U.S. Clinical Trials 2003-2006

Report on the Use and Outcome of the GaBP Ring Autolock™ System: 215 Cases Followed for up to 5 Years

Mathias A.L. Fobi, M.D., F.A.C.S.
Center for Surgical Treatment of Obesity
21520 South Pioneer Blvd., Suite 204
Hawaiian Gardens, California 90716

A report was presented to the FDA in 2007 on the use of the GaBP Ring device in 215 patients with a follow-up of up to 3 years. This report presents the results for the use of the GaBP Ring in 215 patients with up to a 5 year follow-up.

Materials and Method:

Surgical Operation

Patients who contacted the Center for Surgical Treatment of Obesity ("CSTO") for obesity operations are sent informational pamphlets and are referred to the CSTO website (www.fobi-pouch.com). The CSTO specializes mainly in the performance of the banded gastric bypass operation, also commonly called the Fobi-Pouch Operation ("BGBP" or "FPO"), which is characterized by placement of a silastic ring around the pouch to stabilize the stoma and the placement of a gastrostomy site marker to facilitate percutaneous access to the gastric bypassed stomach. Patients who contact the CSTO are general seeking or are specifically referred to the FPO. The 215 patients in this report underwent the BGBP operation with the GaBP Ring device and the gastrostomy site marker. The surgical technique of placing the GaBP Ring has been previously published.[1]

Pre-operative Evaluation

Patients who come to the CSTO for treatment have to attend a two hour session seminar where information on obesity, the medico-psycho-socio-economic ramifications of obesity, the various treatment options, indications for surgical treatment, the surgical treatment options, the risks and outcome of the various surgical options, the need for nutritional and nutrient support after surgery, the need for lifelong follow-up and monitoring, and the need to attend support group meetings are provided and discussed in detail. Details of the BGBP are presented with the rationale for the use of the ring and the gastrostomy site marker.

A patient who has decided to have the BGBP is evaluated by a surgeon or physician's assistant, who obtains a complete history and does a complete physical on the patient. The surgeon at this visit determines if the patient meets the NIH criteria for surgical intervention[2] and answers any questions the patient may have about the BGBP, CSTO and/or the follow up requirements. Once the surgeon determines that the patient meets the NIH criteria, the patient is subjected to evaluation by a nutritionist, a psychotherapist, a cardiologist and a pulmonary consultant. Each of the consultants in this multidisciplinary bariatric team also discusses the operation, risks, possible outcomes and need for long-term follow-up with the patient. These consultants, in addition to determining if the patient is a suitable candidate for surgery, also assist in preparing the patient to have a safe operation.

The patient is also required to attend at least one support group meeting prior to undergoing the surgery. Laboratory evaluations include complete blood count, liver function tests, metabolic, renal and endocrine panels, and hepatitis screening. All men above 40 get a PSA test and women over 40 have a mammogram. In addition, electrocardiograms, echocardiograms and a chest X-ray are done on all patients. Other tests as determined by the consultants are also done as requested.

Data Collection

Data on all bariatric operations performed at the CSTO from 1986 to December 31, 2007 were submitted prospectively and entered into the International Bariatric Surgery Registry ("IBSR"), which was formerly called the National Bariatric Surgery Registry, and is housed by Dr. Edward Mason at the University of Iowa (Iowa City, Iowa).

The data includes the profiles of bariatric surgery patients, including age, sex, height, weight, race, state and country of origin. Data on the level of education, job status, marital status, family history, the use of cigarettes, alcohol and drugs are also collected and entered. Data on the various modalities tried for weight loss are also collected and reported. Data on the various co-morbidities of the patients, including medical, social and psychological morbidities, are also collected and entered. Data on previous surgical operations, particularly bariatric operations, are also collected and entered. Data on the type of bariatric operation and any concurrent operations are also reported. Data on any implants, rings or bands used during the bariatric operations are recorded. Intra-operative complications including bleeding, injuries to other organs and anesthetic complications are also collected and reported. Early post-operative complications (within 30 days of the operation) are collected, entered and submitted. These include deaths, pulmonary embolism, deep venous thrombosis, wound problems, leaks, bleeding, deep and superficial infections, gastric outlet problems, return to surgery, and hospital readmissions. Late complications (after 30 days of the operations), such as band migration, band slippage, bowel obstruction, gastric outlet stenosis, marginal ulcers, ventral incisional hernia, anemia, protein malnutrition and various nutrient deficiencies are also collected and submitted. Surgical outcome, such as amelioration and/or resolution of Type 2 diabetes, sleep apnea, hypertension, hyperlipidemia, arthritis, fibromyelgia, gastroesophageal reflux disease, pseudo tumor cerebri, venous stasis and dermatitis, non-alcoholic liver disease, infertility and amenorrhea, are recorded. The psychosocial outcome, such as increased level of activity, self esteem, job employability, furthering of education and reduction in medication use, are also reported. Last but not least the weight of the patient at various intervals after the bariatric operation, including six months, one year and yearly there after are collected and submitted.

The data on the 215 patients who had the BGBP with the GaBP Ring and gastrostomy site marker was extracted from the IBSR for this report and analysis.

Results:

A total of 215 patients had the GaBP Ring used in the BGBP from April, 2003 to September, 2006 at the CSTO by Dr. Fobi or surgeons under his supervision at three sites, Tri-City Regional Medical Center, Saint Mary's Medical Center and Lancaster Community Hospital. Of this patient population, 48 patients had the operation through an open laparotomy and 167 patients had the operation using a laparoscopic approach. The number of patients at each site, having open laparotomies and laparoscopic procedures are summarized as a percentage of the total 215 patients in the study. **(Table 1)**

Table 1

Surgical Location

Number of Patients Receiving Surgery (N)			
Surgery Site	**Open (N)**	**Laparoscopic (N)**	**N %**
Tri-City Regional Medical Center	38	146	184 (85.6%)
Saint Mary Medical Center	8	14	22 (10.23%)
Lancaster Community Hospital	2	7	9 (4.2%)
TOTAL	48	167	215 (100%)

The patient demographics are summarized by gender, age and initial body mass index ("BMI"). **(Table 2)**

Table 2

Patient Demographics

Number of Patients Receiving Surgery (N)			
Parameter	**Open (N)**	**Laparoscopic (N)**	**N (%)**
Gender			
Females	41	138	179 (83.25%)
Males	7	29	36 (16.75%)
Total	48	167	215 (100%)
Age (in years)			
Mean	41	40	40
Minimum	12	12	12
Maximum	68	71	71
BMI			
Mean	53.18	47.84	48.16
Minimum	31.61	33.16	31.61
Maximum	82.18	81.87	82.18

The pre-existing co-morbidities were recorded for all the study patients. The co-morbidity groups represent the number of patients with a certain amount of pre-existing co-morbidities as a percentage of all 215 patients. **(Table 3)** The study patients had a total of 725 pre-existing co-morbidities which included depression, irregular period, bipolar disease, fibromyalgia, and obsessive compulsive disorder, as well as co-morbidities that have been shown to have an increased effect on the risk of complications including arthritis, asthma, diabetes, gastresophageal reflux disease ("GERD"), high blood pressure, hypercholesterolemia, sleep apnea and urinary incontinence. The number of pre-existing co-morbidities, which relate to a higher risk of post-operative complications, are presented as a percentage of the 725 total pre-existing co-morbidities. **(Table 3)**

Table 3

Pre-operative Co-Morbidities

Number of Patients Receiving Surgery (N)	
Parameter	**N (%)**
Co-Morbidity Groups	
0 Conditions	16 (7.4%)
1-2 Conditions	49 (22.8%)
3-5 Conditions	127 (59.1%)
>5 Conditions	23 (10.7%)
Co-Morbidities Related to Higher Risk of Complication	
Arthritis	111 (15.3%)
GERD	96 (13.2%)
High Blood Pressure	90 (12.4%)
Diabetes Mellitus	66 (9.1%)
Hypercholesterolemia	66 (9.1%)
Sleep Apnea	56 (7.7%)
Urinary Incontinence	34 (4.7%)
Asthma	20 (2.8%)

The follow-up data is available at 6 months, 1 year, 2 years, 3 years, 4 years and 5 years post-operative for patients that completed the follow-up visits. At the time this report was developed, not all patients had reached 3 or more years post-operation, and thus were not eligible for higher post-operative follow-ups. The number of patients that were eligible for post-operative follow-ups and the number of patients that completed the post-operative follow-up visits are summarized. **(Table 4)**

Table 4

Patient Visit Accountability

Number of Patients with Follow-Up Visits (N)		
Post-Operative Time Period	**# Eligible**	**N (%)**
6 Months	215	209 (97.2%)
1 Year	215	205 (95.3%)
2 Years	215	174 (80.9%)
3 Years	178	132 (74.2%)
4 Years	91	68 (74.7%)
5 Years	16	13 (81.3%)

The post-operative complications are separated by open laparotomies and laparoscopic cases, and the number of patients experiencing such complications are presented as a percentage of the 48 open laparotomy cases, the 167 laparoscopic cases, and the total 215 operations performed in the study. **(Table 5a)** The complications are then broken down between early post-operative complications (within 30 days of the operation) and late post-operative complications (greater than 30 days after the operation). It was noted that in the early post-operative complications 6 leaks required re-exploration and the remaining 8 leaks were treated by observation, the 15 gastric outlet stenosis cases required endoscopic dilatation, the 2 deep venous thrombosis cases required re-admission to a hospital and the 1 case of marginal ulcer was treated with medications. **(Table 5b)** In the late post-operative complications, the 5 small bowel obstructions required surgical exploration, the 4 ring slippages required laparoscopic ring removal, the 2 cases of excessive weight loss required ring removal, and the 1 cases of a penetrating ulcer required revision surgery with ring removal because of ring erosion. **(Table 5c)** In total, 10 patients of the 215 patients (4.6%) have had the ring removed, 3 due to contamination from leaks and 7 due to slippage, erosion or excessive weight loss. There have not been any early or late post-operative deaths.

Table 5a

Post-Operative Complications

Number of Patients with Complication (N)			
Complication	**Open (N)**	**Laparoscopic (N)**	**Total (N)(%)**
Leaks	2 (4.1%)	12 (7.2%)	14 (6.5%)
Gastric Outlet Stenosis	5 (10.4%)	10 (6.0%)	15 (7.0%)
Deep Venous Thrombosis	1 (2.1%)	1 (0.6%)	2 (0.9%)
Marginal Ulcer	1 (2.1%)	0 (0.0%)	1 (0.5%)
Small Bowel Obstruction	1 (2.1%)	4 (2.4%)	5 (2.3%)
Ring Slippage	0 (0.0%)	4 (2.4%)	4 (1.9%)
Excessive Weight Loss	1 (2.1%)	1 (0.6%)	2 (0.9%)
Ring Erosion/Penetrating Ulcer	1 (2.1%)	0 (0.0%)	1 (0.5%)
Ventral Incision Hernia	0 (0.0%)	1 (0.6%)	1 (0.5%)
TOTAL	12 (25%)	33 (19.8%)	45 (20.9%)

Table 5b

Early Post-Operative Complications

Number of Patients with Complication (N)			
Complication	**Open (N)**	**Laparoscopic (N)**	**N (%)**
Leaks	2 (4.1%)	12 (7.2%)	14 (6.5%)
Gastric Outlet Stenosis	5 (10.4%)	10 (6.0%)	15 (7.0%)
Deep Venous Thrombosis	1 (2.1%)	1 (0.6%)	2 (0.9%)
Marginal Ulcer	1 (2.1%)	0 (0.0%)	1 (0.5%)
TOTAL	9 (18.7%)	23 (13.8%)	32 (14.9%)

Table 5c

Late Post-Operative Complications

Number of Patients with Complication (N)			
Complication	**Open (N)**	**Laparoscopic (N)**	**N (%)**
Small Bowel Obstruction	1 (2.1%)	4 (2.4%)	5 (2.3%)
Ring Slippage	0 (0.0%)	4 (2.4%)	4 (1.8%)
Excessive Weight Loss	1 (2.1%)	1 (0.6%)	2 (0.9%)
Ring Erosion/Penetrating Ulcer	1 (2.1%)	0 (0.0%)	1 (0.5%)
Ventral Incision Hernia	0 (0.0%)	1 (0.6%)	1 (0.5%)
TOTAL	3 (6.3%)	10 (6.0%)	13 (6.0%)

The percentage excess weight loss ("PEWL") was recorded at 6 months, 1 year and annually up to five years for patients that completed the post-operative follow-up visits as depicted in Table 4. **(Table 6a)** Successful weight loss is measured by the patients' ability to lose greater than or equal to 50% of their excess weight. The success rate is summarized by the number of patients achieving successful weight loss as a percentage of the total follow-up patients for each time period. **(Table 6b)**

Table 6a

Percentage Excess Weight Loss (PEWL)

Number of Patients with Follow-Up Visits (N)			
Post-Operative Time Period	**N**	**Mean PEWL**	**Range PEWL**
6 Months	209	55.8	17.1-108.8
1 Year	205	74.8	33.3-142.9
2 Years	174	79.6	31.9-136.9
3 Years	132	79.1	20.8-136.9
4 Years	68	75.4	32.2-124.4
5 Years	13	74.3	40.9-117.9

Table 6b

Success Rate

Number of Follow-Up Patients with ≥ 50 PEWL (N)		
Post-Operative Time Period	**Follow-up Patients**	**N (%)**
6 Months	209	122 (58.4%)
1 Year	205	186 (90.7%)
2 Years	174	166 (95.5%)
3 Years	132	125 (94.7%)
4 Years	68	63 (92.6%)
5 Years	13	11 (84.6%)

Discussion:

The occurrence of the early and late post-operative complications in this study is the same as reported in the literature using the "surgeon fashioned" rings or bands.[3,4] The incidence of ring-related complications, ring erosion, ring slippage and gastric outlet stenosis are within the range of what is reported in the literature with the "surgeon fashioned" devices. There was 1 ring erosion (0.5%) as compared to those noted using the "surgeon fashioned" ring (1.8%).[5] The percent weight loss at all intervals are identical to those reported after the BGBP, which is higher than in the traditional Gastric Bypass.[6,7,8,9] It was desirable to have a ring that is prefabricated, standardized, sterile and ready to use in the BGBP. The auto-locking mechanism of the GaBP Ring highly enhanced placement of the ring, decreasing surgical trauma and reducing surgical time, particularly in the laparoscopic approach.

Conclusion:

A prefabricated device almost identical to the "surgeon fashioned" silastic ring used in the BGBP operation was used in 215 patients with a follow-up of up to 5 years with no increased morbidity and/or mortality. The GaBP Ring device will be a desirable replacement of the "surgeon fashioned" ring because it is prefabricated, standardized, and sterilized, and the auto-lock mechanism eases placement.

References:

1. Fobi et al. Placement of the GaBP Ring System in the Banded Gastric Bypass Operation. Obes Surg 2005;15:1196-1201.
2. National Institutes of Health Consensus Development Conference Draft Statement Gastrointestinal Surgery for Severe Obesity. Obes Surg 1991;1:257-65.
3. White S. et al Long-Term Outcomes after Gastric Bypass. Obes Surg 2005;15:155-163.
4. Salinas A, Santiago E, Yeguez J et al Silastic Ring Vertical Gastric Bypass: Evolution of Surgical Technique, and Review of 1588 Cases. Obes Surg 2005;15:1403-1417.
5. Fobi, M.A.L., Lee, H., Holness, R., Cabinda, D. Gastric Bypass Operation for Obesity. World J Surg 1998;22:925-935.
6. Fisher BL, Barber AE. Gastric Bypass Procedures. Eur J Gastroenterol Hepatol 1999;11:93-97.
7. Obrien PE, McPhail T, Chaston TB, Dixon JB, Systematic Review of Medium-Term Weight Loss After Bariatric Operations. Obes Surg 2006:16:1032-1040.
8. Marema RT Laparoscopic Roux-en-Y Gastric Bypass: A Step-by-Step Approach. J Am Coll Surg 2005:6:979-982.
9. Stubbs RS, O'Brien I, Jurikova L: What Ring Size Should Be Used In Association With Vertical Gastric Bypass? Obes Surg 2006;16:1298-1303.