SPOTLIGHT ON TECHNOLOGY

A SUPPLEMENT TO *BARIATRIC TIMES*
VOL. 19, NO. 3 • MARCH 2022

BARIATRICTIMES.COM

Standard Bariatrics: A Biodesign Story

This is Part 1 of a two-part series about the journey of a medical device startup to solve an unmet clinical need in bariatric surgery.

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Bariatric Times. 2022;19(3 Suppl 1):S1–S3.

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ABSTRACT

The process of innovation is iterative and messy. The Biodesign innovation process increases the odds of success by making sure innovators are focused on problems worth solving. In this process, the identification of an unmet clinical need is the first step. The best needs are hiding in plain sight - problems you didn't realize you had. The following article outlines the identification of a technical unmet need in bariatric surgery and the journey to solve it.

Keywords: Sleeve gastrectomy, bariatric surgery, stapler, stapling technique, single-fire, obesity, weight-loss surgery, staple line

Innovation in MedTech begins with solving an unmet clinical need. Standard Bariatrics, Inc. is a medical device startup based in Cincinnati, Ohio. Founded in January 2014, the company formed to work on meeting the unmet clinical needs surrounding sleeve gastrectomy pouch creation.

At the highest level of clinical need—the disease state of obesity—we started with one of the most undertreated disease states in medicine. Despite being the most successful treatment strategy, less than one percent of patients who meet the criteria for bariatric surgery receive any form of a bariatric procedure.

This is old news to bariatric surgeons. The thinking went, "If we could find a way to make bariatric surgery seem like gallbladder surgery, which is perceived to be noninvasive and routine to stakeholders (patients, payors, primary care doctors), we might improve the attractiveness of bariatric surgery as a treatment strategy." This came out of the recognition that patients with post prandial right upper quadrant pain and gallbladder are more than likely to have their gallbladder removed even in the absence of an abnormality identified on workup.

Why was there such a low threshold for cholecystectomy but such a high one for bariatric surgery? If we could tweak a bariatric surgery to make it significantly safer and more repeatable, the hope was we could lower the intervention threshold for the surgical treatment of obesity.

INNOVATION PARAMETERS: PLANNING OUR PATH

We didn't want to make a new procedure or have a product that required a premarket approval (PMA) regulatory path, so we looked at the reimbursed bariatric procedures. At the time, the reimbursed procedures in the United States were

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FIGURE 1. Standard Bariatrics Standard Clamp®

FIGURE 2. Standard Bariatrics Titan SGS® stapler

gastric band, Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD-DS) and laparoscopic sleeve gastrectomy (SG). SG was growing rapidly at the time, had better weight loss and reliability than the gastric band, had fewer complications than RYGB and BPD-DS, and was the procedure that carried a perception of being routine and noninvasive like gallbladder surgery.

So, in 2014, what was wrong with SG? The technical complications were much higher than they are today. Leaks and stenoses were greater than one percent. Gastroesophageal reflux disease (GERD) and dysphagia were higher. Length of stay and readmissions were higher. These problems pointed to imperfect pouch anatomy. It appeared that surgeons couldn't create the consistent anatomy they desired using the tools they had available at the time.

After researching sleeve construction, we defined the following technical problem insight: It is hard to make a straight line in floppy, stretchy, two-sided tissue. "Freehanding" with short staplers and a straight bougie results in a high degree of variation in sleeve pouch anatomy. With this, we identified an unmet clinical need that had a technical root cause. If we solved that technical problem, we had the chance to improve the consistency in anatomic output of the sleeve gastrectomy procedure and improve patient outcomes.

THE JOURNEY CONTINUED WITH CLAMP THEN STAPLER

With a technical problem identified, we began brainstorming solutions to make a straight line in floppy, stretchy, two-sided tissue. Clamp ideas seemed to solve the problem, which is why our first business case didn't even contemplate a stapler. Standard Bariatrics, Inc. was going to make a clamp as a stapling guide and partner with stapling companies to help improve the clinical outcomes of SG and make the procedure more attractive to patients.

The idea of a full-length gastric stapler came from our experimentation with gastric clamps. The only clamp prototypes that held along the entire length of the stomach were connected at both ends. Once we realized that we had physics in our favor with this stronger clamp design, we asked, "Can we make a stapler out of this?" The answer was a resounding "Yes!" from Ben Thompson, the first Chief Technology Officer of Standard Bariatrics, Inc., who is now retired.

Ben made a prototype 300mm stapler design to prove the concept with a successful firing in March 2015. Now we had to decide if we should make a clamp or a stapler. This debate lasted several months. Early investors liked the idea of starting with the stapler for the economics (several hundred dollars for a clamp vs. several thousand dollars for a stapler). From my perspective, I didn't think we knew enough about how to clinically use

FIGURE 3. Standard Bougie 38 FR®

a stapler to create a proper design. Conducting clinical development work under investigational device exemption (IDE) clinical studies would be very expensive and would increase the risk to the project.

We decided to make a clamp that we would use clinically and to help us understand how to design the stapler. This could be a business of its own. If the stapler didn't work, at least we would have a small business with the clamp. We would use the clamp to develop the clinical technique and the design requirements for the stapler. We took this one step further and thought, "How can we shorten the development timeline?" We decided to make a reusable clamp that we manufactured in our office. This device had articulation with cable-connected jaws with distal and proximal separation. We received our first United States Food and Drug Administration (FDA) clearance in May 2016.

ANATOMY-BASED SLEEVE DESIGN

Prior to the first cases with our reusable, first-generation standard clamp, we needed a repeatable process to ensure that the pouch was the right size, shape, and distances from key anatomic landmarks. We had market research results showing consensus that surgeons made sleeves 1cm from the gastroesophageal junction, 3cm from the incisura angularis, and 5cm from the pylorus. During clinical sleeve cases, we began identifying these locations with a skin marker tip on a needle driver and used a 60mm stapler through a right-sided trocar without articulation to simulate the function of a straight clamp. This resulted in sleeves that were better than we were

making before. We knew we were on the right track.

We had cadaver lab results that indicated curved sleeve shapes can be made from straight staple lines, so it was not a surprise that this worked. We knew we could move the stomach relative to the stapler to align these marks and get the correct line. It was also well accepted that the staple line should be in the same plane, including equal sides of anterior and posterior stomach in the final sleeve. We would pull the stomach from the cut edge, grabbing equal sides anterior and posterior, and pull at a right angle to the stapler. We used the same technique with the Standard Clamp® (Figure 1), and now with the Titan SGS® stapler (Figure 2).

FIRST CASES WITH THE STANDARD CLAMP

We employed the anatomy-based sleeve design approach to our first cases with our first-generation, reusable standard clamp. We downsized the bougie to an 18FR Salem sump tube, marked the stomach, and introduced the clamp through a right lateral abdominal trocar site. This would give a sleeve size that approximates a 40FR bougie "freehand" sleeve.

During our first cases at the University of Cincinnati in June 2016, we found that it was easier to use our original, reusable standard clamp when we forced the device to clamp from distal to proximal on the stomach. We also found that articulation was unnecessary and potentially harmful. When articulated it was a 25cm long jaw that was hard to control. This led us to immediately update the designs of the Titan SGS stapler and disposable Standard Clamp.

The stapler design became simpler, safer, and more reliable. We also found that the jaw was longer than it needed to be. The data that drove this initial length was the staple line length of sleeves we had made. We discovered that freehand staple lines are inherently inefficient because they meander up, down, and side to side. The staple line created using a clamp is shorter than a freehand staple line. This is a strong value proposition to the hospital because in addition to making more consistent sleeve pouches, using the clamp saves staple reloads.

When we launched the 25cm disposable Standard Clamp in August 2017, the cost savings simplified the value analysis at hospitals. We later launched a 22cm disposable Standard Clamp that was preferentially used by surgeons because the 22cm jaws fit almost all stomachs. Since the first cases in 2016, the Standard Clamp has been used in over 14,000 SG and duodenal switch cases by over 100 bariatric surgeons.

THE STANDARD BOUGIE®

One of the annoying aspects of using the anatomy-based sleeve approach is that the mark 3cm from the incisura angularis is very close to the mark 4–6cm from the pylorus. It takes a lot of retraction finesse to line it up next to the clamp. We found an off-the-shelf bougie solution that helped address this issue. The sizing catheter from Cook® Medical was an 18 French orogastric tube with a spherical balloon at the distal end. We began to use this balloon device to create a reliable internal diameter at the incisura angularis. We placed enough saline in that balloon to inflate it to a 2cm diameter and placed that at the incisura angularis. Then we could secure the clamp next to the bougie all the way down to the antrum. This outcome led to the production of the Standard Bougie 18FR® with a cylindrical balloon at the distal end, a design we carried over to the Standard Bougie 38 FR® (Figure 3) for use with the Titan SGS stapler.

THE PATH OF THE STAPLER

The regulatory path of the Titan SGS stapler was not as straightforward as the staple line it produced. We had preclinical and excised human stomach clinical data showing superior performance of the Titan SGS staple line when compared to long staple lines made with multiple applications of a predicate 60mm stapler. With safety data of the Standard Clamp collected in our Sleeve Equipment and Technique Data Collaborative*, we were confident we could achieve FDA clearance with a 510k without human clinical cases.

We filed our first 510k in November 2019. The FDA requested procedural safety data on the Titan SGS because it is significantly different from the 60mm alligator jaw predicate. We proceeded with the study. Despite the challenges of the pandemic, we were able to get a 60-patient IDE study approved and executed between July 2020 and November 2020. This study was published in February 2022.[1]

We met our endpoints and received FDA clearance in April 2021. The reward for performing the IDE study was that we were able to narrow the indication of the Titan SGS stapler to SG pouch creation. The Titan SGS stapler is currently the only stapler specifically indicated for SG. We launched the Titan SGS stapler in August 2021.

While we are encouraged by its ease of use and performance, we are just getting started developing ways to make bariatric surgery significantly safer and more repeatable to eventually lower the intervention threshold for the surgical treatment of obesity.

ADDITIONAL INFORMATION

*With insights from our scientific advisory board, we created a data collaborative as an addition to the MBSAQIP database. Launched in 2015, the Sleeve Equipment and Technique (SET) Data Collaborative is helping us understand which anatomic sleeve pouch variants were associated with better outcomes.

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FUNDING

This supplement was sponsored by Standard Bariatrics, Inc.

DISCLOSURES

Dr. Thompson is Founder & Chief Medical Officer at Standard Bariatrics, Inc. BT

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