

*EndoFLIP*<sup>®</sup>   
Endolumenal Functional Lumen Imaging Probe

**Can band fill volume  
predict gastric band  
stoma size?**

CROSPON™

## Introduction

It has been previously demonstrated that the stoma created by a gastric band can be directly measured using a standardized technique, EndoFLIP (Crospon, Ireland). We sought to determine if the band fill-volume versus stoma size relationship changes between the time of surgery and at more than one year after surgery.



EndoFLIP system and EF-325 probe

## Methods and Procedures

Stoma-size measurements were taken on 12 (12F) patients who were having a Model APS gastric band (Allergan Inc. Irvine, CA) implanted. The mean patient age was 43 years (range 25-67 years). The mean patient weight was 235 lb (range 149-289 lb) with a mean BMI of 38.7 (range 29.2-50.2). Stoma-size measurements were also taken on 10 (7F) patients who had been fitted with the same type of gastric band at least one year previously. The mean time since surgery was 14.9 months (range 13-22 months). The mean patient age of this latter group was 41 years (range 20-62 years). The mean patient weight was 201 lb (range 172-242 lb) with a mean BMI of 31.4 (range 26.9-34.8).

## Methods and Procedures *(continued)*

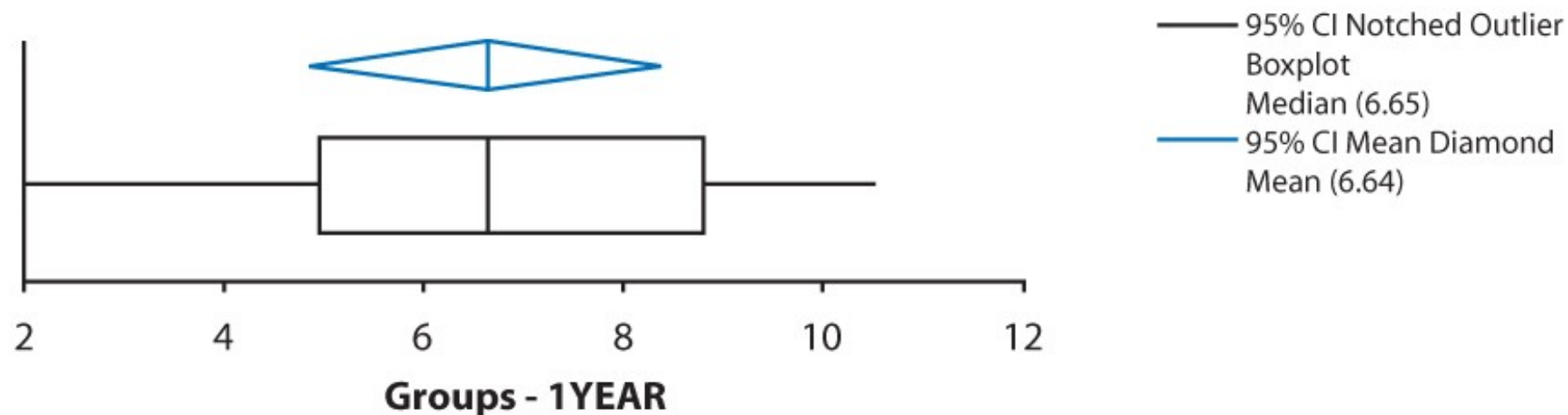
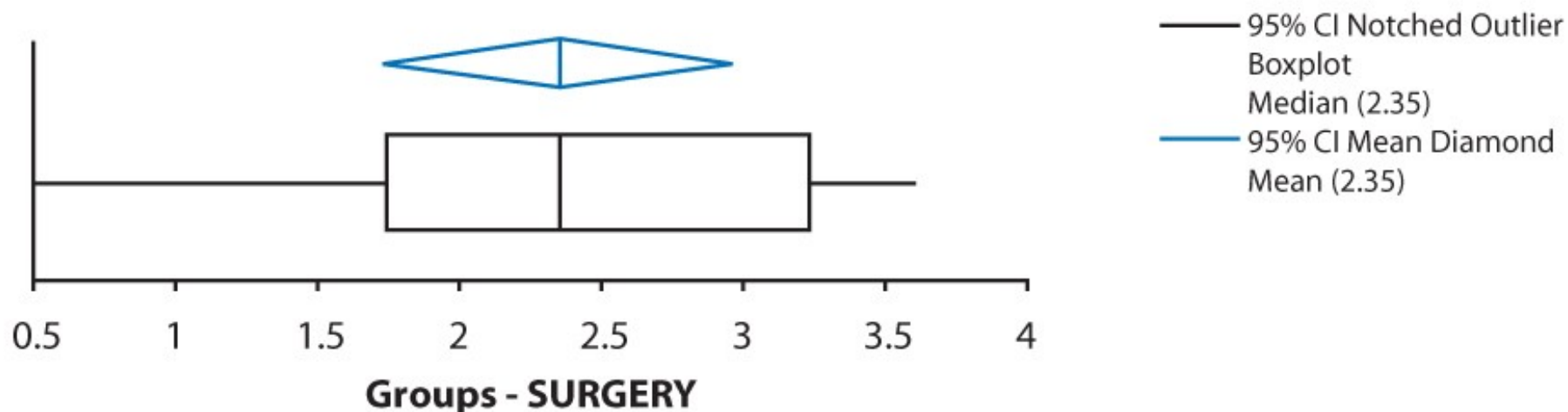
Previous work by the authors has suggested that titrating to a band stoma diameter in the region of 6.5 to 7mm using 30mL inflation in the EndoFLIP balloon catheter may place patients in the Green-Zone. The band-volume required to achieve a 7mm stoma size was measured and compared for both groups.

A model EF-325 catheter was used which has an 8cm long image field. It was deployed transorally to the band stoma. The EndoFLIP system (Figure 1) was used to inflate the balloon catheter with 30mL of a calibrated diluted saline solution. As the band was filled, the stoma size could be measured directly from the EndoFLIP system screen.

## Results

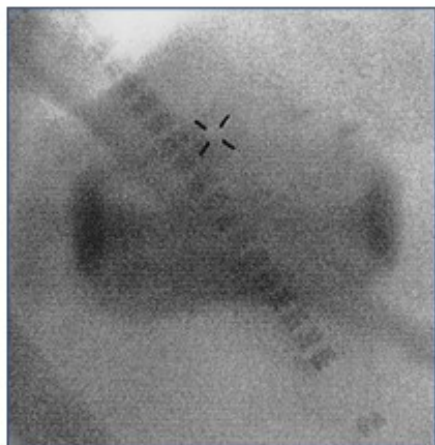
The band fill-volume required to achieve a 7mm stoma size at surgery and after a year post surgery were measured to be (mean  $\pm$  SD)  $2.4 \pm 1.0$  ml and  $6.6 \pm 2.3$  ml respectively, and significantly different ( $p < 0.0001$ ). The mean band fill volume increased by over 4mL in the comparison period. Furthermore, the standard deviation doubled in the same period (Figure 2). It is suggested that the effect of peri-gastric fat elimination over time is evident, as witnessed by the significantly greater band fill-volume required in the post-surgical patient group.

**Figure 2: Comparison of band fill volume at the different periods**



## Conclusion

The variability of band fill-volume required for a desired stoma size, both at surgery, and particularly one year after surgery, provides further evidence that band fill-volume provides little meaningful information as to what stoma size is being created. One reason for this is that any volume infused into the band does not cause the stoma size to change, until the band is pressing snugly on the stomach wall. Further studies are underway to assess if making band adjustments, using stoma diameter measurements to guide such adjustments, impacts on number of adjustments and %EWL in the first year after surgery.



Example of fluoroscopic image of EndoFLIP catheter in band