

Original article

# Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 5-year results of a prospective randomized trial

Luigi Angrisani, M.D.\*, Michele Lorenzo, Ph.D., Vincenzo Borrelli, M.D.

*S. Giovanni Bosco Hospital, Naples, Italy*

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## Abstract

**Background:** To perform a prospective, randomized comparison of laparoscopic adjustable gastric banding (LAGB) and laparoscopic Roux-en-Y gastric bypass (LRYGB).

**Methods:** LAGB, using the pars flaccida technique, and standard LRYGB were performed. From January 2000 to November 2000, 51 patients (mean age  $34.0 \pm 8.9$  years, range 20–49) were randomly allocated to undergo either LAGB ( $n = 27$ , 5 men and 22 women, mean age 33.3 years, mean weight 120 kg, mean body mass index [BMI]  $43.4 \text{ kg/m}^2$ ; percentage of excess weight loss 83.8%) or LRYGB ( $n = 24$ , 4 men and 20 women, mean age 34.7, mean weight 120 kg, mean BMI  $43.8 \text{ kg/m}^2$ , percentage of excess weight loss 83.3). Data on the operative time, complications, reoperations with hospital stay, weight, BMI, percentage of excess weight loss, and co-morbidities were collected yearly. Failure was considered a BMI of  $>35$  at 5 years postoperatively. The data were analyzed using Student's *t* test and Fisher's exact test, with  $P < .05$  considered significant.

**Results:** The mean operative time was  $60 \pm 20$  minutes for the LAGB group and  $220 \pm 100$  minutes for the LRYGB group ( $P < .001$ ). One patient in the LAGB group was lost to follow-up. No patient died. Conversion to laparotomy was performed in 1 (4.2%) of 24 LRYGB patients because of a posterior leak of the gastrojejunal anastomosis. Reoperations were required in 4 (15.2%) of 26 LAGB patients, 2 because of gastric pouch dilation and 2 because of unsatisfactory weight loss. One of these patients required conversion to biliopancreatic diversion; the remaining 3 patients were on the waiting list for LRYGB. Reoperations were required in 3 (12.5%) of the 24 LRYGB patients, and each was because of a potentially lethal complication. No LAGB patient required reoperation because of an early complication. Of the 27 LAGB patients, 3 had hypertension and 1 had sleep apnea. Of the 24 LRYGB patients, 2 had hyperlipemia, 1 had hypertension, and 1 had type 2 diabetes. Five years after surgery, the diabetes, sleep apnea, and hyperlipemia had resolved. At the 5-year (range 60–66 months) follow-up visit, the LRYGB patients had significantly lower weight and BMI and a greater percentage of excess weight loss than did the LAGB patients. Weight loss failure (BMI  $>35 \text{ kg/m}^2$  at 5 yr) was observed in 9 (34.6%) of 26 LAGB patients and in 1 (4.2%) of 24 LRYGB patients ( $P < .001$ ). Of the 26 patients in the LAGB group and 24 in the LRYGB group, 3 (11.5%) and 15 (62.5%) had a BMI of  $<30 \text{ kg/m}^2$ , respectively ( $P < .001$ ).

**Conclusion:** The results of our study have shown that LRYGB results in better weight loss and a reduced number of failures compared with LAGB, despite the significantly longer operative time and life-threatening complications. (*Surg Obes Relat Dis* 2007;3:127–133.) © 2007 American Society for Bariatric Surgery. All rights reserved.

## Keywords:

Lap-Band; Gastric bypass; Weight loss; Co-morbidity; Complications; Prospective randomized study

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\*Reprint requests: Luigi Angrisani, M.D., Division of Endoscopic Surgery, Department of Surgery, S. Giovanni Bosco Hospital, Piazza Vittoria 7, Naples 80121 Italy.

E-mail: luigiangrisani@chirurgiaobesita.it

Surgery for the treatment of obesity is growing exponentially worldwide owing to the concomitant failure of the prevention of this largely psychosocial and genetic predisposition problem and long-term failure of all nonoperative therapy [1,2]. The introduction of laparoscopic techniques has also contributed to the public acceptance of obesity surgery [3,4]. Two operations have been standardized and are commonly performed, laparoscopic adjustable gastric banding (LAGB), performed primarily in Europe, South America, and Australia, and laparoscopic Roux-en-Y gastric bypass (LRYGB), performed primarily in North America [3–8]. This trend has recently been changing owing to the introduction of the Lap-Band system in the United States and a steady increase of LRYGB in Europe [6–8]. These operations are technically and conceptually very different. The criteria for a tailored approach in obesity surgery—to choose the best operation for a given patient—remain controversial, and only a few comparative studies have addressed this topic [9–13]. The primary objective of this study was to perform a prospective randomized comparison of the outcomes of LAGB and LRYGB in patients followed up for a minimum of 5 years.

## Methods

### Patients

The patients referred for surgical treatment of obesity were invited to attend preoperative seminars at which both LAGB and LRYGB (techniques, mechanism of action, mortality, complications, reoperation rate, and short- and long-term weight loss results) were presented and explained in detail. LRYGB had been previously performed by one of us (L.A.) in 5 patients; the risk of being in the early phase of the learning curve was stated, and our policy of a low threshold for conversion to laparotomy was explained. Data published in international studies regarding LRYGB were presented. New patients also had the opportunity of talking to patients who had previously undergone LAGB (>150 patients had undergone surgery by the senior author (L.A.) using the perigastric technique). Candidates were also offered the opportunity to talk to patients who had undergone open Roux-en-Y gastric bypass. After  $\geq 2$  seminars, patients willing to undergo obesity surgery were offered participation in the present study. The inclusion criteria were a body mass index (BMI) of  $>35$  to  $<50$  kg/m<sup>2</sup>, age  $>16$  but  $<50$  years, the absence of a hiatal hernia, and no previous major abdominal operations. To enter the study, patients had to be willing to accept randomization, which occurred 24 hours before surgery, while in the hospital, at which time they were informed of the operation to which they had been randomized. They were allowed to refuse, in which case they were excluded from the trial. They were independently evaluated by a team consisting of an internist, dietician, and psychologist for preoperative selection. A specifically de-

Table 1  
Patient demographics according to group

Characteristic	LAGB	LRYGB
Patients (n)	27	24
Sex (n)		
Male	5	4
Female	22	20
Age (yr)		
Mean	33.8 $\pm$ 9.1	34.1 $\pm$ 8.9
Range	21–50	21–50
Weight (kg)		
Mean	117.1 $\pm$ 12.8	118.2 $\pm$ 13.2
Range	95–147	92–152
BMI (kg/m <sup>2</sup> )		
Mean	43.4 $\pm$ 4.2	43.8 $\pm$ 4.1
Range	38.1–49.2	38.9–48.9
EWL (kg)		
Mean	47.1 $\pm$ 10.9	48.2 $\pm$ 11.7
Range	27–66	29–68
%EWL		
Mean	83.1 $\pm$ 9.2	83.8 $\pm$ 8.9
Range	34.6–126.5	36.9–128.8

LAGB = laparoscopic gastric banding; LRYGB = laparoscopic Roux-en-Y gastric bypass; BMI = body mass index; EWL = estimated weight loss; %EWL = percentage of EWL.

signed informed consent form, approved by the hospital institutional research board, was signed by all enrolled patients after explanation of the study and the risks and benefits of the procedures. From January 2000 to November 2000, 51 patients were randomly allocated by sealed envelope to 1 of the 2 surgical groups: LAGB or LRYGB. The patient demographics are reported in Table 1. Eight patients were excluded from the study after randomization because of their refusal to undergo the procedure to which they had been assigned (5 LRYGB and 3 LAGB). Data on mortality, conversion to an open procedure, postoperative complications leading to reoperation, hospital stay, weight, BMI, decrease in BMI, percentage of excess weight loss, and improvement in co-morbidities were analyzed. Patients of both groups were followed up in the surgeon's office every 3 months for the first year and every 6 months for subsequent years. LAGB patient weight loss data were excluded from the study at conversion to any other bariatric procedure. Band adjustment was performed when clinically required and was individually tailored for each patient to obtain weight loss and symptoms of satiety, defined as subjective referral of fullness after eating compared with their previous visit. The procedure was considered a failure if the patient had a BMI of  $>35$  kg/m<sup>2</sup> at 5 years postoperatively. Data are expressed as the mean  $\pm$  standard deviation, except as otherwise indicated. The data were not examined on an intention-to-treat analysis. Student's *t* test and Fisher's exact test were used for statistical analysis, with *P*  $< .05$  considered significant.

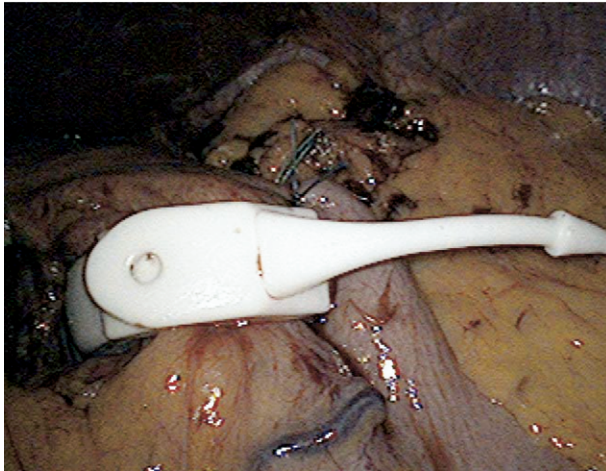


Fig. 1. Lap-Band System positioned using pars flaccida technique.

### Surgical technique

For LABG, the patients were positioned in the reverse Trendelenburg lithotomy position. A closed carbon dioxide pneumoperitoneum was created, and 5 trocars (2 of 10 mm and 3 of 5 mm) were inserted. The dissection was started near the angle of His, above the greater curvature of the stomach. The lesser omentum was opened through the pars flaccida, and the fat on the posterior wall of the lesser sac was retracted to expose the right crus of the diaphragm. A point along the anterior border of this muscle, at its lowermost aspect, was selected, and the peritoneum was opened. The Endo-Grasper Reticulator (U.S. Surgical, Tyco Healthcare, Norwalk, CT) was then passed along this retrogastric tunnel to appear on the greater curvature of the stomach at the site of the previous dissection at the angle of His. The Lap-Band System (Inamed-Allergan, Santa Barbara-Carpinteria, CA) was passed along this pathway and closed and fixed to the stomach using 3–5 gastrogastric stitches (Fig. 1). The port was sutured to the left anterior rectal sheet.

For RYGB, the patients were positioned in the reverse Trendelenburg lithotomy position. A closed carbon dioxide pneumoperitoneum was created, and 6 trocars (5 of 12 mm and 1 of 5 mm) were inserted. The balloon gastric bougie (Inamed-Allergan) was placed transorally in the stomach and inflated with 30 mL of a saline solution and retracted backward by the anesthesiologist to reach the cardioesophageal junction. Dissection was started at its equator in the perigastric space between the neurovascular bundle of Latarjet and the lesser curvature of the stomach using the harmonic scalpel (Ultracision, Ethicon Endo-Surgery, Cincinnati, OH). The retrogastric space was entered and gastric transection performed by multiple linear staplers fired in sequence up to the angle of His. Linear staplers 30–45 Endocutter (Ethicon Endo-Surgery, Cincinnati, OH) and 35, 45, and 60 mm EndoGIA (U.S. Surgical, Tyco Healthcare)

were used interchangeably when available and as required. The flip-top anvil of a 25-mm circular stapler (CEEA, U.S. Surgical, Tyco Healthcare) was advanced transorally into and through the proximal gastric pouch using a modified nasogastric tube anvil apparatus. The Roux limb was constructed by transecting the small bowel 40–60 cm from the ligament of Treitz (Fig. 2). A jejunotomy on the alimentary limb was created, and the circular stapler was introduced transabdominally and advanced into the lumen of the jejunum to create an antecolic, antegastric end-to-side gastrojejunostomy. The jejunotomy was closed with a 60-mm linear stapler. The presence of a gastrojejunostomy leak was tested by injecting 40–60 mL of methylene blue through the nasogastric tube previously positioned into the temporarily clamped alimentary limb. A side-to-side jejunojejunostomy was performed with a 45-mm linear stapler through a jejunotomy 100–150 cm distal to the gastrojejunostomy. The anastomosis was completed using 2-0 polydioxanone continuous suture (LapraTy, Johnson & Johnson, Cincinnati, OH).

### Results

The mean operative time was  $60 \pm 20$  minutes for the LABG group and  $220 \pm 100$  minutes for LRYGB group ( $P < .001$ ). The mean hospital stay was  $2 \pm 1$  days for the LABG group and  $4 \pm 2$  days for the LRYGB group ( $P < .05$ ). Only 1 LRYGB patient required a total intensive care unit stay of 40 days during her very long and complicated postoperative recovery period. One LABG patient was lost to follow-up. No patient died. Reoperation was required in 4 (15.2%) of 26 LABG patients, in 2 because of pouch dilation and 2 for band removal because of inadequate weight loss. One of these procedures was converted to biliopancreatic diversion, and the remaining 3 patients were on a waiting list for LRYGB. Reoperations were required in 3 (12.5%) of 24.

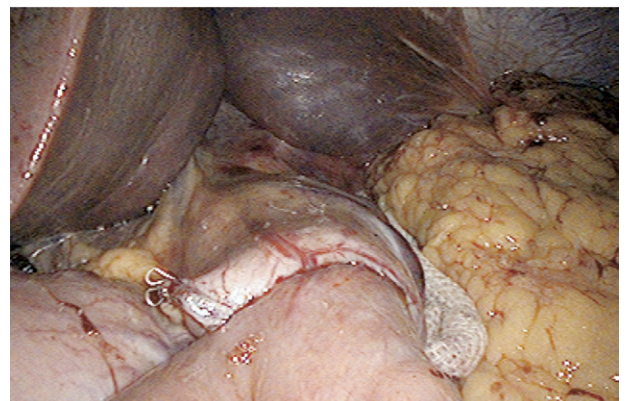


Fig. 2. Gastrojejunal anastomosis in LRYGB.

Table 2  
Early and late surgical complications

Group	Complication	Presentation time	Treatment	Hospital stay
LAGB	GPD	24 mo	Band removal	2 d
	GPD	36 mo	Band removal	3 d
LRYGB	Jejunal perforation	3 d	Perforation suture; intestinal resection	6 mo
	Internal hernia	15 mo	Intestinal resection	11 d
	Posterior pouch leak	Intraoperative	Conversion to laparotomy and suture closure	6 d

GPD = gastric pouch dilation.

### Early complications

Early complications were defined as those occurring <30 days postoperatively. Conversion to laparotomy was required in 1 (4.2%) of the 24 LRYGB patients because of a posterior leak at the gastrojejunal anastomosis revealed during intraoperative methylene blue test; this leak was successfully repaired by interrupted sutures (Table 2). An acute abdomen and sepsis were diagnosed 3 days after gastric bypass in 1 female patient (47 years old, BMI 49 kg/m<sup>2</sup>). At laparotomy, a jejunal perforation, proximal to the jejunojejunostomy, that was due to an iatrogenic small bowel injury, was found and treated by direct closure. The patient subsequently developed recurrent symptoms and sepsis and required jejunal resection and small bowel re-anastomosis. She underwent a difficult postoperative period with a 6-month hospital stay. Early complications necessitating reoperation were absent in the LAGB patients.

### Late complications

Gastric pouch dilation was diagnosed and treated by laparoscopic band removal in 2 (7.6%) of 26 LAGB patients (Table 2). One patient presented with small bowel obstruction 15 months after LRYGB. Diagnostic laparoscopy and subsequent laparotomy revealed a 30–40-cm segment of

alimentary limb ischemia due to an internal hernia. Small bowel resection was performed with an uneventful postoperative recovery.

### Co-morbidities

The patients were all screened preoperatively for the presence of co-morbidities (diabetes, hypertension, and cardiac disorders). In the LAGB group, 3 patients had hypertension and 1 had sleep apnea. In the LRYGB group, 2 patients had hyperlipemia, 1 had hypertension, and 1 had type 2 diabetes. Five years after surgery, the diabetes, sleep apnea, and hyperlipemia had all resolved.

### Weight loss

At 5 years (range 60–66 months) after surgery, the patients in the LRYGB group had a significantly lower weight and BMI and a greater percentage of excess weight loss compared with those in the LAGB group (Figs. 3–5). Weight loss failure (BMI >35 kg/m<sup>2</sup> at 5 yr) was observed in 9 (34.6%) of 26 LAGB patients and 1 (4.2%) of 24 LRYGB patients ( $P < .001$ ). Of the 26 patients in the LAGB group and 24 in the LRYGB group, 3 (11.5%) and 15 (62.5%) had a BMI of <30 kg/m<sup>2</sup>, respectively ( $P < .001$ ).

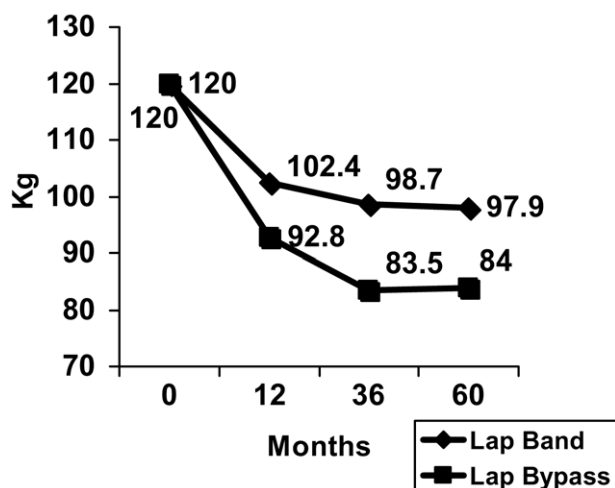


Fig. 3. Comparison of weight between LAGB and LRYGB group during 5 years of follow-up ( $P < .001$  at 5 yr).

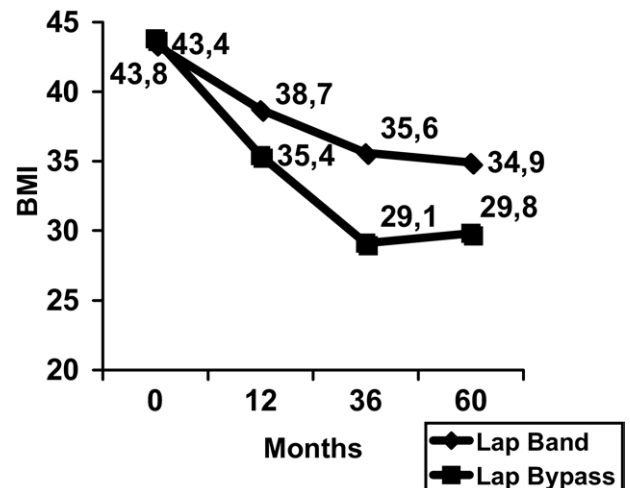


Fig. 4. Comparison of BMI trend between LAGB and LRYGB groups during 5 years of follow-up ( $P < .001$  at 5 yr).

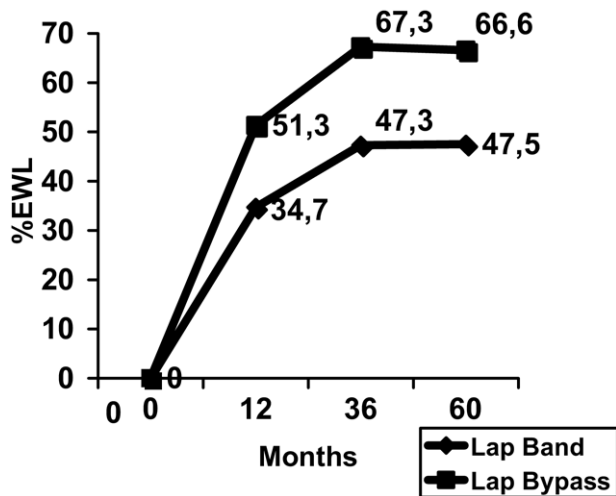


Fig. 5. Comparison of %EWL trend between LAGB and LRYGB groups during 5 years of follow-up ( $P < .001$  at 5 yr).

## Discussion

The use of laparoscopic obesity surgery is growing, with increasing demand from the public and an increase in the number of surgeons involved. The 2 operations most commonly performed are LAGB and LRYGB. At the beginning of the third millennium, LAGB was the procedure of choice in Europe and was introduced in the United States in 2001 [3–8]. Similarly, LRYGB, which was the procedure of choice in the United States, became more popular in Europe [3–8]. The selection criteria for these 2 procedures remain controversial.

Four single-center retrospective comparative studies have been recently published on this topic [10–13]. Two North American studies from Portland, Oregon and New York reported similar weight loss results without a significant difference in complication rates between LAGB and LRYGB at 2 and 3 years of follow-up [10,11]. One study found no difference in the improvement or resolution of co-morbidities between the 2 groups but a better outcome after LRYGB in patients with a self-reported sweet-eating habit [11]. These two studies considered both operations viable alternatives for the surgical treatment of morbid obesity, preferring LAGB for the patients at greatest risk [10,11]. More recently, 2 other comparative retrospective studies have addressed this topic. Galvani et al. [12] reported that LAGB and LRYGB were comparable in terms of weight loss, complications, and the need for reoperation. Cottam et al. [13] reported that at 3 years of follow-up LRYGB provided superior weight and co-morbidity reduction without a significant difference in terms of complications.

Different results were reported in 2 European comparative studies at 2 years of follow-up [14,15]. The French study reported that LRYGB had a lower early and late

complications rate [14]. Similarly, the Swiss study found that LRYGB resulted in significantly better co-morbidity reduction and a lower rate of late complications. These 2 studies reported better weight loss with LRYGB, but their follow-up duration was only 2 years.

Our 5-year prospective, randomized study was undertaken at beginning of the learning curve for LRYGB. However, we considered the design of this trial at a particular point in our experience when a minimum of surgeon and patient bias was present [16]. The perigastric band positioning technique for LAGB was switched to the newer technique for retrogastric tunnel dissection using the pars flaccida approach to reduce band slippage, pouch dilation, and intra-gastric migration. The LRYGB technique was modified from that of Potvin et al. [17] with meticulous pouch calibration and limb length measurement. The indication for using this very complex operation in the non-super-obese was suggested from the experience of Wittgrove and Clark [18].

Our results with non-super-obese patients have confirmed not only the better weight loss results with LRYGB, but also the high rate of LAGB patients with a postoperative BMI of  $>35 \text{ kg/m}^2$  (7 of 26), as well as the 2 other patients who underwent band removal for pouch dilation. However, in our hands, patients undergoing LRYGB were exposed to a greater risk of life-threatening complications. This might have been because of the early phase of our learning curve with this very complex laparoscopic technique. The technical problems we encountered were typical of beginners with this operation, including laparoscopic suturing, inaccurate bowel manipulation, and internal hernia formation (at that time, mesenteric defects were not routinely closed). However, Parikh et al. [19], in their retrospective comparative study of banding, bypass, and biliopancreatic diversion, after the surgeon learning curve, found a significantly lower complication rate in LAGB patients, with a lower incidence of organ resection/long-term disability. In our study, it was not possible to state whether LAGB or LRYGB was more effective in the treatment of obesity co-morbidity because of the low number of co-morbidity problems in either group before surgery. The significantly better weight loss results of this long-term prospective, randomized study in non-super-obese patients have not confirmed the equivalent results reported in the United States by Jan et al. [10] and Kim et al. [11] and are more supportive of the data from Europe [14,15].

It is our current policy to fully inform candidates for bariatric surgery of the risks and benefits of both procedures. Some patients would be pleased to obtain a 47% EWL at 5 years after LAGB without risking life-threatening complications and long-term drug requirements. Others would accept these risks with LRYGB because of the better and easier weight loss. The final choice will be strongly influenced by patients' desires and expectations. LAGB and

LRYGB continue to be routinely performed in our center according to the patient's requirements.

### Disclosures

*The authors have no commercial associations that might be a conflict of interest in relation to this article.*

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### Editorial comment

Obesity has become a serious health problem in most developed countries. The development of multiple co-morbidities in the obese, including hypertension, type 2 diabetes, obstructive sleep apnea, hyperlipidemia, osteoarthritis, venous insufficiency, and abdominal wall herniation, place them at increased risk of morbidity and mortality. Dietary and exercise management can be effective for inducing short-term weight loss; however, most morbidly obese patients regain the weight they lost and enter a vicious circle of weight loss and weight regain. The National Institutes of Health Consensus Conference in 1991 concluded that bariatric surgery was an effective long-term treatment for patients with morbid obesity [1]. The 2 operations recommended by the Consensus Conference were the Roux-en-Y gastric bypass and vertical banded gastroplasty. Since the National Institutes of Health Consensus guideline was issued, several changes in clinical practice have been observed. First, vertical banded gastroplasty is now only rarely performed because of the inferior weight loss compared with gastric bypass and the high rate of late complications [2,3]. Second, the laparoscopic approach for Roux-en-Y gastric bypass, introduced in 1994, is now widely practiced

and considered by most bariatric surgeons to be the procedure of choice [4]. Third, laparoscopic adjustable silicone gastric banding (Lap-Band System, Allergan, Irvine, CA) was introduced in 2001 in the United States and provides an equivalent and much safer restrictive weight loss procedure.

The clinical advantages and patient acceptance of laparoscopic Roux-en-Y gastric bypass and Lap-Band are in large part responsible for the exponential growth in the number of bariatric operations performed in the past decade. In the United States, the number of bariatric operations performed increased from 12,775 in 1998 to 70,256 in 2002, with >140,000 operations estimated to have been performed in 2005 [5]. Since the introduction of the Lap-Band, heated debates have occurred among surgical colleagues as to the efficacy of the Lap-Band compared with laparoscopic Roux-en-Y gastric bypass. The answer will likely be forthcoming after one or more prospective, randomized trials examining the outcome of the Lap-Band procedure versus laparoscopic gastric bypass. Important outcomes that must be examined include weight loss, particularly in the long term (>2 years), changes in co-morbidities and quality of life, and costs.