The Mini-Gastric Bypass:
Patient and Physician Resource Manual

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YOUR INSURANCE MAY STILL PAY FOR SOME OF YOUR BILL

PATIENT’S FINANCIAL RESPONSIBILITIES:

ARRANGE FOR PAYMENT
The Centers for Laparoscopic Obesity Surgery and CLOS

We would like you to know that some surgeons and hospital programs who claim to have some association with Dr. Rutledge, the “Mini-Gastric Bypass”, the Centers for Laparoscopic Obesity Surgery and CLOS.

Dr. Rutledge is the pioneering surgeon who conceived of, named, developed, studied and documented the value of The “Mini-Gastric Bypass” and MGB are the service marks of a complete system of Preoperative, Intra-operative and Post Operative care conceived of, named, developed, studied and documented exclusively by the Centers for Laparoscopic Obesity Surgery and Dr. Rutledge. This healthcare system has been specifically designed to deliver excellent patient care and specially named to allowed it be differentiated from other surgical techniques and to avoid confusion with other programs of questionable quality.

These are Dr. Rutledge’s brand names should be used only with express legal permission and any other use is expressly forbidden. The medical and surgical treatment system developed and designed by Dr Rutledge and his associates includes careful and meticulous preoperative, Intraoperative and post operative care and monitoring.

Numerous studies by Dr Rutledge as well as independent assessments have demonstrated that the “Mini-Gastric Bypass” and MGB system is a safe and effective treatment for severe obesity and outperforms many other types of weight loss surgery. Dr. Rutledge reserves all rights for the “Mini-Gastric Bypass” and MGB system and believe that the use of Mini-Gastric Bypass and MGB be restricted to those surgeons and programs of the Centers for Laparoscopic Obesity Surgery that are legally and contractually approved for its use.

What Do Patients Say About their MGB: 1 YEAR POST OP

I don't know where to begin. I had my surgery on 1/29/02. 25 minutes in MGB surgery. I had no pain. I lost 17 pounds the first week and 37 by 1 month. I was down 112 by 6 months. I couldn't believe it. I talked a few times to Dr. R and his staff. I have all my energy plus. I feel wonderful. I did lose some hair between the months of 4-7. I panicked, but it was fine. I began taking Biotin and ZMA from the GNC store and either my body adjusted or they helped. I am not sure, but my hair is healthy and thick as ever now.

My body is shrinking in proportion and I am loving that part a lot. It makes it easy to shop for clothes. Today I am just very thankful to feel and look like I do. I have avoided alcohol with no problem. Its small thing to give up socially for the bonus I have been given.

I also can say that I haven't had any additional medicines (even over the counter). In October we went on a cruise and so did my surgery buddy, Patti. We played hard and daily were thankful that we had had the surgery prior to going. Lots of foods to try and we did just in small amounts.

I started at 332 and today weighed in at 159. I have now lost 173 pounds. It is slowing down as expected. I eat pretty much whatever I choose, but my choices are usually much different than in the past. I do avoid real ice cream and milk for the most part, but other than that I seem to manage with other foods. The milk products seem to make my stomach very gassy. We always had lots of fruit at our house, but now watermelon, strawberries, and pineapple are staples like milk, bread, and eggs.

In the last year I no longer worry about entering an airplane and whether the seat belt will fit. I never worry if I will take up too much room anywhere. I have been roller skating with my 7 year old many times since fall. My life has always been very full, but now I CAN KEEP UP AND DO IT ALL SMILING. It takes much less effort to climb the arenas, shopping with the team, etc.

I exercise 3 times a week. My friend and I actually were asked to be interviewed for the radio ad for the facility that we exercise. It was fun. We couldn't say that the exercise made us lose weight, but I can see an improvement in my ability and stamina to work out on the equipment. I actually enjoy exercising and I would have never said that before.

I don't have a lot more to add (after rambling for an hour) other than Dr. Rutledge has given me a chance to be an active person I enjoyed so much years ago. I feel like a 39 year old in a 39 year old body. Prior to surgery I was beginning to feel very old before my time. My husband, kids, family, and friends have all been very supportive through this change.

I faithfully take my vitamins, Citrucel, and Actigall. I had my 1 year labs and reviewed them over the phone. Everything looked great. I will have a 1 year check up with my PCP in the next couple of weeks. I have been a little preoccupied. My oldest got married on New Years. I can tell you that it was so nice to not be heavy for this event. I always tried to take pride in dressing and my appearance, but its so much fun right now. I can shop anywhere and I am buying 8's. I don't know if I was ever a 10 before.

For me the MGB surgery has given me exactly what Dr. Rutledge has explained a chance to be on the same playing field as other average size adults.

Good luck and I each of you the success and good days ahead I am experiencing. I wish good health to all.
Introduction: Laparoscopic Bariatric Surgery: A New Hope for Severe Obesity

As Dickens said in the opening lines of A Tale of Two Cities: “It was the best of times, it was the worst of times...” While obesity is reaching epidemic proportions in America, new laparoscopic techniques provide the hope of a short, simple, successful and inexpensive weight loss surgery.

What follows is a review of
1: obesity in America today,
2: surgery for obesity and
3: the Mini-Gastric Bypass  a well proven approach in Advanced Laparoscopic Bariatric Surgery.

The Centers for Excellence in Laparoscopic Obesity Surgery (CELOS), developed by Dr. Rutledge, is a program in Advanced Laparoscopic Obesity that has been shown in hospitals across the country to be a low risk and effective treatment for severe obesity. CELOS has a demonstrated track record of excellent patient satisfaction, weight loss, a low risk of complications and superb levels of patient satisfaction.

American Obesity Epidemic

For the past two decades, we have been living through an epidemic of obesity. The prevalence of obesity has more than doubled in adults and has risen by a factor of more than 3 in children. This escalation in obesity is a time bomb for the future risk of diabetes and other illnesses and for the attendant costs.

“According to the Behavioral Risk Factor Surveillance System (BRFSS), rates of obesity, defined as a body mass index (BMI) >30 kg/m2, have increased continually and dramatically since 1990. By 2003-2004, the National Health and Nutrition Examination Study (NHANES) found that rates of obesity in the US 31% in adult men and 33% for women. Because of this high prevalence and the serious health risks associated with obesity, the increase in this condition constitutes an epidemic that presents a serious and growing public health problem.

Obesity is closing in on tobacco as the nation's No. 1 preventable killer in America. It has been estimated that obesity is responsible for 400,000 deaths in 2000, a 33 percent jump over 1990. Escalating rates of obesity are considered a major public health threat because they are directly linked to a number of disabling and life-threatening diseases. 88 to 97 percent of all cases of Type II diabetes, 57 to 70 percent of coronary heart disease cases, 11 percent of breast cancers, and 10 percent of colon cancers that are diagnosed in overweight Americans are attributable to obesity. Further, about a third of all cases of hypertension are thought to be due to obesity, while 70 percent of gallstone cases are attributable to being overweight. What's more, unhealthy weight is associated with osteoarthritis and gout, along with a number of other disabling conditions.”

The prevalence of severe obesity is also increasing. Severe obesity is defined BMI>40kg/m2. In 2003-2004, 2.8% of US men and 6.9% of US women BMI>40kg/m2. This represents a population of approximately 14 million severely obese individuals: 4 million men and 10 million women.

The Danger and Damage of Severe/Morbid Obesity

Severe obesity has higher rates of morbidity and mortality and decreased quality of life. Mortality rates increase with BMI, with all-cause mortality among severely obese women equal to 117 deaths per 10,000 person-years, ~1.4 times higher than among obese women and almost twice as high as mortality among women of healthy weight. Risk factors for cardiovascular disease are increased, including diabetes, hypertension, and hyperlipidemia.

Diabetes, in particular, is strongly associated with obesity: the prevalence (± standard deviation) of diabetes was 3% among individuals of healthy weight, 6% among over weight individuals, 11% among obese individuals, and 19% among the extremely obese. Over-all Heart and Lung status is severely reduced among the extremely obese, with an impact similar to heart failure. Severely obese individuals who are critically ill tend to have higher rates of morbidity, complications, and mortality. A variety of other physical and psychiatric disorders are also prevalent among the severely obese.

Common medical disorders include sleep apnea, obesity hypoventilation, asthma, gastro-esophageal reflux disease (GERD), hypertension, coronary artery disease and congestive heart failure, stroke, non-alcoholic liver disease and nonalcoholic steatohepatitis with cirrhosis, low back pain, degenerative joint disease (hips, knees), pseudotumor cerebri, urinary stress incontinence, poly-cystic ovary syndrome, increased risk of cancers (esophagus, uterus, breast, prostate, liver, kidney), and ventral and incisional hernias. Severely obese individuals are also at an elevated risk for depression, anxiety, and eating disorders. Severely obesity is generally associated with low scores in all health-related quality-of-life domains in children, adolescents, and adults. In addition, severe obesity is associated with increased healthcare costs: the estimated annual cost of care for severely obese patients was more than double the cost of healthcare for patients of healthy weight, accounting for approximately $11 billion in healthcare expenditures in 2000.3
The Failure of Diet, Exercise and Drug Therapy in the Treatment of Obesity and Morbid Obesity

In a review of all published randomized controlled trials of diet and exercise program\(^4\) showed that diets can cause weight loss, but the average weight loss was only 8 lbs.\(^1\) A loss of 8 lbs in a 300 or 400 pound patient is of little value. There is no scientific data that diet and exercise programs can provide substantial sustainable weight loss for the morbidly obese patient.

The effectiveness of drugs approved for weight loss has also been studied.\(^5\) Compared to diet, exercise and placebo, Orlistat (Xenical, Alli) treated patients lost an additional 6 lbs and patients on sibutramine (Meridia) lost an average of 10 lbs. Orlistat caused gastrointestinal side effects and sibutramine was associated with increases in blood pressure and pulse rate and the drop out rate in these studies was 33% for Orlistat trials and 43% for sibutramine. Orlistat and sibutramine appear to be modestly beneficial for the treatment of adults with obesity,\(^6\) but neither drug provides clinically significant benefits to the morbidly obese patient.

The Promise of Surgery for Morbid Obesity/Surgical Weight Loss

Saves Lives

Morbid obesity is the most dangerous and deadly form of obesity and morbid obesity has the greatest risk to the patient, in terms of decreased life span and increased risk of complications, morbid obesity has been especially refractory to diet, exercise and drug therapy. Fortunately, studies have now reported good results with surgery as a treatment for severe, morbid obesity.

Gastric bypass surgery has now been shown to reduce death rates. In long awaited studies mortality was reduced in patients who had surgery. Recently, two scientific reports published in the prestigious medical journal New England Journal of Medicine, show the benefits of weight loss surgery by saving lives.

Swedish researchers reported a 30% reduction of deaths in obese patients after weight loss surgery. In an American study, there was a reduction of 40% in mortality rates in severely obese patients after gastric bypass surgery. The Swedish Obese Subjects study enrolled 2,010 patients who underwent bariatric surgery and 2,037 matched controls that didn’t wish to have surgery and received alternative treatments.\(^7\) An average of 11 years of follow-up (99.9% follow-up rate) reported the study. During the follow-up period there were 129 deaths in the control group and 101 in the surgery group, a 29% decrease in mortality rate.

In the American report\(^8\), a sample of 7,925 patients that had gastric bypass surgeries was followed for an average of 7.1 years and compared to 7,925 randomly selected control adults. The adjusted death rate was 40% lower with surgery than without it. In regard to specific causes of death for patients that had gastric bypass surgery as compared to the control group (without gastric bypass surgery) it was found that gastric bypass patients had 92% less deaths due to diabetes causes, 59% less deaths due to coronary artery disease, and 60% less death due to cancer.

The studies by Sjöström et al. and Adams et al. showing that weight loss lowers the rate of death are tremendously exciting. Two earlier studies by Flum and Dellinger\(^9\) and by Christou et al.\(^10\) using cross-sectional methods suggested that bariatric surgery improved long-term survival. Sjöström and Adams and their colleagues address this issue differently. Sjöström et al. conducted a prospective, controlled study of bariatric surgery, called the Swedish Obese Subjects (SOS) study, in which overweight patients wishing surgery were matched with equally obese patients not desiring surgery (Table 1). Men with a BMI of 34 or more and women with BMI of 38 or more were eligible, although these values were below those eventually recommended by guidelines of the NIH’s Consensus Conference. At 10 years, weight losses ranged from 14 to 25% among subjects who had undergone one of three surgical procedures, as compared with roughly 2% among control subjects. In the surgery group, there was a significant reduction in the adjusted hazard ratio for death (29%) after an average follow-up of 10.9 years, with a 99.9% ascertainment rate. In addition to the improvement in the risk of diabetes, the reduction in deaths from cancer may also argue in this direction. Sjöström et al. and Adams et al. show that weight loss saves lives in obese patients. Thus, the question as to whether intentional weight loss improves life span has been answered, and the answer appears to be a resounding yes.

Complications Following Roux-en-Y Weight Loss Surgery

A variety of very serious complications can occur following today’s weight loss surgery procedures.\(^11\) These reported complication rates far exceed the low rates seen in the series of Mini-Gastric Bypass patients. As an example as of 12/14/2004, The Medical College of Virginia official Bariatric Surgery program Web site quotes the following “complications for open gastric bypass, with rates at our institution:”\(^12\)
Risks of the Surgery

"This chart lists some complications for open gastric bypass, with rates at our institution:"

<table>
<thead>
<tr>
<th>Complication</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major wound infection</td>
<td>2%</td>
</tr>
<tr>
<td>Incisional Hernia (rate for open gastric bypass)</td>
<td>20%</td>
</tr>
<tr>
<td>Stomal Stenosis (causes temporary vomiting after surgery)</td>
<td>12%</td>
</tr>
<tr>
<td>Ulcer</td>
<td>9%</td>
</tr>
<tr>
<td>Gallstones (with anti-gallstone medication)</td>
<td>2%</td>
</tr>
<tr>
<td>Blood clots in the lungs</td>
<td>0.5%</td>
</tr>
<tr>
<td>Leak from the hook-up/peritonitis</td>
<td>1.5%</td>
</tr>
<tr>
<td>Death</td>
<td>1%</td>
</tr>
</tbody>
</table>

Figure 1: Official Virginia Commonwealth University Medical Center Gastric Bypass Program Complications
http://www.vcu.edu/lesspainsurgery/obesity/risks.htm

As another example of the major risks of weight loss surgery, the following information on complications after weight loss surgery is reported from the International Bariatric Surgery Registry (IBSR), winter 2000-2001 Pooled Report 15.

Complications within 30 days of surgery for obesity of 10,993 patients from IBSR 2000-2001 Winter Pooled Report.14

Atelectasis (46), hyperventilation (1), respiratory undefined (104), wound site Seroma (80), wound infection (48), Splenic injury (27), pleural effusion (11), pleuritis (2), pneumonitis (9), Dehydration (8), Renal, urinary tract infection (4), stoma too large (5), stoma too small (1), ulcers: duodenal, gastric, stomal (jejumun or anastomoses) (5), hepatic, liver hematoma (4), esophageal reflux, esophagitis (3), hernia: incisional (1), ventral (1), dumping syndrome (1), vitamin insufficiency (1), GI Leak (33, 5 deaths), stoma obstruction (luminal - 18); stoma stenosis (15), GI hemorrhage or GI bleeding; 7 due to ulcers, undefined (19), cardiac (4 deaths), pulmonary embolism (19, 11 deaths), respiratory arrest or failure (16, 4 deaths), wound dehiscence 13, small bowel obstruction: Roux-en-y (4), common channel (2), enterostomy (1) undefined (6). Subphrenic / sub hepatic abscess(11); abdominal abscess (1), gastric dilatation (11, 1 death) deep venous thrombosis (6), thrombopylebitis (2), staple line breakdown: linear gastric (3), window (1), enterostomy (3 - 2 deaths), pancreatitis (3); acute cholecystitis (2), neurologic (4, 1 death), gastric fistula 3, peritonitis (2 deaths), 2, other: drug skin problems, balloon dilatation, hemorrhoidectomy, gastroenteritis, undefined. See American Society of Bariatric Surgeons.

Roux en Y Gastric Bypass Makes Some People Sick

The ideal of weight loss surgery is to lose weight of course but even more important is the goal of improved health. Surgeons that perform weight loss surgery consistently point out that the surgery is not only cosmetic but it is designed to improve the health a quality of life of the patients that undergo the operations. Sadly studies that support this contention are lacking. Recently two studies one from Pennsylvania and one from California showed that in fact the RNY gastric bypass make people sicker.

Complications of RNY gastric bypass surgery can be very serious and may not appear for several weeks or months after surgery. For example in a study from The Pennsylvania Health Care Cost Containment Council, an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care, and increasing access for all citizens regardless of ability to pay, in the two years following RNY surgery, the 2,684 gastric bypass surgeries performed in 2001 were followed by 1,050 readmissions (39%) involving digestive system or nutritional and metabolic disorders or additional procedures for obesity. These readmissions accounted for an additional 4,161 hospital days and $22,619,648.00 in hospital charges.15

Patients who have RNY gastric bypass surgery have double the rate of hospitalization in the year following the operation than in the year preceding surgery, according to a study in the October 19 issue of JAMA.16

In California from 1995-2004, a total of 60,077 California residents underwent RNY Gastric Bypass for obesity, with 11,659 in 2004. The average age was 42 years, 84 percent of patients were women, and 88 percent were privately insured or self-pay. The average length of stay for RNY patients was 3.5 days as compared to 24 hours for MGB patients.

For patients with a year of follow-up (1995-2003), 19.3 percent were readmitted within the first year after RNY Gastric Bypass surgery compared with 7.9 percent being admitted in the year before surgery.
In a subset analysis of all patients (24,678) who underwent RNY Gastric Bypass with complete 3-year follow-up, the average percentage of patients admitted in the year prior to RNY Gastric Bypass was 8.4 percent.

In each of the 3 years following RNY Gastric Bypass, the rates of hospitalization remained increased, with 20 percent of patients readmitted in the first year after RNY Gastric Bypass, 18.4 percent in the second year after, and 14.9 percent in the third year after RNY.

Adding all three years together showed that the cumulative admission rate for the 3-year period prior to RNY Gastric Bypass was 20% compared with the cumulative 3-year admission rate AFTER RNY Gastric Bypass of 40%. In other words RNY increased patient’s need for hospitalization by 200%!! If one uses the simple measure of need for hospitalization as a measure of good health then the RNY made people sicker after surgery than they were before the RNY.

For persons with 3 years of follow-up, the average hospital charges were $33,672 for RNY Gastric Bypass, $4,970 for hospitalizations in the 3 years before RNY Gastric Bypass, and $20,651 for hospitalizations in the 3 years after RNY Gastric Bypass. That is to say the average cost to provide medical care to obese patients prior to RNY was about $5,000/3 years before RNY and about $21,000/3 years after RNY a 500% increase.

Furthermore, in the subset of patients with 5 years of follow-up postoperative admission rates remained elevated (average 13%) even into the fifth year after the RNY operation.

The most common reasons for admission prior to RNY Gastric Bypass were obesity related problems (e.g., osteoarthritis, lower extremity cellulitis), and elective operation (e.g., hysterectomy), while the most common reasons for admission after RNY Gastric Bypass were complications related to the RNY procedure, such as ventral hernia repair and gastric revision.

The authors began their study with the "hypothesis in our study that use of health care services should improve, that inpatient care should decrease after RNY Gastric Bypass. However, we found significant and sustained increases in the rates of hospital admission for morbidly obese patients after RNY Gastric Bypass. Annual rates of hospital admission after RNY Gastric Bypass are double than prior to operation and are sustained beyond a year in this population-based study," the authors write.

These findings have serious implications for patients as well as payers and purchasers of health care. Rather than expecting a decrease in inpatient health care utilization after RNY Gastric Bypass, the costs associated with inpatient hospitalization may remain elevated for as many as 5 years following RNY Gastric Bypass.

"The current study demonstrates that the rates of hospitalization doubles in the years after operation and that many of these admissions are directly attributable to the RNY procedure," the researchers conclude.

**Underreported Complications of Bariatric Surgery**

While some studies can make bariatric surgery may appear to be a "silver bullet" for the seriously overweight patient, a simple solution to a previous insoluble problem. But, there is trouble in Paradise. Sadly with the rise in new bariatric programs and amidst glowing reports like those referred to above, there has been a steady stream of reports of deaths, complications, lawsuits, program failures and closures across the United States. A recent cursory review of death, lawsuits and bariatric program closure shows dozens of bariatric surgery program tragedies that have appeared in the media and will likely NEVER be reported in the medical literature quoted above.

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
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<th>Hospital</th>
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Mini-Gastric Bypass - Patient and Physician Manual

6 Fall River MA Boston Herald Saint Anne's Hospital

7 Greenville NC

8 Albuquerque NM Albuquerque Journal University of New Mexico Hospital

9 Carson City NV Review Journal Carson-Tahoe hospital

10 New Richmond OH Argus Leader

11 Providence RI Providence Journal Roger Williams Medical Center

12 Houston TX Houston Chronicle Houston Community Hospital

13 Winchester VA The Winchester Star Winchester Medical Center

14 Tacoma WA Seattle Times

15 Philadelphia PA NBC News 10

16 Virginia Beach VA Inside Edition

The reported results of weight loss surgery are concerning but, many of the deaths and worst complications of Bariatric surgery may go unreported in the medical literature. None of these patients are part of a reported study and their deaths may never be reported in the scientific literature. (Published Monday, September 23, 2002 and Watch one, do one, teach one...35)

In another example of concerns about the actual outcome of bariatric surgery, it was found that almost half of Roux-en-Y gastric bypass patients will need to be re-hospitalized within two years of surgery! The Pennsylvania Health Care Cost Containment Council released a report that revealed the cost of complications from gastric bypass surgery. In the two years following 2,684 Roux-en-Y gastric bypass surgeries performed in the state of Pennsylvania in 2001, there were 1,050 readmissions (39%) for conditions related to the Roux-en-Y gastric bypass. Pennsylvania Health Care Cost Containment Council said the hospital charges for these readmissions totaled nearly $23 million.36

Also raising concerns is the increasing number of state insurance companies that are stopping their coverage of bariatric surgery. State Blue Cross Blue Shield plans in Florida and South Carolina have announced their intent to discontinue their coverage of bariatric surgery because their reviews have show that in contrast to reported studies, have been poor.

Blue Cross Blue Shield of Florida has announced it will stop covering gastric bypass surgery by the end of the 2004.37 The Jacksonville-based company says safety is the main reason it will drop the surgery. Dr. Robert Forster, the company’s chief medical officer and vice president for health care services, said about three in every 1,000 patients die and up to 20 percent of patients return to the hospital for a second procedure.

Controversy in Surgery

Controversy is a hallmark of new ideas and new areas in medicine and surgery. A recent book, “Great Feuds in Medicine” provides a broad overview of the internal and external clashes that went on in the process of the changes that occur in medical practice. Time and time again new ideas in medicine, that are now obviously correct, resulted in debate, turmoil and challenges before the new ideas and treatments were accepted. Examples of changes in medicine that engendered strong controversy and disagreement range from the classic experiences of Lister and Semmelweis who tried to encourage antisepsis and hand washing to today’s experiences with the changing therapy of breast cancer. The history of medicine is filled with controversy over the development of new ideas.

As an example there have been many controversies in the management of breast cancer. Medical practice is commonly rooted in tradition rather than proof: The Halsted radical mastectomy 100 years after its inception the operation continues to thrive in spite of evidence favoring lesser procedures. Many accepted ideas and interventions are perilously disconnected from their true merit. The imperative for doctors to do something sometimes contradicts their pledge to do no harm. Reflection on what is known should guide future action.

Joseph Lister published papers on antisepsis in 1867 and lectured for 3 hours on the subject at a medical congress in Philadelphia in 1876, 9 years later. At the first meeting of the American Surgical Association in 1883, more surgeons opposed his antiseptic principles than supported them. They steadfastly disregarded reports that in European hospitals that implemented his methods, post-surgical problems such as gangrene were no longer rampant. As late as 1900 most surgeries were conducted in the home because hospitals were feared as filthy, foul houses of death.

Recently Dr. Kurt Semm the pioneer of laparoscopic surgery died. Dr. Kurt Semm’s revolutionary techniques in minimally invasive surgery were initially ridiculed. In the 1960s, Semm, a gynecologist and engineer, began working on laparoscopic surgery, in which no large incision is made. Instead, several tiny incisions are made to insert a scope and instruments. Such operations can greatly reduce costs, pain of surgery, complications and recovery time.

"Someday in the future, people will look back at a regular surgical incision as something archaic and barbaric,” Dr. Paul A. Wetter, chairman of the Society of Laparoendoscopic Surgeons, said. "We have Kurt Semm to thank for that.”
Semm, who worked in fertility, developed instruments that allowed the uterus to be manipulated without large incisions being made in the abdominal wall.

In an interview with Litynski in 1994, Semm described one of his innovations.

"I had a patient from Persia," Semm said. "She had come to have a sterilization done and had a visa for only three days." The woman began bleeding heavily and instead of performing a laparotomy - making an abdominal incision to get to the source of the bleeding - Semm decided to use a Roeder loop, in which an intricate knot was started outside the abdomen, slipped through a tube and tied around the source of the bleeding inside.

"But I had no instrument to get the dumb loop into the abdomen," Semm recalled. "So I improvised, and it worked. It was 1975 or 1976." By 1977, use of the loop ligature had become routine in such surgery in his clinic.

When Semm presented his inventions at medical meetings, he was often derided as unethical by people who were shocked at how different his new techniques were.

Once, when he was making a slide presentation on ovarian cysts, "suddenly the projector was unplugged, with the explanation that such unethical surgery should not be presented," Dr. Liselotte Mettler, a student of Semm and deputy director of obstetrics and gynecology at the University of Kiel in Germany, said when she introduced Semm at the 2002 meeting of the Society for Laparoendoscopic Surgeons.

In 1970, after Semm became the chairman of obstetrics and gynecology at the University of Kiel, his co-workers demanded that he undergo a brain scan because, they said, "only a person with brain damage would perform laparoscopic surgery," Mettler said.

Litynski noted in his 1998 article that "an astonished observer" asked in the Feb. 1, 1980, issue of the Medical Tribune, "When will the first appendix or gallbladder disappear into an endoscope?"

"The first half of this question did not wait long for an answer," Litynski wrote. "On Sept. 13 of the same year, Semm performed the first fully laparoscopic appendectomy." Laparoscopic removal of the gallbladder is also now routine, and his technique for hysterectomy is now called the Semm hysterectomy.

Criticism did not deter Semm. "He was persistent and consistent," said Dr. Jordan Phillips, founder of the American Association for Gynecological Laparoscopy and a friend of Semm.

Bariatric Surgery Controversy: Dozens of Types of Weight Loss Surgery?

Given the American Obesity “epidemic” and the value that has been shown from surgical weight loss, what is the type of weight loss surgery that should be recommended? Surgeons and physicians are hotly debating this issue. Here we find a truly remarkable range of recommended surgical procedures for weight loss.

The types of Weight Loss Surgery include: Open Roux-en-Y Gastric Bypass, Laparoscopic Roux-en-Y Gastric Bypass, Silastic Ring Vertical Gastric Bypass (Fobi Pouch), Sleeve Gastrectomy, Micro pouch Gastric Bypass, Antecolic Laparoscopic Roux-en-Y Gastric Bypass, Long Limb Gastric Bypass, Biliopancreatic Diversion, “Greenville” gastric bypass, Biliopancreatic Diversion, Biliopancreatic Diversion with Duodenal Switch, biliopancreatic diversion of Larrad, Gastric Band, Laparoscopic Gastric Band, Laparoscopic Adjustable Gastric Band, Vertical Banded Gastoplasty, Laparoscopic Vertical Banded Gastroplasty, Sleeve Gastrectomy, Gastric Pacemaker and more!

The fact that there are so many different types of surgery offered for obesity clearly shows that none of the different types of surgery have emerged as the “ideal” surgery as the treatment for severe obesity. There is a great deal of controversy in Bariatric surgery because each surgical procedure has its own advantages as well as its own attendant problems and complications. All of the presently available weight loss procedures have MAJOR problems and complications.

The Problem of Obesity and the Solution of Surgery: Benefits vs. Risk

The present day situation of Obesity in America can be summarized in the following ways:
• Obesity is now widely recognized as a major and growing problem in America, reaching epidemic proportions.
• Diet, exercise and drugs are of no definite value in severe (morbid) obesity.
• Weight loss surgery, especially laparoscopic bariatric surgery, provides the promise of a short, simple and effective treatment for severe obesity.
• Numerous studies have identified the benefits of weight loss surgery
• But, these and other studies also show a range of frequent and dangerous complications from weight loss surgery.
• In addition, newspapers and TV stations of America are filled with reports of weight loss surgery problems, complications and deaths that will likely never be reported in the medical literature.
• Many bariatric programs have resulted in tragedy, law suits and closure.
• There are a remarkable number of different types of surgical procedures offered for bariatric surgery and a high level of controversy about the best choices for surgery.
• Because of these and other problems many physicians do not support weight loss surgery.

The Laparoscopic Revolution
American healthcare is constantly changing. One of the most remarkable new changes is the rapid development of new minimally invasive (Laparoscopic) forms of surgery. The laparoscopic revolution has affected many areas of surgery. In all of the areas in which minimally invasive surgery has been adopted, laparoscopic surgery has resulted in better patient outcomes, decreased patient hospital stay, decreased pain, decreased complication rates and shorter time to return to work. In every situation, from cholecystectomy to hernia repair, the laparoscopic approach has resulted in better outcomes. These new developments in surgery, Laparoscopic Surgery and Laparoscopic Bariatric Surgery, have created controversy. But, routinely these new developments in medicine usually cause controversy.

Ideal Weight Loss Surgery
A recent study by Dr. Rutledge of over 500 pre and post operative weight loss surgery patients identified the factors that are important in making up “ideal” surgery for the treatment of severe obesity. The survey demonstrated what patients want in their surgical treatment for obesity. In the study patients felt that an ideal weight loss surgery should be 1-effective, 2-easy to perform and 3-low risk. It should have a simple “Exit Strategy” that is, it should be easy to modify or reverse when necessary. Survey participants felt that an ideal operation should leave little in the way of abdominal adhesions (scar tissue) and rarely cause hernias. It was felt that the operation should be relatively inexpensive and long-term complications should be few and manageable. The surgical procedure should be a part of a program that includes careful preoperative and postoperative follow-up so that results can be continuously evaluated. In an ideal situation the results of the program should be available to outsider patients and other reviewers to allow an objective assessment of the results of the procedure provided.

Patients want these features in the weight loss surgery that they choose. The number and variety of surgical procedures that are presently provided for the surgical treatment of obesity shows that until now the ideal operation for weight loss has not yet been found. When using these factors to judge the various forms of surgery for obesity the Mini-Gastric Bypass is one of the best weight loss procedures available today.

The Mini-Gastric Bypass
The Mini Gastric Bypass (MGB) is a short, simple, successful and inexpensive laparoscopic gastric bypass weight loss surgery. The operation usually takes only 30 to 60 min. and hospitalization is routinely less than 24 hours. The Mini Gastric Bypass is low risk, has good durable long term weight loss, has minimal pain and can be easily reversed or revised. Over 2,725 people from all across America have had the MGB.

The Mini-Gastric Bypass is based upon two widely used, well known and reliable general surgical procedures; the Collis gastroplasty and an antecolic Billroth II loop gastrojejunostomy.

The Mini-Gastric Bypass was developed to try to address the many problems and limitations of the present forms of weight loss surgery. It was felt that a significant number of the ideal features desirable in...
weight loss surgery could be obtained using this minimally invasive approach.

**Laparoscopic Roux-en-Y vs. Mini-gastric Bypass for Obesity**

In the most recent issue of Annals of Surgery researchers show that laparoscopic mini-gastric bypass is a simpler and safer procedure that has no disadvantage compared with laparoscopic Roux-en-Y gastric bypass.

Researchers conducted a prospective, randomized trial to compare treatments of morbid obesity. The team compared the safety and effectiveness of laparoscopic Roux-en-Y gastric bypass and laparoscopic mini-gastric bypass in the treatment of morbid obesity.

Laparoscopic Roux-en-Y gastric bypass has been the gold standard for the treatment of morbid obesity. While laparoscopic mini-gastric bypass has been reported to be a simple and effective treatment, the team report that data from a randomized trial are lacking. The researchers recruited 80 patients who met the National Institute of Health criteria and randomized 40 patients to receive laparoscopic Roux-en-Y gastric bypass and 40 to laparoscopic mini-gastric bypass. The research team reported that the minimum postoperative follow-up was two years and that peroperative data were assessed. The researchers determined late complication, excess weight loss, body mass index, quality of life, and comorbidities. Changes in quality of life were assessed using the Gastro-Intestinal Quality of Life Index.

The researchers found one conversion in the laparoscopic Roux-en-Y gastric bypass group. Operation time was shorter in laparoscopic mini-gastric bypass group and there was no mortality in either group. The team observed that the operative morbidity rate was higher in the laparoscopic Roux-en-Y gastric bypass group, at 20 percent versus 8 percent. The late complications rate was the same in the two groups at 8 percent with no re-operation. The team noted that weight loss was 59 percent and 60 percent at one and two years, respectively, in the laparoscopic Roux-en-Y gastric bypass group. The team noted that percentage weight loss in the group was 65 percent and 64 percent in the laparoscopic mini-gastric bypass group. Residual excess weight of less than 50 percent at two years postoperatively was achieved in 75 percent of patients in the laparoscopic Roux-en-Y gastric bypass group. In comparison, the researchers found that residual excess weight loss at two years in the laparoscopic mini-gastric bypass group was 95 percent. A significant improvement of obesity-related clinical parameters and complete resolution of metabolic syndrome in both groups were noted. In addition, the researchers observed that gastrointestinal quality of life increased significantly without any significant difference between the groups.


**Results of the Mini-Gastric Bypass**

Recently a sample of 358 patients from the series of 2,725 (13%) gastric bypass patients completed their follow up forms for analysis. The results of this recent sample are similar to previous analyses and document the remarkably good results seen in the CELOS series of bariatric patients. The average length of follow up for this sample was just under 2 years (20 months) with a range of 1 to 62 months.

The patient population was made up of 15% men and 85% women with an average age of 39. The average weight of patients was 288 lbs, mean excess body weight was 163 lbs and the mean BMI was 51. The 30 day mortality rate was 0 and the perioperative complication rate was 5.9%. The average operative time was 37.5 minutes and median hospital stay was 1 day.
**Weight Loss**

The mean weight loss at one year was 130 lbs. The mean excess body weight lost was excellent at 80%. The mean BMI at the end of one year was 29. The average change in waist size was 12.6 inches. Weight loss was maintained within 10-15 lbs in >95% of patients up to 5 year follow up. Weight loss was excellent and a plot of weight loss is shown in the figure below.

*Figure 2: 5 year weight loss after the MGB*

**Health Status Improvement**

Health status improvement following surgery was excellent with resolution or improvement in all major associated medical illnesses that were measured (85% of patient with heartburn had resolution of their heartburn, 96% of patients with Shortness of breath had resolution of their Shortness of breath. 17% percent of patients had diabetes at the time of surgery and 83% of diabetics resolved their diabetes following surgery. 37% of patient had sleep apnea and 87% of sleep apnea patients resolved their sleep apnea following surgery. 53% of patients had hypertension and 80% resolved their hypertension. 39% had hypercholesterolemia and 89% resolved their elevated cholesterol after surgery. Urinary incontinence was reported in 35% of patients and this resolved in 82%.)

**Patient and Physician Satisfaction**

Patient and physician satisfaction were measured and 95% of patients and 96% of patient physicians were reported to be satisfied with the surgery and its results.

More detailed assessment of physician performance demonstrated superb and high levels of patient satisfaction. Patients are asked to rate their surgeon's Professional knowledge & technical capabilities, Ability to explain things understandably, Responsiveness to patient concerns, and Amount of time spent with patients, his friendly and caring approach (bedside manner) and his Capacity for gentleness. Each quality was rated from 5 to 1 as Very High = 5, High = 4, Average = 3, Low = 2, Very Low = 1. The results are shown in the table below:
### Table 2: Patient Satisfaction Scores

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<td>Professional knowledge &amp; technical capabilities</td>
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<tr>
<td>Ability to explain things understandably</td>
<td>99% Very High or High</td>
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<tr>
<td>Responsiveness to my concerns</td>
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<td>4.6</td>
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<tr>
<td>Friendly and caring approach (bedside manner)</td>
<td>93% Very High or High</td>
<td>4.6</td>
</tr>
<tr>
<td>Capacity for gentleness</td>
<td>92% Very High or High</td>
<td>4.6</td>
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</table>

Long term complications were few and easily treated in the majority (iron deficiency anemia and dyspepsia/gastritis/ulcer.) Excessive weight loss occurs in <1% of patients. We are now aware of several patients with peptic ulcers diagnosed as "bile reflux" that sought treatment by RNY surgeons that underwent revision by non-CELOS surgeons to Roux-en-Y procedures and did well (0.56%).

In summary then, there are numerous types of weight loss procedures available, all with major problems and complications. A list of the features that would make up an ideal weight loss surgery can be created and used to benchmark various bariatric procedures. The Mini-Gastric Bypass was developed to address the weaknesses and failing of the presently available bariatric procedure and long term data now clearly demonstrates that the Mini-Gastric Bypass fulfills many of the features of an “ideal” weight loss procedure.

**Problems and Complications with the Roux-en-Y: Bowel Obstruction, the “Roux Stasis Syndrome” etcetera**

The Roux-en-Y can result in a variety of difficulties and complications. These include the Roux Stasis Syndrome, Blind Loop Syndrome, small bowel obstruction, stricture, induction of fecal bacteria and marginal ulcer. Small bowel obstruction is being increasingly reported following Roux-en-Y gastric bypass. It appears as though the
The Billroth II Today: the Preferred Technique for Stomach to Bowel Connection

The Billroth II has not changed substantially in concept since it was first performed in 1885 by Theodore Billroth. Surgeons are using the Billroth II technique every day in America and around the world. Many studies show that the Billroth II is preferred over the Roux-en-Y. Laparoscopic surgeons are also commonly using the Billroth II reconstruction for primary gastric adenocarcinoma. The results of 310 patients were analyzed with regard to postoperative complications. Functional results as they relate to the gastric resection were evaluated.

Considering functional results, weight loss continued for the first trimester after surgery, after which it stabilized. Loss of appetite was rarely observed; early after the operation the majority of patients were consuming a normal diet and regularly consumed less than five meals per day (83.6%). Dumping syndrome was uncommon and usually resolved within one year (12.3% three months, 9.5% after one year, 5.2% after two years). Postprandial abdominal fullness was frequently observed (43.1% at three months, 36.1% after one year, 21.3% after three years, and 16.5% after five years).

Billroth II reconstruction after subtotal gastrectomy is associated with a limited risk of anastomotic complications. The incidence of late complications was low and the majority of patients recovered from them within one year after surgery, although the occurrence postprandial abdominal fullness was persistent.

In summary, the Billroth II is a common and routine general surgical procedure. With the new developments in laparoscopy the Billroth II continues to be the standard and most popular method of connecting the stomach with the bowel.

National data also demonstrates that American Surgeons Prefer the Billroth II over the Roux-en-Y. In the United States during 1996 there were approximately 13,000 operations in which the surgeon connected the stomach to the small bowel. 63% chose a Billroth II (loop) and only 19% chose the Roux-en-Y.

What these data show is the vast majority of American Surgeons choose the Billroth II when performing a stomach to bowel connection. To restate this point the Billroth II technique used in the Mini-Gastric Bypass is the technique preferred by...
surgeons in America by a very large margin. It, like all medical interventions, can cause problems and complications but it is a standard routine and preferred technique to perform a gastro-jejunostomy.

The Billroth II Gastro-jejunostomy and the Risk of Stomach Cancer

The Billroth II is the standard method of connecting the stomach to the bowel, but there are some studies have raised concerns about an increased risk of stomach cancer in association with the Billroth II (Bill) type connection used in the Mini-Gastric Bypass. Further review shows that there is either no increased risk or the risk is very small, less than the impact of a healthy diet (see below.)

Several well done, large scale, long term studies have addressed the question of the association of the Billroth II and stomach cancer. Several large studies show that stomach cancer is no more common in Billroth II patients than in non-surgical patients.

There are some studies that appear to show a small increased risk of gastric cancer after the Billroth II but even in these studies the increase is very small. To help understand these issues it is important to look at four things:

- Extensive research shows that gastric cancer has an environmental cause, of which diet, alcohol, cigarettes and occupation appear to be the most important components.

- The MAJOR risk factors of stomach cancer are:
  1) Bacteria Helicobacter pylori (H. pylori), and Diet, especially alcohol, cigarettes, processed meats, salted and pickled foods increase the risk.
  2) Studies of stomach cancer indicate that salted, smoked, pickled, and preserved foods (rich in salt, nitrite, and N-nitroso compounds) are associated with an increased risk of gastric cancer. Some foods contain nitrates and these chemicals can be converted to more harmful compounds (carcinogens) by bacteria in the stomach.
  3) Stomach cancer is more common in countries where salted, smoked, pickled, and preserved foods form a large part of the diet. When refrigeration replaces salting and pickling as a way of preserving food, there is a major drop in the incidence of stomach cancer.
  4) Stomach cancer is more common in smokers and in those with heavy alcohol intake.

- The MAJOR Protective factors are a Low fat diet, Fresh fruits and vegetables and food containing vitamin and other antioxidants. There is good evidence that eating fresh fruits and raw vegetables and a high intake of antioxidants markedly reduce the risks of gastric cancer. Conversely low levels of vitamin C and low intakes of fruit and vegetables are strongly associated with an increase in the risk of stomach cancer.

- In studies that do show an increased risk, the increase in risk is small. The increased risk is roughly equivalent to eating processed meats such as hot dogs and beef jerky.

- If someone is worried about stomach cancer and has a Billroth II, a healthy diet of fresh fruits and vegetables and avoiding alcohol, cigarettes, processed meats, salted and pickled foods will make a much greater impact on the risk of gastric cancer than the Billroth II.

- It is important to note that the studies that do show slight increases in the rate of gastric cancer following Billroth II are in patients that have usually had the Billroth II for ulcer disease. But, ulcers and gastric cancer are both strongly associated with the H. Pylori bacteria. So the slight increase in risk seen in Bill patients may be related to the bacterial infection than the surgery. Thus the studies that find small increased rates of gastric cancer in post gastrectomy patients may be identifying patients that are prone to develop gastric cancer.

- Analysis of these issues can put these studies reporting a small increased risk of gastric cancer into proper perspective.

- Now with all of these factors know to affect the risk of gastric cancer, where is post-gastrectomy positioned as a risk factor?

- Studies show that there is an approximately a threefold increased risk of gastric cancer for frequent consumption of either fresh or processed meats (relative risk 3.1 and 3.2). Gastric cancer risk rises with increasing intake of
smoked and pickled foods (relative risk 3.7.) All of these factors that increase the risk of gastric cancer are as much as twice as high as that seen with the studies showing an effect of gastrectomy on gastric cancer risk. Many studies also show a decreasing risk of stomach cancer with increasing frequency of fresh vegetable consumption. Increased intake of citrus fruits (risk 0.47) and raw-green vegetables (risk 0.56) appear to be protective.

- There are dozens more articles like these but we can summarize these findings as follows:
- The incidence of gastric cancer in the United States has decreased four-fold since 1930 to approximately 7 cases per 100,000 people and is continuing to decline.
- Billroth II post gastrectomy patients are at little or no increased risk of gastric cancer.
- The surgery changes the diet increasing fresh fruits and vegetables, decreases total caloric intake, meat consumption and alcohol intake.
- If either they or their physicians are concerned about gastric cancer then they can either choose not to have a Billroth II or very simple dietary modifications (i.e. cut down on salt, avoid smoking, alcohol and processed meats, smoked and pickled foods while increasing one's intake of fresh fruits and vegetables, with or without supplementation with additional antioxidant vitamins) can have a much greater impact on the patient's lifetime risk of gastric cancer than that of the Mini-Gastric Bypass.
- Another way to put this is to say that a regular diet of heavily salted bologna sandwiches appears to be of greater risk to patients for the development of gastric cancer than the Billroth II.
- It may also be of value to point out that hundreds of general surgeons routinely perform the Billroth II anastomoses on a daily basis. Tens of thousands of patients undergo Billroth II type gastrojejunostomy on a yearly basis and there is no ground swell effort being generated against the risk of the Billroth II type anastomoses.

**Only a small minority of patients with Billroth II get Esophagitis**

Some critics of the Mini-Gastric Bypass have raised concerns about the risk of reflux esophagitis and Barrett’s esophagus after the Billroth II connection performed in the MGB. A cross-sectional study was done in order to assess reflux disease in patients with a Billroth II surgery. Consecutive patients were included in the study. Coincidental pathology (hiatus hernia, ulcer, esophagitis, and cancer) was noted. Over a period of 12 years, 370 consecutive patients with a partial gastrectomy and 268 Billroth II, 102 Billroth I) and three groups of patients were identified. Group 1 included 64 patients (17%) with a hiatus hernia; group 2, only 16 patients (4%) with reflux esophagitis; and group 3, 290 patients (78%) with no problems and only a Billroth resection. They concluded that only a small minority of patients with Billroth II have signs of esophagitis in the long term.

**Billroth II Patients Have Excellent Long Term Survival**

Many studies show that patients that have been treated by surgery that includes a Billroth II operation do very well. Excellent long-term results in Billroth II patients were found in a study of 6,500 patients followed for 30-35 years 102 Billroth II patient had a lower overall mortality than the general population!

**Surgeon Volume and Risk of Death**

Numerous studies have explored the associations between surgeon volume (the number of procedures performed by the surgeon) and mortality for some procedures. In a recent study by Birkmeyer et al death rates among 474,108 patients who underwent one of eight major cardiovascular procedures or cancer resections were studied. The patients treated by high-volume surgeons had lower operative death rates than those treated by low-volume surgeons.

Numerous recent studies also confirm the value of high volume for the delivery of good results in Bariatric surgery. These studies support the results of the series of the Mini-Gastric Bypass showing excellent results in the hands of high volume surgeons.
**The Mini-Gastric Bypass is being Adopted around the US and around the World**

Dr Rutledge and the CELOS have taken these results and a well structured program to hospitals and surgeons across the country (North Carolina, Missouri, Michigan, Arkansas, and Florida.) The results of this strictly controlled and carefully monitored program have been excellent in every way. The associated hospitals and surgeons have found the program to be of the highest quality with excellent patient satisfaction, low complication rates and good reimbursement for low resource utilization. The Mini-Gastric Bypass has also been tested and is being adopted around the world. New programs using the Mini-Gastric Bypass technique of Dr Rutledge are now offering the Mini-Gastric Bypass in Spain, Mexico, Romania, Brazil, Taiwan and other countries. Dr Rutledge has been invited to speak on the MGB in Japan, Spain and Mexico as well as across the US. Scientific studies are now being published that document the advantages of the MGB. As an example a recent prospective trial of the MGB as compared to the Roux-en-YU demonstrated the MGB to be superior.

**Complications of Weight Loss Surgery**

Symptoms Requiring Analysis Following Weight Loss Surgery

No matter what procedure is performed, the complications of bariatric surgery generally present in one of five nonspecific ways: ► abdominal pain, ► suboptimal weight loss, ► diarrhea, ► gastrointestinal bleeding, or ► wound infections. When presented with these complaints, it is crucial for the doctor and patient to include post-bariatric surgery complications in their differential diagnosis for early identification and successful management of these problems.

► **Abdominal Pain**

This is probably the most common symptom following bariatric surgery. Although it is commonly caused by rapid food consumption causing lower esophageal sphincter dilation and spasm, it may signify a postoperative complication especially if the pain starts early in the postoperative course before oral intake has been initiated or if it persists with appropriate modification of the diet. In patients after RNY, this differential could include complications at the anastomosis (leaks, strictures, ulcers), complications due to bowel mobilization (obstruction, strictures, adhesions, internal hernia), or miscellaneous ones such as gallstones or portal vein injury. In patients after LapBand, the complications will most commonly be due to band erosion, malfunction or malposition.

Early suspicion of a leak after RNY or BPD/DS should prompt either early exploration or urgent imaging such as barium swallow or abdominal computed tomography (CT) scan. There should be a very low threshold for urgent reexploration as imaging may be delayed, insufficiently sensitive, or not feasible due to weight limitations. Gastric or esophageal perforation after LapBand is a rare complication; it is diagnosed by either CT scan or barium swallow, preferably done with water soluble contrast.

Pain attributed to stricture or ulcer is best evaluated with upper endoscopy or a barium swallow and often both. Abdominal ultrasound is useful to analyze pain consistent with gallbladder disease. A CT scan may also be useful. The CT can also help diagnose the signs of intestinal obstruction, internal hernia or chronic pain issues. Pain or reflux/regurgitation after LapBand usually should lead to endoscopy and contrast esophagram studies to assess position and check for leaks or dilation. If the work-up is unremarkable, one would need to consider the unmasking of gastrointestinal problems unrelated to bariatric surgery, such as irritable bowel syndrome, esophageal dysmotility and gastroparesis.

Gallstone disease is common after bariatric surgery (3–30%). Ursodiol (Actigall, Urso ) prophylaxis reduces the risk of stone formation, but is imperfect. Some form of bariatric surgery may unmask or exacerbate esophageal dysmotility and gastroparesis. These are relative contraindications to the restrictive procedures [LapBand and vertical banded gastroplasty (VBG)]. If abdominal pain, gastro-esophageal reflux disease (GERD), nausea/vomiting, or food intolerance occurs after LapBand, an excessively tight band may be the cause. As there is an increased chance of perforation, an upper gastrointestinal (UGI) series is the initial test of choice to assess constriction and band position. If GERD symptoms are refractory to band deflation, and band slippage is not evident from the imaging study, an EGD is reasonable.[38] followed by a motility study.

**Suboptimal Weight Loss**

Following RNY surgery, rapid weight loss occurs during the first three months, slows during the remainder of the first year, and then plateaus for most by 18 months. Weight gain is not unusual starting two to three years after surgery. Early or unusual weight gain, however, generally should prompt a workup for leaks and fistulas by UGI series. Staple line dehiscence or gastro-gastric fistula may result in food passage into excluded stomach, resulting in weight gain. After LapBand, causes include pouch enlargement, band slippage, or insufficient restriction. If there is no structural reason for the weight gain, the
most likely explanation for weight regain is dietary noncompliance. Work up requires endoscopy, barium swallow and CT scan.

**Post-bariatric Surgery Diarrhea**

This symptom may be a physiologic response to the procedure itself as a result of malabsorption/maldigestion, bile salt diarrhea, or dumping syndrome. Of these, the most common cause of diarrhea is lactose intolerance. Lactose intolerance is the inability to digest significant amounts of lactose, the major disaccharide sugar found in milk. Lactose intolerance is unavailability of the enzyme lactase, which is produced by the cells that line the proximal small intestine. Lactase breaks down milk sugar into the two simpler component sugars of lactose, glucose and galactose, which are then absorbed into the bloodstream. Not all people deficient in lactase have the symptoms commonly associated with lactose intolerance, but those who do are said to have lactose intolerance. Common symptoms of lactose intolerance are mild to severe nausea, cramps, bloating, gas, and diarrhea. Symptoms begin about 30 minutes to 2 hours after eating or drinking foods containing lactose. The severity of symptoms depends on many factors, including the amount of lactose a person can tolerate and a person’s age, ethnicity, and digestion rate.

Lactose intolerance is easy to treat. No treatment can improve the body’s ability to produce lactase, but symptoms can be controlled through diet. For those who react to very small amounts of lactose or have trouble limiting their intake of foods that contain it, the lactase enzyme is available without a prescription to help people digest foods that contain lactose. The tablets are taken with the first bite of dairy food. Lactase enzyme is also available as a liquid. Adding a few drops of the enzyme makes lactose more digestible for people with lactose intolerance.

Lactose-reduced milk and other products are available at most supermarkets. The milk contains all of the nutrients found in regular milk and remains fresh for about the same length of time, or longer if it is super-pasteurized.

While some gastric bypass patients will experience some dumping within the first 18 months, the incidence of chronic dumping syndrome is 5–10%. Facial flushing, lightheadedness, fatigue, and postprandial diarrhea occur following consumption of sugars and processed starches. Other possibilities include irritable bowel syndrome exacerbated by surgery or preexisting or de-novo food intolerances that developed following surgery. The diagnostic workup should be tailored to the severity of symptoms. In non-severe cases, empiric therapy with supplemental fiber and antibiotics/probiotics for bacterial overgrowth or dietary modification to prevent dumping syndrome (changing the composition of meals, consuming carbohydrates mid-meal, and eating slowly) usually mitigates the symptoms. Avoidance of food intolerances and empiric anticholinergic therapy are reasonable options. No matter the cause of the diarrhea, one has to make sure that patients are not developing nutritional and metabolic complications of bariatric surgery, as discussed in several reviews.

**Gastrointestinal Bleeding**

In the early postoperative period (72 h), significant bleeding is usually due to an intraoperative complication. Endoscopy is dangerous and should lead to a low threshold for early reoperation with intraoperative or laparoscopy-assisted endoscopy. Transient obstruction from clot at the jejuno-jejunal anastomosis may increase risk of perforation at the gastro-jejunal anastomosis or gastric remnant. From 72 h to 1 week, erosions and ulcerations occur at band sites or anastomosis (marginal ulcer).

**Wound Infection and Dehiscence**

Fascial dehiscence occurs in up to 1% of open surgical patients, and is diagnosed and managed surgically. Mesh repairs are common, as reapproximation often fails and may be complicated by abdominal compartment syndrome.

**Anastomotic Leaks**

The leak is the most devastating and fear of laparoscopic surgical complications. If the leak develops early, within 10 postoperative days, signs of toxicity such as tachycardia, fever, and leukocytosis may be present. But tachycardia is the most reliable sign and the absence of a fever and a white blood cell count should not lead one to ignore this possibility. Treatment is urgent reexploration and either direct surgical repair if the tissue is in good condition or take down of the anastomosis if there is significant inflammation present. A large case series of 63 patients with leaks after RNY reports that most were not detected by CT imaging and that most required surgery (63%), with morbidity of 53% and mortality of 10%.

If the leak/fistula develops late, without signs of toxicity, more conservative approaches can be used, usually based around percutaneous drainage to control the area.
**Stenosis**

Post-RNY stenosis may occur at anastomotic sites such as the gastro-jejunal or the jejuno-jejunal, or at sites where the Roux limb traverses the transverse colon or is retrogastric. These partial obstructions may be treated with endoscopic balloon dilation, with a 2.1% perforation rate. Complications include perforation, dumping syndrome, and weight gain.

Stenoses that occur beyond 2 months are usually due to marginal ulceration. Minimizing risk factors (steroids, NSAIDs, and smoking), removing foreign material at the anastomosis (stitch material), and treatment with proton pump inhibitors may help relieve the cause of ulcer and prevent restenosis.

For strictures associated with LapBand, deflating the balloon may be helpful to ease stenosis without substantially increasing the lumen diameter. Irreversible stenosis associated with LapBand is almost always a result of band slippage or erosion. Revisional or removal surgery is generally recommended.

**Anastomotic Ulcers**

Treatment usually consists of antacid therapy. Eradication of Helicobacter pylori is valuable although there are little data supporting this strategy. Carafate Tablets (Sucralfate) can also be tried. Complications from ulcers include gastro-gastric fistula and perforation. If the ulcer is refractory to medical therapy, surgery may be considered.

**Band Malfunction**

Usually band malfunction necessitates deflation of the band. LapBand complications often require reoperation and revision which may be done laparoscopically.

### Gastrointestinal and Nutritional Complications After Weight Loss Surgery

**Late Complications**

The euphoria induced by weight loss in bariatric patients may be replaced by disappointment and regret with the development of new gastrointestinal tract symptoms and complications. Some nutritional, hepatobiliary, luminal, and functional complications are more likely after specific bariatric procedures.

#### Nutritional

<table>
<thead>
<tr>
<th>Vitamin deficiency</th>
<th>LapBand</th>
<th>MGB</th>
<th>RNY</th>
<th>BPD and DS</th>
<th>Prevention</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+++</td>
<td>Multivitamin with iron and vitamin C</td>
<td>Ferrous sulfate 300 mg/d with vitamin C; Intravenous Iron and Consultation with a gynecologist to treat excessive blood loss; 1,000 µg/mo IM or 300-500 µg/d orally or nasal spray 500 µg/wk Folate 1 mg/d usually in multivitamin Folate 1 mg/d</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>Folate 1 mg/d usually in multivitamin</td>
<td>Folate 1 mg/d</td>
</tr>
<tr>
<td>Folic acid</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>Multivitamin, including at least 400 IU vitamin D</td>
<td>Replace vitamin as indicated</td>
</tr>
<tr>
<td>Fat-soluble vitamins A, D, E, K</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+++</td>
<td>Multivitamin with thiamine</td>
<td>50 mg IV</td>
</tr>
<tr>
<td>Thiamine</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+++</td>
<td>Multivitamin with thiamine</td>
<td>50 mg IV</td>
</tr>
<tr>
<td>Mineral deficiency</td>
<td>Calcium Insufficient weight loss</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+++</td>
<td>1,500 mg/d elemental calcium</td>
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<td></td>
<td>Excessive weight loss</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>Revision operation</td>
</tr>
<tr>
<td></td>
<td>insufficient weight loss</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>Revision operation</td>
</tr>
<tr>
<td>Gallstones and sludge</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>Ursodeoxycholic acid 300 mg twice daily for 6 mo; consider elective cholecystectomy</td>
<td>Cholecystectomy</td>
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<tr>
<td>Luminal</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Avoid NSAIDs; consider</td>
<td>Stop NSAIDs; prescribe PPI;</td>
</tr>
<tr>
<td>Stomal</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Avoid NSAIDs; consider</td>
<td>Stop NSAIDs; prescribe PPI;</td>
</tr>
</tbody>
</table>
Ulceration

<table>
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<tr>
<th>Condition</th>
<th>++</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>Surgical technique; prevent ulcers; avoid silastic band</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stomal stenosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Conduct endoscopic dilation; remove silastic band; Surgical revision</td>
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<tr>
<td>Band erosion</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>Surgical technique; Prevent ulcers</td>
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<tr>
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<td>0</td>
<td>+</td>
<td>+</td>
<td>Surgical technique; Prevent ulcers</td>
</tr>
<tr>
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<td>0</td>
<td>+</td>
<td>+</td>
<td>Surgical technique; Prevent ulcers</td>
</tr>
<tr>
<td>Internal hernia</td>
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<td>0</td>
<td>+++</td>
<td>+</td>
<td>Surgical technique; Prevent ulcers</td>
</tr>
<tr>
<td>Bile reflux</td>
<td>0</td>
<td>++</td>
<td>+</td>
<td>0</td>
<td>Surgical technique; Prevent ulcers</td>
</tr>
<tr>
<td>GI tract bleeding</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Avoid NSAIDs</td>
</tr>
<tr>
<td>Dumping syndrome</td>
<td>0</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Small meals; dietary education</td>
</tr>
<tr>
<td>GERD</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Choose correct procedure</td>
</tr>
<tr>
<td>Functional</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dilate stenosis endoscopically; Surgical revision; conduct dietary education</td>
</tr>
</tbody>
</table>

Vomiting

| Condition          | +++| + | + | + | Small meals; prevent ulceration and stenosis |

Diarrhea

| Condition          | 0  | + | + | ++ | Appropriate diet |

Bloating and flatulence

| Condition          | 0  | + | + | ++ | Consider small-bowel bacterial overgrowth |

**Vitamin and Mineral Deficiencies**

Iron deficiency is common in RNY patients, with an incidence as great as 49%. The pathogenesis of iron deficiency is multifactorial. To be absorbed, the ferric iron in foods must first be reduced to the ferrous state. This reduction occurs in the stomach, where it is facilitated by hydrochloric acid. Achlorhydria may develop in RNY patients, leading to a reduction in iron absorption. Gastric acid secretion from the proximal gastric pouch may be absent after bariatric surgery. Postsurgical prophylactic use of histamine2 receptor antagonists (H2-blockers) or proton pump inhibitors also reduces acid secretion and subsequent iron absorption. The reduced intake of iron-rich foods declines substantially after RNY, both because of a decrease in total caloric intake and because of frequent intolerance to iron-rich foods, particularly red meat.

Iron deficiency presents primarily as microcytic anemia. Routine laboratory work (e.g., complete blood cell count, serum iron, transferrin, and ferritin) should be performed and monitored once a year. Iron supplementation is recommended for all RNY patients. In many cases, a standard multivitamin with iron is sufficient. However, when iron deficiency is discovered, treatment may include the use of additional oral iron given as ferrous sulfate 300 mg 3 times daily. Iron supplements should be taken with vitamin C between meals. Some patients will require IV iron infusions because of gastrointestinal intolerance (dyspepsia and constipation) to iron supplements or because of the inability to correct anemia with oral supplements alone. Venofer® is an iron sucrose infusion, which can be used as second line treatment when oral iron therapy is deemed inappropriate or has failed. This may be due to malabsorption, poor tolerance, unacceptable side effects or where there is a need to correct iron deficiency and ensuing anemia urgently.

The absorption of vitamin B12 begins in the stomach, where both pepsin and hydrochloric acid cleave it from foods (primarily meats). B12 deficiency occurs in 26-70% of gastric bypass patients. Mechanisms include achlorhydria, which prevents cleavage of B12 from foods, decreased B12 consumption because of intolerance to meat and milk (2 primary dietary sources), and inadequate secretion of intrinsic factor after surgery.

Clinically significant B12 deficiency may lead to megaloblastic anemia, thrombocytopenia, leukopenia, and glossitis, all reversible with replacement therapy. Several studies have shown that a 300- to 500-µg dose of oral vitamin B12 is sufficient. Other forms of supplementation include sublingual (350 µg/d) and nasal spray (500 µg/wk in 1 nostril).

Folic acid deficiency is another potential complication of RNY, affecting as many as 35% of patients. Folate absorption is facilitated by hydrochloric acid and occurs primarily in the upper one-third of the small intestine. Additionally, vitamin B12...
acts as a coenzyme in converting methyltetrahydrofolate to tetrahydrofolate, so a vitamin B12 deficiency may result in subsequent folate deficiency. Despite these apparent mechanisms for folate deficiency, decreased folate consumption from dietary sources may be the predominant cause. Folate deficiency can present as megaloblastic anemia, thrombocytopenia, leukopenia, or glossitis. Serum deficiencies are quite common (although symptoms are rare), and they are easily corrected with vitamin supplementation. Folate supplementation (1 mg/d) should correct deficiencies. Folate deficiency is a serious threat for women who become pregnant after gastric bypass, with neural tube defects reported in infants. Women of reproductive age should therefore take folate supplementation.

Fat-soluble vitamin deficiency may also occur after MGB, RNY or BPD. Bypassing the duodenum results in delayed mixing of dietary fat with pancreatic enzymes and bile salts, which results in malabsorption of fat and fat-soluble vitamins. This complication occurs more commonly after BPD. Halverson reported vitamin A deficiency in 10% of gastric bypass patients. The predominant symptom is visual difficulties at night. Oral replacement therapy is occasionally needed.

Vitamin D and calcium deficiencies are less likely because they are absorbed preferentially in the jejunum and ileum. Nonetheless, there have been reports of osteomalacia after RNY. Daily supplementation of 400-1200 IU of vitamin D and 1,500 mg of elemental calcium is adequate.

Active absorption of thiamine (vitamin B1) occurs primarily in the proximal small bowel. Humans cannot synthesize thiamine, which is not stored in large quantities, so adequate daily intake is essential. Dietary sources of thiamine include cereals, grains, lean pork, and legumes. Thiamine deficiency may lead to Wernicke-Korsakoff syndrome, which has been described after gastric bypass surgery. Symptom onset is preceded by profuse vomiting along with the rapid weight loss that occurs after bariatric surgery. The restrictive diet after RNY, LapBand and poor dietary choices in the MGB or BPDDS may lead to a reduction in dietary intake of thiamine. Poor dietary choices combined with persistent nausea and vomiting increase the risk of thiamine deficiency. A daily multivitamin prevents thiamine deficiency. When such deficiency is suspected, a 50-mg intramuscular or IV injection of thiamine should correct it.

**Insufficient Weight Loss**

After RNY and LapBand, about 15-35% of patients are unable to lose more than 40-50% of their excess weight, which is generally defined as insufficient weight loss.

While some claim that patient noncompliance is the cause of Inadequate weight loss in the vast majority of patients failure is usually due to the surgical technique. Success of the weight loss is attributed to the surgery and in most cases failure should be attributed to the surgery as well. Both RNY, LapBand can allow patients to snack on high-calorie liquids or solids overcoming the surgical restriction. Most agree that postoperative support groups are most important in the case of surgical procedures that are the least effective, i.e. poor surgery needs lots of support. Diet and exercise and personal commitment are critically important if the surgery is ineffective.

In the case of MGB or RNY the gastric pouch may be too large or bypass may be too short. Some times there could be dehiscence of the staple line in the undivided stomach. An enlarged gastric pouch may be revised easily in the MGB, but RNY revisions are often not done by RNY surgeons because of the increased risk of complications. After LapBand, the gastric pouch may dilate in about 12% of patients due to proximal herniation of the stomach. Deflation of the band can resolve this problem in some patients, long term failure is likely. Studies are increasingly showing that after LapBand weight loss appears good initially but then is followed by progressive increasing failure rates resulting in insufficient weight loss. Fortunately failed lapBand for any reason can easily be converted to the much more successful MGB.

**Excessive Weight Loss**

The RNY and the purely restrictive procedures rarely result in protein calorie malnutrition or excessive weight loss. Such complications are more common after the BPD or the duodenal switch, both of which result in a greater degree of malabsorption. Undernutrition may not be obvious, because patients are expected to lose weight and protein levels will often remain normal initially.

The differential diagnosis includes eating disorders such as anorexia nervosa or bulimia or postsurgical complications. Stomal stenosis or ulceration may lead to vomiting and inadequate caloric intake. Protracted diarrhea could be due to an excessively long Roux limb or an enteric infection. Shortening the Roux limb after RNY or lengthening the common channel after BPD or duodenal switch may be necessary in patients with severe fat and protein malabsorption.

**Hepatobiliary Complications**

Rapid weight loss predisposes bariatric patients to the formation of cholesterol gallstones, irrespective of the type of procedure performed. Within 6 months after surgery, new gallstones develop in as many as 36% of patients and sludge
develops in as many as 13%. Elective cholecystectomy during bariatric surgery appears to be safe, but it increases the length of stay in the hospital and adds considerably to cost.) Routine intraoperative ultrasound with elective cholecystectomy has been advocated only in patients with existing gallstones, because new symptomatic gallstones occur infrequently (7%) and cholecystectomy is usually well tolerated. Only 30% of surgeons performing standard RNY remove normal-appearing gallbladders. The administration of ursodeoxycholic acid for 6 months after surgery reduces the incidence of postoperatively formed gallstones from 32% to 2%.

Nonalcoholic fatty liver disease is a complication of obesity with no effective medical therapy. In studies with small numbers of patients, weight loss induced by bariatric surgery has been shown to improve the histologic changes caused by this condition.

Luminal Complications
Stomal and Marginal Ulceration

Ulceration occurs in as many as 20% of RNY patients and 5% of MGB patients, also called a marginal ulcer. Gastric acid and Helicobacter Pylori cause the ulcers after RNY and MGB. Patients with stomal or marginal ulceration may present with abdominal pain, nausea, vomiting, or gastrointestinal tract bleeding. Ulceration may also lead to stenosis, resulting in symptoms similar to dysphagia or excessive weight loss.

In most cases, diagnosis can be made with an upper endoscopy. Biopsy specimens should be taken for Helicobacter pylori, which should be treated when present. Patients with uncomplicated ulceration may be treated effectively with a proton pump inhibitor, which demonstrates that acid influences the pathogenesis of these ulcers. Patients with refractory non-healing ulcers may require surgical revision. Ingestion of ulcer causing drugs such as cigarettes, alcohol steroids and non-steroidal anti-inflammatory drugs must always be avoided.

**Stomal Stenosis**

Stomal stenosis has been reported in as many as 27% of bariatric patients. An upper gastrointestinal endoscopy is the preferred procedure because it allows therapeutic interventions. Knowing the diameter of the normal anastomosis (10-12 mm) can help avoid unnecessary dilation. Balloon dilation is the preferred procedure. Multiple dilation sessions may be needed.

**Band Erosion and Staple Line Dehiscence**

Symptoms are nonspecific and include abdominal pain, nausea, and vomiting. Diagnosis usually requires, CT scan, endoscopy and barium swallow and upper GI series.

**Internal Hernias**

Because of the frequency of this complication and the danger of bowel infarction and death in RNY patients, awareness of the possibility of internal hernias is important because they may be difficult to diagnose. Symptoms may include nausea vomiting and abdominal pain. A CT scan or upper gastrointestinal series may not be make the diagnosis. Often surgery is based solely on clinical suspicion. RNY internal hernias occur at three sites: (a) where the Roux limb passes through the mesocolon, (b) at the jejunojejunostomy, and (c) between the jejunal and colonic mesenteries. In the MGB only 3 hernias have occurred in over 4000 patients and these were in patients with other prior surgery. Thus the risk of hernia very serious in RNY and almost nonexistent in the MGB.

**Bile Reflux**

After RNY bile reflux into the proximal pouch is uncommon. Studies do show that in RNY patients there is considerable duodenal gastric bile reflux into the bypassed excluded stomach. The clinical significance of this complication has not been established.

**Cancer, the Billroth II and Bile Reflux**

Several studies have raised concerns about bile reflux. The pathophysiologic effect of duodenal contents in the refluxed gastric juice of patients with gastroesophageal reflux disease (GERD) is controversial. Some animal studies have raised concerns about stomach cancer in BII patients. Diet has been shown to be the most important determinant of the development of stomach cancer. While some argue that bile can be the cause of esophagitis in GERD patients it is exceedingly rare that reflux in GERD is "refractory" to acid suppression. That is GERD is reversed by antacid medications that have no effect upon bile. This fact, along with other data, suggests that the concept of bile alone causing esophageal disease is not proven by any other published study. Bile acids or other duodenal content may be a minor contributor to esophageal damage in some patients with advanced forms of GERD. But, there is no convincing evidence that bile alone
cause damage. Therefore, fear of bile reflux should not be an indication for antireflux surgery given our current knowledge.“117 High and low fat diets have been shown to affect the risk of stomach cancer.118 119

Gastrointestinal Tract Bleeding

Upper gastrointestinal tract hemorrhage after RNY, LapBand and MGB is uncommon but is usually caused by erosion or tears caused by forceful and repeated retching in LapBand patients and stomal or marginal ulcer in RNY and MGB patients. The initial investigation of choice is an endoscopy. A radiologically or laparoscopically placed percutaneous gastrostomy may allow endoscopic access to the excluded stomach. Ulcer following MGB or RNY is usually treated with PPI (Proton Pump Inhibitors such as Prilosec, Nexium etc.) and or anti Helicobacter-Pylori therapy.

Dumping Syndrome (See Description in the Discharge Instructions)

The dumping syndrome occurs when the undigested contents of your stomach are transported or “dumped” into your small intestine too rapidly. Most people with dumping syndrome experience signs and symptoms soon after eating. In other people, they may occur later — one to three hours after eating — and they can range from mild or moderate to severe and debilitating. Patients may present with abdominal pain, cramping, flushing, palpitations, diaphoresis, tachycardia, or hypotension. Early dumping syndrome occurs within the first hour after ingestion of a meal and may be related to the sudden distension of the jejunum by hypertonic solids or fluids. Late dumping occurs 1-3 h after eating and is most likely caused by the rapid absorption of glucose, with hyperglycemia triggering an exaggerated insulin release that results in rebound hypoglycemia.

Signs and symptoms

When signs and symptoms occur during a meal or within 15 to 30 minutes following a meal, they may include:

* Nausea
* Vomiting
* Abdominal pain, cramps
* Diarrhea
* Dizziness, lightheadedness
* Bloating, belching
* Fatigue
* Heart palpitations, rapid heart rate

When signs and symptoms develop later, they may include:

* Sweating
* Weakness, fatigue
* Dizziness, lightheadedness
* Shakiness
* Feelings of anxiety, nervousness
* Heart palpitations, rapid heart rate
* Fainting
* Mental confusion

Treatment

Most cases of dumping syndrome improve without any treatment, typically in several months to about a year after signs and symptoms begin. However, if they don't improve on their own, one or more treatment options to slow the emptying of the stomach's contents may help. The choices for managing dumping syndrome include dietary changes, medications and surgery as a last resort.

Dietary changes

Adjusting the diet may relieve the dumping symptoms.

* Eat smaller meals. Try consuming about six small meals a day rather than three larger ones.
* Avoid fluids with meals. Drink liquids only between meals.
* Change the makeup of your diet. Consume more low-carbohydrate foods. In particular, concentrate on a diet low in simple carbohydrates such as sugar (found in sweets like candy, cookies and cakes). Read labels on packaged food before buying, with the goal of not only avoiding foods with sugar in their ingredients list, but also looking for (and staying away from) alternative names for sugar, such as glucose, sucrose, fructose, dextrose, honey and corn syrup. Consume more protein in your diet, and adopt a higher fiber diet and add a fiber supplement to your daily diet.
* Increase pectin intake. Pectin is found in many fruits such as peaches, apples and plums, as well as in some fiber supplements. It can delay the absorption of carbohydrates in the small intestine.

* Slow down when eating acidic foods. Tomatoes and citrus fruits are harder for some people to digest.

* Use low-fat cooking methods. Prepare meat and other foods by broiling, baking or grilling. Fried foods are notorious for causing dumping.

* Remember to consume adequate vitamins, iron and calcium. These can sometimes become depleted in the aftermath of stomach surgery. Discuss this nutritional issue with a registered dietitian.

* Lie down after eating. This may slow down the movement of food into your intestines.

Even with dietary changes, you may continue to experience severe symptoms associated with dumping syndrome.

Medications

Some medications can be used to slow the passage of food out of the stomach, and relieve the signs and symptoms associated with dumping syndrome. These drugs are most appropriate for people with severe signs and symptoms, and they don't work for everyone.

The medications that can be prescribed are:

* Acarbose. This medication delays the digestion of carbohydrates. Doctors prescribe it most often for the management of type 2 diabetes, and it has also been found to be effective in people with late-onset dumping syndrome. Side effects may include sweating, headaches, pallor, sudden hunger and weakness.

* Octreotide (Sandostatin). This anti-diarrheal drug can slow down the emptying of food into the intestine. You take this drug by injecting it under your skin (subcutaneously). Be sure to talk with your doctor about the proper way to self-administer the drug, including optimal choices for injection sites. Long-acting formulations of this medication are available. Because octreotide carries the risk of side effects (diarrhea, bulky stools, gallstones, flatulence, bloating) in some people, doctors recommend it only for people who haven't responded to other treatments.

Surgery

Rarely surgery can be used to revise the initial operation and treat the dumping syndrome. Some surgeons look favorably on this complication, because it sensitizes patients to avoid high-calorie meals that may lead to weight gain. In most patients, dumping syndrome can be prevented and treated with dietary changes. To help avoid rapid emptying of the gastric pouch, patients should eat small meals, avoid carbohydrates at the beginning of a meal, and consume food slowly.

Gastroesophageal Reflux Disease

GERD improves or disappears in most patients after MGB RNY. The small remaining gastric pouch should not contain parietal cells, which can eliminate acid reflux. Conflicting results about the effect of LapBand on GERD have been published. Some have reported a worsening of symptoms, but some show that there may be improvement after LapBand. This may be explained by the length of follow up in the study. Short term the LapBand may help reflux but as time goes by most studies suggest a worsening of reflux usually leading band removal.

Functional Symptoms

Vomiting is frequently a long-term problem in as many as 69% of patients after gastric bypass surgery. Although vomiting is usually caused by overeating, it also may indicate gallbladder disease, ulcer or stomal stenosis. If no abnormality is found on endoscopy or a barium imaging study, the patient most likely is eating larger meals than recommended. Band slippage or erosion should be considered in the patient with vomiting after LapBand.

CELOS Program, the Centers for excellence in Laparoscopic Obesity Surgery

Since 1996 the Institute of Medicine (IOM) has led a nationwide concerted, ongoing effort focused on assessing and improving the nation's quality of care. This Quality Initiative documented the serious and pervasive nature of the nation's overall healthcare quality problem, concluding that "the burden of harm conveyed by the collective impact of all of our health care quality problems is staggering." The status of bariatric surgery in America today is emblematic of this gap in quality. It is clear that there is a real need for service of high quality advanced laparoscopic bariatric surgery program but there is also clear evidence that numerous hospital and surgical programs around the country fall short of this goal of high quality safe medical care.

The Centers for Excellence in Laparoscopic Obesity Surgery (CELOS) were created out of Dr. Rutledge's 20 year background as a professor of surgery at the University of North Carolina and a desire to deliver the highest levels of care in
the specialized field of Advanced Laparoscopic Bariatric Surgery. The foundation of CELOS utilizes all of the applicable quality improvement techniques identified by the Institute of Medicine and other National organizations that have tried to focus on the present gap in quality of care in America. These processes and procedures are detailed later in the document. The processes are continuously monitored and benchmarked to document the quality of these processes and procedures.

Conclusion

In summary then we can say that there is a national and local community need for a low risk and effective and inexpensive long term treatment for severe obesity. The presently available weight loss procedures fall far short of the needs of ideal procedure to meet this need. The Mini-Gastric Bypass was designed to address the many well recognized failures of the present forms of bariatric surgery. The Mini-Gastric Bypass and Dr Rutledge's program in the Centers for Laparoscopic Obesity Surgery have successfully met those benchmark criteria and provides a simple, low risk and effective treatment for severe morbid obesity.
Good morning Mr. J.,

I just wanted to take a moment to tell you of my experience with Mini-Gastric Surgery. In October of 2002 a friend of mine saw an article in the Orlando Sentinel about a seminar for gastric surgery. He knew that I had been struggling with my weight all my life. At that time I was 55 and weighed 330#. I went to the seminar and met Dr Rutledge.

A month or so later I contacted the website and downloaded their package.

It took me until March of 2003 to commit to the surgery and finish the package. There is an extensive screening process they ask you to complete and I thought again and again, "Is this for me? Do I want to change my life this significantly?"

Then I read an email from one of the post surgery patients and she said she had the urge to use the PA system in Wal-Mart to tell everyone how great she feels now, and how she wanted to tell everyone she could how great her experience was in comparison to her daughter who had gastric banding.

You see I'd done my research as they ask, and decided that I like Dr. Rutledge's #s. My brother, who is an anesthesiologist, cautioned me about the surgery. But he has not been overweight all his life - he got my mother's genes. I followed my father's family and each of them weighed over 300# and died relatively young. My father had his FIRST heart attack when he was 50, so I felt I was past due in that dept. 

The post-op letter I read talked about "sacrificing a monster on the operating table and getting rid of the "weight" she had been supporting all her life" It was so easy to do,

and "isn't that grand!" Those words touched me and I quit wavering. I sent in my package and had surgery at 11: am on 5/30/03. To date I have lost over 150# I am keeping it off, I look better than I ever have in my life and I feel GREAT.

Everyone at CLOS was great. Dr Rutledge met us (3 patients for surgery that a.m.) and spoke to us personally before surgery. He also came by my hospital room that evening, after surgery. His office gets copies of all my labs and reports from my PCP, who did 90 day follow ups up until Dec of 2005. Now I'm at every 6 month. My PCP is pleased with my lab #s and my weight as well. The staff and Dr "R" are always just a phone call or email away. Although I get a lot of my "do's & don'ts" from Post Op Email group.

Those folks have "been there & done that". And the staff at CLOS monitor and "chime in" when appropriate. It is an excellent forum and source of information.

As a matter of fact one of the people who had surgery the same morning was a young woman (maybe 19 or 20) - her mother was with her, also a significantly overweight woman. She was a nurse in a hospital in Ohio. Her hospital had a gastric surgery dept which performed a procedure which did not have the positive results that have been experienced with the MGB. She didn't want her daughter to follow in her genetic path and brought her all the way to NC to have this surgery. A definite testament!

A neighbor of mine had a serious weight problem and we had even gone through the same "Optifast" program at a local endocrinologist's office.

Both unsuccessful at keeping our weight off. He asked me about the surgery, I gave him a copy of my "manual" and urged him to consider the MGB. He chose another RNY procedure and a physician in South FL. To date he has been back in the hospital with complications 3 times. One of those additional hospital stays was right after he got home for a potassium imbalance and the most recent was because he had developed a leak. He has been post op for about 18 months. I stress this as it points out another

BIG reason why I chose Dr' Rutledge's program. . . .I have experienced no complications! And I have slowly, steadily lost weight and feel great!
What Do I Have to Do? PreOp Preparation for Surgery

Our goal is to try to continuously improve our process of care in order to have the most successful immediate surgical experience and long-term success. There are both immediate and future ramifications to the surgical treatment of obesity. Our research has shown that by utilizing an extensive preparation process, our patients are better informed and better able to cope with and enjoy the changes that accompany substantial weight loss. The steps to prepare for surgery are as follows:

Use of the Internet and the Web to Improve Patient Care

Physicians and patients have unique technological resources available to improve the patient physician relationship. Online medical information improves the relationship between doctor and patient. The decision-making process improves by sharing the burden of responsibility for knowledge. Further benefits arise from physicians and patients who work together in the information-gathering process. Studies of Web-based patient support have shown the potential to improve care. Patients are interested in supplementing in-person services with Internet-based services relating to their treatment.

Where to Start: Initial Patient Contact

Patients may initially contact The Centers for Laparoscopic Obesity Surgery through a variety of people or methods including: Web, Email, Telephone, Letter, or Direct Face to Face. For each of these types of initial contacts the patient is referred to the new patient web page. New Patient Start up Web Page Web page: http://clos.net/newpt.htm

Why our process is so complex:

Our preoperative and postoperative processes are complex and demanding because:
We are committed to excellence in Pre and Post Education and quality patient care.
To help assist the patient, family local physician and the surgeon with selection of best surgical or nonsurgical therapy
Help in the selection of the best patient candidates for laparoscopic surgical treatment
To help long distance and local patients get the best possible patient care
To educate and inform the local and referring medical physician in the post operative follow up and care
To systematize our medical care and therefore improve the quality of our outcomes

Patient Comments about the CLOS “Packet”

Hi,
I hated doing my packet. But now that it's been almost two years since I had surgery I know the value of having done it. I was a well-informed patient. I am now a well-informed MGB'er. I understand the effect the surgery had on my body and I am much more in tune with what's going on with me. I understand other surgeries and how mine differs. I understand the link between hormones and the surgery and weight loss and hormones. I know what supplements I need and why. I know what to look out for to spot trouble before it becomes a crisis.
I spend time on line at support groups answering questions for people who have had other surgeries. They don't know what to eat. They don't know what to do when something makes them sick. They don't understand their moodiness. They don't know when to call a Dr. and what is normal for a person who has had Weight Loss Surgery. They don't understand why we don't drink coffee or tea; they don't understand why we shouldn't drink soda. They take medications, which are known to be harmful to the liver because no one has told them about the potential harm. In short, they went into this to lose weight and were not well informed about the issues they would be living with for the rest of their lives.
I hope that Dr. Rutledge never discontinues the requirement for the packet in order to have this surgery. I know...you hate that I'm saying that...and I would too if I was still a pre-op, but like our parents used to say..."some day you'll thank me for this"...LOL...and believe me, some day you will be grateful that Dr. Rutledge required this packet.
Flo from Maryland

Although I had my MGB with another surgeon, I had my "booklet" prepared at the time Dr. R was on hold. I certainly do not regret it at all. I learned a lot and when then nurses asked questions I was prepared to answer them. The surgeon that performed my surgery required nothing more than insurance approval to undergo surgery. He also has no restrictions post surgery including any medications and alcohol. I try to follow Dr. R's instructions. Some of the things may not be completely necessary but are safeguards for our health. I wish I could have waited for Dr. R but I'm glad that he helped educate me. By the way, my scale said I was down 100 pounds this morning. What a great feeling and I'm also f

Brenda
6/27/01 highest weight 295 pre-surgery 270/now 170

I can put this into a simple phrase as to why you need to do the packet. It's what I told all of my parents in the Intensive Care Nursery. KNOWLEDGE IS POWER! If you have it, you can help yourself and others to become more than what you are now. You have to take care of yourself.
Valerie

**MGB Application Packet: Submission Requirements & Suggestions**

**MGB Application Packet Check List:**
We suggest that you print out the checklist to help you keep track of where you are in the process and use the checklist to confirm that all your information requirements are included in your packet.

**Dos and Don’ts on Sending in Your Packet**
Please DO send your application packet via FedEx, UPS or Priority Mail. Contact the FedEx representatives or other shipper, not the office staff, to find out if it’s been delivered and if you are due a refund.
Please DO Make a Duplicate Copy of Everything in the Packet. Make a copy of everything in your packet before you send it. We cannot return copies of your packet after they have been submitted.
Please DO submit your packet as loose separate unbound 8½ by 11 inch single sheets of letter-size paper in usual manila folder.
Please DO staple the individual sections together that are more than one page long.
Please DO put colored and labeled tabs on each requirement section on the long right hand side of each different section.
Please DO NOT put the pages in separate plastic sheets.
Please DO NOT submits your packet bound in a notebook, or in a 3-ringed binder.
Please DO make sure that every part of the packet is neatly typed and readable.
MGB Application Packet Steps: What do you have to do?

The steps required to undergo the MGB surgery are detailed below:
Read Selection Guidelines
Join Mailing List
Send in Patient Information
Complete Patient Education (=Read the Manual)
Get Support Letter and Exam from Your Referring Doctor
Write Your Patient Letter
Get Psychological Evaluation
Contact 10 Previous Patients
Photographs
Have Your Family Write a Detailed Support Letter
Preoperative Clinic Visit
Read and Complete Consent Form

1. Read Selection Guidelines

The goal of this section is to try to help you understand who is a good candidate for the laparoscopic weight loss surgery, and why our standards are important to assist us in getting a successful outcome.
These guidelines are not “cookbook” medicine, that is, they are designed to help guide us advising you and not dictate patient selection of the patients for surgery. We review each individual patient’s case and patient selection is not rigid but directed by the following guidelines.
Review and understand the selection guidelines for the Mini-Gastric Bypass.

2. Join Mailing List

As part of your preoperative education and investigation process you are required to join our internet online email mailing list. The MGB mailing list on the internet hosted at Yahoo.com will enable you to learn from other patients’ experiences, and give you additional support in your own journey. You can be added to the online mailing list by filling out the form on our web site: http://clos.net/forms/mailinglist_form.htm

3. Send in Your Patient Information

As part of your process of being evaluated for the surgery we need to review your medical information. We ask that you carefully complete our online information form. This will allow us to review your medical information. The internet form is located at on the web at:
http://clos.net/patinfo.htm.

Note: Please fill this form out completely and carefully.
Take your time to do it all it once, as the form is lengthy.
It must be filled out with phone numbers and addresses.
*** Note IMPORTANT Keep a copy of the form that you submit by printing out the form after you submit it!!!
A good idea is to print out the form, fill it in by hand before trying to complete it online, and then type in all the information in later.

Tips for Completing the Online Patient Information Form

- Before you start: Print out a copy of the blank form and read it carefully.
- Collect all of the information needed to complete the form before you start (insurance information, medication spelling and doses, doctor’s address phone and fax etc.) prior to filling out the form.
- Fill out the form on paper before trying to fill out the form online.
- If you are new to the Internet get help filling out this form from someone who knows how to use the computer and the internet.
- Make sure that you have just signed on to the Internet before you start filling out the form some internet companies will close your connection if you wait to long.
- After you have sent in (submitted) the form on the internet make sure that you get a confirmation page.
Print out the confirmation page and then use the back button on your browser and print out two copies of the form, one to keep and one to take with you to clinic.

4. Complete Your Preoperative Patient Education (=> Read the Manual)

- Read and LEARN the Patient Manual.
- You can get a copy from free from the website at:
- As part of completing your packet for surgery approval, you will need to write a detailed letter explaining the process, the surgery, alternatives to surgery, possible surgery complications, risks of obesity, compliance issues, etc.
- This letter is mandatory, and demonstrates your ability to comprehend the material.
- It is an indication of your ability to comply with the life changes you will need to make in order to have the most successful outcome. Our physicians will reject packets that contain letters that do not address each aspect of the process thoroughly. You must include a plan for physical exercise in this letter.
- We also require a Special Consent Form for Surgery that gives a summary of the surgery and its risks and complications, the cost of the surgery in relation to other weight-reduction surgeries, and other alternative treatments. Please complete this form and bring with you the day of surgery. Please don’t sign the last page until you are at the hospital and in the presence of a nurse.

5. Support Letter and Exam from Your Medical Doctor

A variety of early, medium and long-term complications, problems and illnesses can cause difficulties after the operation. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery are committed to provide long-term follow up for all of his patients after Laparoscopic Gastric Bypass. But, since many patients are from hundreds and even thousands of miles away, it is imperative that patients develop a close relationship with a local medical physician who has the interest and the knowledge to follow patients with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery and care for them throughout the years after surgery.

An interested and committed local physician is also critically important in providing additional assistance in the preoperative evaluation of patients prior to surgery. In addition, our experience has demonstrated that patients are often difficult to contact after operation. In several cases it was a contact with a local physician that allowed us to find our patient and determine how they are doing. This is crucially important given the long-term risks of the gastric bypass as it relates to vitamin and mineral deficiencies. For all of these reasons we require the following process in the preoperative assessment and preparation of patients for Laparoscopic Gastric Bypass:

The patient must obtain a letter from his or her local medical physician. The letter must include:

1. An assessment of your obesity and its impact on you health and quality of life,
2. A detailed thorough and meticulous assessment by your Dr. of your medical, surgical and psychological fitness for surgery, and
3. Demonstrate your Dr’s willingness to follow you after surgery.

All patients are required to have a close working relationship of at least several months with a local physician.

The physician must support the patient’s desire to proceed with Mini-Bypass.

The physician must perform a thorough detailed complete history and physical evaluation as a preoperative screening step prior to considering patient for Laparoscopic Gastric Bypass. This should be included in your packet and be typed usually a minimum one page in length. Scribbled unreadable faxes and check box forms are not acceptable.

The patient must obtain a letter of support and the medical records from their physician and the preoperative history and physical examination for review prior to proceeding with surgery.

The letter must include an assessment of your obesity, its impact on your health and quality of life, an assessment by your Doctor of your medical, surgical and psychological fitness for surgery, and the Doctor’s willingness to commit to follow up with you at 1 month, 3 months, 6 months and 12 months post-op. Please give a copy of the patient education
manual to your Doctor. This will assist him in understanding the long-term implications of this surgery, and educate him for the best possible working relationship.

**Other Medical/Health problems**

If you have other Medical or Health problems you will need to see each of those specialists for their assessment and advice about how your medical and health issues might affect your candidacy for surgery, your risk of surgery and your long term results of surgery. Please ask each of your medical specialists to send Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery a detailed letter describing your special medical or health issues that that particular Doctor is taking care of you for, ask him or her to comment upon how this illness might affect your candidacy for the surgery, your risk of surgery and how it might affect your long-term results after the surgery. Does he/she approve or recommend the surgery in your case? Does he/she support your having the surgery? Please ask that your specialist advise Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery of any special precautions, pre/post-op recommendations for your care. This might include special use of medications or additional consultations or tests.

6. **Patient Letter**

One of the most important efforts of the preoperative preparation of patients for the Laparoscopic Gastric Bypass is an education about the risks and benefits of the operation. When we surveyed patients about our efforts to educate them about Laparoscopic Gastric Bypass surgery, we received a high level of approval.

It’s extremely important that you understand the surgery before you undergo it... as well as your alternatives. If you have to rethink the surgery, its potential complication and its alternatives once or twice... that’s not so bad, as the surgery you are undertaking is life changing and potentially life threatening (as is any surgery). Sure, you’ve thought about it a million times in your mind, but writing it out... that takes a bit more thought. My advice as to writing... pretend you are talking to your best friend... assume s/he is asking you the questions... make your letter your answer to your friend.

The letter requirement is based upon educational research showing that retention of information is improved by asking the learner to think about and write down the information. Patients who are not able to understand enough to write a letter detailing the risks and benefits of the operation will be poor candidates for Laparoscopic Gastric Bypass.

**Options: 1. Written Letter vs. 2. Online Patient Letter Form**

We have now added an online option to complete the patient letter. You now have two options to complete the patient letter requirement of the preoperative patient preparation. You can complete this requirement by typing the letter as described below or by completing the online form on the web. [http://clos.net/pat-letter.htm](http://clos.net/pat-letter.htm)

**Online Patient Letter Form**

[http://clos.net/pat-letter.htm](http://clos.net/pat-letter.htm)

You can now complete the patient letter requirements by completing the online form found at [http://clos.net/pat-letter.htm](http://clos.net/pat-letter.htm)

The online form must be competed in detail to fulfill this requirement.

**Written Patient Letter Contents**

The patient is asked to write a typed letter addressing each of the fifteen topics. The patient is asked to write one typed page on each topic. Hand written letters are not acceptable. The typeface to be used 12 point and the line should be 1 and ½ space on each page.

- Understanding the Risks of Obesity
- Understanding Morbid \ Clinically Severe Obesity
- Understanding Why the Operation is performed
- Understanding How the Operation is performed
- Understanding the Hoped for Benefits of Surgery
- Understanding the Risks of Surgery
- Understanding the Risks of Gastritis, Ulcers and Bile Reflux
- Understanding what to take for Pain and Colds
- Understanding of the Alternatives to Surgery
- Understanding the Post Operative Diet Changes
- Understanding the Risks of Alcohol, Acetaminophen and Liver Disease
- Understanding the Possible Depression after Operation
- Understanding When to Use the Estrogen Patch in Women
- Understanding the Need for Long Term Follow Up
- Understanding the H. Pylori, the Billroth II and the risks of stomach ulcers, gastritis and stomach Cancer
7. **Psychological Evaluation**

All our patients undergo a psychiatric evaluation to assess their psychological status prior to the Gastric Bypass. It is a requirement for a patient to see a psychologist or psychiatrist in preparation for the surgery. The psychiatric evaluation in preparation for surgery is recommended.

An evaluation by your usual medical doctor will not fulfill these criteria. Either a psychologist or a psychiatrist can perform it. A social worker or other therapist is not an acceptable choice. The patient should have a routine psychiatric evaluation to rule out significant eating disorders or other major psychiatric illnesses that may affect the results of surgery.

Patients with inadequately treated depression need to be appropriately diagnosed and treated prior to surgery. Alcohol and drug abuse are also relative contraindications to surgery. The patient must not have unrealistic expectations of the outcome of surgery.

**Guideline for Psychiatric Evaluation**

**Purpose of Evaluation**

The psychiatric evaluation includes a face-to-face interview with the patient. A general evaluation usually takes no more than 1 hour to complete. Several meetings with the patient should not be necessary.

The psychiatric consultation is requested for the purpose of assisting in the diagnosis, treatment, or management of a patient’s possible mental disorder or behavioral problem.

The aim of the psychiatric evaluation is to provide answers to the questions including:

- Patient’s competency in deciding to proceed with gastric bypass. Is the patient competent to decide to proceed with surgery?
- History of Substance Use. Does the patient have a past history of drug or alcohol use, abuse or dependence? If so what role might this play in the future of this patient given the expected stress that occurs in the postoperative period?
- Presence of any Psychiatric diagnosis relevant to the gastric bypasses; in particular is the patient psychotic? If any form of psychiatric illness is identified then prognosis and treatment advice should be included.
- Willingness of the psychologist/psychiatrist to follow and treat the patient in the postoperative period. In addition the letter should include a commitment to be available for consultation in the event that depression occurs in the postoperative period.
- Patient’s ability to handle the stress of the period that follows surgery

The evaluation should respect the patient’s relationship with the primary clinician and should encourage positive resolution of conflicts between the patient and the primary clinician if these emerge as an issue.

**Issues to be addressed in the Psychiatric Evaluation:**

- History of the Present Illness
- Past Psychiatric History
- General Medical History
- History of Substance Use
- Social History
- Occupational History
- Family History
- Review of Systems
- Mental Status Examination
- Functional Assessment
- Information Derived from the Interview Process.

8. **Contact with Preoperative Patients**

We require that all preoperative patients spend time talking with patients that have already undergone surgery Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity. To meet this requirement you have to contact at least 10 previous patients as part of your application package. You must also fill out the online patient contacts form. It is located on the Internet at: [http://clos.net/forms/patient_contacts_form.htm](http://clos.net/forms/patient_contacts_form.htm)

For each of your patient contacts please type the patient’s first and last name, the method of contact, the patient’s email address, the patient’s date of operation, the patient’s preoperative weight, the patient’s weight now, the date of contact and 1-2 paragraphs of written information about the contact demonstrating that the contact was made.

Ask questions such as:

- What did you think about Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery?
- What did you think about Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s staff?
- What did you think about the Hospital?
- How was your experience with the surgery?
- How much pain did you have?
- When did you go back to work?
- How much weight did you lose?
- Would you do it again?

Get the list of volunteer post op patients from Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery. When you have contacted all of your 10 patients, fill out the **ONLINE PATIENT CONTACTS FORM**. Print a copy before you submit it. Submit it online.

You should include a printed copy of this online form in your packet.

9. **Photographs**

These pictures will be used to document your physical size and appearance both before and after surgery. They will be viewed by our physicians in assessing your physical makeup, and may be used in the future to assist you in grasping the physical changes your body has undergone post surgery. We recommend a bathing suit photo, but if you are not comfortable with that, exercise clothes that fit closely to your body would be appropriate. We need to see the shape and
size of your stomach and abdominal area. Note: All photos should show you clothed, Do not send photos without clothing please!

10. Family Letter
The family support letter is vital in documenting that your family knows and understands why you seek this surgery, the changes you will undergo, and the emotional and physical changes that affect you and them. This letter should also explain their understanding of the possible risks as well as benefits of a surgical weight loss option. This letter can allow your family to express their concerns about you, and the state of your health. One of the factors that have been identified from our patient survey is the importance of the family in successfully coping with the stresses that occur in the postoperative period. Patients that live alone and / or are far from their family members appear to have more problems than those with close supportive families. Because of these findings, we are changing our methods for preoperative evaluation as well as the processing of patients prior to consideration for surgery. Some of our main goals include an assessment of the patient’s family structure and education of family members about the patient’s interest in the gastric bypass. This will require that the spouse, parent, brother, sister or adult children accompany the patient to at least one (ideally all) of the clinic visits. This changes our past policy and is designed to improve the quality of care provided to our patients. The family must also be able to learn about and understand the educational issues related to the laparoscopic gastric bypass.
Patients must provide a detailed description of their family and family support structure.
Family member(s) or a friend must accompany the patient to the educational preoperative visits.
Family members must have an equal understanding of the issues related to selection of the Laparoscopic Gastric Bypass.
The Patient will choose a family support member to write their letter. If the patient is married the spouse must submit a family letter.
It must also be signed and notarized when submitted in the packet.

11. Clinic Visit
To make an appointment contact the representative from the CLOS location where you are planning on having surgery, see the front page of the manual for contact information.
Before coming to clinic you may want to have completed your history and physical examination with your Doctor.
Please call in advance if you plan to attend.
When you pre-register, you will be weighed & your waist measured.
Clinic is 3 or more hours long.
Please wear loose fitting two-piece outfits at both Clinics so that the Surgeons of the Centers for Laparoscopic Obesity Surgery can easily examine you prior to surgery and post-op for easier removal of staples. Please do not wear pantyhose or other garments that will hinder your physical examination.
You will return to the Post-operative Clinic the following week for your staple removal and final checkup.

12. Consent Form
We want to assure you and your current and future healthcare providers that we are concerned with the privacy of any health-related information that you or your providers supply to us. We take all necessary precautions to protect the privacy and integrity of your health information, including obtaining your consent and permission that will allow your healthcare providers to share health information about you with us. Please complete the following three forms and include them with the written materials that you provide to us:

Give Consent for Release of Protected Health Information.
This will allow your primary care physician to keep us updated with your progress after you return to his or her care.

Give Permission to Use Photographs and Personal Statements.
We want you to celebrate your success! With your permission, we may want publish your “before and after” photographs as a testimonial to your success with laparoscopic gastric bypass surgery. If you have a personal story or statement that you would like to share, we would also ask for your permission to publish that statement and give you credit for it.

What’s Next
After these steps are completed, you can be scheduled for surgery on the next available date. There is no additional waiting period once you have been approved for surgery.
Selection Guidelines

► Note: Not all patients are candidates for the Laparoscopic Gastric Bypass. Patients ideally should meet the following guidelines.

► Communication Access: You must have a reliable Email address that can accept "attachments." Note: It is Very Important that you DO NOT use your work email address. You can expect to receive a high volume of very personal email at the address that you send us. You need to have a personal email address and not a work email address.

► Preoperative Screening Information: You must complete the online patient information form. http://clos.net/patinfo.htm

► An Age between 16 and 55 is ideal but we often review the cases of older patients on case by case basis and in many patients age up to 81 yeas or old have been approved for surgery. (Older patients need to demonstrate that they are very well motivated, very well informed patients that have strong support of both their family and their physician(s).)

► A BMI of 40 kg/m2 or above, or a BMI of 35 to 40 kg/m2 with comorbidity, (A good rule of thumb is a body weight of over 100 lbs above your ideal body weight.) Rarely we consider patients of lower or higher body weights.

► A body weight no more than 350 lbs.

► Patients must presently be working, either in or out of the home (Patients that are Students or Housewives can meet these guidelines if they are mobile and able to be active. Disabled and wheelchair patients are generally not good candidates for the surgery.)

► No history of previous obesity surgery. That is we do not accept patients that have had previous vertical banded gastropasty, “stomach stapling”, Roux-en-Y or other types of previous weight loss surgery. (We are no longer accepting patients for revision of other types of weight loss surgery.) WE DO offer revisions for failed LapBand surgery.

► No history of major abdominal surgery. (Some operations such as appendectomy, gallbladder removal and a few other operations such as hysterectomy may be acceptable.)

► No history of alcohol abuse or drug use. The patient must sign and notarize an affidavit that they are not using narcotics alcohol or sedatives! No Dilaudid, Fentanyl, Klonopin, Xanax etc. We have found such patients to be profoundly dangerous and poor candidates for surgery!

► The patient must show evidence of a strong, supportive and stable family structure and have the documented support of their immediate family.

► The patient must have a supportive personal physician (family practice or internal medicine) who will: Support the patient’s desire to undergo Laparoscopic Mini-Gastric Bypass
► Perform a detailed, meticulous and complete preoperative evaluation,
► Agree to be actively involved in the postoperative follow up with CELOS.

► No history of major psychiatric illness.

► If the patient has had depression, the patient and his/her psychiatrist must have a plan in place with their psychiatrist for the diagnosis and management of depression post operatively.

► No history of:
► Recent Prednisone Therapy for Any Reason
► Systemic Lupus Erythematosis (SLE)
► Rheumatoid Arthritis
► Other Collagen Vascular Disease

► Patients need to have a documented commitment to participate in a postoperative exercise program

► Evidence that the patient can work with CELOS and staff by following directions and communicating in a timely manner.

► Documented commitment to maintain the initial postoperative and yearly long-term follow-up with CELOS to decrease the risks of complications such as ulcers, vitamin, mineral and other nutritional deficiencies.

► You must have appropriate financial resources to cope with the costs associated with the surgery itself and you must be prepared to manage the post operative period in the event of a problem or complication.
Patient Education

Patient Education Objectives
The goals in patient education are to explain:
- Obesity, Clinically Severe/Morbid Obesity and Its Associated Risks
- Expert Opinion on Surgery as the Recommended Treatment of Severe Obesity
- Types of Weight Loss Surgery
- Mini-Gastric Bypass vs. Roux-En-Y
- The Old Loop Gastric Bypass
- Description of the Mini-Gastric Bypass Surgery
- Results of the Mini-Gastric Bypass
- PreOp Preparation
- Preoperative Instructions
- Patient Selection Guidelines
- The Results of Mini-Gastric Bypass Surgery
- The Risks of the Mini-Gastric Bypass Surgery
- Post Operative Follow up Requirements.

Obesity

Obesity means having too much body fat. It is different from being overweight, which means weighing too much. The weight may come from muscle, bone, fat and/or body water. Both terms mean that a person's weight is greater than what's considered healthy for his or her height.

Obesity occurs over time when you eat more calories than you use. The balance between calories-in and calories-out differs for each person. Factors that might tip the balance include your genetic makeup, overeating, eating high-fat foods and not being physically active.

Being obese increases your risk of diabetes, heart disease, stroke, arthritis and some cancers. If you are obese, losing even 5 to 10 percent of your weight can delay or prevent some of these diseases.

Ghrelin

Quoted mainly from Wikipedia, the free encyclopedia ([http://en.wikipedia.org/wiki/Ghrelin](http://en.wikipedia.org/wiki/Ghrelin))

“Ghrelin is a hormone produced mainly by the lining the fundus of the human stomach that stimulates appetite. Ghrelin levels increase before meals and decrease after meals. Ghrelin is also produced in the hypothalamic arcuate nucleus where it stimulates the secretion of growth hormone from the anterior pituitary gland. In the Mini-Gastric Bypass, the level of ghrelin is reduced in patients, thus causing satiation before it would normally occur. In LapBand patients Ghrelin does not decrease and may actually increase.”

Health Implications

Strong evidence suggests that obesity is associated with increased morbidity and mortality and that weight loss in obese persons reduces important disease risk factors. Obesity is an epidemic. Previous JAMA studies indicated that two in three U.S. adults are classified as overweight or obese, up from fewer than one in four in the early 1960s. Obesity ranks second only to tobacco in causing premature death. It has been linked to high blood pressure, high cholesterol levels, heart disease, diabetes and arthritis.
Obesity Shortens Life

Researchers from Johns Hopkins University School of Medicine conducted a study to pinpoint the number of life years lost due to being overweight or obese. For the study, researchers used information from U.S. Life Tables, Third National Health and Nutrition Examination Survey, and First National Health and Nutrition Epidemiologic Follow-Up Study. The data was used to derive the number of life years lost for adults due to being overweight or obese. The study finds obesity has a direct effect on life span of whites and that the risk was greatest among young obese people. The authors report white men 20 to 30 years old with a BMI of at least 45 reduced their life expectancy by 13 years. Women in that group reduced their life span by eight years. Also, younger blacks with severe obesity reduced their life by 20 years for men and five years for women. However, researchers report blacks over 60 years old who were obese did not show a reduction in the number of years they lived. While the most startling years of life lost numbers are for the very obese, the study shows that even a moderate amount of excess weight has a negative effect on life expectancy. Furthermore, as the degree a person is overweight increases, an accompanying shortening of life span occurs. The surgeon general estimates that public-health costs attributable to being overweight or obese are now about $117 billion per year. It is time for insurers to recognize that an immediate outlay for weight control now will save them money later, and they should buy into uniform reimbursement policies.

Obesity and Disease

In adults, disease risk increases independently with increasing BMI and excess abdominal fat.1 Cardiovascular and other obesity-related disease risks increase significantly when BMI exceeds 25.0 kg per m2. Overall mortality begins to increase with BMI levels greater than 25 kg per m2 and increases most dramatically as BMI levels surpass 30 kg per m2. Waist circumference measurements greater than 40 inches (102 cm) in men and 35 inches (89 cm) in women also indicate an increased risk of obesity-related comorbidities.1 Table 31,10 summarizes a recent classification of disease risk relative to BMI and waist circumference. Obesity in adults is linked to a variety of diseases and conditions. Surgery in obese patients requires special precautions and monitoring, particularly with regard to anesthesia, and cardiac and respiratory care, to minimize the risk of serious complications during surgical and perioperative periods.15 Under most circumstances, obese patients can be treated safely and should not be denied surgical treatment for any disorder when surgery constitutes the most appropriate therapy.15 While obesity in children and adolescents also has immediate health and psychosocial implications, a principal concern is that persistence of overweight and obesity into adulthood increases the risk for some chronic diseases later in life.2,4,9

Calorie Restriction Studies: Caloric restriction extends life

Just as numerous studies have demonstrated that excessive caloric intake and obesity can shorten life, another line of research offers compelling evidence that eating less lengthens life span. Only one intervention has been proven to extend both the average and maximum lifespan of all animal species tested: reducing the consumption of dietary calories, or caloric restriction (CR).125 126 Because CR extends maximum lifespan, scientists believe it actually slows the process of aging. CR is therefore used as a means to study the process of aging.127 128 Caloric restriction has been studied in dozens of animal experiments. In one example shown in the graph the lifespan of four groups of mice, illustrates the dramatic life extension induced by life-long CR.129] The group who ate freely without restriction had the shortest lifespan. The other three groups of mice were subjected to different degrees of food restriction. The results showed that less food resulted in longer lives. Calorie restriction (CR) extends lifespan and reduces the incidence and age of onset of age-related disease in several animal models. To determine if this nutritional intervention has similar actions in a long-lived primate species, the National Institute on Aging (NIA) initiated a study in 1987 to investigate the effects of a 30% CR in male and female rhesus macaques of a broad age range. We have observed physiological effects of CR that parallel rodent studies and may be predictive of an increased lifespan. Specifically, results from the NIA study have demonstrated that CR decreases body weight and fat mass, improves gluoregulatory function, decreases blood pressure and blood lipids, and decreases body temperature. Juvenile males exhibited delayed skeletal and sexual maturation. Adult bone mass was not affected by CR in females nor were several reproductive hormones or menstrual cycling. CR attenuated the age-associated decline in both dehydroepiandrosterone (DHEA) and melatonin in males. Although 81% of the monkeys in the study are still alive, preliminary evidence suggests that CR will have beneficial effects on morbidity and mortality. Decreasing food intake not only extends the lifespan of animals but also reduces the incidence of virtually all diseases of aging such as cancer,130 heart disease,131 diabetes,132 osteoporosis,133 auto-immune disorders,134 neurological decline135 and diseases such as Alzheimer's136 and Parkinson's.137 Overall, Caloric Restriction has been shown to dramatically extend both the life and health of all animals tested.

Lower Weight and Increased Longevity

There are now hundreds of studies showing that lower body weight increases lifespan:
* In 1985, the National Institute of Health, Centers for Disease Control, and the Department of Health and Human Services published a “special report” stating: "Studies based on life insurance data, the American Cancer Society Study and other long-term studies, such as the Framingham Heart Study and the Manitoba Study, indicate that the weights associated with the greatest longevity tend to be below the average weights of the population as long as such weights are not associated with concurrent illness or a history of medical impairment.”

* In 1993, the Journal of the American Medical Association published a study that concluded: "In these prospective data, body weight and mortality were directly related. After accounting for confounding by cigarette smoking and bias resulting from illness-related weight loss or inappropriate control for the biologic effects of obesity, we found no evidence of excess mortality among lean men. Indeed, lowest mortality was observed among men weighing, on average, 20% below the US average for men of comparable age and height.”

* In 1995, a study published in New England Journal of Medicine concluded: "Among women who never smoked, the leanest women... had the lowest mortality, and even women with average weights had higher mortality. Mortality was lowest among women whose weights were below the range of recommended weights in the current U.S. guidelines. Moreover, a weight gain of 10 kg of more since the age of 18 was associated with increased mortality in middle adulthood. These data indicate that the lowest mortality rate for U.S. middle-aged women is found at body weights at least 15 percent below the U.S. average for women of similar age.”

While such studies based on epidemiological data establish correlation, not causation, the bulk of these findings among human populations in addition to laboratory proof that Caloric Restriction extends the lifespan of all other animals supports the idea that decreased caloric intake extends human lifespan.

**The rationale for the treatment of obesity**

The rationale for the treatment of obesity is based on two lines of evidence: 1) studies showing that obesity are related to increased disease and mortality and 2) studies that show that eating less and weight loss reduce the risk factors for disease and extend life. Weight loss (as little as 10 percent of initial body weight) in overweight and obese adults has been shown to reduce various chronic disease risk factors (e.g., hypertension, hyperlipidemia, hyperglycemia) and may decrease morbidity and mortality.† To be of value the treatment must have low rates of its own complications. This is one of the important advantages of the Mini-Gastric Bypass; it has a low risk and low rate of associated complications.

**Features of an “Ideal” Weight Loss Surgery**

An ideal weight loss surgery should be effective, easy to perform and safe. It should have a simple and effective “Exit Strategy”, that is, it should be easy to modify or reverse for inadequate weight loss, weight regain, excessive weight loss or other complications. The ideal operation should leave little in the way of adhesions and rarely cause hernias. The operation should be relatively inexpensive and long-term complications should be rare and manageable. The surgical procedure should be a part of a program that includes careful preoperative and postoperative follow-up so that results can be continuously evaluated. In an ideal situation patients should be available to outsiders to allow an objective assessment of the results of the procedure. These and other desirable features are listed in the table.

Table 3: Desirable Features of an “Ideal” Weight Loss Surgery

<table>
<thead>
<tr>
<th>Features of an &quot;Ideal&quot; Weight Loss Surgery</th>
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<tbody>
<tr>
<td>Low Risk</td>
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<tr>
<td>Major Weight Loss</td>
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<tr>
<td>Easily performed</td>
</tr>
<tr>
<td>Short operative times</td>
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<tr>
<td>Outpatient or short hospital stay</td>
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<tr>
<td>Minimal Blood Loss</td>
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<tr>
<td>No Need for ICU Stay</td>
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<tr>
<td>Minimal Pain</td>
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<tr>
<td>Very High Patient Satisfaction</td>
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<tr>
<td>Easily Reversed or Revised Laparoscopically (i.e. a Good &quot;Exit Strategy&quot;)</td>
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<tr>
<td>Change in eating behavior and preferences</td>
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<tr>
<td>Minimal Retching and Vomiting</td>
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<tr>
<td>Few adhesions or hernias</td>
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<tr>
<td>Minimal impact on Heart and Lung Function</td>
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<tr>
<td>Low Failure Rate</td>
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<tr>
<td>Low Cost</td>
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<tr>
<td>Short Recovery Time</td>
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<tr>
<td>Rapid Return to Work</td>
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<tr>
<td>Low Risk of Pulmonary Embolus</td>
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</tbody>
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Durable weight loss
Low Risk of Ulcer
No Malabsorption or Malabsorption easily managed
No Plastic Foreign Body Material
Easily Verifiable Results
Procedure Performed by a High Volume Bariatric Surgeon
Performed as part of an extensive program of education and follow-up

Dr. Rutledge has performed a recent study of over 500 pre and post operative weight loss surgery patients performed by Dr. Rutledge identified the factors that are important in making up “ideal” surgery for the treatment of severe obesity. Individuals graded each factor in relation to the amount of importance that was placed on each feature. The scale used to grade each factor was graded from 1-5 with 1 – being a factor that was felt to not be important at all, 2 – being not very important, 3 – of some importance, 4 – very important and 5 – being extremely important. The results of the study showed that study patients clearly felt that these issues were very important. Almost half responding patients (45%) felt that all of the factors were either very or extremely important. As might be expected, 94% of patients list Major Weight Loss as very important or extremely important, 91% listed minimal impact on Heart and Lungs as very or extremely important. Other factors that patients felt were very or extremely important was “Very High Patient Satisfaction (90%)”, Low Failure Rate (90%), Durable weight loss (88%), Low Risk of Pulmonary Embolus (85%), Few adhesions or hernias (80%), Short Recovery Time (79%), Low Risk (78%), Easily performed (77%), Minimal Vomiting (76%), Change in eating behavior and preferences (76%), No Need for ICU Stay (75%), Minimal Blood Loss (73%), Low Risk of Ulcer (71%), Low Cost (67%), Performed by a High Volume Surgeon (66%) and Short operative times (64%).

The significance of these factors to each individual and his or her physician may vary but these factors make a clear constellation of factors that define “ideal” weight loss surgery. The number and variety of surgical procedures that are presently provided for the surgical treatment of obesity demonstrates that that the ideal operation for weight loss has yet to be found.

Types of Weight Loss Surgery

Controversy in Bariatric Surgery

Weight loss surgery is full of controversy: gastric banding types of surgery vs. bypass types of surgery, proximal gastric bypasses vs. distal gastric bypasses, bypass types vs. the duodenal switch vs. the Fobi pouch and the new Adjustable Gastric Band. The list goes on and on. There are many different types and variations in the surgical procedures being performed for weight loss in America at this time. Although many studies document the value of surgery for obesity, there remain many physicians and surgeons who are opposed to the idea of the surgical treatment of obesity.

Physician Opposition to the Surgical Treatment of Obesity

It is important to recognize the skepticism and aversion that weight loss surgery generates among some individuals both inside and outside of the medical community. Because of the many associated problems and complications of weight loss surgery many physicians and surgeons prefer to avoid Bariatric surgery entirely141. As an example, in a study by Dr. Mason142 a questionnaire was sent to the chairmen of 151 academic surgery departments in North America asking about the acceptance and use of surgical operations for the treatment of severe obesity. Of the 112 responding chairmen only ¾ indicated that operative treatment should be used and only 2/3 of surgical departments actually provided such operations. This is in contrast to the universal provision of other forms of general surgery such as gallbladder and hernia surgery.

Various Types of Weight Loss Surgery

As the table below demonstrates there are a host of different types and forms of weight loss surgery offered in America and around the world today.

Table 4: Different Types of Weight Loss Surgery

<table>
<thead>
<tr>
<th>Types of Weight Loss Surgery</th>
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<tbody>
<tr>
<td>Open Roux-en-Y Gastric Bypass</td>
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<tr>
<td>Laparoscopic Roux-en-Y Gastric Bypass</td>
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<tr>
<td>Sleeve Gastrectomy</td>
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<tr>
<td>Stilastic Ring Vertical Gastric Bypass (Fobi Pouch)</td>
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<tr>
<td>Micro pouch Gastric Bypass</td>
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<tr>
<td>Antecolic Laparoscopic Roux-en-Y Gastric Bypass</td>
</tr>
<tr>
<td>Long Limb Gastric Bypass</td>
</tr>
<tr>
<td>Biliopancreatic Diversion</td>
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</tbody>
</table>
The Learning Curve: Higher Volume/More Experience = Better Outcomes

When evaluating different types of weight loss surgery it is important to be aware of the well-documented “learning curve” in a surgeon’s initial adoption of a new procedure. There are hundreds of studies that clearly document the improvement in outcomes as the procedure volume increases and the fact that during the early phases of development patient risk is at its greatest.

For example in the study by Bagdasarian et al., a review of laparoscopic removal of the spleen was performed. They performed a review of 33 cases of laparoscopic splenectomy performed at the Ochsner Foundation Hospital between 1992 and 1999. Six conversions to open surgery were necessary during the first eight laparoscopic splenectomies (75.00%) and only one during the last 25 cases (4.00%). They concluded that laparoscopic splenectomy was a safe although complex procedure. They showed that bleeding was the major complication but could be improved with experience. With the short recovery and ready acceptance of patients and physicians, this technique is being used with increasing frequency. But, they pointed out that there was a significant learning curve for the safe completion of this challenging procedure.

The Need for Experience and Supervision

A study from Australia evaluated the learning curve for laparoscopic fundoplication (a laparoscopic surgery for acid reflux somewhat similar to the gastric bypass.) They pointed out that “Although training recommendations have been published by some professional bodies, there is disagreement about what constitutes adequate supervised experience before the solo performance of laparoscopic antireflux surgery, and the true length of the learning curve.” They looked at the outcome of 280 laparoscopic fundoplications undertaken by 11 surgeons during a 4 year period. They found as expected that the complication, reoperation, and laparoscopic to open conversion rates all were higher in the first 50 cases performed. These rates were even higher in the initial first 20 cases, and the first 5 individual cases. These bad outcomes were less likely when experienced supervision could be provided.

They demonstrated that there was indeed a learning curve for laparoscopic fundoplication. They recommended that experienced supervision should be sought by surgeons beginning laparoscopic fundoplication during their first procedures. This might minimize bad outcomes associated with an individual's learning curve.

Surgeons’ Experience Linked to Surgery Outcomes

According to a recent study, undesirable outcomes may be related to the surgeon’s level of experience. Researchers designed two studies to evaluate nationwide rates of complications after antireflux surgery and to assess the association between a surgeon’s experience and negative outcomes. The studies utilized the Washington State discharge database and the U.S. Healthcare Cost and Utilization Project to identify all patients who had antireflux surgery from 1992 to 1997.
Researchers identified 5,528 patients who had undergone antireflux surgery during the five-year period. They found that 1.39% of patients had splenic injury and splenectomy, 0.59% of patients had an esophageal laceration and 0.4% of patients died. The surgeons with the lowest rates of surgical experience had an increased rate of splenectomy (2.86 %,) and death (1.32%). The odds of splenic injury and splenectomy were 2.9 times higher for surgeons with less experience than the rate of injury for more experienced surgeons. Increasing surgeon caseload by one case per year resulted in a 1.7% decrease in the patient fatality rate. The rate of splenectomy and injury to the esophagus also decreased with increasing caseload. Researchers suggested that identifying the association between surgical experience and complications could improve efforts to improve patient safety.

**Descriptions of Various Types of Weight Loss Surgery**

A brief overview and a short discussion of the associated complications of some of these different types of weight loss surgery can help put the Mini-Gastric Bypass surgery in its proper context.

**Vertical Banded Gastroplasty**

Laparoscopic Vertical Banded Gastroplasty (LVBG)

Laparoscopic techniques for VBG are adaptations of the Mason VBG for open surgery.

Five ports (5-12mm) are placed in upper abdomen

A window to the lesser sack is created

An EEA stapler creates a transgastric defect

An Endo-GIA stapler creates the gastric partition or division

A band is placed around the Outlet

Because the normal path of food is unchanged, Malabsorptive complications are less common than in bypass type procedures, but they still can occur. The intake of most vitamins and minerals is below 50% of RDA at 18 months post-op. Mean intakes of iron, calcium and zinc from food were 40%, 71% and 39%. Below the RDA respectively. Furthermore, compliance to multivitamin and mineral supplement intake deteriorated with time.157 Hypokalemia, 158 Thiamine, 159 Zinc, 160 Folate, 161 Riboflavin, 162 B6 and Vitamin B12 deficiency can occur. 165 There is a measurable loss of bone density. 166 As an example a patient, who had a banding procedure, had severe vomiting 1 week after the operation.

Physical examination showed ataxia, disorientation and diplopia. After replacement of vitamin B1 (thiamine) 20 mg i.v. b.i.d., all the neurological signs regressed. Wernicke's encephalopathy, which occurs as a result of thiamine deficiency, is a complication that has been reported after VBG167 168 and other types of weight loss procedures. 169 Complications can include esophageal reflux and dilation or obstruction of the stoma, with the latter two requiring reoperation. Dilation of the outlet stoma is a common reason for weight gain. In one series gastroesophageal reflux occurred in eight (10.1%) cases, outlet dilatation in four (5%) cases, outlet stenosis (diameter 6-8 mm) in 13 (16.4%) cases, outlet stenosis (diameter =5 mm) in four (5%) cases, peanut-type deformation in three (3.7%) cases, and staple-line disruption in 17 (21.5%) cases. 170 In one series 14 patients underwent conversion of failed VBG because of a combination of inadequate weight loss in 13 patients, gastroesophageal reflux in five, and frequent vomiting in four. Only 26% of patients after VBG maintained a weight loss of at least 50% of their excess body weight; 17% underwent Bariatric reoperation with good results. 171 The vomiting often seen after VBG has been shown in some cases to lead to severe vitamin and mineral deficiencies. 172 173 The VBG is notorius for problems with vomiting, staple line breakdown, ulcer and reflux esophagitis. 174 Persistent vomiting was the most common late complication, occurring in 49.3% of one series. 175 In a study by Balsiger et al. 176 they reported that gastroesophageal reflux disease was common after VBG. They reported on 25 patients who underwent revision because of severe symptomatic reflux. The mean duration of Gastroesophageal Reflux Disease symptoms after VBG was 35±8 mo. All patients had severe heartburn with regurgitation and/or vomiting; 1 patients (55%) remained markedly symptomatic despite use of anti-reflux medications. Endoscopic findings in 24 patients included esophagitis (58%), Barrett's esophagus (28%), pachitis (29%), gastritis (21%), and one stomal ulcer (4.0%). Nine patients had a hiatal hernia, and another 3 had pouch enlargement. Only 7 of the 25 patients (28%) had evidence of stenosis at the pouch outlet as documented by endoscopy or contrast studies. They concluded that symptoms of Gastroesophageal Reflux Disease are common after VBG. Revision may be necessary for relief from Gastroesophageal Reflux Disease symptoms in patients who have undergone the VBG.

Laparoscopic adjustable gastric banding has recently been approved for the surgical treatment of morbid obesity in America. In a study of 43 patients (median body mass index [BMI] 43,) preoperatively 12 patients complained of reflux symptoms. Mild esophagitis was detected in 10 patients. Postoperatively 1 patient (2.3%) complained of heartburn and mild esophagitis was diagnosed in one patient (2.3% ). Postoperatively there was significant impairment of LES relaxation and deterioration of esophageal peristalsis with dilatation of the esophagus in some patients. 177 MacLean and colleagues reported on 201 patients who underwent vertical banded gastroplasty and who were followed for a minimum of 2 years. Staple line breakdowns occurred in 48% of patients and 36% underwent re-operation either to repair the staple line failure or to repair a stenosis at the outlet. Only 50% of patients who maintained an intact staple line had durable weight loss of 75% to 100% of excess weight. The procedure was less successful in the super obese, defined as a BMI of >50.
**Gastric Banding**

Laparoscopic Gastric Banding (LGB)

This procedure involves the placement of an adjustable Silastic band below the gastroesophageal junction to create a small (10-20ml) gastric pouch.

Six ports (5-15mm) are placed in upper abdomen

A retrogastric tunnel is created

The inflatable band is inserted just below the gastroesophageal junction

The band is secured to the stomach with sutures

The injection port is connected to the band tubing and place rectus sheath.

Gastric banding uses an external adjustable or nonadjustable band placed around the stomach and has been used extensively in Europe. The device has been included in an FDA approved trial in this country with decidedly mixed results.

The procedure is similar to the vertical banded gastroplasty, but designed to be easier and reversible. Like other gastric surgeries, the literature is dominated by large case series from individual surgeons, who report varying results. The gastric banding procedure is still an evolving procedure with issues of band migration (or slipping) addressed by altering the position of the band and band erosion addressed by stabilizing the placement of the band. Therefore, it is very difficult to compare one series to another. For example, in this country Doherty and colleagues reported on an initial experience with adjustable gastric banding in 40 patients. The authors reported a re-operation rate of 80%. Those with an intact gastric band achieved 41% excess weight loss. In a subsequent study, the authors reported several surgical modifications, including location of the gastric band, and modifications in the device itself. Also, the surgery was performed laparoscopically. Seven of the 22 patients (33%) required re-operation, a considerable improvement. In contrast to this American experience, as a representative example, Miller and Hell report a re-operation rate of only 7% in a case series of 158 patients. Median BMI decreased from 44 kg/m² preoperatively to 28 kg/m² after 36 months. Suter and colleagues compared vertical banded gastroplasty with laparoscopic gastric banding in consecutive case series and reported that laparoscopic gastric banding was associated with significant decrease in postoperative morbidity, primarily due to a decrease in thromboembolism and wound infections. After 2 years of follow-up, there was no significant difference in weight loss between the two groups. DeMaria et al. present their experience with the Laparoscopic Band procedure. They reported their results from one of the eight original U.S. centers performing laparoscopic adjustable silicone gastric banding (LASGB). Of 37 patients undergoing laparoscopic placement of the LASGB device, successful placement occurred in 36 from March 1996 to May 1998. Patients have been followed up for up to 4 years. Five patients (14%) have been lost to follow-up for more than 2 years but at last available follow-up (3-18 months after surgery) had achieved only 18% (range 5-38%) excess weight loss. The LASGB devices were removed in 15 (41%) patients 10 days to 42 months after surgery. Four patients underwent simple removal; 11 were converted to gastric bypass. The most common reason for removal was inadequate weight loss in the presence of a functioning band. The primary reasons for removal in others were infection, leakage from the inflatable silicone ring causing inadequate weight loss, or band slippage. The patients with band slippage had concomitant poor weight loss.

Bands were removed in two others as a result of symptoms related to esophageal dilatation. In 18 of 25 patients (71%) who underwent preoperative and long-term postoperative contrast evaluation, a significantly increased esophageal diameter developed; of these, 13 (72%) had prominent dysphagia, vomiting, or reflex symptoms.

Of the remaining 21 patients with bands, 8 currently desire removal and conversion to gastric bypass for inadequate weight loss. Six of the remaining patients have persistent morbid obesity at least 2 years after surgery but refuse to undergo further surgery or claim to be satisfied with the results. Overall, only four patients achieved a body-mass index of less than 35 and/or at least a 50% reduction in excess weight. Thus, the overall need for band removal and conversion to GBP in this series will ultimately exceed 50%. The authors did not find LASGB to be an effective procedure for the surgical treatment of morbid obesity. Complications after LASGB include esophageal dilatation, band leakage, infection, erosion, and slippage. Inadequate weight loss is common, particularly in African American patients. More study is required to determine the long-term efficacy of the LASGB.

In many ways the silicone band used in the LapBand is reminiscent of the old Angelchik prosthesis. The Angelchik antireflux prosthesis was used for the treatment of acid reflux disease and was associated with complications that require reoperation in 5% to 15% of patients. In a study from Canada a retrospective study of 15 patients who were reoperated for the treatment of complications of the Angelchik prosthesis were studied. The time to reoperation ranged from 3 weeks to 113 months with a mean of 31 months. The reasons for reoperation included swallowing difficulty (8 patients), recurrent reflux (6 patients), and prosthesis migration (1 patient). Ten patients underwent prosthesis removal and fundoplication, 4 had prosthesis removal without fundoplication, and 1 patient had the prosthesis repositioned. Iatrogenic splenic injury occurred in 2 patients (13%); one splenectomy and one splenic repair were done. Four patients (27%) required intraoperative blood transfusion. They concluded that reoperation for complications of the Angelchik antireflux prosthesis can be technically difficult.

**Roux-en-Y Gastric Bypass**

The Roux-en-Y Gastric Bypass consists of two components 1) reduction of the stomach and 2) a Roux-en-Y gastrojejunal anastomosis. Thus food bypasses the duodenum and proximal small bowel. Patients may face a syndrome of nausea;
vomiting, abdominal pain, and postprandial fullness that are known to follow Roux-en-Y gastrojejunostomy. It is thought to result from the jejunal transection performed during the construction of the Roux limb. Some patients who undergo a Roux-en-Y gastrojejunostomy may suffer from crampy abdominal pain, nausea, vomiting of food and bloating made worse by eating. This syndrome, the Roux stasis syndrome, is caused, in part, by a motility disorder of the Roux limb. These symptoms may diagnose in some cases as the “dumping syndrome.”

Well recognized operative complications of the Roux-en-Y include: pulmonary embolus, DVT, leakage, stricture and marginal ulceration of the anastomotic site. Because the normal path of food is disrupted, there are more metabolic complications compared to other gastric restrictive procedures. These include iron deficiency anemia, vitamin B-12 deficiency in approximately 30%-84%, and impaired calcium absorption, all of which can often be corrected by oral supplementation. Another concern is the ability to evaluate the “blind” (or backside) bypassed portion of the stomach.

Griffen summarized the experience of over 10,000 gastric bypass operations from a number of Bariatric surgeons.185 It was estimated that 85% of patients reduced their weight to at least 50% above their ideal weight. In approximately 5,000 patients who were followed for 10 years, 80% were able to maintain this result. Pories and colleagues reported on 608 patients who underwent this gastric bypass procedure and were followed for 1-14 years.186 One of the unique features of this report is that only 3% of patients were lost to follow-up. The average weight loss in that series was excellent at 75% of excess weight at one year; unfortunately it declined to 50% by the eighth year. Flickinger and colleagues reported on the incidence of diabetes and hypertension in a case series of 397 patients.187 Prior to surgery, 22% had diabetes mellitus and 13% had impaired glucose tolerance. After surgery, all but one of the patients remained euglycemic. A total of 57% of patients were hypertensive before surgery compared to only 18% after surgery. Similarly, Pories and colleagues reported that of 163 obese patients with diabetes or impaired glucose tolerances; only 5% remained with inadequate control after gastric bypass surgery and associated weight loss. Other studies have reported that gastric bypass surgery and weight loss are associated with improvements in the lipid profile.188

Metabolic abnormalities are seen more frequently in gastric bypass patients compared to those receiving a vertical banded gastroplasty. Anemia, iron deficiency, vitamin B-12 deficiency, and red blood cell Folate deficiency are commonly seen. Marginal ulcerations are also seen in gastric bypasses.

In a recent study by Lee et al190 245 consecutive patients undergoing the Roux-en-Y at UCLA. The mean preoperative weight was 333±6 lbs with a body mass index of 53±0.8. There were 5 deaths (2.0%) in their series and 38 complications (16%). 38 of the patients (13%) were revisions. Patients undergoing revisions had a complication rate of 30%. There were 27 complications in 207 primary operations for a complication rate of 13% in patients operated upon for the first time. There were 12 (4.9%) anastomotic leaks, 4 leaks (10.5%) in revision procedures and 8 (3.9%) in primary operation. Bowel obstruction or ileus occurred in 6 patients (2.4%), splenectomy occurred in 3 (1.2%), Pulmonary embolus occurred in 3 (1.2%), sepsis of unknown cause in 3, marginal ulcer was found in 2 (0.8%) 10 miscellaneous complications occurred resulting in prolonged hospitalization (>1 wk). 4.1%. The group found that the probability of having a major complication from Roux-en-Y was related to 1) the cause of a revision 2) the patient’s age, 3) the patient’s weight, 4) the presence of hypertension and 5) the presence of diabetes. The contribution of various factors to the risk of morbidity was calculated. The highest risk factor was surgery for revision.

**Mini-Gastric Bypass (Billroth II vs. the Roux-en-Y)**

The Mini-Gastric Bypass was developed to try to deal with the limitations of the present forms of weight loss surgery. It was felt that a significant number of the ideal features desirable in weight loss surgery could be obtained using this minimally invasive approach.

The Mini-Gastric Bypass can be performed using either the Roux-en-Y or the Billroth (Loop) type connection. There are advantages and disadvantage to both approaches of gastrointestinal anastomosis. Both provide a decreased ability to eat and some decrease in the absorption of foods, especially fats. Bile reflux is one concern about the use of the Billroth II loop type connection used in the Mini-Gastric Bypass. This will be discussed in great detail subsequently, but in summary, the main points of the concerns related to this issue are summarized as follows:

The Billroth II, like the Roux-en-Y, is a standard method of connecting the stomach to the bowel and general surgeons select it 3-9 times more often than the Roux-en-Y. The Mini-Gastric Bypass is not the “Old Loop” gastric bypass: The “Old Loop” gastric bypass placed the bowel loop immediately adjacent to the esophagus. The general surgical literature is in uniform agreement that the Billroth II loop type connection should not be placed next to the esophagus, as would occur after total or subtotal gastrectomy. When placed in this position, the bowel loop next to the esophagus, severe reflux esophagitis occurs. The Mini-Gastric Bypass places the gastrojejunal anastomosis at the junction of the body and the antrum of the stomach. This is the same level that any standard Billroth II type loop connections are usually placed when general surgeons to treat problems such as ulcers, trauma and cancer use it.
The location of the gastrojejunal anastomosis is at the junction of the body and the antrum of the stomach, this is approximately 2/3 of the way down the stomach from the esophagus to the pylorus. The Mini-Gastric Bypass is a standard Billroth II gastrojejunostomy; it is not different from the thousands of other Billroth II gastrojejunostomies performed by surgeons across America every year. It is a good but not perfect operative choice.

The Roux-en-Y avoids some of the problems of the Billroth II but it has its own problems.

The most significant problems with the Roux-en-Y are higher reported rates of ulcers, bowel obstruction, difficulty revising the Roux-en-Y laparoscopically for weight loss surgery failures, and the “Roux Stasis Syndrome.” The “Roux Stasis Syndrome” is a debilitating illness that has been reported in up to 30% of Roux-en-Y patients, is characterized by nausea, vomiting, and crampy abdominal pain and is difficult to treat.

Because of the problems with the Roux-en-Y, Dr. Keith Kelly at the Mayo Clinic has performed animal and human trials of a new “uncut” Roux-en-Y that is a modified Billroth II to allow surgeons to avoid use of the Roux-en-Y.

The Billroth II is the most common technique used by surgeons in both America and around the world to connect the stomach to the small bowel. This approach was named for the famous German surgeon who invented the operation technique. The origin of the surgical procedure for gastric resection known as Billroth II was significant in the early surgery of the abdomen. Theodore Billroth successfully performed the first gastrectomy for cancer in Vienna in 1881. Billroth procedure opened modern era of gastric surgery. This was the beginning of modern gastric cancer and ulcer surgery. Remember that 1881 is not long after the first successful use of ether to produce anesthesia for surgery performed in 1846. And it is only 16 years after 1865 when Joseph Lister proved the effectiveness of antiseptic surgery that brought about dramatic decreases in postoperative death rates.

**The Billroth II Today**

The operation of Billroth II gastrectomy has not changed substantially in concept or technique since it was first performed in 1885 by Theodore Billroth. The advent of stapling has made the procedure faster for the surgeon but the operation has remained as painful and as traumatic for the patient. The totally intra-abdominal laparoscopic Billroth II gastrectomy offers a minimally invasive option that is remarkably less traumatic and more ‘patient friendly’. Initial experience in this operation around the world has largely concentrated on resection for benign gastric ulcer. Experience with a small series of 16 cases showed that the laparoscopic Billroth II operation has many advantages over open surgery in terms of postoperative pain, quicker mobilization, fewer wound problems, better cosmesis and quicker discharge. No anastomotic leak, chest or wound complications were encountered. The only problem remains the cost of disposable stapling devices.

The first totally laparoscopic Billroth II gastrectomy was performed in 1992. Questionnaires were sent to every surgeon in the world known by the authors or their contacts to have performed a laparoscopic gastrectomy. It was completed in November 1994. Sixteen surgeons contributed to this study. A total number of 118 cases of laparoscopic gastrectomies, comprising Billroth I (11), Billroth II (87), vagotomy and antrectomy (10), and total gastrectomy (10) had been performed. The indications were gastric and/or duodenal ulcers and benign and malignant gastric tumors. Laparoscopic gastrectomy (most Billroth II) was found to be superior to the open technique by 10 of 16 surgeons because of faster recovery, less pain, and better cosmesis.

Surgeons are using the Billroth II every day in America and around the world. Many studies show that the Billroth II is preferred over the Roux-en-Y. In a study of pancreatic surgery by Art et al 196 Roux-en-Y gastrojejunostomy was performed in 53 cases and Billroth-II anastomosis in 35 patients. Nine cases of ulceration were verified after Roux-Y gastrojejunostomy (18%). After Billroth-II reconstruction anastomotic ulceration was found in only one out of 33 cases (3%). They concluded that Roux-en-Y gastrojejunostomy carries an increased risk of ulceration. Another example of the popularity of the Billroth II is the report by Lorusso et al on 545 consecutive patients, who underwent elective Billroth II gastric resection for ulcer. In a study of recurrent ulceration following gastrectomy for peptic ulcer Browder et al reported on 20 patients who developed ulcer recurrence more than 10 years postoperatively. Twelve patients underwent Roux-en-Y reconstruction, whereas eight patients had Billroth II reconstruction. They had good to excellent clinical results in 80% of patients. The four patients with poor outcomes shared the following characteristics: 1) H. pylori-positive status, 2) presence of a preoperative bezoar, 3) Roux-en-Y reconstruction. They stated, “Our current approach is to avoid Roux-en-Y construction.”

**Surgeons Frequently Choose the Billroth II over Roux-en-Y**

There are some reasonable criticisms of the Billroth II, but in most studies reported in the medical literature surgeons prefer the Billroth II to the Roux-en-Y. A few examples are discussed below. In a study by Pehlivanides et al 199 Roux-en-Y was selected in 6.7% vs. 24% for Billroth II. In a study from France200 the choice of surgery for cancer of the stomach was analyzed. The authors chose to randomize patients to treatment with either a Billroth I or a Billroth II procedure. The Roux-en-Y was not considered. In a study of endoscopy in patients with a Billroth II or a Roux-en-Y anastomosis 2,256 patients were admitted for endoscopy from 1990 to 1994. Of these, 65 (3%) had either an Roux-en-Y or a Billroth II, 91% had Billroth II and 9% had a Roux-en-Y. In a study of gallstones occurring after gastrectomy202 a Billroth II was performed in 251 patients (59.8%) a Billroth I in 117 (32.7%) a Roux-en-Y in 31 (8.6%) and an esophagogastronomy in 1 patient (1.9%).
In another study of endoscopy in gastrectomy patients from Germany203 87% of patients had undergone a BII and 13% had a Roux-en-Y. Although many Bariatric surgeons like the Roux-en-Y type of connection American surgeons use the Billroth II much more commonly. In the United States during 1996 there were an estimated 32.5 million hospital admissions. During that period of time there were approximately 13,000 stomach operations that required the surgeon to connect the stomach to the small bowel. Of these 13,000 patients whose surgeon had to decide how to connect the stomach to the small intestine 63% chose a Billroth II (loop) type of connection. Only 19% chose the Roux-en-Y method to connect the stomach to the small bowel and 18% chose some other method. What these data show is the vast majority of American Surgeons chose the Billroth II type of connection used in the Mini-Gastric Bypass. Studies demonstrate that, by a very large margin, the surgeons choose the Billroth II as the most commonly selected method of connecting the stomach to the small bowel.

### Laparoscopic Billroth II Today

Innovative surgeons that are adopting new laparoscopic approaches to general surgical problems are also commonly using the Billroth II.204 205 206 207 208 209 210 211 212 213 214 215 In a recent study by Azagra et al216 the authors adopted a laparoscopic approach in the treatment of both benign and malignant gastric diseases, even though laparoscopic gastric resection has not yet met with widespread enthusiasm. By April 1997, they had performed Laparoscopic Gastric Resections in 24 patients (8 presented with chronic gastric ulcer, 4 had benign pyloric stenosis, 8 were affected with recurrent duodenal ulcers no longer amenable to treatment, and 4 with persistent symptomatic biliary reflux.) The surgical procedure consisted of a Billroth II distal gastrectomy in 13 cases and Roux-en-Y gastrojejunostomy in 11. The mean duration of the procedure was 150 min (range: 120-200), and blood losses were not remarkable. No major functional sequelae were observed at a mean follow-up of 19 months (range: 2-41), apart from 2 cases of transient diarrhea. They choose the BII more often than the Roux-en-Y and concluded that laparoscopic surgery appears to be an invaluable tool for the treatment of gastric diseases and Laparoscopic gastric resections are a valid option in experienced hands and in selected centers, allowing patients to benefit from a less cumbersome hospital stay and fewer functional sequelae. In a study from Germany in the period October 1993-February 1994, they report on two Billroth-II anastomoses, one Billroth-I anastomosis combined with truncal vagotomy217. In a study from England McCoy states that peptic ulcer surgery has been revitalized by the introduction of minimal access techniques for surgery of chronic and perforated peptic ulcer. He describes the early reports of laparoscopic gastrojejunostomy and Billroth II partial gastrectomy.218 Watson reported on Laparoscopic Billroth II gastrectomy for early gastric cancer.219 Fowler and White reported on five patients who needed resection of the antrum followed by an antecolic intracorporeal gastrojejunostomy (Billroth II).220 Two patients also had bilateral truncal vagotomy, and one had a Roux-en-Y component to the gastrojejunostomy. Except for one patient who had postoperative gastric atony, there were no complications or operative mortality. Short-term follow-up ranging from 9 to 34 months has revealed one patient with recurrent ulcer symptoms, but the other four have had control of their disease. In summary, the Billroth II can be seen to be a routine form of the standard of medical care provided on a daily basis all across the world. With the new developments in laparoscopy one might expect the old Billroth II to lose its appeal but it continues to be selected for the treatment of patients who have undergone various forms of gastric surgery.

### Billroth II Patients Appear to Have Excellent Long Term Survival

Although there are some criticisms of the Billroth II many studies show excellent long-term results in Billroth II patients.221 In a study of patients who underwent partial gastrectomy for benign ulcer disease the risk of death was analyzed. A population-based cohort of 6,459 patients operated on from 1950 through 1958 was followed through 1985. In this series there was a lower overall mortality in the patients that had surgery than the general Swedish population (standardized mortality ratio = 0.94; 95% confidence interval 0.91-0.97). The mortality rate was lower among patients who had had a Billroth II operation. The mortality rate was found to be higher in the BII patients from alcoholism (implying drinking), emphysema (implying smoking), stomach ulcer (presumably the cause of the surgery) and intestinal obstruction (adhesions). The death rate was less in the BII patients from ischemic heart disease and cerebrovascular disease. This could be explained by a weight loss and decreased cholesterol levels caused by the surgery. Probable increased prevalence of risk factors for ulcer disease (smoking, alcoholism, and lower socioeconomic status) in this cohort explains most of these findings. Apart from intestinal obstruction, gallbladder or biliary tract diseases the surgical procedure did not appear to increase mortality beyond one year after operation.

In a very large scale populations based study from Sweden222 the relative risk of developing cancer after partial gastrectomy for benign ulcer disease was examined in a population-based cohort comprising 6,459 patients operated on between 1950 and 1958. Follow-up to 1983 revealed 1,112 patients with cancer versus 1,128 expected cases (relative risk 1.0 (95 per cent confidence interval 0.9-1.1). The overall risk increased over time; it was higher in younger than in older patients but was not related to sex, surgical procedure (Billroth I or II gastrectomy) or diagnosis at operation (duodenal or stomach ulcer).

### GI Tract Reconstruction after Total Gastrectomy

Schlatter carried out the first successful total gastrectomy and antecolic end-to-side esophago-jejunostomy (Billroth II) in 1897 in Zurich. Since the 1800's a large number of different procedures have been suggested as means to deal with this
problem of putting the gut back together after removal of most or all of the stomach. Early on the approach of using a Billroth II type connection to reconstruct the total gastrectomy patient was tried. This placed the bowel loop directly adjacent to the esophagus. While there had been and there continues to be great success in attaching the Billroth II loop to the lower part of the stomach, almost a century ago it was recognized that placing the bowel high on the stomach next to the esophagus led to severe esophagitis. General surgeons have known this for over 100 years. Because of these problems the creation of pouches and anti-reflux mechanisms and a variety of different types of reconstructions has been developed. More than 50 methods of gastric replacement after total gastrectomy have been used. It is clear that a “Billroth II” loop type connection next to the esophagus is not a good choice because of the severe reflux esophagitis that occurs. In total gastrectomy it is crucial to avoid bile reflux. In Total Gastrectomy the Roux-en-Y seems to be the method of choice. Many authors have reported their results with Roux-en-Y construction for bile reflux disease. An analysis of these reports suggests that about 50 per cent of patients have a favorable result, whereas the other half of patients have abdominal symptoms related to the Roux-en-Y procedure.

It is important to note that these studies are analyzing reconstructions following total or near total gastrectomy, that is complete or near complete removal of the stomach. These studies and many others like them do not recommend a Billroth II reconstruction. Studies on near total or total gastrectomy for the last 100 years clearly recognize the fact that gut reconstruction after total or near total gastrectomy should not use a Billroth II connection. On the other hand as discussed above when a smaller portion of the stomach is removed the Billroth II type connection while not perfect is the most commonly chosen type of surgical reconstruction.

**The "Old Loop" Gastric Bypass**

The Mini-Gastric Bypass has been compared to the "Old Loop" Gastric Bypass. The following figures and discussion explain the differences between the Mini-Gastric Bypass, the Standard Billroth II and the "Old Loop" Gastric Bypass.
Billroth II
The Billroth II is the most commonly performed type of connection between the stomach and the small bowel. By a margin of 3 to 1 to 9 to 1 the Billroth II is preferred over the Roux-en-Y when general surgeons choose to connect the stomach to the bowel. The Billroth II is a surgical procedure used routinely in the treatment of trauma, stomach cancer and peptic ulcers. Every year over 13,000 Billroth II surgeries are performed in America alone. In the usual Billroth II the esophagus (A) and the body of the stomach (B) are distant from the Billroth II connection. The Billroth II connects the stomach to the jejunum, the upper-middle portion of the small intestine. Like the Mini-Gastric Bypass the standard Billroth II places the connection between the stomach and the small bowel low on the stomach at the junction between the body and the antrum of the stomach (F, D). (C indicates the outside edge of stomach and E indicates the lower part of the stomach that is often removed in the usual Billroth II surgery.

Figure 1: Standard Billroth II Gastrojejunostomy.

The "Old Loop"
The "Old Loop" Gastric Bypass included a small high stomach pouch (B) that was placed high up on the stomach close to the esophagus (A). The loop (E) that carries bile was placed close to the esophagus (A) and this led to the associated problems with esophagitis that occurred in some surgeon’s experience with the "old loop" type gastric bypass. This configuration is in many ways much like the common general surgical procedure called a total gastrectomy. It is widely agreed that a total gastrectomy is not a good choice for a Billroth II reconstruction. This "old loop" is quite different from the Mini-Gastric Bypass. The "Old Loop" created a stomach pouch that was also based upon the outside edge of the stomach (B, C, D). This kind of pouch commonly stretches leading to failure of weight loss.

Figure 2: "Old Loop" Gastric Bypass

The Mini-Gastric Bypass
The Mini-Gastric Bypass does have a Billroth II type loop connection (E) like the "old loop" bypass, but the loop in the Mini-Gastric Bypass is placed low on the stomach (E) far away from the esophagus (A). This is in the same position as the loop in the standard Billroth II done for ulcers and other diseases. The Mini-Gastric Bypass creates a long narrow "gastric tube" (F) that places the connection of the stomach and the bowel low in the stomach and keeps the stream of bile away from the esophagus (A). The other advantages are that the surgery is easily accessible in the event that the surgery needs to be revised.

Figure 3: Mini-Gastric Bypass
**Gallbladder Removal**

Gallbladder removal (cholecystectomy) during obesity surgery is controversial. Some surgeons perform it routinely while others (i.e. LapBand) never remove the gallbladder at the time of weight loss surgery. Because of the risks of liver disease and of the surgery itself Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery do not remove the gallbladder at the time of the Mini-Gastric Bypass. Some of the reasons for this approach are detailed below.

**Obesity and Liver Disease**

Obesity is associated with mild to severe liver disease and studies show that liver disease increases the risk of complications and death following gallbladder removal.

**Fatty Liver**

Obesity is associated with a number of metabolic and hemodynamic risk factors for cardiovascular disease and type 2 diabetes mellitus. This risk depends on a complex of metabolic and hemodynamic consequences of (visceral) fat accumulation, which probably results from the continuous delivery of fatty acids to the liver via the portal vein. Fatty liver is a relatively common incidental finding in obese individuals. Nonalcoholic fatty liver disease is common in severely obese subjects and can progress to cirrhosis and liver failure.

Triglyceride storage in hepatocytes is another consequence of increased fatty acid supply to the liver. Until recently, hepatic steatosis was considered a harmless condition secondary to obesity or alcoholism. However, it may lead to non-alcoholic hepatic steatosis, which predisposes to liver fibrosis and even cirrhosis. The finding of fatty liver may sometimes indicate the presence of nonalcoholic steatohepatitis (NASH). NASH is a diagnosis applied to a constellation of liver findings that appear similar to alcoholic liver disease but are found in the absence of significant alcohol intake. Specific and effective treatments are needed but until the pathogenesis of this common liver disease is better understood, weight loss will remain the mainstay of treatment for obese patients.

**Nonalcoholic Steatohepatitis**

Nonalcoholic steatohepatitis (NASH) is a common but poorly understood liver disease associated with obesity. NASH is believed to be a disorder of genetic etiology and is the hepatic manifestation of syndrome X, the insulin resistance syndrome. Despite its usually benign course, 20-30% of patients may have cirrhosis and almost half of those may develop complications of portal hypertension, necessitating liver transplantation. Obesity is common in NASH patients and cirrhosis is more common in the morbidly obese. Familial clustering is common, with 18% of patients having a similarly affected first-degree relative. The clinical features that define “Syndrome X” (diabetes, hypertension, hyperlipidemia, and atherosclerotic disease) are common in NASH patients. Unsuspected diabetes or insulin resistance (the hallmark of syndrome X) is present in 85% of those tested. 1% to 2% of liver transplants are now performed because of a pretransplant diagnosis of NASH.

**Cholecystectomy Mortality Rate**

When deciding to remove the gallbladder at the time of weight loss surgery it is important to remember that all medical treatments are associated with risks. Surgery and removal of the gallbladder is no different. Large-scale studies demonstrate that removal of the gallbladder is associated with a variety of risks including death. In a study from New York State the mortality rate was more than 2 of every 1,000 patients undergoing laparoscopic cholecystectomy (0.23%) and 2% for open gallbladder surgery. In another study deaths occurred per 1,000 cholecystectomies performed. In a study from Texas there were 4 deaths in 587 patients (0.7%).

In a large study of from all 54 hospitals in Maryland the operative mortality for all cholecystectomies was between 6 and 8 deaths per 1,000 cholecystectomies performed. In another study the mortality rates were between 0.17% and 3.0% since we have operated upon over 1,300 Mini-Gastric Bypass patients, if the death rate for gallbladder removal was the same as is seen in the Maryland or New York studies there would be an additional 2 to 8 deaths in our series.

**Cholecystectomy Complications**

Complications can occur after removal of the gallbladder. In a study of 587 patients from Texas, these complications included wound infection, postoperative bleeding, persistent pain, pneumonia, retained CBD stones, asthma, papillary stenosis, ileus, and intraoperative bowel injury. Wound infection rates at after gallbladder removal can range from 2% to 6%. In a study from Texas showed that the average duration of surgery for patients with cirrhosis in one study was 1.7 hours (102.0 minutes) versus 1.6 hours (96.0 minutes) for controls. This compares to an average operative time of 30 minutes for the Mini-Gastric Bypass. The gallbladder patients had an average length of hospital stay of 6.5 days for patients with cirrhosis versus 4.8 days for control patients. That compares to an average length of stay for the Mini-Gastric Bypass of less than 1.5 days. Cirrhosis patients were more likely to need blood transfusion. Complications occurred in 6 of 48 patients.
with cirrhosis (13%) and 8 of 187 controls (4%; P < .05). This compares to a complication rate of 5% in Mini-Gastric Bypass patients.
Numerous studies demonstrate that there is a risk of common bile duct injury in patients who undergo laparoscopic gallbladder removal.

**Time, Clots and Complications**

Weight loss surgery has been known to be associated with a high risk of pulmonary embolism, a potentially lethal blood clot to the lung. The incidence of thromboembolism in one series of weight loss surgery was 2.4% (more than 2 per hundred.) Studies show that deep venous thrombosis is a major complication that occurs after laparoscopic cholecystectomy. The incidence of venous thrombosis correlates with the hemodynamic changes that occur in the venous system during pneumoperitoneum. Longer operations have been identified as a potentiating factor for the development of pulmonary embolus.

Studies have shown that air travel is a risk factor for pulmonary embolism and more recently a study showed the relation between pulmonary embolism and time of the flight. The study demonstrated that the duration of air travel is related to the risk of pulmonary embolism. The incidence of pulmonary embolism was much higher among passengers traveling on longer flights.

In summary gallbladder removal is associated with increased operative time and complications and Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not perform gallbladder removal at the time of Mini-Gastric Bypass.

**Problems of the Roux-en-Y**

Like the Billroth II, there are many general surgeons who prefer the Roux-en-Y to the Billroth. In a study from Italy, D’Amato et al. evaluated the functional results after Billroth I, Billroth II and Roux-en-Y reconstruction in subtotal gastrectomy. It was a small study including only 45 patients. They were investigated to evaluate gastro-esophageal reflux (GER) and dynamics of gastric emptying. The study showed that reflux esophagitis was found in 5 BI, in 7 BII and in 2 Roux. They found chronic superficial gastritis was present in 9 BI, in 4 BII and in 3 Roux. There was no statistical significance between assessed quality of life scores in the 3 groups. The authors concluded that in their experience the Roux-en-Y was the technique that they preferred. Enterogastric reflux is common following most ulcer operations. But attempted correction of this problem may result in other difficulties, including delayed emptying due to Roux-en-Y stasis. The literature has many studies both for and against different types of gut reconstruction methods. Although some studies support the Roux-en-Y, there are others that show major problems with its routine use. Roux-en-Y reconstruction is sometimes associated with symptoms that suggest food stasis, as a result of dysmotility of either the gastric remnant and/or the effenter jejunal limb.

**The “Roux Stasis Syndrome”**

Probably the most significant concern with the use of the Roux-en-Y reconstruction technique is the Roux Stasis Syndrome. The Roux stasis syndrome, a syndrome of nausea, vomiting, abdominal pain, and postprandial fullness that follows Roux-en-Y gastrojejunostomy, is thought to result from the jejunal transection performed during the construction of a conventional Roux limb. A number of patients who have a Roux-en-Y gastrojejunostomy suffer from abdominal pain, nausea, vomiting of food and bloating made worse by eating. This syndrome, the Roux stasis syndrome, is caused, in part, by a motility disorder of the Roux limb. Transection of the jejunum during the construction of the limb separates the limb from the natural small intestinal pacemaker located in the duodenum. Entopic pacemakers then appear in the limb and trigger retrograde contractions in its proximal portion. These contractions slow transit through the limb and result in Roux stasis. Studies also show that gut bacteria are affected by the Roux-en-Y. In a study by Schippers et al. intestinal micro flora were examined after partial gastrectomy and Roux-en-Y reconstruction in six dogs. Bacteriological analysis revealed a predominance of fecal bacteria.

Current nonsurgical treatment of the syndrome includes the use of prokinetic agents and intestinal pacing, neither of which has demonstrated long-term benefits. A near-total gastrectomy may speed upper gastrointestinal transit somewhat, but stasis in the Roux limb often persists. Kelly et al. reported that the present approach at the Mayo Clinic aims at preventing the syndrome by the use of an ‘uncut’ Roux limb (a modified Billroth II); an operation which preserves myoneural continuity between the duodenal pacemaker and the Roux limb and so prevents the appearance of ectopic pacemakers and stasis in the limb.

Another attempt at prevention of the Roux Stasis Syndrome has been less successful. In a study by Takahashi et al. an ileal Roux limb, rather than a jejunal Roux limb, was tried to prevent the Roux stasis syndrome that can occur after Roux gastrectomy. An ileal Roux limb was constructed in eight dogs and anastomosed to the gastric remnant after distal hemigastrectomy. Flow of chyme through the jejunum was preserved via an ileo-jejunalostomy and a jejunouleostomy. Six dogs with distal gastrectomy and a conventional Roux gastrojejunostomy served as a control group. Chronic enteric recording electrodes and intraluminal, open-tipped pressure catheters were implanted in all dogs. After recovery, the electrical activity and motility of the Roux limbs and the rates of gastric emptying of liquids and solids were measured. Dogs with a Roux gastrojejunostomy had a slower frequency of pacesetter potentials in the Roux limb, a greater Roux motility index,
and a faster rate of gastric emptying of liquids and solids than did dogs with a Roux gastrojejunostomy. Stomal ulcers, however, developed in seven of the eight ileal Roux limbs but in none of the jejunal Roux limbs. It was concluded that Roux gastrojejunostomy does ameliorate the Roux stasis syndrome, but there is a much greater risk of stomal ulceration in the limb.

The “Uncut Roux”: A Modified Billroth II

Because of the problems with the Roux-en-Y with stasis, bloating, pain, nausea and vomiting Dr. Kelly and others have developed the “Uncut Roux” to try and prevent this debilitating syndrome. It is believed that maintaining muscle and nerve continuity might decrease the incidence of the Roux stasis syndrome. In a study by Mon and Cullen259 the clinical results in patients who underwent an “uncut Roux-en-Y” gastrojejunostomy with patients undergoing a standard Roux-en-Y gastrojejunostomy. Eleven patients underwent gastrectomy and uncut Roux-en-Y gastrojejunostomy and were compared with a cohort of 14 patients who underwent gastrectomy and standard Roux-en-Y gastrojejunostomy. Patients were contacted and charts were reviewed for Visick grade, early and late morbidity and mortality, and incidence of staple line dehiscence. Early postoperative morbidity was 18% in patients undergoing uncut Roux gastrojejunostomy and 28% in patients undergoing standard Roux reconstruction. There were no early postoperative deaths in either group. In the patients undergoing the uncut Roux procedure, no cases of staple line dehiscence were detected clinically (mean follow-up 9 months, range 1 to 48 months). Visick grade improved following the uncut Roux procedure, but changed little after standard Roux reconstruction. Uncut Roux-en-Y gastrojejunostomy can be performed safely with improvement in symptoms. The uncut Roux procedure may provide an alternative for reconstructive gastric surgery.

In another study by Noh the “uncut Roux” was compared to the conventional Roux-en-Y gastrojejunostomy after subtotal gastrectomy. 51 patients had the conventional Roux-en-Y reconstruction and 54 patients had the new type of “uncut Roux”. The Roux stasis syndrome occurred in 19 patients (37.3%) with conventional Roux-en-Y reconstruction, and in 10 patients (18.5%) with uncut Roux-en-Y reconstruction (P = 0.03). He concluded that the “uncut Roux” operation is able to alleviate the Roux stasis syndrome as well as the alkaline reflux gastritis or esophagitis by preserving motility of the Roux limb and diversion of duodenal juice from the gastric remnant.

The “Uncut Roux” Developed to Address Problems of the Roux-en-Y

The configuration in the “Uncut Roux” from Kelly et al and the Mini-Gastric Bypass can be compared. In the “uncut Roux” the surgical technique is described below next to the description of the Mini-Gastric Bypass.

<table>
<thead>
<tr>
<th>Uncut Roux</th>
<th>Mini-Gastric Bypass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial gastrectomy</td>
<td>Division of the stomach</td>
</tr>
<tr>
<td>Connect end of stomach to side of bowel</td>
<td>Connect end of stomach to side of bowel</td>
</tr>
<tr>
<td>Staple (do not cut) upside of bowel</td>
<td></td>
</tr>
<tr>
<td>Connect side of bowel to side of bowel</td>
<td></td>
</tr>
</tbody>
</table>

The similarities are clear in the diagrams. In the event of problems with bile reflux following surgery laparoscopic revision to an “uncut Roux” would be straightforward. After establishing laparoscopic access the abdomen the proximal (upstream side of the bowel would be stapled (not cut.) The next step would be to make a side-to-side connection between the proximal and distal bowel.
The Mini-Gastric Bypass

The results of the Mini-Gastric Bypass series of weight loss surgery compare favorably with other forms of weight loss surgery. There have been two deaths in 2,700 patients for a mortality rate of 0.07%. This is comparable to other series of weight loss surgery. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s average hospital stay is 1.2 + 1.9 days. This is 5-7 days shorter than in other series. The mean operating times are 38.0 + 23 minutes again a fraction that reported for other series. The overall complication rate for the MGB is 5%. This is also ½ to 1/10 of that reported in most other series. In a series of Laparoscopic Gastric Bypasses reported by others and the complication rate was 30%. They also reported 1 death in 275 patients (0.36%) as compared to 0.07% in the MGB series. In several reports of Bariatric surgery, the expected rates of pulmonary embolus for this type of surgery has been estimated to be 1% or greater. In the 1305 people that have had the Mini-Gastric Bypass 0.07% have developed clots in their legs (Deep Vein Thrombosis) and 0.16% has had a pulmonary embolus. This is 10 times lower than seen in other series of gastric bypass. The MGB wound complication rates are remarkably low. In other series acute wound complications in Bariatric surgical patients ranges up to 15%. In a recent study from UCLA by Lee et al, the risks associated with the Roux-en-Y gastric bypass surgery in obese patients were studied. 245 consecutive patients undergoing a Roux-en-Y Gastric Bypass at UCLA were studied. There were 5 deaths (2.0%) and 38 complications (16%). There were 12 anastomotic leaks (4.9%). Other reported complications were Bowel obstruction or ileus occurred in 6 patients (2.4%), splenectomy in 3, (1.2%) Pulmonary embolus in 3, (1.2%) sepsis of unknown cause in 3, ulcer in 2 and 1.2% 10 miscellaneous complications occurred resulting in prolonged hospitalization (>1 wk). 4.1%. In several reports of the outcomes of Bariatric surgery, the expected rates of pulmonary embolus for this type of surgery has been estimated to be 1% or greater. In other series acute wound complications in Bariatric surgical patients ranges up to 15%

**Description of How the Mini-Gastric Bypass is Performed**

The Mini-Gastric Bypass is a simple, straightforward operation that is low risk and effective in getting and maintaining large amount of weight loss. To see the photographs from the surgery go to our website at [http://clos.net/op/descrptn.htm](http://clos.net/op/descrptn.htm). The steps in performing a Mini-Gastric Bypass are the following:

1. Five ports are placed in the abdomen, the liver is retracted out of the way, an Endoscopic stapler is used to “cut” / “staple” a new stomach pouch out of the old stomach, 3-6 feet of the small is bypassed, the tip of the stomach is connected to the small bowel and the connection is closed and the surgery is completed.

2. The “GIA” stapler is used to divide the stomach at junction of the body and the antrum of the stomach. Op Time: 6 minutes

3. The division of the stomach is now continued using the stapler 6 lines of staples cut and seals the new stomach pouch. Estimated Op Time: 7 minutes

4. The stomach is divided parallel to the lesser curvature (inside edge) and up to the EG junction (where the stomach and esophagus meet.) The bypassed stomach on the right and the new stomach pouch is on the left. Estimated Op Time: 10 minutes

5. The new stomach “tube” is on the patient’s right (left on the photo) and the bypassed stomach is on the patient’s left (right on the photo). Estimated Op Time: 15 minutes

6. The new gastric tube on the left and the bypassed stomach is on the right. Estimated Op Time: 18 minutes

7. The Endo-GIA stapler is used to connect the stomach and the bowel. Estimated Op Time: 22 minutes

8. The inspected. Estimated Op Time: 28 minutes

9. The stapler is used to close the anastomosis. Estimated Op Time: 32 minutes

10. The Mini-Gastric Bypass is finished Estimated Op Time: 35 minutes

11. The completed Mini-Gastric Bypass is inspected confirming position of the loop of bowel and the stomach tube.
**Process Improvement**

Numerous studies demonstrate an association between volume and outcomes. The case management/quality assurance database developed to track the outcomes of the Mini-Gastric Bypass was used to perform time series analyses of three critical outcome variables, monthly mean hospital stay, complication rate and operative times. These results are displayed graphically below. In each case the time series analysis demonstrates a steady improvement as the volume of cases increased over time. This is consistent with other studies on volume and outcomes. The shape of the curve of the time series is also of note. In each case a logarithmic curve fits the data showing that the improvement in the outcomes is greatest at the beginning of the series and the improvement continues but declines in magnitude as the series increases in size.

**CLOS and Patient Safety**

“Patient safety has become a major concern of the general public and of policymakers at the State and Federal levels. This interest has been fueled, in part, by news coverage of individuals who were the victims of serious medical errors and by the publication in 1999 of the Institute of Medicine’s (IOM’s) report To Err is Human: Building a Safer Health System. In its report, IOM highlighted the risks of medical care in the United States and shocked the sensibilities of many Americans, in large part through its estimates of the magnitude of medical-errors-related deaths (44,000 to 98,000 deaths per year) and other serious adverse events.” (http://www.ahrq.gov/CLINIC/PTSAFETY/summrpt.htm)

“The Agency for Healthcare Research and Quality (AHRQ) decide to lead in “the development and dissemination of evidence-based, best safety practices to provider organizations.” The AHRQ commissioned the University of California at San Francisco (UCSF) – Stanford University Evidence-based Practice Center (EPC) in January 2001 to review the scientific literature regarding safety improvement.”265 This study was designed to identify a set of patient safety practices that should be used by hospitals. Use of these practices can assist patients throughout the nation in evaluating hospitals and/or health care facilities.” http://www.ahrq.gov/CLINIC/PTSAFETY/summrpt.htm

“Researchers now believe that most medical errors cannot be prevented by perfecting the technical work of individual doctors, nurses, or pharmacists. Improving patient safety often involves the coordinated efforts of multiple members of the health care team, who may adopt strategies from outside health care. One of the most important uses for this report is to inform efforts of providers and health care organizations to improve the safety of the care they provide.”

“Many changes in the present medical practice have been shown to improve patient safety. Practices with the strongest supporting evidence are generally clinical interventions that decrease the risks associated with hospitalization, critical care, or surgery. Many patient safety practices drawn primarily from nonmedical fields (e.g., use of simulators, bar coding, computerized physician order entry, crew resource management) deserve additional research to elucidate their value in the health care environment. The following practices were rated most highly in terms of strength of the evidence supporting more widespread implementation.” http://www.ahrq.gov/CLINIC/PTSAFETY/summrpt.htm 266

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk;
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality;
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections;
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections;
- Asking that patients recall and restate what they have been told during the informed consent process;

In addition for patient safety, the following 12 practices rated most highly, as follows:
- Improved perioperative glucose control to decrease perioperative infections;
- Localizing specific surgeries and procedures to high volume centers;
- Use of supplemental perioperative oxygen to decrease perioperative infections;
- Changes in nursing staffing to decrease overall hospital morbidity and mortality;
- Use of silver alloy-coated urinary catheters to prevent urinary tract infections;
- Computerized physician order entry with computerized decision support systems to decrease medication errors and adverse events primarily due to the drug ordering process;
- Limitations placed on antibiotic use to prevent hospital-acquired infections due to antibiotic-resistant organisms;
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections;
- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk;
- Use of analgesics in the patient with an acutely painful abdomen without compromising diagnostic accuracy; and
- Improved handwashing compliance (via education/behavior change; sink technology and placement; or the use of antimicrobial washing substances).

http://www.ahrq.gov/CLINIC/PTSAFETY/summrpt.htm

Some approaches from fields outside health care can improve patient safety including:
• Incident reporting  
• Computerized physician order entry and decision support as a means of reducing medication errors  
• Promoting a “culture of safety”

Of the 79 patient safety techniques reviewed 47 were relevant to the clinical practice of the Centers for Laparoscopic Obesity Surgery. In 47 out of 47 areas major efforts to improve patient safety identified in the AHRQ report were active areas of effort at the Centers for Laparoscopic Obesity Surgery as well. This unequivocally demonstrated in the table below:

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident Reporting</td>
<td>The CLOS has a data driven incident reporting system</td>
</tr>
<tr>
<td>Root Cause Analysis</td>
<td>Root cause analysis is part of our quality management system</td>
</tr>
<tr>
<td>Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs)</td>
<td>CLOS uses a computer driven order entry system</td>
</tr>
<tr>
<td>The Clinical Pharmacist’s Role in Preventing Adverse Drug Events</td>
<td>In place</td>
</tr>
<tr>
<td>Computer Adverse Drug Event (ADE) Detection and Alerts</td>
<td>Implemented computer driven adverse drug detection system</td>
</tr>
<tr>
<td>Protocols for High-Risk Drugs: Reducing Adverse Drug Events Related to Anticoagulants</td>
<td>Anticoagulants are no longer used removing the risk of anticoagulant bleeding complications</td>
</tr>
<tr>
<td>Unit-Dose Drug Distribution Systems</td>
<td>Drugs are distributed in unit dose format</td>
</tr>
<tr>
<td>Automated Medication Dispensing Devices</td>
<td>Automated dispensing device in place</td>
</tr>
<tr>
<td>Practices to Improve Hand washing Compliance</td>
<td>Hand washing protocols in place</td>
</tr>
<tr>
<td>Impact of Barrier Precautions in Reducing the Transmission of Serious Nosocomial Infections</td>
<td>Closed surgery improves barrier in surgical procedures</td>
</tr>
<tr>
<td>Antibiotic Use Practices on Nosocomial Infections and Antimicrobial Resistance</td>
<td>Antibiotics used per protocols</td>
</tr>
<tr>
<td>Prevention of Nosocomial Urinary Tract Infections</td>
<td>No Foley catheters lead to reduced risk of urinary tract infections</td>
</tr>
<tr>
<td>Prevention of Intravascular Catheter-Associated Infections</td>
<td>No central venous catheters and less than 24 hours of all iv catheters leads to lower risks of catheter associated infections</td>
</tr>
<tr>
<td>Prevention of Ventilator-Associated Pneumonia (VAP)</td>
<td>Short operating times, short acting drugs lead to minimal ventilation periods</td>
</tr>
<tr>
<td>Patient Positioning: Semi-recumbent Positioning</td>
<td>All patients positioned in 60 degree head up to decrease risk of aspiration.</td>
</tr>
<tr>
<td>Localizing Care to High-Volume Centers</td>
<td>Surgery performed by high volume surgeon</td>
</tr>
<tr>
<td>Learning Curves for New Procedures</td>
<td>Learning curve long since passed.</td>
</tr>
<tr>
<td>Prevention of Surgical Site Infections</td>
<td>Short efficient closed procedure leads to lowered rates of infection</td>
</tr>
<tr>
<td>Prophylactic Antibiotics</td>
<td>Protocol antibiotics all given PreOp</td>
</tr>
<tr>
<td>Perioperative Normothermia</td>
<td>Short closed procedure -&gt; maintenance of normothermia</td>
</tr>
<tr>
<td>Supplemental Perioperative Oxygen</td>
<td>Supplemental oxygen per protocol</td>
</tr>
<tr>
<td>Perioperative Glucose Control</td>
<td>Clinical pathway maintains glucose control</td>
</tr>
<tr>
<td>Retained Surgical Sponge</td>
<td>Closed procedure – no surgical sponge</td>
</tr>
<tr>
<td>Pre-Anesthesia Checklists To Improve Patient Safety</td>
<td>Preanesthesia checklist</td>
</tr>
<tr>
<td>The Impact Of Intraoperative Monitoring On Patient Safety</td>
<td>Intraoperative monitoring per protocol</td>
</tr>
<tr>
<td>Beta-blockers and Reduction of Perioperative Cardiac Events</td>
<td>Beta-blockers used in cardiac patients per protocol</td>
</tr>
<tr>
<td>Prevention of Falls in Hospitalized and Institutionalized Older People</td>
<td>Minimal sedation/minimal pain – rapid return to ambulation</td>
</tr>
<tr>
<td>Prevention of Pressure Ulcers in Older Patients ()</td>
<td>No anticoagulants decreases risk of bleeding</td>
</tr>
<tr>
<td>Prevention of Delirium in Older Hospitalized Patients</td>
<td>Minimal sedation because of short surgery time and minimal pain</td>
</tr>
<tr>
<td>Prevention of Venous Thromboembolism</td>
<td>Short surgery, rapid return to full activity</td>
</tr>
<tr>
<td>Prevention of Clinically Significant Gastrointestinal Bleeding</td>
<td>Elimination of anticoagulants decreases risks of GI bleeding</td>
</tr>
</tbody>
</table>
### Pain Management
- **Short surgery, minimal trauma and manipulation – decreased pain.**
- **Range of pain relief: Patient controlled analgesia, supplemental parenteral and oral narcotics. Pretreatment with analgesics.**

### Promoting a Culture of Safety
- **As demonstrated in this list.**

### Information Transfer
- **Data driven research based practice**

### Information Transfer Between Inpatient and Outpatient Pharmacies
- **No hand written prescriptions. Prescriptions computer generated including detailed descriptions of justifications, risks and allergies.**

### Discharge Summaries and Follow-up
- **Computer driven discharge summaries.**

### Fatigue, Sleepiness, and Medical Errors
- **Completely focused on the care of Bariatric patients, no night call.**

### Procedures For Obtaining Informed Consent
- **Extensive preoperative education using audio and video feedback**

### Other Practices Related to Patient Participation
- **Aggressive inclusion of the patient in pre and post operative management**

### Practice Guidelines
- **All patient treated as part of a practice guideline**

### Critical Pathways
- **All patients managed on critical pathway**

### Clinical Decision Support Systems
- **Data driven clinical decision support system**

### Educational Techniques Used in Changing Provider Behavior
- **Data disseminated from DSS**

### Other Approaches to Improving Patient Safety
- **Independent reviews of outcomes and patient satisfaction.**

This report demonstrates that the Centers for Laparoscopic Obesity Surgery are following the leading efforts in the field of patient safety. Americans are highly concerned about the risks of medical errors and patients should recognize and welcome the efforts by Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery to decrease patient’s safety risks.

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**CLOS uses all Applicable Patient Safety Practices from National Quality Forum**

Patient treated by the Centers for Laparoscopic Obesity Surgery do well. They have excellent outcomes and are very satisfied with their care. The reason for the good patient safety record is the commitment by CLOS staff and physicians to patient safety. As and example, in a consensus report released May 15, 2003 by the National Quality Forum representatives of the nation’s leading health care and consumer groups publicly endorsed 30 patient safety practices that should be used in health care settings to reduce the risk of patient harm. Review of these recommendations demonstrates that CLOS is using all of the applicable recommended patient safety practices.

As an example the group recommended informing patients that they are likely to fare better if they have elective surgeries at facilities that have demonstrated superior outcomes; if they have a person who knows their medical history can speak for the patient and help ensure that the patient understands the treatment options; pay special attention to “informed consent” for surgery; and use a computerized order system are among the 30 patient safety practices in the new report, Safe Practices for Better Healthcare: A Consensus Report.

“By achieving consensus on this set of evidence-based, high-priority safe practices, NQF seeks to stimulate their universal implementation in applicable health care settings and, in turn, achieve substantial improvements in patient safety,” said NQF President and CEO Kenneth W. Kizer, M.D. The report is being released in Los Angeles at the NQF’s meeting, Safe Practices for Better Healthcare: It’s Time to Act.

The report reflects consensus among the NQF’s 173 member organizations about the need to put better systems and procedures in place to help prevent medical errors like those outlined in a landmark 1999 Institute of Medicine report. NQF’s member organizations represent all sectors of health care, including health care providers, consumers, employers, insurers, and other stakeholders. Among its members are the AARP, AFL-CIO, the American Hospital Association, the American Medical Association, the American Nurses Association, the American Society of Health-System Pharmacists, the Ford Motor Company, and General Motors.

The NQF consensus report is based in part on work by a team of researchers at AHRQ’s Evidence-based Practice Center at Stanford University/University of California at San Francisco who identified 73 patient safety practices for which there were varying levels of scientific evidence in 2001. Numerous additional candidate measures were considered, and the 30
voluntary consensus standards in the NQF report were culled from a list of 220 candidate practices based on each practice's specificity, effectiveness, potential benefit, generalizability, and readiness for implementation.

"If health care leaders work to implement this important set of voluntary consensus standards, it will go a long way toward preventing medical errors and improving patient safety," said AHRQ Director Carolyn M. Clancy, M.D. "This report, along with the findings from continuing patient safety research sponsored by AHRQ, will help make the nation's health care system a lot safer."

In addition to AHRQ, other agencies and organizations that provided funding for the report include the Centers for Medicare & Medicaid Services, the Robert Wood Johnson Foundation, the California HealthCare Foundation, the Horace W. Goldsmith Foundation, the Department of Veterans Affairs, the United Hospital Fund of New York, and the U.S. Office of Personnel Management.

A private, non-profit public benefit corporation, NQF was created in 1999 in response to the need to develop and implement a national strategy for health care quality measurement and reporting. Established as a unique public-private partnership, NQF has broad participation from more than 170 organizations that represent all sectors of the health care industry. Additional information about NQF and its projects is available at www.qualityforum.org.

CLOS is strongly committed to patient safety and our implementation of these recommended practices can be seen in the table below:

<table>
<thead>
<tr>
<th>Recommended Patient Safety Action</th>
<th>CLOS Response/Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Create a healthcare culture of safety.</td>
<td>As this table demonstrates safety of our patients is something that the staff of CLOS makes a top priority every working day.</td>
</tr>
<tr>
<td>2 For specific elective, high-risk procedures or treatments refer patients to hospitals likely to produce the best outcomes.</td>
<td>CLOS is all about high volume and the best outcomes. At CLOS bariatric surgery is all we do. It is all we think about everyday morning noon and night and our superb outcomes demonstrate the value that comes from that commitment.</td>
</tr>
<tr>
<td>3 Specify an explicit institutional protocol defining what an adequate level is of nurse staffing based on the institution's usual patient mix and the experience and training of its nursing staff.</td>
<td>Staffing at our hospitals is excellent.</td>
</tr>
<tr>
<td>4 All patients in adult general medical and surgical intensive care units (ICUs) should be managed or co-managed by physician specialists having specific training caring for the critically ill and who are board-certified in critical care medicine (i.e., intensivists).</td>
<td>ICU care is necessary in less than 0.5% of our patients and is always performed in concert with consulting specialist.</td>
</tr>
<tr>
<td>5 Encourage each adult to designate a person who (1) knows that patient's medical history and his/her treatment preferences; (2) can speak for the patient when he/she is not able to do so; and (3) can otherwise help ensure that the patient understands his/her treatment and, thus, gets appropriate treatment.</td>
<td>CLOS always requires the patient to be accompanied by a knowledgeable and informed patient advocate who knows the patient's preferences and can speak for the patient.</td>
</tr>
<tr>
<td>6 Pharmacists should participate in all stages of the medication use process, including transcribing of prescriptions, dispensing, and reviewing of new orders before administration.</td>
<td>Our pharmacists participate in all drug selections and we use only standardized abbreviations and all drugs are ordered as both their generic and proprietary trade names.</td>
</tr>
<tr>
<td>7 Verbal orders should be read back to the prescriber—i.e., a caregiver receiving a verbal order should read and repeat the information that the prescriber conveys for the purpose of verifying the accuracy of what was heard.</td>
<td>Verbal orders are used at the very minimum and are repeated back.</td>
</tr>
<tr>
<td>8 Use only standardized, accepted abbreviations and dose designations.</td>
<td>We use only standardized abbreviations and all drugs are ordered as both their generic and proprietary trade names.</td>
</tr>
<tr>
<td>9 Do not prepare patient care summaries or other records from memory. The original source documents (i.e., laboratory or radiology reports, medication administration records, etc.) should be in the transcriber's immediate possession and be visible when it is necessary to transcribe information from one document to another.</td>
<td>All patient documentation is computer driven and meticulously checked.</td>
</tr>
<tr>
<td>10 Ensure caregivers have access to the complete medical record to verify the medications have been ordered or have</td>
<td>We provide our caregivers with one of the most extensive and complete medical records of any</td>
</tr>
<tr>
<td>Step</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td>11</td>
<td>Transfer information, especially changes in recommendations, important and new diagnostic information, etc., is transmitted to all of the patient's caregivers, including outpatient caregivers.</td>
</tr>
<tr>
<td>12</td>
<td>Present informed consent forms in a “user friendly” manner to patients, and where appropriate, parents, guardians and/or families.</td>
</tr>
<tr>
<td>13</td>
<td>Written documentation of the patient’s preference for life-sustaining treatments (including preference for resuscitation, intravenous fluids and nutrition) should be prominently displayed in his or her chart.</td>
</tr>
<tr>
<td>14</td>
<td>Implement a computerized prescriber order entry (CPOE) system.</td>
</tr>
<tr>
<td>15</td>
<td>Patients should maintain a list of current medications and their intended purpose and any medications that they are allergic to or have had idiosyncratic reactions or other untoward reactions to in the past.</td>
</tr>
<tr>
<td>16</td>
<td>Implement a protocol to prevent mislabeling of radiographs.</td>
</tr>
<tr>
<td>17</td>
<td>Implement standardized protocols to prevent wrong site procedures or wrong patient procedures.</td>
</tr>
<tr>
<td>18</td>
<td>Evaluate each patient undergoing elective surgery for his/her risk of acute ischemic cardiac event during surgery and provide prophylactic treatment of high cardiac risk patients receiving anesthesia with beta-blockers.</td>
</tr>
<tr>
<td>19</td>
<td>Upon admission, each patient should be evaluated for his/her risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.</td>
</tr>
<tr>
<td>20</td>
<td>Upon admission, and periodically thereafter, each patient should be evaluated for his/her risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Clinically appropriate methods to prevent DVT/VTE should be utilized.</td>
</tr>
<tr>
<td>21</td>
<td>Implement dedicated anti-thrombotic (anticoagulation) services that ensure coordinated care management.</td>
</tr>
<tr>
<td>22</td>
<td>Upon admission, and periodically thereafter, each patient should be evaluated for the risk of aspiration.</td>
</tr>
<tr>
<td>23</td>
<td>Rigorously adhere to known methods of preventing central venous catheter-related infections.</td>
</tr>
<tr>
<td>24</td>
<td>Each patient should be evaluated in light of his or her planned surgical procedure for the risk of surgical site infection, and appropriate antibiotic prophylaxis and other preventive measures should be implemented based on that evaluation.</td>
</tr>
<tr>
<td>25</td>
<td>Utilize validated protocol to evaluate patients who are at risk for contrast-induced renal failure, and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.</td>
</tr>
<tr>
<td>26</td>
<td>Upon admission, and periodically thereafter, each patient should be evaluated for his/her risk of malnutrition. Clinically appropriate strategies should be employed to prevent malnutrition.</td>
</tr>
<tr>
<td>27</td>
<td>Whenever a pneumatic tourniquet is used, the patient</td>
</tr>
</tbody>
</table>

N/A

N/A
should be evaluated for the risk of ischemic and/or thrombotic complications, and appropriate prophylactic measures taken.

28 Decontaminate hands between each patient encounter to prevent person-to-person transmission of infections.

29 Healthcare workers should be vaccinated against influenza to protect themselves and patients from influenza.

30 Keep workspaces where medications are prepared orderly, well lit, and free of clutter, distraction and noise.

31 Standardize the methods of packaging, storing, and monitoring of medications.

32 Identify all “high alert” drugs in use at the care setting. Designate protocols, guidelines, dosing scales and/or checklists for each “high alert” drug and, communicate this information to all relevant caregivers.

33 Dispense medication in unit-of-use packages

CLOS uses an aggressive approach to hand washing and the success is seen in our wound infection rate of less than 0.1%
Per protocol
Pharmacy pays special attention to work spaces and preparation
Medications and their uses are standardized
All meds for CLOS are part of the clinical practice guideline.

CLOS uses unit dosing

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**Patient Satisfaction**

One of the most important procedure performance indicators is patient satisfaction. The Medicare Office of the Inspector General performed a survey to determine and compare Medicare beneficiary satisfaction with selected outpatient surgical and diagnostic procedures in ambulatory surgical centers (ASCs). The procedures were cataract extraction with intraocular lens implant, upper gastrointestinal endoscopy, colonoscopy and bunionectomy. To assess the quality of care and medical necessity of selected outpatient surgical procedures, the Office of Inspector General (OIG) conducted interviews with beneficiaries and physicians and undertook a medical and financial review of Medicare beneficiary records. They administered a telephone survey to a national sample of Medicare beneficiaries who underwent cataract surgery, upper gastrointestinal endoscopy, colonoscopy and bunionectomy between January and March 1988. They completed interviews with 807 beneficiaries. One of the questions asked was “How would you rate the doctor who performed the procedure?” The results are shown below.


<table>
<thead>
<tr>
<th>Rating</th>
<th>Rating</th>
<th>Number of Responses</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>5</td>
<td>449</td>
<td>56%</td>
</tr>
<tr>
<td>Very Good</td>
<td>4</td>
<td>248</td>
<td>31%</td>
</tr>
<tr>
<td>Good</td>
<td>3</td>
<td>68</td>
<td>8%</td>
</tr>
<tr>
<td>Fair</td>
<td>2</td>
<td>14</td>
<td>2%</td>
</tr>
<tr>
<td>Poor</td>
<td>1</td>
<td>15</td>
<td>2%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>-</td>
<td>6</td>
<td>1%</td>
</tr>
<tr>
<td>No Answer</td>
<td>-</td>
<td>7</td>
<td>1%</td>
</tr>
</tbody>
</table>

As part of the MGB Quality Assurance - Case Management System continuous performance analysis is evaluated by surveying patient’s opinions about Dr. Rutledge. Patients are asked to rate Dr Rutledge’s Professional knowledge & technical capabilities, Ability to explain things understandably, Responsiveness to patient concerns, and Amount of time spent with patients, his friendly and caring approach (bedside manner) and his Capacity for gentleness. Each quality was rated from 5 to 1 as Very High = 5, High = 4, Average = 3, Low = 2, Very Low = 1.

Patient satisfaction profile for Professional knowledge & technical capabilities, ranked highest at 4.92 + 0.3. Ability to explain things understandably next at 4.83 + 0.43. Capacity for gentleness and Friendly and caring approach (bedside manner) were ranked next at 4.61 + 0.67 and 4.6 + 0.69 respectively. Each was rated as very high or excellent. The characteristics “Responsiveness to my concerns” and “Amount of time spent with me” were ranked as very high at 4.44 + 0.83 and 3.93 + 1.05 respectively [Figure 6]

Outcomes: Patient Satisfaction

<table>
<thead>
<tr>
<th>Professional knowledge &amp; technical capabilities</th>
<th>Rating of Dr. Rutledge</th>
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<tbody>
<tr>
<td></td>
<td>4.92 + 0.3 Very High</td>
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<tr>
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</tr>
<tr>
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<td>3.93 + 1.05 High</td>
</tr>
<tr>
<td>Friendly and caring approach (bedside manner)</td>
<td>4.6 + 0.69 Very High</td>
</tr>
<tr>
<td>Capacity for gentleness</td>
<td>4.61 + 0.67 Very High</td>
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Independent Review Confirms High Levels of Patient Satisfaction

The outcomes of MGB have been certified by an independent nationally recognized Certified Public Accounting firm. The firm has extensive contracts and experience performing patient follow up and satisfaction surveys and consultations for numerous North Carolina Hospital corporations. The firm was engaged to perform an objective and unbiased review of patient satisfaction in my laparoscopic gastric bypass patients. The findings of the short-term satisfaction survey conducted at the time of discharge by Dr. Rutledge and the long-term audit conducted by independent reviewers from the CPA firm are consistent. The patients continue to be satisfied with the experience as well as the outcome even after several months have passed.

The primary reasons for undergoing the mini gastric-bypass expressed by the patients were health status improvement along with weight loss. Both goals were consistently satisfied in the population surveyed. The overall satisfaction score was reported by 100% of the patients at a level 5, which is the highest level possible even after several months post operatively. All of the patients surveyed said they would recommend this surgery with this doctor to family and friends.

Value: A Comparison of the Dr. Rutledge’s Series of Mini-Gastric Bypass to National Outcomes

The results with laparoscopic Mini-Gastric Bypass show it to be a high value cost effective therapy for morbid obesity. In a comparison of the costs and resource utilization of my series of laparoscopic gastric bypasses to national averages my results appear better than the national results at every level. Weighted national estimates from HCUP Nationwide Inpatient Sample (NIS) were obtained from the Agency for Healthcare Research and Quality (AHRQ), based on data collected by individual states and provided to AHRQ by the states.

Total number of weighted discharges in the U.S. based on HCUP NIS = 35,406,187 inpatient hospital admissions. For ICD-9-CM Procedure Code 44.31 Gastric Bypass, there were a total of 6,803 discharges.

The mean length of stay was 4.5 days for the national series of gastric bypass patients and the mean hospital charges were $18,504.00.

In the national series there were 23 same-hospitalization deaths (0.34%). In comparison in my series of the over 1,200 laparoscopic gastric bypass there was one death (0.07%) the hospital stay was 1 day in over 90% of patient (mean 1.2 days.) Hospital charges were less than 50% of the national norm. These advantages flow from the minimally invasive nature of the surgery.

Problems with Follow up After Bariatric Surgery:

Surgeons, hospitals and biomedical corporations have a vested interest in patient outcome analysis and assessment of medical treatment effectiveness. One of the key features of the assessment of the value and the quality of the surgical procedure is attention to patient follow up. Numerous academic research studies show that follow up of Bariatric surgical series are very poor. As an example, in a study of 24 patients undergoing obesity surgery reported by Sugerman et al269 five patients were lost to follow-up (21%). In a study of 332 patients undergoing Roux-en-Y gastric bypass forty-five were lost to follow-up (14%). In a study of 36 VBG patients by Field et al271 twenty-five patients were available for follow-up (31% lost to follow up.) In a sample of 22 selected patients we obtained immediate follow up contact and documentation of good outcomes in 21 with in 48 hours of the request (95%). Further documentation of the poor follow up in Bariatric surgery comes from the International Bariatric Surgery Registry.

Follow Up in the International Bariatric Surgery Registry

The International Bariatric Surgery Registry (IBSR) is a national Bariatric database designed to promote optimum care of patients undergoing surgical treatment of severe obesity by functioning as a national and international standard data source. Development of the centralized IBSR database has provided standardized clinical data for comparison purposes. The results are used to study patient selection, practice variation, and operative techniques in surgical treatment of obesity. One of the reports available from the IBSR is a standardized follow-up rate report. These rates are calculated to allow surgeons the ability to determine the completeness of their data. Members may compare their rates with the pooled reports. In the figure below we can see that the average follow up rate in this national registry database is less than 20% at three years.

In another study by Mason follow up was reported as patient contact or beyond a specific time point. In this report he found 65.9% at 6 months, 1 year = 52.1%, 2 y = 29.8%, 3y=18.8%,272 273 Much is written about the importance of follow-up in determining the effect of surgical treatment for obesity upon weight loss. When patients are lost to follow-up, it has been suggested that these patients should be considered as failures.274 In a study by Oria275 he stated “Perhaps the most difficult problem in evaluating results of obesity surgery is the lack of standards for comparison, and the absence of consensus among professionals in definitions, classifications, and standard systems for reporting results.”
**Follow Up Process after the Mini-Gastric Bypass**

The Mini-Gastric Bypass program includes a very extensive commitment to follow up care. From the first patient contact through long term follow up attention is constantly paid to careful and continuous follow up of patients following surgery. The patient must recognize that an operation upon the stomach and upper digestive tract is a serious undertaking with both known and unknown long-term risks that are described by Dr. Rutledge and others. These include but are not limited to, ulcers, reflux, inadequate or excessive weight loss, hair loss, serious vitamin and mineral deficiencies and many other known and unknown problems detailed here and elsewhere. As a result patients must make a firm and legal commitment to fulfilling Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s instructions for long term follow up. You must agree to make every effort to follow up closely with the office and to follow post op directions to protect yourself from these and other problems associated with the bypass. Following surgery patients must agree to not leave the area following surgery for 7 days after surgery and until you have been seen in Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic and have been approved for discharge from the area. Patients must agree preoperatively to return to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic at 1, 3 and 6 months following surgery and every year thereafter for evaluation and further education. In only the most extraordinary circumstances when patients cannot under any circumstances reach Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic patients may try to make arrangements to have an appointment with their local medical Doctor’s clinic and with his/her approval complete that follow up visit with your local medical doctor. In that unusual event, patients must agree to make certain that the medical doctor forwards copies of their clinic visit to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery. Patients must understand and agree that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery expects them to return to his clinic for follow up and it is only in the most unusual circum stances that patients will miss these appointments. Patients must also promise to go to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s web site at [http://clos.net/ff2.htm](http://clos.net/ff2.htm) and complete the “Patient Follow up Form” monthly after surgery. Patients must agree to alert Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s office of any changes in my address, telephone numbers, and email address or health status.

**Weight Loss**

The weight loss following surgery has been reassessed on a continuing basis and remains relatively constant. One of the critical success factors of the surgery is obviously weight loss. Weight loss after MGB is excellent. In a study by Lise et al276 of 111 patients undergoing Stoma Adjustable Silicone Gastric Banding (SASGB) the mean preoperative body weight was 284 lbs and this decreased to 222 lbs. at one year, a loss of 62 lbs. In a study by Choban et al277 the weight change for patients undergoing the Open Roux-en-Y gastric bypass was from 306 + 8 lb. preoperatively to 211 + 55 lb. at one year (95 lbs.) The Mini-Gastric Bypass appears to have comparable weight loss.

**Relief of Associated Medical Illness**

Medical illness was common in patients prior to surgery: As reported in other series of weight loss surgery, resolution of the obesity associated medical illnesses was over 70 - 90% in all cases.

**Leak**

Leak is one of the most feared complications of gastric bypass. It can be protean in its manifestations and lethal if not treated expeditiously. In this series of Mini-Gastric Bypass the overall rate of leaks was 1.5%. This rate declined markedly throughout the series. This rate compares favorably to other reported series. In a series of Lap Roux-en-Y 24 leaks occurred in 1,789 Roux-en-Y Gastric Bypasses (1.3%). There was one death 4.2%.278

**Pulmonary Embolism**

In the study referred to above by Wu et al (Wu EC, Barba CA University of Connecticut School of Medicine, Saint Francis Hospital and Medical Center, Department of Surgery, Hartford, CT, 06105, Current Practices in the Prophylaxis of Venous Thromboembolism in Bariatric Surgery. Obesity Surgery 2000 Feb; 10(1): 7-14), 279 ASBS members were surveyed to determine the incidence of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). In that study there was a self-reported incidence of 2.63% rate of DVT and a 0.95% rate of PE. In Wu’s survey, 48% of respondents had at least one death due to PE. If these comparisons are accurate, the rate of DVT and PE in the Mini-Gastric Bypass are far below those seen in other types of weight loss surgery. This low rate of DVT and PE may be related to the very short operative times, low levels of pain, and early mobilization of patients following the Mini-Gastric Bypass. Prophylactic Greenfield filter placement
has been advocated in morbidly obese patients because of the fear of pulmonary embolus. In a study by Greene et al280 of Greenfield filters placed over three years, the average cost was $4,141.00.

**Incisional Hernias**

Incisional hernia is a serious complication of abdominal surgery. Incisional hernias are frequently reported complications following most types of open weight loss surgery. In the series reported by Brolin282 229 patients were randomized to PDS or Ethibond wound closure. Two of 109 the Ethibond patients had a wound dehiscence. There were 20 incisional hernias (18%) in the Ethibond group and 11 hernias (10%) in the PDS group. In a series reported by Sugerman et al283 incisional hernia occurred in 29% (18/98) of his Gastric Bypass patients. In the present series of 1314 patients, there were no incisional hernias. If the rate of hernias was as high as that seen in other series, then one could have expected several hundred cases of incisional hernias.

In a study by DeMaria and Sugerman284 39 consecutive patients undergoing laparoscopic open ventral hernia repair were compared. The total hospital costs for the laparoscopic repair was $8,273 + $2,950 vs. $12,461 + $5,987 for the open cases. Thus the minimally invasive Mini-Gastric Bypass appears to have a significant advantage in protecting patients from the major risk and costs of subsequent ventral hernia repair that occurs so frequently following open surgery.

**Internal Hernia and Bowel Obstruction**

There is mounting concern that internal hernia formation after laparoscopic Roux-en-Y gastric bypass for morbid obesity remains unrecognized until complications develop. The additional bowel anastomosis required to perform the Roux-en-Y adds to the risk of postoperative internal hernia and bowel obstruction. Studies suggest that patients who undergo laparoscopic Roux-en-Y Gastric Bypass are at a 5 per cent risk for developing small bowel obstruction secondary to internal hernia formation. Edward Felix, MD, medical director of the California Institute of Minimally Invasive Surgery, Fresno, said internal hernia has been a recurrent problem in his own series of Lap Roux-en-Y patients regardless of the type of suturing. In a study reported by Dr. Higa, MD, director of bariatric services, Valley Surgical Specialists, Fresno, Calif. colleagues studied the rate of hernia in 2,000 consecutive patients who underwent laparoscopic Roux-en-Y gastric bypass (LRYGP) between February 1998 and October 2001. Sixty-three patients (3.1%) developed 66 internal hernias. The site of internal hernia varied: 44 occurred at the mesocolon, 14 at the jejunal mesentery and five at Petersen’s space. Preoperative small bowel series and/or CT scan were normal in 20% of patients who were later found to have herniation. Although most patients were symptomatic, 5% of hernias were incidental findings at the time of another surgical procedure. The negative exploration rate is approximately 2%.

In a study from Pennsylvania285 a total of 246 patients underwent Laparoscopic Roux-en-Y Gastric Bypass. A total of 62 patients (25.2%) developed 64 complications. Intestinal obstruction occurred in 7.3% of patients. The intestinal obstruction was secondary to adhesions (n = 6), internal hernia at the level of the transverse mesocolon (n = 3), jejunoojunalostomy stricture (n = 3), and cicatrix around the Roux limb at the level of the transverse mesocolon (n = 3). Other complications included gastrojejunostomy leak (1.6%), symptomatic gallstone disease (2.8%), and gastric remnant perforation (0.8%). In a study from Texas286 100 patients who underwent laparoscopic Roux-en-Y gastric bypass 11 patients had late complications: 5 patients with small bowel obstruction, all due to herniation through the transverse colon mesentery. In a study from Georgia five patients out of 100 were diagnosed with postoperative internal hernia formation. The average time interval to presentation was 104 days. In a study from Virginia287 the reported rate of post operative bowel obstruction was 4.0%. In contrast to these reports of internal hernia and bowel obstruction our series of the Mini-Gastric Bypass there have been no cases of internal hernia or bowel obstruction. l The Mini-Gastric Bypass had a bowel obstruction rate of 4% we would have had 71 patients with bowel obstruction and internal hernias.

**Revision: "Exit Strategy"**

Surgical treatment of obesity often fails. In a study of 125 vertical banded gastroplasty patients a staple-line disruption was observed in 34 cases (27.2 %).288 In 23 cases weight regain occurred, in one case failed to lose weight and in 12 cases the excess weight loss (EWL) was less than 30%. Consideration of any surgical treatment of obesity should also include an evaluation of the operation’s "Exit Strategy," i.e. how the operation can be revised or reversed and what are the revision's associated risks and complications. Revision rates of up to 20-40% are reported with some forms of weight loss surgery because of excessive weight loss, severe unresponsive anemia, persistent nausea and vomiting, unsatisfactory weight loss resulting from staple line disruption, pouch dilatation, and/or stomal enlargement and other problems289, 290, 291. Studies show that the morbidity and mortality are higher for revision than primary surgery292. In a series reported by Champion63 patients undergoing laparoscopic gastric bypass one developed a marginal ulcer and ultimately was reversed (1.6%).294 Lovig et al295 reported a five-year follow-up of 174 morbidly obese patients with gastric banding performed between 1981 and 1985. In their series 48 patients (28%) had 60 late complications requiring 26 reoperations (14.9%). In a series of 170
patients undergoing Bilipancreatic Diversion followed for 7 years the re-operation rate because of these side effects was 7% to 296.

Even newer types of surgery such as the silicone band types of surgery have revision rates of up to 10% to 297 to 298. Miller and Hell299 performed 102 adjustable silicone gastric bandings and 54 Swedish adjustable gastric bandings. They report that the late complications that required reoperation were two pouch dilations (1.3%), three band leakages (2%), one band migration (0.6%), and one late infection of the port (0.6%). Band removal was necessary in one patient because of an esophageal motility disorder. The overall reoperation rate was 7%. This is ten times higher than the 0.6% rate reported in this series of Mini-Gastric Bypass \textit{patients}. In a series of 391 patients undergoing laparoscopic adjustable silicone gastric banding reported by Abu-Abid and Szold a total of 26 (6.4%) reoperations were performed.300 In a series of 40 Lap-Band patients reported by Angriani et al301 8 of 40 patients who underwent laparoscopic adjustable silicone gastric banding experienced proximal gastric pouch dilation (18%) or band dislocation (3%). Band removal was performed in 3 patients with pouch dilation (8%), while in 4 the pouch dilation was successfully treated with deflation of the band. Two patients (5%) were treated with band repositioning. In a study by O'Brien et al302 prolapse of the stomach through the band occurred in 27 of 302 patients (9%). These reported rates of revision are much higher than the revision rate in this series of Mini-Gastric Bypass \textit{patients} (revision rate of 0.5%). From these data it appears that the Mini-Gastric Bypass has a revision rate that seems much lower than that reported for other forms of weight loss surgery. In addition, the reports of greatly increased risks after revision of other forms of weight loss surgery do not appear to be present in the Mini-Gastric Bypass. Revisions of the MGB were easily performed in an hour or less.

**Esophagitis**

Some Bariatric surgeons have raised concerns about the Mini Gastric Bypass operation. They are concerned that it is a laparoscopic return to an operation that was discredited many years ago. Specifically, performing a loop, rather than a Roux, anastomosis to the upper pouch of a gastric bypass will permit bile reflux and the occurrence of bile esophagitis. Esophagitis is a well-described complication of several types of weight loss surgery. In a study by Westling303 of 90 patients undergoing Silicone-adjustable Gastric band 32 patients (35%) were re-operated upon. Erosive esophagitis was the cause requiring reoperation in 14 patients (16%). In a study by Ovrebo304 of gastric banding with respect to post surgical gastroesophageal reflux. The prevalence of acid regurgitation among patients treated with gastric banding increased from 13% preoperatively to 69% following surgery. Acid inhibitors were needed in 81% of patients. The incidence of gastroesophageal reflux increased markedly after gastric banding. In a study of 159 patients after vertical banded gastroplasty 55 of the 159 patients complained of upper gastrointestinal symptoms such as vomiting (72%), esophageal reflux (17%), and epigastric pain (3%). Stenosis of the outlet of the gastric pouch was described in 40 of the 55 symptomatic patients. Esophagitis was observed in 60% of these patients305. In a study of 185 laparoscopic adjustable silicone gastric banding cases there were eight cases (4%) of esophagitis306. These and other studies show that esophagitis is a significant risk in many types of weight loss surgery.

**Marginal Ulcer**

In this series the rate of marginal ulcer following surgery was 5%. One person had a perforated marginal ulcer. All others cases were managed with Proton Pump Inhibitors (PPI) and Carafate. Four cases that failed PPI and Carafate therapy responded to treatment with anti-H. Pylori therapy. This compares favorably to the experience of Capella and Capella307. In their series the incidence of marginal ulceration ranged from 5.1% to 8.5% in differing types of Roux-en-Y gastric bypass. These rates of marginal ulcer are higher than that seen in the Mini-Gastric Bypass. In another series reported by Sapala et al308 they state, "Marginal ulceration after Roux-en-Y gastric bypass (Roux-en-Y Gastric Bypass) is a well-recognized complication. Its incidence varies between 1% and 16%." The factors they identify that are associated with the development of marginal ulceration include: pouch size, pouch orientation, staple line integrity, and mucosal ischemia. Nonsteroidal anti-inflammatory drugs (NSAIDs) and Helicobacter pylori may also contribute to marginal ulceration. In a series by Fox et al.309 the reported rate of marginal ulcer was 12%. Again these reports suggest that the ulcer rate seen in the Mini-Gastric Bypass is as good as or better than that seen in patients undergoing Roux-en-Y types of bypass procedures.

**Mortality Rate**

Studies show that in patients who die after Roux-en-Y gastric bypass, half die due to technical complications, the other half die of complications related to their obesity. Only 20% of patients are suspected to have pulmonary emboli, yet at autopsy, 80% of Roux-en-Y deaths had pulmonary emboli. Fifty percent of deaths in one study were directly attributable to technical complications. One patient died of cirrhosis and one of pulmonary hemorrhage. Three patients died from pulmonary embolism. However, 80% of patients had evidence of pulmonary emboli, despite prophylaxis for deep vein thrombosis. Most patients had some degree of steatohepatitis and hepatic fibrosis (80% and 70%, respectively). There were no deaths from primary cardiac events.310 To date there have been two deaths in the 30 days following surgery for the Mini-Gastric Bypass. In our series of 2700 patients that is a mortality rate of 0.07%. In a recent study from California with in 1,500 patients undergoing the Roux-en-Y Bypass...
laparoscopic gastric bypass the overall complication rate was 14.8% and the death rate was 0.2%.311 In another study the mortality rate of Laparoscopic Roux-en-Y was 0.9%.312 In a report that estimated the national rates of mortality in the US.313 They identified all bariatric procedures (n = 12,203) performed on adults from 1990 to 1997 in hospitals participating in the Nationwide Inpatient Sample. They then applied sampling weights and United States Census data to calculate the national population-based rates of bariatric surgery procedures for each year. The in-hospital mortality was 0.37%. In a study from Loyola the death rate was 1% in a series of open Roux-en-Y patients.314 In a study from New Jersey the reported death rate ranged from 0.4 to 5%.315 In a study from UCLA the reported mortality rate was 1.3%316 In a study of the past 40 years the reported death rates varied from 0-1.5%.317 A recent article reported in the New England Journal of Surgery investigated deaths in gallbladder surgery.318 The overall state wide death rate after gallbladder surgery in Maryland was 0.56% or about 7 times higher than the death rate in the series of Mini-Gastric Bypass patients who are at greatly increased surgical risk because of their obesity and their associated medical illnesses (ASA II-III) and are undergoing a significantly more complex surgical procedure.

In a study by Hannan et al the mortality for patients undergoing laparoscopic and open cholecystectomy in New York State was evaluated.319 The study demonstrated that the mortality rate was lower for laparoscopic cholecystectomy than for the open procedure (0.23% vs. 1.9%), but both of these death rates are higher than the death rate for Mini-Gastric Bypass (0.07%).

In a pooled analysis of reports of patients undergoing laparoscopic Nissen fundoplication published between 1991 and 1995, Perdikis et al320 calculated a mortality rate of 0.2% among 2,453 patients. In a similar analysis for reports on conventional antireflux surgery published between 1980 and 1993, Dent321 identified 4 deaths among 1,152 patients, yielding a mortality rate of 0.35%. The only available population-based data on morbidity and mortality of antireflux surgery are in a report from Finland that included 3,993 open and 1,162 laparoscopic procedures performed in 1987-1996 and found mortality rates of 0.18% and 0.09%, respectively. 322 In each of these cases the mortality rate in the present series of gastric bypass patients is lower than for the much less complex laparoscopic Nissen fundoplication surgery.

In one series the mortality rate was 1.5%.323 In another series of 212 gastric bypass patients there were four postoperative deaths (1.9%)324 and three late deaths. There were 13 anastomotic leaks (6%). 18% had complications. In the series reported Smith et al325 Of 3,855 patients undergoing Roux-en-Y gastric bypass for morbid obesity between 1988 and 1994 the operative mortality was 0.18%. In a study by Baltasar326 of Biliopancreatic Diversion and Duodenal Switch in 23 patients there was one death (4.5%). In a study by Hess327 of 440 patients undergoing Biliopancreatic diversion combined with the duodenal switch there were 2 deaths (0.45%). It has been reported that patients with respiratory insufficiency have a higher operative mortality than patients without pulmonary dysfunction (2.4% vs. 0.2% respectively) after gastric bypass.328 In a study of Diabetics undergoing gastric bypass the mortality rate over the course of the study was 28% in the unoperated patients compared to 9% in the bypass group (including perioperative deaths).329 The mortality rate of 0.07% in Mini-Gastric Bypass patients comparable to that reported in other series of weight loss surgery.

**Hospital Stay: Outpatient Weight Loss Surgery**

Hospital stay is not a perfect measure of outcome but it is valuable as it rolls a variety of different process measures into one measure.

The time series analysis show that Hospital Stay improved over time.

Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s patient profile for length of stay appears to be as good as or better than other reported results in weight loss surgery.

In this study the mean length of stay was 1.2 days. Fifteen patients have been discharged on the day of surgery. In one study the average length of stay for patients hospitalized in 1994 was 3.6 days. 330 In another331 the average length of stay was 7.4 days. In another332 the hospital stay was 3 versus 4 days for vertical banded gastroplasty and distal gastric bypass respectively. The hospital stay reported for the Fobi operation is “usually 4 days”333.

**Operative Times**

In the series from Smith et al334 the average operating time was 78 minutes. In a study by Eriksson et al the mean operating time was 128 minutes.335 Chua reported a mean operating time of 202 min for laparoscopic vertical banded gastroplasty.336 In the study by Nguyen et al337 the operative times for laparoscopic and open Roux-en-Y procedures were 246 + 70 minutes for laparoscopic Roux-en-Y and 294 + 79 minutes for open Roux-en-Y. In a series reporting laparoscopic gastric banding the mean operative time was 106 + 8 minutes.338 In a series of open and laparoscopic adjustable silicone gastric bands the mean operative times were 150 minutes for laparoscopic vs. 76 minutes for open.339 In a series of LapBand patients the operating time was 65 minutes.340 The Mini-Gastric Bypass appears to have a relatively short operating time. As a comparison in the two studies below the operating times of laparoscopic cholecystectomy were reported. In the first study the average duration of surgery was 80 minutes (40-160 minutes). In the second study the duration of anesthesia was 118 minutes. In another study the mean +/- SD operating time was 66.5 + 20.5 min.341
Quality of MGB

The quality and performance of the Mini-Gastric Bypass program is good. In a recent study all of the 418 members of the American Society for Bariatric Surgery were surveyed. The reported yearly number of Bariatric procedures done by each member ranged from 5 to 325, with a mean of 85 surgical procedures per surgeon per year. This volume may account in part for the good results seen in this series.
Standard PreOp Medications for the Mini-Gastric Bypass

The Surgeons of the Centers for Laparoscopic Obesity Surgery
NOTE: Product Substitution is permitted

Milk of Magnesia (Magnesia; Magnesium Hydroxide)
Milk of Magnesia is a laxative to be taken one time on the morning of the day before your surgery early in the morning. The time before the drug begins to work is 30 minutes to 3 hours. Milk of Magnesium is designed to help clean out your colon prior to the operation and make both the surgery and your recovery a little easier. (Note: The Milk of Magnesia is to be taken on the day before your surgery not on the same day of your surgery.)
Label: 60 ml (4 tablespoons) in 1 dose the morning of the day before surgery.
When: The Morning of the day before surgery.

Chlorhexidine, (Hibiclens®)
Shower, (NOT including your hair) twice, once the evening before surgery and again the morning of surgery. This decreases your chances of infections. (Note: Please do not shampoo your hair with Hibiclens and avoid getting it in your eyes or ears.) Chlorhexidine can damage the middle ear (It would be hard to get it there) Corneal injury, including temporary and long term corneal ulceration and corneal swelling has been observed following ocular exposure to Hibiclens, where Chlorhexidine is the active ingredient.
When: The night before surgery and again the morning of surgery.

Prilosec OTC (omeprazole) Non Prescription
Blocks acid production and is used to treat ulcers, heartburn and other conditions caused by too much acid in the stomach. Prilosec OTC (omeprazole) works by reducing the secretion of your stomach acid. This makes your surgery and anesthesia safer. Nexium, Prilosec, Aciphex or Prevacid are all acceptable substitutes.)
Dispense: 2 Boxes 14 tablets 20 mg.
Label: Take one tablet on the night before surgery at 9-11 p.m. and another one tablet on the morning of surgery
When: The night before surgery and morning of surgery.

(Note: We No Longer Use Protonix® (pantoprazole sodium.) We have switched to the over the counter version of Prilosec OTC.)

Levofloxacin (Levaquin):
Levofloxacin is a powerful new antibiotic that is designed to cut the risk of abdominal, lung and wound infection after the operation.
Label: 500 mg, 1 tablet orally on the night before surgery at 9-11 p.m.
Dispense: 1 tablet.
When: The night before surgery.

Metaclopromide (Reglan):
Metaclopromide is a gut stimulant that helps to empty the stomach and protect you from aspiration pneumonia.
Label: 10 mg, 1 tablet orally on the morning of surgery at 4-5 a.m. with a sip of clear liquid.
Dispense: 1 tablet
When: The morning of surgery.
Preoperative Instructions

We want you to be in the best possible health prior to surgery. It will make your surgery safer and improve your chances for a better surgical outcome, and a better overall experience for you. Here is the information that you will need to be aware of in preparing for surgery:

**Two Weeks before Surgery:**

Warning: Do Not Come Alone!

It is critical that you have someone with you for the 7 days following your surgery. If you come alone we will have to cancel your operation.

Stop Taking Any Aspirin, Motrin, Ibuprofen, Naproxen, Advil or Other Arthritis or Pain Medicines

Make certain you do not take any aspirin or aspirin containing medicines for two weeks before surgery because this can increase your risk of bleeding. Aspirin and the other salicylates belong to a group of drugs called nonsteroidal anti-inflammatory drugs (or NSAIDs for short). You should avoid anti-inflammatory agents such as Ibuprofen (Advil) and aspirin products as well as excessive quantities of Vitamin E (the small amount contained in most multi-vitamin preparations is not harmful) for two weeks before surgery, as these inhibit the clotting mechanism and increase your chances of unnecessary operative bleeding. Aspirin-like products, which interfere with blood clotting, can promote bleeding during and after your surgery. P.S. That includes "BC's" and Goody Powders

We recommend that you avoid these over the counter pain relievers following surgery. We recommend that you avoid the Aspirin, Motrin, Ibuprofen, Naproxen, Advil type medicines because of their known risk of stomach irritation and ulcer formation. We recommend avoiding Tylenol type products because of the potential damage to the liver after rapid weight loss. If you need pain relief, you will need a prescription medicine that reduces the chance of damaging your liver or other vital organs.

Warning: Do not start or stop any medicine without the explicit advice of your doctor.

Warning: Do not stop taking Blood Pressure, Heart or other medications without consulting your doctor. Do not stop taking antidepressants without first talking to your doctor. Dangerous and unpleasant side effects may be experienced if you stop taking medications suddenly.

Discuss other Medications

If you currently are taking any medication, please discuss with our surgical staff regarding discontinuation before and after surgery.

Stop the Coffee and Coke and other forms of Caffeine

Caffeine withdrawal can be a very unpleasant experience following surgery. It is recommended that you restrict or at least reduce your intake of caffeine several weeks prior to surgery. Soda is not allowed post-op at all, and you won’t want to deal with caffeine withdrawal during the initial liquids only phase. It is easier to cut down gradually than to go cold turkey!

Several Days before Surgery

Eat lightly for two to three days prior to surgery. Soups, salads, yogurt and other easily digested foods are your best choice during this time. Your intestines change in length and diameter constantly, and our experience has shown that your surgery will be maximized if your intestines are not stretched following a large meal.
No Beards or Mustaches, Shave!
If you have a beard, mustache or other facial hair, you must shave it prior to surgery. We need to place a mask on your face as part of the pre and post anesthesia management. A beard or other facial hair interferes with the mask fit and seal on your face. If you have a beard or mustache you must shave if you want to proceed with operation.

Plan Ahead for Childcare and Transportation Home
You should plan for transportation home or to your hotel following surgery. You cannot drive yourself home from the hospital after surgery. If all goes well you should plan on going home on the morning or afternoon of the day after surgery (i.e. 24 hours after surgery.) Plan ahead for childcare arrangements, transportation, etc. You will need someone to be with you for the 48-72 hours following the day of your surgery. You should not drive for at least a week, and may feel like napping over the next few days. This is a common following anesthesia, as the drugs work their way out of your system.

You Must Stay in the Area
If you do not live within a two-hour drive of our facility, you must agree to stay in a hotel or other nearby accommodations for 7 days following your release from the hospital. This is to assure your safety, and to allow you to come back at anytime if necessary. We can assist you in locating accommodations, and have negotiated with hotels in the area for better rates and amenities. Please call our office if you need assistance in this area.

The Day/Night before Surgery
(See PreOp Medications)
**Milk of Magnesia (Magnesia: Magnesium Hydroxide)** When: The Morning of the day before surgery.
**Chlorhexidine, (Hibiclens®)** when: The night before surgery and the morning of surgery.
**Prilosec OTC (omeprazole)** when: The night before surgery.
**Levofloxacin (Levaquin)**: When: The night before surgery.
Do not smoke or chew gum after midnight.
Do not eat or drink after midnight (a few small sips of water is OK)
Leave all valuables at home
Do not wear any makeup, nail polish, or jewelry. If you have artificial nails, we can use your toenails to check for oxygen levels.
If you have any rings that you cannot remove, please go to a jeweler to have them removed prior to surgery.

The Day of Surgery
Morning of Surgery
**Metaclopramide (Reglan):** When: The morning of surgery.
**Prilosec OTC (omeprazole):** When: The morning of surgery.

Plan on a Place to stay near by if you are from Out of State
If you are from more than 2 hours away from your hospital you are advised to select a hotel in the area to stay close until you have recovered, usually 5-7 days after surgery.

You Must Have Someone to Stay with You
You must have someone stay with you for 24 hours after surgery.

Arrange for Payment
Only MasterCard and Visa accepted or cashiers check or money orders. Personal checks are Not accepted If you are paying with a credit card there is an additional processing fee of 200.00.

What to Bring to the Hospital
Pack lightly. The hospital provides you with minimal toiletries, and you will be wearing a hospital gown (don’t worry, they’re extra large!). You really shouldn’t use your own gowns or robes because of the IV. You will want to wear loose clothing home from the hospital; nothing tight around the waist that will irritate the bandages covering the port sites in your abdominal
area. You may want to bring lollipops, mints or hard candies to suck on, as your mouth will be dry, and you will not be able to drink large amounts at first.

**Complete Your Preoperative Preparation**

- Review the patient education materials.
- Review the informed consent document.

**PreOp Things “To-Do” List**

Shower with Hibiclens (Chlorhexidine) twice, both the evening before and the morning of surgery. You can purchase this at your local drug store.

- Do not smoke or chew gum after 12:00 midnight.
- Do not eat or drink after midnight the night before surgery (A few sips (1-2) of water are OK).
- Leave all of your valuables at home.
- Do not wear any makeup, nail polish, or jewelry.
- If you have rings that are difficult to remove, it is suggested you see a jeweler before admission to help remove them.
- Dentures, hairpins, hearing aids, glasses or contacts must be removed prior to surgery.

**Get to the Hospital 2-4 Hours before Surgery**

Arrive at the Hospital well ahead of the designated time for admission. Operations frequently go faster than planned and you could be delayed if you are not there on time.

- If you are currently taking medication, discuss with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery if you should stop taking it.

**What happens in the Hospital**

- An IV will be started by anesthesia before your transfer to the Operating Room.
- You will be transferred to the Operating Room by the anesthesiologist/anesthetist and met by a surgical nurse who will be with you for the duration of the procedure.
- When you awake, you will be in the Recovery Room. A nurse will be with you for the duration of your stay there (approximately one to three hours).
- When you are returned to your room you will be followed as you recover by the nurses and Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery.
- When you are ready to be discharged, usually on the second day after operation, a staff nurse will talk to you about your home care. They will then call for your prearranged transportation.
- If you have any questions about these instructions or at any time please remember that you should always feel free to call Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery.
- Please leave your home or hotel phone number or where you can be reached. The Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery or the hospital’s nursing staff will contact you to check on your condition.
Discharge Medications

Prilosec OTC (omeprazole) 20 mg QD Dispense: 2 boxes of 14 tablets. Dose: 20 mg. twice per day for 3-4 months following surgery. Note: "NEW We now recommend 3-4 months of Prilosec OTC (omeprazole) following surgery.”

Note: Nexium, Prilosec, Aciphex or Prevacid are all acceptable substitutes.

Ursodiol (Actigall) to prevent gallstones and decrease indigestion from bile reflux. Label: 300 mg. p.o. twice a day (Do not start until two weeks after surgery), Dispense: 60 tablets. Refills: Patient may have 3 Refills. (Note: You should take the Actigall as long as you are losing 10 lbs or more per month typically that is for 3-6 months.)

Bismuth Subsalicylate (Pepto-Bismol): Dispense: one bottle. Dose: 1 tablespoonful every 6 hours of the regular-strength suspension for 1-4 months following surgery. Note: “NEW We now recommend 3-4 months of Pepto-Bismol following surgery.”

Multivitamins 1 tablet three times a day Beginning 2 Weeks After Surgery and then for the rest of your life. The Gastric Bypass is very effective in causing weight loss because it causes malabsorption of fat and calories, which is good. But the Gastric Bypass also causes malabsorption of some vitamins and minerals, which is bad.

Warning: You must plan on taking high doses of multivitamins for the rest of your life after Gastric Bypass. Warning: Most liquid vitamins are NOT recommended because of their low iron content.

Methylcellulose (Citrucel) Dose 1 teaspoon PO BID in 2 - 3 oz. of liquid. Citrucel is a dietary fiber, which has the ability to hold water and form bulk. We use it to 1-coat the lining of the new stomach pouch, 2-increase weight loss and 3-to normalize your bowel movements. (Note: You may substitute Metamucil or its equivalent for the Citrucel if you wish)

Calcium Carbonate / Titracle™, Tums™ Antacid (Nonprescription) Dose: Chew 1 or 2 tablets every 4-8 hours while awake. They can be taken with you other foods or liquids. Tums can be started soon after the surgery and because of the risk of poor calcium absorption after the Mini-Gastric Bypass; you should consider taking some form of calcium supplement for the rest of your life.

The Following Medications are to filled ** ONLY IF NEEDED **

Promethazine (Phenergan) SIG: Dose: 25mg to 50mg ONLY TO BE TAKEN IF needed every 4-6 hrs. for nausea. Phenergan is effective in the relief of nausea, and vomiting. It produces marked sedation in most patients. In general, gastrointestinal side effects are minimal. It is stronger than the Diphenhydramine (Benadryl). Dispense # 20, Patient may have 3 refills.

Metoclopramide (Reglan) ONLY TO BE TAKEN IF needed for nausea. It increases the movements or contractions of the stomach and intestines. Metoclopramide relieves symptoms such as nausea, vomiting, and continued feeling of fullness after meals, and loss of appetite. Metoclopramide is also used, for a short time, to treat symptoms such as heartburn in patients who suffer esophageal injury from reflux of gastric acid into the esophagus. Sig. Dose: Take ONLY as Needed 10 mg 30 minutes by mouth before meals and at bedtime prn. Dispense # 120, Patient may have 3 refills.

Non-Prescription Pain Medication for Mild to Moderate Pain: Tylenol® (Acetaminophen) Elixir. Dose: Tylenol® (Acetaminophen) Elixir (160 mg/ 5 ml) 1-3 tsp (160-480mg) every 4-6 hours as needed for pain. If your pain gets worse call your surgeon, the hospital or the Centers for Laparoscopic Obesity Surgery. This is a potentially dangerous pain medication. Be careful about using this and all medicines, follow the instructions and do not allow others to use this medicine. You should take Tylenol cautiously and according to the instructions, as you would take any medication. Side effects cannot be anticipated. If any develop or change in intensity, call us at the the Centers for Laparoscopic Obesity Surgery as soon as possible. Acetaminophen has been shown to induce hematologic changes and liver and renal dysfunction. The dose selected here is intentionally lower than usual to help avoid liver damage. You can purchase this at most any drug store. Dispense 1 bottle.

Maalox Plus Extra Strength Antacid that is to be taken if you develop indigestion or burning chest pains like indigestion. Label: 1 teaspoon every 2 hours as needed to calm the discomfort of indigestion. Dispense: 1 Bottle. If you have to take more than a few doses call Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery.

Date
The Surgeons of the Centers for Laparoscopic Obesity Surgery
(Note to Pharmacist: Please do not hesitate to call my office to confirm these prescriptions)
Discharge Instructions

Getting Ready to Leave the Hospital after the Mini-Gastric Bypass

Attention:
1. Please read all of these instructions carefully
2. Make Sure You Have Your Prescriptions (Call us if you do not have them.)
3. Please Make a copy of these instructions and give them to your Doctor.

Emergencies

Remember: If you are sick and not feeling well go to the Emergency Room Right Away or Dial 911. You can always come back.
If any problem arises at any time, we stand ready to do everything possible to try and fix it. If you are having any problem at all, please, call and let us know to see if we can help.
If you are sick and not feeling well go to the Emergency Room or Dial 911.
Please call or email the office every day between 12 noon and 5 p.m. leave a message that you are doing well.

If possible please call during the day for routine check in calls.
For emergencies call the Emergency Department and or Dial 911.
Also feel free to call the Surgeons of the Centers for Laparoscopic Obesity Surgery at any time.
If you are having any problems talk to your surgeon or the staff.
Please use call or use email every day post op to let us know how you are doing.

Call, Office Telephone or call the hospital and ask the operator to page your doctor or his staff.

In the event that your surgeon is unavailable call the Local Hospital Emergency Department
Note: When calling for your surgeon, Please be patient and persistent, the paging system can take some time and/or your doctor might be involved in another case.

Warning: Never use email to contact us in an emergency or for any urgent communications.

Daily Contact for the First Week

After hospital discharge we ask that you take a moment every day and let your surgeon and the staff know how you are doing. You can email for routine follow up only. We want to know how you are doing. Make sure you leave a message every day to let us know about your recovery.

Discharge Medicines

Warning: Please do not take any medicines other than those prescribed by Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery unless you discuss them with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery first.

The Mini-Gastric Bypass can be expected to have a high likelihood of curing or improving your diabetes, hypertension, gout, urinary incontinence, osteoarthritis and sleep apnea as well as many of the other illnesses associated with morbid obesity. Because of this, many of the medicines that you were taking before the operation will need to be stopped. Ask Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery will discuss this with you.

Types of Post Op Medications

Type I: Required: These Medications are Required, You are to take them as written, they are Not Optional, and Try not to miss a dose.

Type II: Not required, these medicines are Optional, You are to take them only if the need arises, they Are Optional.

Prilosec OTC (omeprazole) Type I: Required

Dose: 20 mg. by mouth twice a day for the first 3-4 months after surgery. Then if you feel well it can be stopped.

Note: “NEW: We now recommend 3-4 months of Prilosec OTC (omeprazole) following surgery.”

(About 10% of patients will develop “indigestion” type pains at the end of this time and will need another month of the Prilosec OTC (omeprazole). In our experience in some cases the pain can be gastritis or an ulcer causing bacteria called Helicobacter Pylori and will need a special mixture of medications.) Notes: Prilosec OTC (omeprazole) is a medicine widely used to treat ulcers, heartburn and other conditions caused by too much acid in the stomach. Prilosec OTC (omeprazole) works by reducing the secretion of stomach acid. The production of stomach acid is reduced within 30 minutes to an hour. The new healing stomach after Mini-Gastric Bypass is delicate and can be damaged by acid and bile. Prilosec OTC (omeprazole) is designed to protect the healing stomach during the first 4 weeks after surgery. ) Prilosec OTC
(omeprazole) is a potent antacid medicine that is used to reduce the acid production from stomach designed to protect the new stomach pouch from ulcers in the first 4 weeks after the operation. This medicine has been in use for many years and is rather well tolerated. Oral tablets are used twice a day. Side effects: Prilosec OTC (omeprazole) is a well-tolerated medicine and has very few side effects. Side effects that can occur include: Abdominal pain, diarrhea, headache, nausea, vomiting. How to take: Swallow with a few sips of liquid or with a spoonful of yogurt or oatmeal. Don't take with: Alcohol. Any other medicines, even over-the-counter drugs such as cough and cold medicines, nose drops, diet pills, laxatives or caffeine, without consulting with Dr. Rutledge and/or the Surgeons of the Centers for Laparoscopic Obesity Surgery.

**Bismuth Subsalicylate (Pepto-Bismol): Type I: Required**

From MedlinePlus is in the public domain.

**Dose:** 1 tablespoonful every 6 hours of the regular-strength suspension for 1-4 months following surgery.

Bismuth Subsalicylate: (biz muth) (sub sa lis' i late)

**Why is this medication prescribed?**

Bismuth subsalicylate is used to treat diarrhea, heartburn, and upset stomach in adults and children 12 years of age and older. It works by decreasing the flow of fluids and electrolytes into the bowel, reduces inflammation within the intestine, and Bismuth subsalicylate, a component of Pepto-Bismol, is used to protect the stomach lining from acid. It also kills H. pylori.

**How should this medicine be used?**

Bismuth subsalicylate comes as a liquid, tablet, or chewable tablet to be taken by mouth, with or without food. Each day's therapy is packaged on a blister card that contains eight chewable tablets (each containing 262.4 milligrams [mg] of bismuth subsalicylate), Chew and swallow two tablets of bismuth subsalicylate (525 mg) four times a day, with meals and at bedtime.

**What special precautions should I follow?**

Before taking bismuth subsalicylate,

Tell your doctor or pharmacist if you are allergic to salicylate pain relievers such as aspirin, choline magnesium trisalicylate, choline salicylate (Arthropan), diflunisal (Dolobid), magnesium salicylate (Doan's, others), and salsalate (Argesic, Disalcid, Salgesic); or any other medication.

Tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to talk to your doctor or pharmacist about taking bismuth subsalicylate if you take: anticoagulants ('blood thinners') such as warfarin (Coumadin); a daily aspirin; or medication for diabetes, arthritis or gout.

If you are taking tetracycline antibiotics such as demeclocyline (Declomycin), doxycycline (Doryx, Vibramycin), minocycline (Dynacin, Minocin), and tetracycline (Sumycin), take them at least 1 hour before or 3 hours after taking bismuth subsalicylate.

Ask your doctor before taking this medication if you have ever had an ulcer, bleeding problem, stools that are bloody or blackened, or kidney disease. Also ask your doctor before taking bismuth subsalicylate if you have a fever or mucus in your stool. If you will be giving bismuth subsalicylate to a child or teenager, tell the child's doctor if the child has any of the following symptoms before he or she receives the medication: vomiting, listlessness, drowsiness, confusion, aggression, seizures, yellowing of the skin or eyes, weakness, or flu-like symptoms. Also tell the child's doctor if the child has not been drinking normally, has had excessive vomiting or diarrhea, or appears dehydrated.

Ask your doctor about taking this medication if you are pregnant or are breast-feeding.

**What special dietary instructions should I follow?**

Drink plenty of water or other beverages to replace fluids that you may have lost.

**What should I do if I forget a dose?**

If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

**What side effects can this medication cause?**

Bismuth subsalicylate may cause side effects. Some side effects can be serious. If you experience this symptom, stop taking this medication and call your doctor immediately: ringing or buzzing in your ear(s) Bismuth subsalicylate may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.
In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Ask your pharmacist any questions you have about bismuth salicylate. You may notice darkening of the stool and/or tongue while you are taking bismuth salicylate. This darkening is harmless and usually goes away in a few days after you stop taking this medication. It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names: Kaopectate®, Pepto-Bismol®

Note: “NEW: We now recommend 3-4 months of Pepto-Bismol following surgery.”

Allergies: Not to be taken if you have ever had an allergic reaction to bismuth subsalicylate or to other salicylates, such as aspirin, including methyl salicylate (oil of wintergreen), or to any of the following medicines: Ibuprofen (e.g., Motrin) Naproxen (e.g., Naprosyn) or other similar types of pain medications.

Methylcellulose (Citrucel) Nonprescription Type I: Required

Dose: Dose 1 teaspoon or more twice a day in 2-3 oz. of any type of liquid, like Gatorade. Citrucel can also be mixed with yogurt and taken that way as well. Notes: Fiber keeps your stools from becoming either too loose, or dry and hard. Citrucel is a bulk forming dietary fiber, which has the ability to hold water and form bulk. It also acts to coat the lining of the new stomach pouch and to normalize your bowel movements. Cellulose, the fiber in Citrucel, has been shown to help the bowel become healthier, thicker and stronger. Remember that ulcer is one of the long-term risks of this surgery over the long term. Low fiber intake has been shown to be associated with the development of ulcers. Studies show that soluble fiber (like Citrucel) from fruit and vegetables is protective against ulcer. On the other hand refined sugars (junk food) increase the risk of developing an ulcer. Citrucel decreases episodes of diarrhea and helps to prevent or treat constipation. Many studies have shown that increased fiber in the diet increases weight loss. Citrucel fiber also increases the weight lost after surgery. TAKE YOUR CITRUCEL.

Note: The Citrucel is to be started as soon as you go home and continued for life. (Note: See further information on fiber at the end of this section)

Calcium Carbonate / Titralac™, Tums™ ANTACID (Nonprescription) Type I: Required

Dose: Chew 1 or 2 tablets every 4-8 hours while awake. They can be taken with you other foods or liquids. Notes: Calcium carbonate (Titralac™, Tums™) is an antacid that neutralizes or reduces stomach acids. It relieves symptoms in patients with indigestion and heartburn. Calcium carbonate is also a dietary calcium supplement. Tums can be started soon after the surgery and because of the risk of poor calcium absorption after the Mini-Gastric Bypass; you should consider taking some form of calcium supplement for the rest of your life. Generic calcium carbonate tablets are available. You should chew well, or crush the tablets before swallowing; follow with a few sips of water, other fluids or yogurt. Antacids are usually taken after meals and at bedtime. Take your doses at regular intervals. Required, these are Not Optional, Type I: You are to take them as written; they are Not Optional, Try Not to Miss a Dose. (Note: Wait two weeks before starting the Ursodiol (Actigall) and the Multivitamins)

Ursodiol (Actigall) (Do not start until 2 Weeks after Surgery.) Type I: Required

Dose: 300-mg. p.o. twice a day beginning two weeks after surgery. Ursodiol (Actigall) should then be taken for the next 3-6 months after operation depending upon whether or not you have a gallbladder and how well you are doing. Notes: This medication helps to prevent the development of gallstone disease as you loose weight following surgery. It can also help decrease the symptoms of any bile reflux that can occur after surgery. You should take the Actigall as long as you are losing 10 lbs or more per month typically that is for 3-6 months.

Side Effects: This medication may cause diarrhea, stomach pains especially in the upper right side, nausea or vomiting. If you experience any of these symptoms you can stop the Ursodiol (Actigall) and wait 5-10 days and then restart it slowly. Take 1 every other day and work up to the 2 a day. Always take it with food. Other side effects include stomach upset,
Multivitamins (Nonprescription), Type I: Required

Do not start the vitamins until 2 Weeks after Surgery.
Dose: Take the multivitamin at three times the dose recommend by the label on the bottle of vitamins that you have purchased. Do not start the vitamins until 2 Weeks after Surgery. Then, REMEMBER, you need to take vitamins for the rest of your Life. Numerous vitamin brands are probably acceptable. You should select one that includes IRON in the list of minerals. Vitamins have iron and can upset your stomach but they are absolutely necessary. If they cause nausea, stop them for a day or two and then restart and begin with one a day with meals and build up slowly to the three a day. Wal-Mart sells a brand called “OneSource” Multivitamins. One of these three times a day is a good choice. Children's chewable vitamins contain lower amounts of vitamins particularly B12 and they are not recommended.
Warning: The Gastric Bypass is very effective in causing weight loss because it causes malabsorption of fat and calories, which is good for weight loss. But, the Gastric Bypass also causes malabsorption of some vitamins and minerals, which is potentially dangerous to you.
Note: Most Drugs and Medications are NOT malabsorbed after Laparoscopic Mini-Gastric Bypass.
Remember: It is very important that you plan on taking high doses of multivitamins for the rest of your life after Laparoscopic Mini-Gastric Bypass.
The Importance of Folate
Folate is included in the multivitamins that you should take every day. In several epidemiologic investigations, folate intake has appeared to reduce the elevated risk of breast cancer. A recent study showed that Vertical Banded Gastroplasty patients' homocysteine levels increased. This is important because homocysteine has been associated with the risk of hardening of the arteries. The study found that the lower the patients' Folate level, the higher the level of the patients' homocysteine level (Bad). The best recommendation is to make sure to take your vitamins including Folate. Severe obesity exposes one to an increased risk of cardiovascular mortality. Gastroplasty has been shown to induce substantial weight loss and to improve the atherogenic profile of severely obese subjects. However, vitamin deficiencies after gastroplasty have been reported. Because hyperhomocysteinemia, an independent risk factor for increased cardiovascular disease, is influenced by nutritional status (and especially by Folate intake), this study hypothesized that a Folate deficiency induced by gastroplasty could promote hyperhomocysteinemia. They found that plasma homocysteine concentrations increased, on an average, from 9.9 +/- 0.4 to 12.8 +/- 0.6 micromol/L (P < 0.0001). This increase in homocysteine levels was observed in two thirds of the subjects, leading to clear-cut hyperhomocysteinemia (>15 micromol/L) in 32%. The changes in homocysteine concentrations were correlated to weight loss (P < 0.001) and to decrease in plasma Folate concentrations (P < 0.01). Whereas gastroplasty induced a mean 32-kg weight loss and a striking improvement in conventional risk factors, the occurrence of iatrogenic hyperhomocysteinemia might hamper the benefit of surgery in cardiovascular risk in most of the patients. They supported the use of a systematic efficient Folate supplementation after gastroplasty.

Drugs that are NOT Required, They are Optional-Type II:
You are to take them ONLY if the need arises, they ARE Optional.

Non-Prescription Pain Medication for Mild to Moderate Pain: Tylenol® (Acetaminophen) Elixir. Optional-Type II:
Dose: Tylenol® (Acetaminophen) Elixir (160 mg/ 5 ml) 1-3 tsp (160-480mg) every 4-6 hours as needed for pain. If your pain gets worse call your surgeon, the hospital or the Centers for Laparoscopic Obesity Surgery.

This is a potentially dangerous pain medication. Be careful about using this and all medicines, follow the instructions and do not allow others to use this medicine. You should take Tylenol cautiously and according to the instructions, as you would take any medication. Side effects cannot be anticipated. If any develop or change in intensity, call us at the Centers for Laparoscopic Obesity Surgery as soon as possible. Acetaminophen has been shown to induce hematologic changes and liver and renal dysfunction. The dose selected here is intentionally lower than usual to help avoid liver damage. You can purchase this at most any drug store.
Anti-nausea Medicine for Mild to Moderate Nausea: Promethazine (Phenergan®) Optional-Type II:

Dose: 25mg to 50mg as needed every 4-6 hours for nausea. Phenergan is effective in the relief of nausea, and vomiting. It produces marked sedation in most patients. In general, gastrointestinal side effects are minimal. It is stronger than the Diphenhydramine (Benadryl). You will receive 20 tablets from the druggist and you may have 3 refills.

Anti-nausea Medicine for Mild to Moderate Nausea: Metaclopramide (Reglan)

Reglan increases the movements or contractions of the stomach and intestines. Metaclopramide relieves symptoms such as nausea, vomiting, and continued feeling of fullness after meals, and loss of appetite. Metaclopramide is also used, for a short time, to treat symptoms such as heartburn in patients who suffer esophageal injury from reflux of gastric acid into the esophagus. Dose: 10 mg 30 minutes by month before meals and at bedtime. Your prescription will be for 120 tablets (one month) you may have 3 refills. This medicine will add to the effects of alcohol and other CNS depressants (medicines that cause drowsiness). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies, or colds; sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; barbiturates; medicine for seizures; muscle relaxants; or anesthetics, including some dental anesthetics. Check with your doctor before taking any of the above while you are using this medicine. This medicine may cause some people to become dizzy, lightheaded, drowsy, or less alert than they are normally. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert. Possible Side Effects: Rare: Chills; difficulty in speaking or swallowing; dizziness or fainting; fast or irregular heartbeat; fever; general feeling of tiredness or weakness; headache (severe or continuing); inability to move eyes; increase in blood pressure; lip smacking or puckering; loss of balance control; mask-like face; muscle spasms of face, neck, and back; puffing of cheeks; rapid or worm-like movements of tongue; shuffling walk; sore throat; stiffness of arms or legs; trembling and shaking of hands and fingers; tic-like or twitching movements; twisting movements of body; uncontrolled chewing movements; uncontrolled movements of arms and legs; weakness of arms and legs. Beware of Confusion; convulsions (seizures); drowsiness (severe). Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. More common: Diarrhea—with high doses; drowsiness; restlessness. Less common or rare: Breast tenderness and swelling; changes in menstruation; constipation; increased flow of breast milk; mental depression; nausea; skin rash; trouble in sleeping; unusual dryness of mouth; unusual irritability.

Mylanta and Maalox are antacids (Nonprescription) Optional-Type II:

Dose: Take 1 teaspoon every 2 hours as needed if you develop indigestion or burning chest pains like indigestion. You should take antacids to relieve the discomfort of indigestion. If you have to take more than a few doses call Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery to discuss this issue with him.

Supplements

Supplements are an addition to your diet that may be advantageous in your recovery and in the maintenance of your long-term good health. It is important to note that you do not have to take these supplements. They might be of some help but they are not necessary for your recovery. They may be started as soon as you like after surgery. Supplements to consider:

Whey Protein

Whey protein has been shown to have numerous positive effects on wound healing, increased immune function and increased strength and stamina. Recommended Dosage: Add one to three tablespoons to yogurt once or twice a day.

Whey is a natural by-product of cheese making process. Bovine milk has about 3.5 % protein, 80 % of which are caseins and the remaining 20 % are whey proteins. Whey proteins contain all the essential amino acids and have the highest protein quality rating among other proteins. Advances in processing technologies have led to the industrial production of different products with varying protein contents from liquid whey. These products have different biological activities and functional properties. Also recent advances in processing technologies have expanded the commercial use of whey proteins and their products. As a result, whey proteins are used as common ingredients in various products including infant formulas, specialized enteral and clinical protein supplements, sports nutrition products, products specific to weight management and mood control.

The biological components of whey, including lactoferrin, beta-lactoglobulin, alpha-lactalbumin, glycomacropeptide, and immunoglobulins, demonstrate a range of immune-enhancing properties. In addition, whey has the ability to act as an antioxidant, antihypertensive, antitumor, hypolipidemic, antiviral, antibacterial, and chelating agent. The primary mechanism by which whey is thought to exert its effects is by intracellular conversion of the amino acid cysteine to glutathione, a potent intracellular antioxidant. A number of clinical trials have successfully been performed using whey in the treatment of cancer, HIV, hepatitis B, cardiovascular disease, osteoporosis, and as an antimicrobial agent. Whey protein has also exhibited benefit in the arena of exercise performance and enhancement. (Altern Med Rev 2004;9(2):136-156)
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Small increases in calorie intake coupled with declining physical activity resulting in progressive weight and fat gain. Consequently, the obesity epidemic is often reduced to a simple question of energy balance, and proposed strategies accordingly focus upon best approaches to induce negative energy balance.345

However, obesity is a complex genetic trait, with multiple genes interacting to confer relative resistance or susceptibility to positive energy balance. Similarly, dietary components and patterns may affect the same metabolic pathways affected by genetic susceptibility and thereby alter energy portioning and obesity risk. A growing body of evidence suggests that dairy whey contains compounds that exert positive effects and contribute to healthy weight management.

Dairy-rich diets can decrease body fat accumulation and weight gain during periods of over-consumption of an energy dense diet and to increase fat breakdown and oxidation while preserving lean tissue during energy restriction. Dairy is more than twice as effective as calcium alone in inhibiting adiposity, and this additional bioactivity resides in the whey protein fraction. Moreover, calcium is without effect on preserving lean mass during energy restriction, while whey confers significant protection.

The angiotensin converting enzyme (ACE) inhibitory activity of whey contains a portion of this additional activity, as it attenuates autocrine angiotensin II-induced adipocyte lipogenesis. However, combining calcium and whey-derived ACE inhibitors produces an effect that is significantly less potent than that of intact whey, indicating the presence of other anti-obesity factors in whey; the identity of these factors is presently under investigation. Moreover, this combination does not retain the ability of intact whey to protect lean mass. Instead, the branched chain amino acid (BCAA) content of whey appears to contribute significantly to preservation of lean mass during energy restriction and expansion of lean mass in the absence of energy restriction; this effect is likely due to leucine stimulation of muscle protein synthesis and may also contribute to reduced adiposity as a result of the additional energetic cost of muscle protein synthesis.

However, whey-free diets containing BCAA confer less lean mass protection than intact whey.

Conclusions - Whey components have the potential to play a significant role in weight management and protection of lean mass during dieting. While the calcium content of whey accounts for a portion of this effect (<50%), there are clearly other bioactive whey components which also contribute. However, although both ACE-inhibitory peptides and BCAA contribute to this additional bioactivity, they cannot fully account for the anti-obesity and muscle-protective properties of whey, indicating that there are other, as of yet unidentified, whey components which contribute to these effects.

Creatine

Creatine is a naturally occurring substance made from amino acids. It has established itself as a useful sports supplement. Creatine is effective in increasing muscle mass and also has compiled a truly enviable safety record. After creatine supplementation, individuals notice that they have greater strength and/or endurance. These immediate “gains” will subside if you stop taking creatine. The long-term gains associated with creatine supplementation come from the increases in exercise ability. In other words, creatine promotes growth by allowing you to do more. Skeletal muscle function is decreased in obese men and women. Studies have shown that ATP, creatine, glycogen, and lactate are decreased in obese patients. Creatine is a naturally occurring compound found in muscle. It is made from three amino acids - arginine, glycine and methionine. It has been shown that Creatine supplementation can increase muscle energy, stamina, and strength, muscle mass and fat loss. Creatine supplementation enhances maintenance of fat-free mass (muscle) and the progress of muscle strength during training in sedentary females. Recommended Dosage: Creatine Monohydrate is taken 7,500 mg of the powder mixed in liquid 1-3 times daily, depending on how much you can tolerate. European J Applied Physiology Occup Physiology 1998 Jun; 78(1): 83-92 Effect of creatine supplementation during rapid body mass reduction on metabolism and isokinetic muscle performance capacity. Oopik V, Paasuke M, Timpmann S, Medijainen L, Ereline J, Smirnova T. Subjects studied before and after losing a 3-4% of their body weight has shown that muscle strength could be maintained or even enhanced by dietary creatine supplementation.346 The results indicated that creatine supplementation in comparison with placebo treatment during rapid weight loss may help to maintain muscle mass.

Creatine has been shown to prevent muscle fatigue and improve strength. A recent study also shows that it can also prevent mental fatigue as well. Creatine is abundant in muscles and in the brain and is used as an energy source. Using a double-blind placebo-controlled design dietary supplementation with creatine was shown to reduce mental fatigue when subjects repeatedly performed a mathematical calculation.347

Glutamine

Glutamine is the most abundant amino acid in the body. Overall nutrition has a profound effect on the gut; there are specific nutrients that influence the gut lining (epithelium). In the small intestine, glutamine has the most important effects and this amino acid is now considered conditionally essential. Animal studies have shown that there is enhanced growth of the lining of the gut with the administration of glutamine or a fiber-containing diet. Exposure to various types of stress, such as starvation, infection and exercise, can severely deplete glutamine stores, resulting in a spectrum of problems,
including inhibition of muscle protein synthesis and decreased immune function. Supplementation with glutamine can help supply your muscles this important amino acid. Instead of taking glutamine from muscle storage during starvation, your body can rely on the supplemental glutamine you're taking to deal with the additional demands placed on your body. New research strongly suggests that the lining of your gut can be damaged easily. Chemicals, starvation and stress can produce irritation and inflammation of the lining of the gut. Supplemental glutamine may to counter these negative effects. Continuing supplementation is crucial since the average diet contains relatively little glutamine. Glutamine is the principal fuel for the cells that line the stomach and the gut. Studies have shown that Glutamine can decrease damage of jejunum (small bowel) and aid in healing. Glutamine is safe and easy to take and can be a valuable supplement for a sound nutritional program. Research has shown that an increased amount of glutamine can help to protect and heal the digestive tract, strengthen the immune system and improve muscle mass. Glutamine plays a key role within the intestinal tract. Glutamine supplementation can promote intestinal health and help to alleviate symptoms. Glutamine is a primary source of energy for the cells of the gastrointestinal tract. The cells that line the intestine get replaced with new cells every 72 hours. Glutamine plays a key role in the process of intestinal renewal as well as healing and repair of damaged cells. Conversely, it has been proven that a lack of adequate glutamine can result in diarrhea and damage to the intestinal tract. Glutamine supplementation has been shown to promote the healing of damaged or damaged intestinal tract and enhance intestinal regeneration following surgery. Recommended Dosage: 1-5 grams mixed in yogurt 2-4 times per day. Studies have shown that 14 grams of glutamine per day helped AIDS patients keep on muscle and not gain fat. The study also demonstrated improved immune function in AIDS patients receiving supplemental glutamine.

**Glucose Tolerance**

Glucose tolerance is a measure of your body's ability to process glucose. A high level of glucose in your blood can lead to diabetes. Several studies have shown that a high intake of dietary fiber can improve glucose tolerance. Eating more fiber rich foods relieved abdominal pain and bloating for one out of four Irritable Bowel Syndrome (IBS) sufferers in a recent University of Pittsburgh study. Even better when the rest added the antidepressant paroxetine (Paxil), another two out of three reported that their discomfort faded away (Amer. J. Gastroenterology, Sept 2002).

**Fish Oil/Flax Oil Tablets:**

Recommended Dose: 1-2 tablets 1-3 times a day. There are many fatty acids, but only two are essential, meaning they cannot be made by the body and must be obtained through diet or supplementation. Linoleic (an omega-6 fatty acid) and linolenic (an omega-3 fatty acid) are polyunsaturated fatty acids, whose primary sources are vegetable oils and certain types of fish. EFAs have many important physiological roles in the body and are critical for health, growth hormone production, mental functions, healing and recovery. EFAs are useful because they help do so many things in the body and because, after surgery your new low fat diet means that you're not getting nearly enough of them, especially omega-3s. Some of the things they're intimately involved in: increasing insulin sensitivity and insulin binding to receptors in skeletal muscle, increasing binding of IGF-1 (insulin-like growth factor-1) to skeletal muscle, decreasing cholesterol and triglyceride levels, moderating the release of cortisol, stimulating the release of growth hormone, promoting fat mobilization and inhibiting body fat synthesis and storage. There's also evidence that EFAs ameliorate depression, improve mental function and support joint function. And that's just a sampling. Omega-3 fatty acids are found in soybean, canola, walnut and, especially, flaxseed and linseed oils, as well as some fatty fish. The two most important omega-3s are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). While your body can manufacture these, they are made from linolenic acid, which your body can't make. You can also get EPA and DHA directly by eating certain fish, especially sardines, mackerel, herring, salmon and lake trout, or by taking fish oil capsules. You can try a tablespoon or two of premium flaxseed oil every day (one tablespoon per 100 pounds of bodyweight is good). If eating fish is not your thing, take fish oil capsules, downing 3-4 g daily. Information: Several studies suggest that not all fats are the same and that indeed some fats be good for you and treat and reverse different types of disease. Recent studies of the so-called Mediterranean diet suggest that relatively high amounts fat as olive oil actually improved survival. In another study addition of the omega 3 fatty acids (olive oil) improved the outcome of patients with bipolar (manic depressive) disease. Fish and fish oil, rich sources of omega-3 fatty acids, have sparked intense interest studies, which suggest a favorable effect on Heart Disease and other studies, which show a striking improvement in lipid profiles in hyperlipidemic patients. Patients after gastric bypass malabsorb fat and calories in part leading to the weight loss. One concern is the possible deficiency of essential fatty acids. It may be a good idea to take a fatty acid supplement of fish or flax seed oil. It also may be advantageous to use olive oil when possible. Corn and safflower oils on the other hand may not be good choices.

**Bran Tablets:**

Recommended Dose: 1-2 500 mg. tablets 1-3 times per day. Start slow and build up. Information: Fiber has been shown to have a variety of positive effects. Bran has been shown in hundreds of studies to decrease fat absorption, protect the lining of the gut and improve the bowel function. Eating more fiber rich foods relieved abdominal pain and bloating for one out of four Irritable Bowel Syndrome (IBS) sufferers in a recent University of Pittsburgh study. Even better when the rest added the antidepressant paroxetine (Paxil), another two out of three reported that their discomfort faded away (Amer. J. Gastroenterology, Sept 2002).
Activity

You may have heard after other types of surgery that you should beware of vigorous exercise or heavy lifting after surgery. This is not the case with laparoscopic surgery. Vigorous exercise can be started immediately after surgery if you wish. You do not have to start exercising immediately after surgery, but you can if you want to. Exercise does not put your stomach pouch at risk. Walking soon after operation is very helpful in your recovery. You can start water aerobics or swimming within seven days after operation. Weight lifting and sit-ups are fine and are encouraged. Take it easy if your have not done this type of exercise before.

Your white "TED" hose are elastic stockings designed to compress the veins in your legs and help protect you from Deep Vein Thrombosis (clots in your legs) and from Pulmonary Embolus (clots going to your lungs.) You should continue to wear you stockings after you go home until you are back to normal levels of activity.

Bandages and Wounds

Try to get the tape and bandages off of your wounds as soon as possible. The tape can pull the skin and scar and damage your skin. If your bandages get wet or stained, then you should change or remove them. BRUISING OR BLEEDING is common after surgery. Bandages often become stained with blood on the day of surgery. And later if the wound bleeds during the first 24 hours after surgery, press on the area with a clean gauze pad, tissue or cloth for 10 minutes. Bruising often worsens several days after surgery. Bruising or bleeding is usually not a source for concern unless accompanied by steady foul smelling drainage, worsening pain, tenderness, redness or progressive swelling. You may shower or wash the incision gently with mild unscented soap. Between baths, keep the wound dry with a bandage for the first 2 to 3 days after surgery. If a bandage gets wet, change it as soon as convenient. After the first 3 days you can leave the wounds open to air or cover them with a band-aid type bandage if you like.

Patient Instructions for the "Paint" on your abdomen used for the skin sterilization at the time of surgery: We use the 3M DuraPrep Surgical Solution, a bacteria killing skin preparation that acts fast and lasts long. It is recommended that this film remain on the skin after the procedure because it continues to kill bacteria for up to 12 hours and maintains low bacteria counts under dressings for up to 3 days. The film will gradually wear away. If, however, early removal is desired: Soak gauze with 70% isopropyl alcohol and place on the prepped area for at least 40 seconds. Lightly scrub to remove the solution.

Showering after Surgery

It is OK to shower and get your incision wet 1-2 days after the operation but do not soak in a bathtub for a week or 10 days. If the incision becomes red or starts to drain, you should immediately contact Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery.

Your Diet

There are three stages in the diet that you should eat after surgery.

Stage I:

Stage I is from the moment that the operation is completed until 10-14 days after surgery. During this period the surgical wounds are healing and the new connection between the stomach and the small bowel is repairing itself. This is your most dangerous time. It is during the first 10 to 14 days when you are the greatest risk of leakage at this new connection. During stage I, the titanium staples initially hold the stomach and the small bowel together. They are rapidly replaced by the body's own connection based upon the protein called collagen. The titanium staples are only effective for a few days and then the body must heal the stapled areas or they will fall apart. During this period the new "plumbing", the new connections in the gastro-intestinal tract are most at risk of coming undone. If this happens a leak of gastro-intestinal contents and bacteria occur that is very serious and can be lethal.

Because of this fragile connection, during the period of Stage I we ask that you be extremely careful about what and how much you eat. Your postoperative diet in Stage I should consist mainly of fruit and vegetable juices, Gatorade and different types of light soups. Well-chewed Saltine crackers are also a good choice. Thin soups and Yogurt are also very good for you at this point. Orange, grapefruit, tomato, V8, grape and other juices are all good choices. Juices are a good choice because of their high potassium content and the fact that they also contain other vitamins and minerals.

Gatorade is also a good choice because it is light and it contains sodium and potassium. Occasionally the sweet juices can be too sweet and cause the "Dumping Syndrome." You may need to dilute the juices with water. Coffee, tea, sodas are not good choices because of their low potassium and vitamin content.
Yogurt:

Yogurt is a very valuable part of your postoperative diet both right away and forever after. You should eat regular or nonfat yogurt at the very least once a day. Yogurt is a good source of protein and calcium, it coats the lining of the new stomach and it provides healthy bacteria to the gut.

H. pylori is the major cause of chronic gastritis, and a risk factor for peptic ulcer and gastric cancer in humans.

A prospective, randomized, double blind and placebo-controlled study that investigated the effect of L. reuteri on the eradication of Helicobacter pylori. Thirty patients were enrolled, aged 25-56, and suffering from dyspepsia (indigestion) caused by a confirmed infection with H. pylori. 15 patients were given omeprazole (20 mg/day) plus L. reuteri (10^8 CFU, twice daily) and 15 received omeprazole plus placebo, for 30 days. The H. pylori infection was controlled 4 weeks after the end of the therapy in 60% of the patients supplemented with L. reuteri. H. pylori was totally eradicated, while no eradication occurred in the group that received omeprazole plus placebo (p<0.0001). From this study is seems that probiotic supplementation with L. reuteri has a beneficial effect on H. pylori infection in humans, being by itself able to eradicate the bacteria.

Regular intake of yogurt containing Lactobacillus species and Bifidobacterium have been shown to effectively suppress H. pylori infection. Studies have shown that ingesting lactic acid bacteria exerts a suppressive effect on Helicobacter pylori infection in both animals and humans. Supplementing with Lactobacillus- and Bifidobacterium-containing yogurt (AB-yogurt) was shown to improve the rates of eradication of H. pylori in humans. In a study of 59 adult volunteers infected with H. pylori given yogurt with Lactobacillus and Bifidobacterium twice daily after a meal for 6 wk. showed that administration of yogurt decreased the H. pylori. They concluded that regular intake of yogurt containing Lactobacillus and Bifidobacterium effectively suppressed H. pylori infection in humans. The intake of probiotic bacteria during at least 3 months significantly shortened common cold episodes by almost 2 days and reduced the severity of symptoms.

A randomized, double blind placebo-controlled study showed increasing work-place healthiness with the probiotic Lactobacillus reuteri. A prospective study showed that daily supplementation with the probiotic Lactobacillus reuteri could reduce the incidence of common infections and thereby reduce short-term sick leave at a major Swedish workplace. In the placebo group 26% reported sick leave during the study period. In the L. reuteri group 11% reported sick leave (p<0.01). The frequency of sick-days of ordinary weekdays decreased from 0.9% in the placebo group to 0.4% in the L. reuteri group (p<0.01). The effect on sick leave was even more pronounced in the 53 shift-workers in the study: 33% in the placebo group were on sick leave compared with none (0/26) in the L. reuteri group (p<0.005). The daily intake of Lactobacillus reuteri significantly reduced the number of reported sick days of ordinary weekdays due to common infections, and this effect was even more pronounced in the shift-workers.

In a randomized study prophylactic Lactobacillus reduced antibiotic-associated diarrhea in children with respiratory infections.

"Ensure" and other similar commercial supplements often contain high levels of fat and eating or drinking them quickly may lead to dumping syndrome and should be taken very slowly in small amounts or avoided.

Chicken Noodle Soup:

Salty soups, such as chicken noodle soup, are good choices early after surgery. Some heavy cream soups may cause dumping if eaten too quickly and probably should be eaten slowly in small amounts or avoided.

Eat Frequently:

The effects of meal frequency on body composition during weight loss has shown that eating six or more times meals day leads to better retention of lean body mass (muscle.) These studies show that lower frequency of eating intake leads to greater muscle loss even if the same diet is consumed. So eat every few minutes throughout the day.

The Myth of 8 Glasses of Water a Day:

Many people have heard that drinking lots of water helps with weight loss. This wrong and is dangerous right after your Laparoscopic Mini-Gastric Bypass. You can have a little water to drink after surgery but Gatorade, V8, juices and chicken noodle soup are much better choices because they contain some sodium and potassium.

It is important to emphasize that you should take only small amounts of liquids at each feeding during stage I. (No more than 2 - 3 table spoons at a time). Then wait for approximately 10-15 minutes before taking any more. This is done to avoid distending the new small stomach pouch and potentially disruption the new staple line.

Stage II

Stage II in the healing of the stomach after surgery is from 10-24 days following surgery to the time in which you return to a modified regular diet. This can last anywhere from a few days to two months. During this time juices and liquids should continue to be a mainstay of your diet. If you choose you can move quickly through this stage to an almost regular diet. It has been our experience that those patients who work hardest to stay mostly on juices for up to two months have the
The Mini-Gastric Bypass decreases the absorption and digestion of some foods after surgery. There is a risk of malnutrition and so attention to a good balanced healthy diet after surgery is important. We DO recommend some additional protein after the Mini-Gastric Bypass. Some additional protein is probably a good idea but very high levels of protein are probably not necessary. 

Stage III

Stage III is the period when you return to essentially a normal diet. Most anything is really OK if you tolerate it. At this point most patients report that red meat (beef) is often difficult to eat. Bread can be a problem as well. Many patients say that they "crave" fruits and vegetables. Most patients find that they must eat frequently and eat about 20-30% of what they used to eat for a meal. They find that sweets, junk foods and fatty foods are not as enjoyable as they once were and are more often left out of their diet except for in small quantities.

The “Dumping Syndrome”

From Wikipedia, the free encyclopedia

“Gastric dumping syndrome, or rapid gastric emptying, happens when the lower end of the small intestine, the jejunum, fills too quickly with undigested food from the stomach. “Early” dumping begins during or right after a meal. Symptoms of early dumping include nausea, vomiting, bloating, cramping, diarrhea, dizziness and fatigue. “Late” dumping happens 1 to 3 hours after eating. Symptoms of late dumping include weakness, sweating, and dizziness. Many people have both types.”

“In addition, people with this syndrome often suffer from low blood sugar, or hypoglycemia, because the rapid "dumping" of food triggers the pancreas to release excessive amounts of insulin into the bloodstream. This type of hypoglycemia is referred to as "alimentary hypoglycemia".”

The dumping syndrome consists of mild, moderate or severe abdominal pains and cramping, occasionally causes diarrhea, lightheadedness, sweating, and palpitations. A concern after all types of gastric bypass surgery is condition called “dumping syndrome” in which there is discomfort following eating or drinking. This may include mild moderate or severe cramping, full feeling, rapid pulse, weakness, cold sweating, dizziness, and nausea and vomiting can even follow. In simple terms, the rapid movement of food into the small intestine causes this syndrome from the stomach. When there is liquid with the dry/solid foods, it causes a faster movement into the small intestine, sometimes precipitating the dumping syndrome. That is the reason for the recommendation to not have liquids with solid foods or close to eating times.

Other recommendations to help prevent dumping include:
- Six or eight very small meals throughout the day
- Inclusion of protein and fat with carbohydrates, and may even want a relatively low carbohydrate content to decrease the chance of dumping
- Avoid sugar, sweets, and desserts (again, simple carbohydrates digest fastest and move quickest through the system)
- Avoid alcohol and sweet carbonated drinks

The Dumping Syndrome can be caused by sugary foods, fatty foods, too much food or liquid at one time and other foods in individual patients. Changing what you eat and how much you eat can treat the dumping syndrome. Remember that you must eat several small “meals” throughout the day, to be careful of liquids and foods that contain sugar, and to eat foods high in protein (like nonfat yogurt). To reduce the amount of fluid that enters the small intestine, patients are usually encouraged not to drink more than a very small amount at a time. Medicine also can help control the dumping syndrome. The symptoms usually disappear in 3 weeks to 3 months.

Anti-dumping/Mini-Gastric Bypass diet is for persons with the Mini-Gastric Bypass for morbid obesity usually doesn’t tolerate:
Remember you are on Liquids for the first several weeks, this heavier stuff is for later!

Be careful or avoid: Most meat and beef, Highly Sugary or Sweet foods, Greasy Fried or fatty foods, Lactose containing foods such as Milk and dairy products are some times problems (Yogurt often seems to work best.), Bread, especially when fresh or fluffy can form a ball and be a problem (remember to chew your food very, very carefully), Citrus juices and fruits can be too sweet (mix them with water if they bother you)

The best advice is to go very, very slowly on taking any liquids or foods as you begin to adjust to the Mini-Gastric Bypass.

Protein

The gastric bypass decreases the absorption and digestion of some foods after surgery. There is a risk of malnutrition and so attention to a good balanced healthy diet after surgery is important. We DO recommend some additional protein after the Mini-Gastric Bypass. Some additional protein is probably a good idea but very high levels of protein are probably not
Kidney stone patients are often told to limit their dietary intake of calcium. But new research suggests that restricting animal protein and salt may be a better way to prevent kidney stones from recurring. A recent study by Bassily the records of 569 patients who had a partial gastrectomy for ulcer disease were analyzed. Five hundred and seven patients (83.5%) had a Billroth II. They showed that "the risk of gastric cancer was not increased after Billroth II partial gastrectomy." In a study from Finland the risk of gastric cancer after gastric surgery for ulcer disease were analyzed. These patients were followed for over 5,635 person-years. That is, they found that the rate of gastric cancer in the surgery patients was actually lower than that seen in unoperated patients. Many other studies of Billroth II patients have found no evidence of an increased incidence of gastric cancer.

In a study from Finland the risk of gastric cancer after gastric surgery for ulcer disease were analyzed. Six of the 285 patients developed gastric cancer after the operation. The risk of contracting gastric cancer in the rest of the population (individuals who had no operation) of equal size and age during a similar follow-up period was 8 cases. That is to say, the operated

## Bile and Bile Reflux

Quoted from Wikipedia, the free encyclopedia

"Bile is produced by the liver. Cholesterol is also released with the bile, dissolved in the acids and fats found in the concentrated solution. When food is released by the stomach into the duodenum in the form of chyme, the gallbladder releases the concentrated bile to complete digestion."

"The human liver can produce close to one liter of bile per day (depending on body size). 95% of the salts secreted in bile are reabsorbed in the terminal ileum and re-used."

After your surgery with the new connection between the stomach and the bowel new connection it is common to have bile reflux into the new stomach. This is usually worst in the first few weeks after the surgery and improves over time. Rarely it can be so severe that you can have unpleasant episodes of nausea and vomiting. This can be worst at night when you lie down. It is often made worse by eating late at night or just prior to going to bed. It can usually be made better by sleeping in a near sitting position for a few days and avoiding meals late at night. Taking your Prilosec OTC (omeprazole), Pepto-Bismol and Citrucel in the evening prior to bedtime can also be helpful. The supplemental Bran Tablets have also been shown to be helpful as well.

A concern raised by some, is the potential association of the Billroth II (BII) type connection used in the Mini-Gastric Bypass with stomach (gastric) cancer. There are some medical studies that seem to raise concerns about the relation between the Billroth II type connection and gastric cancer. A careful review shows that this is not a reasonable concern. A good and very well done study looking at this question was published in the New England Journal by Schafer et al. In this study performed by the Mayo Clinic studied residents of Minnesota, who had surgery for ulcers between 1935 to 1959. These patients were followed for over 5,635 person-years. They found gastric cancer in only two of the patients in the surgical group, as compared with an expected rate of 3 people. That is, they found that the rate of gastric cancer in the surgery patients was actually lower than that seen in unoperated patients. Many other studies of Billroth II patients have found no evidence of an increased incidence of gastric cancer.

In a recent study by Bassily the records of 569 patients who had a partial gastrectomy for ulcer disease were analyzed. Five hundred and seven patients (83.5%) had a Billroth II. They showed that "the risk of gastric cancer was not increased after Billroth II partial gastrectomy." In a study from Finland the risk of gastric cancer after gastric surgery for ulcer disease were analyzed. Six of the 285 patients developed gastric cancer after the operation. The risk of contracting gastric cancer in the rest of the population (individuals who had no operation) of equal size and age during a similar follow-up period was 8 cases. That is to say, the operated
patients had a lower risk of gastric cancer than the nonoperated patients. This study, as well as many others, shows that the risk of gastric cancer does not significantly increase after partial gastrectomy for benign peptic ulcer.

It is true that there are some studies that appear to show an increased risk of gastric stump cancer as compared to the general population. But these studies are seriously flawed. All of the studies that show slight increases in the rate of gastric cancer following Billroth II include patients that have had the surgery for ulcer disease. The problem with this kind of study design is the fact that gastric ulcer is associated with an increased risk of gastric cancer. For example, in a study by Molloy and Sonnenberg the association between ulcer and gastric cancer was demonstrated in patients from the US Department of Veterans Affairs. 3,078 subjects with gastric cancer were compared with 89,082 people without gastric cancer. This study showed that gastric ulcer patients had an increased rate of gastric cancer (relative risk 1.53, note that this increased risk is similar in magnitude to the increased risk reported in the studies showing an increased risk of gastric cancer in Billroth II surgical patients.) Many other studies confirm these findings that ulcer patients have an increased risk of gastric cancer.

In a study by Hansson published in the New England Journal of Medicine the risk of stomach cancer in 57,936 patients was analyzed. The rate of gastric cancer among patients with gastric ulcers was increased 1.8 times. Again, this value is very similar to that reported for the increase seen in some studies of post-gastrectomy patients. They concluded that gastric ulcer disease and gastric cancer have causative factors in common. Thus the studies that find small increased rates of gastric cancer in post gastrectomy patients may simply be identifying gastric ulcer patients that are prone to develop gastric cancer regardless of any surgery they may have had.

The incidence of gastric cancer in the United States has decreased four-fold since 1930 to approximately 7 cases per 100,000 people. It is important to look at the actual size of the reported possible increased risk of stomach cancer in the series that appear to find an increased risk of stomach cancer in post gastrectomy patients.

In other words, how much of an increased risk are we talking about and how does that compare to other factors involved in the development of gastric cancer. As described above the many studies find no increased risk of gastric cancer in Billroth II patients, but in the studies that do find an increase in risk, how much of an increase is seen and how does this compare to other factors involved in the development of gastric cancer? Analysis of these issues can put these studies reporting an increased risk of gastric cancer into proper perspective.

What causes cancer of the stomach?

No single cause for stomach cancer has been identified but a number of important risk factors are known. Diets rich in salted or smoked foods have been associated with increased cancer risk in many studies. Similarly, some foods contain nitrites and these chemicals can be converted to more harmful compounds (carcinogens) by bacteria in the stomach. Lack of vitamin C, fruit and vegetables may be important. Stomach cancer is more common in smokers and in those with heavy alcohol intake.

**Helicobacter Pylori**

Helicobacter Pylori (H. Pylori) is being increasingly recognized as an important and potentially causative agent in a variety of serious medical illnesses including stomach ulcers and cancer. In recent years studies have reported that infection with Helicobacter pylori (HP) can increase the risk of gastric cancer three to six fold. This data has come from large population studies comparing the rates of HP infection in patients with gastric cancer compared with patients who do not. It has been estimated that HP infection may actually be responsible for approximately 60% of all cases of stomach cancer. At present, there is no general recommendation that antibiotic therapy should be offered to people with the H. Pylori infection. Studies clearly show that H Pylori not gastrectomy appears to be the risk factor associated with gastric cancer and physicians who feel this is of concern can provide treatment to patients to eradicate H. Pylori.

The risk of stomach cancer is higher in close relatives of patients with the disease. Hundreds of articles have looked at factors that affect the development of gastric cancer. These studies of stomach cancer indicate that salted, smoked, pickled, and preserved foods (rich in salt, nitrite, and preformed N-nitroso compounds) are associated with an increased risk of gastric cancer. There is good evidence that the high eating fresh fruit and raw vegetables and a high intake of antioxidants are associated with reduced risks of gastric cancer.

Now with all of these factors know to affect the risk of gastric cancer, where is post-gastrectomy positioned as a risk factor? Extensive research shows that gastric cancer has an environmental cause, of which diet appears to be the most important component. Studies show that there is an approximately a threefold increased risk of gastric cancer for frequent consumption of fresh and processed meats (relative risk 3.1 and 3.2). Gastric cancer risk rises with increasing intake of smoked and pickled foods (relative risk 3.7.) All of these factors that increase the risk of gastric cancer are as much as twice as high as that seen with the studies showing an effect of gastrectomy on gastric cancer risk. Many studies also show a decreasing risk of stomach cancer with increasing frequency of vegetable consumption. Increased intake of citrus fruits (risk 0.47) and raw-green vegetables (risk 0.56) appear to be protective. Consumption of salty snacks more than twice per month has been associated with an 80 percent increased risk. These findings are consistent with many studies around the world that indicate important roles for salt, processed meats, and vegetable consumption in the risk of gastric cancer.

There are dozens more articles like these but we can summarize these findings as follows:

- The incidence of gastric cancer in the United States has decreased four-fold since 1930 to approximately 7 cases per 100,000 people. This is in the range of the risk of being struck by lightning.
- Billroth II post gastrectomy patients are at either a small additional risk or no increased risk of gastric cancer.
If either they or their physicians are concerned about gastric cancer it appears that very simple dietary modifications (i.e. avoiding processed meats, smoked and pickled foods while increasing one's intake of yogurt, fresh fruits and vegetables, with or without supplementation with additional antioxidant vitamins) can have a much greater impact on the patient's lifetime risk of gastric cancer than that of the Mini-Gastric Bypass. Another way to put this is to say that a regular diet of bologna sandwiches appears to be of greater risk to a patient for the development of gastric cancer than the Billroth II.

It may also be of value to point out that thousands of general surgeons routinely perform the Billroth II anastomoses on a daily basis. Tens of thousands of patients undergo Billroth II type gastrojejunostomy on a yearly basis and there is no ground swell effort being generated against the risk of the Billroth II type anastomoses.

The Causes of Stomach Cancer

Following are questions that will help you determine if you're at high risk for developing stomach cancer:

Do you have an existing stomach ulcer? (Stomach ulcers don't necessarily cause stomach cancer, but stomach cancer often originates in people with a stomach ulcer.)
- Are you a heavy eater of food that's been smoked, pickled, barbecued, and salted?
- Have you been exposed to aflatoxins, carcinogenic byproducts of a fungus that grows on seeds, nuts, corn, and other dried foods?
- Do you smoke or drink alcohol heavily?
- Is it possible that you could be suffering from an H. pylori infection? (It causes stomach irritation and ulcers and might contribute to the formation of some cancers.)
- Do you have a personal history of gastritis, pernicious anemia, and gastric polyps?
- Are you involved in an occupation such as coal mining or metal mining?
- Do you live or work in an environment where you inhale dust and fumes?
- Are you male? (Stomach cancer occurs twice as often in men as in woman.)
- Are you African American?

Low dose aspirin bleeding risk: Aspirin “thins” the blood

Even low doses of aspirin can cause internal bleeding in the stomach and intestine, researchers have found. Many doctors recommend that their patients take aspirin to reduce their risk of heart problems. The drug thins the blood, and reduces the risk of clots forming in key blood vessels. “Aspirin treatment should be used only when there is good reason to do so,” said Dr Yoon Kong Loke, Radcliffe Infirmary. It is well known that doses of 300mg a day, which were prescribed in the past, carry a risk of gastrointestinal bleeding. Some experts thought, however, that low doses of aspirin, such as 75mg a day, that is “baby aspirin” carry little risk of side effects. But this theory has been debunked by scientists at the Radcliffe Infirmary in Oxford, who found that long-term use of the drug, even at low doses, does have potentially harmful side effects. They also found no evidence that using expensive “modified release” formulations of aspirin reduces the risk of bleeding. The researchers analyzed 24 previous studies of aspirin, involving almost 66,000 patients. They found that, on average, bleeding occurred in 2.5% of patients taking aspirin compared with 1.4% who were not. Writing in British Medical Journal, the researchers warn that their findings have important implications for everyday practice as the use of aspirin to prevent heart problems is very common. Patients and doctors need to consider the trade-off between the benefits and harms of long term treatment with aspirin, they say. Researcher Dr Yoon Kong Loke said: “There is no doubt that aspirin is an effective drug. “Because of this problem with gut bleeding though, aspirin treatment should be used only when there is good reason to do so.” In an accompanying editorial, Dr Martin Tramer, of Geneva University Hospitals, Switzerland, argues that it is unclear who should be given what dose of aspirin and for how long. Doctors have been treating their patients with low dose aspirin on the understanding that they did more good than harm, he says. But it was wrong to make such an assumption until further research was carried out. A study by researchers at the Wolfson Institute of Preventive Medicine in London published earlier this year found aspirin was linked to a risk of serious bleeding in men with high blood pressure.

To estimate the risk for upper gastrointestinal (UGI) bleeding in patients taking low-dose aspirin, investigators in Spain reviewed charts of and interviewed 903 consecutive hospitalized patients who were diagnosed with cardiovascular disease and who were treated with low-dose aspirin (75-325 mg/day).

During a mean follow-up of 45 months, 41 patients (4.5%) required hospitalization for UGI bleeding (annualized rate, 1.2 events per 100 patient-years). The hospitalization rate remained constant throughout the study. In multivariate analysis, factors that increased the risk for a UGI bleeding event were history of peptic ulcer disease or UGI bleeding (relative risk, 3.1) and aspirin dose above 100 mg/day (RR, 1.8). Factors associated with a decreased risk for UGI bleeding were use of acid antisecretory agents (RR, 0.22) and use of nitrates (RR, 0.73). The authors concluded that the risk for UGI bleeding in patients taking low-dose aspirin is significant and higher than risks documented in prior clinical trials. These results confirm that low-dose aspirin therapy carries a small, but significant, risk for UGI bleeding and that the lowest aspirin dose is the safest. The increased risk for UGI bleeding in patients with peptic ulcer disease reported in this study is similar in magnitude to the reported risk for UGI bleeding associated with NSAIDs. If UGI bleeding risk in patients with peptic ulcer disease is partially mitigated by acid reduction, then this study may underestimate this risk because nearly 40% of patients on antisecretory therapy were taking proton-pump inhibitors, which are more likely to confer protection.
Ulcers, Gastrointestinal Tract Bleeding and the use of Antidepressants

Ulcers, upset stomach and gastritis are some of the most common problems and complaints after Roux-en-Y and MGB surgery. It is very important to be aware of this risk and actively avoid things that increase the risks of gastric irritation and damage where possible and remember to do the things that can help protect the lining of the stomach. Recently several studies have documented the fact that the use of selective serotonin reuptake inhibitors (SSRI’s) increases the risk of upper gastrointestinal tract bleeding by 2-400%. Some prominent SSRIs include Celexa (Citalopram), Luvox (Fluvoxamine), Paxil (Paroxetine), Prozac (Fluoxetine), Zoloft (Sertraline). In a recent study from the Archives of Internal Medicine “Use of Selective Serotonin Reuptake Inhibitors and Risk of Upper Gastrointestinal Tract Bleeding: A Population-Based Cohort Study” the risk of upper gastrointestinal tract (GI) bleeding with use of antidepressant medication was evaluated in all users of antidepressants in Denmark. During periods of SSRI use without use of other drugs associated with upper GI bleeding, we observed 55 upper GI bleeding episodes, which was 360% more than expected. Combined use of an SSRI and nonsteroidal anti-inflammatory drugs or low-dose aspirin increased the risk to 1220% and 520% respectively. Antidepressants without action on the serotonin receptor had no significant effect on the risk of upper GI bleeding. The risk with SSRI use returned to normal after termination of SSRI use.

They concluded that selective serotonin reuptake inhibitors increase the risk of upper GI bleeding, and this effect is potentiated by concurrent use of nonsteroidal anti-inflammatory drugs or low-dose aspirin, whereas an increased risk of upper GI bleeding could not be found with other types of antidepressants.

What you should expect after you leave the hospital

You should be alert and oriented. You should understand what day it is, where you are and what is going on around you. In summary you should feel that you are almost back to normal.

You should be able to stand, walk and move about steadily and without dizziness or lightheadedness. You should be up and walking very often during the day. You should not have undue amounts of pain. You should be able and encouraged to go up and down steps and to be reasonably active during the day and to be able sleep well at night. It is recommended that you alternate periods of rest and activity. You may do normal daily activities, light housework, and walking as tolerated. You will tire more easily for a while after surgery, but gradually the periods of activity will get longer before you need to rest.

You should NOT have high fevers, night sweats or shaking chills at home. You temperature should be less than 101.5. You should be able to breathe comfortably without pain or shortness of breath. You should not be coughing up sputum or blood. You are encouraged to breath deeply, to cough and clear your lungs to open the lungs and help them recover from the operation.

You Should Have a Normal Pulse Rate: After the surgery one of the best indicators that something is wrong is a rapid pulse rate. Often this shows up as the first sign of an important problem. In the first week after surgery get in the habit of taking your pulse several times per day. The more often that you do it the better you will be at it. Your pulse after resting for 10 minutes should be under 100 beats per minute. It is very worrisome if it is over 120 beats per minute. If your pulse is over fast or if you do not feel well call Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery immediately.

You should be able to drink fluids without nausea or vomiting. Remember you have a new and very small stomach. Drink slowly and drink only a small amount at one time. Sip your juices. Don't rush it. Sometimes it may help to dilute your juices with water half and half.

You may have diarrhea for several days after the surgery. This can be severe for a few days and if you are not near a bathroom can lead to accidents in some cases. In every patient so far this problem has resolved in the first week or 10 days following the operation as the body begins to adjust to the new bypass.

You may have constipation: The Sucralfate (Carafate) and other factors can lead to constipation after the operation. Usually this resolves in the first week after the operation. If you are having problems with mild constipation you may try stopping the Sucralfate (Carafate) and taking a small dose of Milk of Magnesia. If you do not feel well remember to call Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery.

You should be able to pass your urine without difficulty. You should not have burning pain, bleeding or hesitancy when you pass you urine.

You may have some clear or bloody drainage from the wounds. If you do, you can change your bandages whenever necessary. The drainage should not be purulent or foul smelling. There may be some bruising around the port site wounds but they should not turn red or swell or become more painful.

You can take a shower. Treat the wounds with care, but they can get wet. You can cover them with a Band-Aid, if you wish.

against UGI bleeding than are H-2 receptor antagonists. This study did not include enough patients who had Helicobacter pylori infection or who were taking nonaspirin NSAIDs to determine their association with UGI bleeding in low-dose aspirin users.
CAUTIONS - "What to Look Out For"

Nausea: Nausea is common for the first several days after surgery. In unusual cases the nausea can be so severe that prevent patients from taking in an adequate amount of liquids. If this happens you need to come back to the hospital to receive intravenous fluids. Rarely this can last as long as several weeks. In every single case so far this has always resolved. For nausea that occurs in the first days after surgery medications such as the Scopolamine patch, Phenergan and benadryl are often helpful.

Nausea and Estrogen Levels: Nausea is common in the first several months of pregnancy. It is felt that the nausea of pregnancy may in part be related to changing hormone levels. We have seen that nausea can occur after Laparoscopic Mini-Gastric Bypass and that this nausea can sometimes be reversed by a low dose estrogen patch, Climara 0.05 mg/day. Climara is indicated for the treatment of menopausal symptoms, hypoestrogenism and the prevention of osteoporosis. Estrogens should not be used by patients with known or suspected pregnancy, breast cancer, estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding, active thromboophlebitis or thromboembolic disorders. Estrogens have been reported to increase the risk of endometrial carcinoma.

Constipation:
Infection: Watch for signs and symptoms of infection. These are: a rapid pulse rate of over 100 beats per minute that does not slow down, a fever greater than 101.5 degrees, chills, increased redness or pus draining from the incision sites. Look for increasing abdominal pain, nausea, vomiting or shortness of breath. If you experience any of these please CALL Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery immediately.

Pneumonia:
Depression: Our experience has shown us that in the period of stress, starvation and weight loss that occurs following Mini-Gastric Bypass mild to severe depression is common. You and your family should look for the signs of depression: Persistent sad, anxious, or "empty" mood, - Loss of interest or pleasure in activities, including sex, Restlessness, irritability, or excessive crying, Feelings of guilt, worthlessness, helplessness, hopelessness, Sleeping too much or too little, early-morning awakening. Decreased energy, fatigue, feeling "slow down". Thoughts of death or suicide. Difficulty concentrating, remembering, or making decisions. Persistent physical symptoms that do not respond to usual treatment. Effective drug and psychological treatments for depression are available. With treatment patients can improve and return to normal quickly. Unfortunately, most depressed persons do not recognize their depression. You and your family need to be aware of the risk of depression in the recovery period and if present we need to discuss possible treatment.

Estrogen and Depression

A recent paper by Soares and colleagues\(^{550}\) points out that previous studies have suggested that estrogen improves depressive symptoms experienced by perimenopausal women. They studied the effect of Climara 17beta-estradiol patch for the treatment of clinically significant depressive disorders in perimenopausal women. Women (aged 40-55 years), with major depressive disorder, dysthymic disorder, or minor depressive disorder were randomized to receive transdermal patches of 17beta-estradiol (100 microgram) or placebo in a 12-week, double-blind, placebo-controlled study.

Remission of depression was observed in 17 (68%) women treated with 17beta-estradiol compared with 5 (20%) in the placebo group (P = .001).

Patients treated with estradiol sustained antidepressant benefit of treatment after the 4-week washout period, although somatic complaints increased in frequency and intensity. Treatment was well tolerated and adverse events were rare in both groups. They concluded that the transdermal estradiol replacement is an effective treatment of depression for perimenopausal women.

Our experience has been that with the rapid decline in estrogen that results from the starvation and weight loss following surgery, there is a significant incidence of depression, anxiety and irritability that is often relieved by short term estrogen patch supplementation. We have had very good results with CLIMARA® (estradiol transdermal system.) This is the leading transdermal (patch) form of estrogen replacement. The CLIMARA® system delivers estrogen directly into the blood stream in the same manner as when it is naturally produced in a woman's body.

The patch is a major drug and has risks as well as benefits:

WHO SHOULD NOT USE ESTROGENS

Estrogens should not be used:
• During pregnancy (see Boxed Warning).
• If you think you may be pregnant, do not use any form of estrogen-containing drug. Using estrogens while you are pregnant may cause your unborn child to have birth defects. Estrogens do not prevent miscarriage.
• If you have unusual vaginal bleeding which has not been evaluated by your doctor (see Boxed Warning). Unusual vaginal bleeding can be a warning sign of cancer of the uterus, especially if it happens after menopause. Your doctor must find out the cause of the bleeding so that he or she can recommend the proper treatment. Taking estrogens without visiting your doctor can cause you serious harm if your vaginal bleeding is caused by cancer of the uterus.
• If you have had cancer.
Since estrogens increase the risk of certain types of cancer, you should not use estrogens if you have ever had cancer of the breast or uterus, unless your doctor recommends that the drug may help in the cancer treatment. (For certain patients with breast or prostate cancer, estrogens may help).
• If you have any circulation problems.
Estrogen drugs should not be used except in unusually special situations in which your doctor judges that you need estrogen therapy so much that the risks are acceptable. Men and women with abnormal blood clotting conditions should avoid estrogen use (see RISKS OF ESTROGENS, below).

- When they do not work.

During menopause, some women develop nervous symptoms or depression. Estrogens do not relieve these symptoms. You may have heard that taking estrogens for years after menopause will keep your skin soft and supple and keep you feeling young. There is no evidence for these claims and such long-term estrogen use may have serious risks.

Some of the “RISKS OF ESTROGENS”
- Cancer of the uterus.
- Cancer of the breast.
- Gallbladder disease.
- Abnormal blood clotting.

You are cautioned to discuss very carefully with your doctor or health care provider all the possible risks and benefits of long-term estrogen and progestin treatment as they affect you personally.

These issues are much less of a concern in our post MGB patients because the surgery itself markedly decreases the patients’ estrogen levels and the patch only acts as a short term bridge to the new life of lower estrogen levels. Taking a short course of the estrogen patch is akin to taking a nicotine patch when someone is quitting smoking. Over the long term one of the greatest advantages of the MGB and weight loss is lower systemic estrogen levels and lower risk of cancer from high estrogen levels.

SIDE EFFECTS

In addition to the risks listed above, the following side effects have been reported with estrogen use:
- Nausea and vomiting.
- Breast tenderness or enlargement.
- Enlargement of benign tumors (“fibroids”) of the uterus.
- Retention of excess fluid. This may make some conditions worsen, such as asthma, epilepsy, migraine, heart disease, or kidney disease.
- A spotty darkening of the skin, particularly on the face.

Sample comments from our patients on short term supplementation with the Climara estrogen patch:

I have had to wear the patch for about 4-5 days the last two months the week before my period. I just get edgy and very bitchy about everything. It helps within an hour or two. I’d probably wear the patch for the whole 7 days, but it doesn’t stick well and taping it to my arm is really annoying. This month I plan to “patch” early so I don’t get all crabby. It is a temporary fix until things settle down with estrogen level. Don’t think of it as permanent, but just one of the things you need to do to be yourself.

Karen McG.

I got grumpy post op and my hubby put the patch on my behind. I felt so much better after that. I used what was in the box (they are good for a week each) and have not needed any since. Every one is different. Try it you might like the way you feel. Don’t feel like if you put it on you will have to use it forever. Good luck.

S.B.

Covey, you need the patch!!!!!!! I used the patch for one month and it really helped keep me on an even keel. Call the CLOS offices and/or your PCP/Gyn for a prescription. You and your fiancé will be so glad that you did!!!!! Good luck,

Alisha Covey,

You may need to switch to the Estrogen Patch... Which seems to work better for new post ops than pills do...? At least that has been the experience of other MGBer’s, rely on their experience! Bw, when I took birth control pills it made me, depressed and bitchier! Couldn’t handle the mix....

Hugs, LyndaV Cushing Oklahoma USA

I used DepoProvera for a while - for birth control and then for hormone control. I know Shelley that you don’t have any problems but I HATED IT and SO DID MY HUSBAND. I was a raving witch with a capital B, had no interest in sex, etc. My OB/GYN even hates it - will use it if a patient requests but doesn’t “recommend” it. It also “supposedly” can make you resistant to losing weight - even though Shelley you obviously haven’t had problems in that area either.

Julie in GA

Lisa,

Mean just doesn’t quiet describe how bad I get when I need my hormones. Death wish for individuals who cross me is more like. Minimal dose. It’s like having a back massage, chocolate and a hot shower all at the same time....I don’t miss my estrogen unless it’s by accident or they post warnings of possible terrorist activity in our area!

Valerie in SC

The patch can cause problems:

Peggy, I had surgery may 01 2002 and last month I had a period for the whole month. This month (21 days later) I started again and thought I was going to bleed to death I was on the estrogen patch and the Dr. took me off that and put me on progestin and the bleeding slowed down immediately and almost stopped by 2 days. I go back for check up tomorrow.

Prayers for you.

Bonnie

Do Not Drive for two weeks or until you are completely back too normal.
Mini-Gastric Bypass - Patient and Physician Manual

NO SMOKING!

Smoking has been shown to be a risk factor for wound infection in surgery. When compared to non-smoking, smoking was significantly associated with wound infection after all types of surgery. Other risk factors associated with complications were diabetes, obesity, alcohol, NSAIDs, duration of surgery, and surgical experience. I know you've heard this before, but it really is an important part of your recovery. Smoking causes narrowing of your blood vessels that in turn decreases circulation. If you smoke you will need to stop as soon as possible. Ask your nurse or Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery for information on smoking cessation drugs and programs.

**Post Op: Vaginal Yeast Infections**

Vaginal yeast infections are caused by a fungus called *Candida albicans*. Yeast infections can be very uncomfortable, but are usually not serious. Symptoms include the following:

- Itching and burning in the vagina and around the outside of the vagina (the vulva, the edge of skin that surround your vagina)
- A white vaginal discharge that may look like cottage cheese

**Swelling**

Yeast infections are so common that ¾ of women will have one at some time in their lives. Half of all women have more than one infection in their lives. If you have symptoms of a yeast infection, you can call Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery or speak with your doctor about your symptoms.

**What causes vaginal yeast infections?**

Yeast are tiny organisms that normally live in small numbers on the skin and inside the vagina. The acidic environment of the vagina helps keep yeast from growing. If the vagina becomes less acidic, too many yeast can grow and cause a vaginal infection. The acidic balance of the vagina can be changed by your period (menstruation), pregnancy, diabetes, certain antibiotics, birth control pills and steroids. Moisture and irritation of the vagina also seem to encourage yeast to grow.

**How are these infections treated?**

Yeast infections are usually treated with a vaginal medication or with a pill form that you take by mouth.

**Should I see my doctor every time I have a yeast infection?**

Be sure to see your own medical doctor the first time you have symptoms of a yeast infection. It's important to make sure you have a yeast infection before you start taking medicine. The symptoms of a yeast infection can sometimes be the symptoms of something else. If you have often been diagnosed with yeast infections, talk to your medical doctor about using a medicine you can buy without a prescription.

**How can I avoid getting another infection?**

Here are things you can do to help prevent another yeast infection:  

- Don't wear tight-fitting or synthetic-fiber clothes.
- Wear cotton underwear.
- Don't wear pantyhose or leotards every day.
- Use your hair dryer on a low, cool setting to help dry your genital area after you bathe or shower and before getting dressed.
- Wipe from front to back after using the toilet. This may help prevent the bacteria that normally live in your rectum from getting into your vagina.
- Change out of wet swimsuits or other damp clothes as soon as you can.
- Don't douche or use feminine hygiene sprays, deodorant sanitary pads or tampons, or bubble bath, and avoid using colored or perfumed toilet paper. These items seem to affect the balance of acidity of the vagina and can lead to symptoms of a yeast infection.

**Antifungal Medications**

**Prescription Drugs Now Available as Over-the-Counter Products**

**Product class: Antifungal medications**

<table>
<thead>
<tr>
<th>Active ingredients/availability</th>
<th>Brand name(s)</th>
<th>OTC indications</th>
<th>Usual dosage</th>
<th>Cost*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole 1%, 100-mg vaginal tablet or applicator full of cream</td>
<td>Gyne-Lotrimin</td>
<td>Treatment of recurrent vaginal yeast infection in persons age 12 years and over</td>
<td>One vaginal tablet or one applicator full of cream vaginally once daily</td>
<td>$12.00 per seven-day treatment regimen</td>
</tr>
<tr>
<td>Clotrimazole 1%, 200-mg vaginal tablet</td>
<td>Gyne-Lotrimin 3</td>
<td>Treatment of recurrent vaginal yeast infection in persons age 12 years and over</td>
<td>One vaginal tablet once daily</td>
<td>$7.00 per three-day treatment regimen</td>
</tr>
<tr>
<td>Butoconazole 1% cream</td>
<td>Femstat 3</td>
<td>Treatment of recurrent vaginal yeast infection in persons age 12 years and over</td>
<td>One applicator full of cream vaginally once daily</td>
<td>$17.00 per three-day treatment regimen</td>
</tr>
<tr>
<td>Miconazole nitrate 1%, 100-mg vaginal suppository or applicator full of cream</td>
<td>Monistat 7</td>
<td>Treatment of recurrent vaginal yeast infection in persons age 12 years and over</td>
<td>One vaginal suppository or one applicator full of cream vaginally once daily</td>
<td>$13.00 per seven-day treatment regimen</td>
</tr>
</tbody>
</table>

*Costs may vary by pharmacy and location.*
In most cases, your appointment will be made for you prior to your departure. http://clos.net/forms/clinic_appointment_form

must understand that it is only in unusual circumstances that you should miss these appointments. return to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery. You are expected to reason, we ask that you or your Doctor please make certain that this is only to be done in unusual circumstances and we expect that your will return to your scheduled clinic visits with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery's clinic for follow up and further education on the week following your operation and then to return every year thereafter for evaluation and further education. Only in extraordinary circumstances should miss your clinic visit with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery's clinic, you must arrange to see your referring physician. Please understand that this is only to be done in unusual circumstances and we expect that your will return to your scheduled clinic visits with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery. In the unusual event that you cannot return to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic, you must arrange to see your referring physician. Please understand that this is only to be done in unusual circumstances and we expect that your will return to your scheduled clinic visits with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery. If you do see you own Doctor for some reason, we ask that you or your Doctor please make certain that a record of the clinic visit and any laboratory work please be forwarded to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery. You are expected to return to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic for follow up and you must understand that it is only in unusual circumstances that you should miss these appointments.
http://clos.net/forms/clinic_appointment_form.htm

In most cases, your appointment will be made for you prior to your departure.
Follow Up

The Laparoscopic Mini-Gastric Bypass program includes a very extensive commitment to follow up care. From the first patient contact through long term follow up attention is constantly paid to careful and continuous follow up of patients following surgery.

The patient must recognize that an operation upon the stomach and upper digestive tract is a serious undertaking with both known and unknown long-term risks that are described by Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery and others. These include but are not limited to, ulcers, reflux, inadequate or excessive weight loss, hair loss, serious vitamin and mineral deficiencies and many other known and unknown problems detailed here and elsewhere. As a result patients must make a firm and legal commitment to fulfilling Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s instructions for long term follow up. You must agree to make every effort to follow up closely with the office and to follow post op directions to protect yourself from these and other problems associated with the bypass.

Following surgery patients must agree to not leave the area following surgery for 7 days after surgery and until you have been seen in Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic and have been approved for discharge from the area.

Patients must agree preoperatively to return to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic at 1, 3 and 6 months following surgery and every year thereafter for evaluation and further education.

In only the most extraordinary circumstances when patients cannot under any circumstances reach Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s clinic patients may try to make arrangements to have an appointment with their local medical Doctor’s clinic and with his/her approval complete that follow up visit with your local medical doctor.

In that unusual event patients must agree to make certain that the medical doctor forwards copies of their clinic visit to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery.

Patients must understand and agree that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery expects them to return to his clinic for follow up and it is only in the most unusual circumstances that patients will miss these appointments.

Patients must also promise to go to Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s website at http://clos.net/ff2.htm and complete the “Patient Follow up Form” monthly after surgery.

Patients must agree to alert Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s office of any changes in my address, telephone numbers, and email address or health status.

When to come back to clinic: You can come back to see Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery at any time.

When to get your staples out: You staples should be removed between 5-10 days after you date of surgery.

When to see Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery: Usually you should plan to see Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery on the clinic that falls closest to 7 days after your date of surgery.

WARNING: it is very important for you to stay in contact with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery.

Also yearly follow up with Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery are required after the first year.

Recommended One Year Follow Up Blood Tests:

- Vitamin B-12 level
- Folate level
- Calcium / Magnesium / Phosphorus levels
- Total Protein / Albumin
- Iron / TIBC, Ferritin
- Transferrin
- CBC (Complete Blood Count)
- Hemoglobin and Hematocrit
- Chem. 7 (Electrolytes and Glucose)
- Liver Panel: SGOT/SGPT Alk Phos, T/D Bilirubin
- Cholesterol Triglyceride Level
- Serum immunoreactive parathyroid hormone
- Hemoglobin A1c level
- Vitamin E and A levels
- Pyridoxal phosphate (Vitamin B-6) level
- DHEA-s, Zinc

Also, please go to: The Online Follow Up Form to complete your monthly follow up form.

Long Term Risks

Osteoporosis: Bone Loss and Gastric Bypass Surgery for Morbid Obesity

Osteoporosis is a common disease with a spectrum ranging from asymptomatic bone loss to disabling hip fracture. The National Institutes of Health consensus conference defined osteoporosis as a disease of increased skeletal fragility accompanied by low bone mineral density (a T score for bone mineral density below –2.5) and microarchitectural deterioration. In the United States, there are 1.5 million osteoporotic fractures per year, with an annual direct cost of nearly $18 billion. It is predicted that the prevalence of fracture will increase by the year 2025, yet less than a quarter of all women who sustain an osteoporotic fracture currently receive appropriate treatment for osteoporosis.

There is growing appreciation that weight loss procedures may be associated with the development of bone disease either with or without abnormal vitamin D metabolism.
Obesity and its Impact on Bone Mineralization

Obesity affects vitamin D metabolism, and bone mineralization. Bone mass is increased because of the additional weight in obese subjects.

Bones of obese individuals are larger and therefore less likely to fracture. Obese individuals have low-circulating serum vitamin D and 25-hydroxyvitamin D, sometimes associated with secondary hyperparathyroidism. Osteomalacia and secondary hyperparathyroidism can occur in obese individuals who have not undergone any kind of gastric surgery.

There is a long-standing recognition of a relationship between gastrointestinal surgery and the development of abnormal vitamin D metabolism and bone disease, osteomalacia, osteitis fibrosa cystica, and osteoporosis.

In a recent study by Coates et al. reported on the loss of bone mass in patients who had undergone Roux-Y gastric bypass. By 9 months patients had lost Bone Mass Density had decreased by 7.8% at the total hip, 9.3% at the trochanter, and 1.6% at the total body. Parathyroid Hormone level and serum 25(OH) vitamin D did not change.

Similar results were found in two previous studies. Women who had undergone laparoscopic gastric banding were investigated in one study. By 12 months, patients had lost 50 pounds; Bone Mineral Density had decreased at the femoral neck by 3.0% and at the total body by 2.1%. Parathyroid Hormone and serum 25(OH) Vitamin D did not change. In a second study, 14 morbidly obese patient that underwent vertical banded gastroplasty by 12 months had lost weight, had lost Bone Mineral Density at the hip. Estrogen levels declined in the women. Studies have also shown that bone loss occurs in patients who lose weight secondary to medical treatments. Gastric surgery and weight loss in morbidly obese individuals cause increased bone resorption and increased bone loss.

Recommendations for management of osteoporosis

Nonpharmacologic Options
Calcium supplementation should probably be a part of the prevention and treatment for all osteoporosis patients. A recent meta-analysis of 15 calcium intervention trials demonstrated an increase of nearly 2 percent in spine bone mineral density after two years. A total calcium intake of 1200 to 1500 mg per day (through diet, supplements, or both) is recommended.

Vitamin D is essential for skeletal maintenance and enhancement of calcium absorption. Low vitamin D levels are a growing problem. As many as two thirds of patients with hip fracture are classified as having a deficiency of vitamin D. One large trial showed a reduction of 33 percent in hip fracture among nursing home residents who were given calcium supplements and vitamin D. Similarly, among older men and women in New England, calcium citrate (500 mg per day) and vitamin D3 (700 IU per day) reduced the risk of fracture. There is also strong evidence that vitamin D supplementation enhances muscle strength and reduces the risk of falling.
Counseling with regard to avoidance of smoking and excessive alcohol intake is routinely warranted, particularly since smoking and alcohol intake have been linked in some studies to greater fracture risk.

**Physical Activity**

Regular physical activity, including aerobic, weight-bearing, and resistance exercise, is effective in increasing bone mineral density of the spine and strengthening muscle mass in postmenopausal women, but there are no large trials establishing whether these interventions reduce the fracture risk.

**Pharmacologic Options**

There is good evidence that treatment can reduce the risk of fracture and improve the quality of life among patients with osteoporosis. Several pharmacologic options are available, and these can be classified according to their mechanism of action. The two main classes of drugs used to treat osteoporosis are antiresorptive agents (agents that block bone resorption by inhibiting the activity of osteoclasts) and anabolic agents (agents that stimulate bone formation by acting primarily on osteoblasts).
Postmenopausal Hormone-Replacement Therapy

Hormone-replacement therapy was once considered the primary therapy for postmenopausal women with osteoporosis. Estrogen slows bone resorption by blocking cytokine signaling to the osteoclast, increases bone mineral density, and reduces the incidence of new vertebral fractures by nearly 50 percent.

Recent concern about the nonskeletal risks associated with long-term use of estrogen (including the risk of breast cancer and the risk of cardiovascular disease); coupled with the availability of other drugs to treat osteoporosis has markedly lessened enthusiasm for hormone-replacement therapy in the treatment and prevention of osteoporosis.

Selective Estrogen-Receptor Modulators

A selective estrogen-receptor modulator such as raloxifene inhibits bone resorption through the same mechanism as do estrogens. Raloxifene increases spine bone mineral density slightly and decreases the risk of vertebral fracture by 40 percent in women with osteoporosis, but it has no effect on the risk of nonvertebral fracture. The risk of breast cancer is reduced with long-term use of raloxifene, although the drug is not approved for this indication. New selective estrogen-receptor modulators are currently in clinical trials.

Bisphosphonates

The bisphosphonates are the most widely prescribed antiresorptive agents and are often considered first-line therapy for the treatment of postmenopausal osteoporosis. Alendronate can cause chemical esophagitis, including severe ulcerations. Studies to date suggest that these agents may possibly cause long-term injury to the gastrointestinal tract, such as stomach ulcers. This risk is greater when people regularly take both bisphosphonates and NSAIDs, common pain

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Table 2. Medications Approved by the Food and Drug Administration for the Treatment or Prevention of Postmenopausal Osteoporosis.  

<table>
<thead>
<tr>
<th>Drug</th>
<th>Method of Administration and Dose</th>
<th>Reduction in Risk of Fracture</th>
<th>Side Effect</th>
<th>FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisphosphonates</td>
<td></td>
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</tr>
<tr>
<td>Alendronate</td>
<td>Oral, 35–70 mg weekly, 5–10 mg daily</td>
<td>Vertebral, nonvertebral, and hip fracture</td>
<td>Esophagitis, myalgias</td>
<td>For treatment and prevention†</td>
</tr>
<tr>
<td>Risedronate</td>
<td>Oral, 30–35 mg weekly, 5 mg daily</td>
<td>Vertebral, nonvertebral, and hip fracture</td>
<td>First dose;</td>
<td></td>
</tr>
<tr>
<td>Ibandronate</td>
<td>Oral, 150 mg monthly, 2.5 mg daily</td>
<td>Vertebral fracture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SERM</td>
<td>Oral</td>
<td>Vertebral fracture</td>
<td>First dose;</td>
<td></td>
</tr>
<tr>
<td>Anabolic agents</td>
<td>Subcutaneous, daily</td>
<td>Vertebral and nonvertebral fracture</td>
<td>Hypercalcemia, nausea, leg cramps</td>
<td>Approved for treatment only; generally used for severe osteoporosis</td>
</tr>
<tr>
<td>PTH (1–34) (teriparatide)</td>
<td>20 μg</td>
<td>Vertebral and nonvertebral fracture</td>
<td>Hypercalcemia, nausea, leg cramps</td>
<td>Approved for treatment only; generally used for severe osteoporosis</td>
</tr>
<tr>
<td>Calcitonin</td>
<td>Subcutaneous or nasal, 100–200 IU</td>
<td>Vertebral fracture only</td>
<td>Nasal stuffiness, nausea</td>
<td>Approved for treatment only; generally used for severe osteoporosis</td>
</tr>
<tr>
<td>Estrogens</td>
<td>Oral or transdermal</td>
<td>Risk of DVT, risk of cardiovascular disease, breast cancer</td>
<td>Approved for prevention only</td>
<td></td>
</tr>
<tr>
<td>Conjugated equine estrogens</td>
<td>Oral, 0.30–1.25 mg daily</td>
<td>Vertebral, nonvertebral, and hip fracture at dose of 0.625 mg daily</td>
<td>Risk of DVT, risk of cardiovascular disease, breast cancer</td>
<td>Approved for prevention only</td>
</tr>
<tr>
<td>17β-estradiol</td>
<td>Oral, 0.025–0.10 mg, or transdermal twice weekly</td>
<td>No data from randomized, controlled trials</td>
<td>Risk of DVT, risk of cardiovascular disease, breast cancer</td>
<td>For prevention only</td>
</tr>
<tr>
<td>Ultra-low-dose (0.014 mg/day, given weekly)</td>
<td>No data available</td>
<td>No data from randomized, controlled trials</td>
<td>Risk of DVT, risk of cardiovascular disease, breast cancer</td>
<td>For prevention only</td>
</tr>
</tbody>
</table>

* All agents approved for treatment have demonstrated efficacy in reducing fractures, as determined in randomized, placebo-controlled trials with fracture as the primary endpoint. DVT denotes deep-vein thrombosis. SERM selective estrogen receptor modulator, and PTH parathyroid hormone.
† There has been limited post-marketing experience with ibandronate for prevention.
‡ There may be a response to the first dose at 150 mg consisting of myalgias, joint aches, and low-grade fever, which is similar to a response to the first intravenous administration of bisphosphonates containing nitrogen.
§ The use of calcitonin is not generally recommended.
¶ A reduction in the risk of hip fracture has not been established for 17β-estradiol in a randomized, controlled trial.
Long-term use of NSAIDs is known to increase the risk of ulcers, so both agents may have a double effect on the stomach lining. A 2002 study, in fact, reported a far higher risk for ulcers (38%) from taking both Fosamax and naproxen compared to either drug alone. (The risk for ulcers was 8% with Fosamax alone and 12% with naproxen alone.) It is not known yet if the risks for these adverse actions are as high with other combinations. For example, ibuprofen may have a lower risk for ulcers than naproxen, and Actonel may have fewer adverse effects on the stomach than Fosamax does. Because so many older people take NSAIDs, regularly clarifying these effects is very important. Alendronate or risedronate once weekly has been shown to reduce the rate of drug-induced esophagitis, as compared with daily doses.

Calcitonin

Calcitonin is a peptide that partially inhibits osteoclast activity. Nasal calcitonin and subcutaneous calcitonin are approved for the treatment of postmenopausal osteoporosis. Although treatment of women with osteoporosis with nasal calcitonin at a dose of 200 IU per day has been shown to reduce the incidence of vertebral (but not nonvertebral) fracture in a single randomized trial.

Anabolic Agents (Synthetic Parathyroid Hormone)

In 2002, synthetic parathyroid hormone (1–34) (teriparatide) was the first anabolic agent approved by the FDA for the treatment of postmenopausal osteoporosis. Unlike antiresorptive agents, parathyroid hormone stimulates bone remodeling by increasing bone formation. In a large randomized trial involving postmenopausal women with severe osteoporosis, 20 µg of parathyroid hormone per day administered subcutaneously markedly increased bone mineral density and reduced vertebral and nonvertebral fractures by more than 50 percent. However, the trial was stopped after 20 months because of concern about the development of osteosarcoma in rats treated with high doses of parathyroid hormone (1–34). As a result, a “black-box” warning was added to the teriparatide label. However, retrospective studies have found no association between osteosarcoma and primary or secondary hyperparathyroidism in humans, and no cases of osteosarcoma have been reported in the more than 200,000 patients treated with parathyroid hormone. The current recommendation is that parathyroid hormone therapy should be limited to persons with moderate-to-severe osteoporosis and that the duration of therapy should not exceed two years. Parathyroid hormone (1–34) is well tolerated, although mild but asymptomatic hypercalcemia (i.e., a serum calcium level between 10.5 and 11.0 mg per deciliter [2.6 and 2.8 mmol per liter]) can occur rarely. Cost and the requirement of subcutaneous administration are major limiting factors.

National Treatment Guidelines

Several professional societies and government agencies have provided guidelines for treatment options.

<table>
<thead>
<tr>
<th>Table 3. Recommended Regimens for the Prevention and Treatment of Postmenopausal Osteoporosis.</th>
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<tr>
<td><strong>Organization</strong></td>
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<tr>
<td>National Osteoporosis Foundation</td>
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<tr>
<td></td>
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<tr>
<td>American Association of Clinical Endocrinology</td>
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<td></td>
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<tr>
<td>U.S. Surgeon General’s Pyramid Approach†</td>
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* Data in this table are from the National Osteoporosis Foundation (2003), Hodgson et al. (2001), and the Office of the Surgeon General (2004). † T scores are the number of standard deviations the bone mineral density measurement is above or below the young-normal mean bone mineral density.

† The pyramid approach consists, in ascending order, of lifestyle changes, the identification of a secondary cause of osteoporosis, and pharmacotherapy.

Figure 5: Recommended Regimens for the Prevention and Treatment of Postmenopausal Osteoporosis.

Summary and Recommendations for the Prevention and Treatment of Osteoporosis
Zinc deficiency can occur when zinc intake is inadequate, when there are increased losses of zinc from the body, or when the body's requirement for zinc increases. There is no specific deficiency disease associated with zinc. General signs of zinc deficiency include poor appetite, weight loss, delayed healing of wounds, taste abnormalities, and mental lethargy. As body stores of zinc decline, these symptoms worsen and are accompanied by diarrhea, hair loss, recurrent infection, and a form of dermatitis -- a skin disorder. Zinc deficiency has also been linked to poor growth in childhood.

Who may need extra zinc?
Deficiency: The signs and symptoms of zinc deficiency include anorexia, growth retardation, delayed sexual maturation, hypogonadism and hypospermia, alopecia, immune disorders, dermatitis, night blindness, impaired taste (hypogeusia), and impaired wound healing. The first signs of zinc deficiency in marginally nourished children are suboptimal growth, without adequate medical supervision. The National Academy of Sciences is currently reviewing recent research and considering new recommendations on zinc intake and risk.

Some food sources of zinc
Raisin bran, 1 oz: 1.5 mg
Chickpeas (garbanzo beans) canned, 1/2 c: 1.3 mg
Milk or yogurt, 1 c: 1.0 mg
Flounder/sole, cooked, 3 oz.: .5 mg
Beef chuck, lean, cooked, 3 oz: 7.4 mg
Pork tenderloin, lean, cooked, 3 oz: 2.2 mg
Baked beans, canned, 1/2 c: 1.8 mg
Cashews, unsalted, dry roasted, 1 oz: 1.6 mg
Pecans, unsalted, dry roasted, 1 oz: 1.6 mg

It is known that severe cases of zinc deficiency can lead to alopecia, diarrhea, emotional disorders, weight loss, infection, bullous-pustular dermatitis and hypogonadism.

Deficiency: The signs and symptoms of zinc deficiency include anorexia, growth retardation, delayed sexual maturation, hypogonadism and hypospermia, alopecia, immune disorders, dermatitis, night blindness, impaired taste (hypogeusia), and impaired wound healing. The first signs of zinc deficiency in marginally nourished children are suboptimal growth, anorexia, and impaired taste. The most serious manifestations of zinc deficiency were reported in Iranian dwarfs. These
adolescent boys, who consumed large amounts of clay, were retarded in growth and sexual development and had anemia, hypogonadism, hepatosplenomegaly, rough skin, and mental lethargy. After treatment with a well-balanced diet containing adequate amounts of zinc for 1 yr, pubic hair appeared, sexual organs increased in size, linear growth was resumed, and the skin became normal. The anemia responded to iron supplements. Zinc deficiency develops in some patients with cirrhosis because the ability to retain zinc is lost.

Biochemical signs associated with zinc deficiency include decreased levels of plasma zinc (< 70 μg/dL).

Hair loss following Weight Loss Surgery

Hair loss is a relatively common occurrence following various types of surgery in general and after weight loss surgery in particular. In a study by Neve et al significant diffuse hair loss occurred in 47 out of 130 patients who underwent vertical banded gastroplasty. All of the study patients had been advised to take a multivitamin supplements. The 47 developed hair loss despite taking the supplement. These patients were then prescribed Zinc Sulfate 200 mg three times a day. There were no other changes in the vitamin supplementation. Following the institution of zinc treatment hair loss stopped and regrowth of hair began in all patients. In five patients hair loss recurred after stopping zinc. This recurrent hair loss was reversed within 6 months of restarting zinc 600 mg daily. They concluded that significant hair loss occurs in about one-third of patients after vertical banded gastroplasty, but that this can be reversed by zinc supplementation.

Colds: What to do in case of a cold?

Many people ask “What can I take for a cold?” This is a common question after Mini-Gastric Bypass. Unfortunately, as many people know, the cure of the common cold, a viral upper respiratory infection, remains elusive. Nothing has yet been shown to be successful in the treatment of a “cold.” In the case of the Flu there are some new medications that may help.

For Colds

Many people ask about:

1) Tylenol (Acetaminophen). It can be somewhat helpful for the aches and pains of a cold but in a Mini-Gastric Bypass patient Tylenol may risk damage to the liver, so we do not recommend it.

2) Aspirin, Motrin, Aleve, etc. These medications can help relieve the aches and pains of a cold but they are also known to cause ulcers in the new stomach of a Mini-Gastric Bypass, so we do not recommend them.

3) Vitamin C. In small doses probably does not hurt the stomach and may be of some help in reducing the length of symptoms of a cold. We do not recommend large doses of Vitamin C because they can irritate the stomach.

4) Echinacea remains controversial as a preventative treatment for colds. The data that I have seen does not show that it works and because it has unknown effects upon the liver and stomach, we do not recommend it.

5) Zinc probably doesn’t help cold symptoms very much but in small to moderate doses Zinc is probably OK.

6) Goldenseal No I worry about your stomach and Liver.

7) Cough syrup? Beware of alcohol, aspirin, Motrin or TYLENOL type products in the syrup, it is usually not necessary and could be harmful. If it does not contain any of those offending drugs then it may be safe.

8) Antihistamines can sometimes help with the "runny nose" that comes along with a cold. (Benadryl or Chlortrimeton) They are probably safe when used in small doses for short periods of time.

9) Nasal Sprays do no usually get into the blood stream in very high doses and thus are much safer than pills taken to help stop a runny nose. Good choice for short term treatment of sinus problems but they can cause trouble in situations where they are used for more than a few days. OK for up to 4 days.

10) Chicken Soup, Rest, Sleep, and Now you are talking! Probably the best advice is to recognize that you are sick and takes time to rest and recover from the illness.

Vitamin and Mineral Deficiencies:

The gastric bypass type surgery has been done for many years and it is clear that the absorption of some vitamin and minerals is decreased after this surgery. The most common problems are iron and vitamin B12 deficiencies. Patients must be aware that Folate, vitamin B12, and iron deficiencies occur after gastric bypass, though the time to development is variable. Vitamin and mineral deficiencies that can be devastating can be prevented by taking the recommended supplemental vitamins and minerals and by carefully monitoring blood levels of these vitamins and minerals. In a study of vitamin E, vitamin B-6, vitamin B-12, and Folate status of gastric bypass surgery patients. By Boylan et al. from the Department of Human Nutrition and Foods, Virginia Polytechnic Institute and State University, Blacksburg. J Am Diet Assoc. 1988 May; 88:5, 579-85 The vitamin E, vitamin B-6, vitamin B-12, and Folate status of 22 gastric bypass subjects aged 23 to 60 years was evaluated before surgery and at 6 and 12 months after surgery. Before the surgery, 77% of patients had adequate plasma vitamin E levels; 36%, adequate plasma Pyridoxal phosphate (vitamin B-6) levels; 100%, adequate plasma vitamin B-12 levels; and 45%, adequate plasma Folate levels. After surgery, some patients did not take the prescribed daily vitamin supplements. Patients that took higher levels of vitamins had higher blood levels of the vitamins than those taking fewer vitamins. In patients taking fewer vitamins blood vitamin levels were often deficient. Patients taking more than 100 micrograms vitamin B-12 daily had good vitamin B-12 levels. This study clearly demonstrated that the more patients took the higher their blood vitamin concentrations were. Moral of the story:
Take your vitamins (Forever) and see your Doctor once a year to have all of your blood levels tested, it a life and death proposition!

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Numerous Studies Link Gastric Bypass Surgery To Serious Neurological Conditions

A recent study concluded that patients who undergo gastric bypass surgery, also known as bariatric surgery, are at risk for long-term vitamin and mineral deficiencies and may develop a variety of serious neurological symptoms. Many of the complications patients experience affect the nervous system, and they are often disabling and irreversible." More than 150 patients who came to the UAMS Neurology Clinic following gastric bypass were included in the report. In 26 of these patients, a link between the surgery and their neurological condition was found.

All of the patients involved in the study had previously undergone the Roux-en-Y gastric bypass procedure. The interval between surgery and onset of neurological symptoms ranged from 4 weeks to 18 years.

The 26 people involved in the study were followed for several years by UAMS physicians and represent the largest compilation of gastric bypass patients with neurological complications ever reported.

"As is evident from our findings, the neurological complications of bariatric surgery involve most parts of the nervous system, and frequently more than one," Juhasz Pocsine said. "The conditions experienced by our patients spanned most regions of the nervous system from the cerebral cortex to the peripheral nerves."

Symptoms of the patients in the study included confusion, auditory hallucinations, optic neuropathy, weakness and loss of sensation in the legs, and pain in the feet, among other conditions. None of the patients had prior neurological symptoms.

Many of the patients also experienced multiple nutritional abnormalities, especially low serum copper, vitamin B12, vitamin D, iron and calcium.

Warning! "Attention should be given to long-term intake of vitamin and mineral supplements to prevent some of these complications and to avoid severe and rapid weight loss," Juhasz Pocsine said. "Patients should be made aware of the symptoms that herald these neurological complications, and physicians should attend to the wide-based nutritional deficiencies as early as possible."

Thiamine Deficiency May Complicate Gastric Bypass

Thiamine deficiency may follow gastric bypass for obesity, according to a case report in the December 27 issue of Neurology. "The neurological complications following gastric bypass surgery are diverse. Vitamin B1 deficiency and Wernicke encephalopathy should be carefully considered in surgically treated obese patients."

The authors describe a 35-year-old woman who developed many symptoms following RNY gastric bypass, including nausea, anorexia, fatigue, apathy, hearing loss, psychomotor slowing, forgetfulness, ataxia, and bilateral hand paresthesias. By the twelfth postoperative week, she had lost 40 lb and had lethargy, confusion, and difficulty walking, which necessitated hospitalization.

Examination showed inattention, fluent speech with decreased comprehension, decreased hearing, strength 3/5 in the lower extremities, vibratory sense decreased in the feet, deep tendon reflexes absent, and wide-based gait. Laboratory abnormalities were a slight elevation in liver enzymes, high serum glucose level (163 mg/dL), and low serum potassium level (2.6 mEq/L). Her mental status continued to decline despite treatment for dehydration.

When hospitalized, her heart rate was 125 beats per minute; she opened her eyes to nail bed pressure but followed no commands and was nonverbal. Pupils were round and fixed at 3 mm; oculocephalic and deep tendon reflexes were absent; and general muscle tone was flaccid without spontaneous movements or withdrawal to painful stimuli. Cerebral spine fluid protein level was 90 mg/dL, and there was diffuse slowing on electroencephalogram.

Brain magnetic resonance imaging (MRI) revealed bilateral symmetric hyperintense signal on T2-weighted and fluid attenuated inversion recovery images at the floor of the fourth ventricle, periaqueductal gray matter, the medial portions of both thalami, and the premotor and motor cortices, with contrast enhancement in all T2 hyperintense regions.

When she was given intravenous (IV) vitamin B1, 100 mg every 8 hours, her oculocephalic reflexes gradually returned to normal, and she eventually became responsive. Follow-up brain MRI 11 days after thiamine repletion showed interval improvement, with less contrast enhancement, but with increased signal on precontrast T1-weighted images in the premotor and motor cortices, likely representing petechial hemorrhages.

"Wernicke encephalopathy is a well-defined syndrome, but difficult to identify in the absence of the classic triad of oculomotor abnormalities, ataxia, and confusion," the authors write. "When a patient presents with unusual symptoms (in
Mini-Gastric Bypass - Patient and Physician Manual

our case with progressive hearing loss, most likely secondary to thalamic involvement), then blood work (red blood cell transketolase levels) and MRI become helpful tools in making the diagnosis."

“This case highlights the variability of Wernicke encephalopathy where the classic trio of eye movement abnormalities, confusion, and ataxia are seen in less than 20% of patients," says Heidi Schwarz, MD, who wrote a related commentary. "It is unusual because the patient also had hearing loss."

Dr. Schwarz notes that bariatric surgery may have other complications, including anemia, vitamin D deficiency and bone resorption, rhabdomyolysis, vitamin A deficiency, and hypocalcemia. Neurologic complications are common, especially when there is intractable vomiting causing myelopathy and ataxia due to deficiencies in vitamin B12, copper, or vitamin E; or peripheral neuropathy, plexopathies, and mononeuropathies due to vitamin or micronutrient deficiencies or as yet unknown causes.

"Although thiamine deficiency was not documented serologically [in this case report], the course, MRI findings, and response to thiamine establish the diagnosis," Dr. Schwarz writes. "Patients who have had bariatric surgery require a high index of suspicion for Wernicke encephalopathy so that prompt treatment can be given to prevent devastating and often permanent disability."


Calcium Deficiency

Obes Surg. 2004 Sep;14(8):1062-6., Calcium metabolism in pre- and postmenopausal morbidly obese women at baseline and after laparoscopic Roux-en-Y gastric bypass., El-Kadre LJ, Rocha PR, de Almeida Tinoco AC, Tinoco RC. Department of Surgery, Sao Jose do Avai Hospital, Itaperuna, RJ, Brazil.

Calcium metabolism in obese women, before and after menopause, at baseline and at 6 and 12 months after laparoscopic Roux-en-Y gastric bypass (LRNY Gastric BypassP).

LRNY Gastric BypassP restricts food intake and produces physiological changes that may be similar to those after high Billroth II subtotal gastrectomy.

METHODS: Serum calcium (Ca), phosphate, bone-specific alkaline phosphatase (BSAP) and 25-hydroxyvitamin D3 (25-OH D) were measured at baseline and 12 months after LRNY Gastric BypassP. Urinary N-telopeptide (u-NTX) was measured at baseline and serum C-telopeptide (s-CTX) at 6 and 12 months after LRNY Gastric BypassP. Parathormone (PTH) was measured at baseline and 6 and 12 months after LRNY Gastric BypassP. Patients were divided into 2 groups: Group I (n=30) pre-menopausal women aged 18-42 y, and Group II (n=30) post-menopausal women aged 40-71 y. Patients with renal, hepatic, metabolic and bone disease, smoking women, as well as patients with u-NTX values at baseline >67 nMBCE/mMCr were excluded.

RESULTS: At baseline, PTH was elevated in 10% of patients in each group, correlated positively with BMI, and low serum calcium values were found in 30% of Group I and 16.7% of Group II.

High values of serum C-telopeptide were seen in Group I at 6 months after surgery and in Group II 12 months after LRNY Gastric BypassP.

Group II showed a greater increase in BSAP at 12 months after LRNY Gastric BypassP. 25-OH D decreased in both groups, and a progressive increase in PTH was observed. Serum calcium did not change in both groups. CONCLUSION: Calcium metabolism is altered in pre- and post-menopausal women following LRNY Gastric BypassP. Calcium and vitamin D supplementation is strongly advised in all patients.

Iron Deficiency

Iron deficiency is very common, even in nongastric bypass patients. The World Health Organization considers iron deficiency the number one nutritional disorder in the world. It affects more than 30% of the world’s population. Iron is an essential mineral and an important component of many proteins. Calcium, polyphenols and tannins found in tea, and phytates, which are a component of plant foods such as legumes, rice and grains, can interfere with iron absorption. Women of childbearing age, pregnant women, older infants and toddlers, and teenage girls are at greatest risk of developing iron deficiency anemia because they have the greatest iron losses and iron needs.

Vitamin A:

Iron deficiency may also be caused by low vitamin A. Vitamin A helps to mobilize iron from its storage sites, so a deficiency of vitamin A limits the body’s ability to use stored iron. This results in an “apparent” iron deficiency because hemoglobin levels are low, even though the body can maintain normal amounts of stored iron.
Signs of iron deficiency anemia

Signs of iron deficiency anemia include feeling tired and weak, decreased work performance, difficulty maintaining body temperature, and decreased immune function, which may decrease resistance to infection.

Supplementary Agents

Adding either ascorbic acid (vitamin C) or succinic acid to ferrous sulfate therapy will improve absorption of iron stores. Ascorbic acid added to iron therapy, however, may exacerbate some of the side effects. Succinic acid added to ferrous sulfate does not appear to increase side effects.

The role of Zinc and Insulin like Growth Factor (IGF-I) in different hematologic abnormalities has been unclear. Studies have found that the addition of zinc to iron supplements increases hemoglobin levels more than iron alone.

One study of pregnant women suggested that zinc affects a hormone called insulin-like growth factor-I (IGF-I), which plays a role in the regulation of red blood cell production.

In a study of women in the second trimester of pregnancy 38 had hemoglobin concentrations below 11.0 g/dL. These 38 women were divided into three groups treated with either iron alone, Zinc alone or both iron and Zinc supplementation. Neither Iron nor zinc supplementation alone changed blood hemoglobin concentrations. In women treated with both iron and zinc Hemoglobin levels were significantly increased. Concentrations of iron, IGF-I and total iron binding capacity (TIBC) were also increased in the group that received both iron and zinc. It was concluded that zinc supplementation can affect hematological deficiencies in pregnant women.

Vitamin A Deficiency after Gastric Bypass

Gastric Bypass and Intestinal surgery can affect eyes years later

Surgery on the intestines can lead to the malabsorption of vitamin A, and this in turn can create eye problems years or even decades after surgery, especially when other illnesses are present, ophthalmologists report.

Ocular disorders that can result from vitamin A deficiency include dry eye, softening of the cornea, damage to the retina, and night blindness, Drs. T. Chae and R. Foroozan explained in the August 2006 issue of the British Journal of Ophthalmology.

The two researchers, from the Baylor College of Medicine in Houston, reviewed the records of patients diagnosed with vitamin A deficiency last year and identified four cases related to gastrointestinal surgery.

One patient developed ocular symptoms within months of gastric bypass surgery, while the other three did not have visual symptoms until at least 18 years after intestinal surgery.

The first of these three with late visual problems was a 69-year-old man who reported having night blindness for four months. He had undergone intestinal bypass surgery 20 years earlier.

The second patient was an 80-year old man who complained of 4 months of decreased vision in the right eye that was worse in dim light. Thirty-six years earlier he had undergone partial small and large bowel resection related to Crohn's disease.

The third patient reported several months of decreased vision in both eyes that was worse at night. Her medical history included "multiple abdominal surgeries 18 to 20 years earlier" as a result of complications from gallbladder surgery.

Eye tests showed abnormalities in all three cases and lab tests confirmed vitamin A deficiency, the investigators report.

The two male patients were treated with injections of vitamin A, and both reported improvements in vision in both eyes within the first week. The woman refused further treatment.

In a related editorial, two other doctors point out that other investigators have reported severe visual complications, including blindness, that followed gastric bypass surgery. They caution that such surgery is being performed more frequently for obesity. "When the remarkable rise in gastric bypass surgical procedures is considered across the world," the physicians write, the possibility of an epidemic of vitamin A deficiency "becomes an alarming reality." SOURCE: British Journal of Ophthalmology, August 2006.
Vitamin A after Gastric Bypass

Vitamin A is actually a family of fat-soluble vitamins. Retinol is one of the most active, or usable, forms of vitamin A, and is found in animal foods such as liver and eggs. It can be converted to retinal and retinoic acid, other active forms of the vitamin A family.

What does Vitamin A do?
Vitamin A plays an important role in vision, bone growth, reproduction, cell division and differentiation. It maintains the surface linings of your eye and your respiratory, urinary, and intestinal tracts. Vitamin A also may help prevent bacteria and viruses from entering your body by maintaining the integrity of skin and mucous membranes.

What foods provide Vitamin A?
Whole eggs, whole milk, and liver are among the few foods that naturally contain vitamin A. Vitamin A is present in the fat portion of whole milk, so it is not found in fat-free milk. Most fat-free milk and dried nonfat milk solids sold in the US are fortified with vitamin A. There are many other fortified foods such as breakfast cereals that also provide vitamin A. Some of the best food sources of Vitamin A and provitamin A carotenoids are listed at the end of this article. It is important to regularly eat foods that provide vitamin A or beta-carotene even though your body can store vitamin A in the liver. Stored vitamin A will help meet your needs when your intake from food is low.

How much Vitamin A do we need?
The Recommended Dietary Allowance (RDA) is the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in each life-stage and gender group. The 1989 RDAs for vitamin A for adults are: 1000 IU (International Units) for men, and 4000 IU for women including pregnant and breastfeeding women.

When can vitamin A deficiency occur?
Signs of vitamin A deficiency include night blindness, dry skin, and decreased resistance to infections. Vitamin A deficiency contributes to blindness by making the eye very dry, damaging the cornea of the eye (called xerophthalmia), and promoting damage to the retina of the eye. Extremely dry skin, dry hair, sloughing off of skin, and broken fingernails are other common signs of vitamin A deficiency. Vitamin A deficiency also decreases resistance to infections, and may contribute to the pneumonia associated with vitamin A deficiency.

There is increased interest in subclinical forms of vitamin A deficiency, described as low storage levels of vitamin A that do not cause overt deficiency symptoms. This mild degree of vitamin A deficiency may increase children's risk of developing respiratory and diarrheal infections, decrease their growth rate, slow bone development, and decrease their likelihood of survival from serious illness.

Who may need extra vitamin A to prevent a deficiency?
Individuals with chronic fat malabsorption also poorly absorb vitamin A. Fat malabsorption can occur with cystic fibrosis, sprue, pancreatic disorders, and after stomach surgery. Healthy adults usually have a one-year reserve of vitamin A stored in their livers and should not be at risk of deficiency during periods of short term fat malabsorption. Long term problems absorbing fat, however, can result in deficiency and may require vitamin A supplementation.

What is the association between vitamin A, beta carotene and cancer?
Surveys suggest an association between diets rich in beta-carotene and vitamin A and a lower risk of many types of cancer, and there is evidence that higher intake of green and yellow vegetables or food sources of beta-carotene and/or vitamin A decreased the risk of lung cancer.

What is the health risk of too much vitamin A?
Hypervitaminosis A refers to high storage levels of vitamin A in the body that can lead to toxic symptoms. Toxicity can result in dry, itchy skin, headache, fatigue, hair loss, loss of appetite, vomiting, and liver damage. When toxic symptoms arise suddenly, which can happen after consuming very large amounts of vitamin A over a short period of time, signs of toxicity include dizziness, blurred vision, and muscular uncoordination. Most cases of vitamin A toxicity result from an excess intake of vitamin A in supplements. A generally recognized safe upper limit of intake for vitamin A from diet and supplements is 8,000 to 10,000 IU per day.

Vitamin A toxicity also can cause severe birth defects. Women of child-bearing age are advised to limit their total daily intake of vitamin A (retinol) from foods and supplements combined to no more than 8,000 IU per day.

Retinoids are compounds that are chemically similar to vitamin A. Over the past 15 years, synthetic retinoids have been prescribed for acne, psoriasis, and other skin disorders. Isotretinoin (sold as Roaccutane or Accutane) is considered an...
effective anti-acne therapy, but at very high doses it can be toxic, which is why this medication is usually saved for the most severe forms of acne. The most serious consequence of this medication is birth defects. It is extremely important for sexually active females who may become pregnant and who take these medications to use an effective method of birth control. Women of childbearing age who take these medications are advised to undergo monthly pregnancy tests to make sure they are not pregnant.

What is the health risk of too many carotenoids?

Provitamin A carotenoids such as beta-carotene are generally considered safe because they are not traditionally associated with specific adverse health effects. The conversion of provitamin A carotenoids from plant foods to vitamin A slows down when body has adequate stores of Vitamin A, so the levels are naturally limited. A high intake of provitamin A carotenoids (from food sources) can turn your skin yellow, but this is not considered dangerous to health.

A study in China tested the ability of four different nutrient combinations to inhibit the development of esophageal and gastric cancers in 30,000 men and women. This study suggested a beneficial role for beta-carotene: after 5 years the participants who took a combination of beta-carotene, selenium and vitamin E had a 13% reduction in cancer deaths. At this time, taking beta-carotene supplements is not recommended.

Food Sources of Vitamin A

The following lists include some of the foods which are good dietary sources of vitamin A and provitamin A carotenoids. The best sources are liver, eggs and fortified milk, many orange fruits and green vegetables. Food manufacturers fortify a wide range of products with Vitamin A. Breakfast cereals, pastries, breads, crackers, cereal grain bars and other foods may be fortified with 10% to 15% of the recommended daily amount for Vitamin A. Read the nutrition facts panel of the food label to determine whether a food provides Vitamin A.

Some animal food sources of Vitamin A

- Beef liver, 3 oz.: 30,325 IU -- 610% of the recommended daily amount
- Chicken liver, 3 oz.: 13,920 IU
- Egg substitute, fortified, 1/4 c: 1355 IU
- Fat free milk, fortified w/ vitamin A, 1 c: 500 IU
- Cheese pizza, 1/8 of a 12” diameter: 380 IU
- Cheddar cheese, 1 oz: 300 IU
- 1 Egg, medium: 280 IU

Some plant food sources of Vitamin A (from beta-carotene)

- 1 raw carrot, 7-8 inches long: 20,250 IU -- 410% of the recommended daily amount
- Carrots, boiled, 1/2 c: 19,150 IU
- 1 Mango, uncooked: 8,050 IU
- Spinach, boiled, 1/2 c: 3,730 IU
- Cantaloupe, raw, 1 c cubes: 5,160 IU
- Kale, boiled, 1/2 c: 4,810
- Red Pepper (sweet) raw: 1/2 c sliced: 2,620 IU
- 1 packet of instant Oatmeal (fortified): 1,050 IU
- Medium sized peach: 525 IU

Fiber Intake and Increased Weight Loss

Increased intake of dietary fiber offers many advantages to both obese and to diabetic individuals. These benefits will be summarized here. [1, 2, 3]. Both soluble and insoluble fiber may contribute to weight control. Soluble fiber slows gastric emptying, decreases mixing of foods and digestive enzymes in the small intestine, and is readily fermented to short-chain fatty acids in the colon. Insoluble fiber accelerates passage of food into the colon, decreases digestion time of foods, physically prevents interaction between digestive enzymes and nutrients, and produces fullness throughout the gastrointestinal tract.
High fiber diets are very effective in the management of Type II diabetics. They lower blood glucose values, diminish need for insulin or oral medications, increase insulin sensitivity, decrease blood pressure, and drop serum cholesterol and triglycerides. Incorporation of additional dietary fiber with the gastric bypass acts synergistically to improve the expected weight loss.

a. Short-term experience

In a study of satiety a high fiber and low fiber 800 cal diets were compared. Obese diabetic men weighing approximately 250 pounds were fed high fiber diets providing 32 grams dietary fiber per day for 10 days and low fiber diets providing 8 grams per day for 10 days. Six times daily, before and after breakfast, lunch and dinner, subjects indicated their feeling of hunger or satiety by circling the descriptive words and putting a mark on a line to indicate their feeling of hunger or satiety. Study participants had significantly lower levels of feelings of hunger. On the high fiber diet, the feeling of satiety was higher at every time point than on the low fiber diet.

In another study of high fiber diets:
- Mild energy restriction - 2000 kcal/day for a person weighing 250 pounds and 60 grams of fiber/day;
- Moderate energy restriction - These high fiber diets provided approximately 5 kcal/pound (1250 kcal/day for a person weighing 250 pounds) and 45 grams of fiber/day;
- Severe energy restriction - These high fiber diets provided approximately 3 kcal/pound (750 kcal/day for a person weighing 250 pounds) and 30 grams of dietary fiber/day.

Weight loss

Since these diets were lower in sodium than their usual diets and for other reasons, some of the weight loss was related to loss of water. While on these weight-reducing diets on the metabolic research ward these subjects were encouraged to be active; some walked several miles per day but most were fairly sedentary. On approximately 2000 kcal/day (8 kcal/pound), seven men lost an average of 1.8 pounds per week over a three-week period. On approximately 1250 kcal/day (5 kcal/pound), seven men lost 3.6 pounds per week. On 800 kcal/day (3 kcal/pound), seven men lost 6.4 pounds per week or 19 pounds during their three-week stay on the metabolic research ward. Most men found the diets acceptable and continued on high fiber, weight reducing diets when discharged from the metabolic ward.

Insulin doses decreased dramatically on all weight-reducing diets. Usually insulin doses were decreased about 50% when starting these weight-reducing diets and were decreased further to avoid hypoglycemia.

Serum lipid values plummeted in all subjects. Average serum cholesterol values decreased 23% and triglycerides decreased 55%.

Blood pressure values, measured three times daily, also decreased significantly with reduction of more than 10% for both systolic and diastolic values

b. Long-term studies

While these obese diabetic individuals responded well to high fiber, weight-reducing diets in the hospital, the critical question is their long-term weight maintenance.

For home management the dietitians instructed most individuals on use of a moderate-energy restricted diet to provide about 5 kcal/pound or 1000-1500 kcal per day. These diets provided about 35-40 grams of fiber/1000 kcal. We obtained follow-up information on 25 obese, diabetic subjects who had participated in a protocol similar to that outlined above. All had been receiving insulin therapy for their diabetes and entered the metabolic ward for a weight-reducing program of approximately 3 weeks duration.

Weight responses. Subjects lost an average of 27 pounds (11.5% of initial body weight). After 2.5 years they were maintaining a weight loss of 15 pounds which represents 6.5% of initial body weight. Expressed differently, they were maintaining 56% of their weight loss at 2.5 years.

Insulin doses fell dramatically with initial weight loss with average values dropping 96%. Insulin was discontinued in 22 of 25 subjects (88%) with their weight loss. However, during the 2.5 year interval, insulin was restarted in nine subjects; thus, 12 of 25 (48%) were taking insulin at the time of follow-up.

Fasting plasma glucose values plummeted despite the major reduction in insulin dose. The values at the nadir of body weight were 43% lower than initial values. With weight gain, glucose values increased and, despite an increase in insulin dose, were 86% of initial values at 2.5 years of follow-up.

THE WORLDWIDE EXPERIENCE
Satiety: Blundell and Burley summarized three types of studies: studies using fiber supplements; studies using fiber-supplemented foods; and studies using high fiber foods. With fiber supplements such as guar gum or fiber tablets in seven of 11 studies investigators reported either decreased hunger or reduced food intake. With fiber-supplemented foods in eight of 11 studies investigators reported either decreased hunger or reduced food intake. With high-fiber foods in four of four studies investigators reported either decreased hunger or reduced food intake. Subsequent studies have confirmed and extended prior investigations. These observations led to the conclusion that dietary fiber intake decreases energy intake and contributes to fullness or satiation and maintains between meal feeling of satiety.

Weight loss: High-fiber, low-energy dense foods are widely used in weight-reducing programs for non-diabetic or diabetic patients. The typical diet recommended for moderate weight loss is generous in complex carbohydrate and fiber and limited in fat and simple sugars. While these high-fiber diets are widely used, there are no persuasive clinical studies documenting that diets providing generous amounts of fiber-rich foods are more effective in promoting weight-loss that equi-caloric diets restricted in high-fiber foods. These clinical studies are difficult to perform because subjects cannot be blinded to their dietary assignment. Clinical studies in this area are required to clearly demonstrate that high-fiber, high-carbohydrate, low-fat diets are superior to equi-caloric low-fiber, high-carbohydrate, and low-fat diets.

While high-fiber food rich diets have not been documented to promote greater weight loss than control diets, the use of fiber supplements is accompanied by significantly greater weight loss than placebo.

CONCLUSIONS

The benefits of high-fiber, weight-reducing diets for diabetic individuals are clear cut. These diets enable diabetic individuals to lose weight and maintain weight loss long-term. These diets also decrease blood glucose values, diminish need for oral hypoglycemic agents or insulin, lower blood pressure, and drop serum lipid values. Fiber supplements are documented to enhance weight loss with a hypocaloric diet. High fiber diets act mechanically, physiologically and chemically to decrease hunger and enhance between meal satiety.
Letter to Your Doctor

Explaining expected recovery and follow up benchmarks and complications (i.e. depression ...)
Request for letter:

I. Assessing the patient’s obesity and its impact on his or her health and quality of life
II. Assessing patient’s medical, surgical and psychological fitness to undergo major abdominal surgery
III. Stating your willingness to follow patient in concert with me over the long term especially for monitoring for vitamin and mineral deficiencies

Dear Dr. 

Your patient has contacted me in reference to being considered for a laparoscopic Mini-Gastric Bypass.

Request for a Letter of Support: I would like to request a letter from you about your patient. I request a letter from the primary medical physician of all of the patients that I consider for laparoscopic Mini-Gastric Bypass to assist me in the evaluation of the patient’s obesity, their candidacy for surgery, to promote the patient’s further consideration of the risks and benefits of surgery and to improve the quality of the post operative care of the patient by requiring the patient to have a documented relationship with a supportive health care provider.

For the patient to be considered for operation the patient must provide me with a letter from his/her physician that includes a detailed assessment of the patient’s obesity and its impact on his or her health and quality of life. I ask for an assessment of the patient’s medical, surgical and psychological fitness to undergo major abdominal surgery (essentially a history and physical examination).

Finally I request that the patient’s physician state his or her willingness to follow the patient in concert with me over the long term. This is especially important for encouraging the patient to remain in contact with healthcare providers to continue his or her multivitamin regimen (3 standard multivitamin tablets per day) and for yearly monitoring for vitamin and mineral levels to identify and treat potential deficiencies.

I ask that you consider providing this letter directly to the patient. It must be included as part of the very extensive application package I require for the patient to create in preparation for surgery. In addition to your letter the patient must provide us with copies of his or her pertinent past medical records, a complete history and physical with the results of a recent CBC, Electrolytes and EKG, a letter of support and understanding of the risks and benefits of surgery from the patient’s family, full length front and side photographs, contact with at minimum 10 of my previous patients who have undergone this surgery and a 10 page letter written by the patient demonstrating knowledge of surgery. All of this information is to be put together into a package that is presented to me to be reviewed prior to operation. We have performed over 2,700 laparoscopic Mini-Gastric Bypass.

Over the 9 years that we have been performing this surgery we have had 3 deaths within 30 days of the surgery in a series of over 3,600 patients. The operative procedure takes an average of 38 minutes in previously unoperated patients and the hospital stay is 1 day in over 95% of patients. The mean weight loss is 140 lbs at one year and we have has greater than 90% success in reversing diabetes, sleep apnea, hypertension etc. We have operated upon patients from all 50 states across the U.S. including Alaska and Florida, as well as Japan, England, Puerto Rico and Iceland. For any further information please call The Centers for Laparoscopic Obesity Surgery.

Your help in the preoperative evaluation of this patient is greatly appreciated.

Sincerely,

Dr. Robert Rutledge
(Private cell phone) 702-953-7066 or 702-714-0011
Email: Drr@clos.net
CLOS West Office 98 E Lake Mead PKWY, Suite 302
Henderson, NV 89015,
Office Phone: 702-456-4643, Personal fax: (909) 494-4290
Web site: http://clos.net
Operative Treatment Consent Agreement:

The purpose of this legal document is to confirm in the presence of witnesses your informed request that you wish to proceed with Mini-Gastric Bypass for obesity.

Preoperative Information and Education

My initials and comments in this form are meant to demonstrate that I understand and completely agree that I have been given extensive preoperative education and information about obesity, the risks of obesity and the risks and possible benefits of the surgical procedures in general and the Mini-Gastric Bypass in particular. I understand that this consent form is designed to provide a written confirmation of these discussions with my surgeon and The Centers for Excellence in Laparoscopic Obesity Surgery support staff and the extensive educational process that I have participated in by repeating and recording some of the more significant medical information given to me.

I understand that this effort of this long document purposefully intended to make me think over my decision to have surgery once again. I confirm that my family, my Doctor and I have extensively reviewed the decision to proceed with this weight loss surgery. This document is a written record of my efforts to be well informed about my decision to proceed with operation. I can confirm that I wish to consent to go forward with the proposed Mini-Gastric Bypass procedure.

My Condition/Diagnosis:

I recognize that I am overweight. I understand that obesity has been shown to be dangerous, unhealthy and increase my risk of death from a variety of medical illnesses. I affirm that I understand that some scientific studies conclude that obesity places individuals at increased risk of disability, respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer and death as well as other serious and less serious medical illnesses. I clearly and completely understand these issues from my own experience, my discussions with my family my discussions with my doctor and from the very extensive reading and discussions with patients of CELOS and my surgeon. From this careful and calculated investigation, I believe strongly that I should be considered for surgery to help me lose weight.

Proposed Procedure:

The Mini-Gastric Bypass: I understand that the procedure that my surgeon has recommended for the treatment my obesity is the Mini-Gastric Bypass. My surgeon with the help and assistance of the staff of The Centers for Excellence in Laparoscopic Obesity Surgery, my doctor, my family and many patients that have undergone Mini-Gastric Bypass have provided me with a detailed explanation of the medical history of the development of the surgical treatment of obesity, gastric surgery as a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the Mini-Gastric Bypass. I have been provided with drawings, photographs, written and verbal descriptions of the operation and other alternative surgeries including Open Roux-en-Y Gastric Bypass, Laparoscopic Roux-en-Y Gastric Bypass, Silastic Ring Vertical Gastric Bypass (Fobi Pouch), Micro pouch Gastric Bypass, Antecolic Laparoscopic Roux-en-Y Gastric Bypass, Long Limb Gastric Bypass, Biliopancreatic Diversion, Biliopancreatic Diversion with Duodenal Switch, Gastric Band, Laparoscopic Gastric Band, Laparoscopic Adjustable Gastric Band, Vertical Banded Gastroplasty, Laparoscopic Vertical Banded Gastroplasty and Others. I have been allowed to talk with patients that have previously undergone the Mini-Gastric Bypass surgery. I have been very strongly encouraged to make every reasonable effort to investigate and understand the details of the operation. I believe that my surgeon and the staff of CELOS have gone beyond what many other doctors do to inform me of the risks and benefits of the surgery and to assist me in making a good decision about obesity and surgery for obesity.

If you agree that, everything in the above paragraph is correct, check Yes Here: □
Controversy in Medicine/Disagreements over the Surgical Treatment of Obesity

I affirm here unequivocally and without reservations that I understand that medical care often faces major controversy. I clearly recognize that Weight Loss Surgery now is filled with controversy: gastric banding types of surgery vs. bypass types of surgery, proximal gastric bypasses vs. distal gastric bypasses, bypass type surgery vs. the duodenal switch vs. the Fobi pouch and the new Adjustable Gastric Band. The list goes of disagreements about whether to have surgery and what kind of surgery is best is extensive. I understand that there are many different types and variations in the surgical procedures being performed for weight loss in America and around the world at this time. I also know that although many studies document the value of surgery for obesity, there remain many physicians and surgeons who are opposed to the idea of any form of surgical treatment of obesity.

I know that because of the numerous problems and complications that can occur with weight loss surgery many physicians and surgeons prefer to avoid bariatric surgery entirely. I clearly realize that there are a variety of different Types of Weight Loss Surgery, some of which are shown in the table below.

Table 5: Different Types of Weight Loss Surgery

<table>
<thead>
<tr>
<th>Types of Weight Loss Surgery</th>
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<tbody>
<tr>
<td>Open Roux-en-Y Gastric Bypass</td>
</tr>
<tr>
<td>Laparoscopic Roux-en-Y Gastric Bypass</td>
</tr>
<tr>
<td>Silastic Ring Vertical Gastric Bypass (Fobi Pouch)</td>
</tr>
<tr>
<td>Micro pouch Gastric Bypass</td>
</tr>
<tr>
<td>Antecolic Laparoscopic Roux-en-Y Gastric Bypass</td>
</tr>
<tr>
<td>Long Limb Gastric Bypass</td>
</tr>
<tr>
<td>Biliopancreatic Diversion</td>
</tr>
<tr>
<td>Biliopancreatic Diversion with Duodenal Switch</td>
</tr>
<tr>
<td>Gastric Band</td>
</tr>
<tr>
<td>Laparoscopic Gastric Band</td>
</tr>
<tr>
<td>Laparoscopic Adjustable Gastric Band</td>
</tr>
<tr>
<td>Vertical Banded Gastroplasty</td>
</tr>
<tr>
<td>Laparoscopic Vertical Banded Gastroplasty</td>
</tr>
<tr>
<td>Others</td>
</tr>
</tbody>
</table>

I understand that it is my surgeon’s feeling that no one of these surgical choices is necessarily bad, but I recognize that each type of surgery has its own associated risks and complications. Their risk and complications have kept all of them from being universally adopted. It demonstrates that surgery for obesity has not yet reached a "perfect" surgical solution. The number and the great variety of the different types of surgery offered for the treatment of obesity and the acrimony and disagreement between practitioners over the selection of the surgical technique suggests that there are opportunities for further improvement of the presently available weight loss surgery. It means that continued assessment of innovations in surgical procedures is appropriate.

I have spent significant time and effort evaluating this question and I believe that the presently available operations for the treatment of obesity can and should be offered to obese individuals. I feel that the need for treatment of obesity is great and that all of the medical, drug and surgical solutions that we have at present are imperfect. I know that I could have chosen any one of these other types of surgical procedures but after a slow careful and detailed investigation, I have decided to have the Mini-Gastric Bypass. I know that the Mini-Gastric Bypass is not perfect, I know that I feel certain risks and complications that can occur, but after reviewing all of the information, I feel comfortable that my family, my doctor and I agree that the Mini-Gastric Bypass is the best choice for me.

The "Old Loop" Gastric Bypass

I know that some critics of the Mini-Gastric Bypass have compared it to the "Old Loop" Gastric Bypass. The following figures and discussion explain the differences between the Mini-Gastric Bypass, the Standard Billroth II and the "Old Loop" Gastric Bypass.
**Billroth II Gastrojejunostomy**

The Billroth II is the most commonly performed type of connection between the stomach and the small bowel. By a margin of 4 to 1, the Billroth II is preferred over the Roux-en-Y when general surgeons choose to connect the stomach to the bowel. The Billroth II is a surgical procedure used routinely in the treatment of trauma, stomach cancer and peptic ulcers. Every year over 16,000, Billroth II surgeries are performed in America alone. In the usual Billroth II, the esophagus and the body of the stomach are distant from the Billroth II connection. The Billroth II connects the stomach to the jejunum, the upper-middle portion of the small intestine. Like the Mini-Gastric Bypass, the standard Billroth II places the connection between the stomach and the small bowel low on the stomach at the junction between the body and the antrum of the stomach. The lower part of the stomach that is often removed in the usual Billroth II surgery.

I know that I do not have to have this kind of surgery. I know that the Mini-Gastric Bypass is a form of gastric bypass that uses the Billroth II type of connection. I know that some surgeons and other doctors do not like the Billroth II type of connection. I am aware of this and want to go ahead. I have weighed the risks and benefits of the surgical techniques used in the MGB and I favor the Billroth II type connection used in the MGB.

If you agree that, everything in the above paragraph is correct, check Yes Here: □
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than two sentences): ________________

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

The "Old Loop" Billroth II Gastrojejunostomy

I know that there was an "Old Loop" Gastric Bypass included a small high stomach pouch that was placed high up on the stomach C.E.L.O.S.e to the esophagus. The loop that carries bile was placed close to the esophagus and this led to the associated problems with esophagitis that occurred in some surgeon’s experience with the “old loop” type gastric bypass. This configuration is in many ways much like the common general surgical procedure called a total gastrectomy. It is widely agreed that a total gastrectomy is not a good choice for a Billroth II reconstruction. This “old loop” is different from the Mini-Gastric Bypass. The “Old Loop” created a stomach pouch that was also based upon the outside edge of the stomach. This kind of pouch commonly stretches leading to failure of weight loss.

I know that there are many surgeons and doctors that feel that the “old loop” gastric bypass and the Mini-Gastric Bypass are similar and since the Old Loop did not work well then the Mini-Gastric Bypass will also do poorly. I have investigated the Mini-Gastric Bypass in detail, I know the difference between the old loop and the MGB and I want to go ahead and have the MGB.

If you agree that, everything in the above paragraph is correct, check Yes Here: □
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than two sentences): ____________________________

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
The Mini-Gastric Bypass

The Mini-Gastric Bypass does have a Billroth II type loop connection like the “old loop” bypass, but the loop in the Mini-Gastric Bypass is placed low on the stomach far away from the esophagus. This is in the same position as the loop in the standard Billroth II done for ulcers and other diseases. The Mini-Gastric Bypass creates a long narrow “gastric tube” that places the connection of the stomach and the bowel low in the stomach and keeps the stream of bile away from the esophagus. The other advantages are that the surgery is easily accessible in the event that the surgery needs to be revised.

Figure 8: Mini-Gastric Bypass

I know that there are many surgeons and doctors that feel that the “old loop” gastric bypass and the Mini-Gastric Bypass are similar and since the Old Loop did not work well then the Mini-Gastric Bypass will also do poorly. I have investigated the Mini-Gastric Bypass in detail. I know the difference between the old loop and the MGB and I want to go ahead and have the MGB.

If you agree that, everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than two sentences):


Previous Mini-Gastric Bypass Results:

I understand that at the present time over 3,500 total Mini-Gastric Bypass operations have been performed. I understand that the overall complication rate in the Mini-Gastric Bypass patients at this time is 5%. I know that two patients died in the first month following surgery giving an overall 30-day mortality rate of 0.08%.

I know that the overall average hospital stay for Mini-Gastric Bypass Patients to date has been 1.1 days. I know that I will probably be discharged from the hospital today or tomorrow, the day after my surgery. I am ready for this and have arranged for travel from the hospital and for care at home.

If you agree that, everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than two sentences):


Risks/Benefits of Proposed Procedure:

Just as there may be some expected benefits from the Mini-Gastric Bypass procedure proposed in my case, I also understand that all medical and surgical procedures, including the Mini-Gastric Bypass involve risks. I have been told and I understand that my obesity increases my risks of these problems and complications.

These risks include:

<table>
<thead>
<tr>
<th>Complications</th>
<th>Description</th>
<th>If you agree and understand check Yes Here: ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic Reactions</td>
<td>All kinds of allergic drug and chemical reactions are possible from my treatment, from minor reactions such as a rash to sudden overwhelming reactions that can cause death.</td>
<td>And initial here: ☐ If you agree and understand check Yes Here: ☐ And initial here: ☐</td>
</tr>
<tr>
<td>Anesthetic Complications</td>
<td>I know and consent to the fact that general Anesthesia will be used to put me to “sleep” for the operation. I am aware that the anesthesia has major and minor risks can be associated with a variety of different complications up to and including death.</td>
<td>And initial here: ☐ If you agree and understand check Yes Here: ☐ And initial here: ☐</td>
</tr>
<tr>
<td>Feeling Sick, Nausea And Vomiting</td>
<td>Some operations, anesthetics and pain-relieving drugs are more likely to cause sickness (nausea) than others. Sickness can often be treated with anti-vomiting drugs (anti-emetics), but it may last from a few hours to several days.</td>
<td>And initial here: ☐ If you agree and understand check Yes Here: ☐ And initial here: ☐</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>You will have a tube in your airway to breathe for you and it may give you a sore throat. The discomfort or pain lasts from a few hours to days.</td>
<td>And initial here: ☐ If you agree and understand check Yes Here: ☐ And initial here: ☐</td>
</tr>
<tr>
<td>Dizziness, Blurred</td>
<td>Your anesthetic or loss of fluids may lower your blood pressure and make you feel</td>
<td>And initial here: ☐ If you agree and understand check Yes Here: ☐ And initial here: ☐</td>
</tr>
</tbody>
</table>
Problems

Stomach

Post Ulcers

Acid/Bile Reflux

Indigestion,

Narrowing

Leak

Infection

Blood Clots

I know that after weight loss operations on the stomach the new connections can leak. The leak can allow stomach acid, bacteria and digestive enzymes to escape into the abdomen causing a severe and potentially lethal infection and or abscess.

I am aware that the surgical complication most commonly related to an increased morbidity and mortality is a suture line leak. I am well aware that this is a technically demanding operation and that a leak rate of 2 to 5% for gastric bypass surgeries and 0.5% for banding procedures is frequently reported. I know that if a leak is suspected, patients may need to undergo x-ray testing or emergency surgery. I am aware that emergency surgery may needed that multiple drains may need to be placed. I know that patients with a leak may also need to be in the intensive care unit for an extended period of time, sometime weeks or months, and I and my family clearly understand that the complication can be lethal.

In the series of over 3,000 patients treated by Dr. «Surgeon» and C.L.O.S. there have 39 leaks, a 1.3% leak rate. This is similar to or less than the reported national results.

Narrowing (stricture)

Narrowing (stricture), inflammation and/or ulceration of the connection between the stomach and the small bowel can occur after the operation this can require emergency operation, intensive care and can sometimes lead to death. To protect your new stomach from ulcers you must never again take aspirin, or aspirin like drugs such as Motrin, Ibuprofen, Naproxen, Relafen or other similar drugs.

Indigestion,

Acid/Bile Reflux or Ulcers

The operation can sometimes lead to severe nausea, vomiting, indigestion, abdominal pain, gastritis or ulcers. This can be severe and can last for days, weeks and possibly even longer. This is especially likely if you have had previous problems with nausea, abdominal pain or ulcers. Nausea is much more common in women than men. Women that have been treated with any type of hormone therapy (Premarin, Estrogen or Birth Control Pills) are much more likely to have nausea and vomiting after surgery. Chronic gastritis has been found in many patients years after the Billroth II. Biliary-duodeno-gastro-esophageal reflux can be injurious on the mucosa of the stomach and the esophagus. Bile reflux if it occurs and causes problems the operation can be revised. In most cases, revision is not necessary.

Ulcers

I know that I may develop an ulcer after surgery. I know I need to avoid ulcer causing foods, habits and medications. I know in some cases the ulcer may require surgery or reversal of my surgery. Studies of patients that have had partial removal of their stomach (Post gastrectomy) can have a variety of different complications. In one study ulcers occurred in 2% of patients, Diarrhea (16%), Dumping (14%), Biliious vomiting (10%), Iron deficiency anemia (12%), B12 deficiency (14%) and Folate deficiency (32%).

Post-gastrectomy (Stomach Removal) Problems

Numerous problems can follow stomach removal surgery. These “post-gastrectomy” problems may occur early after surgery or many months or years later. The early problems relate to the surgery itself. There are many late post-gastrectomy syndromes; these may be more disabling than the dyspeptic symptoms that led to the surgery in the first place.
Loss

Adequate Weight

Deficiencies

Mineral

Hair Loss

Transfusion

Risks of

Function

Loss o

Drugs

Surgery Risks

Bowel Obstruction

Surgery Risks

Laparoscopic

Surgery

Side Effects of

Drugs

Loss of Bodily

Function

Risk of

Transfusion

Hernia

Hair Loss

Vitamin and

Mineral

Deficiencies

Inadequate Weight

Loss

Complications of gastric surgery: Esophagus; Gastroesophageal reflux, Dysphagia Stomach; Delayed gastric emptying, Bezouls, Outlet obstruction, Stomatitis, Recurrent ulcers, Stump carcinoma, Afferent loop syndrome, Small intestine Diarrhea, Dumping syndrome, Bacterial contamination syndrome, Unmasked celiac disease, unmasked pancreatic insufficiency or unmasked lactase deficiency, weight loss and malabsorption. (Iron, Folate, Vitamin B12, Thiamine (vitamin B1), Calcium, Fats, Anemia.) Gallbladder Choledithiasis

Bile Reflux

Reflex of bile acids into the esophagus may contribute to injury of the esophageal lining. Bile is a component of digestive juices normally present in the small intestine. Bile can reflux from the small intestine into the stomach and does so normally. However, in a subset of people who have severe GERD (backwashing of acid and bile into the esophagus), including in those who have Barrett's esophagus, there is an increase for back washing into the esophagus. Although acid plays a primary role in the development of Barrett's esophagus, there is evidence that bile, reflux adds to the effect of acid injury to the esophagus and therefore may contribute to the development of Barrett's esophagus and possibly esophageal adenocarcinoma (cancer).

Dumping Syndrome

Dumping Syndrome (Symptoms of the dumping syndrome include cardiovascular problems with weakness, sweating, nausea, diarrhea and dizziness) can occur in some patients after gastric bypass. This can be so severe that the surgery may have to be reversed or revised.

Bowel Obstruction

Any abdominal operation can leave behind scar that can put the patient at risk for later bowel blockage or obstruction. The bowel can twist, obstruct and even perforate leading to serious complications and even death.

Laparoscopic Surgery

Laparoscopic Surgery uses punctures to enter the abdomen and this can lead to abdominal organ and/or blood vessel injury, bleeding and even death.

Side Effects of Drugs

All drugs have inherent risks and complications and in some cases can cause a wide variety of side effects, reactions and in some cases including death.

Loss of Bodily Function

The performance of surgery and anesthesia can stress the body's systems leading to a variety of complications including nerve damage, stroke, heart attack, limb loss and other problems related to operation and anesthesia.

Risk of Transfusion

Including Hepatitis and Acquired Immune Deficiency Syndrome (AIDS), from the administration of blood and/or blood components. These illnesses are serious and can be fatal.

Hernia

Cuts and incisions in the abdominal wall can lead to hernias after surgery. Hernias can lead to pain, bowel blockage, obstruction and even perforation and death in some cases. Treatment of hernias usually requires another operation.

Hair Loss

Many patients develop hair loss for a period after operation. When this occurs it usually starts around 3-4 months after surgery and resolves at 7-9 months after operation. This usually responds to increased oral intake of protein and vitamins but it may be permanent.

Vitamin and Mineral Deficiencies

After gastric bypass there is a malabsorption of many vitamins and minerals. Patients must take vitamin and mineral supplements forever to protect themselves from these problems.

I know that I also need to have yearly blood tests to measure the blood levels of these vitamins and minerals.

Common deficiencies that can occur after gastric bypass include iron and calcium deficiency, B12, Thiamine and Folate deficiencies.

*** I know there is a risk of Wernicke's encephalopathy and other rare nerve and brain damage if I do not carefully follow these instructions. Wernicke's encephalopathy is a severe syndrome characterised by loss of short-term memory. It is linked to brain damage and is the result of inadequate intake or absorption of thiamine (Vitamin B1) coupled with continued carbohydrate ingestion. ***

I know that this is very important: Patients must take vitamin and mineral supplements continuously and forever. In some cases the deficiencies are so severe that they can lead to nerve and brain damage and the operation must be reversed.

Inadequate Weight Loss

WARNING: Remember that you might not lose weight after the operation. You might gain weight all kinds of problems with my weight after surgery. *There are

If you agree and understand check Yes

Here: □

And initial here:

If you agree and understand check Yes

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If you agree and understand check Yes

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If you agree and understand check Yes

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And initial here:
patients that will fail any type of surgery. Inadequate weight loss is a risk of all types of weight loss surgery and indeed of all types of weight loss treatment.

*I recognize that the Mini-Gastric Bypass is not by any means a perfect treatment and that one of the risks that I face is a real possibility of inadequate weight loss following my Mini-Gastric Bypass surgery.

Excessive Weight Loss

I clearly understand that there is a risk that I might suffer malnutrition and lose too much weight.

I am well aware that some patients sustain excessive weight loss after weight loss operations. I understand that excessive weight loss may require surgical revision or reversal of the bypass to prevent severe malnutrition, nausea or vitamin and mineral deficiencies or even death. I understand that almost 1% of patients lose too much weight following weight loss surgery and need to have surgery to reverse the excessive weight loss.

As part of this agreement, I promise and agree to monitor my weight and health carefully and if excessive weight loss occurs, I will submit to early and appropriate treatment.

I hereby formally and unequivocally state that I am prepared for this possibility of malnutrition and excessive weight loss and can afford to see Dr. «Surgeon» and C.L.O.S. to pay for and receive the appropriate surgical treatment of a revision if necessary.

I understand and expect that the costs of surgery to reverse or revise surgery will be roughly the same as the initial surgery.

Complications of Pregnancy

I understand that obese pregnant women are at high risk for adverse perinatal outcome. I am also aware that there are well known risks to the patient and the baby after surgery for morbid obesity. Vitamin and mineral deficiencies can put the newborn babies of gastric bypass mothers at risk. No pregnancy should occur for the first one to two years after operation. Gastric Bypass has been shown to cause multiple types of vitamin and mineral deficiencies including: iron, B12, Folate, Thiamine, calcium and many others. Many of these deficiencies have been shown to cause birth defects or are suspected that they could cause birth defects. We also know that many patients who lose weight feel that they are well after surgery and forget to take their vitamins. I understand and take full responsibility to be certain not to miss any of my vitamins and obtain obstetric consultation if I decide to go ahead with pregnancy following surgery. I understand all of these risks fully and request that Dr. «Surgeon» proceed with surgery.

Unplanned Pregnancy

Warning to women using Oral Contraceptives (Birth Control Pills): More than 80 million women worldwide take "the pill" to prevent pregnancy. Typical failure rates among pill users are as high as 12% to 20% in some surveys. Other factors have been shown to increase the risk of pill failure: smoking, diarrhea and/or vomiting drug interactions, systemic illness, psychological stress, and menstrual disturbances. Therefore, it is important to recognize that Birth Control Pills may not be an effective method of birth control after the Mini-Gastric Bypass until those factors have resolved. We have found on several occasions that in many cases the hormonal methods of birth control fail after Mini-Gastric Bypass. Couples need to plan another form of non-hormonal birth control for 6-12 months after surgery. Depo-Provera has also been associated with marked cases of nausea in post MGB patients. An unplanned pregnancy can be one of life's most difficult experiences.

Other

Major abdominal surgery, including the Mini-Gastric Bypass, is associated with a large variety of other risks and complications, both recognized and unrecognized that occur both soon after and long after the operation.

Depression

Depression and anxiety are common medical illnesses and have been found to be particularly common after weight loss operations.

Osteoporosis

There is growing appreciation that weight loss procedures may be associated with the development of osteoporosis and bone disease. Osteomalacia (soft bones) and secondary hyperparathyroidism can occur in obese individuals who have not undergone any kind of gastric surgery. There is a long-standing recognition of a relationship between gastrointestinal surgery and the development of bone diseases (osteomalacia, osteitis fibrosa cystica, and osteoporosis). In a study patients who had undergone Roux-Y gastric bypass had lost 8% of Bone Mass Density 9 months. Similar results were found in other studies. Gastric surgery and weight loss in morbidly obese individuals cause increased bone resorption and increased bone loss. Treatment and prevention includes calcium and vitamin D
supplementation and increased physical activity

Cancer Cancer can occur in anyone. Many cancers are more common in obese as compared to thin patients. Overweight men have a significantly higher rate of prostate cancer. Obese women have higher risks of developing breast cancer and cancer of the uterus and ovaries. It is expected, but not certain, that with weight loss you will have an overall decrease in your risk of cancer. The Billroth II connection used in the Mini-Gastric Bypass has been used for almost 100 years and is performed over 16,000 times a year in America to connect the stomach to the bowel. Some studies have suggested that the Billroth II connection used in the Mini-Gastric Bypass can increase the risk of stomach cancer while others do not show this. The studies showing increase risk of stomach cancer are in Billroth II patients that had the surgery for ulcers and since ulcers can cause an increased risk of stomach cancer it may be the stomach ulcer not the Billroth II that causes some studies to show increased risk of stomach cancer after the Billroth II. Diet seems to be much more important as a cause of stomach cancer. Eating processed meats has a much greater effect on increasing stomach cancer risk than the Billroth II. Conversely fresh fruits and vegetables seem to protect against stomach cancer. In the end no one knows what will happen in your case and if you are concerned about stomach cancer then you could either 1) Not have the Mini-Gastric Bypass, 2) Have the Mini-Gastric Bypass and avoid processed meats and eat more fresh fruits and vegetables. In either case stomach cancer is an unlikely event.

Death This is a major and serious operation. It may lead to death from complications. There has been a death in the first week after this surgery in one patient.

Risks and Complications from General Anesthesia

Serious side effects of general anesthesia are well known to occur but fortunately are uncommon. This is not true in people who are unhealthy including people that are obese. Because general anesthesia affects the whole body, it is more likely to cause side effects than local or regional anesthesia. Fortunately, most side effects of general anesthesia are uncommon, minor and can be easily managed. But others can be serious or deadly.

General anesthesia suppresses the normal throat reflexes such as swallowing, coughing, or gagging that prevent aspiration. Aspiration occurs when materials, objects or liquids are inhaled into the respiratory tract (the windpipe or the lungs). To help prevent aspiration, an endotracheal (ET), breathing tube will be inserted during the surgery this is called “general anesthesia.” When an ET tube is in place, the lungs should be protected so stomach contents cannot enter the lungs. Aspiration during anesthesia and surgery is uncommon, but does occur and is a risk of surgery especially in overweight or obese patients. You have been instructed not to eat or drink anything for hours before anesthesia so that the stomach is empty to reduce the risk of aspiration. Anesthesia specialists use many safety measures to minimize the risk of aspiration in all patients but in spite of these measures aspiration and serious or deadly pneumonia can occur.

Insertion or removal of airway tubes for general anesthesia can cause respiratory problems such as coughing; gagging; muscle spasms in the voice box, or larynx (laryngospasm); or bronchial tubes in the lungs (bronchospasm). Insertion of airways also may cause an increase in blood pressure (hypertension) and heart rate (tachycardia). Other complications may include damage to teeth and lips, swelling in the larynx, sore throat, and hoarseness caused by injury or irritation of the larynx. Other serious risks of general anesthesia include changes in blood pressure or heart rate or rhythm, heart attack, or stroke. Death or serious illness or injury due to anesthesia is rare and is usually also related to complications from the surgery. Death has been reported to occur in about 1 in 250,000 people receiving general anesthesia, although risks are greater for those people with obesity and other medical conditions.

Many people who are going to have general anesthesia express concern that they will not be completely unconscious but will “wake up” and have some awareness during the surgical procedure. However, awareness during general anesthesia is uncommon but can happen. By agreeing to surgery and anesthesia in this document you are recognizing that while precautions will be taken to avoid awareness during surgery that it could happen.

To decrease the serious and life threatening risks of anesthesia that lead to death Dr. Rutledge and the physicians and surgeons of the Centers for Excellence in Laparoscopic Obesity Surgery have chosen a very special kind of anesthetic technique that they believe improve your chances of safely recovering from surgery but may increase the chance of awareness during surgery. By your
initials and comments below you agree to proceed with surgery and anesthesia with the full knowledge of the risk of awareness under this anesthesia and by your specific request that this form of anesthesia be used to improve your overall chances of safety.

If you agree that everything in the above paragraph is correct, check Yes Here: 

Initial the paragraphs above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): ____________________________________________________

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**Risks and Complications from General Anesthesia: Awareness During General Anesthesia**

A person who is given general anesthesia but is not unconscious may be aware of what is happening during the procedure. Awareness during actual surgery is rare but can happen. The frequency of anesthesia awareness has been found in multiple studies to range between 0.1% - 0.2% of adult patients undergoing general anesthesia.

Awareness may be recalled as an implicit memory or explicit memory. With implicit memory, information is retained but not consciously recalled. The person may display symptoms similar to post-traumatic stress disorder, including dreams, flashbacks, anxiety, and sleep disturbances. With explicit memory, the person has spontaneous recall of events that occurred during the procedure, such as sounds and sensations of paralysis or pain. Consultation with a psychiatrist or psychologist may be warranted if a person has signs or symptoms of psychological trauma from awareness during surgery.

By your initials and statements below you agree that you are aware of these risks and complications and specifically request that with full knowledge that these potential problems and complications could occur that we proceed with surgery.

If you agree that everything in the above paragraph is correct, check Yes Here: 

Initial the paragraphs above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): ____________________________________________________

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**The use of Total Intravenous Anesthesia (TIVA),**

For the purpose of improving safety and avoiding respiratory complications of anesthesia Dr. Rutledge and the physicians and surgeons of CELOS advocate the use of total intravenous anesthesia (TIVA). TIVA stands for Total IntraVenous Anesthesia: all the medications you receive will be administered through an IV catheter and you will not receive anesthetic gas. Gas anesthetics, while often good choices, are deemed more dangerous than TIVA in your case.

To try to avoid awareness during surgery Dr. Rutledge and the physicians and surgeons of CELOS follow the Practice Advisory Guidance to Clinicians from the American Society of Anesthesiologists:

The practice advisory acknowledges the reported incidence of intraoperative awareness of one to two cases per thousand patients receiving general anesthesia. We also recognize the significant psychological harm that some patients may experience following an episode of awareness. To address this safety concern Dr. Rutledge and the physicians and surgeons of CELOS treat all patients as high risk for awareness, you are now informed that your anesthetic depth will be monitored using multiple modalities. In all of Dr. Rutledge and the physicians and surgeons of CELOS patients brain function monitoring is used on all patients undergoing general anesthesia (BIS Monitoring.)

The majority of ASA members (69%) surveyed believe that brain function monitoring (BIS monitoring) is valuable and should be used to help reduce the incidence of awareness in patients at risk.

If you sustain awareness you agree to inform us so that we can provide assessment, reporting and counseling.

Dr. Rutledge and the physicians and surgeons of CELOS believe that all MGB patients are at risk for intraoperative awareness. Risk factors for awareness include:

* Substance use or abuse;
* Patient history of awareness;
* Difficult intubation;
* Cardiac surgery, Cesarean section, trauma and emergency surgery;
* Reduced anesthetic doses in the presence of paralysis;
* Use of muscle relaxants; and
* Total intravenous anesthesia (TIVA) and other anesthesia techniques.

Clinical Evidence Supporting BIS Monitoring

Brain Function Monitoring
Brain function monitors enable the anesthesia provider to measure the level of consciousness based upon the patient's electroencephalogram (EEG). Adjunctive use of brain functioning monitors during anesthesia has been found to reduce awareness.

The ASA practice advisory provides documentation that BIS monitoring is the only brain monitoring technology or clinical intervention that has been shown in large scale, prospective clinical research to reduce the incidence of awareness.

In summary, you will receive TIVA because Dr. Rutledge and the physicians and surgeons of CELOS believe it is the safest choice. You have a risk of awareness during surgery (about 1-2/1,000.) The BIS electronic brain monitoring system will be used to help protect against awareness.

If you agree that everything in the above paragraph is correct, check Yes Here: □

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________

Excessive Weight Loss after Surgery

I clearly understand that there is a risk that I might lose too much weight.
I am well aware that some patients sustain excessive weight loss after weight loss operations.
I understand that excessive weight loss may require surgical revision or reversal of the bypass to prevent severe malnutrition, nausea or vitamin and mineral deficiencies or even death.
I understand that in the C.E.L.O.S. experience almost 1 out of every 100 patients lose too much weight following weight loss surgery and need to have surgery to reverse the excessive weight loss.
As part of this agreement, I promise and agree to monitor my weight and health carefully and if excessive weight loss occurs, I will submit to early and appropriate treatment.
I here by formally and unequivocally state that I am prepared for this possibility of excessive weight loss and can afford to see Dr. «Surgeon» and C.E.L.O.S. to pay for and receive the appropriate surgical treatment of a revision if necessary.

If you agree that everything in the above paragraph is correct, check Yes Here: □

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________

Special Warning about the Risks of Birth Defects after Gastric Bypass:

Vitamin and mineral deficiencies can put the newborn babies of gastric bypass mothers at special risk of Major Birth Defects. No pregnancy should occur for the first one to two years after operation.
Gastric Bypass has been shown to cause multiple types of vitamin and mineral deficiencies including: iron, B12, Folate, calcium and many others. Many of these deficiencies have been shown to cause birth defects or are suspected that they could cause birth defects.

We also know that many patients who lose weight feel that they are well after surgery and forget to take their vitamins. Patients must be certain not to miss any of their vitamins if they decide to go ahead with pregnancy later.

Warning to women using Oral Contraceptives (Birth Control Pills): Many women take the pill to prevent pregnancy. Typical failure rates among pill users are as high as 12% to 20% in some surveys. Other factors have been shown to increase the risk of pill failure: smoking, diarrhea and/or vomiting drug interactions, systemic illness, psychological stress, and menstrual disturbances.
Therefore BC Pills may not be an effective method after the Mini-Gastric Bypass until those factors have resolved. An unplanned pregnancy can be one of life's most difficult experiences.

If you agree that everything in the above paragraph is correct, check Yes Here: □

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________

Particular risks associated with the Mini-Gastric Bypass

I also realize that there are particular risks associated with the Mini-Gastric Bypass procedure proposed for me and that these risks include, but are not limited to: Bleeding, Leak, Abscess and serious intra-abdominal infection and Blood Clots all of which can lead to repeated operation admission to the intensive care unit and sometimes death.
I realize that my surgeon plans to perform the operation laparoscopically, and that this approach has special risks including injury to the abdominal contents such as blood vessels, the bowel and other organs.

If you agree that everything in the above paragraph is correct, check Yes Here: □

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________
**Importance of Follow Up**

I recognize that an operation upon my stomach and upper digestive tract is a serious undertaking with known long term risks that my surgeon and The Centers for Excellence in Laparoscopic Obesity Surgery educational program have described to me including hair loss, serious vitamin and mineral deficiencies and other known and unknown problems. I am committed to fulfilling my surgeon’s and The Centers for Excellence in Laparoscopic Obesity Surgery’s instructions for long term follow up. I promise I will make every effort to follow his directions to protect myself from these and other problems associated with the bypass. I will not leave the area following surgery for 7 days after surgery and until I have been seen in my surgeon’s clinic and have been approved for discharge from the area.

I will return to my surgeon’s clinic at 1, 3 and 6 months following surgery and every year thereafter for evaluation and further education. In extraordinary circumstances in which I cannot reach my surgeon’s clinic I will go to my local medical Doctor’s clinic and with his/her approval complete that follow up visit with my local medical doctor. In that event I will make certain that my medical doctor forwards copies of my clinic visit to my surgeon The Centers for Excellence in Laparoscopic Obesity Surgery. I understand and agree that my surgeon and The Centers for Excellence in Laparoscopic Obesity Surgery expects me to return to his clinic for follow up and it is only in unusual circumstances that I will miss these appointments. I promise that I will go to The Centers for Excellence in Laparoscopic Obesity Surgery’s web site at [http://clox.net/m2.htm](http://clox.net/m2.htm) and complete the “Patient Follow-Up Form” monthly after surgery. **As part of my commitment to careful follow up, I promise to alert The Centers for Excellence in Laparoscopic Obesity Surgery office of any changes in my address, telephone numbers, email address or health status.**

If you agree that everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

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**Warning About the Risk of Seeing Other Surgeons That Perform the Roux-en-Y Surgery**

Recently several Roux-en-Y surgeons have written a paper saying that they have seen over 30 Mini-Gastric Bypass patients and 19 were operate on and converted to Roux-en-Y by surgery. I know that if I see a non-MGB surgeon that I may get advice to have surgery. I am committed to maintaining follow up with my MGB doctor.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

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**The Doctor-Patient Relationship:**

Follow up is critical for safe long-term health after gastric bypass and for adequate maintenance of a Doctor patient relationship. The follow up requirements have been described above and I have agreed to meet these requirements. These requirements are very important for my safety, are not onerous or unreasonable.

I explicitly agree to comply with the clearly stated need to follow the medical advice for follow up after my surgery.

I know and agree that in the event that I fail to complete my follow up responsibility then I hear-by agree that such actions will terminate my Doctor patient relationship. It is absolutely and unquestionably my responsibility to stay in touch with my doctor after surgery. I know it is important. I know it is a life and death commitment and I agree to stay in touch and compete my follow up.

In the event that I do not comply with the advice and directions of Dr. «Surgeon» then I agree that Dr. «Surgeon» would no longer be able to serve as my physician.

I know and agree that noncompliance in meeting the agreed upon follow up requirements prevents my Doctor from providing me adequate care.

Dr. «Surgeon» has explained to me the critical need for continuous follow up after my surgery. If I decline to follow my Doctor’s advice then we agree such an action would sever our relationship and remove any responsibility my doctor would have to me.
I agree that I am aware and agree that the physician-patient relationship depends on mutual rapport. In the event that I no longer follow my Doctor’s advice and directions then I agree that this will terminate our relationship and any patient care responsibilities, Dr. «Surgeon» would then no longer be my physician.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________
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Follow Up Emergency Telephone Number

I recognize that an operation upon my stomach and upper digestive tract is a serious undertaking with known risks that my surgeon and The Centers for Excellence in Laparoscopic Obesity Surgery educational program have described to me. I promise I will stay in the area within two hours of the hospital and provide a telephone number so I can always be contacted:
Emergency Telephone Contact Number: __________________________
If you agree that everything in the above paragraph is correct, check Yes Here: ☐
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________
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Information Authorization Request and Confirmation

I, «First_Name» «Last_Name», hereby authorize Dr. «Surgeon» and his staff to use my protected health information, and to request and disclose the following enumerated protected health information to my present and any future referring physicians:

Information that will be used or disclosed for my care or for education or information, includes, hospital and other notes with date of service, type of service provided, history, examination findings, lab results, impression, plan, and medications.

This protected health information may be requested and disclosed for the following purposes: instruction, education and follow up.

This authorization shall be in force and effect until revoked by me in writing or when Dr. «Surgeon» and C.E.L.O.S. have released me from care. I, «First_Name» «Last_Name» understand that I have the right to revoke this authorization, in writing, at any time by sending such written notification to Dr. «Surgeon» and C.E.L.O.S..

I understand that information used or disclosed pursuant to this authorization may be subject to disclosure by the recipient and may no longer be protected by federal or state law.

Dr. «Surgeon» and C.E.L.O.S. will not condition my treatment, payment or eligibility for benefits on whether I provide authorization for the requested use or disclosure. I understand that I have the right to:
• Inspect or copy the protected health information to be used or disclosed as permitted under federal law (or state law to the extent the state law provides greater access rights.)
• Refuse to sign this authorization.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________
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Unexpected Outcomes:

I know that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantee has been made about the results that may be obtained from this procedure. I am aware that in the practice of medicine, other unexpected problems, risks or complications not discussed may occur. I also understand that during the course of the proposed procedure unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐
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Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________
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Follow Up: _________________________
**Danger of Leaving the Area:**

I recognize the serious nature of this Mini-Gastric Bypass surgery. I am well informed about the risk and potential for unforeseen complications and even death. I am aware that I need to stay in the area near the hospital to allow my surgeon to be able to diagnose and treat any unexpected problems or complications. I therefore confirm that I am aware I must stay in the area for at least 7 days so I can be available for treatment and appropriate care. I recognize that other procedures might need to be performed and I confirm that I will remain in daily contact with my surgeon and The Centers for Excellence in Laparoscopic Obesity Surgery for the first 2 weeks after my surgery.

If you agree that everything in the above paragraph is correct, check Yes Here: 

Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

**Acknowledgments:**

The available alternatives to the Mini-Gastric Bypass, some of which include: Open Gastric Bypass, Roux-en-Y Gastric Bypass, Vertical Banded Gastroplasty, various diet, exercise and drug treatments have been explained and discussed in detail with me. The potential benefits and risks of the proposed Mini-Gastric Bypass procedure and the likely results with other treatments have been discussed with me in detail. I understand what has been discussed with me as well as the contents of this consent form, and have been given the opportunity to ask questions and have received satisfactory answers.

If you agree that everything in the above paragraph is correct, check Yes Here: 

Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

**Authorization for Interview, Photography and/or Video Recording and Release Medical Information:**

I hereby confirm that I freely approve of the release of my medical information for the purposes of education and advocacy of the rights of obese patients and that I have not in any way been coerced into this authorization. I recognize that I can refuse to approve of this use of my personal medical information with no negative impact upon my care or treatment by the surgeons and staff of The Centers for Excellence in Laparoscopic Obesity Surgery or his staff.

I have had the opportunity to consider whether or not to approve this use of my personal information and I state that I have not be the subject of coercion or undue influence to agree to this release of information. I hereby authorize Dr Robert Rutledge, the surgeons, and staff of The Centers for Excellence in Laparoscopic Obesity Surgery to use any portions or parts of my medical records and information pertaining to the medical history, mental or physical condition, services rendered, or treatment given for the purposes of education of future patients. I understand that his sole use of this information will be in an attempt to help others. The information supplied is to be used to educate individual patients, Doctors as well as other members of the public including Health Insurance Companies and the News Media. This authorization shall become effective immediately.

I consent and agree that still photographs, motion pictures, or television presentations in the form of either live or video tape may be made of me.

This release gives the CELOS the right to use the above-listed visual material in conjunction with the teaching, instruction, training, information and education of employees, patients, the public, insurance companies and others in the public.

I hereby release the CELOS, Dr. «Surgeon» and the hospital and I discharge any claim of any nature against them.

If you agree that everything in the above paragraph is correct, check Yes Here: 

Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

**Consent to Procedure and Treatment:**

Having read this form and talked with my surgeon, my signature below acknowledges that:

I voluntarily give my authorization and consent to the performance of the Mini-Gastric Bypass procedure described above (including the administration of blood and disposal of tissue) by my physician and/or his/her associates assisted by hospital personnel and other trained persons as well as the presence of observers.

If you agree that everything in the above paragraph is correct, check Yes Here: 

Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences):
**Governing Law:**

I clearly and completely agree that this contract between myself, Dr. «Surgeon» and St. Rose Dominican Hospitals - Rose de Lima Campus is governed by the laws of the State of Nevada. I agree that in lieu of proceeding to any court action to mediate any dispute.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________

**Management of any Disputes or Disagreements: Agreement to Binding Arbitration**

Arbitration agreements require that the parties agree to resolve any and all disputes that arise using binding arbitration, rather than in court.

I know that binding arbitration involves the submission of any disputes to a neutral party, usually a retired judge, who renders a decision following a hearing. I agree that arbitration will take the place of a trial before a judge or jury. I agree that the arbitration is binding, and there are no grounds for appealing or setting aside the arbitration decision.

I am aware that there are some advantages and disadvantages of binding arbitration. Binding arbitration is less formal and technical than court, can result in quicker resolution of the dispute, waives the right to have any claims decided in court, provides finality, and severely limits appeals and finally provides a private forum for the dispute.

I agree that this contract between myself, Dr. «Surgeon» and St. Rose Dominican Hospitals - Rose de Lima Campus and all disagreements will be managed by mandatory, private, binding arbitration. I agree that it is efficient, leads to informed decision making, and sustains a cordial unbiased relationship between patients and their physicians.

I agree that the costs will be shared equally for such mediation. In the event of failed mediation then I agree to proceed to arbitration and I agree that any dispute arising out of the agreement will be decided by neutral arbitration as provided for by the laws of the state of Nevada.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

___________________________________________________________________________________
___________________________________________________________________________________
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___________________________________________________________________________________
A Message to Our Patients about Arbitration

The operative consent agreement is an arbitration agreement. By signing this agreement, we (the doctor, the patient, and the hospital) are agreeing that any dispute arising out of the medical services received is to be resolved in binding arbitration rather than a lawsuit in court.

Medical malpractice insurance rates are skyrocketing. Practicing physicians have two options: continue to pay the rapidly escalating charges or try to intervene to decrease the costs of medical liability insurance. Frivolous lawsuits are part of the rise in insurance rates. For example, you may have heard this story:

A woman buys a coffee at McDonald's and drives off with the coffee between her legs. After the coffee spills and scalds her, she sues McDonald's for the coffee being too hot. She wins a $2 million dollar judgment.

The costs and settlements of these and other kinds of lawsuits translate into higher insurance rates. In some cases, doctors are performing unnecessary tests and procedures in a kind of "defensive medicine." Numerous doctors have retired because of the rising costs of malpractice insurance.

"There are factors operating, particularly in Nevada, which make it a prime example of the problems physicians, hospitals, insurers, and patients are facing nationwide," says Carol Golin, editor of the Medical Liability Monitor, which surveys insurance company issues. In Nevada, the number of new lawsuits is reaching record highs and the awards are increasing at unprecedented rates as well.

Experts believe that resolving disputes by arbitration is a good system that addresses many of these issues in ways that are fair for both patients and physicians. A single arbitrator, usually a retired judge, hears the case. This agreement generally helps to limit the legal costs for both patients and physicians. Further, the judgment is more often found to be fair and reasonable on review and both parties are spared some of the problems seen in a public jury trial.

Our goal is to provide the highest quality of medical care and to avoid any such dispute. We have priced our medical care fairly and this is based upon our efforts to limit inappropriate legal costs.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________
___________________________________________________________________________________
___________________________________________________________________________________
____________________________________
_____________________________________________
AN OVERVIEW OF ARBITRATION

Introduction
Arbitration is an alternative dispute resolution procedure that has been endorsed by such groups as various Medical Associations and is a favored method of resolving disputes by the United States Supreme Court. The information included here is provided for your education on some of the basic principles of arbitration.

What is arbitration?
Arbitration is an alternative way of resolving disputes. Instead of disagreements being taken through long and expensive process of court litigation, it is agreed in advance to submit any disputes to an arbitrator for his or her determination. The arbitrator is selected from among numerous retired judges who are available and qualified to serve on these matters, and is mutually agreed upon by both you and the doctor. After a hearing, similar to a court proceeding, the arbitrator makes the decision (“award”). The same laws and same measure of damages, which apply in court proceedings, also apply in arbitration.

Does arbitration prevent you from making a claim?
No. Arbitration allows for a rapid and more straightforward approach to deliberation on issues that may arise and to hear and decide any claims.

Does it prevent you from obtaining a financial award?
No, not at all. Arbitration does not restrict or prevent you from obtaining a financial award in any manner. If the arbitrator accepts and agrees with your claim, he will determine a damage award. The United States Supreme Court has held that arbitration is strongly favored as an expeditious and economical alternative to the court system.

May I be represented by an attorney of my choice?
Yes. All parties to arbitration may be represented by an attorney of his or her choice, at his or her own expense. The arbitrator will hear the facts and decide the matter whether or not the parties are represented by lawyers.

Who is bound by this agreement?
By signing the arbitration agreement, you agree to oblige yourself and others on your behalf to use binding arbitration.

What does arbitration cost?
Arbitration is usually less expensive than court actions. The arbitrator’s fees are ordinarily shared equally by the parties. The amount of those fees will depend upon the complexity and length of the case.

If either party does not like the arbitration result, could there still be a jury trial in court?
The purpose of arbitration is to avoid the expenses, delays, emotional public nature and inconvenience of a court trial. Ms. LastName was made aware that in rare circumstances, arbitration awards may be reviewed, and potentially reversed (“vacated”) by a court.

If you agree that everything in the above paragraph is correct, check Yes Here: ☐
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________

Patient Signature: ___________________________________________ Date: __________________________

Parent or other person authorized to sign for patient:
___________________________________________ Date: __________________________

Witness:
___________________________________________ Date: __________________________

(Robert Rutledge, M.D., License #: 9999)
Insurance Release
The Center for Laparoscopic Obesity Surgery

Friday, May 07, 2010

Re: The Centers for Excellence in Laparoscopic Obesity Surgery and staff accept no responsibility in obtaining insurance coverage

CELOS,

By my signature on this document I am formally recognizing that The Centers for Excellence in Laparoscopic Obesity Surgery does not accept insurance or any kind of third-party billing as payment for services. I also recognize that The Centers for Excellence in Laparoscopic Obesity Surgery’s office will not submit claims to my insurance carrier. This document is designed to clearly state that I am aware of the fact that The Centers for Excellence in Laparoscopic Obesity Surgery does not accept insurance and that I will pay the bills for any and all treatments by my surgeon and the hospital. I understand and agree that payment for my care will be made prior to the time of treatment. In the case of emergency or other unexpected care payment will be made at the time of billing for the treatment.

I do not expect my surgeon, Dr. Rutledge or The Centers for Excellence in Laparoscopic Obesity Surgery office to take any responsibility in filing for insurance coverage. I understand that I will receive a receipt for my treatment. I have been told that I can use this billing information to try to obtain insurance reimbursement. I acknowledge that if I choose to file an insurance claim that all issues dealing with the insurance claim will have to be handled by myself and or my representatives.

I know that my surgeon’s bariatric practice, Dr. Rutledge and The Centers for Excellence in Laparoscopic Obesity Surgery office do not have any working relationship with any medical insurance providers. I am aware that The Centers for Excellence in Laparoscopic Obesity Surgery office will only provide limited and minimal assistance to me in processing claims to my insurance carrier. This assistance is limited to his providing me with a bill and with copies of my medical records upon my request (for which I will be charged a reasonable fee) for services rendered. I understand that insurance reimbursement following treatment will be between myself and my insurance company.

Patient Signature: ____________________________ Date: __________

Parent or other person authorized to sign for patient: ____________________________ Date: __________

Witness: ____________________________ Date: __________

(Physician’s Signature) (Date)
HIPAA: Notice of Information Practices

This notice describes how information about you may be used and disclosed and how you can gain access to this information. Please review carefully.

NOTICE OF INFORMATION PRACTICES

The Center for Laparoscopic Obesity Surgery is dedicated to protecting your medical information. We are required by law to maintain the privacy of protected health information and to provide you with this Notice of our legal duties and privacy practices with the respect to protected health information. Center for Laparoscopic Obesity Surgery is required by law to abide by the terms of this Notice.

1. The Center for Laparoscopic Obesity Surgery may use and disclose protected health information for treatment, payment and healthcare operations. Examples of these include, but are not limited to, requested preschool, or sports physicals, referral to nursing homes, foster care homes, home health agencies and/or referral to other providers for treatment. Payment example includes, but are not limited to, insurance companies for claims including coordination of benefits with other insurers; collection agencies. Healthcare operations include, but are not limited to, internal quality control and assurance including auditing of records.

2. The Center for Laparoscopic Obesity Surgery is permitted or required to use or disclose protected health information without the individual’s written consent or authorization in certain circumstances. Two examples are for public health requirements or court orders.

3. The Center for Laparoscopic Obesity Surgery will not make any other use or disclosure of a patient’s protected health information without the individual’s written authorization. Such authorization may be revoked at any time. Revocation must be written.

4. Center for Laparoscopic Obesity Surgery will abide by the terms of this notice currently in effect at the time of disclosure.

5. Center for Laparoscopic Obesity Surgery reserves the right to change the terms of its notice and to make new notice provisions effective for all protective health information that it maintains. Center for Laparoscopic Obesity Surgery will provide each patient with a copy of any revision of its Notice of Information Practices at the time of their next visit, or at their last known address if there is no need to use or disclose any protected health information of the patient. Copies may also be obtained at any time at our offices.

6. Any patient, guardian, or personal representative has the right to object to the use of their health information for directory purposes.

7. Any patient, guardian, or personal representative has the right to request to inspect or obtain copies of their medical record.

8. Any patient, guardian, or personal representative has the right to request amendments be made to their medical record.

9. Any patient, guardian, or personal representative has the right to request a six year accounting of all disclosure of their medical record. The history will be provided within 60 days of the request and a reasonable charge may be assessed for any copies after the requested 12 month period.

10. Any patient, guardian, or personal representative has the right to request restrictions as to how their health information may be used or disclosed to carry out treatment, payment, or healthcare operations. The Practice is not required to agree to the restriction requested, but if the Practice does agree, The Practice must abide by those restrictions.

11. Any person/patient may file a complaint to the Practice and the Secretary of the Health and Human Services if they believe their privacy rights have been violated. To file a complaint with the practice, please contact the Privacy Officer at the following address and/or phone number for the Center for Laparoscopic Obesity Surgery. Telephone: 704-871-0031. Fax: 704-871-0148. All complaints will be addressed and the results will be reported to the Privacy Officer.

12. It is the policy of the Center for Laparoscopic Obesity Surgery that no retaliatory action will be made against any individual who submits or conveys a complaint of suspected or actual non-compliance of the privacy standards.

The effective date: ______________
Name of Patient or Legal Guardian: ____________________________________________
Signature of Patient or Legal Guardian: _______________________________________
Date: _______________________

HIPAA Notice of Information Practices 802(form1)

Disclaimer: Contents are informational and not intended as legal advice. NCRIC MSO. INC. and its subsidiaries, its employees, agents, and staff, make no representation, guarantee or warranty, express or implied, that these forms are error free or the use of this information will prevent differences of opinion with any other party, and will bear no responsibility or liability for the result or consequences of its use.
Insurance Issues

Dr Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery are no longer accepting insurance
Patients are asked to sign a letter of understanding
It is possible that you can still get your insurance to reimburse you

Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery No Longer Accepts Insurance

At present, Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery do not accept insurance or any kind of third-party billing as payment for services. We will not under any circumstances submit claims to insurance carriers. We do not accept payments or payment plans. We accept money orders, credit cards or certified checks. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery do not accept insurance assignment and does not represent or warrant any availability of insurance reimbursement for any particular claim. The charges you incur for the Mini-Bypass must be paid before your surgery. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery do not accept insurance reimbursement but receipts for your surgery are provided. We can provide our patients with the billing information they need to try to obtain reimbursement from your insurance company. After the surgery you can submit Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s bill to your insurance company. If you choose to file an insurance claim on your own, please be aware that any issue dealing with the insurance companies will have to be handled by yourself. This office and our physicians do not have any working relationship with any medical insurance providers. Our office can only provide minimal assistance to patients in processing claims to their insurance carrier. If you are reimbursed for the surgery, that will be between you and your insurance company. Email our office we can provide you with a letter to submit to your insurance company, only do this after you have submitted you patient information at our website.

Costs and Payment

Note: Payment for the Mini-Gastric Bypass is a Global-Fee Payment Plan
Weight loss surgery and Laparoscopic Gastric Bypass coverage by insurance companies or managed care organizations is variable. The Global-Fee pre-paid plan allows you to know in advance exactly what you will spend for the services. The Global-Fee Payment Plan covers all professional fees by Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery, your Anesthesiologist and Nurse Anesthetist and hospital services for your one to two day hospital stay. This is a “Global Fee” individual portions of the costs are separated, it a single fee paid to the Centers for Laparoscopic Obesity Surgery. No itemization is provided because there is no itemization it is a global fee.

DESCRIPTION

NOTE: This bill is for a “GLOBAL FEE” that covers: 1. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s Professional Fee, 2. Anesthesiologist Professional Fee, 3. Hospital Facility Fee
DIAGNOSES: Morbid Obesity (ICD9 Code 278.01), Dyspnea on Exertion (ICD9 Code 786.09), Fatigue (ICD-9 Code 780.79)
Mild Fatty LiverModerate Fatty Liver
OPERATIVE PROCEDURE: Laparoscopic Mini-Gastric Bypass
ICD-9 PROCEDURE CODES: (Gastric Bypass ICD-9 Code 44.31, Laparoscopy ICD-9 Code 54.21)
CPT CODE: 43659 (Unlisted laparoscopy procedure, stomach).
HOSPITAL STAY: 1 day Admission Date:
Paid in Full - Grand Total: $17,000.00
Note: Make all checks payable to The Centers for Laparoscopic Obesity Surgery.
Note: Insurance reimbursement to be paid to the beneficiary and not to the Centers for Laparoscopic Obesity Surgery.
Sign Letter of Understanding
To prevent possible misunderstandings, I ask that you sign this letter acknowledging that I do not take insurance:
The Centers for Laparoscopic Obesity Surgery

Re: Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery and staff accept no responsibility in obtaining insurance coverage

Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery,

By my signature on this document I am formally recognizing that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not accept insurance or any kind of third-party billing as payment for services. I also recognize that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s office will not submit claims to my insurance carrier.

This document is designed to clearly state that I am aware of the fact that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not accept insurance and that I will pay the bills for any and all treatments by Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery. I understand and agree that payment for my care will be made prior to the time of treatment. In the case of emergency or other unexpected care payment will be made at the time of billing for the treatment.

I do not expect Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery or his office to take any responsibility in filing for insurance coverage. I understand that I will receive a receipt for my treatment. I have been told that I can use this billing information to try to obtain insurance reimbursement. I acknowledge that if I choose to file an insurance claim that all issues dealing with the insurance claim will have to be handled by myself and or my representatives.

I know that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery and his office do not have any working relationship with any medical insurance providers. I am aware that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery and his office will only provide minimal assistance to me in processing claims to my insurance carrier. This assistance is limited to him providing me with a bill and with copies of my medical records upon my request (for which I will be charged a reasonable fee) for services rendered. I understand that insurance reimbursement following treatment will be between my insurance company and me.

Patient Signature:  
___________________________________________ Date:  

Parent or other person authorized to sign for patient:  
___________________________________________ Date:  

Witness:  
___________________________________________ Date:  

Dr. Robert Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery:  
___________________________________________ Date:
Your Insurance May Still Pay for Some of Your Bill

Depending upon your insurance policy and which hospital you choose you may or may not be able to have your surgery paid for either before or after your operation. There are so many different companies and there are so many different policies that each company offers that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery and his office staff can provide no prediction on how this might work in your case. It is really impossible for Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery or the staff in his office to answer your questions about what your particular insurance company and your policy might do as far as the insurance coverage of the hospital is concerned. As stated above Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not accept insurance assignment and does not represent or warrant any availability of insurance reimbursement for any particular claim. The charges you incur for the hospital care for your Mini-Bypass must worked out with the hospital. Like Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery the hospital may be able to provide you with the billing information needed to try to obtain maximum amount of reimbursement from your insurance company. If you choose to file an insurance claim on your own, please be aware that any issue dealing with the insurance companies will have to be handled by yourself. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery's office do not have any working relationship with any medical insurance providers. Our office can only provide minimal assistance to patients in processing claims to their insurance carrier. If you wish to try to be reimbursed for the Hospital costs of the surgery, that will be between you and your insurance company.

Patient’s Financial Responsibilities:

Arrange for Payment

All payments are to be cash, money order, certified check or credit card. There is a 200.00 processing fee for credit card transactions. Payments are to be completed a minimum of 24-48 hours in advance of surgery. All interactions with the patient’s Insurance Company for reimbursement are to be done by the patient and Not by Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery or his office staff. Show that you and your family are prepared for patient support and treatment expenses in the event of problems or complications. WARNING: In the event of serious or major complications the patient agrees to pay the additional expenses of what could be a serious illness. * *

Letter to Your Insurance Company

It is important for you to understand that the patient information that you submit on the Internet will be used to create a letter to your insurance company. This letter will be sent to you as an email attachment in Microsoft Word 2002 format. If you are planning to try to obtain insurance approval then it will be up to you to print out and send this letter to your insurance company to begin the “prior-approval or pre-determination” process with your company. This process varies from company to company and from policy to policy. Under no circumstances can Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery or his office be part of this effort. This is your responsibility. As we stated above, Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not accept insurance. After you submit the patient information form the information that you have submitted will be used to write a letter that can be sent to your insurance company. The letter uses the information that you send in your patient information form to generate a letter about your level of obesity and the associated levels of disability and other medical illnesses. Patients can use this letter in their efforts to obtain support from their healthcare insurers to cover their obesity surgery. But, remember that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not accept insurance or any kind of third-party billing as payment for services. We will not under any circumstances submit claims to insurance carriers. We do not accept payments on time or any form of payment plans. We only accept money orders, credit cards or certified checks. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not accept insurance assignment and does not represent or warrant any availability of insurance reimbursement for any particular claim. The letter that our office will send you is for the private use of you and your primary care physician. It should not in any way be considered an indication that Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery will participate in your insurance plan’s payment network or contracts. Again it needs to be emphasized that the charges you incur for the Mini-Bypass must be paid before your surgery. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery does not accept insurance reimbursement and the letter does not mean that he will be willing to involved with any insurance company contracts. Receipts for your surgery are provided to you. We can provide our patients with the billing information they need to try to obtain reimbursement from your insurance company. You can submit Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery’s bill to your insurance company. If you choose to file an insurance claim on your own, please be aware that any issue dealing with the insurance companies will have to be handled by you, your family or your lawyers. Dr. Rutledge and the Surgeons of the Centers for Laparoscopic Obesity Surgery and his office do not have any working relationship with any medical insurance providers. Our office can only provide minimal assistance to patients in processing claims to their insurance carrier. If you are reimbursed for the surgery, that will be between you and your insurance company.


357 Coates PS, Fernstrom JD, Fernstrom MH, Schauer PR, Greenspan SL 2003 Gastric bypass surgery for morbid obesity leads to an increase in bone turnover and a decrease in bone mass. J Clin Endocrinol Metab 89:1061–1065


360 Coates PS, Fernstrom JD, Fernstrom MH, Schauer PR, Greenspan SL 2003 Gastric bypass surgery for morbid obesity leads to an increase in bone turnover and a decrease in bone mass. J Clin Endocrinol Metab 89:1061–1065


