REZA BAND®
UES Assist Device

CLINICAL STUDY SERIES

Prospective Study Of The REZA BAND® Upper Esophageal Sphincter Assist Device for Treating Extraesophageal Reflux*

AIM

Multicenter prospective study assessing safety and effectiveness of the REZA BAND® UES Assist Device to treat symptoms due to the reflux of gastric contents into the throat and lungs.

METHODS

- Five investigational sites of Otolaryngologists (OT) and Gastroenterologists (GI) in the US enrolled subjects into the study.
- Ninety-five (95) subjects that met inclusion and exclusion criteria and had an Reflux Symptom Index (RSI) score >13 were enrolled, with 89 subjects completing the study.
- Primary effectiveness endpoint was reduction of the RSI score at 4-weeks compared to the RSI score at baseline.
- Success was defined as a 25% reduction of the final RSI score.
- Safety was evaluated by the rate of occurrence, duration and severity of reported adverse events.
- Subjects kept daily diaries throughout the study.

	All N = 95	OT N = 44	GI N = 51
Hoarseness	14.8%	20.5%	9.8%
Throat Clearing	23.2%	34.1%	13.7%
Post Nasal Drip	28.4%	40.9%	17.7%
Difficulty Swallowing	8.4%	11.4%	5.9%
Coughing After Eating	7.4%	9.1%	5.9%
Breathing Difficulties	9.5%	13.6%	5.9%
Troublesome Cough	36.8%	47.7%	27.5%
Lump in Throat	9.5%	13.6%	5.9%
Heartburn	8.4%	9.1%	7.8%

Table 1:
Common Troublesome Reflux Symptoms

	All N = 95	OT N = 44	GI N = 51	p-Value
% RSI Improvement	**54.2%**	**58.1%**	**49.8%**	**0.1317**
% Successful (>25% Improvement)	85.2%	88.1%	82.6%	0.2534
Patient Satisfied	82.8%	85.4%	80.4%	0.1828
Physician Satisfied	94.3%	100.0%	89.1%	0.8743

Table 2:
RSI and Satisfaction Scores

RESULTS

- The 95 subjects reported a mean age of 48.8, a mean BMI of 25.5; 69.5% were female, and 81.1% were Caucasian.
- Most common troublesome symptoms included chronic cough, 36.8% and excess mucus/post nasal drip, 28.4% (Table 1).
- There was a significant ($p<0.0001$) improvement in the RSI score at 2 weeks.
- The RSI scores were sustained and were also significantly ($p<0.0001$) improved at 4 weeks (Figure 1).
- Both OT and GI had same significant RSI improvements (Table 2).

Continued ...

*Data on file.

RESULTS, continued

- Eighty-two percent (82%) of the subjects reported an improvement of greater than 25%.
- Over thirty percent (30.1%) had an improvement of their RSI score of 75% or more.
- Adverse events were generally mild and transient with no study withdrawals due to those events.
- All demographic groups had the same significant RSI score improvement and safety profile.
- Eighty-three percent of patients and 95% of physicians reported satisfaction with the REZA BAND® UES Assist Device.

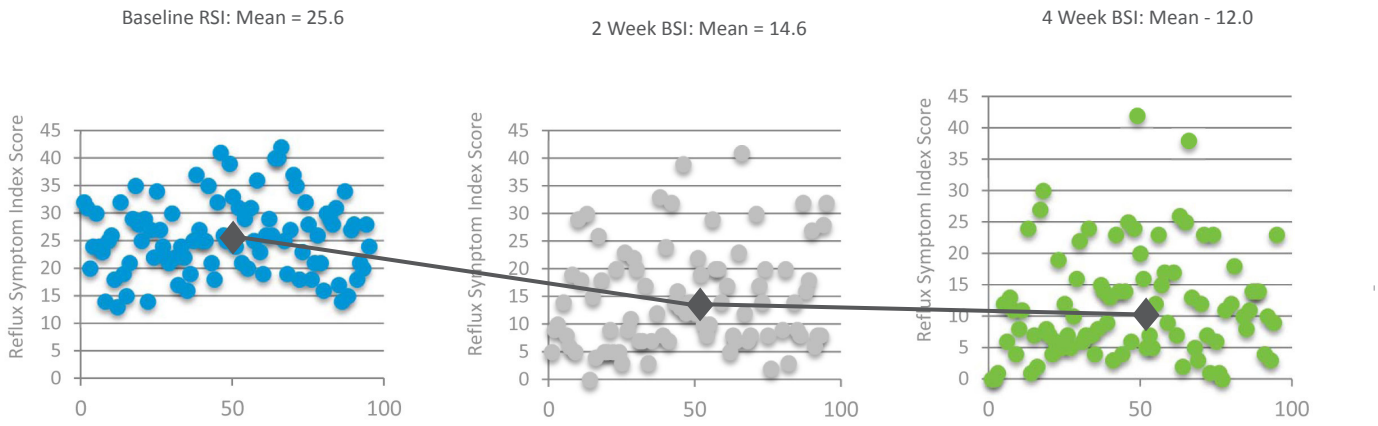

Figure 1:
Reflux Symptom Index Scores

CONCLUSIONS

- The REZA BAND® UES Assist Device is safe and effective for treating symptoms in the patient population that presents with reflux into the throat and lungs.
- All patient and physician groups demonstrated the same significant RSI reduction, safety results and patent and physician satisfaction.
- Given poor response to PPI therapy in many, the REZA BAND® UES Assist Device may be an alternative to treating this difficult group of patients.

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