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Pre-Operative Weight Loss Requirements: Are They Beneficial?

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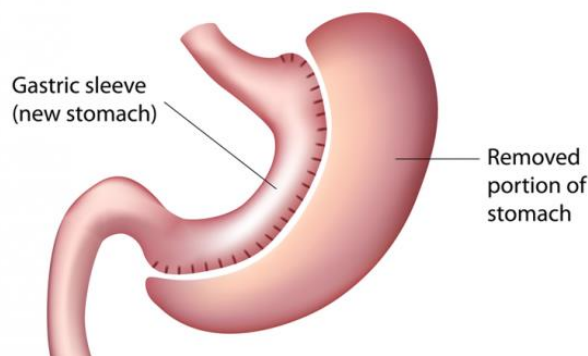
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## Chapter I: Bariatric Surgery

Bariatric surgery is a collection of procedures designed for patients to both lose weight and reduce the burden of debilitating chronic diseases. While surgery carries greater risk than lifestyle modification alone, it is associated with greater weight loss and reduction of comorbidities.<sup>1</sup> Some types of bariatric surgery also have immediate effects on glucose metabolism and appetite regulation that are explained by alterations in gastrointestinal (GI) anatomy rather than weight loss alone.<sup>1</sup> Given these considerations, patients may qualify for bariatric surgery based on BMI and the presence of metabolic comorbidities such as type II diabetes, hypertension, and obstructive sleep apnea. After attempted lifestyle modifications, bariatric surgery is currently recommended for individuals with a BMI of at least 40 kg/m<sup>2</sup> or at least 35 kg/m<sup>2</sup> with one or more comorbidities.<sup>2</sup>

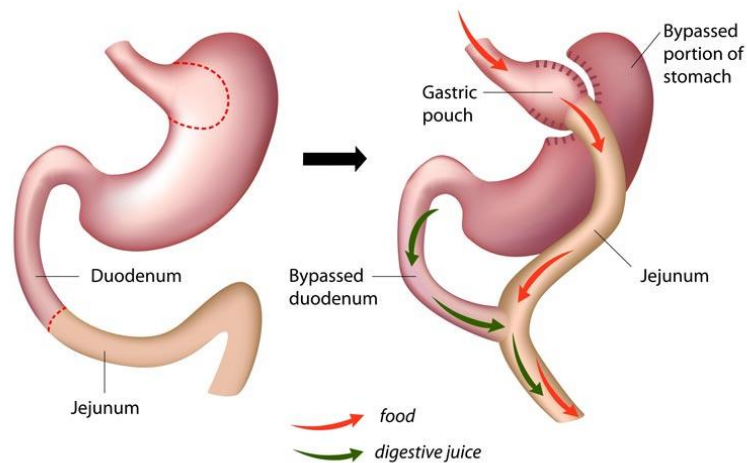
The most common form of bariatric surgery today is the vertical sleeve gastrectomy. The vertical sleeve gastrectomy involves the removal of 80 percent of the stomach to reduce the volume of food or beverage that can be consumed at one time (Figure 1). While initially considered a purely restrictive procedure, recent research suggests that it also has an effect on the regulation of hunger and satiety.<sup>1</sup> This is the most recently adopted bariatric surgery procedure, but it has quickly risen in popularity due to having the lowest complication rate of all currently performed procedures while still facilitating significant weight loss and improvements in glucose tolerance.<sup>1</sup> In 2017, the vertical sleeve gastrectomy accounted for nearly 60 percent of bariatric surgeries performed in the United States.<sup>3</sup>



**Figure 1: An illustration of the anatomy of a vertical sleeve gastrectomy adapted from Alila Medical Media<sup>4</sup>**

While data on the vertical sleeve gastrectomy is promising, the Roux-en-Y gastric bypass is still considered the “gold standard” of bariatric surgery and is the second most commonly performed procedure.<sup>3</sup> This technique was pioneered in the 1970s and refined over

the following decades to reduce the risk of complications.<sup>5</sup> The procedure involves dividing a small pouch from the stomach which is then reconnected to the distal jejunum in order to reduce the volume of food or beverage that can be consumed at one time and limit absorption of the consumed nutrients (Figure 2). Through processes that are not yet fully understood, this anatomical alteration also facilitates weight loss and metabolic modulation via changes to the secretion of hormones that regulate appetite and glucose homeostasis.<sup>5</sup> Although the Roux-en-Y is favored due to lower complication rates than previous methods such as adjustable gastric banding and biliopancreatic diversion, it still carries the risk of post-operative complications such as bleeding, infection, and anastomosis.<sup>5</sup> Despite the complication risk, this procedure is still routinely performed because it surpasses the vertical sleeve gastrectomy in long term weight loss and may cause greater reductions in metabolic syndrome.<sup>6,7</sup>



**Figure 2: An illustration of the anatomy of a Roux-en-Y Gastric Bypass adapted from Alila Medical Media<sup>8</sup>**

The vast majority of weight loss typically occurs in the first six months following surgery when the stomach pouch is smallest and only certain textures can be tolerated.<sup>7</sup> In this period, patients are started on a clear liquid diet emphasizing protein and slowly progress to incorporating all liquids, pureed foods, and then soft foods.<sup>10</sup> Caloric intake during this progression is often at or below 500 kilocalories which causes rapid weight loss.<sup>10</sup> Following this period, caloric intake and tolerance of solid foods typically increases gradually over the first one to two years until individuals enter weight maintenance.<sup>9</sup> Still, lifelong dietary modifications are necessary due to the restrictive-malabsorptive nature of the procedure as well as the potential for weight regain.<sup>10</sup> Some patients face barriers to following these modifications and may

experience higher rates of post-operative complications or sub-optimal weight loss and metabolic outcomes as a consequence.<sup>9</sup> To reduce the risk of poor outcomes, a psychosocial-behavioral evaluation is highly recommended during the screening process to identify any barriers to following nutritional and medical advice.<sup>2</sup> Some barriers such as active addiction or uncontrolled psychiatric conditions may contraindicate the procedure while other behavioral barriers may be worked through with a social worker or dietitian to improve readiness for surgery.<sup>2</sup> These measures are taken to facilitate the best possible patient outcomes regarding optimal weight loss, reduced post-surgical complications, and continued health.

## **Chapter II: Rationale for Pre-operative Weight Loss Requirements for Bariatric Surgery**

Many insurance providers also mandate participation in pre-operative medically supervised weight loss programs in an attempt to further improve surgery readiness and decrease complication risks, but actual weight loss is not always achieved.<sup>12</sup> In response to the lack of pre-operative weight loss experienced by some patients in these programs, some insurance providers and surgery centers have begun to mandate specific pre-operative weight loss requirements. The rationale for instituting pre-operative weight loss requirements included consideration of select evidence for both short-term and long-term benefits. Weight loss before surgery has been shown to reduce abdominal fat mass and liver size which would hypothetically lead to better surgical visualization and outcomes.<sup>13</sup> Many surgical centers prescribe very low-calorie diets immediately prior to surgery to address this, but adherence to these diets is varied and typically unenforced except in the case of medical necessity of weight loss to safely perform the surgery.<sup>13</sup> The introduction of pre-operative weight loss requirements was initially supported by a selection of related studies in which pre-operative weight loss was associated with greater weight loss after surgery and reduced post- and peri-operative complications.<sup>14,15</sup> Despite these benefits, the use of pre-operative weight loss requirements remains controversial. There is significant variation in outcomes between studies, and the true effect of pre-operative weight loss on outcomes is not fully established. Most of the research conducted is purely observational due to the difficulty in conducting randomized controlled trials on this topic. Additionally, outcomes for patients that lost weight without a requirement in place are often extrapolated to patients who would be required to lose weight. This creates a selection bias that fails to account for factors such as social support and access to healthy food that could contribute to greater weight loss both before and after surgery.

When determining whether pre-operative weight loss requirements should be implemented, it is important to consider not only potential benefits but also potential harm to patients. A pre-operative weight loss requirement may significantly prevent or delay the procedure and allow comorbidities to progress, decreasing quality and length of life. A pre-operative weight loss requirement also has the potential to encourage patients to engage in unhealthy dieting behaviors that are damaging to both overall health and long-term weight loss success. Because of these risks, it is imperative that the costs and benefits of pre-operative weight loss requirements be carefully examined and compared when considering a pre-operative weight loss policy.

Based on the potential benefits and preliminary evidence, the University of Washington's Weight Loss Management Center (UW-WLMC) recently instituted a five percent pre-operative weight loss requirement. The aim of this investigation was to review the evidence for whether pre-operative weight loss requirements are beneficial for all patients and whether positive outcomes are observed with pre-operative weight loss in the UW-WLMC population. This was done by conducting a literature review and evaluation of data from the center. These findings were then used to generate a recommendation for the staff of the UW-WLMC to reach a consensus on whether to continue or revise their five percent weight loss requirement.

### **Chapter III: Literature Review**

A review of current literature on pre-operative weight loss for bariatric surgery was conducted to survey potential risks and benefits of instituting a weight loss requirement as well as to determine the overall association between pre-operative weight loss and post-operative weight loss and complication rates. Searches were conducted on the PubMed database using the search terms "bariatric surgery", "gastric bypass", "preoperative weight loss", "weight loss before", "weight loss requirement", and "surgical complications".

Given the breadth of research and the variability of findings, the search was refined to include meta-analyses published within the last decade, excluding previous publications by the same authors. The purpose of focusing on meta-analyses was to determine if there was an overall effect given that much of the research yielded contrasting outcomes. Notable articles included in the meta-analyses were also reviewed to assess methodology and quality. Primary research articles published in the last three years were also evaluated in order to capture recent research that had not yet been included in meta-analyses. Studies were evaluated for quality using the Academy of Nutrition and Dietetics' Quality Criteria Checklist.

The database search returned five meta-analyses, one of which was excluded from the review as it was an older publication by the authors of a newer meta-analysis.<sup>16,17,18,19,20</sup> In all of these analyses, methodological differences between the included studies were immediately clear. Measure of weight loss varied significantly between studies with definitions including absolute body weight loss, percentage total body weight loss, percentage excess body weight loss, and BMI change. Follow-up time was also highly variable as some studies followed the weight loss of patients for only six months while others followed patients for up to two years. The intervals for following complications were even broader, ranging from only a few weeks to two years. Complications were also inconsistently defined which considerably impacted reported incidence rates. These factors made it difficult to directly compare studies and contributed to uncertainty in the conclusions drawn by meta-analyses. Further uncertainty arises from the overall low quality of much of the research included in these analyses which is discussed below.

While greater pre-operative weight loss was associated with greater post-operative weight loss in some studies, others found a neutral or in one case negative association. In each of the meta analyses, a positive association was found in only one half or less of the included studies.<sup>16,17,19,20</sup> The most recent meta-analysis concluded that the overall effect of pre-operative weight loss on post-operative weight loss could not be determined, due in large part to the limited quality of the studies.<sup>16</sup> For the only randomized controlled trial with long term follow-up that was included in the meta-analysis, no effect was observed.<sup>21</sup> Recent research has been of higher quality, but outcomes were similarly mixed. One influential large-scale observational study found a significant positive association between pre- and post-operative weight loss.<sup>22</sup> But two other recent observational studies on insurance provider and center-mandated weight loss requirements showed no association of pre-operative weight loss with post-operative weight loss after two years.<sup>23,24</sup> Notably, in one of these studies, there was an association at six and twelve months which had diminished at two years, suggesting that studies with shorter follow-up times may not have fully captured the plateau of weight loss in both groups.<sup>23</sup> As a whole, there is not enough evidence to suggest that increased pre-operative weight loss will lead to post-operative weight loss, especially if the pre-operative weight loss is mandatory.

Findings with regard to incidence of complications were similarly mixed. The most recent meta-analysis concluded that pre-operative weight loss is associated with decreased rates of some complications, but this conclusion is largely contingent on a recently published large scale observational study by the same authors.<sup>16,25</sup> Still, effects on complication rates may be difficult to detect by smaller studies due to sample size and low incidence rates. Weight loss has been



associated with liver shrinkage and improved glucose tolerance, so there is significant biological plausibility in reducing complications with weight loss.<sup>16</sup> Given the current evidence, there is a possibility that pre-operative weight loss may decrease complication rates, but this has not yet been consistently proven.

It is important to note that none of the meta-analyses included in this review recommended mandatory weight loss requirements, while some recent studies have identified potential risks. Insurance mandated weight loss programs and requirements have been associated with delayed time to operation, program dropout, and increased mortality.<sup>26, 27, 28</sup> The significant burden of these mandates on patients also raises concerns about equity of care. A recent literature review and position statement by the American Society for Metabolic and Bariatric Surgery strongly opposed the implementation of mandatory pre-operative weight loss requirements citing lack of evidence and potential harm to patients.<sup>29</sup>

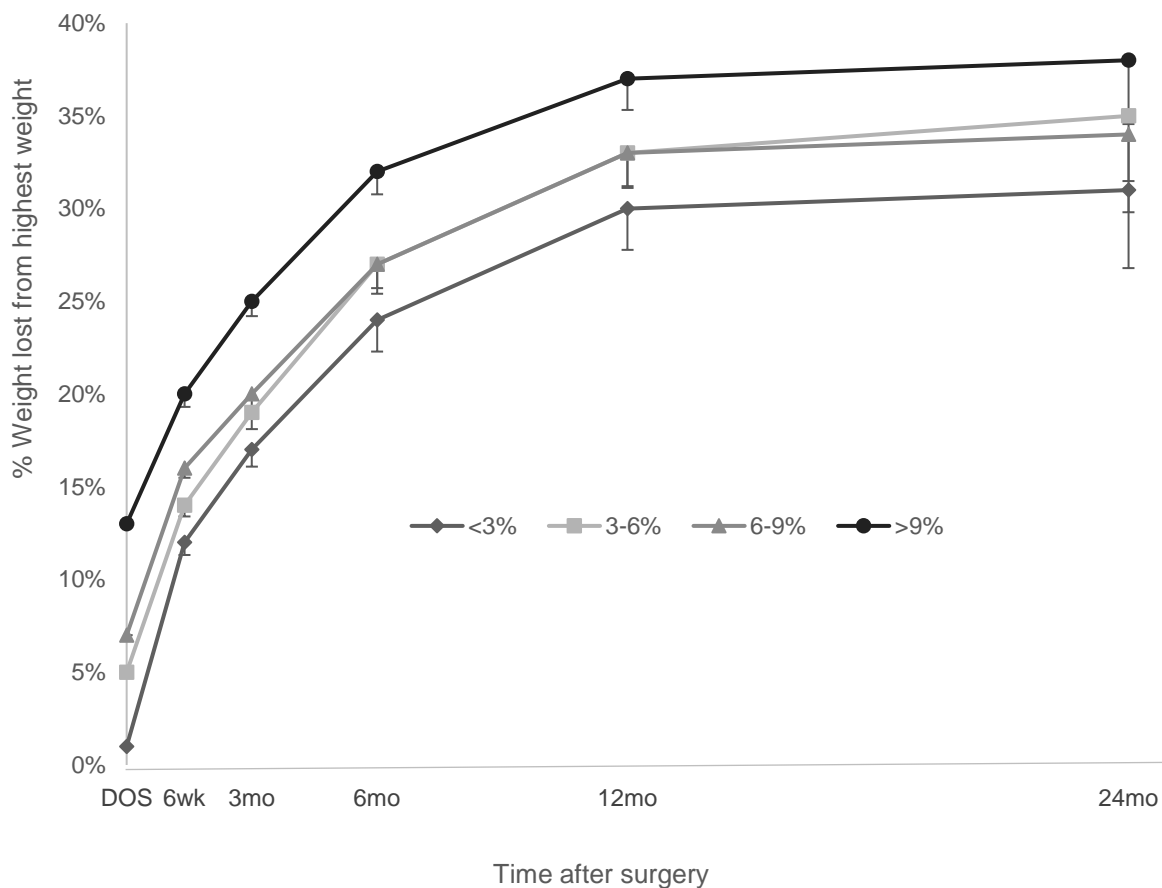
#### **Chapter IV: Site-Specific Data Analysis**

In addition to a literature review, data from patients at the UW-WLMC were also analyzed in order to determine whether there was an association between pre-operative weight loss and outcomes in this particular patient population. Due to sample size and feasibility, post and peri-operative complications could not be analyzed for this site. This analysis was intended as a complement to the literature review for the purpose of providing further evidence for site-specific recommendations.

From 2012-2017, weight loss and BMI data were collected on all patients at the UW-WLMC receiving bariatric surgery for quality improvement purposes. The dataset included highest pre-operative weight and BMI, weight on date of surgery, and all weights and BMI at subsequent weigh-ins. Only patients receiving Roux-en-Y gastric bypass were included as it is the most common procedure performed at this clinic. Patients were separated into quartiles based on pre-operative weight loss which was defined as percentage of body weight lost from highest pre-operative weight on the date that surgery was performed. Timepoints for follow-up were designated at six weeks, three months, six months, one year, and two years in order to capture the rate and plateau of weight loss experienced by each subset of patients. Data were then analyzed using a Student's t-test comparing each quartile to the highest quartile to determine whether there was an association between pre-operative weight loss and post-operative total weight loss. For BMI, quartiles were compared to each other quartile at the initial time point and at 24 months using a Student's t-test. Significance was established at  $p < 0.05$ .

In total, data were analyzed from 397 individuals receiving a Roux-en-Y gastric bypass at the UW-WLMC. Quartiles of pre-operative weight loss aligned evenly at <3%, 3-6%, 6-9% and >9% loss from highest body weight. The average BMI before surgery was 52.3 kg/m<sup>2</sup>.

At all time points, percent weight loss from highest body weight was significantly higher for the highest quartile of pre-operative weight loss than any other quartile with a p-value of <.005 (Figure 3, Table 1). Furthermore, percent weight loss from highest body weight was lowest for the lowest quartile of pre-operative weight loss. However, when only post-operative weight loss is included, there were no significant differences between the quartiles (Table 2). The lower two quartiles of pre-operative weight loss trended toward greater post-operative weight loss than the higher two quartiles of pre-operative weight loss (Table 2). This indicates that the percentage of pre-operative weight loss was not positively associated with the percentage of weight loss that occurred after surgery.



**Figure 3: Percentage of total body weight loss from highest body weight over time by quartile. Error bars indicate low end of 95% confidence interval.**

**Table 1: Percentage of total body weight loss from highest body weight and BMI over time across quartiles of pre-operative weight loss. Sample size for each time point is indicated. \*P<.005 compared to highest quartile of pre-operative weight loss.**

Pre-op	<3%	3-6%	6-9%	>9%
<b>6 weeks</b>	12* n=93	14* n=104	16* n=101	20 n=110
<b>3 months</b>	17* n=70	19* n=67	20* n=71	25 n=83
<b>6 months</b>	24* n=41	27* n=57	27* n=60	32 n=63
<b>12 months</b>	30* n=45	33* n=53	33* n=61	37 n=64
<b>24 months</b>	31* n=28	35* n=24	34* n=36	38 n=34
<b>Initial BMI</b>	50.8*	50.7*	51.3*	55.3
<b>24 mo. BMI</b>	37.7*	33.2	32.6	33.0

**Table 2. Percent post-operative weight loss over time by quartile of pre-operative percent weight loss.**

Interval	<3%	3-6%	6-9%	>9%
<b>DOS - 6 weeks</b>	10.3	9.6	8.6	7.5
<b>6 weeks - 3 months</b>	5.0	5.0	4.0	5.3
<b>3 months - 6 months</b>	7.0	7.2	6.7	7.0
<b>6 months - 12 months</b>	6.7	6.5	6.7	4.4
<b>12 months - 24 months</b>	1.0	2.3	0.8	1.6
<b>Total Post-op (DOS- 24 months)</b>	30.0	30.6	26.9	25.9

For the highest quartile of pre-operative weight loss, initial BMI was significantly higher than for any of the other quartiles (Table 1). In contrast, BMI at 24 months was significantly higher for the lowest quartile of pre-operative weight loss than for any other quartile (Table 1). There were no significant differences or trends in BMI at 24 months for the quartiles with >3% weight loss (Table 1). While those who lost the most weight pre-operatively appeared to have better weight loss outcomes from a total percent weight loss perspective, they actually achieved the same approximate BMI as the lower quartiles. The greater pre-operative weight loss in this group may be explained by medical necessity of weight loss for the operation to be feasible. Pre-operative weight loss may be required in order to perform surgery in this subset of the

population, but this pre-operative loss had little bearing on weight loss outcomes of the surgery. As percent post-operative weight loss are the same across the quartiles, there is no evidence to support that pre-operative loss should be mandated to improve post-operative weight loss.

## **Chapter V: Summary and Recommendations**

At the UW-WLMC, those with the highest percentage of pre-operative weight loss lost the most weight when pre- and post-operative weight loss are combined, but the amount of post-operative weight loss was not associated with pre-operative weight loss (Table 2). Higher pre-operative loss in the last quartile may be partially explained by the higher mean initial BMI of patients in this quartile. Weight loss of greater than three percent was also not associated with BMI after two years. The lack of clear effect of increasing amounts of pre-operative weight loss seen at the UW-WLMC reflects the uncertainty in the current body of research. Associations in the literature between pre-operative weight loss and post-operative weight loss are tenuous at best given significant methodological issues. While there may be some benefit of pre-operative weight loss on incidence of complications, there is at least equally strong evidence of harm through delay or denial of surgery. Given the evidence, it is not appropriate at this time to support mandatory site-specific or insurance-mandated pre-operative weight loss requirements which aligns with the position of ASMBS.<sup>29</sup>

### Recommendations:

1. The five percent weight loss requirement at the UW-WLMC should be discontinued.

Justification: Currently, there is no strong evidence for pre-operative weight loss requirements and current expert recommendations oppose their use. There was no clear association between pre-operative weight loss greater than five percent and weight loss after surgery in this center's patient population, so a five percent requirement is arbitrary and may cause harm to the patient by delay or denial of surgery and concern for encouragement of unhealthy dieting practices.

2. An individualized weight loss goal should be chosen and encouraged.

Justification: Weight loss before surgery may be associated with benefits such as decreased complication rates. Depending on degree of abdominal adiposity and liver size, higher weight loss targets may be appropriate for certain patients to ensure a safe operation.

## **Chapter VI: Application of Evidence**

The findings of this report and above recommendations were presented for consideration to the interdisciplinary staff of the UW-WLMC in a meeting on April 5th, 2018 (Appendix). The staff in attendance consisted of surgeons, social workers, dietitians, nurses, and medical assistants who discussed their perspectives, concerns, and impressions of pre-operative weight loss requirements and the findings of this report. After discussion, the interdisciplinary team voted to remove the five percent pre-operative weight loss requirement in favor of individualized weight loss goals which aligned with the given recommendations.

## **Chapter VII: Next Steps and Future Recommendations**

One significant limitation of this analysis was the lack of data on demographics, comorbidities, and complications in the UW-WLMC population. As such, these findings are not generalizable to all weight loss surgery centers. Future projects at UW-WLMC should aim to fill in these gaps, particularly if a shift in patient demographics is observed at this center. In particular, an analysis of the effects of age, sex, and insurance provider on pre- and post-operative weight loss would elicit useful information for interpreting the data. Another consideration for future projects would be to examine the relation between pre-operative weight loss and presence and remission rate of comorbidities such as type II diabetes in this population as this is a highly clinically significant outcome for bariatric surgery.

There is also significant room for further research as a whole. More large scale and randomized controlled trials are needed to improve certainty about the effects of pre-operative weight loss. Future research should also investigate whether or not mandatory pre-operative weight loss requirements affect eating behaviors and cause unhealthy eating patterns as this was a concern for several providers at UW-WLMC. Going forward, a greater distinction should also be made about the effects of mandatory vs. non-mandatory weight loss as most of the

existing research is on non-mandatory weight loss. Finally, a deeper understanding of the physiologic and socioeconomic factors underlying optimal and sub-optimal weight loss is needed. Until significant benefits can be proven to offset the risks noted in this report, pre-operative weight loss requirements are not recommended.

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## Pre-operative Weight Loss Requirements: Are They Beneficial?

### Background

Pre-operative weight loss requirements have been implemented by insurance providers and clinics with the aim of improving both long and short term outcomes. These requirements were implemented due to several studies that found reductions in post- and peri-operative complications as well as increased weight loss in the months following bariatric surgery. However, other studies found no benefit and potential negative consequences such as delays and denials for surgery. Currently there is no consensus in reviews of the literature as to whether pre-operative weight loss confers any benefit and the quality of evidence remains poor. Inconsistencies in follow-up time, measure of weight loss, and loss to follow-up present challenges to interpreting and comparing findings between studies. For these reasons, researchers and the American Society for Metabolic and Bariatric Surgery cautioned against mandatory pre-operative weight loss.

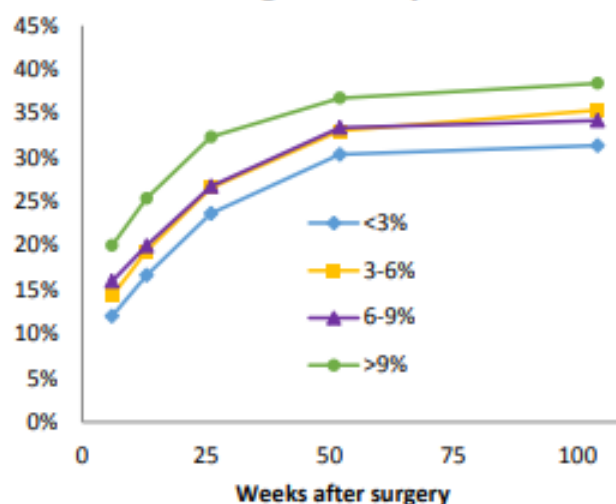
### Data from bypass patients at UW Weight Loss Management Center (2012-2017):

#### % Weight Loss and BMI Change

Pre-op	<3%	3-6%	6-9%	>9%
<b>6 weeks</b>	12* n=93	14* n=104	16* n=101	20 n=110
<b>3 months</b>	17* n=70	19* n=67	20* n=71	25 n=83
<b>6 months</b>	24* n=41	27* n=57	27* n=60	32 n=63
<b>12 months</b>	30* n=45	33* n=53	33* n=61	37 n=64
<b>24 months</b>	31* n=28	35* n=24	34* n=36	38 n=34
<b>Initial BMI</b>	50.8*	50.7*	51.3*	55.3
<b>24 mo. BMI</b>	37.7*	33.2	32.6	33.0

\*p < .005 compared to pre-op loss of >9%

#### % Weight Loss By Quartile



### Summary

- Current evidence for pre-op weight loss requirements is mixed, difficult to interpret, and of poor quality.
- While pre-op weight loss may reduce complications and improve post-op weight loss, it may also delay or prevent surgery, allowing comorbidities to progress.
- At this clinic, pre-operative weight loss beyond 3% is not directly associated with BMI 2 years after surgery.
- Patients at this clinic who lost >9% total body weight before surgery lost the most weight on average, but also tended to have a higher initial BMI on intake
- At this clinic, rate of weight loss after surgery was not associated with amount of pre-operative weight loss

### Recommendation

Pre-operative weight loss of 5% or more should not be mandatory at this clinic. Patients should be encouraged to lose weight prior to surgery, but this absolute requirement is not supported by site-specific outcomes or the larger body of evidence and thus it may delay or prevent patients from reaching a potentially beneficial metabolic surgery.