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Does Intraoperative Gastric Band Adjustment to a Targeted Stoma Size Improve Weight Loss?

One-year Results of a Feasibility Trial

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DOES INTRAOPERATIVE GASTRIC BAND ADJUSTMENT TO A TARGETED STOMA SIZE IMPROVE WEIGHT LOSS?

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ABSTRACT

Aims: When fitted with a gastric band, a patient does not receive their first adjustment until 4 to 6 weeks after surgery. We undertook a study to determine if patients could tolerate a gastric band stoma diameter adjusted to 6.5 to 7mm intraoperatively. We assessed the effect of this adjustment on postoperative weight loss and on the number of band adjustments in the first year after surgery. **Methods:** This was a prospective, single-arm, feasibility clinical trial with historic controls conducted in an ambulatory surgery center using the LapBand AP System or LapBand APL System (Irvine, California). After the band was fitted, an EndoFLIP (Crospon, Galway, Ireland) system was used intraoperatively to set the band stoma diameter. Thirty-five consecutive patients were studied and percent excess weight loss as well as the number of band adjustments in the first year after surgery were compared with 49 historic controls. **Results:** In the 4- to 6-week period after surgery, we observed subjects and controls for the APL and APS banded patients. Mean improvements in excess weight loss were 1.7 percent (15.5 vs. 13.8%; p =not significant) and 6.7 percent (23.1 vs. 16.4%; p =0.06), respectively. One year after surgery, mean improvement in excess weight loss was 11.6 percent (60.3 vs. 48.7%; p <0.05) between subjects and controls for the AP-banded patients. There was no significant difference between the average number of band adjustments (6.5) in the 12 months after surgery for subjects and controls. **Conclusion:** Intraoperative band adjustment is well tolerated. For the LapBand AP, these early findings suggest that intraoperative adjustments appear to improve early weight loss and this improvement appears to be maintained one year after surgery.

KEYWORDS

gastric band, intraoperative gastric band adjustment

INTRODUCTION

The adjustable gastric band has been well established as a highly effective surgical procedure for weight loss, achieving on the order of 50-percent excess weight loss (EWL) at 12 months.¹ As part of the management plan of patients fitted with a gastric band, the band needs to be adjusted to either loosen or tighten the stoma.² This is achieved by injecting saline into the band via a subcutaneously implanted fill port. Typical practice entails not filling the band to tighten the stoma until 4 to 6 weeks after surgery, essentially deferring effective utilization of the band for some time after surgery. Band adjustments thereafter are heuristically based on weight loss achieved to date and patient feedback on satiety. In all cases, the actual stoma size that is

set is unknown to the surgeon. In recent years, a number of techniques have been developed to allow more quantitative stoma adjustments to be performed, including the use of fluoroscopy³⁻⁵ and manometry.⁶ The EndoFLIP system (Crospon, Galway, Ireland) is the first system to permit stoma diameter to be directly measured. We have previously postulated that a stoma diameter of 6.5 to 7mm corresponds to the “Green Zone”.^{2,7} Toouli et al⁸ have reported a mean stoma diameter of 6.47mm, as measured using fluoroscopy, five years after surgery in patients fitted with the Swedish adjustable gastric band.

In this study, we sought to determine if an adjustment to 6.5 to 7mm intraoperatively could be tolerated, if this adjustment would

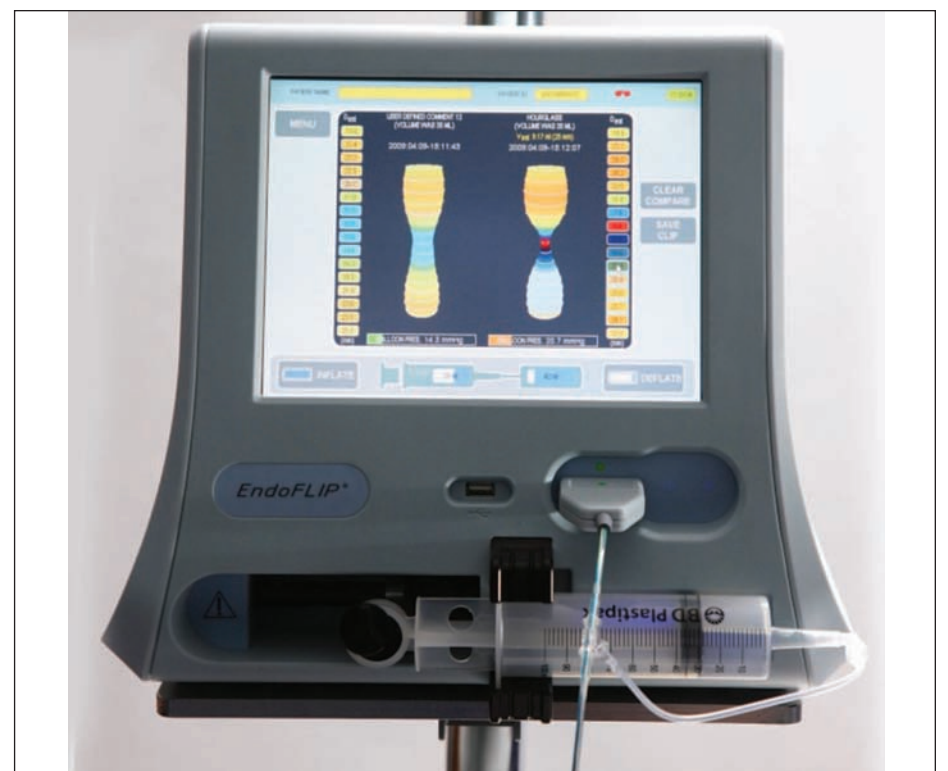


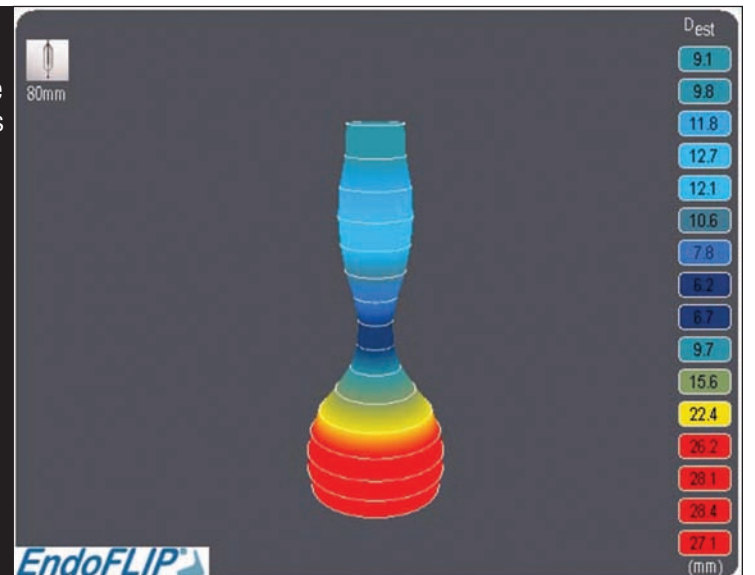
FIGURE 1. EndoFLIP System



FIGURE 2. EndoFLIP Catheter

FIGURE 3.

Example of an EndoFLIP image when catheter is located at the centre in the band. On the right hand side, the diameter at each point along the catheter is displayed, successive diameter measurements being spaced 5mm apart



promote earlier weight loss, and if this improvement would be sustained one year after surgery.

We also sought to determine if intraoperative adjustment reduced the number of band adjustments required in the first year after surgery.

MATERIALS AND METHODS

A prospective, single-arm, clinical trial was conducted with a historical control arm. Any patient undergoing the fitting of an Allergan (Irvine, California) LapBand AP System (APS) or LapBand APL gastric band was eligible to participate. The LapBand AP band is the smaller band in the AP series, permitting a fill volume of 10cc, and is the most commonly used gastric band in the United States. The larger APL band can permit a 14cc

fill. All band surgeries and follow up measurements took place at Specialty Surgery of Fort Worth, Texas, under the direction of Dr. Snow. Each patient had their gastric band fitted in the normal manner. Band size selection was determined by Dr. Snow on an individual case basis and was not dictated by the protocol. During surgical placement of the gastric band but prior to closure of the band, an EndoFLIP BF-325 catheter was deployed transnasally into the band stoma. The band was then closed and the catheter balloon inflated using the EndoFLIP system (Figures 1 and 2) with 30mL of calibrated diluted saline (supplied with the catheter). The catheter position was adjusted longitudinally to ensure the balloon was in the center of the band (Figure 3). The band was then filled

in the normal manner until a stoma diameter of between 6.5 and 7mm was displayed on the EndoFLIP screen.

The primary measured outcomes were percent EWL in the 4- to 6-week and 50- to 52-week period after surgery, along with the number of adjustments in the 12 months after surgery. All percent EWL measurements and the band adjustment history were logged using the LapBase (LapBase Pty, Melbourne, Australia) database program. Patients were scheduled for weight measurements within the 4- to 6-week and 50- to 52-week period after surgery. When measured percent EWL was not available in either the 4- to 6-week or the 50- to 52-week periods after surgery, or for the same periods for the historic controls, these patients were excluded from the statistical analysis.

Thirty-five consecutive surgical gastric band patients were enrolled. For historical controls, the records of 30 patients were consecutively selected from the LapBase system at the surgical center along with the records of a further 20 consecutive patients who were attending for annual routinely scheduled followup endoscopy, comprising a total of 50 historic controls, the only requirement being that their bands had been fitted greater than 12 months prior to the commencement of the study.

A two-sided *t*-test was performed using Minitab V15 (Minitab Inc., State College, Pennsylvania) to evaluate both the percent EWL differences between the subjects and historical controls and the differences in the number of band adjustments for both groups in the first year after surgery. A two-sided *p*-value of 0.05 was considered statistically significant.

RESULTS

Thirty-five patients were enrolled in the study in the period October 2009 to January 2010. Follow-up measurements were taken between November 2009 to January 2011. One patient was included twice in the historic control dataset, therefore, leaving 49 historic controls available for comparison. The preoperative demographics and numbers of patients enrolled in the study by band type are shown in Table 1. The number of patients for which percent EWL measurements were available in the 4- to 6-week and 50- to 52-week periods after surgery are shown in Table 2.

All subjects tolerated the intraoperative adjustment and no bands were required to be loosened in the immediate postoperative period. In the 4- to 6-week period after surgery, a mean EWL

difference of +1.7 percent (15.5 vs. 13.8%) was seen between subjects and controls for the APL banded subjects (95%CI [-5.5,8.9]), *p*=NS. For the APS banded subjects, a mean EWL difference of +6.7 percent (23.1 vs. 16.4%) was seen between subjects and controls (95%CI [-0.28,13.76]), *p*=0.06. One year after surgery, a mean EWL difference of -14.6 percent (31.4 vs. 46.0%) was seen between subjects and controls for the APL banded subjects (95%CI [-30.11,1.1]), *p*=0.07. For the APS banded subjects, a mean EWL difference of +11.6 percent (60.3 vs. 48.7%) was seen between subjects and controls (95%CI [0.17,23.05]), *p*<0.05.

There was no statistically significant difference in the number of adjustments for the 12-month period between subjects and controls for either type of band. For the APL-banded subjects, the mean number of adjustments was 6.8 (95%CI [4.9,8.8]) versus 6.3 (95%CI [4.9,7.6]) for the controls. For the APS banded subjects, the mean number of adjustments was 6.6 (95%CI [5.4,7.7]) versus 6.5 (95%CI [5.4,7.6]) for the controls. In terms of final band fill volume, there was no statistically significant difference in the mean band fill volume at 12 months between subjects and controls. For the APL-banded patients, the mean final band fill volume for the subjects was 7.9mL (95%CI [6.0,9.7]) versus 7.5mL (95%CI [6.9,8.0]) for the controls. For the APS-banded patients, the mean final band fill volume for the subjects was 5.7mL (95%CI [5.1,6.4]) versus 5.3mL (95%CI [4.6,6.0]) for the controls. For the APS-banded subjects, we calculated that during surgery they received on average 35 percent of the band fill volume they ended up with at 12 months.

DISCUSSION

The role of stoma diameter in promoting weight loss remains controversial. Recent evidence suggests stoma diameter is associated with weight loss in gastric bypass procedures.^{9,10} In this study, we sought to determine if a gastric band adjustment to achieve a stoma diameter of 6.5 to 7mm intraoperatively could be tolerated, if this adjustment would promote earlier weight loss, and if this improvement was sustained one year after surgery. We found that intraoperative band adjustment in the region of 6.5 to 7mm was well tolerated. For APS bands, we found an early mean weight loss improvement versus historic controls, the improvement being maintained at 12 months after surgery. We observed a EWL improvement of 10 percent at 12 months; however, we did not

TABLE 1. Preoperative demographics data.

	SUBJECT GROUP (APS) MEAN (SD)	CONTROL GROUP (APS) MEAN (SD)	SUBJECT GROUP (APL) MEAN (SD)	CONTROL GROUP (APL) MEAN (SD)
AGE (years)	43.0 (11.6)	40.1 (11.6)	47.3 (10.0)	46.8 (13.2)
WEIGHT (pounds)	240.9 (33.9)	264.8 (44.4)	328.8 (53.2)	324.5 (73.9)
BMI (kg/m ²)	39.4 (6.0)	42.8 (6.8)	46.9 (8.0)	49.2 (9.3)
N FEMALE	23	31	5	5
N MALE	0	7	7	6

TABLE 2. Number of patients available for follow-up weight measurements.

	SUBJECT GROUP (APS)	CONTROL GROUP (APS)	SUBJECT GROUP (APL)	CONTROL GROUP (APL)
4-6 WEEKS	16	28	7	11
50-52 WEEKS	23	26	12	5

observe the same effect for the APL bands, albeit that this conclusion is based on a low sample size (i.e., 5 patients in the historic arm). For both subjects and controls the mean number of band adjustments in the first year after surgery was not significantly different.

This was an open-label, pragmatic study with a relatively small sample size. The availability of follow-up data in the 4- to 6-week period was unsatisfactory (i.e., patients presenting at 3 or 7 weeks could not be included, and measures were put in place to improve this, resulting in 100 percent follow up at 12 months). One cannot discount the risk of cointervention bias, given that subjects would have had more surgeon interaction because percent EWL was being measured frequently throughout the study. We calculated that the subjects had a mean of 1.8 more surgeon interactions in the first year after surgery than controls. However, the number of adjustments made in the first year was not significantly different. Whereas the APL subjects were well matched with controls, the APS subjects were on average 10 percent less heavy than the historic controls. There were no male subjects fitted with an APS band in the study. A review of the percent EWL of the male APS controls suggests that they had significantly greater weight loss than the female controls, and therefore, we believe that the absence of male participants among the APS subjects biases the estimated weight loss effect in the conservative direction. Since historic controls were used, percent EWL measurements in the periods of interest could not be guaranteed. In this study, 12 of 38 APS and 6 of 11 APL controls did not have a 50- to 52-week percent

EWL measurement. To assess if this missing data introduced bias, the percent EWL differences were recalculated on a last observation carried forward basis, and were found not to effect the conclusions of the study related to the APS band. However, for the APL band, analyzing on this basis, one year after surgery a mean EWL difference of -5.9 percent (31.4 vs. 37.4%) was seen between subjects and controls for the APL-banded subjects (95%CI [-19.3,7.3]), *p*=NS. Therefore, on the basis of this study, we cannot make statistically valid conclusions as to the utility of intraoperative adjustments when using the APL band.

One viewpoint is that early weight loss is conducive to long term weight loss. There appears to be little clinical evidence generated to date to support this viewpoint. This study demonstrates that the instigation of the first band adjustment during surgery appears, with APS bands, to produce more rapid weight loss and the improvement appears to carry through to 12 months after surgery. In some health systems where the first band adjustment may not take place for several months after band placement, intraoperative adjustment affords the opportunity to start a patient losing weight more aggressively in the immediate aftermath of surgery with no apparent risk.

It is interesting to note that the weight loss improvement in the APS subjects does not arise as a consequence of a different band fill volume. However, we have demonstrated¹¹ that the relationship between stoma size and band fill volume varies significantly from patient to patient, and it would be unwise to extrapolate the results of

this study to infer that a 5.7mL band fill is optimum. For the APS subjects in this study, the standard deviation of the final band fill volume was 1.5mL, suggesting a sample band fill range of 2.7 to 8.7mL.

Finally, it should be emphasized that during the year after surgery, band adjustments in the study subjects were conducted in the same manner and frequency as that for the historical controls. Future studies will address the possibility of using stoma-diameter targeted adjustments to potentially reduce the number of postoperative band adjustments.

REFERENCES

1. Garb J, Welch G, Zagarins S, Kuhn J, Romanelli J. Bariatric surgery for the treatment of morbid obesity: a meta-analysis of weight loss outcomes for laparoscopic adjustable gastric banding and laparoscopic gastric bypass. *Obes Surg.* 2009;19(10):1447–1455.
2. Allergan Inc. The Art of Adjustments With the LAP-BAND AP™ System. 2007.
3. Kroh M, Brethauer S, Duellley N, et al. Surgeon-performed fluoroscopy conducted simultaneously during all laparoscopic adjustable gastric band adjustments results in significant alterations in clinical decisions. *Obes Surg.* 2010;20(2):188–192.
4. Cherian PT, Tentzeris V, Sigurdsson A. Variation of outcome in weight loss with band volume adjustments under clinical and radiological control following laparoscopic adjustable gastric banding. *Obes Surg.* 2010;20(1):13–18.
5. Ponce J, Smith AB. Gastric band adjustments: Benefits of fluoroscopy-guided adjustments. *Bariatric Times.* 2010;7(11):8–12.
6. Burton PR, Brown WA, Laurie C, et al. Effects of gastric band adjustments on intraluminal pressure. *Obes Surg.* 2009;19(11):1508–1514.
7. Snow RG, O'Dea J. Is there an optimal gastric band stoma size? *Surg Endosc.* 2010;24(Suppl 1):S318.
8. Toouli J, Kow L, Ramos AC, et al. International multicenter study of safety and effectiveness of Swedish Adjustable Gastric Band in 1-, 3-, and 5-year follow-up cohorts. *Surg Obes Relat Dis.* 2009;5(5):598–609.
9. Mali Jr J, Fernandes FA, Valezi AC, et al. Influence of the actual diameter of the gastric pouch outlet in weight loss after silicon ring Roux-en-Y gastric bypass: An endoscopic study. *Obes Surg.* 2010;20(9):1231–1235.
10. Dayyeh BK, Lautz DB, Thompson CC. Gastrojejunal stoma diameter predicts weight regain after Roux-en-Y gastric bypass. *Clin Gastroenterol Hepatol.* 2011;9(3):228–233.
11. Snow RG, O'Dea J. Can band fill volume predict gastric band stoma size? *Gastroenterology.* 2010;138(5 Suppl 1):S388.

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