Obesity Surgery, 12, 652-660

The Laparoscopic Adjustable Gastric Band (Lap-Band®): A Prospective Study of Medium-Term Effects on Weight, Health and Quality of Life

Paul E. O'Brien, MD, FRACS; John B. Dixon, MBBS, FRACGP; Wendy Brown, MBBS; Linda M. Schachter, MBBS, FRACP; Leon Chapman, MBBS, FRACP; Anthony J. Burn, MBBS, FANZCA; Maureen E. Dixon, BSc; Carlos Scheinkestel, MBBS, FRACP; Christine Halket, RN; Lisa J. Sutherland, BApplSci; Anna Korin, MBBS; Peter Baquie, MBBS, FRACGP

Monash University Department of Surgery, Alfred Hospital, Melbourne, Australia

Background: Obesity is now one of our major public health problems. Effective and acceptable treatment options are needed. The Lap-Band® system is placed laparoscopically and allows adjustment of the level of gastric restriction.

Methods: A prospective study of 709 severely obese patients was conducted over a 6-year period at a university-based multidisciplinary referral center. After extensive preoperative evaluation, patients with a body mass index >35 were treated by Lap-Band® placement. Close follow-up with progressive adjustment of gastric restriction continued permanently. Medical co-morbidities were monitored as part of comprehensive prospective data collection.

Results: There have been no deaths perioperatively or during follow-up. Significant perioperative adverse events occurred in 1.2% only. Reoperation has been needed for prolapse (slippage) in 12.5%, erosion of the band into the stomach in 2.8% and for tubing breaks in 3.6%. A steady progression of weight loss has occurred through the duration of the study with 52 ± 19 %EWL at 24 months (n=333), 53±22 %EWL at 36 months (n=264), 52 ± 24 %EWL at 48 months (n=108), 54 ± 24 %EWL at 60 months (n= 30), and 57 ± 15% EWL at 72 months (n=10). Major improvements have occurred in diabetes, asthma, gastroesophageal reflux, dyslipidemia, sleep apnea and depression. Quality of life as measured by Rand SF-36 shows highly significant improvement.

Conclusions: Placement of the Lap-Band® system provides safe and effective control of severe obesity. The effect on weight loss is durable and is associated with major improvement in health and quality of life. It has the potential to provide a broadly acceptable option for this common and serious disease.

Key words: Morbid obesity, bariatric surgery, gastric banding, device, laparoscopy

Reprint requests to: Professor Paul O'Brien, Chairman, Monash Department of Surgery, Alfred Hospital, Melbourne 3181, Australia. Fax: 61 3 9510 3365;
e-mail: paul.obrien@med.monash.edu.au

Introduction

Obesity is now one of the major health problems of the developed world. In the USA, 22% of the population is estimated to be obese (Body Mass Index BMI >30)[1,2] and more than 12 million are severely obese (BMI >35). An extensive range of common diseases are caused or made worse by obesity, and it has been recently estimated that the annual adult deaths attributable to obesity are nearly 300,000.[3] Additionally the disease causes reduced quality of life because of limitations on physical activity and psychosocial disability. Direct costs for treating obesity-related illness have been estimated to exceed $70 billion per year.[4,5] A further $40 billion is spent annually on weight reduction programs and dietary foods.

The management of this problem remains a major challenge. Optimal and continuous application of a combination of dietary and drug therapy

in association with increased exercise and behavioral modification can, at best, achieve and maintain a 5-10% loss of body weight.[6-8] For the severely obese, this is insufficient to solve the problem. Various forms of gastric stapling procedures have been available for more than 30 years. Gastric bypass provides the best outcomes with loss of 50-80% of excess weight (%EWL). Recent laparoscopic application of the procedure appears to maintain this effectiveness.[9,10] However, the laparoscopic approach is still associated with occasional mortality and serious morbidity and significant anatomical change.

The recent introduction of a laparoscopically-placed adjustable gastric band (LAGB®, Lap-Band® System, Inamed, Santa Barbara, CA) has the potential to offer a more acceptable option for those with severe obesity who do not wish to consider the more invasive, non-adjustable and essentially irreversible alternative of gastric bypass. The LAGB consists of a band of silicone elastomer with an inflatable inner shell and a buckle closure connected by tubing to an access port placed outside the abdominal cavity. The inner diameter of the band can be readily adjusted by the addition or removal of saline through the access port. The band is placed laparoscopically around the upper stomach approximately 1 cm below the esophagogastric junction. The concept was derived from the adjustable gastric band initially described by Kuzmak.[11] Clinical application of the Lap-Band® was initiated by Belachew in 1993[12] and is now in common use in more than 40 countries.

We have been using the LAGB as the primary modality of treatment for severe obesity since 1994 and have maintained a prospective database which stores a comprehensive range of weight measures, health and quality of life outcomes and an adverse events register that enables review of all outcomes during the 6 years and the trends in the data during that time.

Methods

Patients were admitted into the program if they fulfilled each of four criteria:
1) They were severely obese, (i.e. BMI >35 kg/m^2).
2) They had medical, physical or psychosocial problems associated with their obesity.
3) They gave a history of prolonged attempts at weight loss by other means.
4) They were adequately informed and understood and accepted the potential risks and benefits of the procedure, and they expressed a commitment to follow the rules regarding eating and exercise permanently after the procedure.

Preoperative evaluation included clinical assessment by the surgeon (P. O'B) on a minimum of two occasions 1 month apart, and by at least three physicians. A general physician (J.D.) fully documented known medical problems and conducted standardized surveys for quality of life (SF-36)[13,14] and for specific medical problems. A respiratory and sleep physician (L.M.S.) performed a general and respiratory clinical assessment and conducted a comprehensive respiratory function analysis. A specialist physician/endocrinologist (L.C.), who was independent of the primary team of physicians, reported back to the group his assessment of suitability and risk status, after a comprehensive medical and psychosocial review and a review of the biochemical and other investigative data. Selected patients, particularly those with severe asthma or sleep apnea, were assessed by a specialist physician/ intensivist (C.S.), and all patients had a pre-anesthetic consultation with the anesthetist (A.B.)

Biochemical screening included routine hematology, serum electrolytes, and liver function tests, plus screening for diabetes (glucose, insulin, HbA1c, C-peptide), nutritional status (Vit. B_{12}, RBC folate, iron, ferritin, transferrin), thyroid function tests, homocysteine, and lipids (triglycerides, cholesterol, HDL cholesterol, LDL cholesterol). Additional studies were performed for specific patient problems. The pattern of clinical evaluation and investigation has evolved over the course of the study as different needs have been identified. As a consequence, not all patients have had all assessments or investigations.

Each patient was provided with comprehensive information regarding the problem of obesity, the options for treatment and details of the Lap-Band® procedure (risks, outcomes). They were carefully advised of their role in the process and of their particular responsibility to follow the guidelines for

eating and exercise and of the need to attend follow-up permanently. It was stressed to each patient that, as the adjustability of the LAGB is one of the keys to its effectiveness, good outcomes can only be expected if follow-up is properly conducted. These guidelines were provided to them in written form and were explained and reinforced on multiple occasions by the surgeon, the nurse facilitator (C.H.), and the dietician/exercise consultant (L.S.) who designed and supervised an individualized activity program for each patient.

Adjustments to the band were almost always performed in the office at the time of consultation and without radiological imaging. Adjustment was generally indicated if, in the setting of appropriate eating behavior, the rate of weight loss since the previous visit was <0.5 kg/ week. Adjustment was generally not done if weight loss exceeded 1 kg/week. For weight loss between 0.5 and 1 kg /week, further adjustment would be done if the patient was struggling to abide by the rules regarding eating. After an initial priming adjustment of 2 ml, each subsequent adjustment was usually of a volume of 0.3 ml. Generally 5-6 adjustments were done in the first year, 2-3 in the 2nd year and 0-2 each subsequent year. Fluid was removed if there were symptoms of excess tightness – heartburn, regurgitation, vomiting – and also for pregnancy, other illnesses, anesthetics or operations, or travel to remote areas.

All relevant data were entered into and maintained on a computerized database, written specifically for the purpose (LapBase®, AccessMed, Melbourne), using Microsoft Access®. This program provided rapid and easy access to individual patient information, review of single patient data over time, presentation of total group data of all measures and outcomes and the facility to explore for relationships between any of the variables measured. Additionally there were two databases linked to, but not within, LapBase®. The first recorded all perioperative and postoperative adverse events in greater detail than was maintained in the primary program. The second contained a complete record of all test results for each patient (M.D). This was used to support comorbidity subgroup analyses within or independent of LapBase®. These additional databases have been established to support our specific research needs, whereas LapBase® is structured primarily for routine Lap-Band® patient care.

The surgical technique has been reported previously.[15] Key features include placement of the device at approximately 1cm below the esophagogastric junction as indicated by using the calibration tube, anterior fixation from the greater to lesser curve, usually with four sutures, posterior fixation with Marlex mesh regardless of the path of dissection in relation to the apex of the lesser sac, and placement of the access port on the surface of the anterior rectus sheath rather than beneath it as recommended by others.[12]

All patients had a limited barium meal on the morning after operation and then commenced on the fluid diet for 3 weeks followed by a transition to the definitive solid food diet, which was maintained permanently. Discharge from hospital typically occurred between 24 and 72 hours after surgery.

The follow-up program was standardized and maintained, with defaulting patients contacted and rescheduled. Each patient was generally seen each month for the first 6 months and then less frequently to an eventual minimum of 12-monthly review. These reviews were conducted by the surgeon and three general physicians (JD, AK, PB). Any patient who had not been seen for 18 months and could not be contacted to ascertain status was regarded as lost to follow-up. There was a more comprehensive review at each 12 months interval for documentation of the status of any co-morbid conditions and for measure of metabolic and micronutrient status.

Adjustment of the fluid within the system was performed frequently during the postoperative phase. Because of placement of the LAGB on the surface of the anterior rectus sheath, almost all adjustments were performed by palpation and injection of the access port in the consulting room and generally took only a few minutes. There was only rarely the need for radiological imaging.

Data Analysis

Patient demographic details were expressed as mean ± standard deviation. χ^2 method was used to test the significance of differences between proportions. One-way ANOVA (2-sided) was used to

assess for significant change in SF-36 scores. The SPSS[16] statistical software was used for statistical analysis. A *P*-value <0.05 was considered statistically significant.

Results

Patients

A total of 709 patients were treated for obesity by Lap-Band® placement between July 1994 and May 2000. The baseline characteristics of these patients are shown in Table 1. Only 10 patients (1.4%) were lost to follow-up at this time. Within the overall group, there were 50 patients who had had previous surgery for obesity. The specific outcomes for this subgroup are reported elsewhere.[17] However, these patients remain in the analysis of efficacy and adverse events of the present report.

Operative Approach

Operative placement was usually by the laparoscopic approach. The 50 patients who had had prior obesity surgery and an additional 4 patients who had had complex surgery in the left hypochrondrial region had elective open surgery. Conversion from laparoscopic to open placement was needed in 7 patients (1%), mainly because of hepatomegaly or excessive fat making exposure difficult. There have been only 3 conversions in the last 600 patients (0.5%). The duration of the operation for the last 300 patients was 55.6 ± 18 min.

Perioperative Morbidity

There have been no deaths in the perioperative period or during follow-up.

Perioperative morbidity has been low (Table 2).

Table 1. Baseline characteristics of 709 patients treated with Lap-Band® between July 1994 and May 2000.

Male/Female ratio	106 / 603 (15% / 85%)
Age (Median and Range)	41 years (16-71)
Initial Weight (kg)	125.9±25.9 kg (max. 242.7 kg)
Initial BMI	45.0 ± 7 kg/m^2 (max. 77)
Lost to follow-up	10 patients (1.4%)

Table 2. Perioperative morbidity for the 709 patients

Laparoscopic Approach	**648 patients**
Infection at reservoir site	7
DVT	1
Total	**8 (1.2%)**
Open Approach	**61 patients**
Gastric Perforation	2
Infection at reservoir site	5
Other wound infections	12
DVT & PE	1
Respiratory Failure	5
Total	**25 (41%)**

Perioperative events were recorded as a complication if the event led to significant additional treatment, delay in discharge from hospital, readmission and reoperation. For patients having primary laparoscopic placement, only 8 adverse events occurred (1.2%), most commonly due to infection at the site of the access port. When open surgery and reversal of gastric stapling or other bariatric operations was required, a higher rate of complications followed (41%). There have been no adverse events associated with anesthesia.

Reoperation

Late adverse events leading to reoperation have been frequent (Table 3). Prolapse of the stomach through the band (sometimes referred to as slippage), creating an enlarged pouch above the band,

Table 3. Late adverse events leading to reoperation

Prolapse / Slippage	**87 (12.5%)**
Revision / replacement	80
Explantation	7
Reservoir / tubing breaks	**26 (3.6%)**
Erosion into stomach	**20 (2.8%)**
Repair / replacement	15
Explantation	5
Lap-Band Balloon leak	**1**

has occurred in 87 patients (12.5%). This problem usually presented initially as heartburn but progressed to vomiting and complete obstruction in some. No patient with prolapse has developed features of an acute abdomen, and no urgent surgery has been required. Most episodes have been treated by laparoscopic removal of the band and placement of a new Lap-Band® along a path immediately superior to the original path. Revision by reduction of the prolapse alone was used initially but led to further recurrence in most cases and is not recommended. The frequency of prolapse has decreased over the duration of the study in association with modification of techniques used during and after operation. Thus far, there have been two episodes of prolapse in the last 350 patients treated. Undoubtedly, more patients will develop prolapse over time, but the current low number in this latter group is significantly less than would be expected if the pattern of prolapse seen in the first 350 patients continued along the same timeline.

Dilatation of the esophagus was a common finding on barium contrast study if the adjustment was excessive or prolapse was present. Removal of excessive fluid or correction of prolapse was always associated with resolution of the dilatation. No patient in the series has had persisting dilatation after correction of the underlying problem.

Erosion of the band into the stomach has occurred on 20 occasions (2.8%). This problem presents clinically as loss of sense of restriction to eating and weight regain. There has been no acute illness nor clinical features of extragastric leakage. The optimal management is still being determined. Current treatment is for laparoscopic removal with repair of the stomach and replacement of the Lap-Band®.

Tubing breaks have occurred in 26 patients (3.6%) and have always been at the junction with the access port or at the nearby metal connector. Careful straight alignment of the tubing as it passes into the abdomen has limited the problem. A modified access port has been available since mid 1999 and should be expected to further reduce occurrence. The problem is corrected by exposure of the access port, which is lying in the subcutaneous space, and by repair of the tubing or replacement of the access port.

The overall reoperation rate is 18.9%. There was a high frequency (39.3%) in the first 300 patients and a marked reduction in frequency to only 3 reoperations (1.0%) in the last 300 patients. Although the latter patients have had less time for problems to arise, adjustment for the reduced follow-up nevertheless indicates a highly significant reduction in the need for reoperation as more experience has been obtained and techniques have been modified.

Weight Loss

The pattern of weight loss over time is shown in Table 4, and Figure 1. There has been a steady increase in the percent of excess weight lost (%EWL) during the first 2 years, followed by stability of weight status through to 6 years. During the last 4 years, the %EWL is in the region of 53-57 %EWL. Similar patterns are seen with the changes in BMI, which have stabilized around a BMI of 31 kg/m^2. Importantly, there is no evidence of weight regain during this period. Inadequate weight loss (<25 %EWL) was present in 7.9% of patients at 2 yr and 3.8% of patients at 3 yr.

Changes in Co-morbidities

In association with weight loss, there have been many changes in comorbidities in these patients. The effect of weight loss on some of the more common and clinically significant comorbidities is summarized below. More detailed reports on some specific comorbidity changes have been published.[18-20]

Table 4. Percentage of excess weight lost following Lap-Band® placement (Mean ± SD)

Months	n	% EWL
3	709	24 ± 9
6	650	35 ± 14
9	545	42 ± 15
12	492	47 ± 16
18	456	51 ± 19
24	336	53 ± 19
36	273	53 ± 22
48	112	52 ± 23
60	32	54 ± 23
72	10	57 ± 15

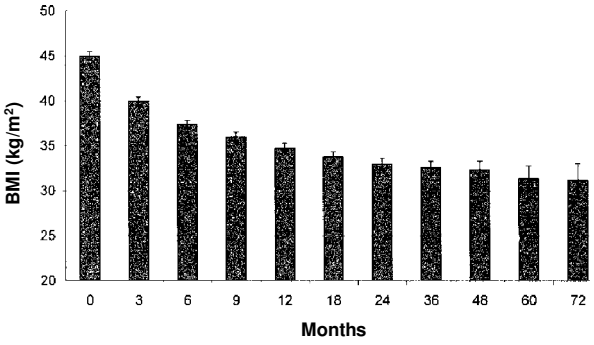

Figure 1. Body mass index (mean ± 95% CI *of the mean*) vs time after Lap-Band placement.

Diabetes

Twenty-eight diabetics were followed for at least 12 months. At follow-up, 15 patients (54%) were non-diabetic in that they were asymptomatic, off all therapy and had normal fasting plasma glucose, serum insulin and HbA1c levels. A further 12 patients (43%) were improved with easier control, less therapy, and improved biochemistry. Only one patient did not experience an improvement.

Asthma

A 1-year review was conducted of 33 asthmatic patients. The Asthma Severity Score, a composite of measures of symptoms and treatments, was 44.5 before operation and 14.3 at follow-up (P <0.001). All 33 patients showed improvement with reduction of medications. Eighteen patients required daily medication preoperatively, whereas only eight were taking medications at follow-up. There was less use of inhaled steroids, and no patient was taking oral steroids. Eleven patients were regarded as non-asthmatic, having no clinical asthma and not requiring treatment. During the year before operation, nine patients had one or more admissions to hospital for acute asthma. No admissions occurred during the 12 months after operation.

Dyslipidemia

The dyslipidemia of obesity is characterized by high triglycerides, decreased HDL-cholesterol and increased numbers of LDL-cholesterol particles but decreased particle size. Thirty-four percent of patients presented with elevated triglyceride levels (>2.0 mmol/l). By 12-months, only 9% had elevated levels. Eighteen percent presented with low HDL-cholesterol levels (<1.0 mmol/l) and by 12-months only 5% had low levels. Total cholesterol levels were not different from the matched community norm[21] and fell 3% (95% CI 1.5-5.4%) with weight loss.

Hypertension

A total of 147 hypertensive patients have been followed for at least 12 months. There was complete resolution of hypertension (normal BP, no treatment) in 80 patients (55%); 45 patients (31%) were improved, 21 (14%) were unchanged and one patient required an increase in medication in an attempt to control blood pressure.

Disturbed Sleep

There were 128 patients followed for at least 12 months. The changes in the prevalence of various disturbances of sleep are detailed elsewhere.[20] Importantly, the frequency of observed sleep apnea was reduced from 33% to 2% over this time.

Reflux Esophagitis

The prevalence of gastroesophageal reflux in 300 consecutive patients was 37%, with 6% having proven severe disease (daily medication with proton pump inhibitors ± additional therapy), 10% having proven moderate disease with symptoms requiring therapy on most days, and 21% having mild symptoms requiring intermittent therapy.[19]

At 12 months after the operation, 48 patients who had moderate or severe disease were assessed; 76% had total resolution of all symptoms and an additional 14% had significantly improved. Reflux esophagitis was regarded as resolved if the patients had no symptoms and no treatment for a 1-month period.

Quality of Life

There was improvement in the Beck Depression Index from 18.0 ± 15 to 6.9 ± 6 at one year and 7.8 ± 9 at 2 years after operation (P <0.001). The quality of life, as measured by Rand SF-36,[22] showed highly significant improvement in all 8 sub-scales which returned to or exceeded the normal values in all cases[13] (Table 5).

Table 5. Health-related quality of life (SF-36) scores pre-surgery and at 1 and 2 year follow-up. Comparison with healthy community levels.[22]

	Pre-surgery (n=398)	1-year (n=248)	2-year (n=119)	*P*-value	Community Levels
Physical Function	46 (23)*	83 (18)*	84 (21)	<0.001*	88
Physical Role	41 (39)*	87 (28)*	87 (30)	<0.001*	83
Pain	63 (23)*	84 (20)*	86 (19)	<0.001*	74
General Health	42 (21)*	77 (18)*	76 (17)	<0.001*	74
Energy	33 (21)*	65 (20)*	64 (21)	<0.001*	59
Social Function	54 (28)*	83 (23)*	82 (26)	<0.001*	83
Emotional Role	52 (42)*	81 (35)*	81 (36)	<0.001*	80
Mental Health	59 (21)*	74 (18)*	72 (19)	<0.001*	73

*One-way ANOVA 2-sided , post-hoc Tukey. All significant changes were between pre-surgery and 1 year. There was no difference between 1-year and 2-year scores.

Discussion

The communities of the developed world have a major and increasing problem with obesity and its attendant comorbidities. Weight loss is now arguably the most effective therapeutic modality in clinical medicine. Currently, significant long-term weight loss can only be achieved by surgical treatment. The data presented indicate that the Lap-Band® procedure provides a safe and effective surgical approach to obesity. There were no deaths and minimal perioperative morbidity. A loss of 53-57% of excess weight was achieved and maintained through a 6-year follow-up. Major improvements in diabetes, hypertension, asthma, gastroesophageal reflux, dyslipidemia and sleep disorders were noted in association with the weight loss. The measures of quality of life indicate restoration of normal values. The one major negative feature of the data was the need for revisional procedures in 19.8% of the patients.

Lap-Band® placement offers major benefits over most alternative procedures by its laparoscopic placement, its adjustability and its reversibility. The ability to adjust the degree of gastric restriction simply and repeatedly is its most important advantage. It enables gentle progression to the optimal setting of restriction, thereby minimizing the liklihood of inducing vomiting and maximizing the effectiveness. The pattern of weight loss over time reflects this effect clearly. Whereas with gastric stapling procedures maximal weight loss frequently occurs at 12-24 months postoperatively followed by a weight increase,[23,24] LAGB patients show continuation of the weight loss over a longer period, and the recidivism of gastric stapling has not yet been seen out to 6 years. Furthermore, the adjustability permits removal of the gastric restriction, should this be clinically indicated, eg. by pregnancy[25] or concurrent illness.

Laparoscopic placement is seen, in this study, to be associated with fewer complications than open surgery.[26] The perioperative incidence of significant adverse events after laparoscopic placement of just over 1% is below the incidence to be expected for major abdominal surgery and is occurring in a group of patients who often have extensive comorbidities and high anesthetic risk status. As those needing open surgery for reversal of previous bariatric operations had a much higher incidence of complications, it would appear that the laparoscopic approach is of great benefit to this particular group of patients.

The adjustability of the Lap-Band® is the key to achieve a gentle, prolonged weight loss and maintenance of weight reduction over time. It is our practice to adjust the tightness of the band frequently to optimize outcome. Placement of the access port on the anterior rectus sheath rather than within rectus abdominis muscle permits adjustment easily in the consulting room without image intensification. We believe that this is a very important factor in the outcomes achieved and should be recommended as the standard approach. We have not identified any negative effect due to this more

superficial placement.

Recent reports of laparoscopic gastric bypass show it to be generally effective and safe, [9,10,27] and a comparison of this procedure with LAGB may be achievable in the future. As both operations require significant technical skill in order to achieve optimal outcomes, it would be important that such a study was only done by a center or multiple centers that had achieved an adequate level of competence for both procedures before onset of a trial. Recent publications of disappointing outcomes occurring during the very early surgical experience with the Lap-Band® should promote study of the importance of the correct technique of surgical placement and the correct application of patient education, follow-up and band adjustment.[28,29]

The need for relatively frequent revisional procedures is a cause for concern. Prolapse of the stomach through the band has been the most frequent (12.5%). Measures have been instituted to minimize this problem.[30] These include higher band placement usually above the lesser sac, more extensive anterior fixation, posterior fixation with mesh, slow and careful introduction of solid food postoperatively and detailed instructions to patients regarding the dangers of overeating and vomiting. In the more recently treated patient group, there has thus far been a marked reduction of the incidence of prolapse (< 1.0% in the last 350 patients), but it is too early in the follow-up of these patients to accept that the problem is resolved. Erosion of the band into the stomach has been infrequent (2.8%) and has followed a pattern which suggests that technical factors are involved. The frequency of the problem reaches a peak in the third hundred group of the patients treated. No erosions have yet occurred in the last 300 patients. Tubing breaks have reduced markedly since more effort has been made at creating a smooth line for the tubing back into the abdomen. Furthermore, by avoiding suture ties on the tubing connector, free sliding of the tubing with body movement has minimized the damage due to repeated kinking. There was a reduced frequency of revisional procedures with each additional cohort of 100 patients. Four patients have required any revisional surgery in the last 350 patients treated. Although longer follow-up is needed, the median follow-up for these patients is 16 months (range 4-25 months), suggesting that future rates of revisional surgery will be markedly lower.

In conclusion, we have found that the Lap-Band® system provides an innovative approach to one of our major health problems. Data, which include follow-up of up to 6 years, indicate that it is safe and effective. It reduces the excess weight by more than 50%, and in doing so it generates major improvements in a range of serious illnesses and in quality of life. Because of its attributes of laparoscopic placement, adjustability and reversibility, it should prove to be an acceptable approach for those suffering from severe obesity.

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(Received March 4, 2002; accepted May 5, 2002)