GERD at all physiologically). Methods: 296 pts (75% female, 91% Caucasian) with either typical (HR/fg), (23%) or extra-esophageal (77%) symptoms complex (cough-38%, chest pain-30%, hoarseness-22%, asthma-5%, post nasal drip 5%) underwent 48 hour Bravo pH monitoring on week off acid suppression therapy. % time pH < 4 (total, upright and supine) were measured. Abnormal reflux was defined as % time pH < 4, total > 5.5%, upright > 8.0% and supine > 3.0%. pH profile as well as demographic data (age, gender, BMI) were compared. Results: 216/296 (73%) pts had abnormal esophageal acid exposure: 92/216 (44%) in both upright and supine positions; 82/216 (38%) in the upright only and 39/216 (18%) in the supine only positions. The median (interquartile) number of reflux events was significantly (p<0.01) higher in pts with upright and supine reflux (86 [59 to106]) than those with supine only 52[37 to 73]) or upright only 62 [43 to 93] reflux pattern. HB and regurgitation were significantly (p=0.03) higher in those with supine only reflux than upright only group. Prevalence of abnormal esophageal acid exposure was similar in those with chief complaint of HR/fg (65%) to those with extra-esophageal symptom's with (54% or 66%) concomitant HR/fg (p=0.3). Conclusions: 1) Reflux disease defined physiologically by abnormal esophageal acid exposure off acid suppressive therapy is common (73%) in pts referred with extra-esophageal symptom's and occurs most commonly in the upright position. 2) The widely held notion that pts with extra-esophageal symptoms without concurrent HR/fgreg are less likely to have reflux should be re-evaluated.

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Long-Term, Safe and Effective Treatment of Gastroesophageal Reflux Disease Using a Sphincter Augmentation Device

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BACKGROUND: We have previously demonstrated that laparoscopic placement of the LINX™ biprostheses (Torax Medical, Shoreview, MN), at the gastroesophageal junction (GEJ), provides safe and effective GERD therapy on a short-term basis [J Gastrointest Surg 2009; 13:241-246]. We now extend those observations to 2 year follow-up. METHODS: The LINX device is a series of linked titanium beads with magnetic cores, placed laparoscopically around the GEJ in the z-line. The magnetic bond between adjacent beads augments the lower esophageal sphincter, restoring its barrier function and preventing reflux. With swallowing, belching or vomiting the beads separate to allow bolus, air or fluid transfer across the sphincter. Moreover, magnetic forces are permanent and never decay. PPI-responsive GERD patients with normal pH scores, hiatal hernias (HH; 3 cm or less), and esophagitis scores up to LA grade 8 were enrolled and implanted with the LINX device. GERD-HRQL scores, eradication of HH, PPI usage, esophageal clearance time (ECT), and CXRs were obtained at baseline, and monitored over 24 months. RESULTS: To date 44 patients (mean age 42.8) have been implanted, with a median duration of 745 days in (range 226-994 days). 39 patients have completed follow-up at 1 year and data is available for 7 patients at 2 years. There were no intra-operative complications and hernias were repaired in only 11% of patients. There have been no erosions or no migration of the device. Mild dysphagia was present in the initial post-op period, but resolved in 91% of patients by 6 months. The device was removed uneventfully in 2 patients: one due to persistent dysphagia and the other for a MR study. Mean % time pH < 4 improved from 11% (range 3-28%) (p = 0.001) and DeMeester score improved from 31.7 to 8.0 (p = 0.003). 28/39 patients (72%) had normal pH scores at 1 year. Median GERD-HRQL scores improved from 26 at baseline to 3.0 at 1 year and 1.0 at 2 years. Endoscopy, barium swallows, and CXRs demonstrated uniform device stability at 1 year with no device-related mucosal injury. Concomitant use of PPI use was reduced from 87% at 1 year to 7% at 2 years. Patients reported the ability to belch and vomit. CONCLUSIONS: Restoration of the reflux barrier using the LINX device appears to be a safe, effective, minimally-invasive, long-term GERD therapy. Objective pH scores demonstrate effective acid neutralization and the long-term side effects commonly seen with Nissen fundoplication. The procedure is reversible and preserves the ability to belch and vomit. A large multi-center pivotal trial is currently underway.