

# Clinical Study Review

**Study Name:** Objective Evidence Demonstrating the Significant Reduction of Extraesophageal Reflux Events with the Reza Band® UES Assist Device

**In Short:** Esophagopharyngeal reflux can be prevented by augmenting the upper esophageal sphincter

**Objective or Subjective (Patient Centric)?** Objective

## Key Physicians Involved:

Medical College of Wisconsin (Gastroenterology) – Reza Shaker MD, Arash Babaei MD

## Study Objective

Determine the presence of induced extraesophageal reflux events with and without the Reza Band, as objectively measured by pharyngeal pH and impedance.

## Methods

**pH, impedance and infusion catheter:** Combined catheter assembly of pH and impedance (outer diameter 4.22 mm) and an infusion catheter (outer diameter 2.44 mm) were nasally placed through one nostril of each subject. The catheter contained 18 impedance sensors spaced 2 cm apart, measuring at a sampling rate of 40 Hz. The catheter was positioned such that at least five pressure sensors were in the pharynx. The infusion port was placed in the distal third of the esophagus and the site was confirmed by the impedance signature of rapid air injection in the distal esophagus in the upright position.

**Infusions:** Each subject underwent multiple acidic infusions. Some had more than others, so the number of subjects and the number of infusions with and without the Reza Band in place are not always equal. Evaluated the pH and impedance changes by the number of infusions and by the number of subjects.

## Subject Group Size/Demographic, Single or Multi-Centered

- 12 subjects with extraesophageal reflux and 7 healthy subjects were tested. The reflux subjects were on long-term acid reducing drugs, complained of persistent regurgitation and extraesophageal symptoms. The healthy subjects had no reflux and were not on any acid reducing drugs.
- Single center

## Timeline

This was an acute study conducted in the lab. The subjects were tested over a few hours and their participation ended.

## Results

Significant reduction of reflux events when the Reza Band was in place when measured by both pH and impedance for the reflux subjects

- pH Change:  $p = 0.0094$
- Impedance Change  $p < 0.0001$
- There were no pH or impedance changes in healthy subjects, with or without the Reza Band in place. This is expected as a healthy UES stops reflux.
- pH drop occurred 91.3% of the time when Reza Band NOT in place and 34.9% when it was in place.
- Impedance drop occurred 66.7% of the time when the Reza Band was NOT in place and 23.2% when it was in place.

## Conclusions

When external pressure of 20-30 mmHg is applied to the cricoid, pH and impedance drops are significantly reduced or totally eliminated, therefore reflux into the pharynx and lungs, is prevented.

## Key Terms and Definitions

**Catheter** – Tubular, flexible instrument passed through body channels

**Concurrent** – Happening at the same time

**HCl** – Hydrochloric acid. A normal component of gastric juice

**Impedance monitoring** – Measures changes in resistance of electrical current in the esophagus when a bolus passes by sensors on a catheter. The bolus will lower the impedance. The impedance stays low when the bolus is present and returns to the higher value when the bolus is gone. Measuring impedance in multiple places in the esophagus shows the direction the bolus is moving. Combined with manometry and pH, impedance provides information about pressure, level of acidity and the direction of bolus movement in the esophagus. Impedance can detect acid and non-acid reflux.

**Intraluminal** – Inside a tube, like the esophagus

**pH testing** – A measure of the acidity of a liquid. One method used to measure if reflux happened or not.

**pH drop** – When pH goes down, it means that there is a stronger acid and reflux is present.

**Impedance drop** – When impedance goes down, that means something is present to interfere with the electrical current inside the esophagus (i.e., reflux).

## Customer Summary

pH or impedance drops are significantly reduced or totally eliminated by the application of external pressure (20-30mmHg) at the cricoid region of the neck, resulting in highly significant improvement of symptoms.

## FAQ

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**How did you come to the trial size/why not more subjects?** The study was conducted by MCW and they studied subjects that were available within their GI practice that met the inclusion and exclusion criteria. Also, some of the subjects in this study were also included in the direct endoscopic visualization study, but not all subjects participated in both studies. There was some overlap.

**How were the subjects diagnosed with EERD?** It was determined by the patient's history of office visits, medical management and various in- and out-patient testing.

**The testing was done when the subjects were awake. What is the impact if the subjects were sleeping?** This study was done in the lab to show "proof of principle" in that applied pressure at the cricoid stops reflux. The studies that followed showed that the applied pressure was the same, lying down or sitting up and that the RB provided significant improvement while sleeping.

**Why would any of the subjects wearing the Reza Band in place still have a pH or impedance drop?** As with any clinical study, there is never 100% "success". The important point is not that there was a single reflux event when the Reza Band was in place, but when the Reza Band in place, there is a huge (significant) reduction in reflux events, clearly showing that applied pressure stops reflux.

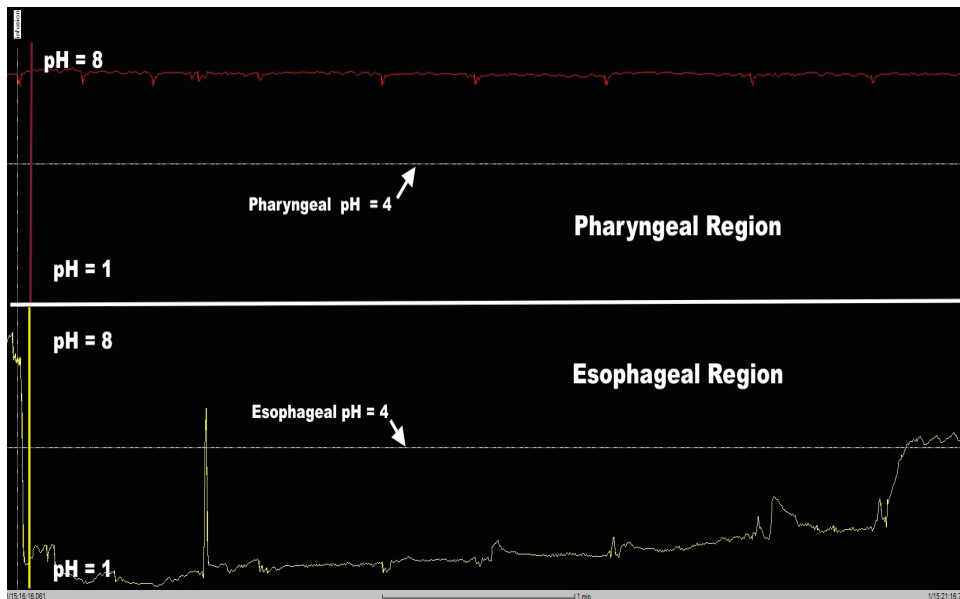
**Why did they look at the results by the number of infusions and the number of subjects?** Since the numbers were not even, looking at it in 2 ways it can sometimes reveal important points. In this study, no matter how you looked at it, the presence of the Reza Band significantly reduced the reflux coming into the throat, which means less reflux into the lungs.

**Why are there fewer healthy subjects than reflux subjects?** Once the study got started, it became clear that even after a few subjects, there would be no reflux with or without the Reza Band. Since the testing is uncomfortable, they decided that they did not need to have more healthy subjects in the study.

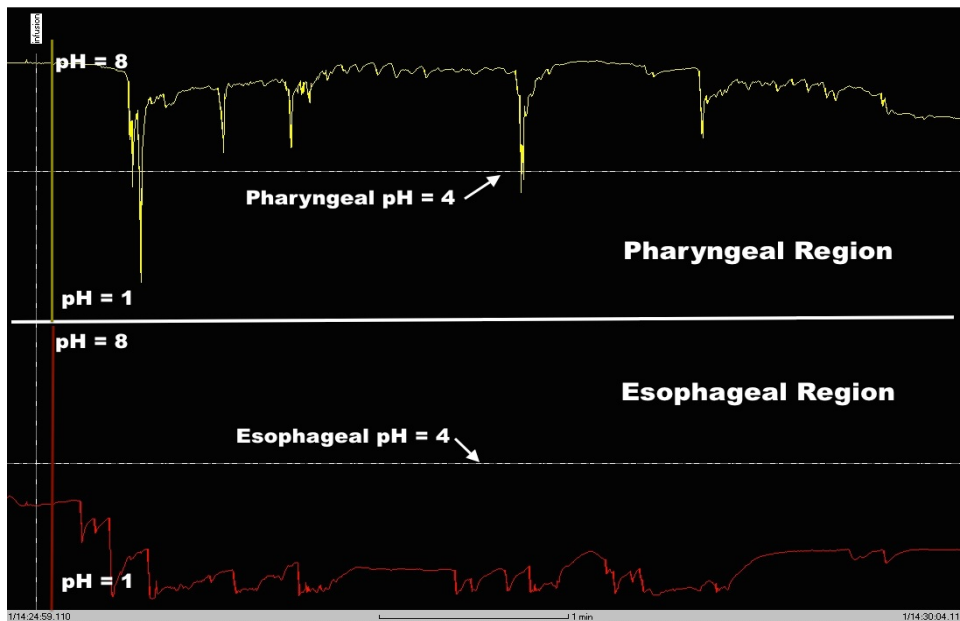
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	# of Infusions	LOW pH	%
WITHOUT Reza Band	69	16	23.2%
WITH Reza Band	43	2	4.7%
p-Value	0.0094		

	# of Infusions	LOW Impedance	%
WITHOUT Reza Band	63	29	46.0%
WITH Reza Band	43	2	4.7%
p-Value	<0.0001		



WITH the Reza Band in Place



WITHOUT the Reza Band in Place