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CLINICAL RESEARCH

Banded Sleeve Gastrectomy—Initial Experience

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Abstract
Background Isolated sleeve gastrectomy is being used with increasing frequency for the treatment of morbid obesity. This study was done to determine the potential benefit of placing a band of processed human dermis around the upper portion of a sleeve gastrectomy to prevent late dilatation and weight gain.
Methods Twenty-seven patients underwent a sleeve gastrectomy followed by placement of a band of biological tissue (AlloDerm®) placed 6 cm from the gastroesophageal junction. The results were compared to 54 patients with a Roux-en-Y gastric bypass (GBP), matched for sex, age, and initial body mass index.
Results All 27 patients had improvement or resolution of their diabetes, hypertension, hyperlipidemia, and sleep apnea after banded sleeve gastrectomy (BSG) similar to the control GBP group. There were no deaths, but one patient had a pulmonary embolus and another had a presumed leak. Symptoms of gastroesophageal reflux disease generally improved. Overall, results were almost identical to patients with GBP.
Conclusions BSG provides results comparable to GBP in the short-term follow-up, but avoids potential long-term complications including internal hernias, postoperative bowel obstructions, anastomotic complications of the jejunojejunostomy, hypoglycemia, bacterial overgrowth, and a spectrum of malabsorptive problems. While this study documents the feasibility and possible benefits of this modification, prospective controlled studies with long-term follow-up are needed to establish its place in procedures for surgical weight loss.

Keywords Morbid obesity · Sleeve gastrectomy · Surgical weight loss · Restrictive band · AlloDerm

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Introduction

Sleeve gastrectomy was originally used as the initial stage of the duodenal switch operation for the treatment of extremely obese patients [1–6]. The results of this procedure were surprisingly good with many patients avoiding subsequent surgery, and isolated sleeve gastrectomy was soon evaluated as a definitive procedure. The outcomes were generally very satisfactory with the percentage of excess weight loss varying between 38% and 83%. Best results were seen in patients with a lower initial body mass index (BMI) [7].

Since none of the intestine is bypassed, the isolated sleeve gastrectomy conserves and expands the benefits of various restrictive procedures at the same time that it avoids a number of potential disadvantages of malabsorptive procedures including internal hernias, adhesion formation, postoperative bowel obstructions, anastomotic complications (such as leak, bleeding, and stricture), hypoglycemia, bacterial overgrowth, and a spectrum of malabsorptive problems. In addition, several studies have shown sleeve gastrectomy to have superior weight loss than gastric banding [6, 8–10]. However, a number of complications have been reported with sleeve gastrectomy including staple line leakage, dilatation of the remaining stomach,

esophageal dilatation, and symptoms of regurgitation [11–13]. Also, weight loss after sleeve gastrectomy has generally not been quite as good as with either a Roux-en-Y gastric bypass (GBP) or biliopancreatic diversion (BPD).

To address some of these issues and better restrict the amount of food consumed at one time, we have performed a series of sleeve gastrectomies in which a biological, nonsynthetic restrictive band has been placed around the upper stomach to further limit the volume of food intake and prevent dilatation of the stomach distal to the band, thus combining the potential benefits of sleeve gastrectomy and vertical banded gastroplasty (VBG). This reports our initial short-term experience.

Table 1 Appetite rating scale

10	Constantly hungry, severe
9	Constantly hungry, not severe
8	Hungry most of time
7	Hungry before meals
6	Hungry when food is around
5	Normal
4	Appetite reduced some of the time
3	Appetite reduced most of the time
2	No appetite but not nauseated
1	No appetite at all, but occasionally nauseated
0	No appetite, constant nausea

Materials and Methods

Twenty-seven patients underwent a banded sleeve gastrectomy (BSG) between February 28, 2006 and May 1, 2008. To assure at least 3 months follow-up, final evaluations were made on October 1, 2008. Their average age was 46 years (16–64 years), and their mean BMI was 48. Patients with diabetes were not included initially, but five diabetic patients were included after our initial experience. Patients with a BMI>60 were also not included so that the BSG could be evaluated as a stand-alone procedure in typical patients. A control group of 54 recent patients with GBP, matched for sex, age, and initial BMI and treated during the approximate time period was selected by computer from our database for comparison. All of the operations were done by the same surgeon.

The sleeve gastrectomy was done from approximately 6 cm proximal to the pylorus to the gastroesophageal junction (angle of His) over a 50-Fg bougie using an Ethicon stapler (45 mm, blue or green loads; Cincinnati, OH, USA). The stapled resection line was oversewn with either 3-0 Prolene® (Ethicon, Cincinnati, OH, USA) or 3-0 PDS® (Ethicon, Cincinnati, OH, USA). A piece of AlloDerm® (LifeCell Corporation, Branchburg, NJ, USA) measuring approximately 1.5×6 cm was wrapped around the stomach and the ends were approximated with 3-0 Prolene® to form a band with the top edge being approximately 6 cm from the gastroesophageal junction. This was performed over an intraluminal 38-Fg bougie sizer and was done so that the tip of a Kelly clamp would fit snugly but without force underneath the band. Since this was placed through a small opening between the blood vessels immediately adjacent to the stomach, there was felt to be reduced opportunity for slippage. Tests for leakage were done by insufflation with 10 L O_2/min via an orogastric tube after a clamp was placed to temporarily occlude the pylorus to achieve complete distention of the remaining stomach. Patients were offered clear liquids the night of operation and advanced to pureed diets on the second postoperative day. They were discharged with a median of 2 days. All patients and controls were seen by the senior author approximately 2 and 6 weeks and 3, 6, 12, 18, and 24 months postoperatively. Comorbid conditions were counted as being present if the patient was receiving treatment for the condition. All patients were carefully evaluated for dysphagia, gastroesophageal reflux disease, appetite score (Table 1), and satisfaction score (Table 2).

This procedure was reviewed and approved by The Christ Hospital Institutional Review Board and all

Table 2 Satisfaction scale

+10	Ecstatic—things couldn't be better
9	Excellent—much better than I expected
8	Excellent—all that I had expected
7	Excellent—no significant problems
6	Good outcome—very happy
5	Good outcome—happy with results
4	Good outcome—somewhat happy
3	Fair—improved
2	Fair—some improvement
1	Fair—very little improvement
0	My life is no better, no worse
−1	There is a promise of improvement
−2	Minor problems
−3	Many things worse
−4	Interferes with life
−5	I wish I had not done it
−6	Most things worse
−7	Major persistent problems related to surgery
−8	Much worse than before
−9	My life is ruined
−10	Disastrous. Totally dissatisfied. Things couldn't be worse

Table 3 Comparison of results of patients with BSG compared to controls with GBP

	BSG	GBP
Average age	45.4	43.8
Sex (M/F)	5 (18.5%)/22 (81.5%)	10 (18.5%)/44 (81.5%)
Average LOS (days)	2.7	2.4

patients gave informed consent. There was no commercial support.

Results

All 27 patients had improvement or resolution of their diabetes, hypertension, hyperlipidemia, and sleep apnea after BSG, similar to the control GBP group (Tables 3 and 4). Joint-related pain was improved at least to the extent achieved in patients with GBP. The changes in BMI for individual patients were similar to the controls (Fig. 1).

There were no deaths in either group. One patient had a prolonged hospital stay (6 days) because of persistent atelectasis. There were no other significant complications during the initial hospital stay. One patient returned on postoperative day 17 with a pulmonary embolus, but recovered completely. Another patient developed a subphrenic abscess associated with a gastric perforation on postoperative day 20, possibly from a staple line leak. Three patients had nausea, requiring medications immediately postop, which resolved. Fifteen patients had preoperative symptoms of reflux or heartburn relieved by antacids, but this resolved completely in eight patients and symptoms improved in the rest. Three patients developed new but mild symptoms of reflux or heartburn postoperatively. The higher incidence of reflux or heartburn in the BSG group at 1 year may have been from more specific questioning regarding symptomatology. No definitive radiologic tests to demonstrate reflux were done. No patient or control had repair of a hiatal hernia. The average food capacity with meals was approximately 4 oz of solid food according to the patients' estimates using a volume indicator, and most patients noted discomfort only when they ate too fast. Postoperative radiographic studies showed the site of band placement with slight restriction of passage of barium (Fig. 2). Intolerance to certain foods occurred in 24 of 27 patients (e.g. to pasta, chicken, or beef), similar to patients with GBP. Changes in appetite and overall satisfaction were almost identical between the groups at 6 months and 1 year (Tables 3 and 4). These scales were derived locally.

Discussion

The isolated sleeve gastrectomy has been compared to other bariatric procedures in several reports. Himpens et al. [8] performed a prospective randomized study comparing

Table 4 Comparison of results of patients with BSG compared to controls with GBP

	BSG			GBP		
	Preop (n=27)	6months (n=21)	1year (n=19)	Preop (n=54)	6months (n=45)	1year (n=52)
Average BMI	49.6	36.6	31.6	50.0	35.9	31.8
Decrease in excess BMI (%)		53.2	73.1		58.5	75.7
DM (% total) (average medians ± SE)	5 (18.5)* (1.4±0.3)	1 (4.8) (1.0±0.2)	0 (0.0) (0.0±0.0)	24 (44.4)* (2.1±0.3)	6 (13.3) (1.0±0.1)	6 (11.5) (1.3±0.2)
HTN (% total) (average medians ± SE)	14 (51.9) (1.5±0.2)	6 (28.6) (1.2±0.2)	5 (26.3) (1.2±0.3)	32 (59.3) (1.8±0.2)	8 (17.8) (1.3±0.2)	11 (21.2) (1.2±0.2)
Hyperlipidemia (% total) (average medians ± SE)	6 (22.2) (1.3±0.2)	2 (9.5) (1.0±0.2)	2 (10.5) (1.0±0.2)	19 (35.2) (1.0±0.1)	1 (2.2) (1.0±0.1)	4 (7.8) (1.0±0.1)
SA (% total)	9 (33.3)	1 (4.8)	0 (0.0)	21 (38.9)	2 (4.4)	5 (9.6)
DJD (% total)	23 (85.2)	10 (47.6)	11 (57.9)	51 (94.4)	28 (62.2)	29 (55.8)
GERD (% total)	15 (55.6)	5 (23.8)	7 (36.8)**	25 (46.3)	6 (13.3)	6 (11.5)**
Average satisfaction score		9.2[a]	9.3[a]		8.5	8.8
Average appetite score	7.0	5.0***	5.1	7.4	3.8***	4.4

*p=0.04; **p=0.04; ***p=0.02

[a] Excludes patient with the leak

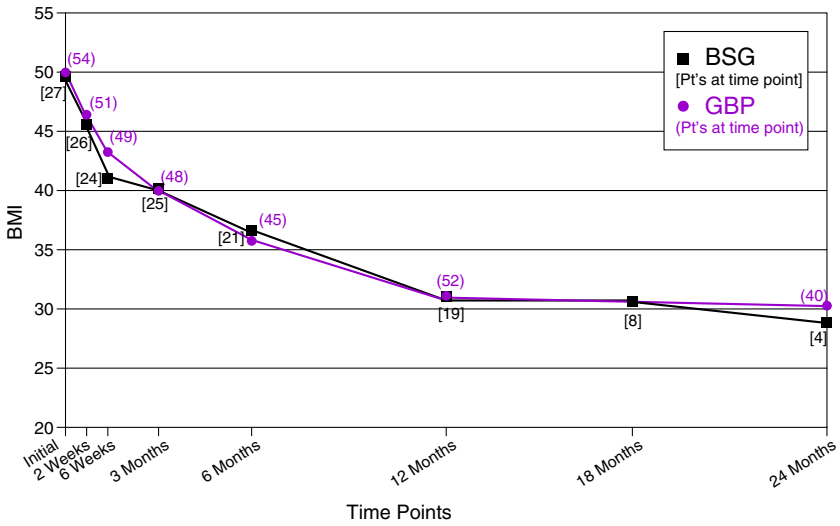

Fig. 1 Changes in BMI for individual patients with BSG compared to matched controls with GBP

Note: The decreasing numbers of patients for BSG represent the fact that the patients had their procedures before that time period. There were no losses to follow-up.

laparoscopic gastric banding and laparoscopic sleeve gastrectomy. After 1 and 3 years, weight loss and the loss of appetite were better after a sleeve gastrectomy, and there were fewer complications of the sleeve gastrectomy compared to gastric banding. Lee et al. [6] and Jan et al. [9] also showed the superiority for weight loss of sleeve gastrectomy over the LapBand®. Karamanakos et al. [10] reported even greater weight loss after sleeve gastrectomy than GBP. These findings support an expanded use of sleeve gastrectomy. Gagner et al. [3] also concluded that sleeve gastrectomy is more beneficial than lap banding for short-term weight loss in super-super obese patients.

Fig. 2 Upper gastrointestinal series 1 year after BSG. Note the very mild dilation of the pouch above the band

Several modifications of the BSG can be done which might improve long-term results. These include tightening of the band (e.g., from 6 to 5 cm circumference), modifying the size of the bougies (e.g., from 50 to 40 Fg), and shortening the distance of the band from the GE junction (e.g., from 6 to 4 cm). Parikh et al. [14] reported that similar results were obtained up to 1 year with 40- and 60-Fg bougies. However, other studies have suggested that there is more weight loss with smaller bougies [1, 4, 15]. Use of an adjustable gastric band is also an option. Greenstein and Jacobs [16] recently reported placement of a laparoscopically inserted gastric band around the upper part of the stomach that had a previous sleeve gastrectomy that had become dilated and was associated with poor weight loss. At 9 months, the patient had a 57% loss of excess body weight, suggesting the utility of combining banding with sleeve gastrectomy. Arceo-Olaiz and colleagues [17] have used a synthetic band in association with the laparoscopic Roux-en-Y GBP. They found that the band was associated with an increased frequency of vomiting but this was minimal, and there was no difference in the amount of weight lost over a 24-month period. However, Fobi et al. [18] reported better weight loss with a similar banded Roux-en-Y. Another modification of a band with a sleeve gastrectomy was evaluated by de Paula et al. [19] who reported a series of 19 patients who had a laparoscopic sleeve gastrectomy over a 30-Fg orogastric calibration tube with placement of a silicone band around the stomach 3–4 cm below the cardia. This differs from our study in that the band was not absorbable, but more importantly, they interposed a 100-cm-long segment of

ileum into the jejunum 50 cm from the ligament of Treitz to provide a "neuroendocrine brake." Type 2 diabetes, hypertension, and hyperlipidemia all resolved or were improved, similar to the patients in our study. Gabriel et al. [20] performed a laparoscopic adjustable gastric banding with a BPD and reported as much as 99.6% reduction in excess weight at 2 years. However, no data were given regarding metabolic complications. These procedures are more invasive than the BSG but represent other means for a combined restrictive/malabsorptive procedure. In addition, they used synthetic materials for banding while we used human collagen. Human collagen was selected for our studies because it resists infection, provides good strength, and is ultimately replaced by the patient's blood vessels and fibroblasts [21]. It maintains good long-term tensile strength when used in hernia repairs, and there has been no evidence of an inflammatory response. Nocca et al. [22] reported that porcine collagen was less reactive than synthetic materials when used as a band for VBG in female pigs.

Because the upper small intestine is not bypassed with a sleeve gastrectomy, we were concerned initially that a BSG would not resolve type 2 diabetes mellitus before significant weight loss occurred. However, four patients promptly resolved their diabetes, and the other patient reduced medications (three to one) over 6 months, consistent with the recent reports of Vidal et al. [23, 24].

To our knowledge, this is the first report of using human collagen as a band for sleeve gastrectomy. The procedure combines the potential benefits of a sleeve gastrectomy with a VBG. The VBG, however, has been associated with many late failures, often after 5 years, including pouch dilatation, gastrogastric fistula, outlet stenosis, and erosion of the band. All of these require revisional surgery with significant risk. The material used in this study has several potential advantages over synthetic materials as there is no foreign body reaction and it is eventually replaced by the patient's own tissues. Whether or not late stenosis will occur remains to be seen, but if it does, it might possibly be easier to dilate without revision since there is no synthetic material involved.

After short-term follow-up, the BSG as described has results similar to GBP but with potentially fewer long-term complications: (1) no synthetic material is used—the band consists of human collagen, (2) no malabsorption occurs—none of the bowel is bypassed, (3) decrease of adhesions and subsequent bowel obstructions—no bowel manipulation, (4) hunger is controlled—removal of 90% of the stomach, (5) late complications are avoided—decrease in dumping and hypoglycemia (from GLP-1), (6) weight loss comparable to GBP, and (7) no significant increase in symptoms of reflux. More patients with a long-term follow-up in tightly controlled studies will be necessary to provide definitive conclusions regarding long-term benefits.

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