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University of Nevada, Reno

**A Retrospective Study of Roux-en-Y Gastric Bypass Patients: Trends and Needs for
Increased Dietary Guidance**

A thesis submitted in partial fulfillment
of the requirements for the degree of

Bachelor of Science in Nutrition and the Honors Program

By

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prepared under our supervision by

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Abstract

Laposcopic Roux-en-Y gastric bypass (LRYGB), although procedurally highly effective, also requires a high level of patient commitment to lifelong dietary and lifestyle changes that dictate its effectiveness. By retrospectively examining the patient files of 105 LRYGB patients throughout their first 13 months post-operation, this study anticipated to identify a statistically significant correlation between the number of times a one-year post operative LRYGB patient meets with a registered dietitian (RD) and that patient's overall success of weight loss as determined by the rate and continued maintenance of weight loss. After evaluating the data set, it was determined that the sample size was too small to yield a statistically relevant conclusion. However, two statistically significant observations were uncovered: (1) a significant decline in weight loss in both males and females was observed in the 4th chronological month post-surgery; and (2) and as months from surgery date increased, the average percent of weight loss observed declined. One conclusion that can be drawn from these observations is that all members of the healthcare team involved with gastric bypass patients should focus particular attention on patient follow-ups and the patient's weight-loss maintenance in the 4th chronological month post-surgery and thereafter.

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Introduction

Over the last two decades, obesity has become an epidemic within the United States. According to a 2010 report published by The Centers for Disease Control (2010), nearly 72.5 million U.S. adults were obese - roughly one-third of the population. Furthermore, based on the Behavioral Risk Factor Surveillance System, the number of self-reported adult obesity cases increased by approximately 2.4 million adults between the years 2007 to 2009.

Laparoscopic Roux-en-Y gastric bypass (LRYGB) was first mainstreamed in 1994 as a means of surgically managing obesity, and it has become an increasingly popular form of treatment for the obese and morbidly obese (Shikora et al., 2005). Although numerous healthful means of weight loss and weight maintenance exist, bariatric surgery, LRYGB in particular, has proven to have superior weight loss outcomes and more success in a patient's ability to maintain long-term weight loss. In addition to marked weight loss, those who qualify for bariatric surgery also tend to see a disappearance of many co-morbidities associated with obesity, some as soon as 24 hours after surgery; thus making bariatric surgery even more enticing (Grief & Miranda, 2010). This stated, it has become apparent that the level of commitment the patient has to lifelong changes in diet and lifestyle changes largely dictate the long-term outcome of the procedure performed (Thomas & Marcus, 2010).

As with any medical procedure, there are risks associated with surgically managed obesity. One of these risks is largely grounded in the nutritional realm. Post LRYGB patients in particular experiences lifelong, and often drastic, changes to their nutritional needs and eating behaviors. Due to these changes, bariatric surgery is an area

within the dietetic community in which the role of a registered dietitian (RD) is crucial (Kushnar & Neff, 2010).

The National Institutes of Health Consensus Development Conference Panel in 1991 established qualifying standards for bariatric surgery patients (Consensus Development Conference Panel, 1991). Adults with a body mass index (BMI) greater than or equal to 40, or a BMI greater than or equal to 35 with the presence of high-risk conditions related to obesity (e.g., heart disease, diabetes, sleep apnea) are candidates for surgical weight loss procedures. The seemingly never-ending expansion of the obese population, an increased willingness of many large health insurance companies, Medicare included, to pay for weight loss surgery, and the increased safety and success of the procedure have created a boom in the field of bariatric surgery. Indeed, the number of bariatric procedures performed in the United States between 1998 and 2004 increased 10 fold, jumping from 13,386 in 1998 to 121,055 in 2004. It was projected that 2010 will have seen over 220,000 bariatric procedures performed (Kulick, Hart & Deen, 2010).

The American Society of Metabolic and Bariatric Surgery (ASMBS) was founded in 1983 in response to the growing popularity of bariatric procedures. The mission of ASMBS is to improve and advance the art and science of bariatric surgery through education and support programs for surgeons and other healthcare professionals (the American Society for Metabolic and Bariatric Surgery, 2007). In the aim of improving bariatric healthcare quality and patient safety, the ASMBS and the Surgical Review Corporation created the Bariatric Surgery Centers of Excellence (BSCOE) program. As stated on the Surgical Review Corporations website:

“The BSCOE designation has enabled patients and other stakeholders

to distinguish surgeons and facilities providing superior bariatric surgery care. The program's success has also helped re-establish credibility for the specialty, with bariatric surgeons emerging as leaders in healthcare quality" (Surgical Review Corporation, 2010).

To be distinguished as a BSCOE, the facility must meet the Surgical Review Corporation's requirements. There are 10 requirements for hospitals, and an additional two requirements for freestanding outpatient facilities. The 10 requirements for surgical settings are as follows: institutional commitment to excellence, surgical experience and volumes, designated medical director, responsive critical care support, appropriate equipment and instruments, surgeon dedication and qualified call coverage, clinical pathways and standardized operating procedures, bariatric nurses, physician extenders and program coordinator, patient support groups, and lastly long-term patient follow up (Surgical Review Corporation, 2010). The additional two requirements for freestanding outpatient facilities are patient selection and facility licensing and accreditation. The most notable of these requirements pertaining to this study is the endorsement of long-term patient follow up. The surgical center utilized in this study is a BSCOE; thus examining the impact of long-term patient follow up on surgical outcomes will become an area of interest within this study.

Another impact of the large and growing number of bariatric procedures is the formation of an ever increasing population group that requires special dietary attention from the entire health care community, particularly, patients who have undergone the most common form of bariatric surgery, LRYGB (Steinbrook, 2004). The LRYGB procedure permanently alters the patients' food tolerances, selections, restrictions and

dietary needs (Thirlby, Bahiraei, Randall, & Drewoski, 2006). The LRYGB procedure also places the patient at an increased risk of both macro and micronutrient deficiencies throughout their lifetime, making nutritional counseling and guidance a chief priority for these patients’.

Background

A. The LRYGB Procedure

In LRYGB, a small pouch is surgically created just below the gastroesophageal junction of the stomach, thereby limiting the amount of food the patient can consume in one sitting to roughly 20-30 mL. In addition to using this food restriction mechanism to induce weight loss, LRYGB employs the use of malabsorption, thereby making the procedure different from the gastric banding variations of weight loss surgery.

Malabsorption is induced by bisecting the jejunum into two branches, the first portion is bypassed, along with the duodenum. The distal portion of the jejunum is reattached to the new stomach pouch (Kulick et al., 2010). A substantial portion of nutrient absorption occurs in the bypassed section of the small intestine, thus reducing the amount of nutrients absorbed during the digestive process. And while the mechanism of malabsorption helps assist in the facilitation of weight loss when compared to a purely restrictive procedure (i.e. gastric banding), it also presents a lifelong challenge to sustain proper nutritional status and malnutrition prevention.

B. Post-Surgical Nutritional Needs and Physiology

As outlined above, one of the largest hurdles confronting post-LRYGB patients is maintaining an adequate nutritional status. Although numerous articles exist, written both from the surgical and RD prospective, identifying the changes to a post-LRYGB

patient's digestive system, those articles and changes most notable will here be summarized and reviewed. For additional information regarding the differences between the nutritional requirements of an average adult as compared with those of an average post-LRYGB adult, a table of nutrients most affected can be found in Appendix A.

Maintaining a sufficiently balanced level of protein is crucial before and after undergoing any form of bariatric surgery. According to the in-house dietitian for the bariatric center this study was conducted at, prior to any bariatric surgery, the patient is often advised to lose roughly 10% of their excess body fat (Shoenberger, personal communication, 2011). Surgeons have found that by eliminating 10% of excess body weight decreases the chances of complications both during and after surgery (Still et al., 2007). This weight loss is largely accomplished through the use of meal-replacement protein shakes. The shakes are often specially formulated for the bariatric patient, and are low-calorie, low-residue, and low-fat, yet remain nutritionally dense. The shakes also serve as a means to wean the patient and the digestive track off whole foods in preparation for surgery (Shoenberger, personal communication, 2011).

The protein shakes are continued post-surgery as the primary source of nutrients while the digestive system is healing, then becoming less frequent as more foods are reintroduced into the patient's diet, although the patients often continue drinking the protein shakes after regaining a fully rounded diet, as a means to avoid becoming protein deficient - a common ongoing risk post surgery (Shoenberger, personal communication, 2011). The risk of protein deficiency post-LRYGB arises because protein is mainly metabolized and introduced into the blood stream in the jejunum and mid-ileum of the small intestine. Given that a portion of the jejunum is bypassed during digestion and a

patient's reduced food intake (due to the reduced size of the stomach), monitoring the protein status of post-operative LRYGB patients is crucial. When compared to bariatric procedures that only employ restrictive mechanisms, as in the LAP BAND procedure, LRYGB patients develop protein malnutrition 11% more frequently (Coupaye et al., 2009). Furthermore, some LRYGB patients experience intolerances to protein rich foods, such as fibrous meats, during their first year post-surgery. For protein, the recommended intake during the first-year post- surgery is 1.0-1.5 g/kg ideal body weight (Moize et al., 2003), which is markedly more than the .8 g/kg of protein recommended for the average healthy adult (United States Department of Agriculture, 2010).

Largely correlated to the LRYGB patients' risk of protein deficiency is the risk of developing anemia. Gastric acid in the stomach aides in the conversion of Fe^{3+} , the form of iron found naturally in food sources, to Fe^{2+} , the form of iron that is best absorbed in the body. With the size of the stomach severely reduced, less gastric acid is produced, thus leaving less available for the conversion of Fe^{3+} to Fe^{2+} . Additionally, the jejunum is the primary site of iron absorption, and a portion of this segment of intestine is bypassed in LRYGB, further increasing the risk of iron deficiency. Anemia is currently the leading nutrient deficiency seen in post-LRYGB patients with approximately 50% of patients exhibiting signs and symptoms within four years of the procedure (von Drygalski & Andris, 2009). Left unchecked, patients have a substantially higher risk of developing severe anemia. Given the heightened risk of the post-LRYGB patient for developing protein deficiency and iron deficiency anemia, closely monitoring a post-LRYGB patient's daily protein consumption becomes a top priority for the RD.

Bariatric surgery patients are also at increased risk for accelerated bone loss due to interferences with how both calcium and vitamin D are absorbed (Goode, Brolin, Chowdhury, & Shapses, 2004). Calcium, again, is absorbed primarily in the duodenum and proximal jejunum with the aid of vitamin D and gastric acid. As mentioned previously, the reduced size of the stomach pouch decreases the amount of gastric acid produced and the duodenum and proximal jejunum are bypassed, thus decreasing the absorption of calcium. In addition to calcium, vitamin D is another nutrient that proves difficult for the post-surgical LRYGB patient to maintain adequate levels of. This is because vitamin D is a fat soluble vitamin, meaning it requires certain levels of dietary fat, biliary and pancreatic secretions to be absorbed into the body, and the post-surgical diets of LRYGB patients is largely low-fat in nature due to intolerance linked to altered fat-absorption mechanisms after surgery (Compher, Badellino, & Boullata, 2008; Kulick et al, 2010).

For similar reasons that a patient is at risk for vitamin D deficiency, other fat-soluble vitamins, including vitamins A, K and E, have been reported to decrease in patients after LRYGB (Eckert et al., 2010; Boylan, Sugerman, & Driskell, 1988; Slater et al., 2004).

The B vitamins (B₁₂, thiamin, B₆ and folate) require monitoring as well in a post LRYGB patient. Asymptomatic thiamin deficiency has been reported in up to 18% of patients' 1-year post RYGB (Clements et al., 2006). Vitamin B₁₂ deficiency presents itself in nearly one of every three LRYGB patients by the time they reach three-years post operation. Absorbed in the distal end of the ileum when combined with intrinsic factor (produced in the now bypassed antrum of the stomach), vitamin B₁₂ becomes

deficient when the body's natural stores become depleted. Since the physical structure of a post LRYGB patients' stomach does not allow for the proper mixing of food with gastric secretions and enzymes required to release the vitamin from food sources, B₁₂ is kept unavailable to bind with the necessary intrinsic factor for absorption (Vargas-Ruiz, Hernandez-Rivera, & Herrera, 2008). Once depleted, it is necessary to obtain proper levels of vitamin B₁₂ from supplementation.

In addition to having altered nutritional needs, there also exist recommended dietary behavior modifications LRYGB patients should adhere to. These modifications include eating portions no bigger than ~1 cup, eating 3 meals and 2 snacks per day, and waiting roughly 30 minutes after eating to consume any fluids (Kulick et al., 2010). There is also a recommended progression diet to transition a LRYGB patient to a normal diet after surgery. This progressive diet marks points in time after surgery a patient is more likely to seek the guidance of an RD, and thus becomes a topic of importance in respect to the goals of this study. At the bariatric center where this study was conducted, the major food transitions after surgery are:

- week 1, consisting of full liquids only
- week 2, composed of pureed foods free of lumps
- weeks 3-4, where soft foods are allowed and the patient can work their way up to foods found in their normal diets with caution and as they feel confident to do so, and
- roughly 1 month after surgery, patients are expected to be eating fully from their normal diet

After one month following surgery, the only restriction for the patient is to avoid eating tough or stringy foods until around months 3 and 4, or until the patient has demonstrated the practices of chewing well and eating slowly. The avoidance of stringy and tough foods is to avoid the tendency they have of getting stuck in the upper digestion tract (Shoenberger, personal communication, 2011).

C. The Role of the Registered Dietitian

After reviewing many of the nutritional changes occurring for the post-operative LRYGB patient, the need to carefully monitor patients' diets and supplementation patterns becomes evident. Monitoring each patient closely helps ensure that the alterations made to the gastrointestinal tract remain safe for the individual, and that malnutrition does not arise. Although the surgeons, doctors, and nurses possess knowledge of the specialized nutritional care gastric bypass patients require, it is the registered dietitian that is best suited for the job of giving nutritional guidance and monitoring. Unlike other members of the care team, the registered dietitian has a very specialized and detailed educational background devoted entirely to nutrition. Doctors and nurses on the other hand, may have had only a few courses on nutrition, since it is not designed to be their main focus. In addition, while other members of the care team have a multitude of job duties to oversee, the dietitians main and only focus is that of tending to patients' diet and nutritional concerns.

Given the registered dietitians' specialized educational background in nutrition, and their sole dedication to the nutritional concerns of patients, they are the best suited member of the care team to monitor and address the nutritional complexities bariatric surgery patients face.

D. A Review of Prior Literature

Given the relatively new nature of the field of bariatric surgery, the amount of prior research on the subject of post-surgical dietary counseling is more limited than in other surgical fields. Notwithstanding, there exists a seminal body of literature that this study intends to build upon. One of the primary texts used when considering the scope of this study is a review written by Dr. Doina Kulick and associates in 2010 entitled, “The Bariatric Surgery Patient: A Growing Role for Registered Dietitians.” In the article, Kulick examines how bariatric surgery affects the nutritional needs of patients and acknowledges the existence of a greater need for RD involvement due to the nutritional complexities bariatric surgery results in. They then propose specific ways the RD should be utilized as part of the care team in both pre-operative and post-operative stages. She concludes by writing, “Because of the pre- and postoperative dietary issues, RDs can assess, monitor, and counsel patients in order to improve adherence and reduce the risk of nutrient deficiencies. However, many of the current dietary and nutrition recommendations for the bariatric patient are based on expert opinion or observational studies. Therefore, this is an opportunity for future research to provide more evidence-based recommendations for best practice in the nutrition evaluation and management of the bariatric patient” (Kulick et al., 2010).

A study published in 2008 in the Journal of Gastrointestinal Surgery aimed to explore the causation of sub-optimal weight loss following Roux-en-Y gastric bypass, a topic this study also hopes to probe. The study reviewed 495 patients who underwent open Roux-en-Y gastric bypass performed by a single surgeon at the same bariatric center between the years 1999 to 2004. Of the 495 patients, the study labeled 55 to have

experienced sub-optimal weight loss, which was defined as having failed to lose at least 40% of excess body weight by 12 months post-surgery. An unadjusted bivariate analysis and adjusted multivariate analysis showed that an increased initial BMI, having diabetes mellitus, and being male was associated with the sub-optimal outcome. Further, the adjusted multivariate analysis indicated that sub-optimal weight loss was associated with the patient having Medicare insurance (Melton et al., 2008). The correlations found in this study are eye-opening, and will be variables to recognize moving forward. In addition to using some of the groundwork done in this study, the following question is left unanswered; does there exist a particular point (in months) throughout the first year post-surgery that is most closely associated with a decline in weight loss? If so, could this “falling off the wagon”, so to speak, indicate a specific time in which intervention in the form of additional nutritional counseling by an RD counteract a sub-optimal weight loss?

Using the ideas reviewed by Kulick and associates concerning the large and gravely important role that the RD plays in a LRYGB patient’s on-going care both before and after surgery, combined with the 2008 finding of Melton and colleagues as to proposed reasons some patients experience sub-optimal weight loss, the framework for the ensuing study is laid. Whereas previous studies have merely examined the reasons as to why including an RD on the care team of a LRYGB patient is necessary, there has yet to surface any statistical evidence of the practices’ effectiveness. Ideally, an evaluation of post-operative LRYGB patients receiving RD care, and a positive correlation to a more successful weight loss outcome, is needed. That correlation is precisely what this study aims to find: a statistically significant correlation between the number of times a one-year post operative LRYGB patient meets with an RD and that patient’s overall success of

weight loss as determined by the rate and continued maintenance of weight loss. This study will focus on ascertaining support for the suggestion that periodic consultations with an RD during the first year post-operation is an effective way to monitor the safety and effectiveness of the behavioral and nutritional changes being made by the LRYGB patient to their dietary habits and is an integral and necessary component of post-LRYGB patient care. It is also proposed that through this study, a positive correlation between increased consultations with an RD and optimal weight loss by 13 months, +/- 2 weeks, will be found. Lastly, we have set an additional goal of identifying specific time points within the time frame of 13 months, +/- 2 weeks, that LRYGB patients would most benefit by a consultation with an RD, based on rates of weight loss and expected transitions in the diet.

Method

Participants

With the aid and cooperation of Western Bariatric Institute (WBI), a BSCOE, this study was conducted retrospectively, utilizing the medical records of all LRYGB adult patients from January 1, 2009 to January 1, 2010, roughly 115 to 130 individuals. The exclusion criteria used omitted the data of any adult patients that experienced serious medical complications as a result of the laparoscopic Roux-en-Y gastric bypass procedure. Serious post surgical complications were defined as, but not limited to, infections and intractable nausea and vomiting, as these conditions would interfere with weight loss, as well as any necessity for the patient to be placed on either total parenteral

nutrition or tube feeding for any period of time exceeding one month. After applying the exclusion criteria to the participant pool, 105 patients remained eligible for the study.

Baseline Data

According to a WBI's Demographic Analysis Report ranging from the dates January 1, 2008 to November 30, 2010, out of the 763 patients undergoing LRYGB, 80.5% of the patients were female, 19.5% male. Patients between the ages of 30 and 50 comprised 77.1%; 6.6% were in the 20s; and a low of 1.4% were in their 70s. A 63% majority of the patients were married, whereas 29.3% were either single or divorced, and 7.6% were either widowed, separated or did not wish to specify their marital status. A majority of the patients were Caucasian (81.8%), then trailed by Hispanic (8.2%), then "other" at 5.2%. All other races recorded included American Indian, African American, Pacific Islander, and Asian, all of which totaled 4.8% of the patient pool.

From WBI's Total Weight Loss Report dated from January 1, 2006 to November 30, 2010, pre-operatively, the average weight was 283.6 lbs and the average BMI was 46.28. Appendix B depicts this baseline data.

Procedure

The 105 eligible participants, identified by a patient number only, and the participant's baseline data were provided to the study via a spreadsheet prepared by WBI. The baseline data were then transferred to a new spreadsheet identifying each patient by study number ranging from 001-105. No key exists linking the patient's study number to their patient record number.

Baseline data included the following information: date of operation, gender, age, race, initial weight, height and BMI, as well as ideal weight. Additional participant

information contained in their electronic medical records was then collected on site at WBI using a computer belonging to WBI. The additional information collected was segmented into two categories: clinical data and dietitian data.

The clinical data was comprised of the number of times and dates the patient made visits to WBI in the time span of plus or minus 1 month and plus or minus 1 week from their date of surgery, as well as the patient's weight and BMI at each visit. Also, if the patient saw either the dietitian at WBI or their affiliated hospital during this same time frame, the date of their visit, their weight and BMI at the time of the visit, the dietitians assessment of the patient's compliance to the post-surgery diet recommendations, as well as any further recommendations the dietitian made to the patient was recorded.

Throughout the entirety of the study, no individual identifiable information was collected, recorded, or reported. The primary variables being examined are the patients' overall weight loss success as determined by their rate and maintenance of the weight loss within the 13 months following surgery, and how often they met with the staff dietitian. After the data collection, the information was saved onto a flash drive specifically designated for the study and was immediately taken to faculty mentor and co-investigator, Dr. Judith Ashley's lab in the Sarah Fleishman Building at the University of Nevada, Reno, room 111 and uploaded onto the College of Agriculture, Biotechnology, and Natural Resources' secure server. In addition, all protocol and procedures were cleared with the University of Nevada, Reno's institutional review board prior to the start of the study.

Measures

The analytical standards of mean, median and frequency were used to capture snapshot generalizations, and summarize important information about the data set. Also, general methods comprised of both paired and unpaired t-tests, as well as standard measurements of frequencies and means. T-tests were used to compare baseline and subsequent visits to WBI to obtain the following results, and Pearson correlation coefficients were used to determine overall significant trends.

Results

The data examined did not provide a sufficient sample size to accurately answer the original hypothesis question regarding the correlation between ongoing RD guidance and a more successful weight loss outcome after the first 13 months. In lieu of not being able to examine this hypothesis, the study then shifted focus on what trends were observed in the data set, and what could be inferred from these trends.

Demographics

Analysis of the Western Bariatric Institute data on 105 female and male subjects over 13 months post surgery showed some trends involving the demographics of patient population in the clinic. For gender, a much larger number of women than men involved in the study underwent bariatric surgery. Table 1 shows that of the 105 patients examined, women comprised 77.14%, with a frequency of 81, compared to men who comprised 22.86%, with a frequency of 24.

Table 1
Gender Frequency of the 105 Study Participants

Gender	Frequency	Percent
Female	81	77.14
Male	24	22.86

The second demographic trend of interest was in the ethnicity distribution of the patients involved in the study. Table 2 demonstrates that there were a total of four racial/ethnic groups identified within the data set. The highest percent of patients were those identified as White (87.62%), with the second highest percent identified as Hispanic (8.57%), and a smaller percent of African American (1.9%) and Other (1.9%). The original records did not specify any further the category of “Other” as an ethnic/racial background.

Table 2
Distribution of Ethnicities Amongst the Study Participants

Race	Frequency	Percent
Caucasian	92	87.62
African American	0	1.9
Hispanic	9	8.57
Other	2	1.9

For the age of the patients, participants were analyzed using three different groups: age 40 and younger, 41 to 50, and age 51 and older. Table 3 shows that 35.24% were within the first age group, 31.43% within the second, and 33.33% within the third.

Table 3
Variations in Age Within the Study Group

Age Group	Frequency	Percent
Less than or equal to 40	37	35.24
41 to 50	33	31.43
51 and older	35	33.33

The last demographic area examined was the initial BMI classifications within which the patients fell before their LRYGB procedure. Without question, the classifications of underweight, normal weight, and even overweight were null and void. To be a candidate for LRYGB a patient must have a BMI greater than or equal to 40, or 35 with the presence of co-morbidities. Understanding the demographics of the participant's initial BMI categories contributes to the final understanding of the results regarding the rates of the patients' weight loss because it provides a standardized baseline measurement to which the results can be compared against. Also, knowing the baseline BMI categories of the participants helps to determine significance in the rates of weight loss that were observed, and provides a tool to track successful weight loss by the participants' movement throughout the different obesity categories. The standard sub-classifications within the obese category that were focused on for our analysis included: Class 1 (BMI of 30-35), class 2 (35-39.9 BMI), and Class 3 for extreme obesity (>40 BMI). Table 4 shows that the 105 patients in this study fell only within two of these classes: 2 and 3, with 78.1% in class 3.

Table 4
Frequency of Baseline BMI Categories of Participants

BMI Class	Frequency	Percent
Extreme Obesity (Greater than or equal to 40)	82	78.1
Class II Obesity (35-39.9)	23	21.9

Weight Loss

The significant finding found within the weight loss data set was simply that significant weight loss did occur over the 13-month time frame of the study (Pearson correlation coefficient = -0.93 , $P < 0.0001$). Although not significant, there were some trends of interest that were observed. One such trend shows that the weight loss rates of males and females (expressed as the mean percent of baseline weight lost) remained relatively the same, comparing males with females over the 13 months of the study, and is shown in Figure 1.

Figure 1
Weight Loss Over a 13-Month Period of Males Compared to Females

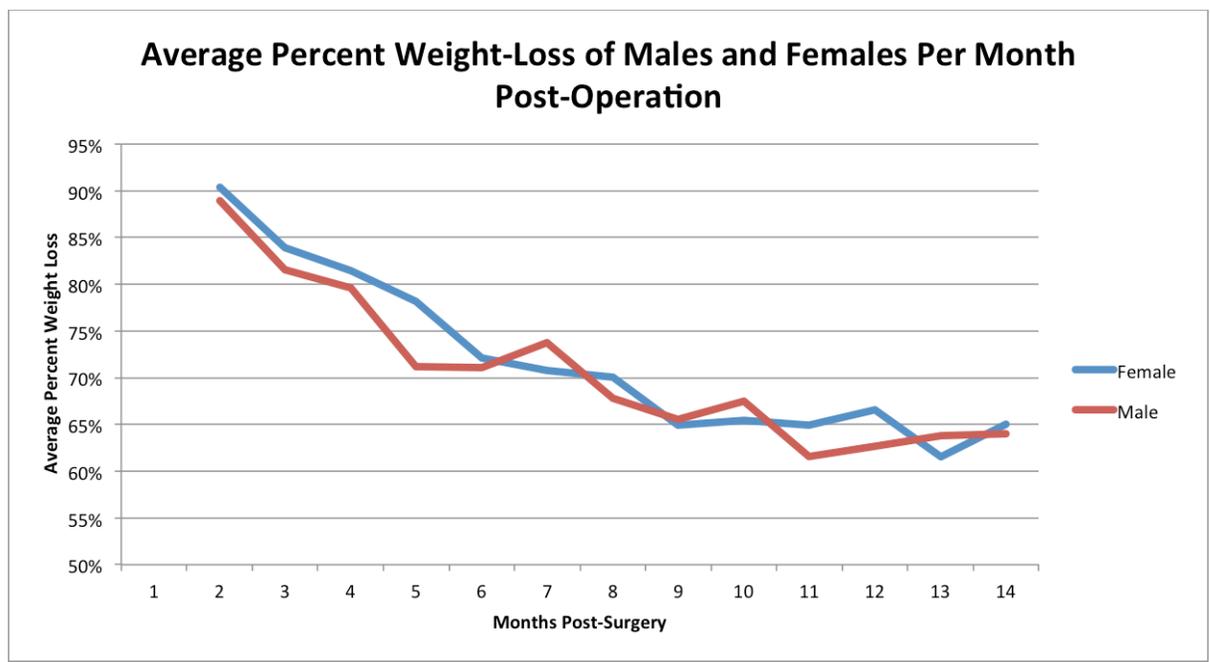


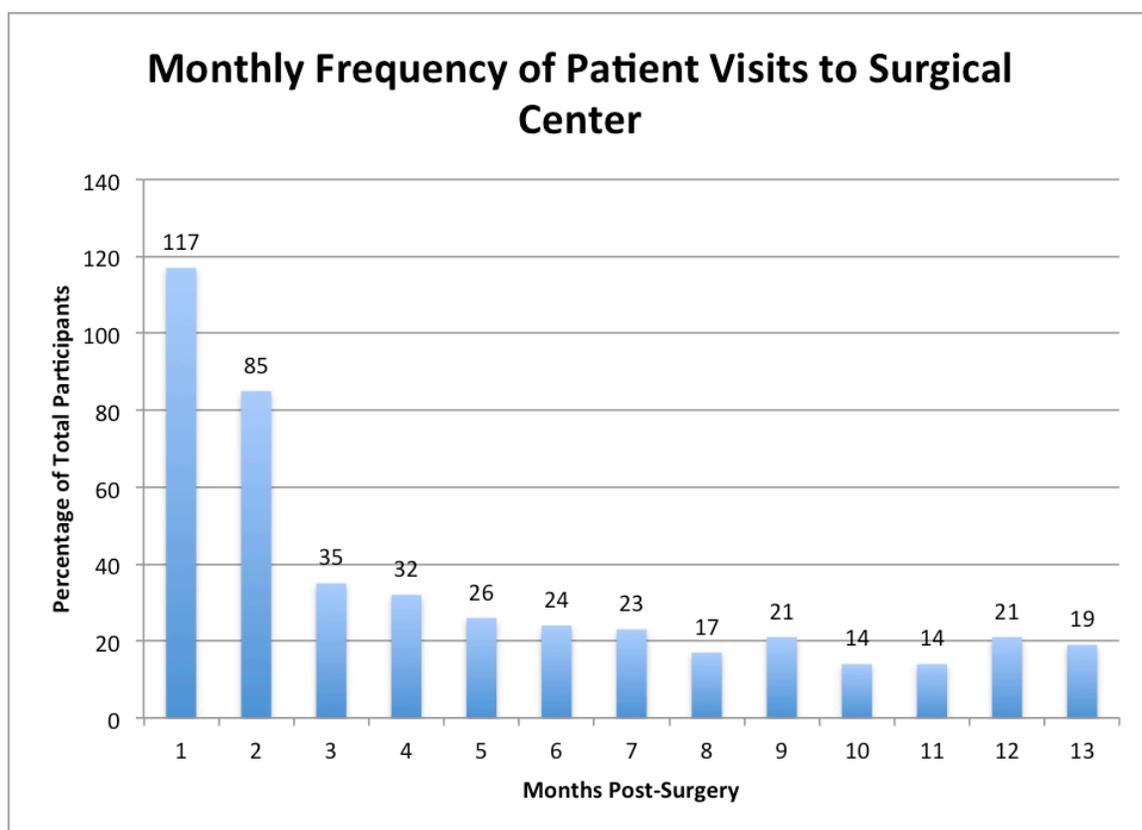
Table 5 lists the specific mean percent weight loss for each month post surgery. One trend seen is that monthly mean percent weight loss in females ranged from a mean high of 90.4% (occurring in the first month) to 61.0% (in the 12th month post- surgery).

Table 5
Mean Percent Weight Loss for Males and Females

Months Post-Surgery	Female Mean	Male Mean
1	90.4%	88.9%
2	84.0%	81.6%
3	81.5%	79.6%
4	78.2%	71.2%
5	72.1%	71.1%
6	70.7%	73.7%
7	70.0%	67.8%
8	64.9%	65.6%
9	65.4%	67.5%
10	64.9%	61.6%
11	66.5%	62.6%
12	61.5%	63.8%
13	65.0%	64.0%

For males, weight loss showed a similar distribution. The highest mean weight loss of 88.9% occurring in the first post-surgery month and the lowest mean occurring near the end of the 13-month time period, in month 10, at 61.6%, was observed. The difference in mean weight loss between the male and female patients ranged from 0% (-2.3%) to 7%. In addition, average percent weight loss on a per month basis following surgery for patients as a whole (as opposed to separated by gender), and average BMI on a per month basis following surgery for patients as a whole can be found in appendix C.

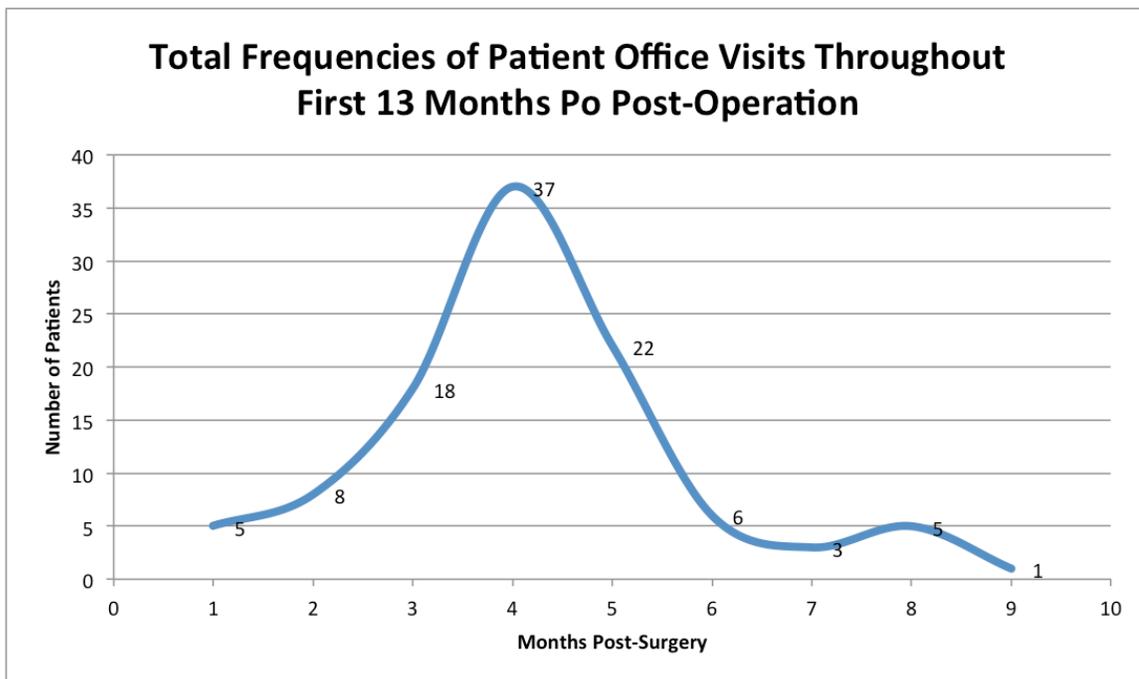
Figure 2
Number of Patient Visits on Each Month Post-Operatively



Next we analyzed the data to answer the hypothesis of whether there exists a positive correlation between visits with a dietitian and a better weight loss outcome. However, we found that the group of patients that had seen a dietitian post-operatively was only 21, too small of a sample size to determine any significance. Instead, the focus was shifted towards attempting to identify time markers within the first 13 months post-operatively that would indicate when patients would most benefit from meeting with a dietitian based on rates of weight loss – to accomplish this, several different aspects of the data were examined. The frequency of visits post-operatively on a per month basis is

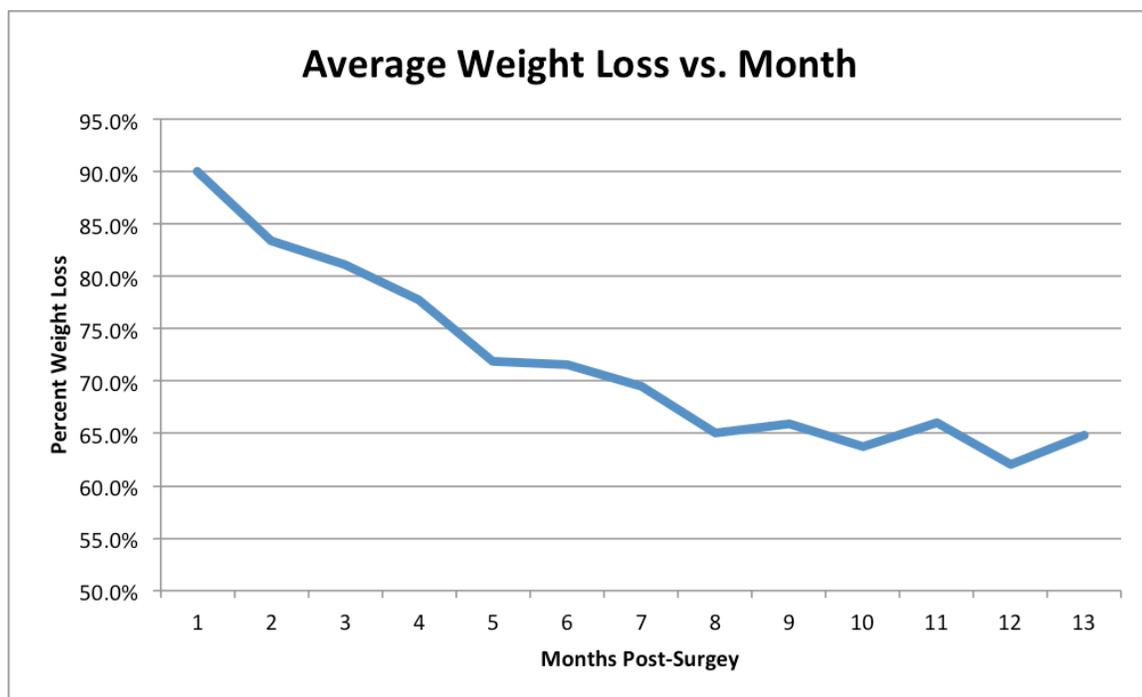
shown in Figure 2, and Figure 3 displays the frequencies of individual visits by patients after surgery, and were the two items used to examine the new focus.

Figure 3
Frequency of Monthly Patient Visits per Patient



The sharpest monthly declines in patient visits to the clinic were at months 3 and 10. In the second month, 83 patients were seen, whereas in the third month, only 35 patients visited the clinic, a decrease of 48 individuals. The second largest decline was 7 patients, 21 patients in month 9, compared to only 14 in month 10. Additionally, we found that the largest difference in the number of times the participants made visits to the clinic was from 5 to 6 visits.

Figure 4
*Average Percent Weight Loss of Participants for Each Month Post-LRYBG
 for 13 Months*



A total of 22 participants visited the clinic 5 times after their procedure, and only 6 participants returned for a 6th visit. The data from Figure 2 and 3 combined suggest that developing a program that encourages post-LRYGB patients to return for follow-ups in the 3rd and 10th month post-surgery, as well as curbing the 6th month decline in patient visits would be most beneficial.

We then calculated the average weight lost on a per month basis. As expected, individuals had a significant decline in weight overall at the end of the 13-month study (Pearson correlation coefficient = -0.93 , $P < 0.0001$). This significant finding is clearly depicted in Figure 4. Although not statistically significant, Figure 4 also shows that there was a decline in the rate at which patients were experiencing weight loss the farther out

they got from their initial date of surgery. This trend is concurrent with the known ebb and flow of dieting and weight loss. We then examined the drop in mean percent weight loss between months, and discovered the largest drop was between the first and second months (6.6% decline), as well as the fourth and fifth months (5.9% decline). Again, when both the decrease in patient visits and the sharpest declines in rate of weight loss per month were analyzed, month 3 appeared to be a crucial time for patients. In month 3 the rate of weight loss slows significantly, as well as the number of patients whom consulted with one of the health professional at the weight loss center.

The last area of data collection that was examined was the nature of patient's consultations with either the WBI dietitian or one of the RDs at the affiliated hospital. Statistical measures were not run on this data, as this set of data merely serves the qualitative purposes of interest. Of the patients that did see an RD during their first 13 months following their LRYGB procedure, the RDs comments and notes regarding the patient's visit were observed and classified. Decreasing the speed of eating was the least common of the patients' RD consultations. Both increasing the variety of foods consumed as well as increasing protein were the most prevalent remarks of the RD consultations.

Discussion

Rationale and Summary of Results

A review of the results indicated only one statistically significant observation: that over the course of 13-months after undergoing LRYGB, individuals experienced significant weight loss. However, other trends were found that are areas of interest, and

may present opportunities for future research. The first of these trends was that a drop-off in weight loss in both males and females was observed in the 4th chronological month from surgery. The second trend of interest was the finding that as months from surgery date increased, average percent of weight loss observed declined. Another related trend includes a decline in the 3rd and 10th months in the number follow-up visits to the clinic. A variety of conclusions may be deduced from these findings.

The existence of a decline in the average percent of weight loss occurring in the third month is not startling, and is in line with expected trends of weight loss following a LRYGB procedure. As with any form of weight loss intervention, rates of weight loss are expected to be highest at the beginning of the intervention, then steadily decline as the participants weight declines. Possible reasons for the decline are numerous.

One reason for the decline in average percent weight loss may be that around this time, patients normally experience a full re-introduction to a diet lacking any major restrictions. Relatively speaking, up until this point, patients have been on a diet comprised of many meal replacement protein shakes in order to prepare their bodies for the rigors of surgery. The protein shakes continue after surgery to help ease the digestive tract into a normal functioning state, and to help patients maintain their protein status. As patients' are advised by the dietitian and care team to begin incorporating different foods into their diet, it is a slow process, and patients' often struggle with some foods they previously consumed with ease. Common foods that are often troublesome to post-LRYGB patients are bread products and meats, particularly stringy and tough meats, as well as foods high in fat and sugar. Around this four-month marker, many of these

transitions have been made, and patients are tempted to retreat to their pre-bariatric surgery diet.

Not only is a patients' variety of food selection broadened, but also the amount they can consume. It is generally accepted knowledge of practice in the bariatric medical field that as time increases after any bariatric procedure, the greater the risk of the patient inadvertently expanding the size of their stomach. One of many causes for this is that patients often eventually discover they can tolerate larger portions than what is advised. An increase in portions, along with the increased freedom of food selections have the potential for de-railing the rate of weight loss a patient had previously been experiencing.

There may also be a psychological component to the decrease in percentage weight loss around the fourth chronological month following LRYGB, as well as a decline in the number of time patients make visits to the surgical center for check-ups. As with any new change to lifestyle, the motivation behind the behavior change is strongest when first initiated, then gradually fades as time goes on, sometimes resulting in an abandonment of the eating modifications trying to be instilled. The waning of motivation is strongly observed in many various weight loss efforts, and post-LRYGB diets are not exempt.

In regards to the significant finding that as the months from surgery date increased, the average percent of weight loss observed also declined may be explained by the natural progression of weight loss. In any type of weight loss endeavor, the body's rate of weight loss naturally declines as more weight is shed, and weight loss behaviors tend to slacken due to lack of novelty and decreased motivation. The two steepest

declines in weight loss percentage occurred between months one and two, as well as months four and five.

The decline in patient follow-up visits in the third and tenth months may also be attributable to a vast number of alternative reasoning.

The decline in the third month may be the result of the resurgence of a “normal” eating pattern and diet. As stated previously, it is around the third month post-surgery that the patient should be physically able to eat an ample well-rounded diet. By this time, the patient has already discovered which foods are comfortable to eat, and which foods cause them discomfort, therefore their eating behavior returns to their pre-surgery habits. Because of this “normalcy”, perhaps patients do not feel a follow-up is necessary.

The tenth month decline again could be attributed to a sense of normalcy, but also perhaps complacency. At this point, the patient has been living their new life-style for almost a year, and they may have grown comfortable with the changes. Consequently, this may lead them to feel able to eliminating the guidance of a doctor or RD. This reasoning and decline in visits then is not necessarily a negative occurrence. It is the goal of the care team to guide and teach the patient how to comfortably and safely live their new lifestyle independently, and if the assumption of the 10-month decline stated above is correct, that goal has been met. However, the confidence to discontinue the guidance of the care team can become problematic if the patient in fact is not yet ready to be independent in their new lifestyle.

A study conducted in 2008 at UCLA Medical Center Department of Surgery identified that post-operative weight gain and inability to maintain long-term follow-ups were two on-going problems encountered in their study – a finding that supports the

conclusions and concerns of this study. In addition, the UCLA study comes to an overall similar conclusion that “an effective method for long-term patient follow-up remains elusive and may contribute to post-operative weight regain in some patients” (Tejirian et al., 2008).

Strengths and Limitations

Although the initial study hypothesis could not be statistically addressed based on the clinical data available, insightful information was gained on the trends of patient behavior and weight loss during their first year after having undergone LRYGB.

The results indicate crucial points along the first 13 months following surgery that care teams should consider focusing upon. If surgical centers and bariatric RDs were more fervent in patient follow-ups around the third, fourth, and tenth months post-operation, perhaps patients might avoid the decline in percent weight loss observed at these months. Also, more diligent follow-ups may aid surgical centers in obtaining a more complete and detailed patient record of follow-ups during the first, and most crucial, 13 months after surgery. Obtaining more complete and detailed patient records following surgeries would subsequently allow bariatric centers to hopefully improve overall weight loss results for their individual patients.

Throughout conducting this study, multiple factors, such as human error and lack of consistency, were identified that may have played a role in determining the result outcomes. Additionally, the area of concentration we had originally anticipated examining was inaccessible given the study’s data set.

The first factor that may have had an effect on the study outcomes is human error, as with any study. Measures were taken to reduce the impact that human error might

have had on the study in the form of multiple individuals reviewing the data and results several times, but the chance that there existed an error in the data set is always a plausible factor that needs to be considered. Also, although measures were taken aiming to reduce human error within the data set we collected and analyzed, we cannot attest to the data set provided by WBI which we utilized to derive our conclusions. In fact, one of the two leading limiting factors we had to compensate for was the lack of consistency contained within the medical records examined. The lack of consistency found is presumably due to the fact that WBI functions not as a research facility, but as a privately owned medical center. Unlike a facility designed to drive research, consistency is not as crucial as merely clearly communicating the information important to the patient's care team. As a consequence of this, not all personnel within the facility utilize the same charting structure. Also, not all the notes made within the patients' files were completed by the WBI staff.

A clear instance of this inconsistency is in the dietitian notes. The WBI dietitian notes as well as the notes of the dietitians employed by the affiliated hospital were uploaded into the digital medical records of their patients. The two facilities employed different forms to record and summarize the nature of patient consults. Furthermore, during the time frame the study was examined, there was a change in the staff dietitian at WBI. The earlier RD used a narrative style of chart reporting, and the current RD used a standardized form for charting, resulting in different and variable information found within patient consultation records.

The inconsistency found within the RD portion of the medical records, along with a sheer lack of individuals making use of RD's as part of the post-surgical care team is

what hindered the ability to address the original hypothesis question, whether or not regular consults with an RD during a patient's first year post-LRYGB impacted their success in weight loss, unanswerable. Out of 105 participants, only a small fraction of them saw an RD following their surgery, 21 to be exact. The result was a sample size too small to derive any statistically significant results. Had the sample size been larger, the answer to this question would have been a valuable asset to the bariatric and dietetic practices, and perhaps may serve as a prompt for WBI and other bariatric surgery centers that also see low rates in RD consults to increase the level at which they advocate for patients to utilize an RD as part of their long-term care team.

Additional Directions for Future Research

Looking towards the future, multiple avenues of additional research surrounding the realm of dietetics and bariatric surgery are left unanswered. Based upon this research the most obvious of these unanswered questions is whether the number and frequency of regular consultations with an RD affects the outcome of weight loss resulting from LRYGB, or other forms of bariatric procedures. A larger sample size than the one found in this study would need to be utilized in order to address this question. Additionally, the ability to create a randomized study with an intervention group that meets regularly with a RD exclusive to the study for a designated amount of time following their procedure would be ideal. Attempting to answer this hypothesis using a retrospective study does not guarantee a large, comparable sample size, nor does it allow for the control of other variables that may have confounded with this study like inconsistency in RD's and charting protocol.

Testing the results of this study may also be an interesting avenue of future research. Creating a test group that is required to be seen for a check-up by their surgical center in the third or fourth and tenth months following surgery to examine if this behavior affects the weight loss outcome at the one year post-operation date would also be a good base for further study. The outcome of this proposed study would either validate or dismiss that the dropping off of patient-care team connection in these months is statistically relevant to weight loss success.

Concluding Remarks

In closing, despite the major advances that have been made medically and surgically to bariatric surgery since its introduction roughly a decade ago, there exists a need now to improve patient follow-up care. Devising a more efficient, comprehensive, and consistent means of patient follow-up care spanning patients' first year post-operatively may aid in the obstacles of weight re-gain and inability to maintain weight loss. Based off the findings of this study, the 3rd, 4th, and 10th months following surgery remain months that follow-up care is at it's lowest and percent weight-loss most markedly declines, and should therefore be points at which the care team of a post-LRYGB patient should be more focused. In addition, placing more of an emphasis on the roles of the RD on the post-LRYGB patient care team appears needed. The highly specialized educational training of RDs on nutrition and proper nutritional counseling makes them the ideal member of the care team to head the largely nutritionally related post-surgical follow-up care. Lastly, further research into post-surgical bariatric surgery care is needed to fully understand the current limitations and possible solutions.

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Appendix A

Recommended Daily Allowances (RDA) and Adequate Intakes (AI) of an Average Adult

Versus a Post-LRYGB

Nutrient	Iron RDA (mg/day)	Water AI (L/day)	CHO (% of total daily calories)	Protein RDA (g/kg/day)	Vit. B ₁₂ RDA (µg/day)	Calcium AI (mg/day)
Average Adult (31-50 y.o.)	8 (males) 18(females)	2.7-3.7	45-65%	0.8	2.4	1,000
Post- LRYGB Adult (31-50 y.o.)	Minimum of 18	Minimum of 1.9	40-60%	1-1.5	350	1,500- 2,000

SOURCE: Nelms, Sucher, & Long, 2007 and Shoenberger, 2011.

Appendix B

From Western Bariatric Institute's Demographic Analysis Report on LRYGB patients

dated from January 1, 2008 to November 30, 2010.

Variations of Gender in LRYGB Patients
at WBI From 1/1/2008 to 11/30/2010

	n*	%
Female	587	80.5
Male	142	19.5

n* = number of patients

Variations in Age in LRYGB Patients
at WBI From 1/1/2008 to 11/30/2010

	n	%
20s	48	6.6
30s	152	20.9
40s	210	28.8
50s	200	27.4
60s	109	15.0
70s	10	1.4

Variations in Marital Status of LRYGB Patients at WBI from 1/1/2008 to 11/30/2010

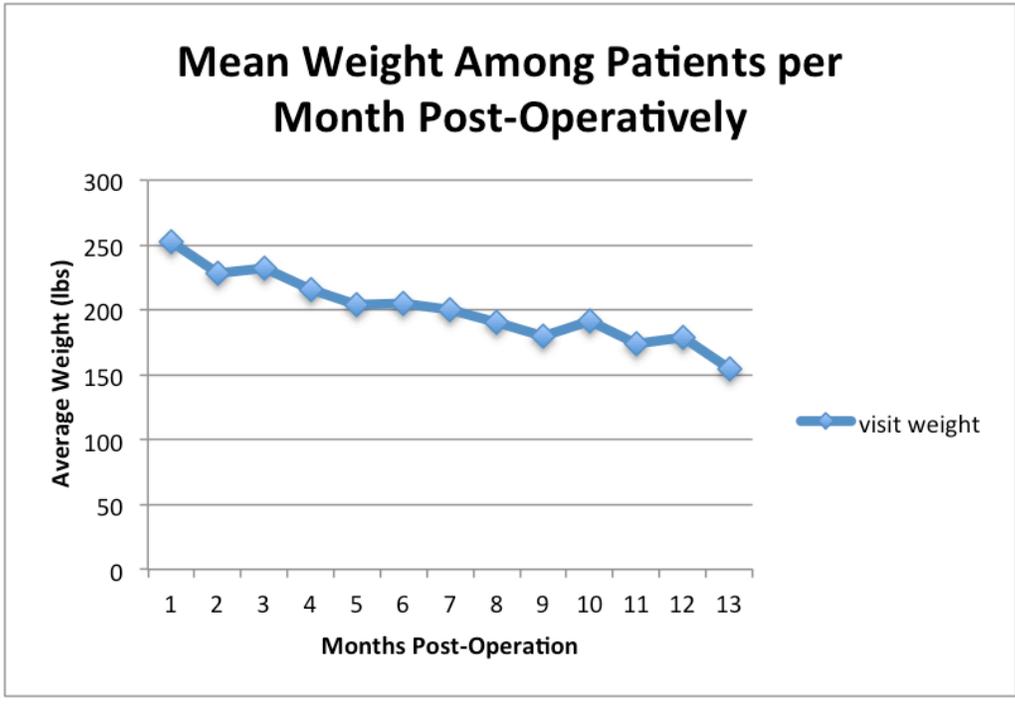
	n	%
Married	459	63.0
Single	133	18.2
Divorced	81	11.1
Not Specified	27	3.7
Widowed	20	2.7
Separated	9	1.2

Variations in Race in LRYGB Patients at WBI From 1/1/2008 to 11/30/2010

	n	%
White	596	81.8
Hispanic	60	8.2
Other	38	5.2
American Indian	18	2.5
African American	12	1.6
Pacific Islander	3	0.4
Asian	2	0.3

Appendix C

Average percent weight loss on a per month basis following surgery for patients as a whole, as opposed to separated by gender.



Average body mass index on a per month basis following surgery

