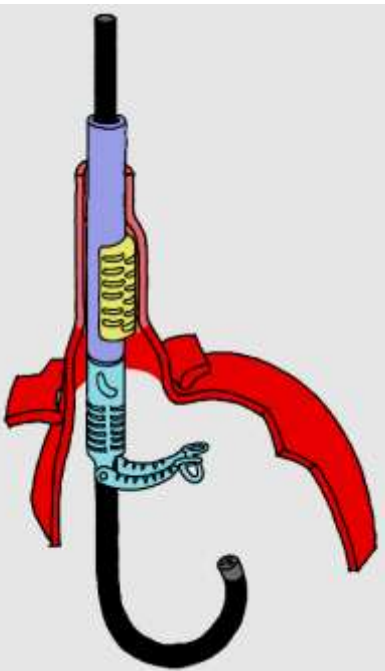
- A 12 mois 68% des patients ont arreté ou réduit l'utilisation des IPP
- 30% ont amélioré leur score ph metrique à 6 mois
- 41 % ont des douleurs pharyngées
- 20 % douleurs abdominales



Systemes de suture ou plicature

Esophyx

Réalise comme la chirurgie une véritable fundoplicature qui inclut toutes les couches gastriques sur une longueur de 5 cm et une circonférence de 280°



Systemes de suture ou plicature

Esophyx

World J Surg. 2010 Apr;34(4):750-7.

Effect of transoral incisionless fundoplication on symptoms, PPI use, and pH-impedance refluxes of GERD patients.

Testoni PA, Corsetti M, Di Pietro S, Castellaneta AG, Vailati C, Masci E, Passaretti S.

Division of Gastroenterology and Gastrointestinal Endoscopy, San Raffaele Scientific Institute, Vita-Salute San Raffaele University, via Olgettina 58, 20132, Milan, Italy. testoni.pieralberto@hsr.it

Abstract

BACKGROUND: Three previous studies from the same institution have reported that transoral incisionless fundoplication (TIF) with the Esophyx device is effective for creating a continent gastroesophageal valve and for good functional results as measured only by pH-metry in patients with gastroesophageal reflux disease (GERD). The objective of the present study was to evaluate the effect of TIF on symptoms, use of proton pump inhibitors (PPI), esophageal motility, and pH-impedance in patients with symptomatic GERD. **METHODS:** Twenty consecutive patients were enrolled to complete the GERD-HRQL and GERD-QUAL questionnaires while on and off PPI. They were also examined by upper gastrointestinal (GI) endoscopy to determine Hill grade and Jobe length of the gastroesophageal valve, and to check for hiatal hernia and esophagitis, esophageal manometry, and pH-impedance before and 6 months after TIF. **RESULTS:** Six months after TIF, the GERD-HRQL and GERD-QUAL scores off-PPI therapy and the number of total and acid pH-impedance refluxes were significantly reduced ($p < 0.05$). The PPI had been completely stopped in 55% of the patient and was reduced in 22% of the patients. **CONCLUSIONS:** At 6-month follow-up, TIF performed using the Esophyx device reduces symptoms and pH-impedance refluxes, allowing interruption or reduction of PPI use in 78% of patients with GERD.

Systemes de suture ou plicature

[World J Surg. 2008 Aug;32\(8\):1676-88.](#)

Antireflux transoral incisionless fundoplication using Esophyx: 12-month results of a prospective multicenter study.

[Cadière GB](#), [Buset M](#), [Muls V](#), [Rajan A](#), [Rösch T](#), [Eckardt AJ](#), [Weerts J](#), [Bastens B](#), [Costamagna G](#), [Marchese M](#), [Louis H](#), [Mana F](#), [Sermon F](#), [Gawlicka AK](#), [Daniel MA](#), [Devière J](#).

Department of Digestive Surgery, Centre Hospitalier Universitaire St. Pierre, 322 rue Haute, Brussels 1000, Belgium. Guy-Bernard_CADIERE@stpierre-bru.be

Comment in:

[World J Surg. 2008 Aug;32\(8\):1578-80.](#)

Abstract

BACKGROUND: A novel transoral incisionless fundoplication (TIF) procedure using the Esophyx system with SerosaFuse fasteners was designed to reconstruct a full-thickness valve at the gastroesophageal junction through tailored delivery of multiple fasteners during a single-device insertion. The safety and efficacy of TIF for treating gastroesophageal reflux disease (GERD) were evaluated in a prospective multicenter trial. **METHODS:** Patients (n = 86) with chronic GERD treated with proton pump inhibitors (PPIs) were enrolled. Exclusion criteria included an irreducible hiatal hernia > 2 cm. **RESULTS:** The TIF procedure (n = 84) reduced all hiatal hernias (n = 49) and constructed valves measuring 4 cm (2-6 cm) and 230 degrees (160 degrees -300 degrees). Serious adverse events consisted of two esophageal perforations upon device insertion and one case of postoperative intraluminal bleeding. Other adverse events were mild and transient. At 12 months, aggregate (n = 79) and stratified Hill grade I tight (n = 21) results showed 73% and 86% of patients with >or=50% improvement in GERD health-related quality of life (HRQL) scores, 85% discontinuation of daily PPI use, and 81% complete cessation of PPIs; 37% and 48% normalization of esophageal acid exposure; 60% and 89% hiatal hernia reduction; and 62% and 80% esophagitis reduction, respectively. More than 50% of patients with Hill grade I tight valves had a normalized cardia circumference. Resting pressure of the lower esophageal sphincter (LES) was improved significantly (p < 0.001), by 53%. Esophyx-TIF cured GERD in 56% of patients based on their symptom reduction and PPI discontinuation. **CONCLUSION:** The 12-month results showed that Esophyx-TIF was safe and effective in improving quality of life and for reducing symptoms, PPI use, hiatal hernia, and esophagitis, as well as increasing the LES resting pressure and normalizing esophageal pH and cardia circumference in chronic GERD patients.

Systemes de suture ou plicature

- Conclusion : The 12-month results showed that EsophyXTIF was safe and effective in improving quality of life and for reducing symptoms, PPI use, hiatal hernia, and esophagitis, as well as increasing the LES resting pressure and normalizing esophageal pH and cardia circumference in chronic GERD patients.

Systemes de suture ou plicature

Surg Endosc (2009) 23:957–964
DOI 10.1007/s00464-009-0384-8

ORIGINAL ARTICLES

Two-year results of a feasibility study on antireflux transoral incisionless fundoplication using EsophyX

Guy-Bernard Cadière · Nathalie Van Sante ·
Jaime E. Graves · Anna K. Gawlicka ·
Amin Rajan

Conclusion The results at 2 years supported the long-term safety and durability of TIF and its sustained effect on the elimination of heartburn, esophagitis, ≤ 2 cm hiatal hernia, and daily dependence on PPIs.

Stretta

Radiofréquence

CURON STRETTA Sunnyvale, CA USA



Radiofréquence

Stretta

Ozawa et al.

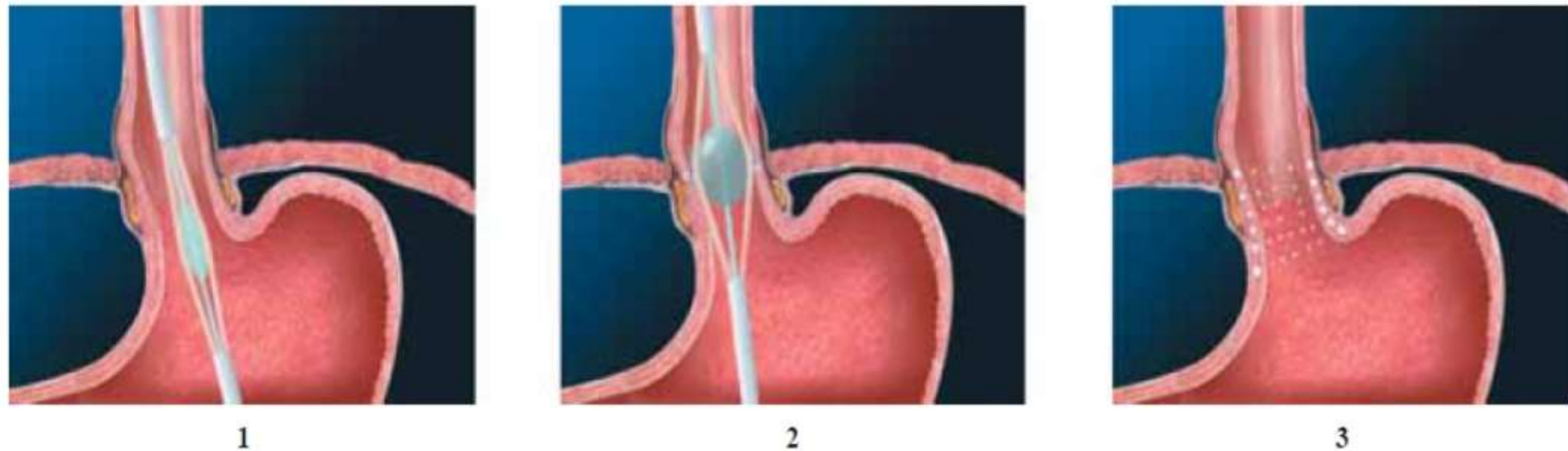


Fig. Stretta procedure.

1: The Stretta® Catheter is guided using a guide wire and inserted into the stomach.

2: RF energy is applied to a total of eight points at a level 1 cm caudal to the Z line.

3: View after the completion of the operation. RF energy is applied to eight points at 4 different levels and at 12 points on 2 different levels for a total of 56 points (Permission for use of these illustrations has been obtained from Curon Medical).

Stretta

Radiofréquence

- Le traitement par Radiofréquence est sans danger, et dure jusqu'à au moins 4 ans

Volume 65, No. 3 : 2007 GASTROINTESTINAL ENDOSCOPY 375

[Gastrointest Endosc. 2007 Mar;65\(3\):367-72.](#)

Sustained improvement in symptoms of GERD and antisecretory drug use: 4-year follow-up of the Stretta procedure.

[Noar MD, Lotti-Emran S.](#)

[Heartburn and Reflux Study Center, Endoscopic Microsurgery Associates, 7402 York Road, Towson, MD 21204, USA.](#)

Comment In:

[Nat Clin Pract Gastroenterol Hepatol. 2007 Dec;4\(12\):654-5.](#)

[Gastrointest Endosc. 2007 Mar;65\(3\):375-6.](#)

[Gastrointest Endosc. 2007 Mar;65\(3\):373-4.](#)

Abstract

BACKGROUND: Approximately 20% of patients with GERD do not respond to medical therapy. The Stretta radiofrequency antireflux procedure represents an alternative to failed drug therapy for GERD. **OBJECTIVE:** The aim of this study was to assess symptom and medication changes after the Stretta procedure during a 4-year follow-up period. **DESIGN:** Prospective case series on intent-to-treat basis. **SETTING:** Community practice. **PATIENTS:** Patients with GERD with persistent symptoms despite twice-daily proton pump inhibitor (PPI) medications. **INTERVENTIONS:** The Stretta procedure was performed in drug-refractory patients with GERD diagnosed by the presence of endoscopically evidenced esophagitis or abnormal esophageal pH testing. Symptom assessment was performed with a validated health-related quality-of-life questionnaire (with and without medication) at baseline and 6, 12, 24, 36, and 48 months after treatment. Complications of the procedure and medication usage were analyzed. **MAIN OUTCOME MEASUREMENTS:** Significant changes in symptom scores, GERD quality-of-life parameters, and medication usage on the basis of clinical outcomes. **RESULTS:** We report on a series of 109 consecutive patients treated with the Stretta procedure who have reached 4-year follow-up. Complete long-term follow-up assessment was available in matched data for 109 patients at 12 months, 108 patients at 24 months, 102 patients at 36 months, and 96 patients at 48 months. A second procedure was performed in 13 patients. Heartburn scores decreased from 3.6 to 1.18 ($P < .001$), total heartburn score (GERD health-related quality-of-life questionnaire) decreased from 27.8 to 7.1 ($P < .001$), and patient satisfaction improved from 1.4 to 3.8 ($P < .001$) (see). Medication usage decreased significantly from 100% of patients on twice-daily PPI therapy at baseline to 75% of patients showing elimination of medications or only as-needed use of antacids/over-the-counter PPIs at 48 months ($P < 0.005$). There were no serious complications of the procedure. **LIMITATIONS:** This is an uncontrolled, nonrandomized case series in consecutive patients that does not include long-term pH or motility studies. **CONCLUSIONS:** This study in drug-refractory patients with GERD found the Stretta procedure to be a safe, effective, and durable treatment that produced significant improvements in heartburn and quality of life and decreased medication usage during a 4-year period of follow-up.

Radiofréquence

Ann. Surg. • May 2003

The New Paradigm

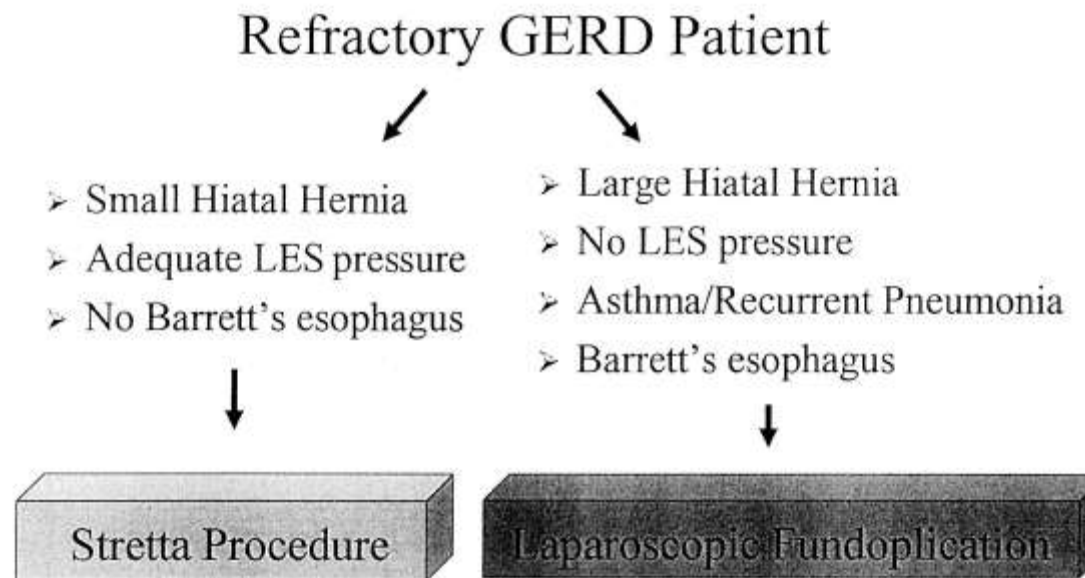


Figure 10. Our proposed paradigm for the surgical treatment of GERD. Patients are stratified to treatment with Stretta or LF according to size of hiatal hernia, LES pressure, and presence or absence of significant pulmonary symptoms or Barrett's esophagus.

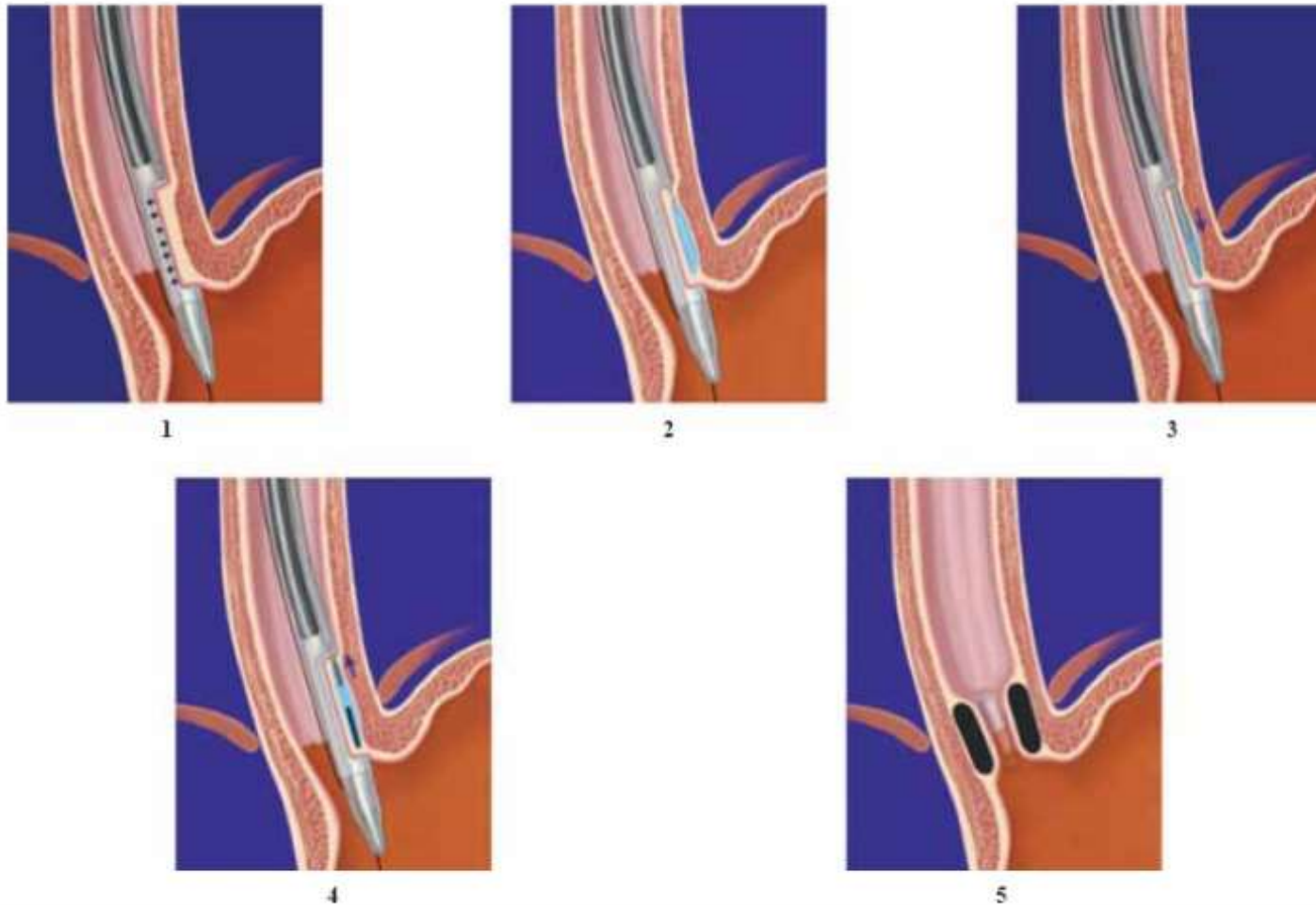
Injections de matériel synthétique inerte

Gatekeeper

Fig. 6. Gatekeeper procedure.

- 1: The esophagus wall is aspirated.
- 2: Normal saline is injected into the submucosal layer.
- 3: A pocket is created in the submucosal layer.
- 4: The HYPAN prosthesis is implanted in the pocket.
- 5: View after the completion of the operation

Ozawa et al.



Injections de matériel synthétique inerte

Gatekeeper

Surg Endosc. 2010 Mar 3. [Epub ahead of print]

Prospective randomized controlled trial of an injectable esophageal prosthesis versus a sham procedure for endoscopic treatment of gastroesophageal reflux disease.

Fockens P, Cohen L, Edmundowicz SA, Binmoeller K, Rothstein RI, Smith D, Lin E, Nickl N, Overholt B, Kahrilas PJ, Vakil N, Abdel Aziz Hassan AM, Lehman GA.

Academic Medical Center, University of Amsterdam, P.O. Box 22700, 1100 DE, Amsterdam, the Netherlands.

Abstract

BACKGROUND: This study aimed to assess whether endoscopic implantation of an injectable esophageal prosthesis, the Gatekeeper Reflux Repair System (GK), is a safe and effective therapy for controlling gastroesophageal reflux disease (GERD). **METHODS:** A prospective, randomized, sham-controlled, single-blinded, international multicenter study planned final enrollment of 204 patients in three groups: up to 60 lead-in, 96 GK, and 48 sham patients. The sham patients were allowed to cross over to the GK treatment arm or exit the study at 6 months. The primary end points were (1) reduction in serious device- and procedure-related adverse device effects compared with a surgical composite complication rate and (2) reduction in heartburn symptoms 6 months after the GK procedure compared with the sham procedure. The secondary end point was improved esophageal pH (total time pH was <4) 6 months after the GK procedure compared with baseline. **RESULTS:** A planned interim analysis was performed after 143 patients were enrolled (25 lead-in, 75 GK, and 43 sham patients), and the GK study was terminated early due to lack of compelling efficacy data. Four reported serious adverse events had occurred (2 perforations, 1 pulmonary infiltrate related to a perforation, and 1 severe chest pain) at termination of the study with no mortality or long-term sequelae. Heartburn symptoms had improved significantly at 6 months compared with baseline in the GK group ($p < 0.0001$) and the sham group ($p < 0.0001$), but no significant between-group difference in improvement was observed ($p = 0.146$). Esophageal acid exposure had improved significantly at 6 months compared with baseline in the GK group ($p = 0.021$) and the sham group ($p = 0.003$), but no significant between-group difference in improvement was observed ($p = 0.27$). **CONCLUSIONS:** The GK procedure was associated with some serious but infrequent complications. No statistically significant difference in outcomes was observed between the treatment and control groups at 6 months compared with baseline.

Injections de matériel synthétique inerte

Enteryx



Fig. 5. Enteryx procedure.
1: Enteryx[®] is infused into the muscular and submucosal layers at a point about 1-2 mm caudal to the Z line.
2: EVOH polymerizes (Permission for use of these illustrations has been obtained from Boston Scientific).

Au total

Endocinch

ESD

Enteryx

Gatekeeper



Stretta

Plicator

Esophyx

Chirurgie vs Endoscopie ?

Endoscopic and laparoscopic treatment of gastroesophageal reflux.

Watson DJ, Immanuel A.

Flinders University Department of Surgery, Flinders Medical Centre, Bedford Park, South Australia 5042, Australia.
david.watson@flinders.edu.au

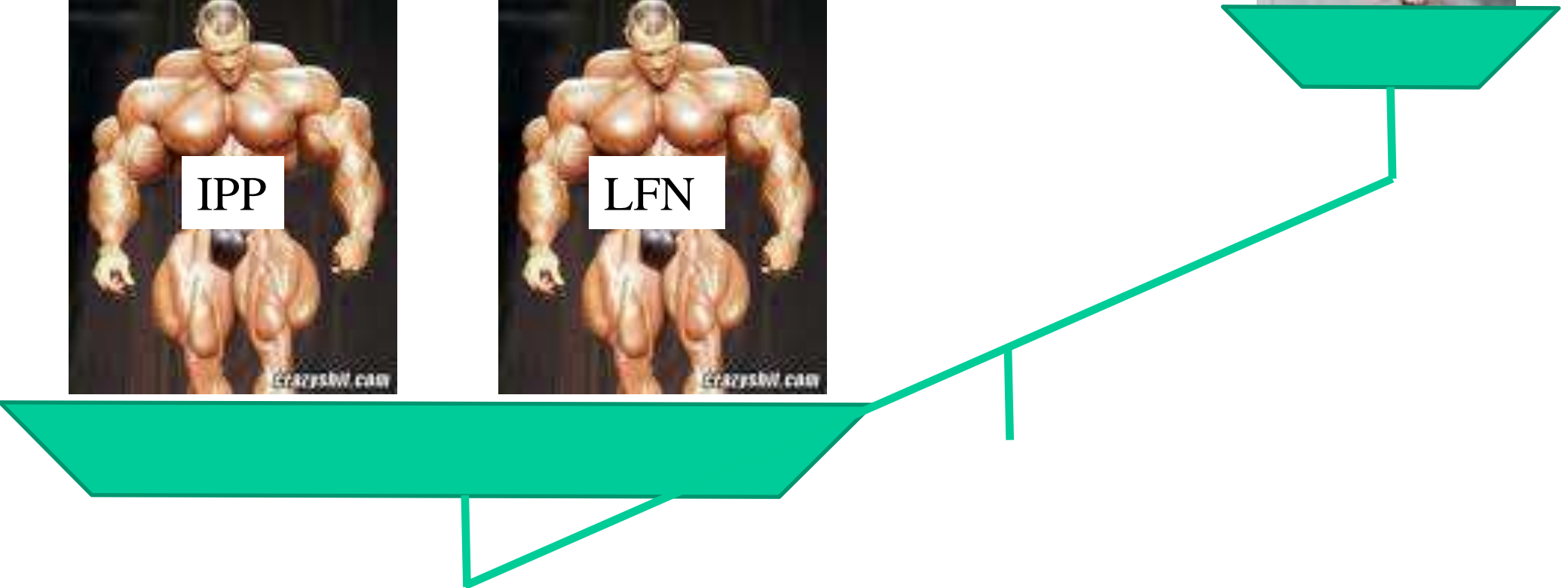
Abstract

Gastroesophageal reflux is extremely common in Western countries. For selected patients, there is an established role for the surgical treatment of reflux, and possibly an emerging role for endoscopic antireflux procedures. Randomized trials have compared medical versus surgical management, laparoscopic versus open surgery and partial versus total funduplications. However, the evidence base for endoscopic procedures is limited to some small sham-controlled studies, and cohort studies with short-term follow-up. Laparoscopic fundoplication has been shown to be an effective antireflux operation. It facilitates quicker convalescence and is associated with fewer complications, but has a similar longer term outcome compared with open antireflux surgery. In most randomized trials, antireflux surgery achieves at least as good control of reflux as medical therapy, and these studies support a wider application of surgery for the treatment of moderate-to-severe reflux. Laparoscopic partial fundoplication is an **effective surgical procedure with fewer side effects**, and it may achieve high rates of patient satisfaction at late follow-up. Many of the early endoscopic antireflux procedures have failed to achieve effective reflux control, and they have been withdrawn from the market. Newer procedures have the potential to fashion a surgical fundoplication. However, at present there is **insufficient evidence to establish the safety and efficacy of endoscopic procedures** for the treatment of gastroesophageal reflux, and no endoscopic procedure has achieved equivalent reflux control to that achieved by surgical fundoplication.

Au total



Endoscopic



CONCLUSION

- At present there is insufficient evidence to determine the safety and efficacy of endoscopic procedures for gastro-oesophageal reflux disease, particularly in the long term.

Br J Surg. 2009 Feb;96(2):128-36.

Systematic review of endoscopic treatments for gastro-oesophageal reflux disease.

[Chen D](#), [Barber C](#), [McLoughlin P](#), [Thavaneswaran P](#), [Jamieson GG](#), [Maddern GJ](#).

Department of Surgery, University of Adelaide and The Queen Elizabeth Hospital, South Australia, Australia.