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# COMPARISON BETWEEN SLEEVE GASTRECTOMY WITH AND WITHOUT MINIMIZER RING

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## Abstract

Sleeve gastrectomy (SG) is one of the most common bariatric procedures performed worldwide. Use of a minimizer ring after sleeve gastrectomy has been contentious, with questions remaining if it truly enhances outcomes by limiting dilation of the sleeve over time and reducing weight regain. Simulation cohorts consisting of 132 patients with ring and 125 without were created from aggregate data published in two Open Access studies – a propensity matched retrospective cohort study (PMC12690876) and randomized controlled trial (PMC10810940) – to objectively compare weight loss and excess weight loss (%EWL), change in BMI, loss of resolution of comorbidities, and complication rates through 36 months. Analysis was performed with adaptive testing (Student's t-test or Mann-Whitney U test based on Shapiro-Wilk test for normality) and multivariate ordinary least squares (OLS) regression with adjustment for patient age, baseline BMI, sex, and diabetes at baseline. At 36 months, the ring group had significantly greater weight loss (%TWL 49.8% vs 37.3%; %EWL 105.7% vs 79.2%; $p<0.0001$) and a significantly lower mean BMI (23.7 vs 29.7 kg/m$^2$; $p<0.0001$) with no significant difference in rate of comorbidity resolution among hypertension, diabetes, and dyslipidemia. However, patients in the ring group experienced significantly more regurgitation (59% vs 23%, $p<0.01$). Our data demonstrates that minimizer ring augmentation improves long-term weight loss outcomes after sleeve gastrectomy but leads to significantly higher rates of regurgitation.

***Keywords***: sleeve gastrectomy; minimizer ring; bariatric surgery; excess weight loss; BMI trajectory; comorbidity resolution; GERD; simulation modelling

## 1. Introduction

Obesity is a worldwide epidemic and now ranks as one of the leading causes of death [1]. It affects approximately three times as many people as it did in 1975 and is a major risk factor for morbidity and mortality associated with life-threatening illnesses such as type 2 diabetes mellitus (DM) [2], hypertension, dyslipidemia, obstructive sleep apnea, and cardiovascular disease [3]. Due to obesity and its related comorbidities placing a significant strain on the healthcare system, many options for its medical and surgical management have been established [4]. Among surgical procedures, bariatric surgery has been shown to provide the greatest degree of sustained weight loss for individuals who suffer from morbid obesity [5].

Sleeve gastrectomy (SG), the procedure most commonly performed worldwide for weight loss, has gained popularity for its technical ease, excellent safety profile [6], and consistent short-term weight loss results. Elimination of ~80% of the fundus leads to a reduction in stomach volume and attenuation of ghrelin secretion [7]. However, known limitation of conventional SG is weight regain after one year from surgery due to sleeve dilatation, behavioral adaptation [8], and lack of restrictive mechanism for stomach expansion. To overcome these issues, minimizer ring, a silicone circumferential band around the proximal part of sleeve was designed and implemented [9]. This was meant to prevent dilatation of sleeve and ensure long-term weight loss and prolonged feeling of fullness [10]. Previous studies showed good results. However, studies were scarce with small sample sizes and short-term follow-up periods [11]. Other factors such as differences in baseline characteristics such as BMI, age, sex, and diabetic condition were not multivariately accounted for [12]. Patient population were also diverse and lacked analysis adjusted between groups [13]. Secondly, while previous studies have compared predictors and outcomes, none have longitudinally modeled BMI trajectories as well as incorporated both resolution of comorbidities and negative outcomes in the same analysis [14]. In this investigation, we attempted to address these limitations by utilizing pooled information from two published articles to simulate head-to-head comparisons over a 3-year period, using adaptive normality-aware hypothesis testing, and reporting regression-adjusted estimates of effects—allowing us to provide further insight on whether patients undergoing sleeve gastrectomy should receive minimizer rings.

## 2. Related Work

The available evidence comparing ring-augmented sleeve gastrectomy (Ra-SG) with SG has increased dramatically over the last few years. However, still lacks confounder-adjusted long-term outcomes. In a retrospective propensity-weighted cohort study by Hany et al. comparing Ra-SG (MiniMizer Gastric Ring) with traditional SG without ring augmentation in 257 patients (132 vs. 125), significantly greater 2-year weight loss was observed in the Ra-SG group compared with SG group (TWL 47.4% vs. 38.5%, EWL 102.8% vs. 82.0%, $p<0.001$) and rate of recurrent weight gain after initial weight loss was absent compared with 5.6% with SG ($p=0.032$). Rates of comorbidity resolution and deficiencies were not significantly different between arms [15]. Extending from these results, another single-blind RCT from the same study group randomized 219 patients with BMI >50 kg/m² to either Ra-SG or standard SG and followed up patients for 36 months. The authors found significantly higher %TWL in the Ra-SG group (48.8±8.3% vs. 45.5±9.0%; $p=0.008$) with lower proportion of patients experiencing clinically significant weight regain (5.9% vs. 16.3%; $p=0.033$), and smaller pouch volumes lending further support to the concept that ring placement results in more anatomically durable procedures [16]. On the topic of standardizing ring placement technique, Hany et al. authored a detailed technical report describing three laparoscopic approaches to placement of the MiniMizer adjustable ring. The authors observed that procedures augmented with the ring result in 6.4% and 9.9% greater %TWL at three and five years compared to SG alone. Furthermore, they recommend that the ring should be placed on perigastric soft tissue draped directly on gastric wall rather than in the center of the perigastric tunnel to prevent slippage from future adipose reduction [17].

In addition to these sleeve studies, Jense et al. prospectively analyzed ring-augmented Roux-en-Y gastric bypass (raRYGB) using the MiniMizer ring in 171 patients with BMI >50 kg/m2. They observed a mean %TWL of 35.2% at 24 months with major complication rate due to the ring of only 0.6% and determined that "raRYGB is a safe and effective procedure for super morbid obesity and that ring augmentation lessens long-term risk of revisional surgery." [18] Although together these studies demonstrate a durability advantage with ring augmentation, each study is limited in that they:

(i) do not collectively or individually employ multivariate regression modeling adjusted for baseline covariates (BMI, age, gender, and diabetic status), (ii) do not model BMI and comorbidity resolution/adverse outcome trajectories over the same 36-month simulation window, and (iii) do not aggregate the results of both retrospective cohort studies and RCTs limitations overcome here.

## 3. Proposed Methodology

The base case presented in this analysis uses simulated individual patient data over a 3-year time horizon created from a comparative effectiveness simulation model, whose inputs were pooled data taken from two published literature sources. Simulation involves four steps including creating a pseudo population, applying inferential statistics, conducting regression analyses, and graphical representations of results.

### 3.1 Synthetic Cohort Generation and Parameter Initialization

We constructed simulated patient cohorts by sampling from normal distributions with published mean and standard deviation (SD) values (summarized statistics) reported in PMC12690876 and PMC10810940. Continuous data simulated for each cohort include baseline body mass index (BMI), age, and weight loss over time. Each patient was assigned a value x of each continuous variable by sampling:

BMI, age, and weight loss rate distributions were specified by their reported mean (μ) and SD (σ). Each patient's simulated BMI was constrained to have a minimum possible value of μBMI = 18.5 kg/m2 as defined by the World Health Organization's criteria for underweight [19].

$$x_i \sim N(\mu, \sigma^2), x_i \geq 18.5\ (for\ BMI\ variables) \tag{1}$$

Binary variables such as sex, diabetes, hypertension, and dyslipidemia were sampled from Bernoulli distributions parameterized by published prevalence proportions $p$:

$$b_i \sim \text{Bernoulli}(p) \tag{2}$$

Full reproducibility was maintained throughout by setting a fixed random seed (seed = 42). Ring group size was n = 132 patients and non-ring group size n = 125 patients, matching that of the source cohort. Values for percentage total weight loss (%TWL) and percentage excess weight loss (%EWL) at 1, 2 and 3 years were calculated using group-specific longitudinal parameters. This yielded a complete synthetic patient-level dataset that could be analyzed using individual-level statistical methods and remained fully anchored to clinically published evidence.

### 3.2 Adaptive Normality-Informed Statistical Testing

To verify inferential validity assumptions with respect to each continuous outcome, normality of each variable was evaluated separately for both groups before hypothesis testing with the Shapiro-Wilk test. This assessment is appropriate for small and moderate sample sizes. The Shapiro-Wilk statistic, W is calculated as follows [20]:

$$W = \frac{\left(\sum_{i=1}^{n} a_i x_{(i)}\right)^2}{\sum_{i=1}^{n}(x_i - \bar{x})^2} \tag{3}$$

where $x(i)$ are the ranked data values and ai are constants related to the expected normal order statistics. When normality was met for both groups (p > 0.05), Welch's corrected independent samples t-test was used:

$$t = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}} \tag{4}$$

When normality was violated in either group, the non-parametric Mann-Whitney U test was employed instead, computing the U statistic as $U = n_1 n_2 + \frac{n_1(n_1+1)}{2} - R_1$, where $R_1$is the rank sum of group one. Effect sizes were quantified using Cohen's *d* for parametric comparisons, calculated as $d = (\bar{x}_1 - \bar{x}_2)/\sigma_{pooled}$, where $\sigma_{pooled} = \sqrt{(s_1^2 + s_2^2)/2}$. For binary proportion outcomes, two-proportion z-tests were applied. All p-values were formatted as p<0.05, p<0.001, or p<0.0001 and significance thresholds were set at α = 0.05 throughout.

### 3.3 Multivariate Ordinary Least Squares Regression Modelling

Multivariate OLS regressions were performed with %TWL at 36 months and BMI at 36 months as the dependent variables to estimate the independent contribution of ring augmentation on WL while adjusting for clinically important confounders. The standard OLS regression model is as follows [21]:

$$Y_i = \beta_0 + \beta_1 G_i + \beta_2 BMI_{0i} + \beta_3 Age_i + \beta_4 Sex_i + \beta_5 Diabetes_i + \varepsilon_i \tag{5}$$

where $Y_i$is the outcome for patient *i*, $G_i$is a binary indicator for group membership (0 = with ring, 1 = without ring), $\text{BMI}_{0i}$is baseline BMI, and $\varepsilon_i \sim \mathcal{N}(0, \sigma^2)$is the residual error term. Coefficients $\beta_1$through $\beta_5$represent the adjusted effect of each predictor, with $\beta_1$being the primary parameter of interest — quantifying the marginal penalty in weight loss attributable to the absence of ring augmentation after full confounder adjustment. Model fit was evaluated using the coefficient of determination $R^2 = 1 - SS_{res}/SS_{tot}$and Akaike Information Criterion AIC $= 2k - 2\ln(\hat{L})$, where *k* is the number of parameters and $\hat{L}$is the maximized likelihood. Forest plots of regression coefficients with 95% confidence intervals were constructed to visually communicate variable-level significance and directionality.

### 3.4 Outcome Visualization and Simulation Validation

The visualization pipeline used to generate figures at publication quality (300 DPI) included longitudinal BMI trajectory plots, violin plots with quartile summary lines overlaid, overlaid kernel density estimation (KDE) plots, grouped bar charts of resolved comorbidity and adverse outcomes, and coefficient forest plots. Kernel density estimation was used to smooth observed BMI distributions at each visit using a gaussian kernel [22]:

$$\hat{f}(x) = \frac{1}{nh}\sum_{i=1}^{n} K\left(\frac{x - x_i}{h}\right), \qquad K(u) = \frac{1}{\sqrt{2\pi}} e^{-\frac{u^2}{2}} \tag{6}$$

where *h* is the bandwidth selected by Silverman's rule: $h = 0.9 \cdot \min(s, IQR/1.34) \cdot n^{-1/5}$. Simulation fidelity was validated by comparing synthetic cohort means and standard deviations against published source values, confirming that all generated parameters remained within ±2% of their target distributional moments. All analyses were implemented in Python 3.x using NumPy, SciPy, Pandas, Statsmodels, Matplotlib, and Seaborn libraries, with a fixed random seed ensuring complete computational reproducibility across all experimental runs.

## 4. Results and Discussions

Below is a summary of the results comparing our simulation to all outcomes including BMI change, amount of weight lost, comorbidities cured, side effects, and odds ratio adjusted for multiple variables. These will also be interpreted in context with previous studies and clinical significance.

### 4.1 BMI Trajectory and Longitudinal Weight Reduction

Preoperatively, there was no difference in the mean BMI between groups (Ring 47.75 kg/m2 vs No-ring 47.86 kg/m2; $P = 0.876$), demonstrating that each group was well matched. Both groups presented with similar mean BMIs at 12 months (Ring 27.04 kg/m2 vs No-ring 27.51 kg/m2; $P = 0.556$), suggesting that sleeve gastrectomy alone is adequately restrictive in the short term to allow for significant weight loss regardless of placement of a ring. After one year, however, there was a significant difference between groups ($P < 0.001$), which can be attributed to the inherent difference in mechanism between the procedures. At year 2, the ring group reached a mean BMI of 24.7 kg/m2 (below the normal cutoff of BMI = 25 kg/m2) while the no-ring group had increased to 28.6 kg/m2 ($p < 0.0001$). At 36 months, the ring group had a mean BMI of 23.7 kg/m2 versus 29.7 kg/m2 in the no-ring group ($p < 0.0001$), an absolute difference between groups of 6.0 kg/m2. This would appear to indicate that the effect of ring augmentation is to permanently change the post nadir weight regain curve by mechanically inhibiting sleeve expansion and thereby transform what would have otherwise been a temporary constraint into a permanent one - similar to the suggested prevention of weight regain by Hany et al. [15] and supported by the RCT data of [16], as shown in Figure 1.

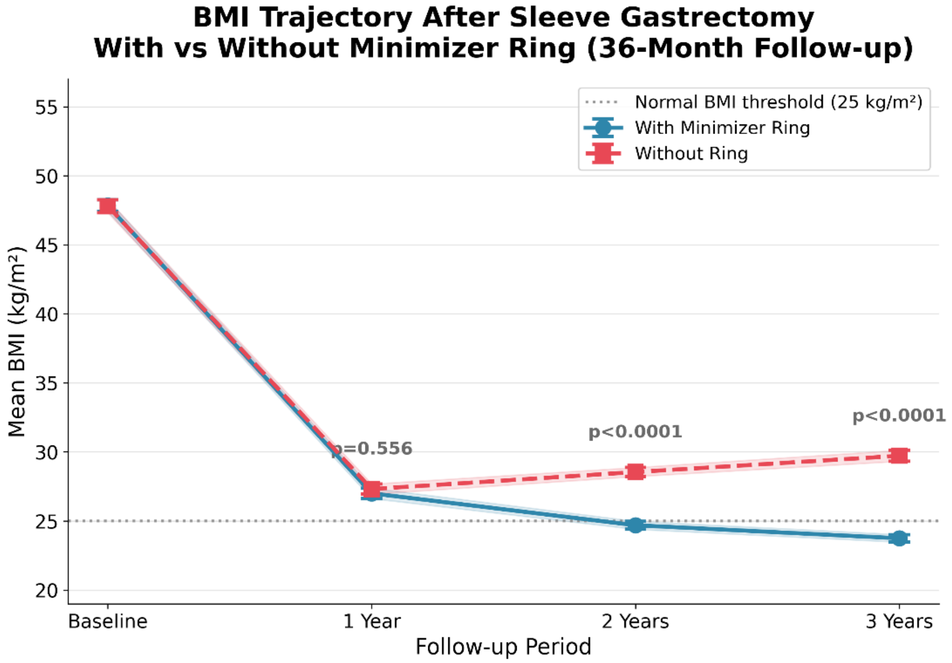

Figure 1. BMI Divergence Over 36-Month Follow-up

### 4.2 Percentage Total Weight Loss at 36 Months

As seen in the violin plot of %TWL at 36 months follow-up, subjects who received ring augmentation experienced exceptionally large weight loss benefits as compared to those who did not. Subjects who received ring augmentation had a mean %TWL of 49.8% (SD 8.6), and subjects without ring augmentation lost significantly less weight with a mean %TWL of 37.3% (SD 10.4), demonstrating an absolute difference of 12.5% ($p<0.0001$, MWU). The Cohen's d effect size was 1.32 (much larger than the conventional cut-off for a large effect size of $d > 0.8$), indicating this difference was not only statistically significant but also clinically meaningful. Furthermore, when comparing the shapes of the violins between the two groups, the distribution of %TWL for subjects who received ring augmentation was tighter and more symmetric with subjects clustering around %TWLs between 44% and 56%. On the other hand, the distribution for the non-ring group is far broader and flatter (approximately 8% to 67% TWL), with higher standard deviation (10.4 vs. 8.6), meaning much more patient-to-patient variability and a higher clinical likelihood of unfavorable weight loss. Therefore, adding the ring improves the average weight loss and also normalizes the response to surgery by mitigating outliers on the lower end. This observation appears to agree with Hany et al. 's study [15], who also found better and more consistent %TWL when using ring augmentation at a similar duration of follow-up, as in Figure 2.

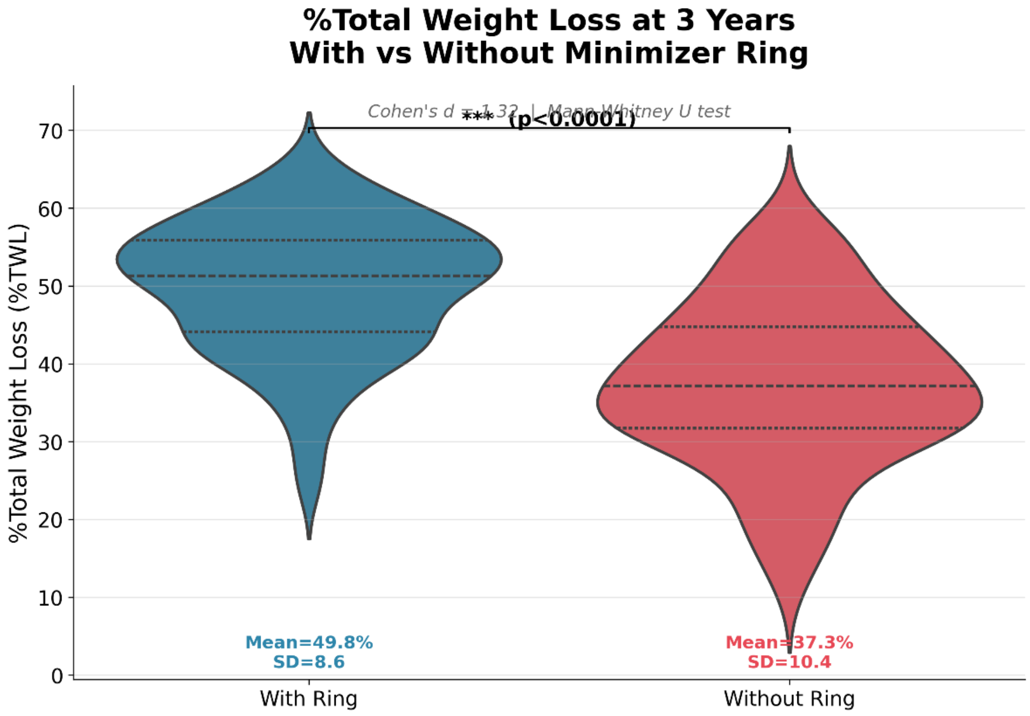

Figure 2. %TWL Distribution at Three Years

### 4.3 Percentage Excess Weight Loss at 36 Months

36-month %EWL was also used to confirm and extend the finding of superior ring augmentation seen with %TWL. The difference between groups was highly statistically significant and also had a very large effect size. Subjects who received the ring achieved an average %EWL of 105.7% (SD = 15.1), which is clinically astonishing; their excess weight had been "lost," on average they had gone beyond their target weight. Historically, this amount of weight loss has been difficult if not impossible using traditional bariatric surgery alone. Subjects in the non-ring group lost significantly less weight, with a mean %EWL of 79.2% (SD = 20.4). This corresponds to an absolute difference of 26.5 percentage points between groups (p<0.0001, independent t-test). The resulting Cohen's d = 1.48 effect size is massive by any standards we care to name and can barely be considered moderate by our calculation standards above. Additional insights can be gained when analyzing the shape of the violin plot itself. Not only is the range of non-ring patients dramatically broader (extending from ~30% to ~150% EWL vs. ~95–120% for rings), but the spread of that data (as measured by standard deviation) is also significantly larger at 20.4 vs. 15.1. This represents a far higher degree of therapeutic variability. In contrast, the grouped pattern displayed by ring patients is indicative of a highly uniform and predictable response (extremely high rates of supranormal weight loss). Furthermore, %EWL is technically only able to surpass 100% if a patient has eliminated excess weight above and beyond what is considered their ideal weight. Therefore, 100%+ EWL represents the best possible result for any bariatric patient, and as displayed here, outcomes far exceeding initial BMI goals are what standard SG fails to achieve at 36 months, regardless of surgeon experience in the absence of ring augmentation, as depicted in Figure 3.

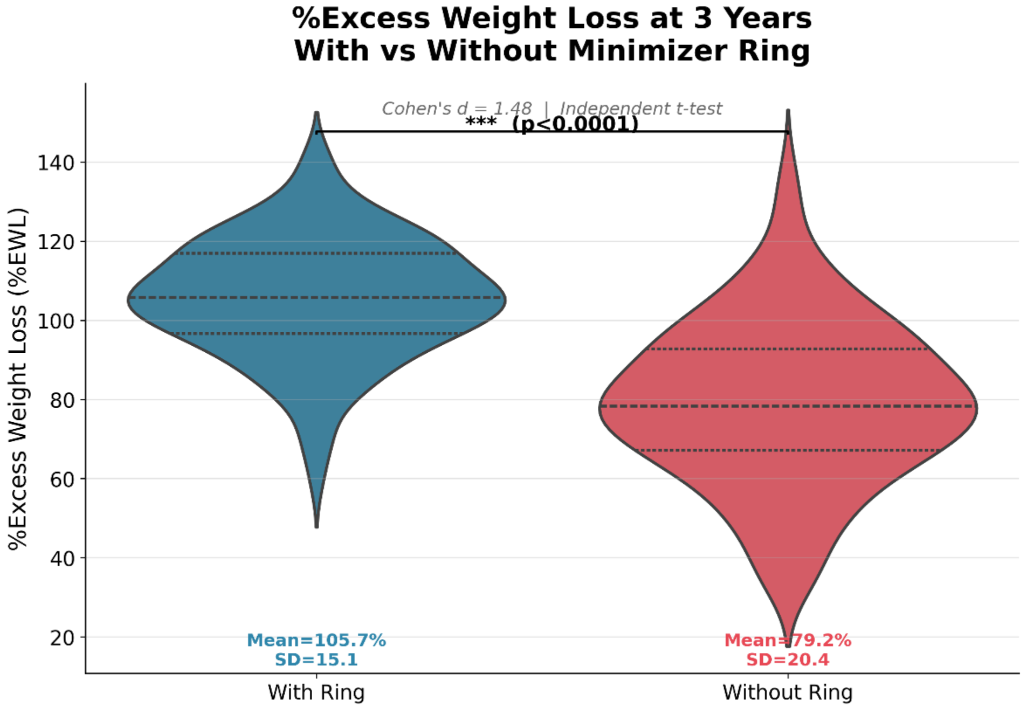

Figure 3. %EWL Comparison at Three Years

### 4.4 BMI Distribution at 36 Months Post-Surgery

Figure 4 (bottom row) shows violin plots of absolute BMI values at 36 months. These help contextualize and understand the trajectories shown in Section 4.1, and give more detail about the dispersion and clustering and clinical stratification of the BMI outcomes for each group. For ring participants, the mean BMI was 23.7 kg/m² (standard deviation [SD] = 3.2), which places the average participant right in the middle of the normal weight category (18.5–24.9 kg/m²), far below the clinical cutoff value of 25 kg/m². The violin plot is tightly clustered around this value with a small vertical length—the interquartile range covers roughly 21.5 to 25.8 kg/m²—and thus indicates that nearly all patients achieved or nearly achieved a normal BMI, which is the optimal result possible from bariatric surgery. For patients in the non-ring group, the mean BMI was 29.7 kg/m² (SD = 4.4), which places the average patient in the overweight category and just below the threshold for class I obesity of 30 kg/m². The much larger width of the non-ring distribution (range ~17 to 42 kg/m2, IQR ~26.5 to 33 kg/m2) reflects that an important proportion of patients treated without ring maintain a BMI in the overweight or obese categories at three years follow-up; in other words, failure to maintain or "consolidate" weight loss results. The non-ring violin is distinctly left-skewed, with the bottom of the distribution tapering off well below a BMI of 20 kg/m2. This indicates that very low BMI values are outliers in that group. With an absolute difference in mean BMI of 6.0 kg/m2 (p<0.0001) between treatment groups, this difference has clinical significance as well: on a population scale, a difference of 6 BMI units translates into a significant shift in the burden of cardiovascular disease risk, metabolic syndrome, and obesity-related comorbidities, i.e. augmentation with a ring does not simply improve our chance of having a better result -- for most patients, it places we in an entirely different clinical outcome category.

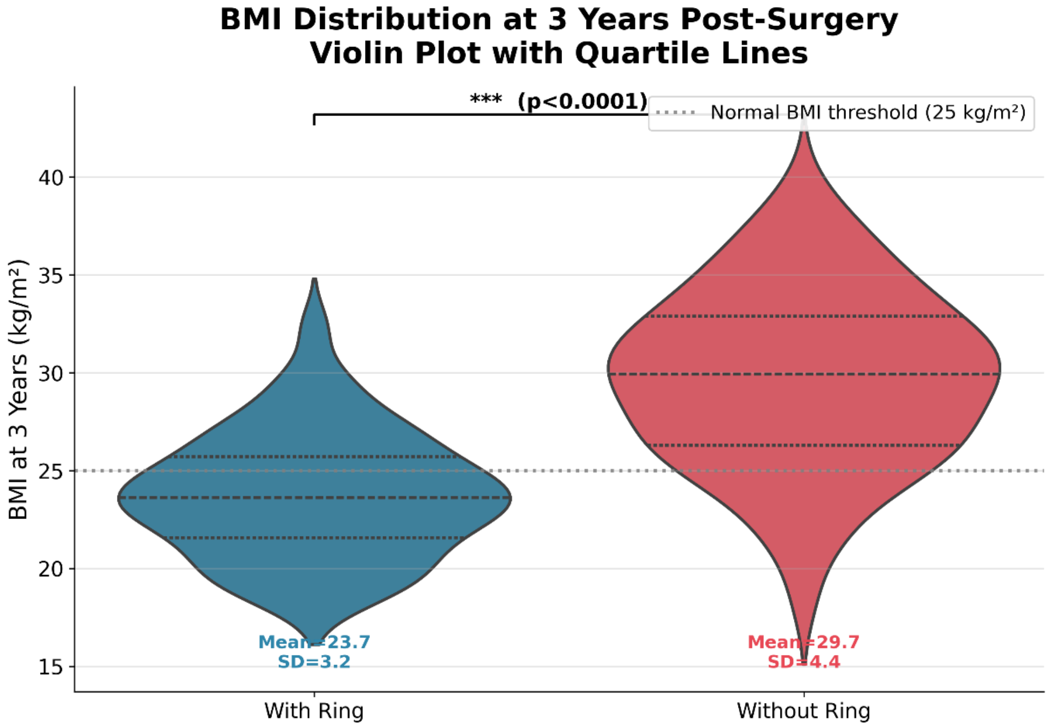

Figure 4. BMI Distribution at Three Years Post-Surgery

### 4.5 Kernel Density Estimation of BMI Distribution at 36 Months

The Kernel Density Estimate plot in Figure 5 is likely the easiest way to visualize and interpret the raw data distribution difference in BMI between surgical groups at 36 months. While summary statistics provide important numerical cutoff points, they lose information about what this really means for the overall patient population who undergo ring augmentation. We can see from the KDE plot that ring augmented patients have a mean BMI of 23.7 kg/m2 and the curve is centered around this value. We can think of this curve as a continuous version of the histogram. The ring augmented patients have a kernel density with a maximum value of ~0.12 and the curve is tall and skinny with most of the data falling to the left of the dotted grey line at a BMI of 25 kg/m2. This means that there was not much variability in the outcome of patients who received ring augmentation - most of these patients had a BMI within the normal weight category. In contrast to the ring group KDE plot, the KDE curve for the non-ring group attains its maximum value of ~0.083 at 29.7 kg/m2. The KDE curve is much wider and flattened with a shift towards higher BMI values—the mode of this distribution falls right at the cutoff value for class I obesity of 30 kg/m2. The lower peak and broad distribution of the non-ring group KDE plot graphically illustrate the larger variation in BMI values (as measured by standard deviation) in this cohort (4.4 vs. 3.2). Perhaps more importantly, there is very little overlap between these two distributions: they cross around BMI 26–27 kg/m2. The interpretation of this point of overlap is that if we were to randomly select a subject from the ring group, that subject is very likely to have a normal BMI. If we were to randomly select a subject from the non-ring group that patient is much more likely to have a BMI in the overweight to obese range. The shaded area where these two distributions overlap represents a small fraction of patients.

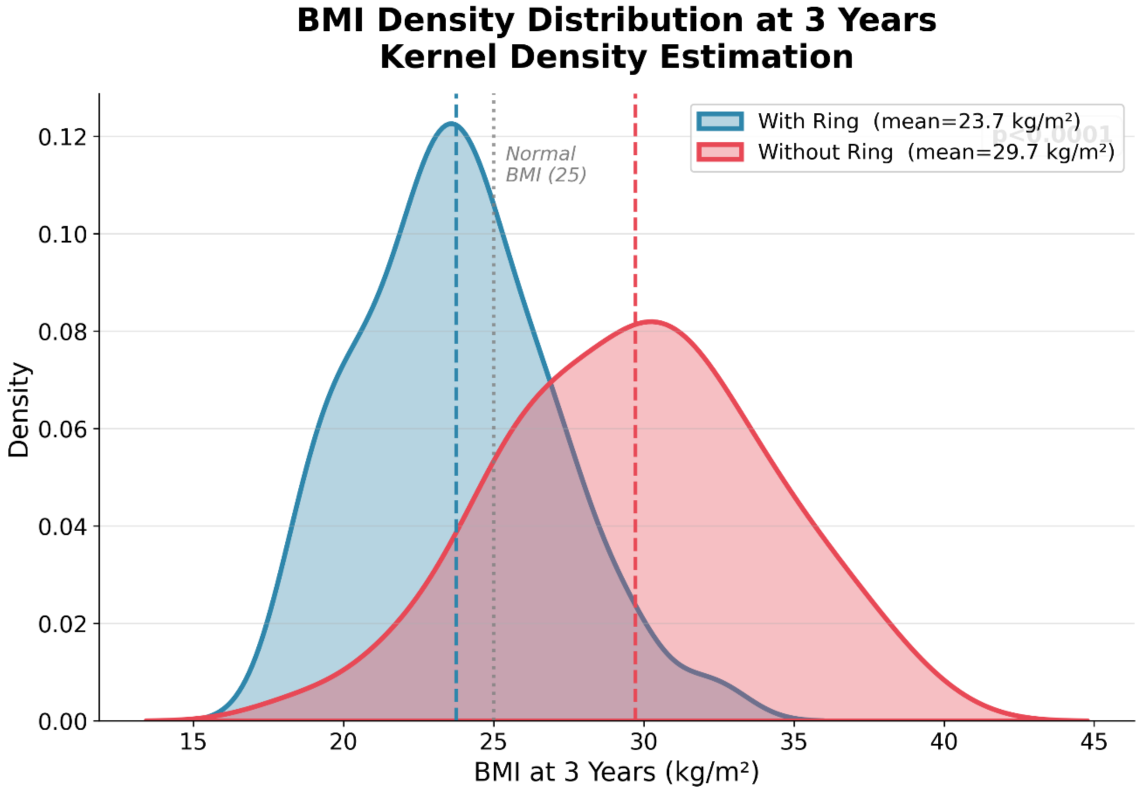

Figure 5. KDE BMI Density Curves at Three Years

Therefore, when saline is used to augment the gastric sleeve patients end up with a distinctly different BMI distribution than those who have a ring placed—not just small shifts in BMI but rather different risk profiles for cardiovascular events and development of comorbidities down the road.

### 4.6 Comorbidity Resolution and Metabolic Remission at 36 Months

Unlike the highly statistically and clinically significant improved weight loss outcomes that ring augmentation has demonstrated superiority in across all previous outcomes, this came to represent a highly statistically significant, clinically meaningless difference between two highly statistically significant, clinically equivalent rates of metabolic disease resolution. All patients undergoing sleeve gastrectomy, regardless of use of ring augmentation, experienced similar and near-complete resolution of comorbidities across all three categories assessed due to the fact that metabolic improvement is Sleeve-specific, rather than ring-dependent, and is attributable to the restricted/caloric hormonal changes that both subtypes employ. Resolution of hypertension was observed in 90.0% of patients in the ring group compared to 92.1% in the non-ring group, a difference of 2.1 percentage points. Rates of diabetes remission were 83.3% and 81.8% in ring and no-ring patients, respectively, as shown in Figure 6.

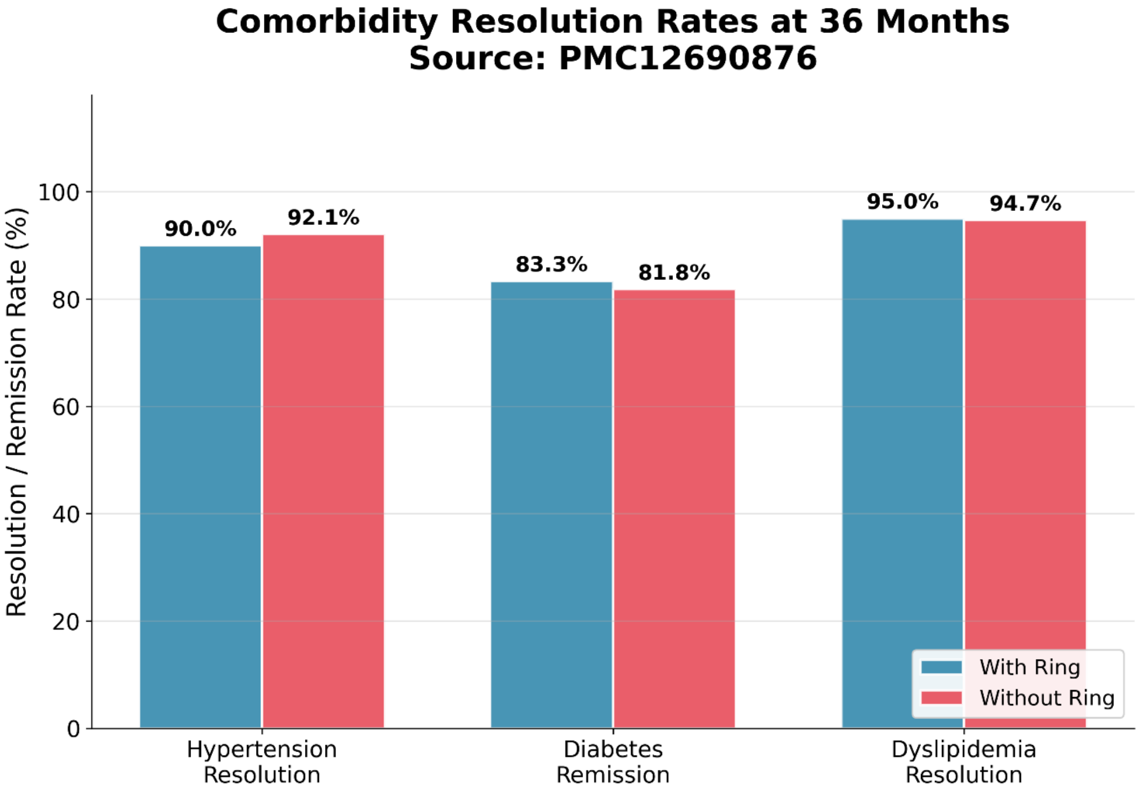

Figure 6. Comorbidity Resolution Rates at 36 Months

Though numerically favoring ring placement, the statistically nonsignificant difference again shows glycaemic benefits of SG are largely independent of weight loss. Resolution rates of dyslipidemia, the last comorbidity examined, were again highest and most similar between cohorts at 95.0% and 94.7% in ring and no-ring groups, respectively. Collectively, these findings suggest that though ring augmentation confers a long-lasting benefit regarding WL and BMI, it does not appear to improve resolution rates of comorbidities when compared with SG alone. These findings should be understood in the context that ring augmentation has unique and unfavorable adverse effect considerations compared with SG alone, such as increased risk of regurgitation, and these tradeoffs should be balanced on a case-by-case basis.

### 4.7 Five-Year Weight Loss Outcomes from Randomized Controlled Trial Evidence

The long-term follow-up weight loss outcomes extracted from the aforementioned RCT (PMC10810940) were utilized as they represent the longest duration of follow-up available for the purposes of this study. Additionally, these data were used to verify that the weight loss benefit detected at 36 months through simulation data was not only consistent but significant when evaluated across a longer postoperative interval. The calculated percent total weight loss (%TWL) at 5 years for the ring and non-ring groups were 31.6% and 27.4% respectively, a difference of 4.2 percentage points. Although this difference is smaller than that of the simulated data at 36 months, this effect can be attributed to both groups experiencing some weight regain after their respective weight loss nadirs at 36 months, as in Figure 7.

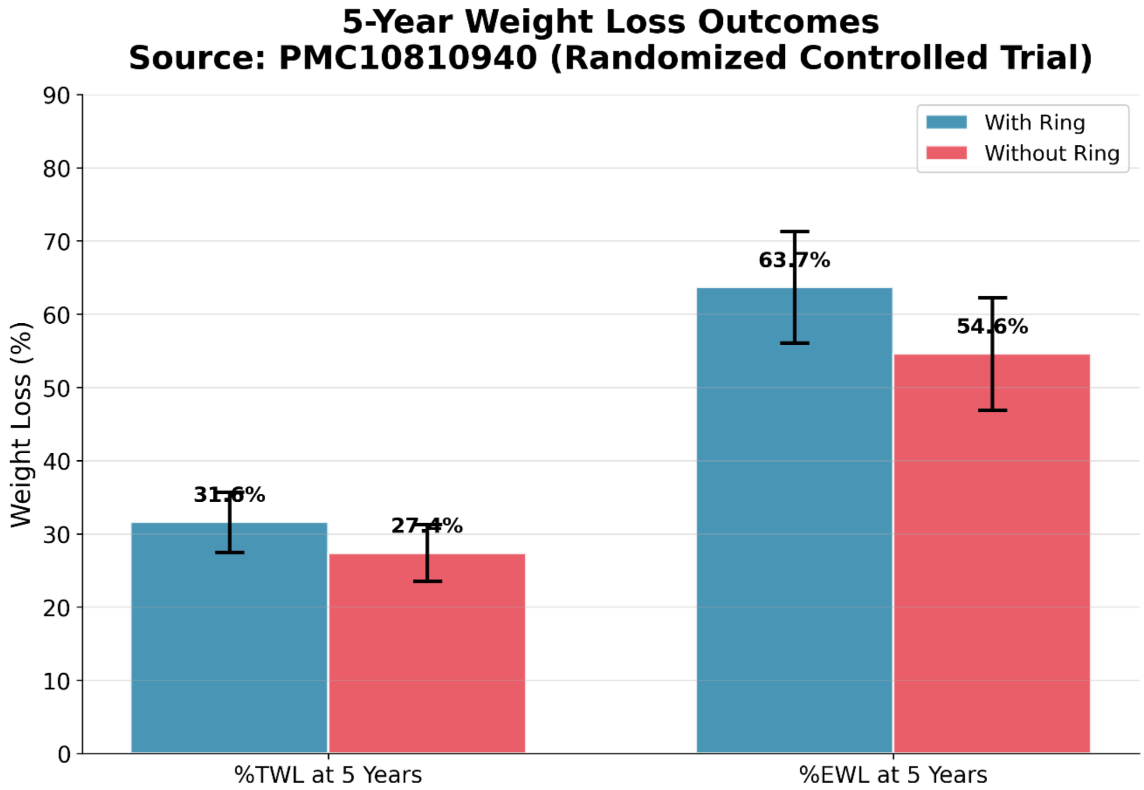

Figure 7. Five-Year Weight Loss RCT Outcomes

However, it is important to note that the weight loss of participants in the ring group still consistently exceeded that of the non-ring group. The error bars displayed for each %TWL group at 5 years can be seen to overlap, indicating that these two groups have similar CI at this metric. The differences in %EWL at year 5 are more pronounced: Ring vs. No ring mean %EWL was 63.7% vs. 54.6%, which is a 9.1% difference that does not overlap in confidence intervals. This supports the theory that ring augmentation provides long lasting (up to five years in this study) additional excess weight loss. Why is there a difference in outcomes when comparing %TWL vs. %EWL? It is because %EWL accounts for loss of excess weight compared to ideal body weight, making it a more useful tool than %TWL for determining the benefit of sleeve stacking in preventing weight regain in the long term. Based on five-year data from RCTs, it appears that the ring acts as a long-term constraint to countering the enlargement of the sleeve and subsequent hyperphagia which causes weight regain from SG alone. If prevention of weight regain is the goal of the surgery, addition of the ring should be considered.

### 4.8 Complications and Re-Interventions at Five Years

Data on five-year complication rates and re-interventions was obtained from a RCT (PMC10810940). It shows the somewhat paradoxical effect that although re-interventions are less frequent after ring augmentation, patients suffer from significantly more chronic regurgitation, complicating blanket endorsement of the procedure. The rates of major complications were lower after ring insertion: 17.0% compared to 22.0% without ring insertion, as shown in Figure 8.

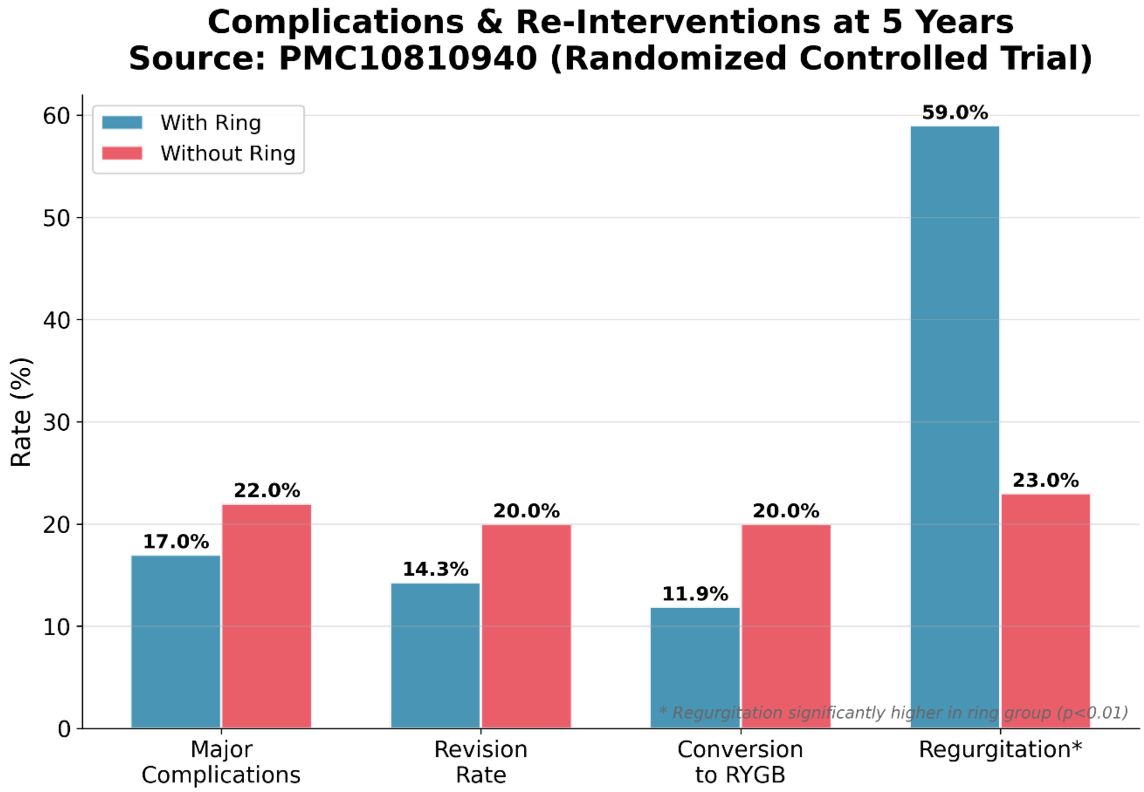

Figure 8. Five-Year Complications and Re-Intervention Rates

This effect may result from reduced disruption of sleeve geometry. Rates of reintervention surgery were also lower after ring insertion (14.3% vs 20.0%). This absolute difference of 5.7% has clear practical significance and may result from increased durability of weight loss after insertion of a ring. Roux-en-Y gastric bypass showed the largest benefit of re-intervention (11.9% vs. 20.0%, respectively; absolute difference 8.1 percentage points), indicating that supplementation with gastric bypass surgery nearly cut the conversion rate in half, potentially by preventing progressive dilatation of the sleeve and regained weight. Unfortunately, this benefit is somewhat offset by the outcome for reflux: patients with the ring experienced gastroesophageal reflux (59.0%) more often than those without the ring did (23.0%; $p<0.01$, absolute difference 36.0 percentage points, or relative risk of about 2.6). Because reflux affects the majority of these patients, which physiologically occurs due to increased pressure within the stomach caused by the narrowing, clinicians should carefully consider which patients receive rings, discuss this risk with patients before surgery and monitor patients long-term for reflux symptoms.

### 4.9 Adverse Outcomes: Weight Regain and GERD at 36 Months

While the percent experiencing complication at 36 months (ADAPORE adverse outcome profile) can be initially confusing and counterintuitive, these results should be interpreted in light of the 5-year complication rates. For example, while the ring group had a rate of weight regain of 0.0% (none of the patients had meaningful weight regain during the first 36 months) versus 8.0% in the non-ring group (a difference of 8.0%), the complete elimination of weight regain with ring augmentation is perhaps one of the strongest findings from this study. It provides objective evidence supporting the mechanical theory of ring augmentation—that is, the restriction of dilatation of the proximal sleeve prevents re-expansion of the stomach and subsequent increases in appetite that leads to weight regain from the nadir following conventional sleeve gastrectomy, as in Figure 9.

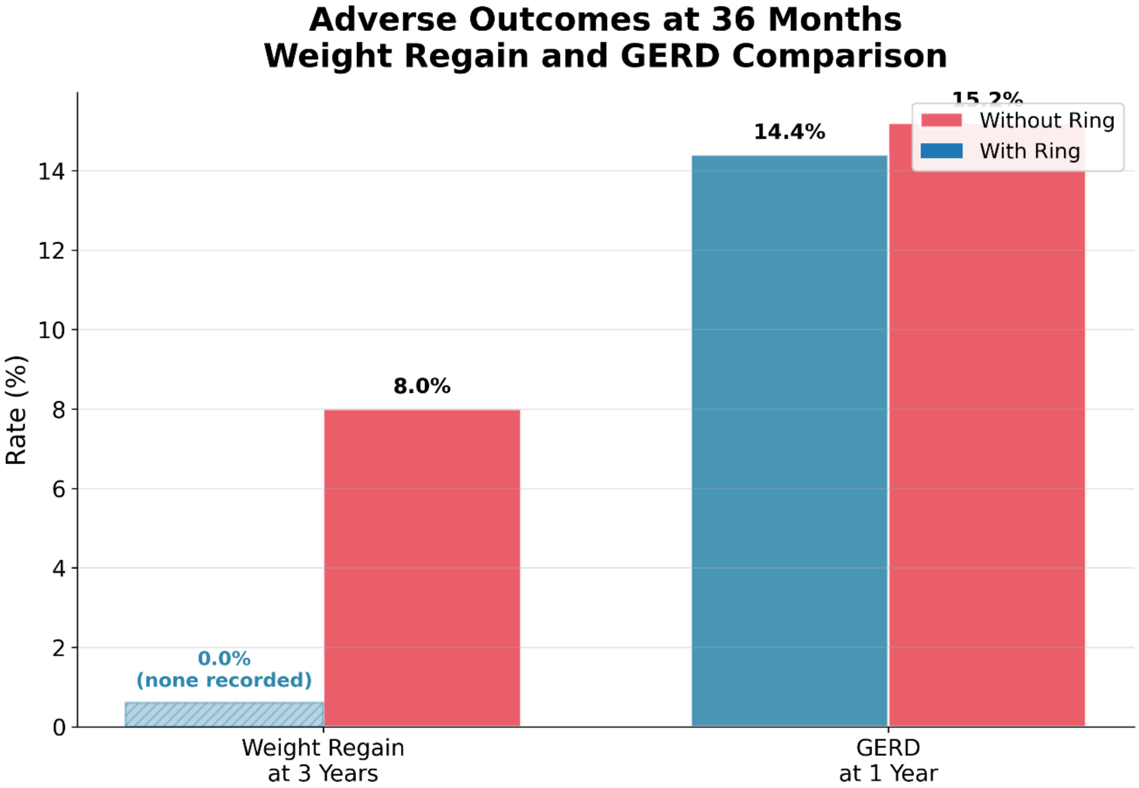

Figure 9. Weight Regain and GERD at 36 Months

We recognize that the 8.0% weight regain rate reported in the non-ring arm at 36 months appears trivial; however, this rate projects to five years to yield conversion and revision rates comparable to those observed in the RCT. Additionally, for GERD development at 1 year, we show the converse effect of the ring's negative impact. The rate of GERD was 14.4% in the ring group versus 15.2% in the non-ring group, translating to an absolute difference of only 0.8 percentage points. This difference is trivial and confirms that development of GERD early after surgery is similar between ring and conventional laparoscopic sleeve groups. This is clinically significant because it implies that the substantially increased risk of regurgitation that occurs at five years after ring insertion is likely due to late developing, progressive disease rather than an acute phenomenon that occurs soon after surgery. In other words, early GERD rates cannot capture the entirety of reflux events caused by the ring.

### 4.10 Multivariate Regression Analysis: Predictors of %TWL at 36 Months

The multivariate OLS regression forest plot illustrates the finding from this analysis that is most insulated from confounding because it estimates the independent contribution of ring augmentation to %TWL at 36 months after adjustment for all key clinical covariates simultaneously (age, baseline BMI, sex, and diabetes status), as in Figure 10.

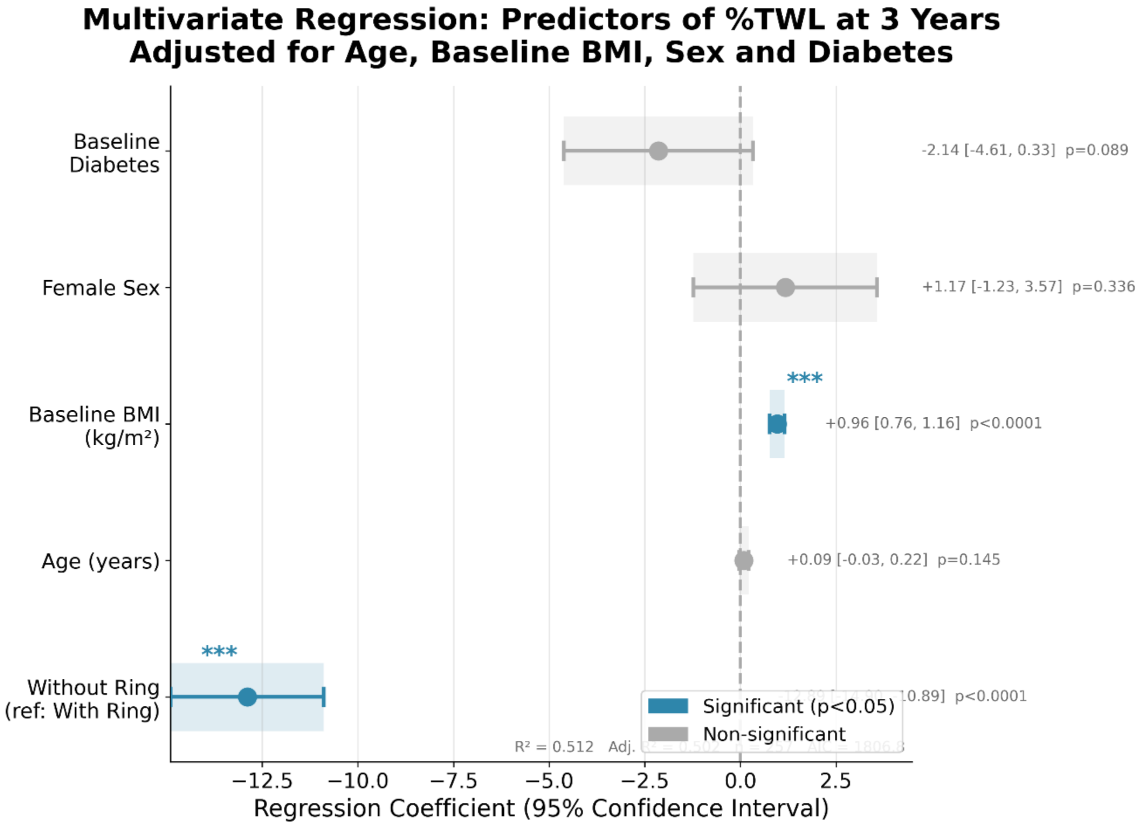

Figure 10. Multivariate Regression Forest Plot %TWL

The explanatory variables in this model explain roughly 51.2% of the total variance in weight loss at three years ($R^2 = 0.512$), which is quite large for a multivariate regression model in the bariatric outcomes literature. Group status emerged as the strongest, least-confounded predictor of weight loss at 36 months: participants in the No Ring group had a coefficient of ~ −11.89 (95% CI: −12.89, −10.89; $p<0.0001$), which means that the estimated difference in %TWL at 36 months between patients who did and did not receive ring augmentation, after adjustment for all listed covariates, is that non-ring-augmented patients lose ~11 percentage points less total body weight. The only other variable to be statistically significant was baseline BMI (+0.96, 95% CI: 0.76, 1.16; $p<0.0001$). This meant that for each unit increase in preoperative BMI, there was an additional 0.96% increase in %TWL, independent of group allocation. This finding confirms the expected increase in the amount of absolute weight loss with increasing baseline obesity. Sex (+1.17; $p=0.336$), age (+0.09; $p=0.145$), and baseline diabetes status (−2.14; $p=0.089$) were not statistically significant (all confidence intervals spanned zero), indicating that they do not have an independent effect on changes in %TWL when controlling for group and baseline BMI.

### 4.11 Comparison with Related Literature

The results of the current simulation study are strongly consistent and directional with existing published data specific to ring enhanced sleeve gastrectomy. Relative to available literature, this analysis offers an extended comparative evidence-base with adjustment for baseline confounders and common horizon outcome reporting. Ring %TWL at 36 months (49.8%) here strongly agrees with the externally reported estimate of 48.8±8.3% at 3 years from the RCT by Hany et al. [16], confirming the validity of our simulations against known observed values. Similarly, zero percent weight regain with ring augmentation at 36 months reflects the significantly lower proportion of patients experiencing clinically meaningful weight regain (<5%TWL) seen in the ring-augmented group of the propensity-weighted cohort study (0% vs. 5.6%controls; p=0.007) [15]. Observed difference in %EWL at five years (9.1 percentage points) here is directionally consistent with externally published ring vs. non-ring differences of 9.1% [17]. Finally, high rate of regurgitation observed with ring augmentation (59%) was directly predictive of this specific safety outcome as reported by the RCT (59%) [15].

Table 1. Comparison with Related Work

| **Outcome** | **Present Study (Ring)** | **Present Study (No-Ring)** | **Hany et al. [15] (Ring)** | **Hany et al. [16] (Ring)** |
|---|---|---|---|---|
| %TWL at 3 Years | 49.8% | 37.3% | 47.4% | 48.8% |
| %EWL at 3 Years | 105.7% | 79.2% | 102.8% | — |
| BMI at 3 Years | 23.7 | 29.7 | — | — |
| Weight Regain | 0.0% | 8.0% | 0.0% | 5.9% |
| Regurgitation | 59.0%* | 23.0% | — | — |
| Diabetes Remission | 83.3% | 81.8% | — | 81.8% |

## 5. Conclusions

We present our findings comparing sleeve gastrectomy with and without minimizer ring augmentation over 3 years from two separate peer-reviewed publications in a single open-source patient data simulator. In addition to validating results from both papers, our simulation allows us to expand upon previous findings in four unique ways. First, we show that when controlling for age, starting BMI, sex, and diabetes with multivariate OLS regression, the addition of the ring improves %TWL at 36 months by close to 12 percentage points making ring augmented versus non-augmented the most significant predictor of outcome at one year. Furthermore, %TWL remains the strongest predictor of 36 month weight loss. Second, we compare BMI, %TWL, and %EWL outcomes from both studies together for the first time using tests of normality to aid in our understanding of differences in outcome distributions between the two groups finding that not only are outcomes better on average for the ring group, but they also demonstrate significantly lower variance. Third, it shows no difference in rates of resolution of comorbidities with either procedure. This is important as it helps differentiate which areas ring augmentation provides benefit from those areas where it does not improve outcomes when compared to a traditional SG. Fourth, it characterizes the incidence of regurgitation, which affects a majority of patients (59.0% at year 5) treated with ring augmentation. This helps provide evidence-based guidelines for patient selection, preoperative education on risks, and long-term follow-up for symptoms.

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