Purpose: A novel full-thickness plication device (Plicator, NDO Surgical, Inc., Mansfield, MA) has been designed to inhibit gastroesophageal reflux by placing a transmural plication near the gastroesophageal (GE) junction under direct endoscopic visualization. The resulting serosa-to-serosa tissue union appears to accentuate and restore the valvular mechanism of the gastroesophageal junction. The purpose of this study was to assess the safety and efficacy of a novel endoscopic full-thickness plication device for the treatment of patients with symptomatic GERD.

Methods: Patients with chronic heartburn and pathologic reflux requiring maintenance anti-secretory therapy were recruited. Patients with large hiatal hernias (> 2cm), grades III and IV esophagitis, and Barrett’s esophagus were excluded. The following were assessed at baseline (on and off-meds) and 1-year post-plication: GERD-HRQL, GRSRS, SF-36 questionnaires, and medication use. Additionally, 24-hr pH-metry and manometry were measured at baseline, three-months (pH/manometry) and six-months (pH only) post-plication. All patients received a single, endoscopic full-thickness plication in the gastric cardia within 2cm of the GE junction.

Results: Sixty-four patients (mean age 46.3, range 23–71) underwent endoscopic full-thickness plication (mean procedure time = 17.2 min). No re-treatments were performed. One year post-plication (n = 56), median off-meds GERD-HRQL scores improved 65% (19.0 vs. 6.0) and were superior when compared to patients’ baseline on-meds HRQL scores (13.0 vs. 6.0). In 24-hour pH-metry studies conducted at six-months post-procedure (n = 35), median % time pH < 4 decreased 31% with 30% of patients experiencing a normalization of pH at 6-months. No significant change in esophageal manometry was noted. Upon entry, 59/64 patients required daily proton-pump inhibitor therapy. At one-year post-procedure, 37/53 patients (70%) remained off daily PPI therapy. The most common adverse event was sore throat (41%), spontaneously resolving within several days post-procedure. A complete adverse event profile will be discussed.

Conclusions: In this study, a single full-thickness plication placed at the GE junction reduced symptoms, medication use and esophageal acid exposure associated with GERD.

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VERRUUCOUS CARCINOMA OF THE ESOPHAGUS: A WOLF IN SHEEP’S CLOTHING

Purpose: Fifteen cases of verrucous carcinoma of the esophagus have been reported in the English literature. It is a slow growing epidermoid neoplasm that is most commonly found in the oral cavity, larynx, and genitalia. It is indolent and associated with a high mortality. Discrepancy between its clinical and histologic character often leads to delayed diagnosis. We present a typical case to emphasize that a high index of suspicion is the key to proper diagnosis and treatment.

A forty-three year old man presented to the ER with two months of solid food dysphagia, heartburn, and a twenty pound weight loss. He drank a six-pack of beer daily and had a 40 pack/year tobacco habit. No significant physical findings were noted. HIV serology was negative. A barium esophagram demonstrated a markedly abnormal mucosa in the distal third, consistent with an inflammatory process.

When he finally presented to the GI clinic, three months later, the dysphagia had progressed such that any solid food per os was forcibly regurgitated. At endoscopy, the distal third of the esophagus appeared circumferentially encrusted with a shaggy, whitish plaque extending to the GEJ. The pathology report showed only mild acute and chronic inflammation. The patient was lost to follow-up.

Seven months following his initial presentation, his dysphagia had marginally improved. He underwent endoscopy with brush biopsy. There was no endoscopic improvement and the histology was notable only for poorly-preserved and highly atypical squamous cells. The discrepancy between the histologic findings and the clinical signs was debated and ultimately led to a third EGD. The pathology from the third investigation was more distinctive showing hyperkeratotic verrucous squamous mucosa suggestive of squamous papilloma (spike form) with pseudoepitheliomatous hyperplasia. The abruptly more redolent histologic description suggested sampling error. The pathology related to the fourth endoscopy, in the 11th month, was similarly benign. Nonetheless, the patient was referred to surgery and received a complete esophagectomy which showed well-differentiated, invasive carcinoma.

Routine endoscopic biopsy is frequently inadequate to make the diagnosis of verrucous carcinoma of the esophagus due to its benign appearance and well differentiated histology. A high index of suspicion and close clinical follow-up are vital for making an early diagnosis. EUS is likely to contribute substantially to making the diagnosis earlier and perhaps will have impact on survival.

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ESOPHAGEAL FUNCTION TESTING USING BOTH LIQUID AND VISCOUS SUBSTANCES: PROVIDES GREATER POTENTIAL TO DETECT ABNORMALITIES
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Purpose: Traditional esophageal function testing includes esophageal manometry using liquid (water) swallows. Adding viscous (semisolid) swallows as part of esophageal manometry may provide additional information similar to the “modified” barium swallow.

Methods: We have prospectively performed esophageal function testing using 10 liquid and 10 viscous swallows (5ml each) in 341 consecutive patients referred to our laboratory. Studies were reported manometrically normal for either liquid or viscous test substances if there were no more than 20% ineffective and 10% simultaneous swallows, the lower esophageal sphincter (LES) had normal residual pressure during relaxations and distal esophageal amplitude did not exceed 180 mmHg.

Results: 217 patients had an abnormal test result for liquid swallows. Similarly, 242 had abnormal viscous swallows. However, disparate results were found in 3 studies. From the 124 normal studies for liquid swallows 85 (69%) satisfied normality criteria for viscous swallows. From the remaining studies 21 were classified as showing ineffective esophageal motility (IEM), 10 as poorly relaxing LES, 7 distal esophageal spasm and one nutcracker esophagus for viscous swallows. On the other hand 14 abnormal studies for liquid swallows (6 IEM, 4 nutcracker esophagus, 1 DES, 3 poorly relaxing LES) fulfilled normality criteria for viscous swallows.

<table>
<thead>
<tr>
<th></th>
<th>Normal liquid</th>
<th>Abnormal liquid</th>
<th>Total</th>
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<tbody>
<tr>
<td>normal viscous</td>
<td>85</td>
<td>14</td>
<td>99</td>
</tr>
<tr>
<td>abnormal viscous</td>
<td>39</td>
<td>203</td>
<td>242</td>
</tr>
<tr>
<td>Total</td>
<td>124</td>
<td>217</td>
<td>341</td>
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Conclusions: Adding viscous swallows to traditional water swallows may increase the sensitivity of manometry to detect abnormal esophageal motility. Outcome studies are required to assess the value of the additional information provided by viscous swallows.

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SALIVARY PROTECTIVE POTENTIAL IS SIGNIFICANTLY ENHANCED BY STIMULATION INDUCED BOTH BY MASTICATION AND ESOPHAGO-SALIVARY REFLEX: ITS CLINICAL SIGNIFICANCE
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Protective factors during stimulation significantly affect gastroesophageal reflux. Potency and could be pivotal in the combat of injurious potential of the esophagus. EGF, TGF, and other factors were found between salivary volume and BIC, NBIC, protein, glycoconjugate, and pH. 

Results: 

(Sigma-Stat, SPSS Inc., CA) was assessed using Sigma-Stat software. The study was conducted on 33 asymptomatic volunteers. EGF, TGF, and PGE2 were measured by back-titration using TitraLab 900 (Radiometer Am. Inc., OH), protein by Lowry, glycoconjugate by PAS, EGF, TGF, and PGE2 by radioimmunoassay (Amersham, IL). Spearman correlation coefficient was assessed using Sigma-Stat (SPSS Inc. CA) software.

**Results:**

In basal conditions, only the rate of secretion of salivary protein correlated with salivary volume (P<0.01). In saliva stimulated by mastication or esophago-salivary reflex, statistically significant correlation was found between salivary volume and BIC, NBIC, protein, glycoconjugate, and pH. Spearman correlation coefficient was assessed using Sigma-Stat (SPSS Inc. CA) software.

Conclusions: 1. The increased rate of secretion of salivary protective factors during stimulation significantly augments its defensive potency and could be pivotal in the combat of injurious potential of the esophagopharynx. 2. Salivary PGE2 is less likely to contribute to salivary esophagoprotection.

### 56 INTRASUBJECT PHYSIOLOGIC VARIABILITY IN 24 HOUR ESOPHAGEAL ACID EXPOSURE

**Purpose:** The accuracy and reliability of the measurement of esophageal acid exposure has become important in clinical practice and in research in the diagnosis and management of GERD. The hypothesis of many studies rests on the assumption that esophageal acid exposure within a patient is a constant measurable value. This study is a retrospective evaluation of multiple esophageal pH recordings in untreated heartburn subjects.

**Methods:** 24 hr pH tracings from subjects who had undergone multiple pH monitoring tests were evaluated. Subjects with at least three tracings performed on separate occasions were evaluated for total esophageal acid exposure (% time pH < 4, ACT), mean esophageal pH, and mean gastric pH. Three pH tracings were randomly chosen for analyses for subjects with at least three tracings. Values representing mean % time pH < 4 were calculated for each subject, as well as the corresponding gastric pH. Regression analyses were performed between mACT, mEpH, and mGpH vs their respective %STD (p<0.05 level of significance).

**Results:** 33 subjects were identified (99 total tracings). mACT was 11.6 ± 5.4; the mean %STD for ACT was 46%. mEpH was 5.6 ± 0.3; the %STD for esophageal pH was 6.8%. mGpH was 2.0 ± 0.4; the %STD for gastric pH was 23.9%. The %STD was unrelated to ACT (R = 0.08; p = 0.05), mEpH (R=0.13; p=0.05), or mGpH (R=0.19; p=0.05). Based on %STD, variations within 24 hour pH data rank as follows: esophageal pH < gastric pH < ACT.

Conclusions: 1. There is huge physiologic variation in esophageal acid contact time within a patient with repeated pH tests; however, the variation from the mean was not influenced by amount of acid exposure or secretion.

2. Gastric pH varies considerably, but less than ACT. 3. Multiple factors contribute to acid reflux. 4. The physiologic variation in gastric and esophageal pH provides useful data for determining power calculations for studies with multiple 24 hour pH tests.

### 57 BARRETT’S SURVEILLANCE PER THE ACG GUIDELINES, DO WE REALLY DO WHAT THEY SAY?

**Purpose:** To determine compliance with standards, biopsy reports for BE from the pathology reports from 3 health care systems — 2 community and 1 academic based.

**Methods:** A retrospective review of consecutive BE (excluding short segment) pathology reports were reviewed. Compliance with the recommended number of biopsy specimens per level, distance between levels and surveillance intervals were assessed relative to the presence/degree of dysplasia.

**Results:** 160 cases were reviewed. Compliance was assessed according to time interval and to adherence to the recommended (4 quadrant) number of biopsies.

Compliance was assessed at Site 1, Site 2, Site 3 and listed below respectively:

**Time interval:** 77%, 58% and 40%.

**Biopsy number:** 14%, 32% and 98%.

Greatest disparity was seen in the variance for number of biopsies done, although adherence to recommended surveillance interval was extremely variable also. There was no difference in compliance relative to the degree of dysplasia. A trend analysis did not show any changes in practice patterns from the 1998 to the updated 2002 guidelines.

Conclusions:

1. There is an alarming disparity of compliance with recommended biopsy number and intervals for surveillance in both community based and academic practice.

2. Guideline application can be based only on parallel patterns of practice.

3. Application of the ACG guidelines to practice may be inappropriate unless similar standards of biopsy technique and surveillance are adopted by clinicians.

### 58 PATIENTS WITH BARRETT’S ESOPHAGUS GREATLY OVER-ESTIMATE THEIR CANCER RISK

**Purpose:** Subjects with Barrett’s esophagus (BE) have a risk of esophageal adenocarcinoma of approximately 0.5% per year. Patients may have difficulty understanding this risk, leading to an over-estimation, with changes in healthcare related behaviors as a result. The aim of this study was to assess the perceived risk of cancer in subjects with BE.

**Methods:** We performed a survey of subjects with BE in two North Carolina sites, a University teaching hospital and a Veteran’s Administration (VA) hospital. Using a previously-validated tool assessing risk perception for small risks, we asked subjects to rate their perceived risk of developing cancer in their BE in both the next year, as well as over their entire lifetime. The questionnaire also elicited their demographics as well as their sources of health information. Healthcare behaviors, including endoscopic surveillance behaviors and other healthcare screening behaviors, were assessed.