Hypothesis: A technique of the laparoscopic Roux-en-Y gastric bypass can be developed that is safe, effective, and practical in the community setting.

Design: A case series of 400 morbidly obese and super-obese individuals who underwent the laparoscopic Roux-en-Y gastric bypass over a 22-month period.

Setting: Community private practice in Fresno, Calif.

Patients: A consecutive sample of 400 patients (70 males and 330 females) who met National Institutes of Health criteria for recommendation of a bariatric procedure. Only patients who had a previous gastric or bariatric procedure were excluded from this sample.


Main Outcome Measures: Weight loss, complications, length of hospital stay, successful completion of the operation, and operative times were measured.

Results: Open conversion was required in 12 patients (6 males and 6 females) and a secondary operation for incomplete division of the stomach was required in 2 patients early in the case series. Alternative exposure and fixation techniques greatly reduced these occurrences. There were 6 staple-line failures owing to a change in the manufacture of the instrument. There were no leaks at the gastrojejunal anastomosis, but 21 patients required endoscopic balloon dilation for significant stenosis. The average hospital stay was 1.6 days for the patients who underwent laparoscopy and 2.7 days for patients requiring open conversion. Average excessive weight loss was 69% at 12 months. Operative times are between 60 and 90 minutes. Other complications are described.

Conclusion: The Roux-en-Y gastric bypass can be safely and effectively performed in the community setting using advanced laparoscopic techniques.

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PATIENTS AND METHODS

PATIENTS

All patients (70 males and 330 females, aged between 13 and 70 years) were evaluated for surgery using National Institutes of Health guidelines.6 Each patient was coun-
seled by the operative surgeon (K.D.H.) and advised of other bariatric surgical procedures and bariatric surgical pro-
grams. All patients were considered candidates for the la-
paroscopic procedure regardless of weight, body mass index (BMI), (weight, in kilograms, divided by height, in meters squared) or the presence of previous operations (except for gastric or bariatric procedures). It was our intention to de-
terminate exclusion criteria as early as possible.

The operative technique evolved to compensate for oc-
currences we had not experienced with the open surgery, such as internal hernias. Exposure and retraction meth-
ods developed that allowed a higher success rate and shorter operative times.

This case series represents patients operated on by a single surgeon (K.D.H.). Although one of us (K.B.B.) has performed over 200 such procedures, these are not in-
cluded in this case series to simplify comparative data.

SURGICAL TECHNIQUE

The patient is placed supine in a gentle reverse-
Trendelenburg position. Standard perioperative antibi-
otic agents and subcutaneous heparin sodium are admin-
istered and antiembolism devices are used. Bowel
preparation consists of clear liquids for 24 hours prior to surgery.

The pneumoperitoneum and abdominal entry is es-
established with an 11-mm trocar (ENDOPATH Optiview
11-mm Optical Trocar; Ethicon Endo-Surgery Inc). Three
more blunt 12-mm ports were created using a 12-mm tro-
car (ENDOPATH Optiview 12-mm Optical Trocar;
Ethicon Endo-Surgery Inc) and a single 5-mm or 10-mm
port for liver retraction is placed Figure 1. Adhesions from
previous surgical procedures are mobilized to allow dis-
placement of the omentum to the upper abdomen. If the
adhesions are too dense or the omentum bulky, the lesser
sac is entered through the gastrocolic ligament. The liga-
ment of Treitz is visualized by creating an opening through
the transverse mesocolon. The proximal jejunum is di-
vided 5 to 10 cm distal to the ligament of Treitz with a
45-mm linear cutter, 2.5-mm stapler (ENDOPATH Endo-
scopic Linear Cutter 45 mm; Ethicon Endo-Surgery Inc).
The mesentry is divided with the same stapler and the Roux
limb is measured. For patients whose BMI is less than 50,
a 100-cm limb is measured; for those whose BMI is greater
than 50, we use a 150-cm limb. A side-to-side jejunoeje-
unostomy is performed using the 45-mm linear cutter,
2.5-mm stapler. The enterotomy is closed with inter-
rupted 3-0 polyglactin (Vicryl) sutures. The mesenteric de-
fect is closed with 3-0 silk sutures.

The gastric pouch is estimated at 20 mL and created
by repeated application of the 35-mm linear cutter, 3.5-mm
stapler (ENDOPATH Endoscopic Linear Cutter 35 mm;
Ethicon Endo-Surgery Inc). The vagus nerves are pre-
served. The pouch is based on the lesser curve and ori-
ented vertically with the exclusion of the gastric fundus.
We believe, as does MacLean et al,7 this configuration im-
proves emptying and prevents subsequent dilation of the
pouch. The Roux limb is brought up in a retrocolic position
and lies anterior to the stomach remnant. The mesocolon
is attached to the Roux limb with three 3-0 silk inter-
rupted sutures to prevent migration of the limb. The gas-
 trojejunostomy is a standard 2-layer, hand-sewn anasto-
mosis performed with 3-0 polyglactin sutures, running and
interrupted, and sized with an intraluminal 32F tube
(Figure 2).

The skin is closed with staples. The trocar fascial open-
ings are not closed.

equate. All patients were successfully reexplored la-
paroscopically except for 2 who required open decompression. We now use nonabsorbable sutures in these critical areas. The incidence of postoperative internal hernias is now less than 1%.

Stenosis at the gastrojejunostomy anastomosis oc-
curred in 21 patients (5.25%). All were successfully treated
with endoscopic balloon dilation. One patient de-
veloped stenosis of the Roux limb due to constriction at the
mesocolon. This required laparoscopic exploration to en-
large this opening.

There were 6 occurrences of staple-line failures.
These were either detected at the time of surgery or within
12 to 24 hours after surgery. In all cases, they were re-
paired laparoscopically and although the patients stayed
an average of 2 days longer, they suffered no long-term sequelae. As this occurred well into our case series, it was
difficult to explain until the manufacturer disclosed hav-
ing recently modified the 45-mm linear cutter, 3.5-mm
stapler. In retrospect, the staple-line failures only oc-
curred with the improved version; we have not seen this
problem since we returned to using the 35-mm linear cut-
ter with 3.5-mm stapler for gastric partitioning.
One patient developed lower extremity weakness requiring readmission to the hospital. Magnetic resonance imaging and neurologic consultation diagnosed the problem as central pontine myelolysis. This rare disorder is usually seen in alcoholic and malnourished patients associated with hyponatremia. This patient lost 26.1 kg in 2 months and had normal electrolyte levels and nutritional values. The problem spontaneously resolved over the course of several months.

There were 2 major complications involving perforation. One occurred in an elderly patient with diabetes mellitus. On reexploration, a gastric perforation was found proximal to the gastrojejunostomy. We hypothesize a thermal injury from the Harmonic scalpel weakened this area. The other was a staple-line disruption owing to severe gastric distension secondary to meat the patient ingested the night prior to surgery. The meat bezoar became impacted at the jejunojejunostomy and caused the obstruction. This patient also suffered from a severe gastrografin aspiration pneumonitis at the time of induction of anesthesia. Both patients have done well following a hospital stay of 17 and 30 days, respectively.

Four patients developed marginal ulcers. The use of nonsteroidal anti-inflammatory drugs likely played a role even though patients are routinely counseled against their use. Two patients presented with pain, 1 patient developed hematemesis but did not require transfusion, and 1 patient presented with perforation requiring exploration and revision of the gastrojejunostomy.

Operative times varied greatly at first as we developed and improved on our retraction and dissection techniques. Currently, the operation can be performed reliably in 60 to 90 minutes, comparing favorably with our open procedure (Figure 3).

Average hospital stay without major complications for the patient who underwent laparoscopy was 1.6 days. The average hospital stay for those patients requiring open conversion was 2.7 days.

Nine patients developed symptomatic cholelithiasis. All patients underwent successful laparoscopic cholecystectomy.

Table 1. Complications of Laparoscopic Roux-en-Y Gastric Bypass

<table>
<thead>
<tr>
<th>Complication</th>
<th>Total No. of Patients</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staple-line disruption (bezoar)</td>
<td>1</td>
<td>Reoperation</td>
</tr>
<tr>
<td>Gastric perforation</td>
<td>1</td>
<td>Reoperation</td>
</tr>
<tr>
<td>Internal hernia</td>
<td>14</td>
<td>Laparoscopic reduction (12 patients) or open reduction (2 patients)</td>
</tr>
<tr>
<td>Gastrojejunostomy stenosis</td>
<td>21</td>
<td>Endoscopic balloon dilation</td>
</tr>
<tr>
<td>Intra-gastric hematoma</td>
<td>1</td>
<td>Readmission to the hospital</td>
</tr>
<tr>
<td>Incomplete transection of stomach</td>
<td>2</td>
<td>Reoperation (open)</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>1</td>
<td>4-U transfusion</td>
</tr>
<tr>
<td>Marginal ulcer</td>
<td>3</td>
<td>Medical management</td>
</tr>
<tr>
<td>Marginal ulcer with perforation</td>
<td>1</td>
<td>Exploration</td>
</tr>
<tr>
<td>Staple-line failures</td>
<td>6</td>
<td>Laparoscopic repair and drainage</td>
</tr>
<tr>
<td>Central pontine myelolysis</td>
<td>1</td>
<td>Readmission to the hospital</td>
</tr>
<tr>
<td>Symptomatic gallstones</td>
<td>9</td>
<td>Laparoscopic cholecystectomy</td>
</tr>
</tbody>
</table>

Figure 1. The patient is supine with attention to the pressure areas. The surgeon performs the entire procedure from the right side of the patient. The assistant and scrub nurse assist in operating the camera. Inset, The ports are placed as depicted in the epigastrium.

Figure 2. The gastric pouch is vertically oriented and estimated 20 mL in volume. The Roux limb is 100 to 150 cm in length and is retrocolic and retrogastric in position. The gastrojejunostomy is a standard 2-layer, hand-sewn anastomosis sized to 32F catheter.

Figure 3. The patient is supine with attention to the pressure areas. The surgeon performs the entire procedure from the right side of the patient. The assistant and scrub nurse assist in operating the camera. Inset, The ports are placed as depicted in the epigastrium.
Figure 3. Operative times with experience. Operative times varied considerably at first as different exposure and retraction techniques were developed. Operative times include patients who have had previous abdominal procedures and who required concomitant cholecystectomy.

Average excessive weight loss was 69% at 12 months but varied according to initial BMI (Figure 4 and Table 2). There were 3 patients who were lighter than their ideal body weight at 1 year. The average BMI of this group was 21 (not clinically underweight). In addition, there were no nutritional deficiencies identified in these 3 patients. (Measured values at 1 year included complete blood cell count and the levels of serum protein, albumin, vitamin B₁₂, folate, iron, and iron-binding capacity.)

As with many advanced laparoscopic procedures, the learning curve can be a long and arduous journey. We did not select only ideal patients, as we wanted to determine who was not a candidate for the laparoscopic procedure as early as possible. We discovered the additional challenges of the larger patients required that we develop exposure techniques that were beneficial to all patients. We used only standard length trocars and instruments. Operative times have gradually improved as our experience and development of techniques has allowed more directed and safer dissection. Operative times of 60 to 90 minutes are usual and are actually shorter than for our open gastric bypass.

We have seen 2 life-threatening complications that we have not as yet experienced with the open procedures: that of staple-line disruption secondary to meat bezoar and gastric perforation from thermal injury. Although similar complications have been described, counseling patients about their “last meal” and more careful dissection with the Harmonic scalpel should eliminate these complications.

Internal hernias have only occurred in the laparoscopic case series, apparently due to decreased intra-abdominal adhesions. By using nonabsorbable sutures for fixation of the Roux limb at the mesocolon and at the small-bowel mesentery, this now occurs with a frequency of less than 1%.

Stenosis of the gastrojejunostomy was a significant problem requiring endoscopic balloon dilation in 5.25% of our patients. Our experience compares favorably with the 9% to 20% stenosis rate reported in a recent review. With any mechanical stapling device, one can expect a certain failure rate. It was fortunate that a sufficient volume of cases revealed an early problem with the improved 45-mm linear cutter with 3.5-mm stapler. The manufacturer responded in a professional and expeditious manner that helped us to identify and correct this problem.

The laparoscopic Roux-en-Y gastric bypass has been shown to be safe and effective for the nonsuper obese patient (BMI <50) by Wittgrove et al. More recently, using similar techniques, Nguyen et al were able to perform this procedure on a patient with a BMI of 61. We have not found absolute patient size, BMI, or the presence of previous operations to be prohibitive in our case series. Actually, it is advantageous to dissect low pelvic adhesions laparoscopically rather than extend the traditional upper midline incision. In 1 patient who had an incarcerated ventral hernia that had failed 4 previous attempts at repair, we were able to perform the laparoscopic Roux-en-Y gastric bypass without disruption of the hernia. Subsequent repair will hopefully have a higher degree of success after significant weight loss has occurred.

Symptomatic cholelithiasis occurred in only 2.25% of our patients. Our data does not support concomitant routine cholecystectomy. However, all patients with symptoms suggestive of gallstones were evaluated preoperatively and laparoscopic cholecystectomy was performed prior to or during the gastric bypass. Other patients were prescribed ursodiol for 6 months following surgery.

Table 2. Excessive Weight Loss at 12 Months

<table>
<thead>
<tr>
<th>Initial BMI, kg/m²</th>
<th>EWL, %</th>
<th>Total No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40</td>
<td>79</td>
<td>12</td>
</tr>
<tr>
<td>40-50</td>
<td>71</td>
<td>32</td>
</tr>
<tr>
<td>&gt;50-60</td>
<td>55</td>
<td>12</td>
</tr>
<tr>
<td>&gt;60-70</td>
<td>48</td>
<td>1</td>
</tr>
<tr>
<td>70+</td>
<td>37</td>
<td>1</td>
</tr>
</tbody>
</table>

*BMI indicates body mass index; EWL, excessive weight loss.
The pediatric age group (aged <18 years) deserves special consideration. We have performed this procedure on 2 pediatric patients (aged 13 and 17 years), but only after extensive counseling and cooperation with the local pediatric weight management program and their pediatricians. These patients were essentially “physiologically adults.” We do not advocate surgical weight loss in the pediatric age group as a routine.

Initially, very few patients opted for the open procedure despite extensive counseling and disclosure of our limited experience with the laparoscopic technique. This underscores the responsibility we have as surgeons to look at new technology critically. Patients seem too willing to accept an unknown and possibly higher complication rate to avoid the pain and/or problems associated with larger incisions. The question is not: Can we perform this procedure laparoscopically; rather, should we perform this procedure laparoscopically? Each surgeon must evaluate his or her own technical abilities in this regard. More importantly, each surgeon must evaluate his or her commitment to the lifelong support required of the bariatric patient.

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Corresponding author: Kelvin D. Higa, MD, Valley Surgical Specialists, 7202 N Millbrook Ave, Suite 105, Fresno, CA 93720.

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21. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
22. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-

DISCUSSION

Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-

day a remarkable single-surgeon experience of laparoscopic Roux-

en-Y gastric bypass in morbid obesity including 400 patients op-
23. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
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25. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-

Regarding a learning curve caring for these patients. During this series only 12 patients required conversion to laparotomy at the initial operation. Currently, the conversion rate is less than 1%. The operation is typically performed in 60 to 90 minutes using 4 disposable trocars and 5 abdominal puncture sites. Most pa-
26. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
27. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
28. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-

This represents a remarkable series, and Dr Higa de-
29. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
30. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
31. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-

Early weight loss results would appear to be comparable to the best series available for the Roux-en-Y gastric bypass, and I have no significant concerns about the anatomical result achieved by this procedure. For those of you who do not do bariatric surgery, the different weight loss, depending on the initial BMI of the patient, is something that has been demonstrated with virtually any type of bariatric procedure.

I do have a few observations and some questions. The first is the issue of the internal hernias. In our early experience with laparoscopic gastric bypass procedures at Stanford [University], we also had several internal hernias through the transverse mesocolon. This is a problem that was unique to us during the laparoscopic procedures, one that we had not seen with open surgery, and it clearly requires careful attention to fixa-
32. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
33. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-
34. Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented to-

The third has to do with the length of stay of these patients. I note that the patients that were converted to open stayed an average of only 2.7 days in the hospital. Clearly Dr
Higa has a practice geared toward early discharge and it is important always to remember that many apparent improvements in outcome attributed to laparoscopic procedures can probably be achieved with open surgery as well if we just set our minds to it.

My fourth comment is that there is clearly a learning curve for these procedures. In Dr Higa’s case this was undoubtedly due to the development of a new technique and partly to the acquisition of technical facility. His learning curve looks to be about 150 cases, and, as I look back on my own, it looks to be nearly perfectly superimposable on his. To some extent this curve for future generations may be shorter as the technical details of the procedure become better understood, but I think it is always going to be a very long one. These are not easy procedures to develop proficiency in.

Finally, this year Americans are going to spend somewhere between $30 and $50 billion on diet programs trying to lose weight. Every bit of evidence that we have available to us at the present time suggests that 1 year from now we will weigh more than we do today. The only reasonable option at this time for patients who are dangerously overweight is surgery, and if Dr Higa’s results can be widely reproduced, I believe that we will see a substantial and justifiable increase in the performance of bariatric surgery.

I have the following questions. Actually, you anticipated my first and that is how you are selecting patients. My understanding is that you are excluding no one except for patients with previous gastric operations. Have you seen any problems with patients with advanced cardiomyopathy of obesity or significant carbon dioxide retention? Second, what are you doing for deep vein thrombosis prophylaxis? Four hundred bariatric procedures without a single deep venous thrombosis or pulmonary embolus is really quite remarkable.

The third is, how do you decide whether to dilate an anastomosis? In talking with other surgeons who perform bariatric surgery, it strikes me that the criteria for dilating anastomoses vary tremendously and I wonder at what point you decide that that is appropriate.

Finally, who should be doing these operations? My bias is that these procedures must be performed only by surgeons with previous gastric operations. Have you seen any problems with patients with advanced cardiomyopathy of obesity or significant carbon dioxide retention? Second, what are you doing for deep vein thrombosis prophylaxis? Four hundred bariatric procedures without a single deep venous thrombosis or pulmonary embolus is really quite remarkable.

In the ideal setting a prospective randomized study as you can see with our data. So I do not have a real good answer for that. I think that as time goes on individuals will select themselves based on their interest, commitment, and degree of laparoscopic skill.

Dr Wolfe asked a good question about formal data acquisition looking back at our open experience and our present experience. In the ideal setting a prospective randomized study of open vs laparoscopic would be of value, but patients really won’t stand for that. The idea of minimally invasive technology is such a powerful tool that patients are willing to sacrifice a lot of things including an unknown safety factor. We are convinced that our present laparoscopic experience is superior to our personal open experience.

Follow-up is difficult in this group of patients. Third-party payers do not recognize the need for lifetime follow-up, so many patients are unwilling to pay for visits, especially if they perceive there to be no problems. Our patients sign agreements to be followed for at least 1 year in our office, but too many do not. Although our first case was 2 years ago, we were not as productive in the first year of this study. Therefore, most of our patients have not been out of surgery for 12 months. I agree with the need for long-term results.