**CLINICAL STUDY SERIES**

**Prevention of Esophagopharyngeal Reflux By Augmenting The Upper Esophageal Sphincter (UES) Pressure Barrier**

**AIM**
Demonstrate that reflux events can be prevented by application of slight external pressure at the cricoid.

**METHODS**
Fourteen (14) subjects with clinically established extra-esophageal reflux and 12 healthy volunteers were studied. All underwent intra-esophageal slow infusion to induce reflux. Concurrent pharyngoscopic and manometric measurements were performed for all subjects to determine the presence of reflux. Measurements were performed with and without externally applied pressure at the cricoid.

Evaluated both manual and device assisted external pressure at the cricoid for the effectiveness of preventing reflux from going above the UES.

**RESULTS**

- **Figure 1: Esophagopharyngeal Reflux**
  - Without UES Assist Device: 9/13
  - With UES Assist Device: 16/39
  - $p < 0.0001$

- **Figure 2: Sensation of Regurgitation**
  - Without UES Assist Device: 1/13
  - With UES Assist Device: 1/39
  - $p < 0.01$

- Objectively verified reflux events above the UES were significantly reduced when the UES Assist Device was in place (Figure 1) when measured by both the number of subjects as well as by the number of infusions (Figure 1).

- All reflux subjects reported the sensation of regurgitation without the UES Assist Device, but was significantly reduced with the device in place (Figure 2).

---

RESULTS

- Established that there was a direct relationship between applied external pressure and measured intraluminal pressure (Figure 3).
- There was a significant sustained increase in UES intraluminal pressure of 21(±9) mmHg and 26(±10) mmHg in healthy and reflux subjects, respectively (p<0.001) over baseline (Figure 4).

CONCLUSIONS
1. An external pressure applied at the cricoid of 20 to 30 mmHg prevents reflux above the UES.
2. Application of cricoid pressure augments the UES intraluminal pressure.
3. Pressure at the cricoid significantly reduces the sensation of regurgitation.
4. The slow infusion technique was shown to uncover UES incompetence.

NOTE: The Reflux Band™ was formerly known as the Reza Band®