

CLINICAL STUDY SERIES

Objective Evidence Demonstrating the Significant Reduction of Extraesophageal Reflux Events with the Reflux Band™ UES Assist Device*

AIM

Determine the presence of induced extraesophageal reflux events with and without the Reflux Band™ UES Assist Device, as objectively measured by direct trans-nasal pharyngoscopic visualization, pharyngeal pH and pharyngeal impedance.

METHODS

- Twelve (12) subjects with clinically established extraesophageal reflux and 7 healthy volunteers were studied.
- Slow infusion (1ml/sec) of green colored HCl (0.1 N) was used to simulate refluxate.
- Pharyngeal pH events (defined as a drop of >3 pH units and lasting > than 3 seconds) and pharyngeal impedance changes were recorded.
- The 12 subjects with a dysfunctional UES and the 7 healthy subjects underwent 69 and 21 slow infusions, respectively.
- pH and impedance tracings were synchronized with trans-nasal pharyngoscopic visualization.

	Number of Infusions	Incidence of Reflux (Low pH)	%
Without Reflux Band™	69	16	23.2%
With Reflux Band™	43	2	4.7%
p-Value	0.0094		

Table 1

	Number of Infusions	Incidence of Reflux (Reduced Impedance)	%
Without Reflux Band™	63	29	46.0%
With Reflux Band™	43	2	4.7%
p-Value	<0.0001		

Table 2

RESULTS

- There was a significant reduction of reflux events, as measured by pharyngeal pH, when the Reflux Band™ UES Assist Device was present (Table 1).
- When measuring the change in pharyngeal impedance, it was also seen that reflux events were significantly reduced when the Reflux Band™ UES Assist Device was in place (Table 2).
- Trans-nasal pharyngoscopic visualization clearly showed reduction of reflux for UES compromised subjects with and without the Reflux Band™ UES Assist Device in place. Figure 1 is with the Reflux Band™ UES Assist Device in place.

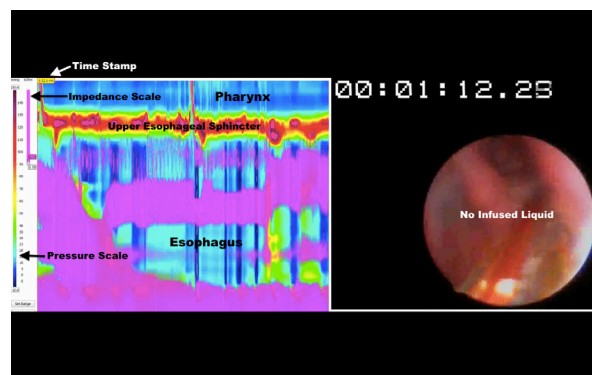


Figure 1: With Reflux Band™ UES Assist Device in place

Continued ...

*Data on file.

RESULTS, continued

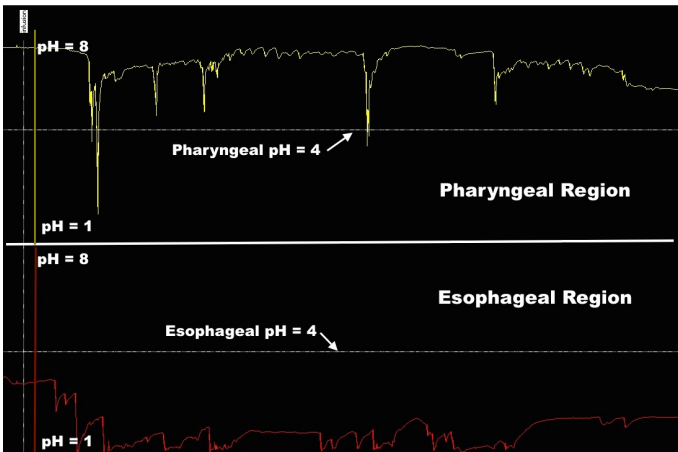


Figure 2: Without the Reflux Band™ UES Assist Device

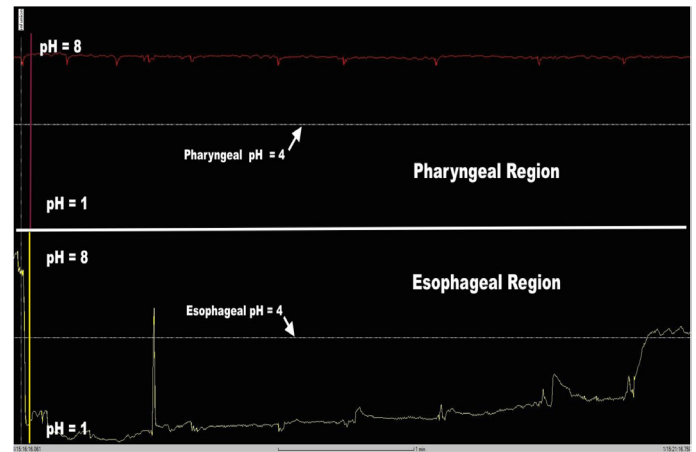


Figure 3: With Reflux Band™ UES Assist Device

- The changes in pH demonstrated that the presence of the infused reflux was significantly reduced when the Reflux Band™ UES Assist Device was in place can be seen Figures 2 and 3.

CONCLUSIONS

- Trans-nasal pharyngoscopic visualization, pH and impedance tracings all confirm a significant reduction in reflux events with the Reflux Band™ UES Assist Device in place.
- The Reflux Band™ UES Assist Device is safe, as there were no adverse events or complications observed during the study.
- The Reflux Band™ UES Assist Device allows the compromised UES to function normally.

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

RefluxBand™

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