

## CLINICAL STUDY SERIES

# Correlation of Externally Applied Cricoid Pressure to Intraluminal Pressure\*

### AIMS

Determine the relationship between externally applied cricoid pressure and resulting intraluminal pressure at the UES.  
Determine the effect of the Somna Therapeutics External Manometer on intraluminal pressure.

### METHODS

- Seven (7) subjects with clinically established extraesophageal reflux and 7 healthy volunteers were studied.
- External pressure was applied manually and with the Reflux Band™ UES Assist Device at 10 to 50 mmHg in upright and supine positions.
- Intraluminal pressure measured 3 times with solid-state circumferential manometry catheter and externally with the Somna External Manometer.
- Both the nadir and the average UES pressure were determined.
- Measured intraluminal pressure with and without the Pressure Sensor in place.

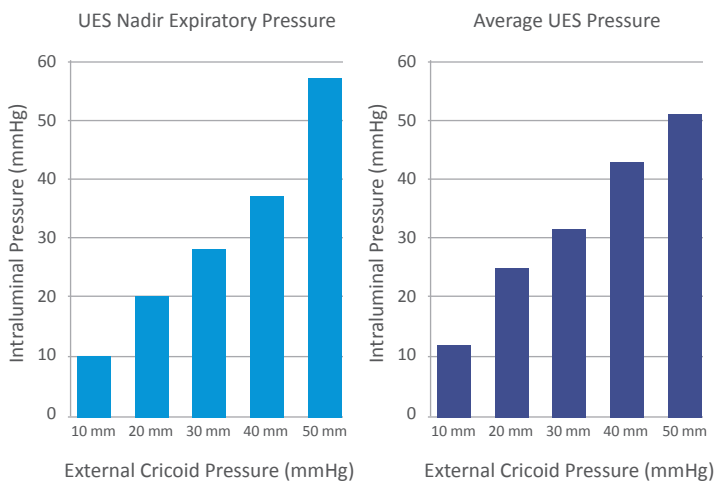


Figure 1: Reflux Band™ Applied Pressure

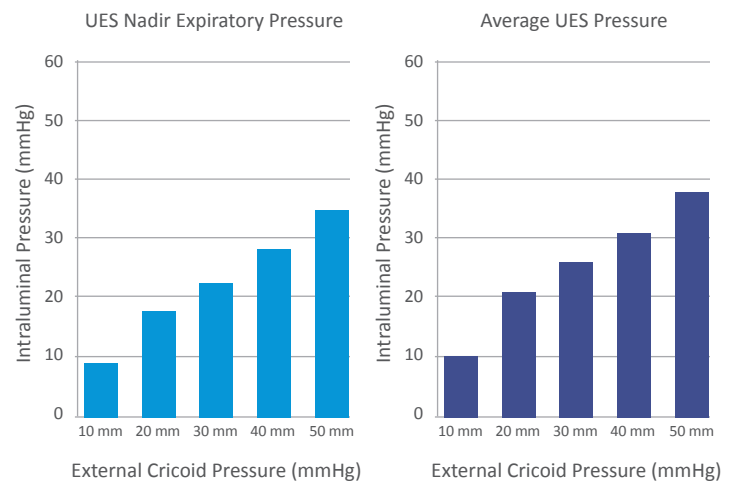


Figure 2: Manually Applied Pressure

### RESULTS

- Fourteen (14) subjects reported a mean age (SD) of 59 (21) years old, a mean BMI (SD) of 28.9 (5.5) and a mean neck circumference (SD) of 14.7 (1.0)".
- There were no adverse events or complications reported.
- Pressure applied by the Reflux Band™ was highly correlated to the intraluminal pressure at the UES (Figure 1).
- The externally applied manual pressure was highly correlated to the intraluminal pressure at the UES (Figure 2).

Continued ...

\*Data on file.

## RESULTS, continued

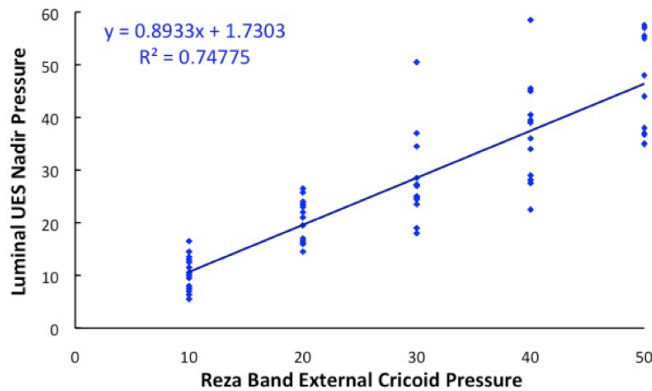


Figure 3: Reflux Band™ Applied Pressure—  
Correlation to Intraluminal Pressure

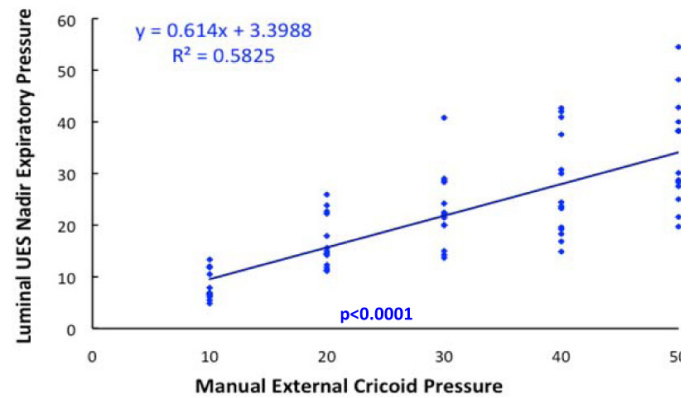


Figure 4: Manually Applied Pressure—  
Correlation to Intraluminal Pressure

## RESULTS

- The Reflux Band™, as well as manually applied pressure, were highly correlated for both the nadir and the average intraluminal pressure.
- Externally applied pressure for both the upright and supine positions for the Reflux Band™ and the manual technique were highly correlated to the intraluminal pressure (Figures 3 and 4).

## CONCLUSIONS

- UES pressure increase is significantly correlated with external cricoid pressure irrespective of position, type of pressure application or measurement technique.
- Nadir luminal UES pressure is highly correlated with external cricoid pressure ( $p < 0.0001$ ).
- The Reflux Band™ applied pressure of 20 and 30 mmHg resulted in consistently correlated luminal UES pressure increase.
- External manual cricoid pressure of 20 and 30 mmHg resulted in correlated intraluminal UES pressure.
- The Pressure Sensor had no clinical affect on the intraluminal UES pressure.

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

# RefluxBand™

Somna Therapeutics, LLC  
W175 N11081 Stonewood Drive  
Germantown, WI 53022 USA  
262-345-5553  
www.refluxband.com



EC REP

Wellkang Ltd (www.CE-marking.eu)  
29 Harley St., London W1G 9QR, UK

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