



Stomach Intestinal Pylorus Sparing (SIPS) Surgery for Morbid Obesity: Retrospective Analyses of Our Preliminary Experience

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Abstract

Background Although the duodenal switch (DS) has been the most effective weight loss surgical procedure, it is a small minority of the total bariatric surgical cases performed. Modifications that can make the operation technically simpler and reduce a long-term risk of short bowel syndrome would be of benefit. The aim of this study was to detail our initial experience with a modified DS called stomach intestinal pylorus sparing (SIPS) procedure.

Methods Data from patients who underwent a primary SIPS procedure performed by two surgeons at two centers from January 2013 to August 2014 were retrospectively analyzed. All revisions of prior bariatric procedures were excluded.

Regression analyses were performed for all follow-up weight loss data.

Results One hundred twenty-three patients were available. One hundred two patients were beyond 1 year postoperative, with data available for 64 (62 % followed up). The mean body mass index (BMI) was 49.4 kg/m². Two patients had diarrhea (1.6 %), four had abdominal hematoma (3.2 %), and one had a stricture (0.8 %) in the gastric sleeve. Two patients (1.6 %) were readmitted within 30 days. One patient (0.8 %) was reoperated due to an early postoperative ulcer. At 1 year, patients had an average change in BMI of 19 units (kg/m²), which was compared to an average of 38 % of total weight loss or 72 % of excess weight loss.

Conclusions Modification of the classic DS to one with a single anastomosis and a longer common channel had effective weight loss results. Morbidity seems comparable to other stapling reconstructive procedures. Future analyses are needed to determine whether a SIPS procedure reduces the risk of future small bowel obstructions and micronutrient deficiencies.

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Introduction

If modifications of the duodenal switch (DS) could be done that make the operation technically easier, retain the majority of its efficacy, and reduce the likelihood of nutritional deficiencies, this would be an important advance. While DS surgery and biliopancreatic diversion (BPD) are considered the most effective bariatric procedures for weight loss, as well as for amelioration of diabetes, and metabolic disease [1, 2], they represent a minority of total cases performed. The purpose of

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this report is to disclose our preliminary results with a modified DS that we called stomach intestinal pylorus sparing (SIPS) procedure.

Both surgeons that have contributed to this report have years of experience with laparoscopic duodenal switch. As with all procedures, there are individual practice preferences. For classic DS, the authors performed the sleeve gastrectomy with a bougie size ranging from 40 to 44 Fr. The common channel was 125 cm, and the alimentary limb was 1.75 m. This results in food coming into contact with of 3 m of bowel.

An interesting paradox is whether it is best to restore intestinal continuity following duodenal transection with a Roux limb and distal anastomosis or a loop with an afferent and efferent limb. Juan Antonio Torres and Anders Sanchez in Spain have presented 5-year data supporting loop reconstruction. They have reported an operation named single anastomosis duodenal-ileal (SADI) bypass [3]. Their original version had a sleeve performed over a 54-French bougie with 2 m of bowel preserved. More recently, they have increased the bowel length to 2.5 m. Importantly, with 5 years of experience, they did not report a single incidence of afferent loop syndrome or major complications related to the loop construction [4].

SIPS is similar in design. SIPS differs in that a smaller bougie is utilized (42 vs 54 French), and intestinal length of the food pathway is longer (originally 2 m, now 2.5 m in SADI vs 3 m in SIPS). SIPS longer than bowel length theoretically reduces the risk of short bowel syndrome and provides a margin if bowel is not accurately measured. For many individuals, less than 2 m of total intestinal length carries a prohibitive risk for short bowel syndrome even with the ileocecal valve present [5]. 2.5 m is adequate for the majority of patients. SIPS accounts for an approximately 20 % risk of inaccuracy, thus lengthening to 3 m.

The purpose of this article is to report the early results of 123 patients that have had the SIPS procedure performed by two surgeons at different locations within the USA.

Materials and Methods

This is a retrospective analysis of the initial experience from two surgeons, Mitchell Roslin (MR) and Daniel Cottam (DC), at three centers: Bariatric Medicine Institute in Utah (performed by DC), NS-LIJ-Lenox Hill Hospital in Utah, and Northern Westchester Hospital in New York (performed by MR).

This study has been approved by the institutional review board prior to data collection. The data were collected from the patients who underwent surgery between January 2013 and August 2014. Inclusion criteria were adults aged 18+ and primary SIPS procedure. Any secondary or revisional procedures were excluded from the analyses.

Descriptive statistics were used to analyze preoperative characteristics such as age, weight, height, and body mass index (BMI). A linear regression analysis was carried out for the follow-up weight loss data using the SigmaPlot™ 11.0 software.

The procedure time was investigated separately between the two sites, due to some variations. Patients from New York had over-sewing of the staple line with the omentum for the gastric sleeve and synchronous cholecystectomy performed in 32 of 36 patients, whereas data from Utah represents solely SIPS procedure time.

A comparison of the preoperative metrics such as age and BMI was also made using a one-tailed *t* test between the Utah and New York subsets to look for any baseline changes.

Surgical Technique

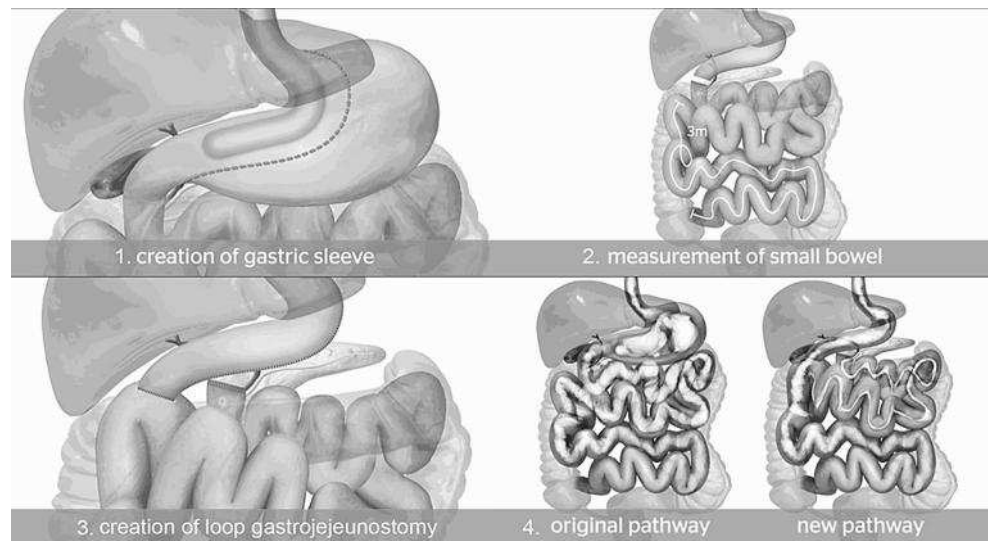
Our techniques have not been described previously. There are slight variations technically between the two centers. However, the first step of the procedure is to create a sleeve gastrectomy over a 42-French bougie (MR over-sews the staple line, while DC does not). Any hiatal hernias seen are repaired as per the routine of the operating surgeons. Once the sleeve is complete, the gastroepiploic vessels are taken down from the end of the sleeve staple line past the pylorus to where the perforating vessels from the pancreas enter the duodenum. This is almost always 2 to 3 cm beyond the pylorus. A blunt instrument is passed behind the duodenum to create a passageway for the division of the duodenum. The duodenum is now divided with an Endo GIA™ stapler (Covidien). If a cholecystectomy is planned, it is performed at this time.

The terminal ileum is now located, and 3 m of small bowel is measured. The anti-mesenteric border of the bowel at this point is attached to the end of the proximal duodenum staple line using an absorbable suture. The loop is set up so the efferent limb is descending on the patient's right and the afferent limb is ascending, coming up from the left. A duodenotomy and enterotomy are made that are approximately 2 cm. The enterotomy is as big as technically possible since it plays no role in the weight loss of the procedure. The enterotomy is closed with a running posterior layer and a running anterior layer. The anastomosis is tested intraoperatively for leaks (using methylene blue, endoscopy, or nasogastric tube). For graphical illustration of surgical technique, refer to Fig. 1.

Results

The analyzed sample size of the study is 123 (87 in UT and 36 in NY), of which 78 (63 %) are females. The preoperative characteristics and the rates of

Fig. 1 Illustration of the SIPS procedure



comorbidities are shown in Table 1. There are a total of 102 patients beyond the 1-year postoperative mark, with data available for 64 (62.7 %, 1-year follow-up). The rest were lost to follow-up. A male patient in the NY subset was diagnosed with a bleeding pre-pyloric ulcer in the early postoperative period. The ulcer was resected, and he was converted to Roux-en-Y gastric bypass (RYGB), which was thus not included in subsequent data analysis.

The mean procedure time overall was 96 min. The mean procedure time was 78 min for Utah subset and 147 min for New York. The extra time difference in the NY subset is attributed to the synchronous cholecystectomy and over-sewing of the gastric sleeve staple line.

Table 1 Preoperative characteristics

	<i>n</i> (%)
Sample size	123 (Utah = 87, NY = 36)
Male	45 (36.6)
Female	78 (63.4)
Age (years) ^a	50 ± 13.1
Weight (lb) ^a	313.1 ± 68.7
Height (in.) ^a	66.7 ± 3.8
BMI ^a	49.4 ± 9.2
Ideal body weight (lb) ^a	139.7 ± 24.6
Excess body weight (lb) ^a	175 ± 64.9
Rates of comorbidities	
Sleep apnea	60 (48)
Diabetes	55 (43.9)
GERD	47 (38.2)
Hypertension	60 (48)

^a Values are expressed as means ± SD

Readmission rate for below and above 30-day postoperative period was similar (1.6 %; *n* = 2 in each group).

Two patients complained of constipation, and two had diarrhea. Four patients had intra-abdominal hematoma, one of which was complicated by an infection. Two patients had dysphagia that required intervention (esophagogastroduodenoscopy), one of which was found to have a stricture in the gastric sleeve and the second patient had no identifiable defects. There were no strictures noted in the gastrointestinal anastomosis in this data set. Table 2 highlights all the operative outcomes.

Postoperative nutritional data such as vitamins A, D, B₁, and B₁₂ and serum albumin were also analyzed. The lab results were available for a total of 78 (68 %) patients. Overall mean values for the nutritional data were close to normal (refer to Table 4).

Table 2 Operative outcomes

Outcomes	<i>n</i> (%)
Diarrhea	2 (1.6)
Abdominal hematoma	4 (3.2)
Infected abdominal hematoma	1 (0.8)
Stricture in gastric sleeve	1 (0.8)
Stricture in gastrointestinal anastomosis	0 (0)
Overall procedure time (min) ^a	96.1 ± 42.7
NY subset ^a	147.7 ± 42
UT subset ^a	78.6 ± 25.4
Length of hospital stay (days) ^a	2 ± 0.9
Under 30-day readmission rate	2 (1.6)
Reoperations	1 (0.8)

^a Values are expressed as means ± SD

Weight Loss Analysis

The weight loss data were categorized into five sections as demonstrated in Table 3. Out of a sample size of 123, 114 patients were included in the weight loss regression analysis. Nine patients did not follow up after the day of surgery, and their data were included only in the analyses of operative outcomes. In the first month, an average change in BMI of 5.4 BMI units was noted, which translates to an average of 20 % of excess weight loss (EWL). Patients had about 33 lb of total weight loss (TWL) in the first month, which almost doubled to an average of 64 lb by the sixth month. At a 1-year mark, patients had an average change in BMI close to 19 units, which correlates to about 84 % loss of excess BMI.

A site-site comparison between New York and Utah patients was performed. There was no significant difference in preoperative BMI (mean 49.6 kg/m² for NY and 49.4 kg/m² for UT) between the two populations. However, the difference in age was found to be statistically significant ($p=0.003$) with the mean age of 46 for NY and 52 for UT patients. The EWL for both populations after the SIPS procedure was found to be similar. The reason for a larger sample in the Utah group is likely due to a single insurance benefit in Utah. This makes it more difficult for patients to undergo two-stage procedures (excluded in our analysis), thus having more patients opt for SIPS initially.

Discussion

Our study demonstrates that SIPS is an effective weight loss procedure that requires a further and more detailed study. Certainly, the weight loss results are encouraging. In addition, they were obtained in a cohort that had an average BMI of almost 50, with nearly identical data at two different sites.

Analyses of our results suggest that on average, patients will lose over 19 BMI units, 1 year from surgery. As with any retrospective analysis, limitations exist. Patients follow up at different intervals and also miss appointments. That being stated, weight loss is impressive and based on historical comparison greater than vertical sleeve gastrectomy (VSG).

The original concept of BPD as advocated by Scopinaro et al. [6] and modified to the duodenal switch by Hess et al. [1] and Marceau et al. [7] is to create a large gastric pouch to allow adequate intake and rely on the passage of ingested food into the fecal stream. These surgeons suggested a bougie size of 60 French and common channels generally under 100 cm. Four to six bowel movements daily were to be expected as reported in these studies.

Recently, a randomized trial compared RYGB to DS in super-morbidly obese patients [8]. DS patients had much greater weight loss (22 BMI units in DS compared to 13 in RYGB) identical to satisfaction scores but a higher chance of revision and gastrointestinal disturbances. Editorial comments attached to the article expressed concerns about the DS. On the other hand, the article clearly showed that 5-year weight loss in this cohort with gastric bypass was not sufficient to reduce their BMI to either expected or their desired level. As a result, there is a great unmet need for an operation that has greater efficacy than RYGB and fewer side effects than standard DS.

The theory behind SIPS is to combine a vertical sleeve that is slightly larger than standard VSG, with an intestinal shortening procedure. By shortening intestinal length, combined with resection of the fundus and greater curvature, food consumed reaches the distal intestine more rapidly. We believe that this stimulates the cells in this region to release incretins that alter hunger and satiety. The preservation of 3 m of the intestine along with the ileocecal valve may reduce the risk of malnutrition and diarrhea. As there is no clear anatomic boundary that separates the jejunum from the ileum, we are not sure that a duodenal ileostomy is actually performed. Our goal and philosophy is to stimulate the distal small intestine but not to promote poor absorption and diarrhea. We do not want to convey that a duodenal ileostomy is part of the procedure. The term ileostomy perpetuates the concept of frequent bowel movements, which is not our objective. We also want to emphasize the preservation of the pyloric valve (pyloric sparing (PS)). The pylorus provides control of solid emptying, reducing the chances of dumping syndrome and assisting in maintaining a physiologically based rate of gastric emptying. Thus, with SIPS, our hope is that we can provide an efficacious procedure that offers improved quality of life,

Table 3 Follow-up weight loss data

Duration	1 month (<i>n</i> = 112/114)	3 months (<i>n</i> = 104/114)	6 months (<i>n</i> = 92/114)	1 year (<i>n</i> = 64/102)
Change in BMI (kg/m ²)	5.4 ± 0.7	10 ± 0.4	14.4 ± 0.5	19.2 ± 0.5
Excess BMI loss (%)	23.5 ± 2.7	43.9 ± 2	63.5 ± 2.4	84 ± 6.3
Total weight loss (lb)	33.9 ± 4.9	64.8 ± 3.3	93.5 ± 3.7	121.9 ± 3.7
Total weight loss (%)	10.8 ± 0.8	20.1 ± 0.6	29.1 ± 0.7	38.6 ± 0.7
Excess weight loss (%)	20.3 ± 1.9	38.4 ± 1.5	55.4 ± 1.7	72.3 ± 1.7

Values are expressed as means ± confidence interval

reduction in hunger, and increase in satiety while minimizing diarrhea and frequent bowel movements. Only long-term follow-up will be able to determine whether we can meet these lofty goals.

Some may question whether another modification of currently preformed procedures is necessary. As mentioned in the introduction, DS and BPD offer the greatest weight loss and lowest recidivism of any studied surgical weight loss procedure. Yet, they remain performed and offered by few surgeons. New data may make many reconsiderations. Unfortunately, weight loss may not be adequate with VSG and RYGB for those with super-morbid obesity [9–12]. Recidivism appears to be a significant issue in this subpopulation. Furthermore, following RYGB, recurrence rates of diabetes that approach 30 % have been reported [13–15]. For those with profound insulin resistance, RYGB may not be the best metabolic procedure. An approach that has the efficacy of DS, but is technically simpler and reproducible and limits concerns about micronutrient deficiencies and malnutrition, would be the most attractive addition for many practices.

A more significant cause for increased interest is finding an acceptable approach for post-VSG recipients with weight regain or inadequate weight loss. Conversion to RYGB does not seem to be effective [16], and conversion to conventional DS is very concerning due to its high complexity and risks of malnutrition. As a result, although performed as a primary procedure in this study, we believe that our results will stimulate discussion as to whether SIPS is an alternative for this patient population.

In the evaluation of a new concept, there are multiple things to consider such as technical difficulty, early procedure-related complications, and potential issues that are caused by the new anatomical configuration. Our early complication profile is consistent with other procedures that involve stapling and reconstruction. Unfortunately, there will always be a risk of bleeding (4 patients) and infection (1 percutaneous drainage). In this early series, there were no anastomotic leaks or perioperative surgical mortality. It is important to note that both surgeons have had previous experience encircling the duodenum. Thus, there was no case of postoperative pancreatitis, stump leak, or adverse consequence of periduodenal dissection.

The major difference between SIPS and DS is the absence of the distal anastomosis. It is essential to discuss the advantages and disadvantages of a Roux construction. A Roux construction has been standard for most American bariatric surgeons. Assets include eliminating bile reflux, the ability to reach the top of stomach and even distal esophagus, and the ability to separate food from the biliary and pancreatic juices.

Does bile reflux need to be avoided especially in a post-pyloric construction? It is imperative to point out that bile is always present in the duodenum and is a normal finding on endoscopy. With a post-pyloric construction, we cannot

believe that gastric exposure would be considerably different than following VSG. The importance of biliary diversion has been a source of international debate. The majority of American bariatric surgeons have not adapted mini-gastric bypass (MGB) popularized by Dr. Rutledge [17, 18]. Internationally, this procedure continues to gain popularity [19, 20]. Those against this procedure highlight the risk of late cancer caused by excessive exposure to bile [18]. Proponents emphasize the data that has been accumulated over the past 10 years and the low rate of people requiring revisions from the loop reconstruction [21]. It is essential to understand the profound difference between SIPS, SADI, and MGB. For SIPS and SADI, this is a post-pyloric reconstruction; thus, bile is brought back to the point that it originated. Unless there is a distal obstruction or a nonfunctioning pylorus, gastric exposure should not be increased over baseline. Additionally, as the duodenal cuff is much lower than the gastric pouch, a Roux is not needed to provide length.

Advocates for Roux limbs cite a significant and important study published in the *Annals of Surgery*. This study compared a Roux-en-Y reconstruction to Billroth II in patients who had ulcer disease. They found a higher incidence of gastritis and esophagitis in Billroth II 10 years post-surgery [22]. The alarming aspect of this data is that it takes many years to develop a pouch cancer. As a result, it is reasonable to extrapolate that the risk of pouch cancer would be greater in loop patients than Roux patients following surgery. Although they have not been many reports of cancers following MGB, many remain cautious. There are profound differences in SIPS to the Billroth II done for ulcer disease. In ulcer disease, there is a proximal loop draining directly to the stomach. In SIPS, the anastomosis is several meters downstream and past the pyloric valve. As a result, we would speculate that bile exposure should be less than that seen in sleeve gastrectomy.

Finally, what is the contribution of a separate alimentary limb, biliopancreatic limb, and common channel in bariatric surgery? Is there an advantage, or is the total bowel length used for food ingestion the critical variable? Our early data suggests that effective weight loss can be achieved without this separation. While our study did not quantitate the gastrointestinal quality of life and symptoms, our low readmission rate and absence of early revisions are encouraging.

What are the potential disadvantages of a Roux configuration? The bowel needs to be divided which injures the intestinal pacemaker. There is the theoretical risk of Roux stasis syndrome [23]. A Roux limb is a pedicle; thus, there is a risk of vascular compromise and subsequent leak and/or stricture. A distal anastomosis has to be performed to recreate intestinal continuity. This means that there is a risk of complication from this attachment that includes leak, stricture, intussusception, and obstruction. It takes time to create the anastomosis, and there is the monetary cost of additional time and staplers. A mesenteric defect is created that can be a site of intestinal

obstruction. Of course, none of these concerns are sentinel or we could not have performed the high number of Roux-based procedures that have been done for surgical weight loss. But, that does not mean that we should not raise the question. Within our entire subset, not a single patient required therapeutic endoscopy for anastomotic stricture or marginal ulcer. In addition, there were no readmissions for small bowel obstruction. Only further follow-up can determine whether the avoidance of a distal anastomosis can reduce the incidence of post-bariatric surgery bowel obstruction. However, this is a major issue. Internal hernias and bowel obstruction requiring resection has been a source of major morbidity and mortality. Patients have required bowel transplantation and been permanently disabled [24]. While rates have decreased with a better technique and closure of potential spaces, it still occurs. There is still a potential space present in SIPS, the area under the small bowel that is brought up for the loop construction. To date, we have not encountered any migration into this space causing obstruction. Additionally, this has also not been reported by Dr. Sanchez and Dr. Torres with SADI procedures [3]. Yet, it is an area that requires close monitoring. Should migration occur, techniques to close this potential space have to be developed. Our concern would be to make a large space, where spontaneous reduction can happen, and convert to a small space that could be a source of incarceration and strangulation.

Another theoretical concern is an afferent loop syndrome [25]. To date, we have not encountered this with any patient. A major limitation of our data is that it is a retrospective analysis. As a result, patients were followed up by a standard practice. It is our intention to see our patients every 3 months for the first year with blood work at 3 months and 1 year. Unfortunately, blood work is obtained at a variety of dates and the majority of patients did not have a preoperative measurement of micronutrients to allow calculation about the risk of acquired deficit. Our rate of diarrhea and need for readmission were low. The admissions for poor intake responded favorably to rehydration and nutritional counseling with close aftercare to

check on intake. No patient required outpatient TPN or feeding tube. A realistic concern regarding a primary SIPS, DS, or SADI is a loss of follow-up and a lack of compliance with supplements. Our patients were placed on the identical vitamin and mineral supplements as our standard DS patients (Table 4). This analysis is not intended to answer these critical questions or mitigate these realistic concerns. The mean albumin for our patients at ≥ 12 months was 3.9 which is normal. The range for that subset is 2 to 4.9. This includes two patients who had albumin levels of 2 and 2.5. The first patient developed mononucleosis during the collection date and had significantly low nutritional intake. The patient's albumin has now rebounded and is normal. The second patient had a mid-gastric sleeve stricture during the data analysis which led to dysphagia and decreased intake. The patient has since been dilated, and her lab results are now normal.

What our data clearly demonstrates is that SIPS has effective early weight loss results that are reproducible at two sites. While there is surgical risk, the perioperative complication profile is similar to historical reports of other reconstructive procedures. There have been no alarming early consequences for not having proximal biliary diversion. Weight loss does not seem to be compromised by the absence of separate limbs. A sleeve size over a 42-French bougie appears to be an adequate size to allow intake of enough liquids and calories to prevent symptomatic dehydration and protein deficiency. Instead of an alimentary limb and common channel, a single intestinal path that is 3 m long is created which is in contact with an ingested material. As the average intestinal length ranges from 6 to 8 m, we believe that we are attaching to the mid portion of the gut. Two patients reported diarrhea, and none required surgical intervention to this point. Analysis of the current data set was sufficient to get funding for the prospective multicenter SIPS clinical trial (ClinicalTrials.gov identifier: NCT02275208) that is now ongoing. We believe that this prospective data that will mandate synchronous follow-up will be important in deciphering the potential advantages of our approach.

Table 4 Postoperative nutritional data

Months	Vit D	Vit B ₁	Vit B ₁₂	Vit A	Albumin
≥ 1 ($n = 78/114$)	34.1 ± 16.8	121.9 ± 60.4	963.6 ± 530.6	39.5 ± 15	4 ± 0.5
<i>R</i>	11–121	6–233.5	253–3084	10–83	2–4.9
≥ 6 ($n = 58/92$)	35.9 ± 17.7	123.9 ± 62.4	1000.5 ± 457.9	41.4 ± 16	4 ± 0.5
<i>R</i>	11–121	7–233.5	253–3084	10–83	2–4.9
≥ 12 ($n = 31/64$)	38.1 ± 22	132.2 ± 58.4	1011.4 ± 632.9	44.2 ± 17.4	3.9 ± 0.6
<i>R</i>	11–121	12–233.5	253–3084	15–83	2–4.9
Normal levels	30–100	70–180	200–1100	38–98	3.5–5

Values given in means \pm standard deviation

R range

Conclusions

In summary, our early results are encouraging. Additionally, we will continue to closely monitor this cohort to determine whether any require conversion to standard DS or other revisions. With those caveats, our early results have added to our belief that a Roux limb is not necessary following post-pyloric bariatric surgery. Furthermore, elimination with preservation of adequate bowel length may improve outcomes and accessibility for post-pyloric bariatric surgical procedures. Future studies are needed to further evaluate the SIPS procedure and assess long-term complications.

Compliance with Ethical Standards This article does not contain any studies with human participants or animals performed by any of the authors.

Conflict of Interest Brian Mitzman has no conflicts of interest to declare. Daniel Cottam is a teaching consultant for Medtronic/Covidien and Vision Medical Sciences. Richie Goriparthi has no conflicts of interest to declare. Samuel Cottam has no conflicts of interest to declare. Hinali Zaveri has no conflicts of interest to declare. Amit Surve has no conflicts of interest to declare. Mitchell Roslin is a teaching consultant for Johnson & Johnson Incorporated and Medtronic/Covidien Limited where he receives compensation. He is also in the scientific advisory board at SurgiQuest and ValenTx and has stocks options in them.

Informed Consent For this type of retrospective study, formal consent is not required.

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