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Research Articles

Long-Term Outcomes after Gastric Bypass

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Background: While a great deal has been published regarding the short- and medium-term outcomes of gastric bypass surgery, much less information is available regarding long-term follow-up. Such information would be valuable in changing attitudes towards this surgery.

Methods: 342 severely obese patients underwent gastric bypass between June 1990 and April 2003 by a single surgeon. Careful preoperative documentation and follow-up have been maintained on a computerized database. Where necessary, recent follow-up information has been gained by mailed questionnaire and blood tests.

Results: Follow-up data from within the last 12 months is available for 88% of patients. Follow-up time ranges from 0-14 years, with a median of 48.6 months. Of those lost to follow-up, only 24 (7%) have <12 months follow-up. The series includes 261 females and 81 males. Preoperative BMI ranged from 28-99 (median 44). Before surgery, hypertension was present in 138, type 2 diabetes in 62, and dyslipidemia in 265. There was no 30-day peri-operative mortality. Three life-threatening complications occurred. BMI and % excess weight loss after 1, 2, 5 and 10 years were 28.7 and 89%, 28.3 and 87%, 31.2 and 70% and 31 and 75%, respectively. At most recent follow-up, 62% of those with hypertension before surgery were cured and 25% had improved. 85% of those with type 2 diabetes were cured and 10% had improved. No patients with impaired glucose tolerance had progressed to diabetes. 34% of those with dyslipidemia were cured and 38% had improved.

Conclusion: The excellent outcomes, in terms of weight loss and improvement in co-morbidities, seen in both the short- and medium-term after gastric bypass, are well maintained into the longer-term.

Key words: Gastric bypass, morbid obesity, long-term follow-up, weight loss, co-morbidities, hypertension, diabetes, dyslipidemia, bariatric surgery

Introduction

Obesity is becoming a worldwide epidemic. It is particularly visible in developed countries and is showing no signs of abating. Populations appear helpless to avoid or improve the problem. At a time when obesity is worsening in countries where it has been an issue for many years, it is emerging as a problem in other countries, where it was hitherto seldom seen. The increase in childhood obesity suggests the burden will pass to the coming generations who are likely to be even heavier than their parents. The implications of a worsening worldwide epidemic are immense.

Severe obesity is a biological, psychological and social disaster. The co-morbid conditions associated with obesity are chronic and ultimately life-threatening. Diabetes, hypertension, dyslipidemia, heart disease, respiratory failure, joint degeneration and cancer have all been implicated with excessive weight.[1,2] Life expectancy and quality of life are reduced in the obese. For the community, the loss of productivity and the costs of health-care are significant and could become crippling.

Politicians, the creators of public health policy and medical professionals alike seem unable to determine where efforts might best be focused. Primary prevention is a worthy goal, but the means of achieving it remain elusive. Successful management of established obesity seems equally elusive, because the conventional approaches of dietary restriction and exercise programs are almost always

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ineffective in achieving substantial long-term weight loss.[3] Even the modern pharmacological approaches, although encouraging, are unable to achieve a major impact on severe obesity.[4] We are left treating the numerous and difficult co-morbidities of obesity, or end-stage disease.

Meanwhile, bariatric surgery has been evolving over the past 50 years, and is becoming increasingly accepted in some countries by both the public and the medical establishment as a legitimate solution to severe obesity. Surgery can help individuals achieve what is otherwise unattainable. Gastric bypass remains the operation of choice for both weight loss and reduction in co-morbidities. While there is now abundant published literature supporting the short- and medium-term efficacy of gastric bypass surgery,[5-8] long-term follow-up data remains relatively scant.[9]

This report presents a single surgeon's experience with gastric bypass over a 14-year period, with current follow-up in 88% of patients. It focuses on the outcomes of weight loss and the improvement in the metabolic co-morbidities of hypertension, type 2 diabetes and dyslipidemia.

Methods

A total of 342 consecutive patients underwent their first bariatric operation at Wakefield Hospital between June 1990 and April 2003. All surgery was performed by a single surgeon (RS). During this time, two similar forms of gastric bypass, both initially described by Fobi,[10,11] were performed. The first, which we have termed silastic ring Roux-en-Y gastric bypass (SRGBP), is shown in Figure 1A and has been previously described in detail by our group.[12] The subsequent modification of this technique, known as a Fobi pouch, is shown in Figure 1B, and differs principally from SRGBP in that gastric transection is performed to overcome subsequent staple-line disruption.

Fobi pouch was performed under general anesthesia with epidural analgesia, as follows. Through an upper midline incision, a window was produced adjacent to the lesser curvature of the stomach 9 cm from the angle of His, and a passage was created from this point, behind the stomach, to the angle of

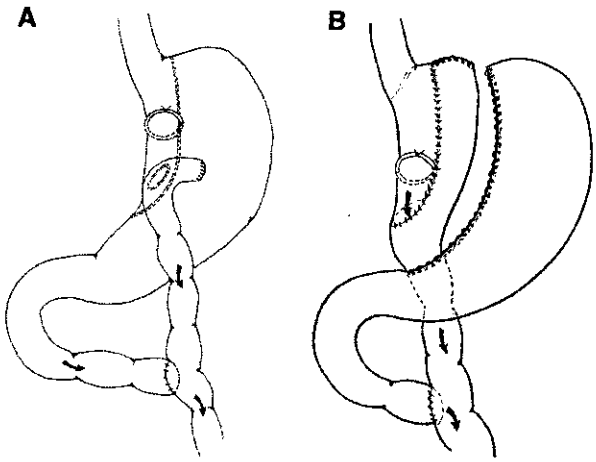

Figure 1. Diagramatic representation of (A) silastic ring gastric bypass (SRGBP) and (B) Fobi pouch operation.

His. A TCT-10® linear stapler-cutter (Johnson & Johnson) was positioned between these two points, and its position was adjusted before firing, so as to produce a blind lesser curvature gastric pouch 7-8 cm in length and 1.5-2 cm in diameter. Firing of the stapler achieves gastric transection, with 2 rows of staples on either side. The staple-line on the bypassed stomach was oversewn with a continuous 2/0 Ethibond suture. A 70-cm Roux-loop of jejunum was fashioned, with the entero-entero anastomosis performed with two layers of 2/0 chromic catgut at a convenient point 40-60 cm from the ligament of Treitz. The Roux-loop was passed in a retrocolic, retrogastric fashion to lie alongside the newly created lesser curvature pouch, separating this from the oversewn distal stomach. The Roux-loop is sutured to the lesser curvature pouch, in two layers with 2/0 polypropylene (Prolene®) in such a way as to create a serosal patch over a buried staple-line. A 6.0 cm (for age <50 years) or 6.5 cm (for age >50 years) length of 8F silastic rubber tubing was passed circumferentially around the lesser curve pouch 5 cm from the angle of His, and defined the size of the pouch above the ring (approximately 10-15 ml). This was fixed in place with an internal 2/0 Prolene suture. The Prolene sutures creating the serosal patch above the ring were continued to a point 1-2 cm beyond the silastic ring, at which point a 2-layer end-to-side gastro-jejunal anastomosis 1-1.5 cm long was created, after removal of a portion of the staple-line. The inner layer was fashioned with all-coats 2/0 chromic catgut, and the outer seromuscu-

lar layer completed with 2/0 Prolene.

Mesenteric defects were closed, and cholecystectomy was performed if gallstones were present. The upper abdominal cavity was lavaged with warm saline and the abdomen was closed with a mass No. 1 nylon suture. The subcutaneous fat layer was vigorously lavaged with saline so as to dislodge all loose fat, and skin was closed with subcuticular Vicryl® suture (Johnson and Johnson) and steristrips. All patients received a single intra-operative dose of a prophylactic antibiotic (usually Cefotetan® 2 g), and were commenced on preoperative Clexane® (Aventis) 20 mg subcutaneously for DVT/PE prophylaxis. The latter was continued daily after surgery, until discharge. Epidural analgesia was continued postoperatively for 4 days. Urinary catheters were not employed and patients were initially mobilized off the side of the bed 4 hours postoperatively.

A prospective, computerized database has been maintained on all patients, including relevant preoperative details of weight, height, BMI, % excess weight, existence of co-morbidities, operative details, complications and follow-up data. Patients were seen or assessed postoperatively at 3-monthly intervals for the first year, at 6-monthly intervals for the second year, and annually thereafter. Detailed preoperative blood tests included fasting lipid profiles, HbA1c, fasting glucose in known diabetics and glucose tolerance test in all other patients. Early postoperative complications were assessed clinically and entered into the database immediately following discharge. Medium- and long-term complications seen during follow-up included anastomotic stenosis, ulceration, staple-line disruption and incisional hernia.

Data collected during follow-up included weight and changes in co-morbidities. Blood tests taken before each follow-up visit included fasting lipids, fasting glucose, HbA1c, iron indices, serum and red cell folate, and vitamin B_{12} levels. All patients were commenced on a multivitamin tablet at the first postoperative visit and recommended to remain on this for life. Supplementation of Vitamin B_{12}, folic acid and iron was given as indicated by blood tests. In the case of vitamin B_{12} and folic acid, supplements were maintained life-long once a deficiency appeared. Where regular follow-up had been lost or information was lacking, this was gathered by a phone call or mailed questionnaire, coupled with blood tests.

In patients who were stable at 2 years, follow-up evolved to a point where it was accomplished by annual questionnaire and a set of blood tests. Questionnaires covered such issues as current weight, medications, new medical problems and alteration in eating habits. A laboratory request form for a fasting blood test was sent out with each questionnaire. Patients were reviewed in the Clinic, as and when problems arose.

Our primary focus in analyzing the data was to look at weight loss and changes in metabolic co-morbidities. We were interested to determine how quickly the co-morbidities resolved and whether they remained so over time. Medium- and long-term complications following surgery were also important. These included the need for re-operation, such as removal of the silastic ring, revision for staple-line disruption or other reason, adhesiolysis for bowel obstruction, cholecystectomy and repair of incisional hernia. The need for nutritional supplementation following the gastric bypass was also assessed.

The co-morbidities of particular interest were hypertension, diabetes, and dyslipidemia. Hypertension was deemed to be present if patients were taking antihypertensive medication or had a diastolic pressure in >90 mmHg. Diabetes was determined by history or preoperative oral glucose tolerance test. Dyslipidemia was judged present if one or more of the following abnormalities existed on fasting lipid profile: total cholesterol >5.0 mmol/l (>195 mg/dl), triglycerides >2.0 mmol/l (>180 mg/dl), or total cholesterol/HDL cholesterol >4.5. Changes in co-morbidities were classified as follows:

Resolution: normalization of the co-morbidity without requirement for medication;

Improvement: better control of the co-morbidity with the same or reduced medication;

No change: no evidence of resolution or improvement.

Staple-line disruption was suspected when there was either substantial weight regain or a marked change in eating capability. It was frequently associated with pain related to the presence of stomal ulceration. Confirmation of the diagnosis was made by either barium meal or gastroscopy.

All numerical data was expressed as median ± standard deviation with a range. Changes in lipid profiles were analyzed using a paired Student t-test. A P-value <0.05 was considered as statistical significance. Weight loss is demonstrated by reduction in weight, BMI and the percentage of excess weight lost (%EWL). Excess weight was calculated by determining ideal body weight from the New York Metropolitan Life Insurance Tables (1983) and subtracting this from the preoperative weight.

Results

There were 81 males and 261 females, aged between 15 and 68 years at the time of surgery (median 43 years). Of these, 175 (51%) had an SRGBP and 167 (49%) had a Fobi pouch procedure. The latter were all performed after August 1997. Mean operating time (excluding anesthetic time) was 120 minutes (60-420 min) and blood loss was 200 ml (100-4000 ml). Fifty-six patients (16%) had coincidental cholecystectomy for gallstones, and 2 (0.6%) required splenectomy during the surgery for control of bleeding.

Perioperative complications are outlined in Table 1. There were no anastomotic leaks, but one patient had peritonitis from a leak at the esophagogastric junction presumed to be related to a "tear-through" of a suture placed at that point for the creation of the serosal patch over the staple-line. This patient required re-operation and drainage of an upper abdominal collection. Twenty-four patients suffered respiratory complications postoperatively, principally atelectasis or infection. There was a single case of pulmonary embolism, which presented 1 month postoperatively. One patient with severe obstructive sleep apnea and obesity hypoventilation syndrome presented a major management problem in the postoperative first 24 hours because of respiratory failure. Cardiac complications were seen in 5 patients (congestive heart failure 2, atrial fibrillation 3). There was no 30-day mortality, although 3 life-threatening complications (referred to above) did occur. The median hospital stay was 7 days (3-43).

Of the total 342 patients, 260 (76%) have been followed for >2 years and 133 (39%) for at least 5 years. Follow-up data from within the last 12 months is available for 88% of the patients. The median follow-up period is 48.6 months (0-164). Only one patient had no follow-up at all. At the time of analysis, 5 patients were deceased, none for reasons related to gastric bypass surgery. Of those lost to follow-up, 22 (6.4%) were able to be located but did not respond to either questionnaire or telephone call, and the remaining 21 patients (6.4%) could not be located.

Ninety-one patients (27%) underwent re-operation, on 113 occasions, during which a total of 125 different procedures were performed (Table 2). All 25 revisions, and 16 of the 23 ring removals (70%) were performed on patients who underwent SRGBP. Only 26 patients (7%) who had a Fobi pouch procedure required further surgery. A total of 33 patients who had SRGBP (19%) are known to have had partial staple-line disruption, of whom 25 have had revision surgery with gastric transection (i.e. conversion to Fobi pouch).

The following late complications were observed. Stomal ulceration developed in 22 patients (6%), usually in association with staple-line disruption or NSAID use. Anastomotic stenosis was seen in 12

Table 1. Perioperative complications occurring in 342 patients after gastric bypass

Complication	Number
wound infection	38 (11%)
peritonitis	1 (0.3%)
respiratory complication	24 (7%)
cardiac complication	5 (1%)
urinary tract infection	4 (1%)
deep venous thrombosis	2 (0.6%)
intra-abdominal abscess	1 (0.3%)
other	11 (3%)

Table 2. Nature of re-operations required in 91 patients after gastric bypass

Re-operation	Number
ring removal	23 (7%)
revision	25 (7%)
bowel obstruction	2 (0.6%)
incisional hernia	15 (4%)
abdominoplasty	31 (9%)
cholecystectomy	23 (7%)

patients (4%) and was resolved in all instances by a series of balloon dilatations. An incisional hernia developed in 23 patients (7%), of whom 15 have had this repaired. Two episodes of ring erosion occurred, both in association with staple-line disruption and ulceration. Removal of the silastic ring was undertaken in 23 patients (6.7%) because of major restriction to solid food. This was most often required for those with the smaller diameter ring as shown in the Table 3. Cholecystectomy was necessary in 23 patients (7%) during the follow-up period for symptomatic gallstones. This was undertaken and accomplished laparoscopically in almost all instances.

Mean ± sd preoperative weight, BMI and % excess weight were 131.9 ± 33.5 kg (72-360), 46.2 ± 9.2 kg/m^2 (28-99) and 92% (22-335) respectively. The operation produced excellent weight loss, with maximum loss achieved after 18 months as shown in the Figure 2. There was good maintenance of weight loss thereafter with mean ± sd %EWL at 1, 2, 5, 10 and 14 years of 88.5 ± 40.5%, 87.1 ± 35.7%, 69.9 ± 26.5%, 74.6 ± 55.2% and 58.5 ± 3.5% and mean ± sd BMI at 1, 2, 5, 10 and 14 years of 28.7 ± 5.76, 28.3 ± 5.69, 31.2 ± 5.96, 31.0 ± 6.21 and 32.5 ± 0.7 kg/m^2 (Figures 3 and 4). Not surprisingly, better weight loss was achieved and maintained in those who did not experience staple-line disruption or need silastic ring removal.

The outcomes of patients' co-morbidities are shown in Table 4. Hypertension was present in 138 patients before surgery, of whom follow-up is available in 134. Following surgery, hypertension resolved in 85 (62%), improved in 34 (25%), remained unchanged in 11 (8%) and became worse in 4 (3%). During the period of follow-up, hypertension recurred in 9 patients, none of whom had had significant weight regain.

Before surgery, 62 patients had type 2 diabetes: 27 were taking oral hypoglycemic agents, 18 were taking insulin, 5 were "diet controlled" and 12 were diagnosed at the time of preoperative testing. Following surgery, 53 (85%) were completely cured of diabetes, determined by fasting blood glucose

Table 3. Requirement for ring removal related to ring size

Size of ring	Number	Rings removed
no ring	2	-
5.5 cm	66	10 (15%)
6.0 cm	181	11 (6%)
6.5 cm	92	2 (2%)
7.0 cm	1	0 (0%)

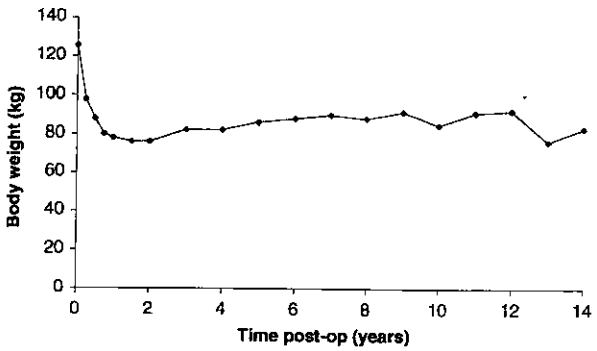

Figure 2. Graph showing median weight of 342 patients before and after gastric bypass.

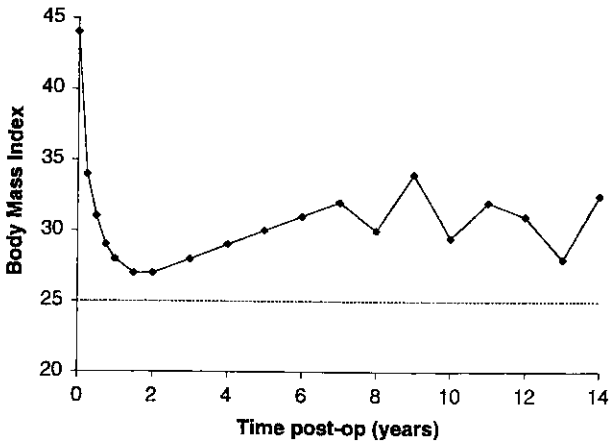

Figure 3. Graph of median Body Mass Index (BMI) in 342 patients before and after gastric bypass.

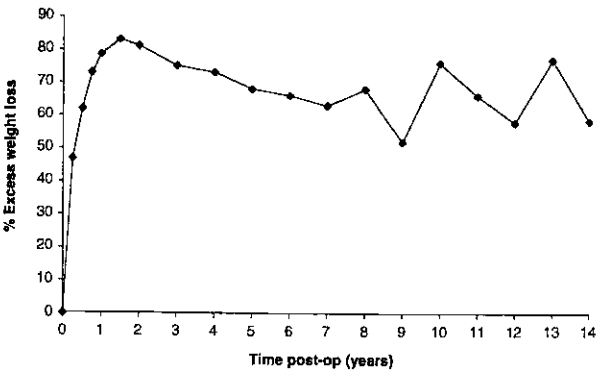

Figure 4. Graph showing median % excess weight loss after gastric bypass in 342 patients.

Table 4. Changes in co-morbidities after gastric bypass

	resolved	improved	unchanged	worse	unknown
Hypertension	62%	25%	8%	3%	nil
IGT	91%	nil	nil	nil	9%
Diabetes	85%	10%	nil	2%	3%
Dyslipidemia	34%	38%	7%	10%	11%

IGT = impaired glucose tolerance

(mmol/l) and HbA1c (%) levels of 7.0 or lower. Two patients had no follow-up blood results, 6 patients showed improved glycemic control, and a single patient had worse fasting blood glucose and HbA1c levels, despite satisfactory maintenance of weight loss. Of the 7 who remained diabetic, two required insulin and two required oral medication, but in all instances, at much reduced doses. Abnormal glucose tolerance was found in 66 patients before surgery; of these, none progressed to diabetes during follow-up, although 6 have been lost to long-term follow-up.

Deranged lipids were present in 81% (265/327) before surgery. Of those identified as dyslipidemic preoperatively, 73% had elevated cholesterol, 31% had elevated triglycerides and 54% had an elevated cholesterol/HDL ratio. At last follow-up, hypercholesterolemia had resolved in 33% and improved in another 34%. Hypertriglyceridemia had resolved in 73% and improved in another 10%. Elevated cholesterol/HDL ratios reverted to normal in 74% and improved in another 12%. Overall dyslipidemia was completely resolved postoperatively in 89 patients (34%), improved in 101 (38%), remained unchanged in 19 (7%) and had deteriorated in 27 (10%). Follow-up fasting lipid data was not able to be obtained in 29 patients (11%), most of whom had surgery >10 years ago, at which time follow-up fasting lipid tests were not routinely being performed.

Vitamin B_{12} deficiency developed in 217 patients (63%) mostly within 2 years of surgery and required institution of regular vitamin B_{12} injections. Folate deficiency developed in 159 (46%), requiring daily supplementation, and iron supplementation was required from time to time in 215 (63%).

At the time of each follow-up consultation or questionnaire, patients were asked to indicate the range of food that they were able to eat. This was categorized as either "almost normal", "minor restriction" or "major restriction". This information was not available for 6 patients, but in the remaining 336, 221 (66%) described the range of food eaten as "almost normal" at the time of their most recent follow-up, 94 (28%) indicated they had "minor restriction", and 21 (6%) declared a "major restriction".

Patients were also asked for their overall satisfaction regarding the outcome of their surgery. This was categorized as "pleased", "neutral" or "unhappy". Again, there was no data for 6 patients (the same 6 as above), but at the most recent follow-up, 282 (84%) were pleased, 32 (9.5%) felt neutral, and 22 (6.5%) were unhappy. Of the 22 patients who were unhappy, 16 had undergone significant weight regain, and in 8 of these, staple-line disruption had been confirmed. A further 3 patients were unhappy because of complications related to surgery (2 incisional hernias and 1 who suffered an anastomotic leak at the time of revision surgery), and 2 had unacceptable eating difficulties despite ring removal.

Discussion

Although there has been a wealth of documentation to show the occurrence and benefits of short- and medium-term weight loss following gastric bypass, the long-term benefits are less well-documented. The use of a prospective database at our clinic since 1990, coupled with a very high rate of follow-up, allows us to analyze a moderately large group of patients out to 14 years. The results support the use of gastric bypass in the severely obese, both for the achievement of

long-term weight loss and resolution or improvement of important metabolic co-morbidities.

The goal for most patients who undergo bariatric surgery is the achievement of substantial weight loss, with the objective being to improve quality of life and the prospects of good health. The two most commonly employed operations today are laparoscopic banding and gastric bypass. Both these operations undoubtedly accomplish significant weight loss and improvement in co-morbidities.[5-9,13-15] Gastric bypass is generally regarded as the gold standard operation and is reported to achieve a greater weight loss and with greater reliability. Most reports of gastric bypass document mean %EWL of 65-75% after 2-5 years.[5-9] This compares with mean %EWL of 50-60% at 5 years for laparoscopic banding.[13-16] The present study indicates that weight loss after gastric bypass, with the inclusion of a silastic ring, is well maintained out to 14 years, and that the principal reason for weight regain in this group of patients is either staple-line disruption or ring removal. While there is general accord amongst those performing bariatric surgery that gastric transection is an important component of gastric bypass, there is less agreement that the placement of a ring around the gastric pouch is important. Before the adoption of gastric transection at the Wakefield Gastroenterology Centre, the staple-line was created with the TA90B stapler, which was probably the most reliable of the stapling devices used in this type of surgery. Our finding of 19% staple-line disruption to the present time is in line with other published accounts[17,18] and clearly indicates the advisability of gastric transection. Although gastro-gastric fistulae have been reported after gastric transection,[19] we have never seen this after a Fobi pouch procedure, which interposes the Roux-loop between the gastric staple-lines, and indeed creates a serosal patch over the staple-line of the gastric pouch. This would seem to provide an additional measure of security.

The purpose of the silastic ring is to slow the rate of emptying from the gastric pouch and to prevent the outlet from enlarging with the passage of time, which is one of the recognized reasons for weight regain after gastric bypass. The prediction of many that ring erosion would be a problem has not been borne out. We have only seen this on two occasions, both in the context of staple-line disruption and ulceration. It was clear, however, from our early experience that a 5.5-cm circumference ring was a little small and needed to be removed in about 15% of patients,[20] to permit a reasonable quality of eating. Thus, we moved to placing 6.0-cm and 6.5-cm circumference rings, depending on the patient's age. This was predicated on the belief that the motility of the esophagus and gastric pouch above the ring may be less vigorous with aging, and therefore make a bigger ring desirable. This policy led to a dramatic reduction in the number of rings requiring removal, as reported in this study. Ring removal is almost always associated with a degree of weight regain, generally of between 5 and 15 kg. We now believe that a 6.5-cm ring is the optimal size for most patients and expect to remove this in only around 2% or patients. This can usually be accomplished laparoscopically. With gastric transection and the use of larger rings comes an expectation that our long-term weight loss figures will improve, because there should no longer be problems with staple-line disruption and ring removal.

That improvement in co-morbidities is accomplished by bariatric surgery is now well-documented.[5,9,21,22] The improvements and even resolution seen in the metabolic co-morbidities of hypertension, diabetes and dyslipidemia are particularly important and are likely to be associated with improved life expectancy. These diseases are becoming a particular scourge on Western societies and are consuming huge sums of money in the pursuit of what is so often only poor control. That gastric bypass can provide long-term cure in about 85% of severely obese type 2 diabetics[23] and prevent others from becoming diabetic[5] is of immense value to the individual and society. Similarly to find long-term resolution or improved control of hypertension in this difficult group of patients,[5,24,25] who often require multiple medications in an attempt to control the problem, is of real importance. Dyslipidemia, particularly hypertriglyceridemia and elevated cholesterol/HDL cholesterol are also resolved or improved, much more reliably and impressively than with any medication, which benefit is also maintained over time.[5,26] The combination of these changes must have an important bearing on life expectancy in the severely obese and should lead to a new paradigm for the management of these metabolically-based diseases when seen in association with severe obesity.

There is growing evidence to indicate that insulin resistance may be central to both hypertension and dyslipidemia as well as type 2 diabetes.[27-31] Gastric bypass has been found to lead to a rapid and substantial improvement, or even loss of, insulin resistance, and it is very likely that this provides the explanation for the rapid improvement or loss of these conditions seen after surgery. That this occurs well ahead of weight loss is an important observation which may ultimately lead to unlocking the mystery surrounding the mechanism of insulin resistance itself.[32]

It is interesting to note that satisfaction with the outcome of surgery was most commonly linked to the degree of weight loss or weight regain. However, as important that the improvement in co-morbidities is, in the end the majority of patients who seek this surgery, do so with weight loss as their primary objective. Although at times this objective may not be stated as the most important, it nevertheless usually underpins the decision to proceed with surgery. For this reason, it is important that surgeons who undertake this form of surgery seek to perform the most effective operation that they can, as safely as they can. Gastric bypass consistently performs better than gastric banding or gastroplasty in terms of reliability and extent of weight loss and deservedly remains the choice bariatric operation. While definitive description of the most effective form of gastric bypass is not yet possible, it is likely to entail creation of a small vertical pouch with gastric transaction, and possibly the placement of a 6.5-cm silastic ring.

Long-term follow-up of bariatric surgery patients requires collection of accurate clinical and biochemical information that can only be achieved with appropriate resources and a commitment from both clinical teams and their patients. Regrettably, this is seldom achieved, and as a result the data supporting the use of surgery in the severely obese which should be so compelling is so easily ignored or criticized by funders of health-care and policy-makers. It is hoped that the information provided by this study and others like it will provide greater impetus for the development and the expansion of bariatric surgery for the benefit of those who suffer this disabling and ultimately devastating condition.

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