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Laparoscopic Adjustable Gastric Band: 4-Year Experience and Learning Curve

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ABSTRACT

Background and Objectives: Laparoscopic adjustable gastric banding has become the most popular procedure for the treatment of morbid obesity in Europe. The objectives of this series are to report the results of the 4-year experience of a single surgeon and to define the learning curve.

Methods: A retrospective review of 156 patients who underwent laparoscopic adjustable gastric banding between October 2006 and May 2010 was performed. Patients were separated into 3 groups: group 1 comprised the first 50 patients; group 2 comprised the second 50 patients; and group 3 comprised the last group of patients, with a total of 56 patients.

Results: The male-to-female ratio was 1:4 (33 male and 133 female patients). The mean age was 38 years (range, 17–62 years). The mean preoperative body mass index was 44.9 kg/m^2. The mean percent excess weight loss was 41.7% at the 1-year follow-up visit (153 patients, 98%), 49.7% at the 2-year follow-up visit (147 patients, 94%), and 50.2% at the 3-year follow-up visit (127 patients, 81%). The overall complication rate and major complication rate were 15.4% and 3.2%, respectively. There were no deaths. Percent excess weight loss, length of hospitalization (in days), and complication rates were compared among the 3 groups. No significant differences were noted among the groups except in the number of complications ($P < .001$), but all data were clearly improved in groups 2 and 3.

Conclusions: The analyses in this study have documented one more time that laparoscopic adjustable gastric banding is an effective procedure for the treatment of morbid obesity, achieving >50% excess weight loss at 3 years. It is a procedure with certain complications even when performed by a surgeon with previous experience in laparoscopic surgery. According to our subset analysis, the learning curve is at least 50 procedures.

Key Words: Laparoscopic adjustable gastric band, Morbid obesity, Complications, Learning curve.

INTRODUCTION

Morbid obesity has become a global epidemic affecting persons of all ages. According to the World Health Organization, >40 million children aged <5 years were overweight in 2011,[1] and obesity has emerged as one of the most important health and socioeconomic issues.[2] Among the surgical procedures used for the treatment of morbid obesity, laparoscopic adjustable gastric banding (LAGB) has become the most popular in Europe because of low complication rates, short length of stay, and reversibility.[3–6] An additional advantage of LAGB is the shorter surgical learning curve in comparison with other laparoscopic procedures for obesity, but there are very few articles published on this.[7,8]

The purposes of this study are to present the 4-year experience of LAGB for a single surgeon, who performed all the operations with the pars flaccida technique, and to define the learning curve, comparing results such as percent excess weight loss (EWL), complications, and length of hospitalization (in days) based on the number of operations performed.

MATERIALS AND METHODS

We studied retrospective data on patients who underwent LAGB between October 2006 and May 2010 for the treatment of morbid obesity. Data were collected from clinical and operative records.

Eligibility for surgery was defined according to the 1991 National Institutes of Health Consensus Conference recommendations.[9] Patients with missing data (n = 6) and patients with a history of bariatric surgery (n = 3) were excluded from further analysis.

Patients were admitted to the hospital the day before surgery. Preoperative evaluation included blood tests, a

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chest radiograph, an electrocardiogram, and an upper gastrointestinal series to exclude hiatal hernia and cancer. Patients with a body mass index (BMI) ≥50 kg/m^2 were transferred postoperatively to the intensive care unit, where they stayed for 1 day. Oral fluids were commenced on the day of the operation, whereas the dietician team recommended the diet to patients on postoperative day 1 and thereafter.

A single surgeon (P.A.) with 15 years' experience in laparoscopic surgery performed all operations. The pars flaccida technique was used, securing the band by fixation to the walls of the stomach with 2 sutures. Drainage was not commonly used. Two different gastric bands were used during the study period. For the first 87 operations, the Adhesix-Bioring gastric band (Cousin Biotech, Wervicq-Sud, France) was used, and for the next 69 operations, the Swedish adjustable gastric band (Ethicon Endo-Surgery, Cincinnati, Ohio) was used.

Retrospective data collected included age; sex; length of hospitalization (in days); complications; deaths; preoperative BMI; total number of adjustments; and percent EWL at the 1-, 2-, and 3-year follow-up visits. Early complications were defined as complications occurring ≤30 days postoperatively. Our definition of major complications includes hemorrhage, esophageal perforation, and band slip, whereas port-tubing disconnection, port displacement, and port-site infection were characterized as minor complications. EWL was calculated as a percent based on the ideal body weight as defined by the method of Hamwi.[10] The Hamwi computation for ideal body weight is based on weight and height according to the following formula: 48 kg for the first 152.4 cm of height and then 1.1 kg for each additional centimeter for male patients, and 45 kg for the first 152.4 cm of height and then 0.9 kg for each additional centimeter for female patients.[10] Obesity was classified as a BMI ≥30 kg/m^2, with further subclassification as follows: class I, BMI of 30–34.9 kg/m^2; class II, BMI of 35–39.9 kg/m^2; and class III, BMI ≥40 kg/m^2.[11] Failure was defined as <25% EWL, major reoperation, or conversion, whereas success was considered >50% EWL. The length of hospitalization was defined as the number of days between the index procedure and discharge. The amount of saline solution injected into the port was defined according to weight loss, reflux signs, vomiting, and severe solid-food intolerance. All follow-up visits took place at our clinic every 3 months during the first year and every 6 months thereafter.

Statistically comparative analysis for categorical variables was performed with the χ^2 test. The normality distribution of quantitative variables was assessed with the Kolmogorov-Smirnov test and with histograms. Comparative analysis of the quantitative variables was performed by use of the Student *t* test. Differences between groups were analyzed with 1-way analysis of variance (ANOVA) or the nonparametric Kruskal-Wallis test for non–normally distributed variables. Statistical analyses were performed with SPSS software (version 21.0; SPSS, Chicago, Illinois), and $P < .05$ was considered statistically significant.

RESULTS

General Outcomes

During the study period, 156 patients underwent LAGB for morbid obesity. The male-to-female ratio was 1:4 (33 male and 133 female patients). The mean age was 38 years (range, 17–62 years), with 3.8% of patients aged ≥60 years. The mean preoperative weight was 128.2 kg (range, 90–180 kg), and the mean preoperative BMI was 45.3

Table 1.
Patient Characteristics

Variable	Data
Total No. of patients	156
Demographic data	
Age (y)	
Mean (SD)	37.92 (11.6)
Median (range)	38 (17–62)
Male/female sex	33 (21.2%)/123 (78.8%)
Preoperative weight (kg)	
Mean (SD)	128.2 (19.28)
Median (range)	128.2 (90–180)
Preoperative BMI (kg/m^2)	
Mean (SD)	45.3 (5.2)
Median (range)	44.9 (35.4–63.9)
Obesity class	
I (BMI of 30–34.9 kg/m^2)	0
II (BMI of 35–39.9 kg/m^2)	21 (13.5%)
III (BMI ≥40 kg/m^2)	135 (86.5%)
Superobesity (BMI ≥60 kg/m^2)	3 (2%)
Length of hospitalization (d)	
Mean (SD)	2.55 (2.13)
Median (range)	2 (1–13)
Mortality	0 (0%)

kg/m^2 (range, 35.4–63.9 kg/m^2). Of our patients, 111 (86.5%) were in obesity class III; only 3 patients (2%) were characterized as superobese, with BMI ≥60 kg/m^2. The mean length of hospitalization was 2.55 days (range, 1–13 days; SD, 2.13 days). The patients' characteristics are shown in **Table 1**.

The mean percent EWL was 41.7% at the 1-year follow-up visit (153 patients, 98%), 49.7% at the 2-year follow-up visit (147 patients, 94%), and 50.2% at the 3-year follow-up visit (127 patients, 81%). **Figure 1** presents the percent EWL during the 3-year observation period.

Conversions

Three conversions to an open procedure were performed: one because of esophageal perforation during the mobilization of its intra-abdominal part, one because of hem-

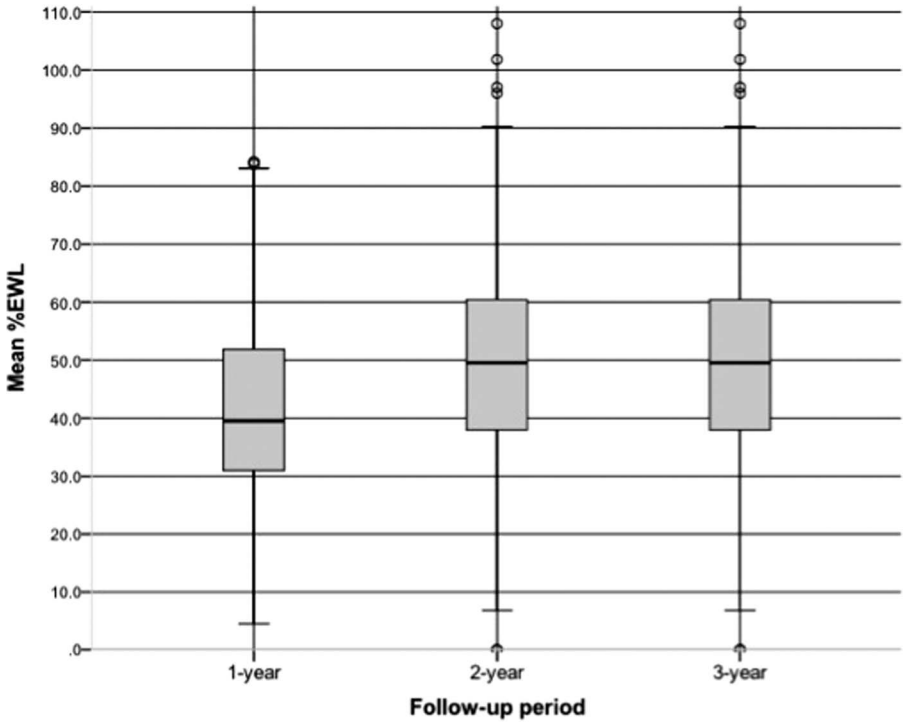

Figure 1. Mean percent EWL after LAGB.

Table 2.
Complications

	Early Complications	Late Complications	Overall Rate of Complications
Minor			12.2%
Port displacement	1 (0.6%)	10 (6.4%)	7%
Port-site infection	2 (1.3%)	3 (1.9%)	3.2%
Port-tubing disconnection	0	2 (1.3%)	1.3%
LRTI[a]	1 (0.6%)	0	0.7%
Major			3.2%
Band slip	0	2 (1.3%)	1.3%
Hemorrhage	2 (1.3%)	0	1.3%
Esophageal perforation	1 (0.6%)	0	0.7%

[a]LRTI = lower respiratory tract infection.

orrhage from the spleen, and one because of hemorrhage from the mesentery during trocar insertion. The median age of these patients was 31 years, and the mean BMI was 42.8 kg/m^2.

Complications

The overall complication rate was 15.4%. Early complications occurred in 7 patients (4.5%), and late complications occurred in 17 patients (10.9%). The major complication rate was 3.2%. We had a total of 11 port displacements, 5 port-site infections, 1 lower respiratory tract infection, 2 port-tubing disconnections, 2 band slips, 2 hemorrhages, and 1 esophageal perforation. All minor complications and port-tubing disconnections were treated conservatively or with repair with patients under local anesthesia. Two patients with late band slips (which occurred 2 years after LAGB) underwent reoperation with open sleeve gastrectomy. The 3 cases with complications of hemorrhage and esophageal perforation were converted to open operations. There were no perioperative or postoperative deaths. **Table 2** presents classifications and rates of complications.

Table 3.
Distribution of Obesity Classification in Groups 1, 2, and 3

	Group 1	Group 2	Group 3
Class II	7 (4.5%)	8 (5.1%)	6 (3.8%)
Class III	43 (27.6%)	42 (26.9%)	50 (32.1%)

Number of Adjustments

The mean number of adjustments (injections into the port) was 3.46 (range, 1–7). Correlation between the 3-year percent EWL and number of adjustments was statistically significant ($P < .001$, Pearson correlation).

Learning Curve

We divided the patients in our study into 3 groups: group 1 comprised the first 50 patients; group 2 comprised the second 50 patients; and group 3 comprised the last group of patients, with a total of 56 patients.

Table 4.
Results in Relation to Subsequent Operation Number

	Group 1	Group 2	Group 3	*P* Value
% EWL at 1-y follow-up[a]	40.2 (n = 49)	41.6 (n = 50)	43.3 (n = 54)	.619[d]
Success (%)[b]	24.5	34	31.5	
Failure (%)[c]	24.5	18	11.1	
% EWL at 2-y follow-up[a]	48.3 (n = 46)	48.5 (n = 50)	52 (n = 51)	.555[d]
Success (%)[b]	47.5	42	54.9	
Failure (%)[c]	17.4	10	3.9	
% EWL at 3-y follow-up[a]	48.4 (n = 40)	49.9 (n = 45)	52 (n = 42)	.699[d]
Success (%)[b]	47.5	46.7	50	
Failure (%)[c]	15	6.7	2.4	
No. of complications (%)				
Overall	16 (32)	5 (10)	3 (5.4)	<.001[e]
Major	3 (6)	0 (0)	1 (1.8)	.004[e]
No. of reoperations/conversions (%)	3 (6)	1 (2)	1 (1.8)	
Mean length of hospitalization (range) (d)	2.78 (1–12)	2.54 (1–13)	2.38 (1–7)	.952[f]

[a]Mean values are presented.
[b]Success is defined as >50% EWL.
[c]Failure is defined as <25% EWL.
[d]One-way ANOVA.
[e]χ^2 Test.
[f]Kruskal-Wallis test.

The mean preoperative BMI was 44.9 kg/m^2 (range, 35.8–57.6 kg/m^2) in group 1, 45.7 kg/m^2 (range, 35.4–61.3 kg/m^2) in group 2, and 45.2 kg/m^2 (range, 37.5–63.9 kg/m^2) in group 3, with no statistically significant differences ($P = .753$, 1-way ANOVA). Even all obesity classes were equally represented in each of the 3 experimental cohorts ($P = .722$, χ^2 test) (**Table 3**).

A subset analysis was performed, and the groups were comparable for percent EWL at the 1-, 2-, and 3-year follow-up visits; number of complications; and mean hospital stay (**Table 4**).

There were no statistically significant differences among the 3 groups in percent EWL at the 1-year follow-up visit ($P = .619$), percent EWL at the 2-year follow-up visit ($P = .555$), or percent EWL at the 3-year follow-up visit ($P = .699$) (**Figure 2**). The success rate achieved at the 3-year follow-up visit was 47.5%, 46.7%, and 50% in group 1, group 2, and group 3, respectively. Complications occurred in 16 patients (32%) in group 1, in 5 patients in group 2 (10%), and in 3 patients (5.4%) in group 3, differences that approached statistical significance ($P < .001$, χ^2 test) (**Figure 3**). Three major complications occurred in our study in group 1, none in group 2, and one in group 3 ($P = .004$). The mean hospital stay was 2.78 days in group 1, 2.54 days in group 2, and 2.38 days in group 3. No significant difference was noted ($P = .952$, Kruskal-Wallis test). Finally, the mean number of adjustments was 2.9 in group 1, 3.52 in group 2, and 3.75 in group 3 ($P = .008$, 1-way ANOVA). **Figure 4** shows the mean percent EWL at the 3-year follow-up visit in correlation with the number of adjustments in the 3 groups.

DISCUSSION

This is a retrospective study of 156 cases of LAGB. The strengths of our study are that a single surgeon performed all the operations, always using the pars flaccida technique, and that a high rate of patient participation even at the 3-year follow-up visit was achieved, minimizing the potential bias. The 1-, 2-, and 3-year follow-up visits were attended by 98%, 94%, and 81% of our patients, respectively.

This study reports progressive and durable weight loss, achieving 41.7%, 49.7%, and 50.2% EWL at 1 year, 2 years,

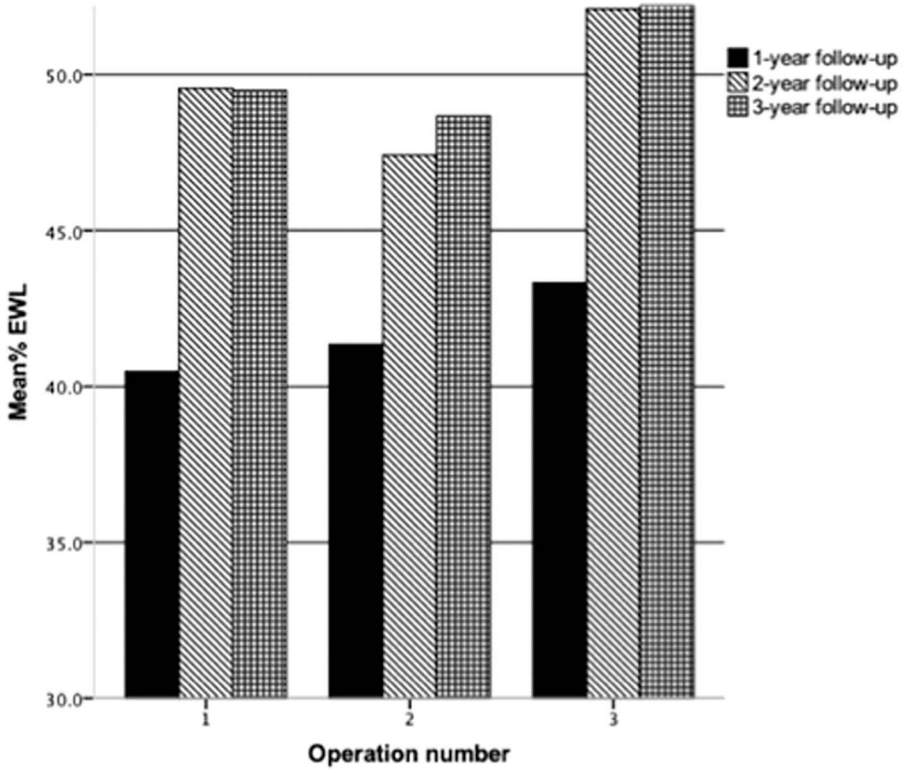

Figure 2. Percent EWL after LAGB in groups 1, 2, and 3 during follow-up period. No statistically significant differences in percent EWL were shown among the 3 groups ($P > .05$).

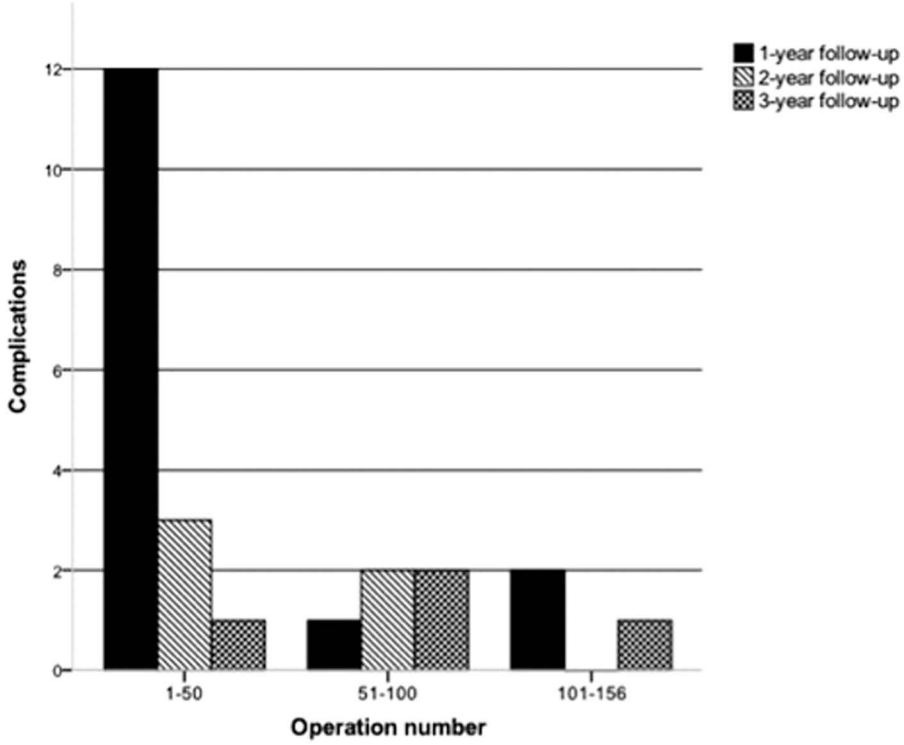

Figure 3. Complications after LAGB in groups 1, 2, and 3 during follow-up period. Statistically significant differences in complication rates were shown among the 3 groups ($P < .001$).

and 3 years, respectively. These results are comparable with those of previous large series from the United States and Europe with similar high rates of patient participation at follow-up.[12–15]

The complication rates reported in the literature vary widely. We report an overall complication rate of 15.4%, which is higher than that reported by Chapman et al[16] in a systematic literature review or by Nguyen et al[17] but is comparable with previous studies.[18,19] The early and late complication rates in our series were 4.7% and 10.9%, respectively, which are lower than those reported by other investigators.[20,21] Our port-related complication rate of 10.2% is in line with the literature.[22] Despite the fact that pouch dilatations and band erosions have been reported as major complications in many published studies,[21,23,24] such complications did not occur in our patients. This could be explained by the fact that our follow-up period was only up to 3 years. Nevertheless, we had 5 major complications (3.2%), including 1 esophageal perforation, which—to our knowledge—has never been reported. There were no deaths.

The second objective of our study was to determine a potential learning curve specific to LAGB even for a surgeon with previous advanced laparoscopic experience. Many articles have been published on learning curves for laparoscopic surgery, but very few for LAGB. Shapiro et al[7] defines the first 30 operations as the potential learning curve, whereas Weiner et al[8] assume that the first 100 operations define the learning curve. We did not identify any statistically significant correlation in our 3 groups with respect to percent EWL achieved or length of hospitalization, but the data clearly improved in groups 2 and 3. It is characteristic that the failure rate at the 3-year follow-up visit in group 3 was only 2.4% whereas half of the group's patients achieved 50% EWL during the same period. A statistically significant correlation was found ($P = .043$, χ^2 test) in failure rate (as this defined in the "Materials and Methods" section) at the 3-year follow-up visit between the first 50 operations and the next 106 because operations were evaluated as failures in 9 of 40 patients in group 1 and in 8 of a cumulative 87 patients in groups 2 and 3. On the other hand, the complication rate was 32% in group 1 but only 10% in group 2 and 5.4% in group 3, and major complications were minimized in groups 2 and 3. All severe complications of hemorrhage and esophageal perforation occurred in group 1. Finally, the number of adjustments gradually increased in the 3 groups. It is

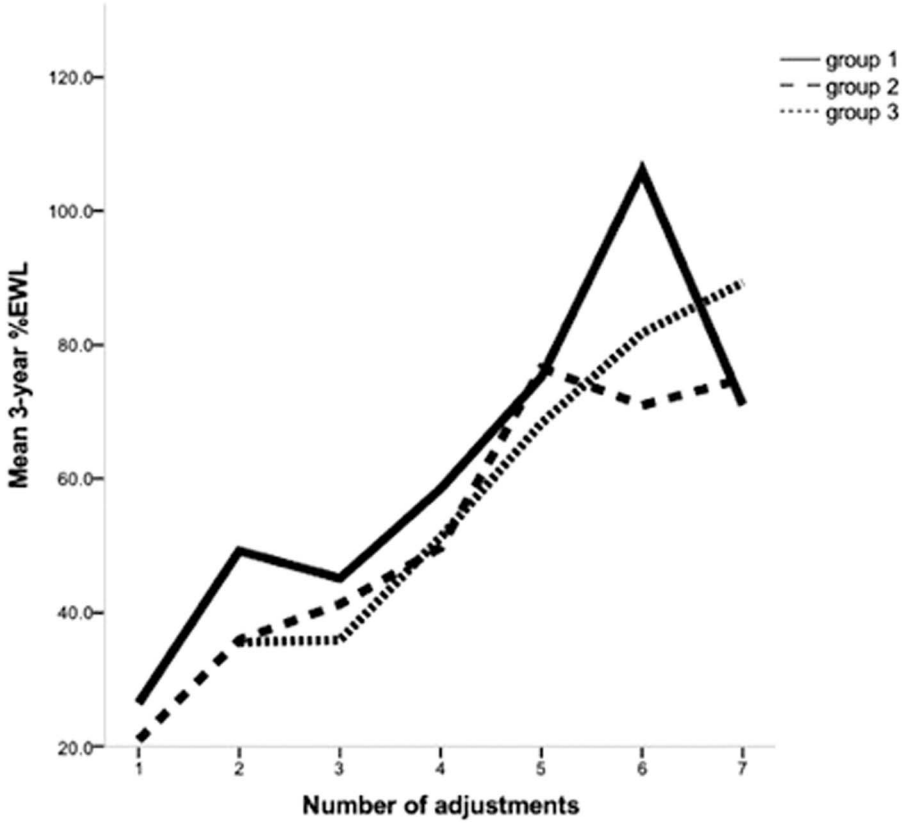

Figure 4. Mean percent EWL at 3-year follow-up visit in correlation to number of adjustments in groups 1, 2, and 3.

documented in the literature that frequent adjustments correlate with better weight loss results.[25,26] This could explain the fact that as the surgeon's experience increases, more adjustments are used.

CONCLUSIONS

The analyses in this study have documented one more time that LAGB is an effective procedure for the treatment of morbid obesity, achieving >50% EWL at 3 years. Furthermore, it is a procedure with certain complications even when performed by a surgeon with previous experience in laparoscopic surgery. Finally, according to our subset analysis, the surgeon's learning curve is at least 50 operations.

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