Size Matters: Gastric Pouch Size as a Predictor of Weight Loss Following Laparoscopic Roux-Y Gastric Bypass

Joyce I. Kaufman

Yale University

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19 MAY 2006

Date
Size Matters: Gastric Pouch Size As Predictor of Weight Loss Following Laparoscopic Roux-Y Gastric Bypass

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Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
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by
Joyce I Kaufman

2006
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Abstract

Introduction: The identification of relevant components of successful weight reduction surgery is the most important endeavor in the latest research aiming to increase excess weight loss. Over the past twenty years there has been ongoing discussion about the importance of gastric pouch size as one of the key factors influencing weight loss after restrictive weight reduction surgery. The goal of our analysis is to determine the relationship between gastric pouch size and weight reduction following laparoscopic Roux-Y gastric bypass (LRYGB).

Methods: Between August 2002 and March 2005, 321 LRYGB procedures were performed at the same institution. Patient demographics were entered into a longitudinal, prospective database. Upper gastrointestinal series were performed in all patients on postoperative day one. Assuming that pouch depth remained constant, pouch size was calculated as area (cm²) utilizing digital imaging technology and internal standardization for measurement. Linear regression analysis was performed to determine the association between pouch size and weight loss at 6 and 12 months postoperatively. Adjustment was made for age, gender, and preoperative BMI.

Results: Mean age was 41 years (range, 17-64); 262 patients were female (81.6%); mean preoperative BMI was 51.1 kg/m² (range, 36.1-89.9 kg/m²). Mean 6 month %EWL was 50.5 (range, 13.4-85.5%) and mean 12 month %EWL was 62.5 (range, 14.6-98.1). Mean pouch size was 63.9 cm² (range, 8.6-248.0 cm²). A statistically significant inverse correlation between pouch size and %EWL was found at 6 months (β = -0.241, p<0.01) and at 12 months (β = -0.302, p<0.02). A significant correlation was found between pouch size, male gender and preoperative BMI but not between pouch size and age.

Conclusion: Our analysis demonstrates that gastric pouch size is one important component for successful weight reduction following LRYGB. The creation of a small gastric pouch should be encouraged as the initial step towards ideal weight loss.
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Introduction

With the prevalence of morbid obesity ever increasing and few if any successful alternatives, patients are seeking out bariatric surgery as definitive treatment in record numbers. With the decreased associated morbidity and mortality, laparoscopic Roux-Y gastric bypass (LRYGB) has emerged as the procedure of choice for those electing surgery. Since all patients must first demonstrate failed non-surgical regimens, LRYGB frequently provides a last resort. Consequently, it is imperative that the factors contributing to a successful outcome be elucidated. Over the past twenty years, debate has ensued about the import of gastric pouch size as one of these factors, yet a paucity of literature exists substantiating the association between gastric pouch size and weight loss following gastric bypass surgery.

The goal of this analysis is to determine the relationship between the surgically created gastric pouch and excess weight loss specifically after laparoscopic Roux-Y gastric bypass, as well as to identify any factors possibly confounding this association. We hypothesized that there is a significant inverse relationship between pouch size and resultant excess weight loss, i.e. the smaller the pouch the greater the weight loss.
Background:

Obesity is not a new phenomenon. Neither are the societal stigma and prejudice associated with it. Perhaps most interestingly, the surgical treatment for obesity is not novel to the 20th century. Claudius Aelian (170-235 A.D.) in his treatise on Ancient Greece, *Historical Miscellany*, wrote of a man of gluttony too ashamed to leave his house because of his extreme corpulence and the physicians who attempted a surgical remedy for his affliction while he was sleeping. [1] Though we do not know the particulars of the procedure, nor its outcome, we are left with a treatment precedent for today’s epidemic of obesity. Using the standard measurement of body mass index (BMI) in kilograms/meters$^2$, which has been shown to accurately reflect body fat stores, a BMI $\geq 25$ kg/m$^2$ is overweight and $\geq 30$ kg/m$^2$ is obese. A BMI of 40 kg/m$^2$ roughly reflects 100 lbs of overweight for an average adult male. [2] Once a disease associated with excess means, privilege, and social status, in the past 50 years there has been a greater rise in the rates of obesity amongst those who are poor, minorities and underprivileged.[3] Roughly 55% of Americans are now considered obese, with a BMI $\geq 30$ kg/m$^2$.

Though the rates of obesity remained steady in the first two-thirds of the twentieth century, between 1970 and 2000, the number of obese Americans nearly doubled. (Figure 1)
While there are many elaborate theories offered as explanation for the cause of this phenomenon, one argument that persists is that the rates of physical labour have decreased, wages have increased, and the price of calorie dense foods have decreased relative to natural and complex carbohydrate alternatives. While the answer to this question remains elusive, one thing is for certain: the rise in obesity reflects an increase in caloric consumption with a decrease in energy expenditure. Finkelstein et al. writes that this trend in obesity over the past 50 years can be explained simply by an increase in the American diet of 50-100 calories per day. [4]
The implications of obesity transcend mere cosmetics, as it is a major cause of comorbidities, including type two diabetes, cardiovascular disease, stroke, hypertension, hyperlipidemia, gallbladder disease, sleep apnea, Pickwickian syndrome, arthropathies, uterine, prostate and breast cancers and infertility, among others. [5-8]
The risk of these comorbid conditions rises directly with an increase in BMI, and both morbidity and mortality are proportional to degree of overweight [9], as depicted in Figure 2. Furthermore, higher BMI, and obesity specifically, is associated with an increase in all cause mortality. [9] In 2002, 400,000 U.S. deaths were attributed to obesity related causes, making it the second most common cause of death from a modifiable behavior, lagging only behind smoking. [10] With 53 million obese, adult Americans, and 17.5 million obese or overweight children and without any evidence of the epidemic plateauing or approaching a downward trend [11] the cost to the health care system is astronomical. Though reports vary slightly, most agree that as of 2003, ~ 7-9% of total annual medical expenditures or between $70 and $95 billion dollars are spent on obesity related diseases, approximately half of which are paid for by Medicare and Medicaid. [12, 13]
Increased Risk of Obesity Related Diseases with Higher BMI

<table>
<thead>
<tr>
<th>Disease</th>
<th>BMI of 25 or less</th>
<th>BMI between 25 and 30</th>
<th>BMI between 30 and 35</th>
<th>BMI of 35 or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis</td>
<td>1.00</td>
<td>1.56</td>
<td>1.87</td>
<td>2.39</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>1.00</td>
<td>1.39</td>
<td>1.66</td>
<td>1.67</td>
</tr>
<tr>
<td>Diabetes (Type 2)</td>
<td>1.00</td>
<td>2.42</td>
<td>3.35</td>
<td>6.16</td>
</tr>
<tr>
<td>Gallstones</td>
<td>1.00</td>
<td>1.97</td>
<td>3.30</td>
<td>5.48</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.00</td>
<td>1.92</td>
<td>2.62</td>
<td>3.77</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.00</td>
<td>1.53</td>
<td>1.59</td>
<td>1.75</td>
</tr>
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</table>

Figure 2. Risk of Comorbid Conditions with Increasing BMI.

Figure 3 shows the direct cost of obesity related co-morbidities and their percentage of total disease direct cost. Sturm et al, in his analysis of the economic consequences of obesity, found that obese adults have 36% higher average annual medical costs than those adults of normal weight. [15] Furthering the economic impact of obesity, Colditz reports that obese workers take more sick leave and are on more disability due to weight related problems than do their normal weight counterparts; potentially 10% of sick leave and disability pensions in women may be attributed to obesity and its associated conditions. [16] In Sweden, obese workers were found between 1.5 to 1.9 times more likely to take sick leave than their normal weight counterparts, and 12% of women had disability pensions attributable to obesity, at a cost of $300 million for 1 million women in the adult population. [17] Wolf confirmed similar findings for the U.S. work force, “in 1994, there were 263 million restricted activity days and 58.4 million work days lost among those with BMI >27 kg/m², when
compared to nonobese individuals. Annually, lost productivity amounts to $5.7 billion dollars.” [18]

For men, even moderate obesity is associated with a 50% increase in the probability of limiting activities of daily living (ADLs), a figure that rises to 300% with severe obesity. These estimates are even more severe for women, as this probability of ADL limitation doubles with moderate and quadruples with severe obesity. [15]

<table>
<thead>
<tr>
<th>Disease</th>
<th>Direct Cost of Obesity</th>
<th>Direct Cost of Disease</th>
<th>Direct Cost of Obesity as % of Total Direct Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis</td>
<td>$7.4</td>
<td>$23.1</td>
<td>32%</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>$2.1</td>
<td>$10.2</td>
<td>21%</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>$30.6</td>
<td>$101.8</td>
<td>30%</td>
</tr>
<tr>
<td>Colorectal Cancer</td>
<td>$2.0</td>
<td>$10.0</td>
<td>20%</td>
</tr>
<tr>
<td>Diabetes (Type 2)</td>
<td>$20.5</td>
<td>$47.2</td>
<td>43%</td>
</tr>
<tr>
<td>Endometrial Cancer</td>
<td>$0.6</td>
<td>$2.5</td>
<td>24%</td>
</tr>
<tr>
<td>ESRD</td>
<td>$3.0</td>
<td>$14.9</td>
<td>20%</td>
</tr>
<tr>
<td>Gallstones</td>
<td>$3.5</td>
<td>$7.7</td>
<td>45%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>$9.6</td>
<td>$24.5</td>
<td>39%</td>
</tr>
<tr>
<td>Liver Disease</td>
<td>$3.4</td>
<td>$9.7</td>
<td>35%</td>
</tr>
<tr>
<td>Low Back Pain</td>
<td>$3.5</td>
<td>$19.2</td>
<td>18%</td>
</tr>
<tr>
<td>Renal Cell Cancer</td>
<td>$0.5</td>
<td>$1.6</td>
<td>31%</td>
</tr>
<tr>
<td>Obstructive Sleep Apnea</td>
<td>$0.2</td>
<td>$0.4</td>
<td>50%</td>
</tr>
<tr>
<td>Stroke</td>
<td>$8.1</td>
<td>$29.5</td>
<td>27%</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td>$7.6</td>
<td>$29.2</td>
<td>26%</td>
</tr>
<tr>
<td>Total Direct Cost</td>
<td>$102.2</td>
<td>$331.4</td>
<td>31%</td>
</tr>
</tbody>
</table>

Figure 3. Cost of Obesity Related Comorbidities.
Seeking to remedy or at least abate the health implications of obesity, in 1991, the National Institutes of Health convened a consensus panel on the surgical treatment of obesity. Although not the first panel held of this sort, either by this institution or by others, the panel delineated a set of guidelines that are still in practice today. Recommendations include that obese patients should first undergo medically supervised efforts at calorie restricting diets, with a goal of 10% weight reduction per year through a combination of caloric restriction and behaviour therapy. [9] However, in the intervening time, studies examining the effects of calorie restriction are not encouraging for those suffering with obesity. Very low calorie diets (600-800 cal/day) have been shown to reduce weight by only 4% over 3-5 years (Figure 4), well less than the recommended reduction of 10% per year. [20] Furthermore, recidivism rates are very high, exceeding 90% within five years. [2, 10]

![Figure 4. Outcome of Very Low Calorie Diets Over Time.](image-url)
Perhaps more surprisingly, exercise also has not been shown to promote and induce weight loss in this population [2, 22], but it has been shown to improve cardiovascular health, which is otherwise compromised by the state of obesity and is therefore recommended by the panel. Overweight and obese patients should be advised to begin regular exercise six out of seven days per week.

Efforts at pharmacological intervention have also been put forth as potential therapy for obesity, but with limited success and sometimes dire consequences. At the time of the 1996 NIH consensus, drugs recommended for the treatment of obesity included phentermine hydrochloride, fenfluramine hydrochloride, fenflafexine hydrochloride (fen-phen) and sibutramine. The former were ultimately taken off the market because of their implication in severe valvulopathies. [23] Interestingly, in 1994, the year that fen-phen prescriptions went from 50,000 to 1 million per year, there was a corresponding decrease in the number of bariatric procedures, but in the year those drugs were taken off the market (1997), there was a sharp increase in the number of bariatric surgeries performed. [24] Sibutramine, a noradrenergic and serotonin reuptake inhibitor, remains on the market although it has not been shown to significantly impact long term weight loss and is contraindicated in patients with hypertension or a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. [25] Finally, since the 1997 consensus report, orlistat,[26] which blocks absorption of dietary fat by inhibiting the activity of pancreatic lipase [27] has been approved for weight loss though it too has many side effects and has
not yet been shown to significantly lower excess body weight. Figure 5 shows the long-term efficacy of the three common weight loss drugs as compared with placebo.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Weight Loss above effect of placebo (%)</th>
<th>Weight loss above effect of placebo (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phentermine</td>
<td>8.1</td>
<td>17.4</td>
</tr>
<tr>
<td>Sibutramine</td>
<td>5.0</td>
<td>9.5</td>
</tr>
<tr>
<td>Orlistat</td>
<td>3.5</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Figure 5. Comparison of Popular Weight Loss Drugs.

Finally, with respect to pharmacotherapy for obesity, many are skeptical about prescribing additional medications to patients who frequently are already on complicated pharmaceutical regimens for comorbid conditions out of concern for inducing noncompliance.[26]

The only option put forth by the 1991 consensus panel that repeatedly has been proven to impact long term weight loss, is surgery; and in 1996, the NIH panel maintained that surgery remains “the only effective therapy for morbid obesity.” [28] An earlier consensus panel, convened in 1978, had initially conferred on and approved jejunoileal bypass surgery for the treatment of obesity. [29] However, by 1991, when the panel reconvened, experience had shown that this surgery was dangerous, resulting in severe electrolyte and nutritional deficiencies. In the
intervening time, however, numerous other surgical procedures emerged, which have proven both safer and equally efficacious as the original one recommended. Edward Mason wrote that the ideal bariatric operation should limit the ability to overeat and yet allow normal nutrition. [30] MacLean echoed Mason's sentiment, noting that the "ideal operation for obesity should rely on manipulation of satiety rather than the production of malabsorption." [31] All of the surgical procedures for weight loss involve the creation of an effective gastric pouch, smaller than the normal anatomic stomach. Theorists posit that passive stretch of the stomach following ingestion of food stimulates satiety, probably via afferent vagal signaling. However, even the earliest bariatric surgeons recognized the loophole in this theory, noting: "Even with the pouch left after 75% gastrectomy, the determined glutton can maintain his weight." [32] Patients can undermine the success of the procedure by consuming high calorie liquids, alcohol or not ceasing to eat once they have reached satiety.

Today, there are four basic classes of bariatric surgery: Malabsorptive: including jejunoileal bypass, biliopancreatic diversion and duodenal switch. Malabsorptive/Restrictive: including Roux-Y gastric bypass (both short and long limb). Restrictive: including gastric banding (ringed, vertical, and horizontal gastroplasty). A fourth group: Experimental, includes gastric pacing, which is in phase 3 trials. The four most commonly performed procedures are depicted in Figure 6.
Regardless of the specific procedure, several guiding principles have emerged regarding bariatric surgery in and of itself:

1. low risk of mortality (< 1%)
2. low risk of morbidity (<10%)
3. long term reduction of excess body weight (>50% EWL in at least 75% pts)
4. low rate of reoperation
5. reversible and reproducible

6. result in an improved quality of life. [10, 34, 35]

While an in-depth description of each of the bariatric procedures is beyond the scope of this paper, some discussion is necessary to help elucidate why laparoscopic Roux-Y gastric bypass has emerged as the “gold standard” and the procedure of choice in the United States. In the 1950s, jejunoileal bypass was being performed as a malabsorptive/maldigestive procedure for morbid obesity. The operation functionally limited the small intestine length and surface area, which resulted in decreased digestion and decreased subsequent absorption of digested elements. However, complication rates were incredibly high: gas-bloat syndrome, steatorrhea, electrolyte imbalance, nephrolithiasis, hepatic fibrosis and impaired mentation [36] were more the norm than the exception. Cirrhosis was the most serious complication, conjectured to be due to the absorption of bacterial overgrowth degradation products. The absorption of these products also caused rheumatoid arthritis due to antigen (the degraded bacterial byproducts)-antibody complexes, which were found to be deposited in joint spaces [37]. Ultimately, the jejunoileal bypass was abandoned and should not be used in practice today.

Restrictive procedures, typified by laparoscopic adjustable gastric banding and vertical banded gastroplasty, rely on the construction of a small gastric pouch with a restricted outlet along the lesser curvature of the stomach. [29] Many patients opt for
a banding procedure because it has the lowest long-term complication rate [37] and
does not alter normal anatomy. [38] It is worthwhile to note that outside the United
States, and in Europe and Australia in particular, gastric banding procedures are the
most frequent surgical procedures for obesity.[38] Sugerman found that severe
gastric reflux, which can develop after vertical banded gastroplasty, resolves after
patients undergo conversion to gastric bypass. He also credits gastric bypass with
being more efficacious than vertical banded gastroplasty in normalizing glucose
tolerance in those patients without over non-insulin dependent diabetes mellitus. [37,
39]

Weight loss after banding, however, remains marginal. Proximal pouch dilation is the
most frequent cause of post-operative complication,[40] which some argue is the
cause of the inferior weight loss. Biliopancreatic diversion, which entails gastric
restriction and diverts bile and pancreatic fluids into the distal ileum [22] results in the
most drastic weight loss, but complications and nutritional deficiencies are more
commonly the rule than the exception thereby deviating sharply from the above
stated preeminent guideline for bariatric surgery, i.e. low morbidity and mortality.

In one of the longest prospective studies comparing long-term outcomes after
obesity surgery, Sjostrom published the resultant weight loss after each of the three
common procedures as compared with conventional, non-surgical treatment of
obesity. His findings are depicted in Figure 7. As have many other authors,
Sjostrom confirmed gastric bypass as the most successful procedure with respect to long-term weight loss. [41]

Figure 7. Weight Loss Following The Three Common Bariatric Procedures. Printed with permission; copyright © 2004 NEJM. All Rights reserved. [41]

Regardless of the specific type, bariatric surgery has demonstrated significant achievements with respect to reducing the health impact of obesity. In the Swedish Obesity Study, Sjostrom showed that those treated with surgery as compared with conventional medical therapy had higher two and ten year rates of recovery from diabetes, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension, and hyperuricemia. [41] Buchwald goes so far as to declare that the
surgical treatment of obesity ameliorates the medical, social, economic, comorbid conditions of morbid obesity, and is cost effective. [11] Larsen et al demonstrated that poor self-confidence, neuroticism and depression, frequently concomitant with the state of obesity, virtually disappear after bariatric surgery. [42]

Patient Eligibility for Surgery
As surgical techniques have evolved over recent years, those who are candidates for bariatric surgery have also increased. Once, it was considered those with super-obesity (BMI ≥ 50 kg/m²) or super-super obesity (BMI ≥ 60 kg/m²), those older than 60 or adolescents, were ineligible due to technical constraints and operative risk. However, with more sophisticated screening procedures, and safer operative techniques, bariatric procedures have been performed successfully on these once ineligible patients.[43] In general, however, selection criteria initially elucidated by the NIH consensus panel and augmented by surgeons, remain fairly consistent:

1. Patients with BMI ≥ 40 kg/m² or ≥ 35 kg/m² with comorbid conditions.
2. Documented failed previous attempts at conventional and/or medical therapy.
3. Motivated patients who are cooperative with pre-operative counseling and educational efforts.
4. Understanding of the procedure’s risks and benefits.
5. Be amenable and ready to undergo lifelong follow up and medical supervision.
Acceptance of Bariatric Surgery
Bariatric surgery has evolved from what it once was and the evolution is most evident by its growing popularity. In 1994, only 22% of internists admitted to knowing about bariatric surgery, 7% of internists knew of patients treated with surgery, 3% had read about it, none would recommend it or refer a patient, and 18% would advise against it. [44] Yet by 1996, when Edward Mason surveyed 151 chairmen of academic surgical departments, 71% acknowledged that the surgery was safe and 77% thought it should be used for the treatment of obesity. [45] Between 1998 and 2002, the number of bariatric procedures increased from 12,774 to 70,774 or an increase of 6.4% to 37.7% procedures per 100,000 [46] and the number of surgeons in the American Society of Bariatric Surgeons increased from 258 to 631. (Figure 8)
California alone demonstrated a 4115% increase in the number of weight restrictive procedures in that same four year period, indicating that bariatric surgery is on the rise and is becoming mainstream. It is estimated that 140,000 bariatric procedures will be performed in the United States in 2005. [47] The brisk rise in the number of bariatric procedures (Figure 9) parallels the dissemination of and competence with laparoscopic procedures. Cottam and Nguyen liken the frequency to the rise in antireflux procedures between 1991 and 1996 after the introduction and widespread utilization of laparoscopy. [47, 48]

Figure 9. Rise of Bariatric Procedures 1990-2002.
Still, only 1 in 600 morbidly obese patients have undergone gastric bypass, “suggesting poor acceptance of open gastric bypass by patients and physicians with regard to perioperative outcomes.” [47] Unfortunately, with the rates of obesity as they are presently, surgical therapy has not, nor shows any signs of, making dent in the epidemic from a community health standpoint [38] even despite studies showing that weight loss is greater after and the cost of surgery is exceeded within five years of conventional medical therapy. [11] Nevertheless, with the gain in life expectancy, improved overall health and psychosocial condition, plus the greater employment opportunities that surgery affords, surgical therapy for the treatment of obesity will continue to become more popular and more mainstream in the absence of any other viable alternatives.

Rationale for Laparoscopy
Because the procedures are similar between laparoscopic and open, one would expect that outcomes should be similar between the two. And in fact, studies comparing estimates of excess weight loss are comparable between the two techniques, given sufficient follow-up. Comparing long term weight loss between laparoscopic and open gastric bypass, studies demonstrate a higher percentage of excess weight loss after laparoscopically performed gastric bypass at six months, a difference that disappears by one and three years after surgery. [47, 49, 50] Nguyen posits this early result is due to faster resumption of physical activity and initiation of exercise programs in the laparoscopic group. [47]
However, when analyzing the two different approaches other factors besides weight loss come into play. Although open gastric bypass can be performed safely with low morbidity and mortality, wound complications, including infections and incisional hernias are still formidable risks. Kellum et al quote these complications are as high as 15% and 20%, respectively. [51] There is still much debate about the degree of post-operative pain associated with the two procedures – Nguyen [47, 52] argues that less pain medication is used by patients after laparoscopic procedures. In general, the adoption of a laparoscopic approach has been based on the rationale that there are fewer wound-related complications, less postoperative pain, and faster convalescence. [47, 52, 53] Nguyen goes on to argue that pulmonary function in an already vulnerable population, is less compromised in laparoscopically treated patients, since “the extent of depression of pulmonary function is related to the magnitude of operative trauma.”[47] Only three randomized trials are known to compare laparoscopic versus open gastric bypass, the first was based on 51 patients by Westling and Gustavsson, in which they found no difference in postoperative pain, length of hospital stay or length of convalescence. [54] Looking at the National Inpatient Survey for 2001, Livingston found that hospital costs were lowest with laparoscopic bariatric procedures (versus open), despite having greater equipment/procedural costs. Overall, laparoscopic Roux-Y gastric bypass was most cost effective when all factors were taken into account. It is worthwhile to point out
that although LRYGB had the lowest medical complication rate, it had the highest technical complication rate. [55] (Figures 10, 11)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LRYGBP</th>
<th>Open RYGBP</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (min)</td>
<td>285 ± 50</td>
<td>155 ± 48</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>EBL* (mL)</td>
<td>125 ± 68</td>
<td>305 ± 83</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>ICU stay (days)</td>
<td>0</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Hospital LOS (days)</td>
<td>3.5 ± 0.69</td>
<td>4.8 ± 1.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Transfusions</td>
<td>0</td>
<td>2</td>
<td>-</td>
</tr>
</tbody>
</table>

*estimated blood loss. Values are mean ± SD

Figure 10. Operative/Perioperative Data Following the Open and Laparoscopic Approaches.

<table>
<thead>
<tr>
<th>Cost of gastric bypass using the laparoscopic and open approach*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter</td>
</tr>
<tr>
<td>----------------------------</td>
</tr>
<tr>
<td>Direct Cost</td>
</tr>
<tr>
<td>Indirect Cost</td>
</tr>
<tr>
<td>Total Cost</td>
</tr>
</tbody>
</table>

* Cost = U.S. Dollars. Values are mean ± SD

Figure 11. Cost of Gastric Bypass Using the Open and Laparoscopic Approaches.
History of Gastric Bypass

An ideal operation for control of obesity should limit ability to overeat and yet should allow normal nutrition. Subtotal gastric resection would satisfy these objectives but is too radical and irreversible.

Gastric bypass is an operation exactly like Billroth II gastric resection except that nothing is removed. A 15 to 30 per cent fundic segment is anastomosed to the upper jejunum. The distal segment of stomach is closed and sutured to the surface of the fundic pouch. [30]

So wrote Edward E. Mason, M.D. Ph.D., FACS and Chikashi Ito, M.D. in the first paper about gastric bypass for the treatment of morbid obesity. Although preceded by the introduction of malabsorptive procedures in the 1950’s, it wasn’t until 1967 that Mason and Ito first published their account of gastric bypass in a morbidly obese woman. In the late 1950’s, Mason, then a junior surgical resident at the University of Minnesota performing antral exclusion on dogs as a model for ulcer production, noted that severe weight loss, a side effect of the procedure, could be safely accomplished and could prove beneficial to obese patients. The inaugural human subject was a 50-year old female who stood 4 feet 10 inches tall and weighed 208 pounds (BMI = 43.5 kg/m2). Mason and Ito performed a gastric bypass, transecting the stomach horizontally [36] leaving 20 percent of the proximal gastric fundus anastomosed to the jejunum, 24 inches beyond the Ligament of Treitz. The gastroenterostomy was anterior to the colon and the distal closed segment of the stomach was sutured to the anterior surface of the fundic segment, [30] creating an upper gastric pouch between 100 mL and 150 mL with a stoma 12 mm in diameter.
It is important to point out that in this foundational operation, Mason and Ito performed a loop and not a Roux limb bypass, as will be discussed below. The patient subsequently lost 60 pounds over 9 months. Early satiety and sweet intolerance, which appeared within two months of the procedure, were the patient's only complaints after surgery.

Figure 12. Original Mason and Ito Gastric Bypass with Gastric Transection and Loop Gastrojejunostomy.

Mason and Ito conclude their first paper by calling for the investigation of and caution against the widespread use of gastric bypass before sufficient testing of the procedure was completed.

In 1977, Alden revised the gastric bypass procedure by stapling across the stomach horizontally, without dividing the stomach. He too used a loop gastrojejunostomy.
In that same year, Griffen published the bypass procedure with an alteration: the Roux-Y gastrojejunostomy instead of the loop. [58] (Figure 13) Henry and Jane Buchwald cite the advantages to the Roux-Y over the loop gastrojejunostomy as avoiding tension on the loop and preventing bile reflux back into the gastric pouch. [36] Randomized trials comparing the Roux-Y to the then standard loop, demonstrated weight loss comparable to the levels reached by jejunoileal bypass, which until then had led to superior results.

Further contributions to the gastric bypass procedure include: a vertically stapled stomach and a long-limb Roux-Y bypass for super-obese patients and for those with unsatisfactory results after conventional (short-limb) Roux-Y bypass. Long-limb gastric bypass has since been advocated as a primary procedure for super-obese patients. [59, 60] In 1994, Wittgrove, Clark and Tremblay first reported the technique of laparoscopic Roux-Y gastric bypass. [61] Higa, in 1999, suggested hand-sewing the gastrojejunostomy laparoscopically as a means of preventing anastomotic leaks that could complicate laparoscopic gastric bypass. [36, 62]
Various incarnations of the gastric bypass are still in practice today based on the training, skill and preference of the surgeon.

Significance of the Gastric Pouch Size

By 1972, Mason and Ito had performed and subsequently published their series of 24 patients, all treated with 90% gastric bypass. Reinhold notes, however, that 30% of the series necessitated revisional procedures because the original pouch created (~150 cc) was too large and led to inadequate results. [63] Mason himself agrees with this notion as is evident in his 1981 book, *Surgery for Morbid Obesity*, in which he consistently and adamantly stresses (no less than eight times) the need for a “small gastric pouch.” [64]
After Mason published a revision paper recommending a restricted pouch, subsequent papers echoed the sentiment, seemingly taking it as gospel and considering it a technical requirement for the procedure, without much reflection or testing. In his comparison of gastric and jejunooileal bypasses, Alden credits improved outcome on reduced pouch and gastroenterostomy sizes. [57] Early on in the practice of gastric bypass, surgeons routinely measured pouch volume intraoperatively. MacLean measured the pouch by using an esophageal tube, filling it with saline and occluding the outflow before stapling across the stomach. [65] Alder called for mandating intraoperative standards to assure reproducible pouch and stoma sizes. [66] Yet even as the bypass procedures evolved as described above, validation of pouch size seemed to be left off the list of variables to test with respect to gastric bypass. A literature review using MEDLINE, PubMed and Cochrane Databases yielded only two papers specifically devoted to testing the notion that pouch size effected outcome after gastric bypass. The literature search did yield numerous articles outlining the best way to measure the pouch volume after gastric bypass.

Curiously, the majority of articles raising the question of pouch volume and its corollary, pouch dilatation was more often (and frequently) discussed in the literature regarding gastroplasty and gastric banding procedures. Much attention is paid to the subject and although the consensus seems to fall in support of pouch size affecting outcome after gastroplasty.[67, 68]
Lundell, in his 1987 paper, “Measurement of Pouch Volume and Stoma Diameter After Gastropasty,” found a significant correlation between stoma diameter and weight reduction during the first six postoperative months, but found no correlation between pouch volume and weight loss. [67] Nevertheless, Lundell, too, called for precise measurement of pouch volume and stoma diameter [after gastroplasty] to evaluate long-term results of bariatric surgery after declaring “successful results in the short and long term have implied the establishment of a small fundic pouch combined with a narrow and stable outlet.” In 1981, Naslund published the results of a randomized prospective study of 57 patients that compared gastric bypass and gastroplasty, in which pouch and stoma sizes were included as variables of interest. In it, Naslund found that there was a correlation between pouch and stoma sizes and postoperative weight loss after gastroplasty, but not a similar correlation after gastric bypass. He writes, “In gastric bypass, the pouch size, at least if initially less than 50 mL, does not seem to be of the same importance as in gastroplasty. Patients with larger pouches lost weight as much weight as those with smaller ones.” He ascribes this difference in importance of pouch size to possible different mechanisms of weight loss between the two procedures: gastroplasty has an effect because of mechanical factors, which he thought was insufficient to explain weight loss after gastric bypass. [69] In 1995, Naslund revisited the question of pouch volume affecting weight loss, this time posing the question with respect to vertical banded gastroplasty. With intraoperative saline measurements, he looked at three pouch volumes: 20 mL, 30 mL and >40 mL, but was unable to show a difference in weight.
loss between the three groups. [70] (Figure 14) While no definitive answer exists in the literature regarding an absolute upper limit to the size of the gastric pouch for gastric banding, it appears that pouch dilatation is accepted as a real and significant complication of gastric banding, one that may necessitate reoperation for band repositioning. [40, 71-73] Why then have pouch size and pouch dilatation not been similar concerns after gastric bypass?

Figure 14. Weight Loss as a Function of Pouch Volume After Vertical Banded Gastroplasty.

Laparoscopic Gastric Bypass Surgery at Yale New Haven Hospital
Patients are taken to the operating room, placed in the supine position and prepped and draped in the standard surgical sterile fashion using the sequential application of Hibiclens® (Regent Medical Americas, LLC., Norcross, GA) soap and DuraPrep™ (3M™, St. Paul, MN) solutions. Initial port access is in the patient’s right upper abdomen at a site approximately three fingerbreadths below the xiphoid process,
slightly right of the midline. The site is anesthetized using a combination (0.5% marcaine and 1% lidocaine) anesthetic and a 12-millimeter skin incision is made, followed by Veress needle insertion. The abdomen is insufflated to achieve a 15 torr pneumoperitoneum with carbon dioxide. With adequate pneumoperitoneum achieved, the Veress needle is withdrawn and a 12-millimeter port is inserted into the abdomen. Using a 5-millimeter, thirty degree laparoscope, the abdomen is assessed before proceeding with direct visualization of subsequent port placements.

The second port is placed approximately one fingerbreadth below the left costal margin in the anterior axillary line; the third is approximately three to four fingerbreadths below the costal margin in the left midclavicular line. Three additional ports are placed as well, as depicted in Figure 15. With the exception of the first port, all remaining ports are 5-mm in diameter.
The left lateral segment of the liver is retracted anteriorly and cephalad, providing appropriate exposure of the gastroesophageal junction. The pars flaccida of the lesser omentum is divided, along with the gastrohepatic ligament, using an AutoSonix™ device. Using a 45-mm/3.5 mm stapler, the cardia is transected approximately 1-2 centimeters below the gastroesophageal junction. The rest of the stomach is transected with sequential firings of the stapler, yielding a proximal gastric pouch with an approximate 30 mL capacity. (Figures 16)
Next, attention is turned to the Ligament of Treitz, which is identified and the jejunum is followed approximately 25-30 cm distally until its maximal mesenteric length is found. At this point, the 45 mm/3.5 mm stapler is used to transect the jejunum. The mesentery is divided using an EndoGIA™ stapler (Figure 17) and attention is paid to both limbs of the intestine, ensuring they are pink and viable after the division.

Next, the Roux (efferent) intestinal limb is maneuvered in an antecolic, antegastric fashion and positioned next to the previously transected gastric pouch, and a posterior row of stay sutures are placed between the gastric pouch the jejunal limb using an EndoStitch device. Two parallel enterotomies are then created, one in the Roux limb of the jejunum and one in the gastric pouch, and a side-to-side
gastrojejunostomy is created by a single firing of the EndoGIA™ 30mm/3.5 mm stapler. The stapler insertion site defect is then closed using a running #0 Surgidac™ suture placed with the aid of an EndoStitch™ device. The suture line is imbricated using three #0 Surgidac™ sutures in a horizontal mattress fashion. (Figure 18)

![Figure 18. Gastrojejunostomy, Posterior Row Sutures.](image)

Attention is next turned toward the creation of the jejunostomy. Using an umbilical tape, 60 cm of Roux limb jejunum is measured and marked with a single 2-0 Surgidac™ suture. The previously transected proximal jejunum is then aligned in an antiperistaltic fashion with the point 60 cm distal to the Roux limb. The two limbs of intestine are secured to one another using two interrupted sutures placed in a seromuscular, antimesenteric fashion. Once secured, two parallel enterotomies are made using an AutoSonix™ device: one on the proximal jejunum and one on the distal Roux limb and then using a 45 mm/3.5 mm stapler, a side-to-side anastomosis is created. (Figure 19) Three sutures are used to close the defect from the stapler site,
which are then elevated and the staple line defect is completely closed by firing the 45 mm/3.5 mm stapler. (Figure 20) Peterson's space is subsequently closed using two interrupted sutures.
After inspection of the anastomosis, an endoscope is passed through the mouth, down the esophagus and through the gastrojejunal anastomosis, to ensure the newly created anastomosis is intact, patent and not under tension. (Figure 22)
The scope is then withdrawn to the level of the gastric pouch and an anastomotic leak test performed: the gastric pouch is insufflated, while simultaneously flooding the operative field with normal saline. (Figure 23) In the absence of bubbling, it can safely be assumed no leaks exist along the anastomotic suture lines and the endoscope is withdrawn.
A 19 French round Jackson-Pratt drain is inserted and placed next to the gastrojejunal anastomosis; The drain is exteriorized through the left lateral most incision and secured with two interrupted 2-0 Nylon sutures. The liver retractor is closed and withdrawn from the right lateral most port under direct laparoscopic visualization. All of the other ports are then withdrawn and the abdomen desufflated of all carbon dioxide. The port sites are reinjected with combination anesthetic and the subcutaneous tissue and the 12-mm port is closed with Biosyn™ suture in an interrupted subcuticular fashion. All five of the remaining incisions are coapted with Inderemil™ surgical adhesive and dressed with Band-Aids™.

The patient is extubated and transferred to the Post-Anesthesia Care Unit when determined stable by the anesthesiologist. Patients are subsequently transferred to a surgical floor bed, where they are kept nothing per os overnight, and provided with a morphine sulfate pain pump for pain prophylaxis.

An upper gastrointestinal (UGI) contrast evaluation of the gastric pouch is routinely performed on the first postoperative day. The pouch is maximally distended under continuous fluoroscopy and an anteroposterior (AP) film (Figure 24) and sequential spot images (Figure 25) are obtained once maximal distension is confirmed by the attending radiologist. Once anastomotic leaks are ruled out and gastric pouch emptying ensured by the swallow study, patients are advanced to a liquid gastric bypass diet and pain medications are changed to liquid oxycodone and the Jackson
Pratt drain is removed. The patient is ambulated and discharged to home as soon as they feel ready. Follow-up is scheduled for 2-weeks, 2-months, 6-months, 12-months and annually thereafter.
Figure 25. Typical Postoperative UGI Spot Films.
Methods

Between August 2002 and March 2005, 321 laparoscopic Roux-Y gastric bypasses were performed by two surgeons at Yale New Haven Hospital. All patients met the preoperative criteria of morbid obesity: 100% or 45.5 kg in excess of their ideal body weight. All underwent psychiatric evaluation, received printed material and were counseled regarding operative risk and alternative procedures. Patient demographics, including age, gender, preoperative weight and BMI, excess body weight, operating time, length of hospital stay and complications were entered into a prospective, longitudinal Microsoft Excel database in accordance with HIPAA guidelines. [75] Patient weights, post-operative BMI, and %EWL were recorded on routine follow-up visits to the surgeons’ office at 6, 12 and 24 months. All information was retrieved retrospectively.

On the morning of post-operative day one, all LRYGB patients routinely undergo a Gastrografin® swallow study. An anteroposterior plain radiograph (AP film) is taken, which is followed by six and ten spot swallow images. Lateral radiographs were not included in the study due to equipment constraints imposed by patients’ size. Included on the AP film is a standard marker for calibration purposes. After completion, the swallow study films are scanned and digitized, and included in the patient’s electronic medical record.
Because so few patients were eligible for 24 month follow-up at the time of writing, only 6 and 12 month data are included in this analysis.

**Calculating the Pouch Size**

Patient swallow studies were retrieved using Synapse, the Yale New Haven Hospital radiographic imaging software. Because films were variable, two different techniques were utilized to measure gastric pouch size; both methods assumed pouch depth remained constant between subjects. The first technique utilized an internal marker as a standard to calculate the vertebral height on the AP film. This height was then used in the subsequent spot film, ensuring the same vertebra was being measured, and the maximum length and width of the most distended pouch was measured and the area (in cm²) was determined. (Figures 26 and 27)
Figure 26. Method A for Measuring Pouch Size: AP Film.

Figure 27. Method A for Measuring Pouch Size: Spot Film.
Alternatively, if the gastric pouch appeared fully distended in the AP film, the internal marker was used to measure the maximum length and width directly on the AP film, without need for measuring the spot films. (Figure 28) The technique used was a modification of the one described by Halverson [76] as well as by Anderson and Pedersen [77], but again, due to technical limitations, lateral films were not taken and therefore the volume, which otherwise would have been measured by calculating the length x width x 4/3π to obtain the volume.

Figure 28. Method B for Measuring Pouch Size: AP Film.
Statistical Analysis

Equations pertaining to weight are shown in Figure 29.

<table>
<thead>
<tr>
<th>Calculations</th>
<th>Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Mass Index</td>
<td>( \text{Weight (kilograms)} \div \text{height}^2 \text{ (meters)} )</td>
</tr>
<tr>
<td>Ideal Body Weight*</td>
<td>Male 5' 3&quot; 135 lbs, add 3 lbs per inch</td>
</tr>
<tr>
<td></td>
<td>Female 5' 0&quot; 119 lbs, add 3 lbs per inch</td>
</tr>
<tr>
<td>Excess Weight</td>
<td>( \text{Operative Weight} - \text{Ideal Body Weight} )</td>
</tr>
<tr>
<td>% Excess Weight Loss</td>
<td>( \left( \frac{\text{Operative Weight} - \text{Follow-up Weight}}{\text{Operative Excess Weight}} \right) \times 100 )</td>
</tr>
</tbody>
</table>

Figure 29. Weight Equations.

* IBW based on Metropolitan Life Insurance Tables. [78]

Linear and multiple regression analyses were performed using SPSS 13.0 (SPSS Inc., Chicago, IL) to determine the association between pouch size and excess weight loss at six and twelve months postoperatively. Adjustments were made for age, gender and preoperative BMI. Prior to analysis, all factors were examined with SPSS for accuracy of data entry, distribution and the assumptions of parametric statistical analysis. Because the preoperative BMI and pouch size distributions were found to be positively skewed, the natural log (ln) was used to transform these factors in order to fulfill the normality assumption.
Analysis of variance was tested by subdividing pouch size and preoperative BMI into discreet groups to test the difference in means between pouch size, preoperative BMI and gender. Tukey and planned contrasts were utilized to explore the effect of pouch size on excess weight loss at six and twelve postoperative months.

Minitab was used to generate all graphical data, which included analysis of %EWL and BMI as a function of pouch area, gender and age. Initial SPSS analysis examined all patients individually; Minitab analysis examined individual patients as well as patients grouped by age decade.
Results

Patients
Three hundred twenty one patients underwent surgery and were included in the initial analysis pool. Mean patient age was 41 years (range 17-64); 262 were female (81.5%) (Figure 30); mean age for men was older than for women. (Figures 31, 32) Mean preoperative BMI was 51.1 kg/m² (range, 36.1-89.9 kg/m²), which demonstrated a moderate positive skew. (Figure 33). Mean 6 month %EWL was 50.5% (range, 13.4-85.5%) and mean 12 month %EWL was 62.5% (range 14.6-98.1). Mean pouch size was 63.9 cm² (range, 8.6-248.0 cm²), with a significant positive skew. (Figure 34) Patients between the ages of 30 and 50 represented the greatest number of patients (Figure 35), who also had the highest BMI. (Figure 36)
Sixty-nine patients were lost to follow-up at the six month mark, eight of whom subsequently returned for their 12-month post-operative appointments. These
patients were included in the 12 month analysis, but not in the six month measurement. One-hundred fifty-one patients did not keep their 12 month appointment, three of whom subsequently returned for their 24-month post-operative appointments. Thirty-three patients were eligible for and had 24 month post-operative follow-up weights. Two-hundred sixteen Gastrografin® swallow studies were available for review.

Figure 32. Patient Mean Ages by Gender.
Figure 33. Distribution of Preoperative BMI.

Figure 34. Distribution of Pouch Area.
Figure 35. Percentage of Patients by Age Decade.

Figure 36. Preoperative BMI by Age Decade.
Findings
Multiple linear regression analysis was used to examine the relationship between age, gender, preoperative BMI, pouch size and excess weight loss at 6 and 12 months postoperatively. A statistically significant negative correlation between pouch size and percent excess weight loss (%EWL) was found at the sixth post-operative month ($\beta = -0.241, p<0.01$) as well as at the twelfth post-operative month ($\beta = -0.302, p<0.02$) (Figures 37, 38), with adjustments made for age, gender and preoperative BMI (unadjusted 6-month $\beta = -0.39$, $p<0.001$ and 12-month $\beta = -0.383$, $p<0.001$). Linear regression analysis confirmed rate of change in %EWL as a function of pouch size remained relatively constant from the time of procedure through month twelve. (Figure 39)
Figure 38. 12-Month %EWL as a Function of Pouch Area.

Figure 39. Rate of %EWL as a Function of Pouch Size.
There was a statistically significant positive correlation between male gender and pouch size $r = .144, p < 0.04$ (Figure 40) after adjustments were made for age and preoperative BMI (unadjusted $r = .168, p < 0.02$). With adjustment for age and gender, there was a statistically significant positive correlation between preoperative BMI and pouch size (adjusted $r = .197, p < 0.04$, unadjusted $r = .192, p < 0.01$). (Figure 41) No correlation was found between pouch size and age when adjustments were made for gender and preoperative BMI $\beta = .083, p = .23$.

![Pouch Area Correlated to Gender](image)

Figure 40. Mean Pouch Size by Gender.
Preoperative BMI in correlation with Pouch Size

Act Area = 14.80 + 0.9681 Preop BMI

Figure 41. Preoperative BMI in Correlation with Pouch Size.

To determine analysis of variance, patients were grouped into five categories according to their pouch size and weight loss at 6 and 12 months post-operatively was evaluated in more detail. Group means of %EWL at 6 and 12 months are shown in Figure 42. Tukey and planned contrast analysis revealed statistically significant group mean differences in %EWL at 6 and 12 months. (Figure 43)

<table>
<thead>
<tr>
<th>Group</th>
<th>6 month %EWL mean, n</th>
<th>12 month %EWL mean, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (&lt;30 cm2)</td>
<td>54.6, n=36</td>
<td>63.6, n=15</td>
</tr>
<tr>
<td>Group 2 (30-80 cm2)</td>
<td>65.0, n=53</td>
<td>69.3, n=57</td>
</tr>
<tr>
<td>Group 3 (60-90 cm2)</td>
<td>48.3, n=40</td>
<td>60.6, n=20</td>
</tr>
<tr>
<td>Group 4 (90-120 cm2)</td>
<td>45.4, n=20</td>
<td>53.0, n=11</td>
</tr>
<tr>
<td>Group 5 (&gt;120 cm2)</td>
<td>39.8, n=18</td>
<td>47.6, n=16</td>
</tr>
</tbody>
</table>

Figure 42. Group Means by Pouch Size.
To tease out further correlations and analysis of variance, patients were grouped again based on their preoperative BMI. Three different groups corresponding to low, intermediate and high BMI were evaluated against pouch size using analysis of variance $F(2,213) = 4.654$, $p=.011$ and post hoc planned contrasts. Group A: <50 kg/m$^2$, Group B: 50-60 kg/m$^2$ and Group C: >60 kg/m$^2$. ANOVA testing demonstrated: Group A: mean 56.1, n=120; Group B: mean 65, n=65; and Group C: mean 73.7, n=31. (Figure 44) A statistically significant difference was found between Group A and Groups B and C ($p<0.05$).
These data demonstrate a significant inverse correlation between the size of the gastric pouch constructed during LRYGB: patients with smaller pouch sizes lost significantly more weight at 6 and 12 months postoperatively. Male gender and preoperative BMI were factors that influenced the construction of larger gastric pouches.

Summarizing the results of the contrasts, we found that with the exemption of a few pair-wise comparisons, the weight loss was significantly greater for the groups with smaller pouch sizes.
Preview of Preliminary Results
At the time of writing, significant data was only available for 6 and 12 month follow-up. However, in anticipation of future analysis, review of preliminary data from the 24 month yielded interesting findings. Figure 45 demonstrates a stepwise analysis of %EWL as a function of age decade.

![Graph showing %EWL versus Age Decade](image)

**Figure 45.** %EWL versus Age Decade.

While patients in their sixties initially lose a percentage of their excess weight quickly in the first six months, their rate of weight loss quickly drops off and they ultimately lose less weight than younger patients by the 24th month. Percent excess weight loss parallels patient ages except for patients in their thirties, who lose weight more quickly than older patients and those in their twenties. There was insufficient data at
the time of writing to confirm whether the slope of weight loss for patients younger than 20 will remain the same. Figure 46 illustrates the corollary, decreasing BMI over 24 months.

![Figure 46. BMI versus Age Decade.](image)

Future analyses will continue to look at time points beyond two postoperative years and aim to include more complete patient follow-up.
Discussion

Obesity is on the rise. It has become a global problem that now disproportionately affects minorities and the underprivileged. [3, 37] Surgery has proven the only effective therapy and Roux-Y gastric bypass, first developed in 1966, has become the most frequently performed bariatric procedure in the U.S. Several components play key roles in achieving optimal weight loss after gastric bypass surgery and their identification is the most important endeavor in the latest research aiming to increase excess weight loss. Patient factors, including compliance with proper diet and exercise, cannot be over emphasized. Those technical considerations that contribute to outcome success must also be analyzed and tested systematically. Of these, size of the surgically created gastric pouch and the caliber of the gastrojejunostomy stoma have been debated for more than twenty years but without systematic methodological testing. There is a lack of substantiating literature regarding the relationship between pouch size and excess weight loss after Roux-Y gastric bypass surgery and the exact nature of the association between pouch size and EWL remains elusive.

Despite numerous consensus panels convened to define surgical technique, [79] there is no standard recommendation or guideline concerning intraoperative measurement of the gastric pouch. Some surgeons have historically measured the volume of the pouch while performing the procedure, [76] a practice which persists in some centers. To date, the majority of literature describing intraoperative measurements and the rationale for doing so refers to gastric banding procedures [70, 80-82], not to gastric
bypass surgery. The literature that does exist regarding gastric bypass is lacking in two regards. Firstly, the literature predominantly predates current laparoscopic practice and secondly, most authors measure pouch size months and sometimes years after the surgery was performed. In 1996, Flanagan published his method of measuring functional pouch volume by asking patients to ingest cottage cheese and report their level of satiety before return visits anywhere from 3 months to 2 years postoperatively. He then assumed the amount of cottage cheese consumed correlated with pouch volume and found no association between pouch size and weight loss. Besides his unconventional method for measuring pouch size, his study, by virtue of measuring the pouch long after the procedure, very likely introduces confounding factors, such as passive stretch pouch enlargement from overeating and pouch hyperplasia, which can occur after the surgery. [83] Because Flanagan measured the pouch indirectly and so long after surgery, we believe his findings do not contradict our own association between pouch size and excess weight loss. Flanagan’s report is only one example of several that demonstrates the unreliability of measuring pouch size after a variable amount of time and therefore precludes the ability to make reliable inferences about intraoperative pouch size and its correlation to excess weight loss.

Precise measurement of the gastric pouch is equally important and challenging. Literature of the past decades describes many different ways about how to measure gastric pouch size. [76, 83, 84] In 1977, Alder [66] advocated the precise
intraoperative measurement of pouch size with injected saline through a nasogastric tube prior to stapling the stomach. [76] Other techniques used to measure pouch size were innovative creations like Fogarty catheters attached to a nasogastric tube inflated with fluid. [85] And although the efficacy and efficiency of these former methods are questionable, the early recommendation to measure pouch size precisely is an important element of surgical practice that our present study wishes to expand upon and endorse in order to draw more reliable inferences about the correlation between pouch size and weight loss. In light of the controversy concerning this relationship, there are not enough efficient methods available to measure pouch size intraoperatively or shortly thereafter (one exemption is the inflatable balloon used in gastric banding surgery). Most bariatric surgeons today therefore estimate the pouch size from a specific distance from the gastroesophageal junction or by transecting the stomach between the second and third right gastric arterial cascades.

The measurement of gastric pouch size postoperatively has also proved technically difficult. Radiographically, attempting to measure a three-dimensional pouch volume from a two-dimensional filled-contrast pouch image is mathematically challenging and only allows for an estimate of volume by measuring maximal pouch height and length; this is therefore a limitation in our current study design. The National Institutes of Health is currently testing imaging software that counts pixels, so in the near future it may be possible to measure pouch volume by contrast intensity. However, in the absence of any current more accurate way of feasibly measuring
pouch volume that we have come across, we assume that our swallow evaluation is sufficiently accurate to give an acceptable opinion about the relative pouch size one day after surgery. Similar conclusions were drawn by Kuzmak measuring the pouch size with a Gastrografin® swallow evaluation. [80] Furthermore, we believe the technique acceptable as Forsell demonstrated that pouch volume measured by swallow evaluation and MRI fall into the same volume category. [86] One other consideration is that our measurement might underestimate the actual pouch size due to mucosal edema in the pouch. However, the assumption was made that all pouches sustained similar overall trauma and mucosal edema was therefore comparable between pouches. Additionally, postoperative anastomotic edema might result in a tighter stoma which would delay stomal contrast emptying, thereby stretching the pouch and portraying a larger pouch. The diameter of the stoma is another oft discussed factor in weight loss after restrictive procedures, [67, 77, 85, 87, 88] but we were unable to include it in our analysis because of an inability to adequately measure the stoma during swallow evaluation. Nevertheless, we heed the early recommendations and acknowledge that a small stoma diameter is an important factor in restricting solid food from passing too quickly and easily into the Roux limb, and contributing to passive stretching of the pouch, which is responsible for inducing the feeling of satiety, limiting caloric intake and ultimately causing weight loss. To this end, the surgeons in this study aim for a stoma size of approximately 12 to 15 millimeters.
While recognizing that the precise and timely intraoperative measurement of gastric pouch size is challenging with current surgical methods, the problems emerging from postoperative pouch measurements (such as the estimation of a three-dimensional pouch from a two-dimensional contrast area), and the possibility of radiographically underestimating pouch size from mucosal edema, we nevertheless are convinced that precise measurement of the pouch size intraoperatively or shortly thereafter is indispensable for any study aiming to make a valid claim about the relationship between pouch size and resultant weight loss. With acknowledgement of all the aforementioned limitations, our study still confirmed that there is a significant inverse relationship between pouch size and excess weight loss.

After establishing the negative correlation between pouch size and excess weight loss, further analysis of those factors that could possibly influence results: age, gender and preoperative BMI, were evaluated. To the best of our knowledge, no existing literature concerning the relationship between pouch size, weight loss and gastric bypass evaluates these factors. No significant correlation between age and gastric pouch size was found, but interestingly, we did find that male gender was significantly correlated with a bigger pouch size and subsequently with a lower percent excess weight loss. We posit one explanation for this finding may be that males have more intraabdominal fat, which translates to a more challenging dissection and a more difficult operation overall, resulting in the construction of a bigger pouch. Additionally, we found a statistically significant positive correlation between
preoperative BMI and pouch size, possibly indicating that increased BMI may similarly lead to a more challenging operation, which again results in an increased pouch size.

Analyzing these potential confounders, we identified higher preoperative BMI and male gender as risk factors for larger pouches and decreased subsequent overall weight loss. These findings need to be addressed conscientiously in the hope that acknowledgement will guide practice toward the creation of a smaller pouch, especially in male patients and those with increased preoperative BMI.

In conclusion, our study clearly demonstrates that when the importance of precise pouch measurement is acknowledged and when the pouch size is measured within a short period of time after surgery, size does in fact matter: there is a significant inverse relationship between the size of the surgically constructed pouch and excess weight loss following laparoscopic Roux-Y gastric bypass.

Until such a time that our limitations are addressed and firm recommendations are made regarding intraoperative pouch measurements, we must continue to heed the guiding principles by Edward E. Mason, the founding father of gastric bypass:

*Operative procedure must be standardized and the technique carefully documented after each operation. Data must be collected in a standardized fashion and analyzed. We must find out the life-long results so that we can inform patients as to the
consequence of their choice of operation. This review of past experience and exchange of information is the time-honored basis for continued improvement in outcome after surgical treatment.
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