



# Multisite study of Titan SGS stapler in longitudinal gastric resection

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## Abstract

**Background** Standardization of the laparoscopic sleeve gastrectomy procedure is needed to improve patient outcomes. A single-fire 23 cm stapler was developed to streamline the operation. Comparative testing conducted on excised human tissue has demonstrated the superiority of the novel Titan SGS stapler to two commonly utilized commercial devices in both staple line integrity and burst pressure. We hypothesized that the stapler would be safe and effective in creating longitudinal gastric resections in human patients.

**Methods** 61 patients were enrolled to undergo gastric resection with the Titan SGS stapler. Perioperative interventions and post-operative adverse events were recorded. Upper GI study was completed on post-operative day 1, and patients were followed for 6 weeks post-operatively to determine any subacute device-related adverse events.

**Results** Surgeon feedback for intraoperative device utilization and post-operative gastric pouch shape were positive. Adverse events were found to be mild, limited, and generally well-known effects of bariatric surgery. One episode of post-operative hemorrhage required surgical takeback, with no criminal bleeding vessel identified.

**Conclusion** The Titan SGS stapler is both safe and effective in sleeve gastrectomy pouch creation.

**Keywords** Stomach stapling · Surgical staples · Sleeve gastrectomy

As the prevalence of obesity continues to surge in the United States, with rates in the adult population greater than 42% in 2018 [1], laparoscopic sleeve gastrectomy (LSG) has become the most common bariatric procedure performed, accounting for 61.4% of all bariatric procedures completed in 2018 [2]. Numerous studies have confirmed both the efficacy and safety of this procedure [3–6]. However, differences

in operative techniques such as oversewing, bougie size, and distance of the staple line from the pylorus may lead to less than optimal outcomes [7]. Ideal tubular sleeve anatomy is achieved in less than 40% of radiologically studied sleeves resulting in variable outcomes for the patients, including reduced weight loss efficiency and gastroesophageal reflux [8]. Recent efforts have been made towards standardization of the procedure in order to improve patient outcomes, decrease operative time, and reduce costs [9, 10].

The Titan SGS stapler is a novel stapling device that was developed to optimize and streamline the LSG operation, utilizing a single-fire staple mechanism instead of at least three staple loads required to traverse the length of the gastric greater curvature. The proposed benefits of this stapler include decreased operative time, removal of junctions in the staple line, and elimination of angulation between staple loads. Without multiple crossed staple lines, the Titan eliminates the surgeons' search for and removal of the migratory "crotch staple" which has been identified as a risk of leak [11]. Comparative testing conducted on excised human tissue revealed the superiority of the Titan SGS stapler to two commonly utilized commercial devices in both staple

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line integrity and burst pressure, noting that over one third of experimentally created leaks occur at stapler junctions [12]. The Titan SGS has additionally been demonstrated as safe and effective in gastric resection in acute and chronic porcine studies.

This study is the first experience for use of the Titan SGS stapler in humans. The purpose of this study was to demonstrate the safety and usability of the Titan SGS stapler in creating longitudinal gastric resections, with safety defined by the absence of device-related adverse events in the study period and usability evaluated based on surgeon impression of the device and resulting gastric pouch following each use. We hypothesized that use of the Titan SGS stapler would be both safe and effective in longitudinal gastric resection.

## Materials and methods

This was a multisite, open-label study of the Titan SGS stapler for use in longitudinal gastric resection. The study protocol was approved by the Institutional Review Board at Advarra (Pro00041969) with reliance reviews performed at each clinical site. The investigational device study was conducted under a Food and Drug Administration (FDA) investigational device exemption (IDE) G200085. The trial was carried out in accordance with International Conference on Harmonization Good Clinical Practice (ICH GCP) and the United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56 and 21 CFR Part 812) and was registered on clinicalTrials.gov (NCT04347837).

### Titan SGS stapler

The Titan SGS is a single-use sterile stapler used for stapling and cutting during laparoscopic and open surgical procedures. This novel stapler is designed for single-staple load creation of a longitudinal gastric resection line. The device forms staples in the standard “B” shape to secure targeted tissue that uniquely (compared to current commercial staplers) range in closed staple height of 1.2 to 2.2 mm along the single-staple line. The stapling device along with its cable and power supply unit are seen in Fig. 1. A representative image of the stapler traversing the gastric curve, prior to, and after firing staples is shown in Fig. 2. It is used with the Standard trocar, a 19 mm trocar which is adaptable for use with standard laparoscopic instruments, shown in Fig. 3.

### Patients

Participants were selected from the trial physicians’ existing patient populations and screened for eligibility. Inclusion criteria were defined as patients age 18 to 65 undergoing a



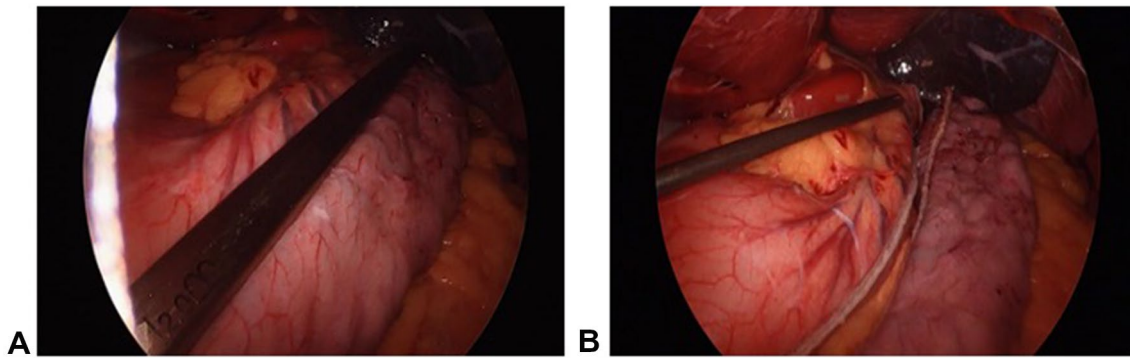
Fig. 1 Titan SGS stapling device and power cord

procedure requiring longitudinal gastric resection including laparoscopic sleeve gastrectomy, laparoscopic gastric wedge resection, and laparoscopic duodenal switch. Exclusion criteria included incarceration, prior gastric or foregut surgery, pre-existing bleeding disorder, systemic anticoagulation, and significant organ system disease (Stage III chronic kidney disease, liver cirrhosis, congestive heart failure with ejection fraction < 50%, COPD with oxygen requirement, or uncontrolled diabetes mellitus as defined by hemoglobin A1c > 10). Qualifying patients were enrolled between July 2, 2020 and November 3, 2020 and underwent informed consent and documentation with trained study personnel.

### Endpoints

The primary endpoint of this study was the rate of Device-Related Adverse Events (DRAEs) with a defined performance goal of 2 or fewer events, with secondary endpoints being the rate of Unanticipated Device-Related Adverse Effects (UADEs) by seriousness, as well as the rate of anticipated non-serious events, and the usability of Titan SGS in longitudinal gastric resection. DRAEs were defined as follows:

- Post-operative leak as defined by positive intraoperative air bubble leak test, post-operative upper GI or CT evaluation by radiologist, or re-operative findings consistent with gastric leak
- Abdominal/deep space abscess
- Staple line bleeding requiring transfusion or re-operation either intraoperatively or post-operatively within the first 72 h of surgery start time
- Gastric stricture as defined by the need for reintervention (such as balloon dilation) or re-operation (such as conversion from a sleeve gastrectomy to a Roux-en-Y gastric bypass) for stricture, and
- Injury to surrounding tissue as defined by intraoperative repair of an adjacent organ (small or large bowel repair or resection due to injury, repair of the diaphragm, repair



**Fig. 2** Intraoperative view of Titan SGS Stapler configuration with stomach in gastric resection **A** before and **B** after firing



**Fig. 3** 19 mm Standard Trocar for use with Titan SGS stapler

of the liver, repair or removal of the spleen) need for re-operation for missed injury directly due to the stapler

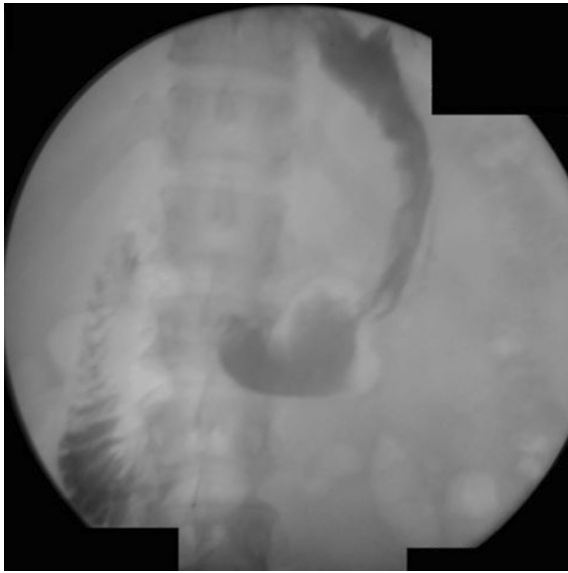
### Perioperative care and follow-up

Demographic data were collected pre-operatively including age, sex, race, height, weight, and indication for operation. Intraoperatively, longitudinal gastric resection was undertaken as the surgeon would perform the procedure in standard form. After mobilization of the stomach, the Standard Trocar was placed (Fig. 3), and the Titan SGS stapler (Fig. 1) was introduced. A timeout was taken prior to firing to ensure proper placement of the stapler along the gastric curve (Fig. 2A). After firing the stapler, the resultant anatomy was assessed for bleeding immediately, and any interventions for hemostasis noted (Fig. 2B). An air bubble leak test was then performed. The resected portion of stomach was removed from the Standard Trocar site and analyzed for tissue thickness. Trocar sites were closed according to routine surgeon practice. On post-operative day 1, an upper GI study was obtained per local protocol (as demonstrated in Fig. 4). Both surgeon and radiologist assessment were collected.

The index hospital stay was recorded in terms of length of stay and any adverse events. Readmissions, if any, were recorded and adverse events noted. A 6-week follow-up period was included to determine the occurrence of any possible subacute device-related adverse events.

### Statistical methods

Statistical analysis was performed using SAS version 9.4 (SAS Institute Inc., Cary, NC 27513, USA). Continuous variables were summarized using the following standard descriptive summary statistics: number of observations, arithmetic mean, standard deviation, minimum, lower quartile, median, upper quartile, and maximum. Categorical data were described using absolute and relative frequencies.



**Fig. 4** Example of Upper GI study

Confidence intervals were to be understood as two-sided confidence intervals.

## Results

Sixty-two participants were enrolled between July 2, 2020 and November 3, 2020, and a 6-week follow-up visit to assess any additional adverse events was conducted for all evaluable participants. All participants completed study follow-up. 61/62 patients met all inclusion and exclusion criteria. One participant was mistakenly enrolled after failure to pre-operatively recognize the exclusion criterion of Stage III CKD. This participant was excluded from the per-protocol analysis. A summary of the patient demographic data is included as Table 1, categorized by surgical procedure. Study inclusion criteria specified patients requiring longitudinal gastric resection including LSG, laparoscopic gastric wedge resection, and laparoscopic duodenal switch/loop duodenal switch.

Intraoperatively, interventions were used to manage minor bleeding along the staple line. As these maneuvers are common in LSG practice, they were not considered adverse events. Intraoperative interventions utilized are included in Table 2. The mean duration of the procedure was 85.6 min with a minimum of 32 min and a maximum of 139 min. Study endpoint evaluations for patients enrolled are summarized in Table 3. Surgeon feedback was overwhelmingly positive, as well as feedback from enrolled patients at follow-up.

A study stopping rule was included in order to pause the study in the event that greater than two DRAEs occurred during this study. This threshold was not met over the

duration of the study period. Adverse events were collected through 6-week follow-up for all participants. There were no UADEs reported during the study. A review of the adverse events by classification is summarized by type in Table 4. These adverse events were found within the study population but are also common among patients undergoing LSG.

The one DRAE which occurred during the study was a staple line bleed. The patient experienced post-operative tachycardia without hypotension and did not require administration of blood products but underwent takeback operation for abdominal washout per surgeon discretion on post-operative day 1. No specific bleeding vessel identified at the time of re-operation and the patient was discharged to home on post-operative day 2, prolonging the hospital stay by one day.

There were two other bleeding complications in the study that were determined to not be due to the staple line. One was a post-operative hemorrhage requiring transfusion from a peri-splenic vessel partially torn and inadequately addressed during dissection. This attribution was based on procedural video review by operating surgeon and study PI. The other bleeding event was a delayed bleed from the duodenal dissection bed observed on diagnostic laparoscopy at post-operative day 7. This attribution was based on CT scan and takeback video reviewed by operating surgeon and study PI. Additionally, this patient had been discharged on prophylactic rivaroxaban (2.5 mg BID), which may have been a contributing factor to the delayed bleeding event.

## Discussion

This multicenter study aimed to determine the safety and efficacy of a newly available linear gastric stapler, the Titan SGS, for use in longitudinal gastric resection. Laparoscopic sleeve gastrectomy has become the most common bariatric procedure performed in the United States, and alongside the loop duodenal switch, which was also performed on this patient population, needs standardization for optimization of outcomes. This stapler was created to simplify and streamline the procedure, which could minimize surgeon variability, lead to shorter operative times, and improve standardization of the sleeve structure.

The Titan SGS stapler evolved from the Standard Clamp (Standard Bariatrics, Cincinnati, OH), a 25 cm disposable atraumatic tissue clamp designed to guide stapler placement along the gastric curvature [13]. This clamp, which has been used in over 10,000 laparoscopic sleeve gastrectomies, allows for fixation of the full gastric staple line before and during staple fires for a clear visualization of the linear cut in order to avoid zig-zag or spiraling of the staple line. All four participating surgeons had previous experience with use of the Standard Clamp in longitudinal sleeve gastrectomies.

**Table 1** Patient demographic data

	Laparoscopic sleeve gastrectomy ( <i>N</i> = 52)	Laparoscopic duodenal switch/loop duodenal switch ( <i>N</i> = 9)	All participants ( <i>N</i> = 61)
Age (years)			
Mean (SD)	40.1 (9.99)	44.0 (10.27)	40.7 (10.04)
Sex [ <i>n</i> (%)]			
Female	41 (79)	8 (89)	49 (80)
Male	11 (21)	1 (11)	12 (20)
Height (cm)			
Mean (SD)	167.5 (9.87)	166.6 (8.37)	176.4 (9.60)
Weight (kg)			
Mean (SD)	129.1 (25.97)	131.7 (29.18)	129.5 (26.23)
BMI (kg/m <sup>2</sup> )			
Mean (SD)	45.9 (7.45)	47.6 (10.89)	46.2 (7.96)
Race [ <i>n</i> (%)]			
Black	11 (21)	2 (22)	12 (21)
White	41 (79)	7 (78)	48 (79)
Ethnicity [ <i>n</i> (%)]			
Hispanic or Latino	2 (4)	1 (11)	13 (21)
Non-Hispanic, Non- Latino	37 (71)	8 (89)	45 (74)
Unknown/Not reported	13 (25)	0 (0)	13 (21)
ASA class [ <i>n</i> (%)]			
Mild Systemic Disease	12 (23)	0 (0)	12 (20)
Severe systemic disease	38 (73)	5 (56)	43 (70)
Severe systemic disease/Constant threat to life	2 (4)	4 (44)	6 (10)
Diabetes [ <i>n</i> (%)]			
No	39 (75)	4 (44)	43 (70)
Yes: Insulin	5 (10)	2 (22)	7 (11)
Yes: Non-Insulin	8 (15)	3 (33)	11 (18)
Functional status [ <i>n</i> (%)]			
Independent	52 (100)	9 (100)	61 (100)

**Table 2** Staple line interventions

	Per-protocol population <i>N</i> (%)
Any intervention to manage minor bleeding along the staple line [ <i>n</i> (%)]	
≥ 1	39/61 (64%)
None	22/61 (36%)
Clips used to manage minor bleeding along staple line [ <i>n</i> (%)]	
No	47/61 (77%)
Yes	14/61 (23%)
Cautery used to manage minor bleeding along staple line [ <i>n</i> (%)]	
No	41/61 (67%)
Yes	20/61 (33%)

The Titan stapler is an advancement from this, removing the need for repeated or overlapping short staple fires. With the ability to plan and place a single line of staples in one fire, surgeon and device variation are removed, to maximize consistency in sleeve gastrectomy outcomes.

Study endpoints were met with no deviation from expected outcomes. (Need to expand on this some.) Adverse events by classification were all anticipated relating to the procedure and in line with what is currently ordinary standard post-operative events. Most adverse events were

**Table 3** Summary of study endpoint outcomes—Per Protocol population

Primary endpoint	Study outcome-per-protocol population <i>N</i> (%)
Rate of Device-Related Adverse Events (DRAEs)	1/61 (1.6%)
Secondary endpoints	Study outcome-per-protocol population <i>N</i> (%)
Rate of Unanticipated Device-Related Adverse Effects (UADEs) by Seriousness	0/61
Rate of Anticipated, non-serious events	59 AEs in 34 participants
Rate of Serious Adverse Events (SAEs) by relatedness	1/61 (1.6%)
Usability of the Titan SGS to resect the stomach as determined by intraoperative assessment by the Surgeon	61/61 (100%) rated acceptable

**Table 4** Summary of AEs by type—Per-protocol population

AE	Count	Severe Count	SAE	Ongoing
General				
Pain (not specific to incisions)	6			
Fatigue/ lethargy	4			2
FEN/GI				
Nausea/ vomiting	7			1
Constipation	15			3
Stomach virus	1			
H. Pylori	1			
Hypokalemia	1			
Hunger	1			1
Dehydration	2			2
Dysphagia	2			
Reflux/heartburn/indigestion	3			2
Cardiovascular				
Orthostatic hypotension	1			
Pulmonary				
Negative eval for PE and pneumonia	1			
Hematological				
Staple line bleeding	1	1	1	
Post-op Hemorrhage requiring transfusion	1	1	1	
Post-op hematoma	1		1	
Integumentary				
Wound erythema or itching	2			
Incisional pain	2			
Rash	2			
Wound seepage or hematoma	3			1
Infectious				
COVID-19	3		1	
Gynecologic				
Yeast infection	1			
Bacterial vaginosis	1			1
Urologic				
Kidney stones	1			
Hematuria	1			
Total	64	2	4	13



classified as mild, with full recovery and no ongoing sequelae, and the majority of events were related to nausea and constipation, both well-known post-operative effects of bariatric surgery. The rate of the use of any intraoperative bleeding interventions was comparable with findings in the literature for currently available staplers (58% use with Ethicon Echelon GST vs 64% use with Titan SGS.) [14] Surgeon feedback was positive, in both ratings of the Titan SGS stapler performance, and of surgical outcomes in gastric pouch formation. Additionally, no leaks were detected on upper GI study routinely performed on all participants.

The one device-related adverse outcome of early post-operative bleed requiring re-operation was an anticipated adverse event expected with this procedure and use of staplers in general. Post-operative hemorrhage is an unfortunate and rare complication that is discussed with patients as a risk of any major invasive procedure. Overall incidence of post-operative bleeding in bariatric surgery is reported to be 3% [15], with half of this due to hemorrhage at the staple line [16]. This patient represents 1.6% of our study population, comparable to the current benchmarks in bariatric surgery. This patient's complication was identified rapidly after a syncopal event with tachycardia on the patient care floor post-operatively. The patient was intervened on acutely and intraoperatively there was no actively bleeding vessel, cut momentum, or avulsed tissue identified. The patient recovered well, was released to home on post-operative day 2, with no sequelae of the event. Taking into account the three bleeding events—one device related and two not device related—the overall bleeding event rate for this study was 4.9% (3/61). Although this rate is above the published 3%, the staple line specific bleeding rate was 1.6%, which is comparable to the published 1.5% benchmark in laparoscopic sleeve gastrectomy.

A limitation of our study is the small sample size of both patients and participating surgeons. Given the overall population of 62 patients and an expected clinical leak rate of 1%, there may not have been enough patients enrolled to have demonstrated a clinically appreciable leak rate, as well as other very low incidence adverse effects. Future studies will be appropriately powered for low incidence outcomes, including staple line bleeding and staple line leak rates.

Previous studies have shown that optimal stapler selection during LSG is of utmost importance [17]. Regarding staple height, taller staples with under compression of gastric tissue can lead to decreased integrity of the staple line, predisposing to leaks or bleeding [18]. However, over compression of the staple line has been historically thought to cause ischemia and also lead to complications [19]. More recent data, however, supports increased compression leading to improved outcomes, with increased hemostasis, decreased incidence of leak [20], and potentially decreased stricture rates [21]. The Titan SGS stapler operates using

a graduated staple height formation optimized for gastric tissue [22]. This removes surgeon variation or inaccuracy from the choice of staple height, and outcomes were shown to be consistent with current expected outcomes. The proven safety and efficacy of this stapler may lead to more consistent operative technique and outcomes in bariatric surgery.

## Conclusion

The Titan SGS stapler was both safe and effective in sleeve gastrectomy pouch creation.

## Declarations

**Disclosures** Dr. Jon Thompson is the founder and CMO of Standard Bariatrics, Inc. Dr. Salyer, Dr. Hoffman, Dr. Burstein, Dr. Enochs, Dr. Watkins, Dr. Kuethe, and Dr. Goodman do not have conflicts of interest or financial ties to disclose. The study was funded by Standard Bariatrics, Inc. via study-specific independent budgeting and contracts with the University of Cincinnati, SUNY Buffalo and WakeMed.

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