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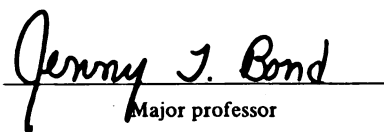
SHORT- AND LONG-TERM NUTRITIONAL OUTCOMES FOLLOWING
GASTROPLASTY SURGERY FOR MORBID OBESITY

presented by

LISA ANNE VAN DYKE

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of the requirements for

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By

Lisa Anne Van Dyke

A THESIS

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ABSTRACT

SHORT- AND LONG-TERM NUTRITIONAL OUTCOMES
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By

Lisa Anne Van Dyke

Forty-six adults who had received the Gomez gastroplasty procedure in the previous two and one-half years participated in a post-operative, cross-sectional study of the nutritional outcomes of gastroplasty surgery. All subjects were evaluated using a 24-hour dietary recall, a food behavior questionnaire, anthropometric measurements, and serum transferrin and iron. Mean weight and triceps skinfold decreased significantly over time for at least one year post-operatively. Mean daily protein intake increased from 29% of the RDA in the early post-operative period to 94% of the RDA by one year. Mean mid-arm muscle circumference and serum transferrin were normal throughout the study period. Mean daily iron intake was significantly less than two-thirds of the RDA and mean serum iron concentration was in the normal range throughout the study period. Vitamin and mineral supplementation decreased significantly with time following surgery while the intakes of energy and several nutrients remained at sub-RDA levels. Many patients had experienced some vomiting problems and had trouble tolerating tough, stringy, or bulky foods.

To David

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INTRODUCTION

The gastroplasty procedure for morbid obesity involves a surgical alteration of the stomach which induces a drastic limitation of food intake. The nutritional status of gastroplasty patients following surgery may be compromised due to this limited intake. Little information regarding nutritional outcomes of the surgery has been reported. This study was a post-operative, cross-sectional assessment of changes in nutritional status occurring over time following gastroplasty surgery. The patient population consisted of forty-six individuals who had experienced the gastroplasty procedure within the previous two and one-half years. Patients were assessed using anthropometric measurements of triceps skinfold, mid-arm circumference and mid-arm muscle circumference; concentrations of serum iron and transferrin; daily dietary intakes of energy, protein, vitamin A, vitamin C, several B vitamins, iron, and zinc; and a questionnaire regarding food habits and possible clinical signs of nutritional deficiency.

BACKGROUND

Obesity: Etiology, Effects, and Treatment

Obesity has been defined as "a pathologic condition characterized by an accumulation of fat much in excess of that necessary for optimal body function (Mayer, 1980)." It may be a life threatening disorder and it prevails as the most common nutritional problem in the United States today. It is a complex problem and treatment is frustrating and often unsuccessful. This serious and complex problem may require radical solutions in some persons.

Understanding obesity requires an understanding of the principle of energy balance and its influence on weight fluctuation. The concept is simple. Assuming that there are no changes in fluid status or body composition, when the energy intake of an individual is equal to energy output, he/she is in energy balance and weight is maintained. When energy intake is less than output, there is a negative balance, which if maintained over an extended period of time, produces weight loss. Obesity is the result of a positive energy balance in which an individual's intake exceeds his/her output over an extended period of time. Obesity is commonly defined as a weight which is 20% above ideal weight, and morbid obesity, as 100 pounds above ideal weight (Krause and Mahan, 1979).

The complexity of obesity stems from the variety of factors contributing to both excessive energy intake and decreased energy output.

A comprehensive review of these factors has been published (Garrow, 1978), and a few are listed here. Energy intake may be affected by psychological, emotional, and social factors which cause a person to eat beyond the point of satiety and need (Wooley and Wooley, 1975). It may also be affected by hormonal and neural abnormalities which alter the appetite control mechanism of certain individuals such that they require more food to reach the point of satiety than others (Bray, 1974; Bray and Gallagher, 1975; Liebling et al., 1975).

Energy output may be affected by alterations in any of the three components of output--physical activity, basal metabolic rate, and dietary induced thermogenesis. Physical activity is the most obvious contributing factor in that those individuals who perform more physical work will expend more energy. Researchers have suggested that some animals or humans may have a decreased basal metabolic rate due to inactivity of enzymes such as the sodium-potassium ATPase (Bray et al., 1981), abnormal hormonal and neural output (Bray and Gallagher, 1975; Inoue et al., 1978) and the lack of brown adipose tissue (Goldberg and Morgan, 1981). It has also been suggested that the dietary induced thermogenesis of humans may vary according to circumstances such as level of overfeeding (Miller et al., 1967).

The many physical, psychological, emotional, and social effects associated with obesity compound the complexity of the problem. Listing the problems is even tedious. Physical problems include respiratory difficulties, hypertension, hirsutism, menstrual irregularities, impotence, gall stones, skin problems, osteoarthritis, diabetes mellitus, cardiovascular disorders, renal disorders,

gastrointestinal disorders, hepatic and biliary disorders, hiatal hernia, hyperlipidemia, complications with surgery, and as a result of all of these problems, an increased mortality rate (Krause and Mahan, 1979; Abraham and Johnson, 1980; Drenick, 1980; Mayer, 1980). Psychological and emotional problems associated with obesity stem, in part, from discrimination in social and economic opportunities in employment, education, insurance, and medical care (Denbesten and Kuchenbecker, 1980). Social rejection and the inability to function as a normal person (i.e. sit in a normal size chair, fit behind the wheel of a car, etc.) also contribute to the cultivation of low self esteem and a tendency to withdraw from society and to continue overeating for consolation.

In the obese individual most of these problems can be ameliorated by weight loss. Many methods of weight reduction have been proposed and most are based on the creation of an energy deficit over an extended period of time. Conservative methods are based on reduction of intake and concomitant elevation of physical activity. Behavior modification and group therapy have been used to encourage obese individuals to maintain an energy deficit in this way (Jordan and Levitz, 1975). Fasting and jaw wiring are more drastic methods for reduction of energy intake (Schemmel, 1980; Mason, 1981a). Drug therapy including the use of diuretics for loss of excess "water weight", thyroid hormone for increased basal metabolic rate, and amphetamines or CNS stimulants to decrease appetite have been used with limited success (Silverstone, 1975).

Conservative methods of weight loss are most desirable because they are associated with low risks of morbidity and mortality. Unfortunately, they have very low long-term success rates in patients who are morbidly obese (Kannel and Bordon, 1979). Recognizing that many morbidly obese individuals are unable to lose weight by conventional methods, and recognizing the risks of morbidity and mortality associated with obesity, it is sometimes justifiable to try more drastic methods of weight reduction. Surgical treatment of obesity is a drastic method which is justifiable if the benefits obtained from the resulting weight loss outweigh the risks associated with the surgery itself and metabolic consequences of the procedure.

Surgical Treatment: Jejunioileostomy

The first bypass surgical procedure used for morbid obesity was the jejunocolic bypass initiated by Payne et al. in 1963. Several diarrheal and metabolic problems with this procedure led to the development of the end (of jejunum) to end (of ileum) and end to side jejunioileostomies which are currently used to some extent. In these procedures, a segment of 10-20 inches of jejunum is measured and resected. The proximal jejunum which is still continuous with the duodenum is anastomosed to the ileum at a point which is 4-20 inches from the ileocecal valve. In the end to side jejunioileostomy, the ileum is not resected and the bypassed portion of the gastrointestinal tract is left intact. In the end to end anastomosis, the ileum is resected and the bypassed portion of the intestine is drained into the colon.

The physiological basis for weight loss with this procedure is thought to be the induction of controlled malabsorption which is not dependent on limited food intake. Satisfactory weight loss of 70% of the weight which is in excess of ideal weight after one year and 75% after three years (Denbesten and Kuchenbecker, 1980), has been experienced by most patients who have remained in follow-up care following the procedure. Other benefits that have accompanied the procedure include lowered cholesterol and triglyceride levels, improved joint function, decreased insulin requirements, improved pulmonary function and work tolerance, reduction in blood pressure, improved self esteem, improved body image and economic rehabilitation (Denbesten and Kuchenbecker, 1980).

Unfortunately, the many complications that have resulted from the jejunoileostomy seem to outweigh the benefits (Table 1). As can be seen from Table 1, nutrition related problems are particularly common. These are due to malabsorption of nutrients through the shortened gastrointestinal tract and to electrolyte abnormalities.

Surgical Treatment: Gastric Bypass and Gastroplasty

Gastric partitioning procedures for treatment of morbid obesity became widely used because of the severe metabolic problems associated with the jejunoileostomy. The first type of gastric partitioning procedure was called the gastric bypass and was developed by Mason in 1966 (Mason, 1975). In the most popular version of this procedure used today, a small proximal pouch is isolated from the distal stomach by a row of staples. The resulting proximal gastric pouch is sutured

Table 1. Prevalence of common complications following surgery for morbid obesity reported as percentages of patients having the problem.

Jejunioileostomy ^a		Gastric Bypass ^a	
Mortality	3%	Operative mortality	3%
Short-Term		Leak rate	2.5-4%
Thromboembolic disease	1-5%	Wound problems	8%
Wound infection	2-8%	Stomal ulceration	1.8%
Severe nausea and vomiting	3%	Frequent vomiting after meals	15%
Wound dehiscence	1-3%	Occasional vomiting after meals	45%
Long-Term		Dumping	10%
Urinary calculi	3-20%	Failure to lost 10% or more of initial weight	1.8%
Severe electrolyte imbalance	5-8%	Early obstruction of gastro-jejunosomy (1 in 7 need re-op)	5%
Cholelithiasis and cholecystitis	0-13%	Rehospitalization	12%
Progressive liver disease	2-7%	Reoperation for inadequate weight loss	4%
Intestinal obstruction	2%		
Peptic ulcer	1-2%		
Colonic pseudo-obstruction	1-20%		
Bypass enteropathy	1-2%		
Minor Complications			
Diarrhea	100%		
Weakness 6 months	80%	Gastroplasty (compiled from several studies and listed if reported in more than one study)	
Hypokalemia and hypocalcemia	80%		
Hypoproteinemia and hair loss	50%		
Vomiting	50%		
Thirst	50%	Wound sepsis 6% (b), 4.5% (c), 1.3% (d), 20% (e), 1.1% (g), 8.3% (i)	
Hypoglycemia	30%		
Arthralgias	15-20%	Dehiscence .5% (b), 1% (c), 2.8% (e), % (h)	
Incisional hernia	3%	Subphronic abscess 1% (b), 7.6% (d)	
Anemias secondary to B ₁₂ , folate, iron	30%	Pulmonary embolus 1% (c), 1.4% (e), % (f), 8.3% (i)	
Rehospitalization	8-50%	Hernia 1% (c), 3.8% (d)	
Takedown	2-25%	Vomiting with overeating % (b, c, d, f, h, i)	

a. Compiled in a review by Denbesten and Kuchenbecker, 1980.

b. Gomez, 1979.

c. Pace, 1979.

d. Freeman and Burchett, 1980.

e. Cohn et al., 1981.

f. Laws et al., 1981.

g. Linner, 1982.

h. Lozner et al., 1981.

i. Mason, 1981c.

directly to the jejunum. The mechanism for weight loss with this procedure is limitation of food intake due to the small holding capacity of the proximal gastric pouch.

Weight losses similar to those following jejunoileostomy have been experienced by patients who have undergone gastric bypass. Many patients have lost 70% of excess weight within three years following the bypass (Denbesten and Kuchenbecker, 1980). Benefits accompanying the weight loss include lowering of blood pressure, more easily managed diabetes, and decreased blood lipid levels. Complications have also followed the procedure but are fewer than those associated with jejunoileostomy (Table 1).

The gastropasty, a second type of gastric partitioning procedure, was developed by Printen and Mason in 1971 (Printen and Mason, 1973). The procedure is more advantageous than the gastric bypass in that it is simpler to perform and there is no anastomosis to produce anastomotic leak and infection. In the gastropasty procedure described by Gomez (1979), the stomach is divided by a line of staples as in the gastric bypass. However, a small space is left in the staple line leaving an artificial pylorus between the proximal and distal gastric pouches. The remainder of the gastrointestinal tract is left intact. As with the gastric bypass, the mechanism for weight loss with the gastropasty procedure is limitation of food intake due to the small holding capacity of the proximal gastric pouch.

Initial attempts at gastropasty for morbid obesity produced insufficient weight loss. Printen and Mason (1973) reported only 20% of weight loss one year post-surgery. This is much less than the 70% loss

of excess weight experienced one year post-operatively by patients who had undergone jejunoileostomy or gastric bypass. It is now known that in order for the surgery to be successful it is critical that the proximal gastric pouch be made no bigger than 50 ml. and that the artificial pylorus be only 9-12 mm. in diameter (Mason, 1980).

Following these specifications, some surgeons have recently performed gastroplasties which have produced weight loss approaching that produced by the jejunoileostomy and gastric bypass. Gomez (1979) has reported an average loss of 34.1% of initial body weight or 62% of excess weight at 12 months post-surgery. Lozner et al. (1981) have had similar results at 12 months post-surgery equalling an average loss of 34% of initial weight. Pace et al. (1979) have reported a total weight loss of 29% at 12 months post-surgery; Freeman (1980), 26% at 18 months; and Mason (1981), 27% at 12 months. More recently Cohn et al. (1981) have reported a loss of 20% of pre-surgery weight at nine months, and Linner (1982) 44.7% of excess weight at two years post-surgery.

While different techniques of the gastroplasty surgery have been used with varying degrees of success, many researchers agree that a key to successful weight loss with gastroplasty is the patient's commitment to a permanent change in lifestyle. Two very important steps in the procedure are: 1) careful screening of patients before surgery with elimination of those unwilling to comply with necessary changes, and 2) provision of a follow-up program which will encourage patients to maintain their new lifestyles. It is thought by some that an important short-term change is the avoidance of solid foods for the first eight weeks following surgery. This prevents excessive

stressing and possible rupture of the staple line which is thought to require an eight week healing period (Ellison et al., 1980). Long-term changes required for adequate weight loss with gastroplasty include compliance with specifications for dietary intake and increased physical activity.

Short-term benefits and complications resulting from gastroplasty have been reported. Benefits include decreased insulin requirements for diabetics, improved glucose tolerance curves, decreased blood pressure, normalization of blood lipid levels, normalization of menstrual cycles, and increased fertility (Freeman and Burchett, 1980; Lozner et al., 1981). Commonly reported complications resulting from gastroplasty surgery were compiled from several studies and are reported in Table 1.

LITERATURE REVIEW: NUTRITIONAL OUTCOMES OF GASTRIC PARTITIONING FOR MORBID OBESITY

Consideration of nutritional outcomes of gastric partitioning procedures is important since the procedures involve an alteration of the gastrointestinal tract and drastic limitation of food intake. All reported nutritional studies of gastric partitioning to date have been done on gastric bypass patients. Both short- and long-term studies have been completed. Data on nutrient intake, eating patterns, problems with vomiting, satiety, clinical symptoms and tissue concentrations of nutrients have been reported. A nutritional profile of gastric bypass patients can be constructed from these data and areas for further research suggested.

Short-Term Nutritional Studies of Gastric Bypass Patients

Brown et al. (1982) studied some short-term nutritional effects of gastric bypass surgery with the hypothesis that gastric bypass patients may be in a catabolic state as in semistarvation. They selected 12 female patients for gastric bypass surgery who showed potential for giving accurate and complete information and potential for following through with the study. Parameters studied were weight loss, dietary intake (using a three day food record), nitrogen balance, fecal fat, serum total protein, transferrin, albumin, glucose, cholesterol, triglycerides, iron, vitamin A and beta-carotene. All measurements were made pre-operatively and three months

post-operatively.

The authors reported that the mean weight loss was 49 ± 10 pounds or 17% of pre-operative weight in three months. Dietary intake of energy, carbohydrate, fat, iron, vitamin A, and cholesterol all decreased significantly following surgery while the percent distribution of carbohydrate, protein, and fat remained the same. Specific intakes reported by the authors are listed in Table 2. It was reported that patients ate more often but smaller amounts following surgery, that they avoided fried foods, eliminated red meat except ground beef, avoided milk, eliminated bread and rolls, drank more water, and were not interested in candy or sweets.

Biochemical results were also reported. Total protein, albumin, and transferrin concentrations in serum were normal both before and at three months following surgery. Nitrogen balance (determined from total urinary nitrogen plus a correction factor of three) was positive before, but negative after surgery (three months post-operative). After surgery, serum triglyceride, blood cholesterol, and blood glucose concentrations were lower than before surgery but within normal limits. Serum vitamin A and beta-carotene levels were within normal limits before surgery but slightly subnormal three months post-operative. Serum iron was normal before surgery and rose slightly but not significantly after surgery. There was no significant change in fecal fat following surgery.

Results were interpreted by the authors in light of what would be expected of a person undergoing semistarvation for three months. Decreased energy intake was considered responsible for weight loss

Table 2. Mean daily nutrient intakes of energy, protein, fat, cholesterol, iron and vitamin A for gastric bypass patients at zero and three months post-operative.

Nutrient	Time	
	<u>Pre-Operative</u>	<u>Post-Operative</u>
Energy (Kcal)	2,819 $\pm$ 305	566 $\pm$ 78.0
Protein (gm)	103 $\pm$ 8	24 $\pm$ 3.0
Fat (gm)	127 $\pm$ 16	24 $\pm$ 4.0
Carbohydrate (gm)	322 $\pm$ 38	65 $\pm$ 9.0
Cholesterol (mg)	493 $\pm$ 73	114 $\pm$ 20.0
Iron (mg)	18 $\pm$ 2	3 $\pm$ 0.4
Vitamin A (RE)	2,230 $\pm$ 594	376 $\pm$ 141.0

^aData reported by Brown et al., 1982.

and negative nitrogen balance was thought to be indicative of a catabolic state. Normal visceral protein concentrations were thought to be inconclusive with the reasoning that genuine protein deficiency is not usually documented after only three months of semistarvation. Apparently the authors considered "genuine protein deficiency" to be that evidenced by compromised visceral protein concentrations. The authors pointed out that decreases in triglyceride, cholesterol, and glucose are all characteristic of semistarvation. They stated that vitamin A stores may have been low following surgery since intakes were well below the RDA and serum vitamin A concentrations were below normal levels. Although serum iron levels were normal, the authors pointed out that at this stage of semistarvation, serum iron levels may be normal while tissue levels are low and that the slight increase in serum iron following surgery may be indicative of iron deficiency. Although not specifically stated by the authors, the possibility of iron deficiency seems further substantiated by the fact that iron intakes following surgery were below the RDA.

In comments on food habits, the authors stated that the protein intake was not of high biological value. They stated that many patients avoided red meats because they found them difficult to tolerate. They suggested that this intolerance may be due to lack of proteolytic enzymes and HCl from the stomach to begin digestion.

Citing the reduced energy intake in particular, the authors concluded that gastric bypass patients require close nutritional monitoring especially in the first six months following surgery. They suggested that patients would benefit from more nutritional

counseling which would enable them to select balanced diets.

Updegraff and Neufeld (1981) cited problems with vomiting and peripheral neuropathy as reasons for assessing the nutritional status of gastric bypass patients. They were particularly interested in changes in body composition with weight loss. The patient population included any person receiving gastric bypass at the University of Kansas Medical Center over a three month period. Twelve patients completed the study. Dietary intake was assessed using a 24 hour recall (excluding supplements) and a five item questionnaire; anthropometric measurements of weight, height, triceps skinfold (TSF) and mid-arm circumference (MAC) were made; biochemical concentrations of serum iron, transferrin and folacin and 24 hour urinary creatinine were measured. Data were collected both before surgery and four months after surgery.

An average weight loss of 55.7 pounds or 19.6% of pre-operative weight was reported at four months post-op. Specific intakes reported by the authors are listed in Table 3. Intakes of iron and protein before surgery were not significantly lower than the RDA as determined using the paired t-test; after, both were significantly lower. Folacin intake was significantly lower than the RDA both before and, to a greater extent, after surgery.

The authors suggested that protein intake was decreased because eating large quantities of protein-rich food was physically prohibited by the surgery and because patients had a decreased tolerance of meat and milk. The decreased folate intake was attributed to the avoidance of bulky foods such as green leafy

vegetables high in folacin because of the small holding capacity of the stomach pouch. Although the authors gave no reason for decreased iron intake, it seems likely that it was due to the intolerance of some meats which are a good source of iron.

Serum concentrations of transferrin, iron, and folacin were normal both before and after surgery and did not reflect decreased intake. While no significant changes in serum iron and transferrin were observed, a significant increase in serum folacin was documented. The authors pointed out the fact, as did Brown et al. (1982), that normal serum iron levels can be maintained for some time by body stores and that normal visceral protein levels can be maintained in stages of early protein deficiency. They suggested that serum folacin levels may only reflect recent intake and in this case may have been due to folacin taken. (All patients were taking a multiple vitamin plus iron at least once a day.) Iron content of the supplement was also thought to contribute to normal serum iron levels.

While triceps skinfold (TSF) measurements were unchanged following surgery, mid-arm circumference (MAC) and mid-arm muscle circumference (MAMC) were significantly decreased. Both pre-surgery and post-surgery MAMC values were above the 50th percentile of United States anthropometric standards. Creatinine height index (CHI) was determined for six patients and was found to be significantly decreased to subnormal levels following surgery. It was stated by the authors that decreases in both CHI and MAMC reflect decreased protein intake and catabolism of somatic protein. The authors did point out, however, that all anthropometric measurements (TSF, MAC,

MAMC) should be "viewed as inconclusive" due to possible error associated with measuring obese subjects.

Indications of decreased protein intake and compromised protein status (as measured by CHI and MAMC) are in agreement with results and conclusions reported by Brown et al. (1982). The authors conclude that these problems, in addition to intolerance of protein foods and problems with vomiting, indicate the urgent need for nutritional guidance and education following surgery. They suggest that long-term follow-up is needed to determine the nutritional status of gastric bypass patients as body weight stabilizes.

In a comparison of the dietary intakes and liver fat content of jejunoileal bypass patients and gastric bypass patients, Rogus et al. (1981) report on the weight loss, serum albumin, and dietary intakes of 13 gastric bypass patients before surgery and at three and six months following surgery. Weight loss was reported as 54 ± 3.8 pounds between zero and three months and as an additional 16 ± 3.8 pounds between three and six months. Albumin levels were found to be normal and not significantly different at zero, three, and six months. Results obtained from the dietary recall are listed in Table 4.

While the authors made no further comment on these data, some conclusions can be made. Not surprisingly, intake was drastically reduced after surgery and appeared to be the cause for weight loss. Albumin levels were normal throughout the study period in agreement with results reported by Brown et al. (1982). It is interesting to note that while protein and energy intakes were low at three months

Table 4. Mean daily nutrient intakes of energy, carbohydrate, and fat in gastric bypass patients at zero, three, and six months post-op.^a

Nutrient	Time		
	<u>0 Months</u>	<u>3 Months</u>	<u>6 Months</u>
Energy (kcal)	6,000 $\pm$ 818	740 $\pm$ 128	1,286 $\pm$ 286
CHO (gm)	699 $\pm$ 119	73 $\pm$ 11	129 $\pm$ 39
Protein (gm)	206 $\pm$ 27	35 $\pm$ 5	55 $\pm$ 6
Fat (gm)	251 $\pm$ 33	36 $\pm$ 8	61 $\pm$ 13

^aData reported by Rogus and Blumenthal, 1981.

post-operative, as in both studies cited above, they approached normal levels at six months. These data would seem to indicate that the protein status of gastric bypass patients improves as time progresses. It would have been interesting if the authors had measured serum transferrin, MAMC, CHI, and nitrogen balance for further evaluation of protein status.

The only clinical symptoms of gastric bypass surgery which have been attributed to nutritional deficiency were neurological disorders. Printen and Mason (1977) diagnosed peripheral neuropathy in four out of 524 patients, each at one of post-surgery times, six weeks, three months, four months, and six months. All four were treated with 50-100 mg/day of thiamin and three received additional nutrients. Symptoms gradually disappeared following treatment. Hemreck et al. (1976) diagnosed sustained clonus and peripheral polyneuritis in two out of 72 patients between zero and two years post-operative. The two patients were treated with vitamin B complex supplements and an adequate diet resulting in a gradual improvement of symptoms. The authors of both studies concluded that the neurological disorders were probably due to protein or B vitamin deficiencies and that the deficiencies may have resulted from excessive vomiting.

Long-Term Nutritional Studies of Gastric Bypass Patients

Halimi et al. (1981) focused on the appetitive behavior of 80 gastric bypass patients, each of whom had had the operation either six months, one year, or two years previously. Percent excess weight loss was determined and reported as $45.4 \pm 19.9\%$ for the six

months post-operative group, $54.8 \pm 20.7\%$ for the one year group, and $55.5 \pm 18.9\%$ for the two year group. Food habits were assessed using a modified 24 hour recall (including food category frequencies without specifications of amounts) and a questionnaire.

The authors found that these gastric bypass patients, one year and two years after surgery, ate less frequently than before surgery and patients from all three groups (six months, one year and two years post-operative) ate from a fewer number of food categories. When all 80 patients were considered as a whole, they ate less high fat and carbohydrate foods, more high protein foods, less high caloric beverages, more low caloric beverages, and the same number of fruit, vegetable, and alternative protein foods than before surgery. Results from the questionnaire regarding satiety included several responses such as the following: (1) Before surgery patients ate all the food on their plates; after surgery, they rarely or never finished. (2) Before, they stopped when no food was available; after, when they had no more desire for food. (3) Before, they needed lots of will power; after, they needed none.

Halmi et al. (1981) suggested that the results indicated that mechanical effects of surgery on eating behavior were as expected in that patients appeared to be eating less. In general, the shift towards eating more nutrient dense foods and the changes in attitude regarding satiety seemed favorable. It is disappointing, though, that the authors looked only at food frequencies without assessing amounts of foods and nutrients, which would provide more conclusive results.

The authors also made the comment that the patients' avoidance of calorically dense foods may have been due to effects from the dumping syndrome. They suggested that the patients may avoid the high caloric foods only as long as they experience discomfort from them. In light of this comment concerning high caloric foods it is interesting to consider a comment made by patients in response to the questionnaire that if they experience no discomfort or pain after eating, they would eat just as much as they did before surgery. It appears that the signal for limiting intake in these patients is not a feeling of "fullness" but pain and discomfort. The authors concluded that it is likely that the continuing effects of the bypass surgery are necessary to maintain the changed eating behavior patterns.

Mason (1981b) also reported some long-term intake patterns and food habits of gastric bypass patients. His population included approximately 200 patients who responded to a mailed questionnaire. Most patients had undergone surgery within the previous two years.

Protein intakes appeared to change over time in this population. Mason found that 47% of his patients limited themselves to one or no servings of meat and over half to one serving of milk per day during the first year post-op. He also reported that one-third of his patients had protein intakes of less than ten gm/day for six weeks following surgery and that at two years post-operative this same group had intakes of 40 gm/day. A larger percentage of the patients he contacted had protein intakes of 20 gm/day for six weeks following surgery and 60 gm/day by 18 months. While 40-60 grams of

protein per day at 18 months post-surgery is probably adequate depending on the sex and age of each patient, 10-20 gms per day during the six weeks following surgery is most likely an inadequate intake. Mason suggested that it may be beneficial to use protein supplementation in an early dietary routine of gastric bypass patients.

Intakes of bread, fruits, and vegetables have also reportedly been low. Mason found that up to two years post-surgery over half of his patients who had undergone gastric bypass had only one to two servings per day of fruit and vegetables and one to two servings per day of bread. It is not clear whether these reduced intakes simply reflected a decrease in total food intake, which is to be expected, or whether they reflected an imbalanced intake in which these foods were replaced by less nutritious ones. While decreased intakes of specific food groups may only reflect expected results, reports of protein intolerance and low intakes of fruits and vegetables suggest possible unexpected nutritional deficiencies.

Mason reported frequent vomiting in 11-17% of patients, occasional vomiting in 39-53% and rare occurrences of vomiting in the others. Reasons for vomiting have been reported by Mason's patients as eating too fast, eating too much, or eating a certain food which simply "does not agree." Twenty-five per cent of the patients attributed vomiting to meats and 20% to some other food item.

In further comments on vomiting and satiety, Mason stated that some patients had no sensation of fullness and judge from past experience how much food can be eaten without causing vomiting.

Other patients become uncomfortable and deliberately vomit. Reportedly, once the overload of food has been released, there is no continued sensation of nausea or pain.

Finally, Mason suggested that vomiting was related to the size of the proximal gastric pouch. Many of his patients had had their stomachs calibrated to a specific small size while the pouches of others had not been carefully measured. Patients who had gastric bypass without calibration of the stomach size experienced little change in vomiting over time. Later patients who had their stomachs calibrated seemed to have decreased frequency of vomiting over time. Mason concluded that the latter phenomena was because the smaller calibrated pouch is always filled by approximately the same amount while the uncalibrated pouch seems to hold varying amounts.

Additional long-term nutrition information was found in the medical-surgical assessment of gastric bypass surgery patients by Halverson et al. (1981). The patient population included 69 patients, all of whom had undergone gastric bypass operations at Barnes Hospital/Washington University Medical Center between 1977 and 1980. The clinical and metabolic data reported in this study were obtained before surgery and at a mean of 20 (± 10) months after surgery (unless specified otherwise). Weight loss was reported as $57 \pm 20\%$ of excess weight.

Nutrition related metabolic abnormalities included hypokalemia, hypomagnesemia, hypovitaminosis, and anemia. Thirty-three percent (22 patients) of the patients were hypokalemic. The hypokalemia was seen within the first two months of surgery (at the time of lowest

food intake) and persisted beyond the sixth month in only 14 of all of the patients. Nine of these 22 patients were taking diuretics (type not specified) and all of these were hypokalemic before surgery. All patients were treated successfully with oral potassium supplementation.

Mild hypomagnesemia was seen in six patients (9%). It resolved spontaneously in two patients and with magnesium supplementation in the others. Low serum levels of vitamin A were seen in 18% of the patients: B₁₂, in 26%; folate, in 9%; and vitamin K, 20%. All deficient levels were corrected with supplementation.

Mild anemia (Hct 35%) was reported in twelve patients (18%) following surgery. This was reportedly due to iron deficiency in five patients, blood loss through hemorrhoids and menometrorrhagia in two patients and unknown causes in five patients. (Although the authors did not state it, it seems possible that the anemia of these latter patients was due to B₁₂, folacin or intrinsic factor deficiency.) Iron deficiency (serum iron < 80 µg/dl) was reported in 13 patients (20%). Only five of these patients were anemic and ten had high or normal total iron binding capacity.

Pouch size of patients was estimated radiographically and was found to correlate negatively with weight loss. Many of the complications following surgery were attributed by the authors to over-eating. Nine of the 14 rehospitalizations for complications due to gastric bypass were attributed to non-compliance with the dietary regimen.

The authors also reported some information on food habits. Immediately after surgery all patients reportedly felt full after just a little food and all but one patient reported that appetite had dramatically decreased. Patients ate fewer meals per day and spent 23 ± 9 minutes eating an average meal. Vomiting was reported infrequently. Only 18% of the patients had vomited at any time in the hospital, 41% had reported vomiting at at least two office visits, and 16% had the problem persist beyond the first three months after surgery. Twenty-seven percent of the patients said that stringy meats caused vomiting. Ten percent reported mild heartburn after surgery and eight percent began ant-acid therapy after surgery.

This report of lack of vomiting is interesting in light of the authors' routine procedure of starting patients on solid foods before discharge from the hospital. Others have suggested that solids should not be started until eight weeks post-op to allow for staple line healing (Ellison et al., 1980). It would seem that eating solid foods so soon after surgery would lead to early distress and vomiting.

In discussion of these nutrition related outcomes the authors suggest that since electrolyte abnormalities were corrected by supplementation, they are due to inadequate intake rather than to malabsorption or any other pathologic change. Iron deficiency was thought to be due to the shunting of food around the duodenum in some patients although it is apparent from the report that it can be corrected with iron supplementation. No explanation was given for hypovitaminosis, but the authors expressed concern that it existed

in spite of daily oral multivitamin supplementation (reported by 85% of patients). Vomiting was reportedly an infrequent problem and had always been corrected by modification of eating behavior.

It was concluded by the authors that daily oral vitamin supplementation and periodic monitoring of serum electrolyte and vitamin levels is important in the care of gastric bypass patients. Although not specifically suggested by the authors, it seems evident that monitoring of iron levels and iron supplementation for deficient cases are also important for care of gastric bypass patients.

Summary: Nutritional Profile of Gastric Bypass Patients

A summary of the nutritional studies cited above provides a tentative and incomplete nutritional profile of gastric bypass patients. Some short-term and long-term data on dietary intakes have been collected. At three to four months post-surgery patients reportedly had intakes well below the RDA of energy, protein, iron, folacin and vitamin A. Protein intakes at or approaching RDA levels have been documented at six months and two years post-operatively. Total amounts of both the fruit and vegetable group, and the bread group have reportedly been only one to two servings per day each up to two years post-surgery.

Data on appetitive behavior, satiety, and problems with vomiting have been interesting. It has been suggested by one author that short- and longer-term patients seem to eat some foods high in protein and low caloric beverages more frequently than before surgery; high fat foods, high carbohydrate foods and high caloric

beverages less frequently; and fruits, vegetables and alternative protein foods with the same frequency. Evidence has been cited which suggests that the patients' desire for food has decreased following gastropasty surgery. It might be concluded, though, that often, the signal for satiety seems not to be a feeling of fullness, but a feeling of pain or discomfort or a knowledge of the amount of food that will induce emesis. Vomiting reportedly has been a problem for approximately 50% of all gastric bypass patients and seems to decrease with time in patients who have had their stomach pouches calibrated to a small size. Authors have suggested that vomiting was caused by excessive eating, eating too fast, or specific food items--meats, milk, fried foods, bulky foods, and sweets having been commonly reported.

Nutrition related biochemical data of gastric bypass patients have been reported although none were specific for long-term patients. Serum concentrations of total protein, albumin, transferrin, iron, and folacin were reportedly normal at three to four months post-operative while serum vitamin A was slightly subnormal. Creatinine height index was lower than presurgery levels at four months post-op according to one researcher. Mild cases of hypokalemia, hypomagnesemia, anemia, and hypovitaminosis (vitamin A, B₁₂, folacin, vitamin K) have been documented between three and 40 months post-op.

Short-term anthropometric and nutrition related clinical data have been reported although long-term data have not. Reportedly, mid-arm circumference and mid-arm muscle circumference were significantly lower than presurgery levels at four months post-op while

that of triceps skinfold was unchanged at four months. According to two studies, a small percentage of gastric bypass patients have suffered from peripheral neuropathy within one year post-surgery which seemed to have been due to B vitamin or protein deficiency caused by severe vomiting problems.

Need for Future Research

Some nutritional data pertaining to short-term patients, zero to six months post-surgery, have been reported while data specific for long-term patients is lacking. In light of specific food intolerances and possible clinical signs of nutritional deficiency, future studies of short-term patients should include dietary intake and biochemical analysis of additional nutrients such as the B vitamins, vitamin C, electrolytes, and zinc. Future nutritional assessment of long-term patients should include detailed analysis of dietary intake, biochemical measures of protein, vitamins and minerals, anthropometric measures, and nutrition related clinical observations.

JUSTIFICATION FOR NUTRITIONAL ASSESSMENT OF GASTROPLASTY PATIENTS

Nutritional studies of gastric partitioning patients have been limited to gastric bypass patients. Gastroplasty surgery also involves an alteration of the stomach and drastic limitation of food intake but differs from gastric bypass surgery in that the intestinal tract is left intact. Nutritional assessment of both short-term and long-term gastroplasty patients is needed both to supplement current nutritional data concerning gastric partitioning patients and to provide nutritional data specific for gastroplasty patients.

Since the gastrointestinal tract is left intact following gastroplasty, it was suspected that inadequate intake would be a major cause of any resulting nutritional deficiencies. For this nutritional assessment, emphasis was placed on factors resulting from the surgery which might have an effect on dietary intake. Intolerance of protein foods was one such factor which had been observed in gastroplasty patients and was reported (Mojzisik and Martin, 1981). Vomiting after gastroplasty, documented by several surgeons (Table 1), was another factor which was thought might have an effect on dietary intake. Finally, the small capacity of the stomach pouch was thought to be a possible deterrent to eating bulky vitamin-rich foods such as green leafy vegetables, as was suspected of gastric bypass patients (Updegraff and Neufeld, 1981).

The purpose of this study was to assess the nutritional status of both short- and long-term gastroplasty patients, and to document changes in status over time. In light of the factors affecting dietary intake listed above, this study was centered on assessment of protein, iron, zinc, vitamin A, the B vitamins, and vitamin C status. Weight loss and problems with vomiting were also assessed. Hypotheses made prior to the study concerning nutritional outcomes of gastroplasty are listed in Table 5.

Table 5. Hypotheses: Nutritional Outcomes of Gastroplasty.

-
1. The patients have a low caloric intake (< 1500 Kcal/day).^a
 2. The patients have experienced significant weight loss. (Seven to ten pounds per month for the first year and progressive weight loss over the second year.)^b
 - 3a. The patients have trouble tolerating meats, milk, cheese and eggs.
 - 3b. Low intakes of these foods have lowered the protein, iron, and vitamin B₁₂ status of the patients.
 - 4a. The patients avoid eating bulky foods such as fruits and vegetables which quickly fill the gastric pouch.
 - 4b. This has lowered the folacin, vitamin A, and vitamin C status of the patients.
 5. The patients had trouble with chronic vomiting particularly during the first two months following surgery. This problem still occurs with overeating.
-

^aBased on intakes reported by Updegraff and Neufeld (1981).

^bBased on a rough average of weight loss reported in several studies (Pace et al., 1979; Freeman and Burchett, 1980; Mason, 1980; Laws and Piantadosi, 1981; Lozner et al., 1981).

METHOD

Preliminary Work

The principal investigator became acquainted with the Nutrition Support Team of Butterworth Hospital in January 1981 upon the suggestion of her major professor, Dr. Jenny Bond. She was introduced to the gastroplasty problem by Dr. Mark McCamish, Research Coordinator for the Nutrition Support Team. A review of the literature was completed in the spring and a meeting for initiation of the project was held at Butterworth Hospital in June. Those present were Dr. Mark McCamish, Dr. Jenny Bond, Dr. Richard Dean (Director of the Nutrition Support Team), Jan Cronquist (assistant researcher for the team), and Lisa Van Dyke (the principal investigator).

The proposal was approved by the principal investigator's graduate committee (consisting of Drs. Bond, McCamish, and Dean and two additional Michigan State University Department of Food Science and Human Nutrition faculty members, Dr. Rachel Schemmel and Dr. Wanda Chenoweth) in September, 1981 with the stipulation that the questionnaire be revised and pre-tested. The proposal was given to Lee Pool, MD, gastroplasty surgeon for the patients in this study, and to the dietitians of Butterworth Hospital for review.

The questionnaire was pre-tested and revised to its final form (Appendix A) with suggestions from Drs. Schemmel, Bond, and Chenoweth,

Dr. Pool (gastroplasty surgeon), and Butterworth Hospital dietitians. A consent form including an explanation of the study and patient rights had also been developed and is included in Appendix B.

Several biochemical tests had been initially proposed for use in this study including serum transferrin, albumin, iron, vitamin B₁₂, folate, vitamin A, vitamin C, Hb, Hct, and total lymphocyte count. For minimization of costs, biochemical tests were limited to serum iron, transferrin and zinc, and through the mediation of Drs. McCamish and Dean a special account was set up by Butterworth Hospital for charges to be accrued. Charges were eventually to be paid by the hospital.

Prior to initiation of the study, the principal investigator received training in conducting a 24-hour recall, making anthropometric measurements, and using the MSU nutrient data bank analysis. In addition to this, an announcement concerning the study was made at the December 1981 meeting of the bypass surgery support group made up of Dr. Pool's bypass surgery patients. The study was approved by the Michigan State University Committee for Research on Human Subjects (UCRIHS), and both the research and human rights committees of Butterworth Hospital.

Selection of the Patient Population

Names of approximately 150 gastroplasty patients who had undergone the Gomez gastroplasty procedure (Gomez, 1979) by Lee Pool, MD were provided by Dr. Pool and divided into four groups according to time since surgery. Group one included patients who had had surgery within

the previous six weeks; group two, six weeks to six months; group three, six months to one year, and group four, one year and over. Since neither funding nor time was available for assessment of all patients, a sample was selected. Names of patients were written on index cards and a sample of 24 cards was randomly drawn from each of groups two, three, and four with the prospect of obtaining at least 12 willing participants per group. There were less than 24 patients in group one so all group one patients were contacted. Each of the patients selected was introduced to the study by a letter signed by Dr. Pool and the principal investigator (Appendix C). A second letter explaining the purpose and content of the study and the rights and benefits of participants was mailed within a week following the introductory letter (Appendix D). Within another week patients who had been sent letters were contacted by telephone by the principal investigator in random order and those willing and able to participate were asked to come to Butterworth Hospital for a nutritional assessment. When all patients had been contacted, groups one and four still had less than 12 participants. Additional names of recent patients (group one) were obtained from Dr. Pool's office and fifteen names from the original list of group four patients were selected for contact concerning the study. These additional patients were contacted using the procedure previously described.

Nutritional Assessment Schedule

Approximately one hour was needed for the complete nutritional assessment of patients including administration of the 24-hour recall

and questionnaire, anthropometric measurement and drawing of blood samples. Each patient was met in the main lobby of Butterworth Hospital at the appointed time by the principal investigator and escorted to an empty office of the Nutrition Support Team. The purpose of the study, procedure to be followed, and potential risks and benefits for the patient were explained. The consent form was signed, the 24-hour recall was conducted, the questionnaire was completed, and anthropometric measurements were taken. Participants were then taken by the principal investigator to the outpatient clinic to be weighed and finally to the Butterworth laboratory to have blood samples drawn. A more detailed description of the assessment schedule has been included in Appendix E.

Dietary Assessment

A 24-hour recall was chosen for assessment of nutrient intake and was conducted by the principal investigator for each patient. Since traditional food models were not appropriate for the small amounts of food eaten by gastroplasty patients, a set of measuring spoons and cups, a six ounce glass and sixteen ounce bowl were made available to most patients for help in identification of amounts of foods eaten. Interviews for most patients were conducted on one of days Tuesday through Saturday to avoid Sunday nutrient intakes which are reportedly not usual for females (Beaton et al., 1979). Intakes (excluding supplements) were analyzed using the MSU Nutrient Data Bank and specific intakes of energy, vitamins A and C, thiamin, riboflavin, vitamin B-6, Vitamin B-12, niacin, folacin, iron and zinc were

calculated and compared to both two-thirds and 100 per cent of the 1980 RDA's. Differences between groups were also evaluated for assessment of changes in intake over time. Protein intake was further evaluated using a food frequency question concerning intake of meat, eggs, cheese, and beans, and was compared to protein intake determined from the 24-hour recall.

In addition to the 24-hour recall, a 17 item questionnaire (Appendix A) was used to assess patient satiety, vomiting problems, food habits, and possible reasons for poor weight loss. Questions concerning frequency of protein intake, and clinical symptoms (discussed elsewhere in this methods chapter) were included in this questionnaire. In an attempt to pinpoint foods avoided specifically as a result of surgery, patients were also asked to report foods they avoided for other reasons such as personal dislike or high cost. The questionnaire was composed primarily of open ended response questions.

The principal investigator read each question from the questionnaire, provided any further explanation needed, and wrote down patient answers. Steelcase chairs were provided for the comfort of both the participant and the principal investigator.

Clinical Assessment

A complete clinical evaluation was neither feasible nor absolutely essential for an accurate assessment of nutritional status in this study. Consequently, patients were simply asked if they had any physical problems since surgery that they had not had prior to surgery. For evaluation of these responses, the principal investigator speculated

on possible relationships between problems cited and nutritional deficiencies.

Anthropometric Assessment

Dr. Pool made patient records available to the principal investigator for the determination of each patient's weight at the time of surgery. Post-surgery weight, triceps skinfold (TSF), and mid-arm circumference (MAC) were all measured at the time of the nutritional assessment. Post-surgery weight included light summer clothing and in most cases shoes were removed prior to weighing. TSF was measured with a Lange Skinfold Caliper. Both TSF and MAC were measured in accordance to Jelliffe (Jelliffe, 1966).

Ideal weight was determined for each individual using one of the following equations (Davidson, 1976):

106 lbs/5 ft + 6 lbs/inch for males

100 lbs/5 ft + 5 lbs/inch for females

These equations were chosen because they are frequently used to calculate desirable body weight and are used by the Nutrition Support Team of Butterworth Hospital.

Percent excess weight lost for each individual was calculated with the equation,

$$\frac{(\text{pre-surgery weight}) - (\text{post-surgery weight})}{(\text{pre-surgery weight}) - (\text{ideal weight})}$$

Weight loss per month for each individual was calculated with the equation,

$$\frac{(\text{pre-surgery wt}) - (\text{post-surgery wt})}{\text{number of days post-op}} \times \frac{30 \text{ days}}{\text{month}}$$

Mid-arm circumference (MAMC) was calculated according to the procedure of Blackburn et al. (1979) from MAC and TSF using the standard equation,

$$\text{MAMC (cm)} = \text{MAC (cm)} - 0.314 \times \text{TSF (mm)}$$

For evaluation of anthropometric measurements, mean weight loss per month was compared to the hypothesized seven to ten pounds per month (Table 5), and TSF, MAC, and MAMC were compared to norms established from data collected in the Ten State Nutrition Survey of 1968-1970 (Frisancho, 1974). Also, differences between groups were evaluated for assessment of changes in anthropometric measurements over time.

Biochemical Assessment

Two non-fasting blood samples were drawn from subjects by Butterworth Hospital laboratory personnel following each patient interview and completion of anthropometric measurements. One sample was analyzed in the Butterworth Hospital Laboratory immediately for serum iron and transferrin concentrations. The other sample was frozen for future analysis of serum zinc concentration. Group means were compared to Butterworth Hospital laboratory standards and differences between groups were evaluated.

Statistical Analysis

Comparisons were made between actual values and normal or expected values for assessment of the nutritional status of each group. Comparisons between groups were made for assessment of changes in nutritional status over time. The paired t test was used for comparison between nutrient intakes and the RDA's. The Bonferroni t-test and the Bonferroni chi-square test (Gill, 1978) for between group comparisons of quantitative and qualitative data, respectively were used as recommended by Dr. John Gill, statistics professor in the Department of Animal Science of Michigan State University.

RESULTS

Patient Population

Thirty-nine females and seven males who had undergone gastroplasty surgery by Lee Pool, MD at Butterworth Hospital between November 11, 1979 and July 16, 1982, participated in this study. Nutritional assessments were conducted between June 15, 1982 and August 18, 1982. Patients had an average pre-surgery weight of 277 pounds and an average age at the time of the nutritional assessment of 38.7 years. Three patients had received a revision of a former gastroplasty surgery, and the remainder had received gastroplasty as their first surgery for morbid obesity. (Care was taken not to include patients who had received a revision of jejunoileal bypass concomitant with a gastroplasty procedure.) The four groups were quite homogeneous with respect to pre-surgery weight and age (Table 6). They differed in that groups two and three included males while groups one and four did not. In addition to this, all patients of groups one and two and most of group three (32 patients total) had stoma (artificial pylorus in the staple line between the two gastric pouches) reinforcement with silastic tubing and two patients from group three along with all of group four (14 patients total) had stoma reinforcement with sutures (Table 6). According to Dr. Pool, the switch was made to silastic tubing in the more recent patients because it was thought that this

Table 6. Patient population.

Group	Time post-operative	N and gender	Pre-operative weight (lbs)	Age (yrs)	Stoma reinforcement
1	0 - 6 wks	7 F	260 (216-326) ^a	42 (28-59)	7 ST ^b
2	6 wk - 6 mo	11 F 3 M	280 (206-440)	36 (25-45)	14 ST
3	6 mo - 1 yr	9 F 4 M	282 (206-363)	41 (36-49)	11 ST 2 SUC ^c
4	1 yr+	12 F	279 (210-400)	38 (22-46)	12 SU

^aMean (range)

^bST = silastic tubing.

^cSU = sutures.

would more effectively prevent stoma dilation and thus more effectively limit food intake and ultimately cause greater weight loss.

Anthropometric Assessment

Weight Loss. Weight loss was, as hypothesized, at least seven to ten pounds per month in groups one, two and three (Table 7). The percent excess weight loss of group three was found to be significantly greater than that of each of groups one and two ($p < 0.05$). The percent excess weight loss of group four was found to be less, though not significantly less, than that of group three. The data seem indicative of increased weight loss with time at least until one year post-operative. A summary of weight loss data has been compiled in Table 7.

Triceps Skinfold (TSF), Mid-Arm Circumference (MAC), Mid-Arm Muscle Circumference (MAMC). The mean TSF of group three was found to be significantly less than that of each of groups one and two. The TSF of group four was found to be greater, though not significantly greater, than that of group three. The progression of decreased TSF was similar to the progression of weight loss and seemed indicative of decreased TSF with time at least until one year post-operative. No difference was found between groups for either MAMC or MAC.

Mean anthropometric values were compared to normal values of women aged 34-44 (Frisancho, 1974) since most participants were in this category of individuals. Mean TSF was above the 95th percentile in groups one, two, and four, and between the 85th and 95th percentiles

Table 7. Mean weight loss.

Group	Weight loss (lbs)	% Excess Weight Loss ^a	Weight Loss/Month (lbs)
1	25.0 ± 5.5 ^b	19.3 ± 3.9	23.7 ± 4.6
2	49.0 ± 15.2	33.9 ± 9.3	13.2 ± 2.1
3	76.5 ± 26.5	53.8 ± 20.8	8.7 ± 2.9
4	58.5 ± 43.1	38.4 ± 23.4	3.1 ± 2.1

^aDifferences between groups 1 and 3, and 2 and 3 were significant (p < .05).

^bMean ± SD.

in group three. Mean MAC was above the 95th percentile in group one and between the 85th and 95th percentiles in groups two, three, and four. Mean MAMC was between the 85th and 95th percentiles in groups one and three, and between the 50th and 85th percentiles in groups two and four. Anthropometric data for TSF, MAC, and MAMC have been summarized in Table 8.

Biochemical Assessment

Mean Serum iron and transferrin concentrations for each group were within the normal range used by the Butterworth Hospital laboratory (Table 9). Iron concentrations, however, were in the low end of the normal range. No significant differences were found between groups for these values. The data seem to reflect unchanged serum iron and transferrin concentrations with time following surgery.

Clinical Assessment

Responses to a question concerning physical problems since surgery (Appendix A, Question 12) are reported here if they were given more than once (Table 10). The patient who had spots on her legs described them as red spots with a purple center. She said that they had been treated unsuccessfully with multi-vitamin therapy but somewhat successfully with antibiotic therapy.

Table 8. Mean anthropometric measurements.

Group	TSF (mm) ^a	MAC (cm)	MAMC (cm)
1	51.5 ± 4.4 ^b	41.4 ± 4.6	25.2 ± 3.9
2	47.0 ± 10.1	38.0 ± 3.3	23.3 ± 1.9
3	36.5 ± 11.2	36.9 ± 8.9	25.4 ± 6.5
4	46.1 ± 6.7	37.2 ± 5.6	22.6 ± 4.6

^aDifferences between groups 1 and 3 and 2 and 3 were significant (p < 0.05).

^bMean ± SD.

Table 9. Mean serum transferrin and iron concentrations.

Group	Transferrin (mg/dl)	Iron (µg/dl)
1	201.1 ± 44.2 ^b	58.9 ± 21.0
2	241.8 ± 36.1	56.2 ± 17.0
3	242.4 ± 45.7	52.8 ± 24.9
4	241.3 ± 25.7	54.7 ± 17.7
Normal Range ^a	150 - 300	40 - 150

^aUsed by Butterworth Hospital Laboratory.

^bMean ± SD.

Table 10. Physical problems occurring since gastropasty surgery as reported by participants.^a

Problem	No. of Responses
More tired	4
Constipation	3
Nervousness or mood swings	2
Leg problems (one of: cramps, numbness, spots)	3
Hair loss	2
Cold all the time	2
Feel better	5

^a21 patients responded.

Dietary Assessment

Intakes of energy, protein, vitamin A, vitamin C, several B vitamins, iron, and zinc and percent of the RDA for each group are listed in Table 11. Those intakes indicated by a "b" were found to be significantly lower than the RDA ($p < 0.05$). Those indicated by a "c" were found to be significantly lower than 67% of the RDA ($p < 0.05$). Intakes of all the nutrients calculated were significantly lower than 100% of the RDA in at least one group. It should also be noted that several of those nutrient intakes which were significantly lower than 67% of the RDA were well below 50% of the RDA.

Intakes for which significant differences between groups were found are listed in Table 12. The greater energy, protein, niacin, and zinc intakes of the long-term patients over the short-term patients seem to reflect increased intakes of these nutrients with time. It should be emphasized, however, that intakes of energy and niacin were still significantly lower than the RDA in group four and that of zinc, significantly lower than 67% of the RDA in group four.

Protein intake was further evaluated with a food frequency question concerning the intake of meat, eggs, cheese, and beans (Appendix A, Question 11). Since patients rarely reported eating beans, this question was assumed to be a measure of intake of protein foods containing a complete complement of amino acids. Mean daily intakes of complete protein as calculated from these data were not significantly different (Table 13). Comparisons of these values to the mean daily protein intakes calculated from the 24-hour recall can

Table 11. Mean daily dietary intake.

	Energy		Protein		Iron	
	Kcal	% RDA	gm	% RDA	mg	% RDA
Group 1	362±186 ^a	19±9 ^b	13±7	29±16 ^b	3.7±3.7	30±37 ^b
Group 2	746±390	34±17 ^b	35±25	73±52	5.1±3.1	34±23 ^b
Group 3	1006±428	46±22 ^b	36±12	76±24 ^c	6.4±2.3	43±18 ^b
Group 4	1168±846	58±42 ^b	42±28	94±56	8.0±5.2	45±29 ^b
	Zinc		Vitamin A		Vitamin C	
	mg	% RDA	IU	% RDA	mg	% RDA
Group 1	1.7±1.1	11±7 ^b	1706±1484	43±37 ^b	29±18	48±31 ^c
Group 2	4.0±3.1	27±21 ^b	1507±1034	36±26 ^b	39±55	64±91
Group 3	3.8±1.8	26±12 ^b	2023±1430	47±35 ^c	40±41	65±69
Group 4	5.7±3.3	38±22 ^b	2049±1747	51±44 ^c	54±73	90±122
	Thiamine		Niacin		Folacin	
	mg	% RDA	mg	% RDA	µg	% RDA
Group 1	.17±0.09	17±9 ^c	2.7±1.9	21±15 ^b	74±82	8±2 ^b
Group 2	.72±1.3	68±134	8.2±6.0	57±38 ^b	119±87	18±20 ^b
Group 3	.49±0.24	46±26 ^c	11.1±5.5	78±41 ^c	110±105	30±22 ^b
Group 4	1.05±1.5	101±133	10.2±6.7	57±37 ^c	31±10	28±36 ^b
	Vitamin B-12		Riboflavin		Vitamin B-6	
	µg	% RDA	mg	% RDA	µg	% RDA
Group 1	1.3±1.2	43±79	.32±.25	27±21 ^b	278±131	14±7 ^b
Group 2	1.1±1.0	38±34 ^c	.60±.41	47±31 ^b	421±435	21±21 ^b
Group 3	1.3±2.5	44±39 ^c	.59±.31	46±28 ^b	511±317	25±16 ^b
Group 4	2.2±2.5	74±83	.77±.60	63±48 ^b	653±635	33±39 ^b

^aMean±SD.^bSignificantly lower than 67% of the RDA (p < 0.05).^cSignificantly lower than 100% of the RDA (p < 0.05).

Table 12. Mean daily intake of kilocalories, protein, niacin, and zinc: significant differences between groups.

Nutrient	Significant difference	p Value
Energy	Group 1 vs Group 4	.05
Protein	Group 1 vs Group 4	.05
Niacin	Group 3 vs Group 1 Group 4 vs Group 1	.05 .05
Zinc	Group 1 vs Group 4	.05

Table 13. Protein intake determined from food frequency and percent of protein intake calculated from food frequency compared to 24-hour recall (%).

Group	Protein intake (gms) food frequency	$\frac{\text{Food frequency protein}}{\text{24-Hour recall protein}} (\%)$
1	14 $\pm$ 4	105
2	28 $\pm$ 19	81
3	25 $\pm$ 13	71
4	25 $\pm$ 12	60

be reported as a percentage (Table 13). In all groups, the major sources of protein appeared to be complete protein. While the absolute amount of complete protein eaten seems to have remained constant over time since gastroplasty surgery, the ratio of complete to incomplete protein seems to have decreased with time.

Eating Habits and Satiety. Questions related to satiety and eating habits included questions on ounces of food eaten per meal, type of food usually eaten (liquid, pureed, soft, regular), number of meals eaten per day, time between eating a meal and feeling hungry, satisfaction or dissatisfaction with a limited intake, experience with bulky foods, experience with fad diets, and whether a vitamin supplement was taken regularly (Appendix A, Questions 1,2,4,5,13,18,17).

Reports of ounces of food eaten per meal and type of food eaten are summarized in Table 14. Patients had been instructed by the dietitian to think of their food in terms of volume by ounces (e.g. 1 oz of pureed meat or vegetable is equal to one tablespoon). It was assumed that patient responses to this question were based on a mental estimate of the volume of food eaten. Two patients said that the amount of food eaten per meal varied from day to day and two others specified that the amount depended on what the food was. Patients ate an average of 2.4 meals per day with no significant differences between groups. Six patients said that they snacked in addition to this and three said that the number of meals eaten depended on the type of food eaten.

Time between eating a meal and feeling hungry seemed to have been longer following surgery than before surgery but was not significantly

Table 14. Mean ounces of food intake and consistency of diet reported by respondents.

Group	Ounces of food eaten per meal	Consistency of diet ^a	
1	3.0 ^b	puree soft regular	(4) ^c (2) (1)
2	4.3	puree and soft regular	(1) (13)
3	4.8	regular	(13)
4	7.5	regular	(12)

^a46 patients responded.

^bDifferences between groups 1 and 4 and 2 and 4 were significant ($p < 0.01$).

^cThe number in parentheses indicates the number of respondents.

different between groups following surgery (Table 15). Five patients said that they never felt hungry and eight specified that the time period depended on the type of food eaten. One patient said that she never felt full but never felt hungry, and another, that she ate out of habit, not according to hunger. One patient stated that since his routine since surgery was different, he really could not say whether the time period was different than before surgery.

When asked if their desire to eat was satisfied when they felt full, 33 patients said yes and ten said no and there was no significant difference between groups. Patients were also asked what types of things (food or change in lifestyle) they missed because they were unable to eat as before. Responses are listed in Table 16. Other things mentioned as being missed were chewing, and eating a whole meal with some of everything. One patient did not like the uncertainty of not knowing whether a food would cause vomiting and another was frustrated because she could not appease her nervousness by eating. Twelve patients reported that they did not miss anything.

The question "Do you avoid any foods because they fill up your stomach too quickly?" elicited a blank response from 33 patients and the listing of a few foods from 13 patients (Table 17).

When asked if they were on any special diet besides that prescribed for gastropasty patients only five of the patients said yes and gave one of the following responses: no salt diet; T.O.P.S. (Take Off Pounds Sensibly--a weight loss organization); Cambridge--one meal per day; and the National Weight Loss Clinic (another weight loss organization).

Table 15. Hours between eating a meal and feeling hungry reported by post-surgery respondents and comparison to pre-surgery times as recalled from memory.

Group	Hours between meal and hunger (mean)	Compared to pre-surgery ^a	
1	5.8	same longer	(1) ^b (6)
2	4.6	shorter same longer	(1) (1) (11)
3	6.6	longer	(13)
4	7.4	longer	(12)

^a46 patients responded.

^bThe number in parentheses indicates the number of respondents.

Table 16. Responses to question regarding foods or activities missed after surgery.^a

Response	No. of Responses
certain foods missed	16
drinking lots of fluids missed	5
eating in special social gatherings missed	3
food still smells or looks good	5
certain foods craved	5
nothing	12

^a46 patients responded.

Table 17. Bulky foods avoided reported by respondents.^a

Food	Number of Responses
none	33
bread	5
lettuce	3
beef	3
rice, pea soup, potato chips, fruits, corn, peas	each mentioned once

^a46 patients responded and some gave more than one response.

In one final question concerning food habits, patients were asked if they were taking a vitamin supplement regularly. Responses are listed in Table 18. The difference between groups one and four is probably significant at the $p < 0.1$ level. The significance is only probable because the Bonferroni chi-square values at the 0.1 level have not been calculated and can only be extrapolated from other values. It appeared that the Bonferroni chi-square values at the 0.1 level would have been similar to the chi-square statistic calculated for the comparison between groups one and four.

Vomiting Problems and Food Intolerance. Questions 7, 8, and 10 (Appendix A) focused on vomiting problems and food intolerance. Questions 14, 15, and 16 (Appendix A) were used to discount any foods that were avoided for reasons not related to the surgery. Therefore, those foods avoided because they were expensive, were always disliked, or for any other reason were not included in the analysis of foods not tolerated well as a result of surgery.

Questions asked concerning vomiting were designed by the principal investigator to get an idea of the initiation, frequency, duration, and cause of the problem. Frequency and duration were difficult for the patients to quantify but most were able to specify when the problem started and what the cause was. When asked if they had problems with vomiting, and, if so, when the problem began, various answers were given (Table 19). The difference between groups one and two versus groups three and four in response to the former part of the question was significant ($p < 0.05$). Most patients

Table 18. Daily vitamin and mineral supplementation reported by respondents.^a

Group	Supplementation?	
	Yes	No
1	6	1 ^b
2	11	3
3	11	2
4	6	6

^a46 patients responded.

^bThe difference between groups 1 and 4 was probably significant ($p < 0.1$).

Table 19. Incidence, initiation, and speculated (by participant) cause of vomiting.

Group	Problem? ^a		When Started ^b		
	Yes	No	0-1 Week	1 Weeks	6 Weeks or When Solid Food Started
1	4	3	3	1	0
2	13	1 ^c	4	0	7
3	13	0	3	0	7
4	12	0	7	1	2
Speculated Cause ^d (by participant)			Number of Responses		
Specific foods			17		
Overeating or eating too fast			27		
Self-induced			3		
Emotional status			3		
Unknown cause			4		

^a46 patients responded.

^b35 out of the 42 patients having vomiting problems responded.

^cThe difference between groups 1 and 2 versus groups 3 and 4 was significant ($p < 0.05$).

^d40 out of the 42 patients having vomiting problems responded and some gave more than one response.

seemed to have started having vomiting problems either within a week following surgery or when solid foods were started at six weeks post-op. Vomiting was attributed primarily to two causes--specific foods or eating too much or too fast (Table 19). Ten patients who had attributed vomiting to overeating said that they had learned from experience how much they could eat without having to vomit.

Patients were asked if any particular foods caused nausea, vomiting, stomach pain, or intestinal pain. Significant differences were found between groups one and three, one and four, two and three, and two and four in the number of foods causing distress reported by respondents (Table 20).

Meats were most frequently reported as being difficult to tolerate, but some fruits, vegetables, and breads were also mentioned (Table 21). Since it was suspected before the study that meats were often not well tolerated, patients were asked which meats were most easily tolerated. Responses to this question are also summarized in Table 21.

Patients often gave further information regarding foods that caused problems. Orange juice, oranges, apples, strawberries, and tomato products were implicated for fiber content or acidity. Lettuce was commonly described as "giving a knotty feeling" or "just sitting in the stomach." Some specified that tough beef or that cut with the grain caused problems. Others said that any beef including hamburger or beef chewed well caused problems. Two patients said that while they could not tolerate a ground beef patty, they could eat ground beef in chili. Another said that her tolerance of ground beef depended on how the meat was packed, and another, that ground beef was less

Table 20. Number of foods causing distress reported by respondents.

Group	Number of Foods
1	1.6 ± 1.1 ^{a,b}
2	1.9 ± 1.2
3	7.2 ± 4.1
4	6.2 ± 4.7

^aDifferences between groups 1 and 3, 1 and 4, 2 and 3, and 2 and 4 were significant ($p < 0.05$).

^bMean ± SD.

Table 21. Types of foods and specific foods causing distress and meats most easily tolerated.

Foods Causing Distress	Number of Responses
<u>Types of Food</u>	
Meats	79
Vegetables	41
Fruits	42
Breads	12
Dairy Products	10
<u>Specific Food^a</u>	
Roast Beef or Steak	19
Hamburger	13
Tomato Products	7
Raw Carrot	7
Lettuce	8
Orange	9
Apple	7
Bread	8 ^b
<u>Meats Most Easily Tolerated^c</u>	
Chicken	20
Fish	14
Turkey	5
Ground Beef	4
Roast Beef or Steak	2
All Well Tolerated	17

^a45 patients responded and some patients gave more than one response.

^bFour respondents specified white bread and one specified dark.

^c46 patients respondents and some gave more than one response.

easily tolerated than steak. Hot dogs were implicated for skins or spiciness. Most of those having trouble with chicken specified fried or barbecued chicken. Those complaining about white bread stated that the bread seemed to "ball up" or "glom" in the stomach. Some patients specified that greasy foods caused problems.

Most patients described the discomfort following eating as a heavy or knotty feeling in the stomach which eventually (after a few hours) was relieved when food passed through the pylorus or was vomited. Some, however, stated that certain foods would come back up immediately. One patient said that she could tell when a food was not going to stay down because it felt like something was being put into a sore when she ate. Two patients mentioned chest pain and headache as being part of the discomfort associated with eating.

Patients were asked, finally, if they could do anything to help digestion. Many suggestions had to do with preparation of food. Grinding food, boiling meat, cutting meat across the grain, mixing foods before eating (roast beef and mashed potatoes, string beans and potatoes, beef and applesauce or steak sauce), removal of skins, avoidance of greasy foods, cooking food well, eating beef with lots of liquid, toasting bread, cooking vegetables (rather than eating them raw), drinking water with oranges, and breaking up hamburger were all mentioned. Chewing gum and drinking hot tea were each suggested as aids to digestion. One patient said that the more she exercised, the better her digestion was, and another, that taking a walk after eating a meal was helpful for digestion. Suggestions for sticking to a low calorie, nutrient dense diet included eating from a small plate,

buying food in small cans (to prevent food wastage), melting cheese in tomato soup for protein, and blending fruit in with a milkshake. Several of these suggestions had been made by the dietitian in the diet instruction given to patients.

Possible Factors Preventing Weight Loss. It was suggested that patients having less than expected weight loss may have eaten solids too soon following surgery causing a ruptured staple line or that they may have been taking in excessive amounts of high caloric liquids which pass easily through the artificial pylorus. Responses to question three (Appendix A) showed that patients began eating solid foods at an average of 5.8 weeks post-operative, only slightly earlier than the recommended starting date for eating solid foods of six weeks post-op. It appears that weight loss failure could not be attributed to early intake of solids in this group of patients.

Responses to question six (Appendix A) showed that ten patients were taking in over 200 kcal per day in liquids. The paired t test was used to compare total daily energy intakes and percent excess weight lost of each of these patients to the group averages of each and no significant differences were found. One of the patients from group four, however, was taking in 560 kcal per day primarily from soda pop and weighed more at the time of the interview than before surgery. Another from group four called herself a "coke-a-holic" and drank 1298 kcal of Coca-Cola per day. She had lost 24% of her excess weight as opposed to the group average of 34 percent.

DISCUSSION

The purpose of this study was to assess the nutritional status of both short- and long-term gastropasty patients and to evaluate changes in status over time following surgery. It was hypothesized that patients would have significant weight loss, decreased energy intakes, trouble tolerating protein foods resulting in the lowering of protein, iron, zinc, and vitamin B₁₂ status, trouble tolerating vitamin rich bulky foods such as green leafy vegetables and whole grain breads resulting in insufficiencies of vitamin A, the B vitamins, and vitamin C, and problems with vomiting (Table 2). This nutritional assessment was focused on an evaluation of these hypotheses and included additional questions concerning food habits, satiety, and possible factors preventing weight loss.

Methodology

Anthropometric measurements of TSF and MAC were made primarily for the determination of MAMC as an assessment of somatic protein status (Blackburn et al., 1979). The validity of measurements in this study should be questioned because of the difficulty of measuring TSF on morbidly obese individuals. In this study, patients were encountered who had fat folds hanging down several inches from the back of the arm and others who had fat built up unevenly around the arm. It seems that in neither case would a measurement of the width of the fatfold

on the back of the arm be a valid measure of the fat layer surrounding the triceps. Difficulties in making TSF measurements on morbidly obese individuals have also been documented by Bray et al. (1978). They stated that often the skinfold calipers were not large enough to encompass the fat fold and that the delineation of the skinfold in morbidly obese individuals was difficult. It should also be noted that TSF may not truly reflect total body fat in patients who are losing weight since catabolism of fat with weight loss may not be evenly distributed throughout the body (Edwards, 1950). Bray et al. (1978) showed that there was poor correlation between TSF and weight loss.

It should be noted that dietary instruction for gastroplasty patients within a few days post-operative and at six weeks post-operative was routinely given by the Butterworth dietitians. Patients were instructed to gradually progress from liquid to solid foods following surgery in order to prevent stressing of the staple line. They were instructed to eat only liquids from one to two weeks post-op (336 kilocalories and 13 grams of protein per day); semi-liquid foods including pureed meats and vegetables from two to four weeks post-op (313 kilocalories and 15 grams of protein per day) and soft foods including eggs, fish, poultry, and cooked vegetables from six to twelve weeks post-op (425 kilocalories and 20 grams of protein per day). They were also instructed to take a multiple vitamin and mineral supplement daily.

A 24-hour recall was chosen for assessment of nutrient intake. The 24-hour recall was chosen because it is simpler and less time

consuming than other assessment methods. Also, Gersovitz et al. (1978) showed that it is a valid measure of dietary intake for group comparisons.

Standards used for the assessment of nutrient intake were the Recommended Dietary Allowances (RDA's) established by the Food and Nutrition Board of the National Academy of Sciences (1980). The RDA's are standards set for population groups. They have been set at levels well above the average need for individual groups categorized according to sex and age so that most (97 percent) individuals consuming nutrients at RDA levels are getting what they need for growth and maintenance of body function. It is stated relative to the RDA's, that "intakes below the recommended allowance for a nutrient are not necessarily inadequate, but the risk of having an inadequate intake increases to the extent that intake is less than the level recommended as safe" (RDA, 1980). Therefore, the intakes reported here as being significantly lower than the RDA are not necessarily inadequate to meet body needs, but the adequacy of the intakes is at least questionable and of concern. Presumably, then, the greater the difference between intakes less than the RDA and the RDA, the less likely it is that actual needs are met.

While statistical analysis is not conventionally used for assessment of nutrient intake with respect to the RDA, it has been used by another researcher (Updegraff and Neufeld, 1981) and seems appropriate. In a discussion on the use and interpretation of the RDA's Hegsted (1972) says, "...it is also certain that when we know that population A has an average intake that it is higher than population B, we cannot assume that population A is better fed than population B...we would

like to know something about the distribution of intakes within the population." Statistical analysis takes into account the distribution of data points. It is a more valid method than simple comparisons of group means for assessment of differences between groups.

The Bonferroni t-test was used for between group comparisons of quantitative data and the Bonferroni chi-square test, for between group comparisons of qualitative data. The Bonferroni tests are used for non-independent multiple comparisons of means in the case of the t-test and proportions of counts in the case of the chi-square test. The purpose of the tests is to protect the overall level of type one error for a set of comparisons.

Weight Loss and Triceps Skinfold

Weight loss up to one year after gastroplasty surgery was as expected in comparison to other gastroplasty studies (Table 1) at least seven to ten pounds per month. The fact that the percent excess weight loss of group three was significantly greater than that of groups one and two seems indicative of increased weight loss with time following surgery at least up to one year post-operative. The finding that the percent excess weight loss of group four was lower, though not significantly lower, than that of group three is difficult to interpret. It may be indicative of a leveling off of weight loss by one year post-operative or may reflect a trend toward regaining of weight at that time. This trend in weight loss is probably related to the trend of increased energy intake with time following surgery. Interpretation of weight loss data is further complicated by method of

stoma reinforcement. The weight loss of group four may simply indicate that stoma reinforcement with silastic tubing is more effective than with sutures.

Although the primary reason for measuring TSF was for use in calculation of MAMC, it is interesting to consider TSF data alone. Recognizing the limitations of anthropometric measurements in this study, some conclusions can be made from TSF data. Mean TSF values for all four groups were at least above the 85th percentile of American women aged 34-44 years (Frisancho, 1974). Seltzer and Mayer (1965) compiled anthropometric data and suggested that an individual having TSF above the 85th percentile should be classified as obese. Since the data compiled by Frisancho (1974) from the Ten State Nutrition Survey of 1968 to 1970 are similar to those of Seltzer and Mayer, it can be concluded, not surprisingly, that this is indeed a sample of obese persons. The significantly lower TSF values of group three as compared to groups one and two may reflect a catabolism of fat shortly after surgery. Updegraff and Neufeld (1981) reported that there was no significant difference between pre-surgery TSF and four months post-surgery TSF of gastric bypass patients. This is in agreement with the early changes in TSF seen in this study and seems to indicate that fat catabolism as measured by TSF is not identifiable until six months after gastric partitioning. The higher, though not significantly higher, TSF of group four may reflect either a leveling off of fat catabolism or a trend toward regeneration of fat. This may be related to the trend in weight loss or method of stoma reinforcement.

Energy Intake

Energy intake was less than 1500 kilocalories per day in all four groups as was hypothesized (Table 1), and was significantly lower than two-thirds of the RDA in all four groups. The kilocalorie intake of group one was roughly equal to that perscribed by the dietitians for these patients. Energy intakes of gastric bypass patients reported by other researchers (Brown et al., 1982; Updegraff and Neufeld, 1981; Rogus et al., 1981) at three months (566 kilocalories), four months (790 kilocalories and 740 kilocalories) and six months (1,286 kilocalories) were similar to those reported here for six weeks to six months post-op (746 kilocalories) and six months to one year post-op (1006 kilocalories). It should be kept in mind that low intakes of foods are to be expected since the purpose of the gastroplasty is to restrict the amount of food that a patient can eat. Low intakes of specific nutrients, then, may to some extent be an artifact of these low energy intakes and the dietary intake of a gastroplasty patient may be no different than that of an individual on a very low calorie diet. However, the composition of the food intake of this sample seemed to have been affected by specific food intolerances which were caused by the surgery. This finding will be addressed later in the discussion. It would have been interesting to have compared the nutritional status of gastroplasty patients to that of a control group consisting of morbidly obese individuals who had maintained energy intakes comparable to those in this study over a two year period. However, time and money restraints rendered the use of such a control group impossible.

The significantly greater energy intakes of group four as compared to group one seem indicative of increased intake with time at least until two years post-operative. Rogus et al. (1981) also documented an increase in energy intake with time following surgery at least up to six months after gastric bypass. It seems that the increase in energy intakes may be due to a stretching of the stomach pouch with time following surgery.

Intolerances of Meats and Bulky Foods and Nutritional Status of Several Nutrients

Results show that patients did have trouble tolerating some protein foods. Because the intolerance was primarily of tough and stringy meats rather than softer protein foods, the cause of the intolerance appeared to be a mechanical problem rather than a chemical one. This possibility will be discussed later with consideration of other food intolerances.

Protein intake, though significantly lower than two-thirds of the RDA in group one was significantly greater and at least equal to the RDA in group four. This seems indicative of increased protein intake with time following surgery up to levels at least equal to the RDA by one year post-operative. Protein intakes of gastric bypass patients reported by other researchers (Brown et al., 1982; Updegraff and Neufeld, 1981; Rogus et al., 1981; Mason, 1981) three, four and six months and two years post-operative were similar to those found at comparable times in this study. Rogus et al. (1981) documented an increase in protein intake between three and six months following

surgery and Mason reported that patients at two years post-operative had greater protein intakes than those only one year following surgery. These reports are in agreement with the increasing trend in protein intake over time in this sample. The very low protein intake of group one might be explained by the fact that patients were eating primarily liquids and pureed foods at that time and had a very limited capacity for food. It is interesting, however, that protein intake increased with time to RDA levels in spite of the report of many patients that tough and stringy meats were difficult to tolerate. The dietitians working with the patients pointed out that the nutrition education material given to gastroplasty patients following surgery emphasizes the need for protein, and that the increased protein intake of patients with time may have resulted from a special effort on the part of patients to meet their protein needs. The source of protein was probably softer more tender foods such as ground meats, dairy products, eggs, and some breads and vegetables.

The frequency of intake of meat, eggs, and cheese seems to show that the majority of the protein intake was of food quality--complete in amino acids--in all four groups. This phenomena increases the likelihood that patients were obtaining enough protein to meet actual needs.

Biochemical and anthropometric data add further information concerning the protein status of gastroplasty patients. Mean serum transferrin was within the normal range in all four groups and was not significantly different between groups. Unchanged and normal serum transferrin concentrations between zero and three months

post-operative (Brown et al., 1982) and zero and four months post-surgery (Updegraff and Neufeld, 1981) have been documented in gastric bypass patients. Brown et al. (1982) also reported normal and unchanged total protein concentrations between zero and three months post-operative, and Rogus et al. (1981) reported normal and unchanged albumin concentrations between zero, three, and six months post-surgery. The mean MAMC values of all four groups were acceptable and at least above the 50th percentile of American women aged 34-44. They were not significantly different between groups.

In light of the problems associated with making anthropometric measurements on obese subjects, the MAMC values reported here must be interpreted with caution. It might be valid to conclude that somatic protein stores of these patients were adequate to maintain normal visceral protein concentrations during the time of lowest protein intake, zero to six weeks post-op and that protein intakes returned to adequate levels before somatic stores were compromised to a dangerously low level. It does not seem possible, however, that somatic stores remained constant with time following surgery as the data, showing no significant differences in MAMC between groups, suggest. Low energy intake, catabolism of protein stores due to the stress of surgery, and wound healing all increase the body's need for protein. Since protein intakes of this population were low under these circumstances, it would seem that somatic stores would have been catabolized for provision of needed protein and that MAMC would have significantly decreased in size at some point following surgery. Updegraff and Neufeld (1981), in a study of gastric bypass patients,

found a significant decrease in MAMC between zero and four months post-operative and stated (with some qualification) that this reflected catabolism of somatic protein following surgery. Negative nitrogen balance at three months post-operative (Brown et al., 1982) and significantly reduced creatinine height index between zero and four months (Updegraff and Neufeld, 1981) have also been reported for gastric bypass patients and seem to substantiate the occurrence of protein catabolism following surgery. A decrease in MAMC values may have occurred between pre-surgery and post-surgery times in this sample, but pre-surgery data were not available for analysis.

It had been suspected that the iron, zinc, and vitamin B₁₂ status of gastroplasty patients might have been compromised since a major source of these nutrients is the meat patients often had trouble tolerating. Iron intake was found to be significantly lower than two-thirds of the RDA in all four groups and not significantly different between groups. Iron intakes of groups one and two were similar to those reported for gastric bypass patients at three months (Brown et al., 1982) and four months (Updegraff and Neufeld, 1981) post-op. Zinc intake, like that of iron, was found to be significantly lower than two-thirds of the RDA in all four groups although statistical analysis did show a trend toward increased intake with time. Vitamin B₁₂ intake, on the other hand, was at RDA levels in group four and seems to be related to the protein intake of group four. Intakes of these nutrients seem congruous with the data that the protein foods most easily tolerated by patients were chicken, fish and dairy products. These are relatively poor sources of iron and

zinc but fish and dairy products are good sources of vitamin B₁₂. The primary sources of iron and zinc in these patients were probably eggs and plant products.

In spite of the low iron intakes, serum iron concentrations were maintained within a normal range in all four groups. Maintenance of normal serum iron concentrations was also found for gastric bypass patients at three months post-op (Brown et al., 1982) and four months post-operative (Updegraff and Neufeld, 1981). Since many patients were taking vitamin and mineral supplements, it is thought that iron supplementation may have accounted for the maintenance of normal serum iron concentrations. It should be emphasized that serum iron concentrations may only reflect recent intake and may not be an accurate measure of iron stores. This possibility was also suggested by Brown et al. (1982) and Updegraff and Neufeld (1981). It should also be noted that although serum iron concentrations were normal, they were in the low end of the normal range. Therefore, it is possible that the iron stores of patients in this study were compromised.

Patients did not seem to consciously avoid eating bulky foods "because they filled up the stomach pouch too quickly" (Appendix A, Question 13). However, many did report that some fruits and vegetables were difficult to digest.

Intakes of several vitamins were found to be low and may be related to specific food intolerances. It might be concluded that low intakes of folacin and vitamin A were related to avoidance of bulky foods such as green leafy vegetables and carrots. Updegraff and Neufeld (1981) reported that the folic acid intakes of gastric

bypass patients were significantly reduced between zero and four months post-op. They suggested that this decrease may have been related to the bulkiness of foods high in folacin and the small capacity of the gastric pouch. Serum folacin concentrations had actually increased, however, and the authors concluded that this was due to the recent intakes of folate in a vitamin supplement. Brown et al. (1982) reported low vitamin A intakes of gastric bypass patients at three months post-op concomitant with slightly subnormal serum vitamin A concentration. Although the authors did not speculate on the relationship between low vitamin A intake and specific food intolerances they did conclude that vitamin A stores were low. Avoidance of bulky whole grain products and enriched "glomy" breads might be implicated for the low intakes of several of the B vitamins. It is not known why thiamine intakes were equal to the RDA in group four, and this may be of no practical significance. Vitamin C intake may have been at adequate levels in some groups because it is more easily accessible in liquid form, such as in orange juice, than are many of the other nutrients.

It should be pointed out again that low intakes of specific nutrients may simply have been artifact of the low energy intakes. The dietary intakes of gastroplasty patients may be no different than those of morbidly obese individuals consuming a comparable low energy intake over an extended period of time.

Regardless of the reason for the low intakes, the fact remains that intakes of many nutrients were much lower than the RDA and were not increasing significantly with time following surgery. This is

of particular concern since the number of patients taking vitamin supplements (Appendix A, Question 7) appeared to be significantly lower in group four than in group one. Patients seemed to get out of the habit of taking vitamin supplements as time passed following surgery while their intakes of several nutrients remained at a low level. While biochemical data were not available for a more complete assessment of the status of many of these nutrients, intake data itself is reason for concern that patients may not be getting the nutrients they need.

Cursory assessment of clinical status with the question concerning physical problems since surgery (Appendix A, Question 12) added little, if any, information to the assessment of nutritional status. Reports of tiredness may be related to some type of anemia secondary to protein, iron, folacin or vitamin B₁₂ deficiencies, and neurological disorders, to B vitamin deficiencies, but symptoms reported were vague and inconclusive. Constipation may have been related to the smaller volume of food and fiber passing through the gastro-intestinal tract and hair loss may have been due to protein deficiency. Feeling cold all the time may have resulted from the loss of fat. Perhaps the most significant response to this negatively slanted question was that of the five patients who said that they felt better following surgery. (A more neutral form of the question would have been, "Did you feel any different physically after surgery than before?")

Vomiting Problems and Food Intolerance

It is interesting that there was a significant difference between the first half (groups one and two) and second half (groups three and four) of the sample population in number of patients who had had some vomiting problems, the first half being less than the second half. This might be interpreted in light of the second part of the question concerning when vomiting problems began. Of those who were able to specify when the problem started only two of the patients said that the problem began between one and six weeks. Half of the remainder said that the problem started within a week following surgery and the other half said that the problem started at approximately six weeks post-operative or when solid foods were started. It is apparent that most patients started having vomiting problems either within a week following surgery or not until they started eating solid foods. It might be predicted, then, that those patients in group one who had not yet experienced vomiting problems would begin having problems when solid foods were started. Those who had problems within a week following surgery may have tried to eat too much food too soon following surgery although this was not documented in the study.

Most often, the cause of vomiting was thought by patients to have been either eating too much or eating too fast or specific foods. Mason (1981) reported these same reasons for vomiting in gastric bypass patients. It seems that the frequency and severity of vomiting problems was difficult for patients to quantify because of the nature of the cause. Vomiting seemed to occur in response to a specific

factor such as a certain food or eating too fast rather than to occur on a regular time schedule. Patients reported that avoidance of those factors prevented the vomiting.

Since specific foods were reported as causing vomiting an attempt was made to identify the characteristics of the foods which made them intolerable. First of all, it was found that the number of foods mentioned by each patient as causing some type of intolerance increased with time. Since patients gradually introduced new foods into their diets, this probably was simply a reflection of the number of foods the patient had tried.

Meats were the food most often cited by patients as being difficult to tolerate. Many patients specified that the tough, stringy types or cuts of meat caused the most problems. Several researchers (Brown et al., 1982; Updegraff and Neufeld, 1981; Mason, 1981; Halverson, 1981) reported that this intolerance of meats was true for gastric bypass patients. Brown speculated that the meat intolerance may have been due to a lack of proteolytic enzymes and HCl from the stomach to begin digestion. However, parietal cells are located in the fundus and it would seem that enough hydrochloric acid (HCl) could be secreted by these cells to begin digestion in the small proximal gastric pouch.

Comments made by patients concerning types of foods which caused distress, type of intolerance, and practices which made food more tolerable seemed to indicate that the type of vomiting which was caused by certain foods was usually due to mechanical rather than chemical limitations. Specifically, it appeared to be due to the

small capacity of the stomach and the narrow stoma connecting the proximal and distal stomach pouches. It seems possible that the restriction of these foods to such a small pouch might prevent hydrochloric acid (HCl) from penetrating a bolus of food for the first step of digestion in the stomach. The undigested food, then, would be unable to pass through the narrow stoma. This would explain why tough, stringy, fibrous, or bulky foods were those mentioned most often as causing vomiting problems since they would seem the least able to pass through the narrow stoma (even though chewed well) without first being digested by HCl. The practice of mixing foods such as beef and mashed potatoes as an aid to digestion might be explained by this theory in that this might prevent the formation of an impenetrable bolus of food and thus allow HCl to begin digestion. The heavy or knotty feeling following eating would seem characteristic of that resulting from a bolus of food sitting in the proximal pouch unable to pass through the stoma. The reason for avoidance of spicy and greasy foods is not known.

Eating Habits and Satiety

Gastroplasty surgery had an effect on the eating habits and satiety of the patients in this study as measured by several questions (Appendix A, Questions 1,2,4,5, and 18). As time passed following surgery, patients ate more per meal although the number of meals eaten per day remained constant. This would seem to indicate that as time passed following surgery the capacity of the stomach pouch increased allowing more food to be eaten at one time. Patients stated that the

length of time that they felt full following a meal had increased compared to pre-surgery. This "satiety time" did not change with time following surgery.

It is important to consider what actually "signals" a gastroplasty patient to stop eating. Ideally the signal would be a full, but not unpleasant, feeling. It is interesting that many of the patients in this study who attributed vomiting to overeating said that it took time for them to learn to gauge just how much their stomachs could hold without inducing vomiting. Mason (1981) also stated that some of his gastric bypass patients had no sensation of fullness and learned to judge from past experience how much their stomachs could hold without causing vomiting. In a study of gastric bypass patients by Halmi et al. (1981) some patients stated that if they had experienced no discomfort or pain after eating, they would have eaten just as much as they did before surgery. It appears from such reports that in some gastric partitioning patients, the signal for limiting intake is not a feeling of fullness but a feeling of pain or discomfort or a "sight" estimation of the amount of food that the stomach can hold.

Although most patients stated that their desire to eat was satisfied when they felt full, many stated that they missed certain things in relation to food. It seems from these responses that a feeling of fullness, pain or discomfort following eating did not remove all desire for food. Patients in this study did not seem to be following "fad" diets as was suspected.

Possible Factors Preventing Weight Loss

Two factors thought to be possible deterrents of weight loss in gastroplasty patients were drinking high calorie liquids which could easily pass through the stoma or eating too much food too soon following surgery causing a ruptured staple line. Neither of these practices was prevalent in this group of patients. Mason (1981) stated that it is true that patients could defeat the surgery by eating many small meals or snacks per day, but that the important question is whether or not they actually do it. It seems that with proper instruction most patients would be able to avoid such practices that inhibit weight loss.

SUMMARY

Consideration of nutritional outcomes of gastroplasty surgery is important since the procedure involves an alteration of the stomach and drastic limitation of food intake. The objective of this study was to assess the nutritional status of both short- and long-term gastroplasty patients and to document changes in status over time.

The sample population included 46 patients from a cross-section of approximately 150 gastroplasty patients who had undergone gastroplasty surgery over the previous two and one-half years by the same surgeon. The sample was divided into four groups according to time since surgery. Methodological tools used were a 24-hour recall for assessment of intake of several nutrients; a questionnaire for assessment of problems with vomiting, food intolerances, food habits and satiety, possible clinical signs of nutritional deficiency and possible factors preventing weight loss; anthropometric measurements including weight, height, triceps skinfold, mid-arm circumference, and mid-arm muscle circumference; and serum concentrations of transferrin and iron. Comparisons were made between actual values and norms or expected values for assessment of the nutritional status of each group. Comparisons were made between groups for assessment of changes in nutritional status over time.

Weight loss was as expected compared to other gastroplasty studies at least up to one year post-operative in that mean weight loss per

month up to one year post-operative was at least seven to ten pounds per month. Weight loss seemed to progress with time at least until one year post-surgery, but the trend following one year could not be determined from these data.

Energy intakes of each group were less than 1500 kilocalories per day. Energy intake seemed to increase with time following surgery at least until two years post-op, although intakes were significantly lower than two-thirds of the RDA throughout the period of study.

Many patients had trouble tolerating some foods high in protein, primarily tough stringy meats. This appeared to be due to the small capacity of the gastric pouch and the narrow stoma connecting the proximal and distal gastric pouches. During the first six weeks post-op, protein intakes were significantly lower than two-thirds of the RDA. In spite of this, mid-arm muscle circumference and serum transferrin remained normal and unchanged throughout the period of study. It appeared that somatic protein stores were adequate to maintain normal serum transferrin concentration throughout the period of low protein intake. Protein intake increased with time and reached 100% of the RDA by one year following surgery. These data were indicative of adequate protein status throughout the two year study period.

Iron intakes were significantly lower than two-thirds of the RDA and serum iron concentrations were in the low normal range up to two years post-operative. Serum iron concentrations were probably maintained by iron supplements throughout this time period and may not reflect iron stores. Iron status as determined from these data

was questionable. Vitamin B₁₂ intake reached 100% of the RDA at least by one year post-operative and zinc intake increased with time but was much lower than two-thirds of the RDA even by two years post-op.

Many patients reported an intolerance of bulky foods such as apples, oranges, and breads. Generally this intolerance seemed to be due to the small capacity of the stomach pouch and the limitation of passage of food through the narrow stoma. Vitamin C and thiamin intakes, though at sub-RDA levels in the first six weeks post-operative were adequate at least by one year. Niacin intakes increased with time following surgery but were significantly lower than the RDA even by two years post-operative. Intakes of vitamin A, riboflavin, vitamin B-6 and folacin were significantly lower than two-thirds of the RDA in most groups and did not significantly increase with time. Low intakes of several nutrients are of particular concern since vitamin and mineral supplementation seemed to have decreased with time following surgery.

Problems with vomiting were experienced by most patients and usually began either within one week following surgery or at the time solid foods were started. The most common causes of vomiting were bulky or stringy foods and eating too much or eating too fast. Many patients stated that they learned to prevent vomiting by carefully monitoring the amount of food they ate or by avoiding the foods that caused the problem.

Eating habits and satiety were affected by gastropasty surgery. Patients stated that the length of time they felt full following a

meal had increased compared to before surgery. This "satiety time" did not change with time following surgery. As time passed following surgery, patients ate more per meal but the number of meals eaten per day did not change. After surgery, even though patients reached the point of satiety earlier following a meal than before surgery, they stated that they still missed certain things in relation to food. Patients did not seem to overcome the volume restriction produced by the surgery by eating too much food too soon post-operatively or by drinking high calorie liquids.

In general, the data seem to indicate that gastroplasty surgery was successful in limiting food intake and ultimately causing weight loss. Although low levels of food ingestion following surgery were expected, it was important to document low intakes of specific nutrients and to evaluate the effect of these low intakes on the health of patients.

Protein status seemed adequate throughout the period of study. Somatic stores were probably catabolized for provision of needed protein early post-op but stores were probably more than adequate to meet this need. Although serum iron concentration was normal throughout the study period, iron status was at least questionable because intakes were significantly lower than two-thirds of the RDA throughout the study period and serum iron concentrations were in the low end of the normal range.

Intakes of several other nutrients were well below the RDA and showed no trend to increase with time following surgery. This was of particular concern in light of the finding that the practice of taking

vitamin and mineral supplements seemed to decrease with time following surgery. Although no biochemical data were available for a more in-depth assessment of the status of these nutrients, intake data alone were a sufficient reason for concern that patients were not getting the nutrition they needed to maintain maximum health.

While low food intakes were expected, of perhaps greater interest was the effect of the surgery on food habits. The data demonstrate that the surgery does not just limit the amount of food patients can ingest but also limits the type of food patients can tolerate.

CONCLUSIONS

Gastroplasty patients should receive nutritional follow-up for at least two years after surgery. This might include a semi-annual assessment of dietary intake with biochemical and clinical evaluations of those nutrients which continue to be low in the diet. Deficiencies should be treated.

Nutrition education should include an emphasis on protein intake particularly during the first six weeks following surgery. Intake of nutrient dense foods and vitamin and mineral supplements should be emphasized for at least two years after surgery.

APPENDICES

APPENDIX A

DIETARY QUESTIONNAIRE

1. Approximately how many ounces of food are you eating per meal at the present time? What form is the food in?
ounces: _____ form: _____ liquid _____ puree
_____ soft _____ regular
2. How many meals do you usually eat per day?
number: _____
3. (to be asked of patients who are eating solid foods)
Can you remember approximately when you started to eat solid (not blended or pureed) foods after having surgery? If yes, when?
If no, during which of the following time periods did you begin eating solid foods?
_____ yes _____ no
time: _____ check one:
_____ 0-3 weeks
_____ 3-6 weeks
_____ 6 wks-3 months
_____ 3 months+
4. After you eat a meal, how much time passes before you feel hungry?
Is this period of time shorter or longer than it usually was before surgery?
time: _____ compared to pre-surgery:
_____ shorter
_____ longer
5. Is your desire to eat satisfied when you stomach feels full?
_____ yes _____ no
What kinds of things (types of food or otherwise) do you miss because you are unable to eat as before?
6. What kinds of liquids do you usually drink? How many times per week do you drink these? How much do you usually drink each time?

6. (cont.) Do you ever drink the following liquids? How many times per week do you drink these and how much do you usually drink each time?

Amount/frequency

Fruit juice
Alcohol
Beer
Wine
Regular (not diet or unsw.)
kool-aid, soft drinks, etc.

7. Have you had problems with vomiting since surgery? If so, when did this begin and how many times per week did you vomit? How long did this continue?

___yes ___no
began:

frequency:

duration:

Do you have problems with vomiting now? What do you think has caused this problem?

___yes ___no
frequency:

cause:

8. Since you had surgery, have any particular foods caused nausea, vomiting, stomach pain, or intestinal pain? If yes, which foods? Have any of the following foods given you any of the problems just mentioned: beef, chicken, eggs, milk, cheese, bread, fruits, and vegetables?

FOOD	TYPE OF INT.	SPECIFICATIONS
beef		
chicken		
eggs		
milk		
cheese		
bread		
fruit		
veg		

Do you avoid eating the above mentioned foods because of the discomfort they cause?

___yes ___no

Did these foods have the same effects before surgery? If yes, which ones?

___yes ___no
foods:

Can you prepare the food in any way or do anything to make these foods more tolerable?

___yes ___no
what?

9. Which types of meats do you tolerate best now?
types:

10. How many times per week do you eat meat, eggs, cheese or beans?
frequency?

meat
eggs
cheese
beans

11. Have you had any physical problems besides those mentioned above that you did not have before surgery?

___yes ___no
problems:

12. Do you avoid eating any particular foods because they fill up your stomach too quickly? If yes, what are they?

___yes ___no
foods:

13. Do you avoid buying any particular kinds of foods because they are too expensive? What kinds?

___yes ___no
kind all just expensive items or brands

14. Are there any particular foods that you have always disliked and still dislike (taste, texture, etc.)? Do you avoid eating them?

___yes ___no
foods:

Avoid?

☐yes

☐no

15. Are there any foods that you do not eat for other reasons?

If yes, what foods?

☐yes

☐no

foods:

16. Are you taking a vitamin supplement or any other diet supplement?

If so, what is it?

☐yes

☐no

type and/or brand

17. Are you consuming a special diet (other than that prescribed for gastroplasty patients)? If yes, what kind? Who prescribed?

☐yes

☐no

kind:

who prescribed:

18. Do you think that the nutrition education material you received in the hospital and as an outpatient was beneficial to you?

☐yes

☐no

why?

why not?

19. What information was lacking in the nutrition education material that you would have liked to have included?

APPENDIX B

APPENDIX B
INTRODUCTORY LETTER

DRS. JOHNSTON, OATES & POOL, P. C.

WILLIAM L. JOHNSTON, M. D.
SAMUEL M. OATES, M. D.
LEE R. POOL, M. D.
LESLIE B. WONG, M. D.
245 STATE STREET, S. E. - SUITE 306
GRAND RAPIDS, MICHIGAN 49503

The Surgical Education Department of Butterworth Hospital and the Department of Food Science and Human Nutrition of Michigan State University are conducting a study on the nutritional effects of gastroplasty surgery. We are asking a sample of those patients who have undergone gastroplasty surgery under the direction of Lee Pool, M.D., to take part in the study. Your participation would help us to insure that gastroplasty patients receive the best possible care.

Thank you for your time. Lisa Van Dyke, who is working on this study in fulfillment of requirements for her Master of Science degree at Michigan State University, will be letting you know more about the study soon.

Sincerely,

Lee Pool, M.D.

Lisa Van Dyke, Graduate Student

APPENDIX C

APPENDIX C
EXPLANATION LETTER

DRS. JOHNSTON, OATES & POOL, P. C.

WILLIAM L. JOHNSTON, M. D.
SAMUEL M. OATES, M. D.
LEE R. POOL, M. D.
LESLIE B. WONG, M. D.
245 STATE STREET, S.E. - SUITE 306
GRAND RAPIDS, MICHIGAN 49503

As you know, a gastroplasty nutrition study of Dr. Lee Pool's patients is being conducted by the Surgical Education Department of Butterworth Hospital and the Food Science and Human Nutrition Department of Michigan State University. I have been working with Dr. Pool on this study and would like to explain it to you here in more detail. I thought it might be helpful to do this by answering some questions that you may have as a potential participant.

1. What is the purpose of this study?

The purpose of this study is to insure that gastroplasty patients are receiving the best possible nutritional care.

2. What would I be required to do as a participant in this study?

You would be asked to come to Butterworth Hospital for a one and a half hour long appointment. At that time you would have a blood sample drawn: have height, weight, and upper arm measurements made; and be asked questions about the food you have been eating.

3. How are you going to use these tests and questions to measure my nutritional status?

The blood sample will be analyzed for levels of protein and iron. Weight and height will be measured for the determination of weight loss since surgery and for comparison to standard weight for height, and upper arm measures will be used as indicators of body leanness and muscle mass. Questions regarding food intake will help us to insure that you are getting an adequate amount of nutrients.

4. Will I be subject to any risks if I participate in this study?

Risks associated with the study are minimal. Blood samples will be drawn by Butterworth Hospital personnel who routinely perform the procedure and all information that you give us will be kept strictly confidential.

5. What benefits will I receive from the study?

Results of your tests and an evaluation of your nutritional status as measured by those tests will be made available to you upon request. Information obtained from the compilation of data from all participants will help to insure that all gastroplasty patients are receiving adequate nutritional care. Results of the study will also be made available to you upon request.

6. If I decide to take part in the study am I obligated to go through the complete data collection procedure?

You are free to withdraw from the study at any time without penalty.

7. How much money will this cost me?

Nothing.

While results from this study could be very beneficial for gastroplasty patients, they will not be informative unless enough patients participate. Please seriously consider taking part in this study for the benefit of yourself and for all who have undergone gastroplasty surgery.

Thanks again for your time. I will be calling you soon to answer any questions you may have and to set up an appointment time if you are able to participate.

Sincerely,

Lisa Van Dyke, Graduate Student
Michigan State University

APPENDIX D

APPENDIX D
CONSENT FORM

I, _____, agree to participate as a subject in the study on the nutritional effects of gastroplasty surgery for morbid obesity conducted by Lisa Van Dyke, nutrition graduate student, Michigan State University. The purpose of the study and procedures to be used have been explained to me and I understand them. I agree to have a blood sample drawn for analysis, to participate in a dietary interview, to answer questions concerning my dietary intake and physical state of being, and to have anthropometric measurements taken. I understand the risks associated with these procedures and understand that in the unlikely event of physical injury resulting from research procedures, Michigan State University, its agents, and employees will assume that responsibility as required by law. Emergency medical treatment for injuries or illness is available where the injury or illness is incurred in the course of an experiment. I have been advised that I should look toward my own health insurance program for payment of said medical expenses. I know that I may withdraw from the study at any time without penalty, that the results will be kept in strict confidence, and that the results will be made available to me upon my request.

Signed _____

Date _____

APPENDIX E

APPENDIX E

NUTRITIONAL ASSESSMENT SCHEDULE

<u>Time</u>	<u>Activity and/or Explanation</u>
0-5 minutes	The participant was met in the main lobby of Butterworth Hospital by the principal investigator (PI) and taken to a vacant office (whatever was available from the Nutrition Support Team that day). The breeze was shot and the fat was chewed.
5-10 minutes	The consent form was presented to the participant by the PI with the following explanation: "The first thing I need to have you do is sign this consent form. The purpose of it is basically to make sure that you understand what the study is all about and what your rights are. I know that part of it sounds kind of technical and is hard to understand so if you have any questions, feel free to ask."
10-25 minutes	The 24-hour recall was conducted and preceded by the following explanation: "The first thing we were interested in finding out was what gastroplasty patients normally eat. One way of measuring that is simply by asking a person what he or she has eaten over a 24-hour period. --That's often a pretty good measure of what someone usually eats. (The PI realizes that this is technically only a good measure for groups. However, this general explanation seemed appropriate for this situation.) I'll be asking you to identify foods you ate, to specify types of food or in some cases how the food was cooked (e.g. type of bread, type of milk, components of a casserole, how egg cooked), and to specify amounts of foods eaten. This may seem tedious but helps us to get a more accurate idea of your intake." The 24-hour recall was continued as follows: "So, if today is Tuesday, I'd like you to think back to yesterday--Monday. After you got up Monday, what was the first thing you ate and how much of it did you eat?...Did you eat anything else at that time?...What was the next thing you ate...etc." The 24-hour recall was concluded with: "I will use this to determine your intake of specific nutrients using a computer at MSU. I'll do that by first of all coding each food item you

mentioned with a specific number. The numbers will be plugged into the computer program and your intake of specific nutrients will be printed out and compared to the Recommended Dietary Allowances. There's nothing magic about the computer.-It just makes the analysis easier to do."

- 25-40 minutes The questionnaire was introduced as follows:
 "We also wanted to get an idea of food habits of patients following surgery. This questionnaire was developed after reading studies done by other gastroplasty surgeons and with suggestions from Dr. Pool and nutrition professors at Michigan State. I'll read each question and you answer as best as possible. Feel free to ask about anything that doesn't make sense."
- 40-41 minutes The remainder of the assessment was introduced as follows:
 "We just have a couple more things to do. I'll be taking your arm measurements using this skinfold caliper, then we'll go to the outpatient clinic to be weighed and finally to the lab where your blood sample will be taken."
- 41-45 minutes Before anthropometric measurements were made, the PI said:
 "The first thing I'll be doing is measuring the circumference of your arm half way between your shoulder and elbow like this. Now, let me explain what all of this means. Keep in mind that there are three main tissues in your arm--the fat, muscle and bone. Using this instrument called a skinfold caliper, I can measure the fat in your arm like so...Now, knowing the fat fold measurement and assuming that bone width is some certain standard size, the only tissue left of unknown size is the muscle. But since we do know the total circumference of the arm we can calculate muscle size. The muscle size is a measure of your protein status since the muscle is made up primarily of protein and if you aren't eating enough protein, your body will start breaking down the muscle."
- 45-50 minutes Patients were taken to the outpatient clinic to be weighed.
- 50-60 minutes Patients were taken to the lab to have blood samples drawn. On the way from the outpatient clinic to the lab the following explanation for blood analysis was provided:

"We had suspected from reading other studies that patients would have trouble tolerating protein. So we thought it would be important to measure blood concentrations of protein, iron, and zinc. --Iron and zinc because they are largely found in protein foods."

Conclusion

Patients were left at the lab, thanked for participating, and told that they would be hearing about the results of the study later in the year.

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