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Tri-Staple™ 2.0 Reinforced Reloads: Preloaded Buttressing for Bariatric Procedures

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Advances in Staple Line Reinforcement

Staple line buttressing is increasingly recognized as a standard of care for an array of thoracic, abdominal, and gastrointestinal resections.[1-3] In fact, the majority of bariatric surgeons were using buttressing for sleeve gastrectomies by 2013,[3] and multiple bariatric surgery studies associate staple line buttressing with a reduction in complications, particularly bleeding.[4,5] Over the past several years, device manufacturers have advanced the materials and device design to optimize strength and seal, and improve procedural efficiency.[6] The incorporation of 3 staple lines and preloaded buttressing material are among the most significant of these advances.[7]

Alfonso Torquati, MD, MSCI, a bariatric surgeon at Rush University Medical Group, in Chicago, Illinois, reinforces the staple line in gastric bypass, sleeve gastrectomy, and revision procedures. Dr Torquati has witnessed the evolution of the technology throughout his career, and although he has extensive experience with numerous stapling devices, he has used the Tri-Staple™ 2.0 reinforced reload (Figure 1) almost exclusively from the time of its introduction and for every case. "When I joined the practice at Rush, we were buttressing with both of the staplers we had available, but it wasn't long before all the bariatric surgeons switched to the Tri-Staple™ device," Dr Torquati said.

Efficiency

Tri-Staple™ reinforced reloads are the only reloads that come with prefixed buttressing, which speeds operating time (Figure 2). In fact, a survey of 250 surgeons and nurses found that using a preloaded buttress saved 7 to 10 minutes compared to a separately loaded buttress.[8,a] According to Dr Torquati, several devices incorporate methods to facilitate loading of the buttressing material, but additional steps can introduce chances for error. "Our OR scrub technicians are much happier with the Tri-Staple™ reinforced reloads. They no longer spend time pulling strings or taking the other required steps to ensure proper alignment," he said. "It means more efficiency during the procedure."[8,a]

The Technology

Reload Size

Tri-Staple™ 2.0 reinforced reloads provide the benefit of individualized color-coded staple loads. The black cartridge is appropriate for extra thick tissue, and has staple heights ranging from 4.0 mm in the innermost row to 4.5 and 5.0 mm in the middle and outer rows, respectively. The purple cartridge is designed for medium/thick tissue and provides staple heights of 3.0, 3.5, and 4.0 mm. Both black and

Figure 1. Tri-Staple™ 2.0 reinforced reloads.

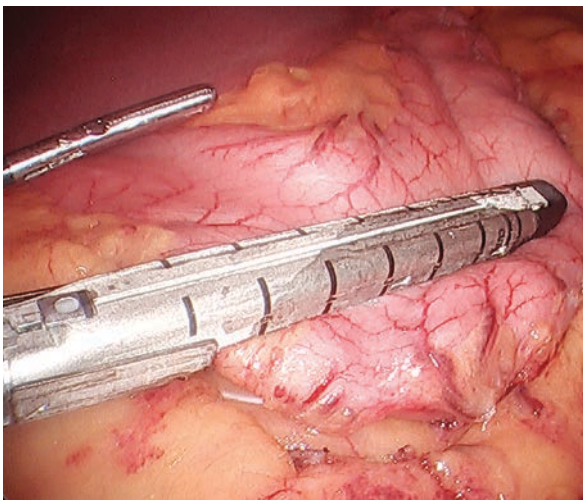

Figure 2. Tri-Staple™ reinforced reloads are the only reloads that come with prefixed buttressing.

purple cartridges are available in 45 and 60 mm lengths. Dr Torquati says he starts with the black loads in most patients and, as appropriate, moves to purple loads for thinner tissue. Occasionally in thick tissue, he will fire 2 staple lines from black cartridges.

Dr Torquati thinks the ability to adjust to tissue thickness represents an important advance in initial bariatric surgeries as well as revisions, which represent a significant proportion of his cases. He typically uses the black reload when tissue is thickened by inflammation to ensure adequate reinforcement. "Different loads allow me to adjust the closure to the patient's anatomy, while the variable height adds strength without impairing the vascularization needed for healing," Dr Torquati said.[9,10,b-d]

The Material

Relative to composite materials, the polyglycolic acid buttressing material used in the Tri-Staple™ 2.0 reinforced reload device was developed with small uniformly packed fibers, resulting in less material mass at implantation with greater strength,[9,b,c] and according to Dr Torquati, this represents an important advance. "This current material is flexible. It is stable but resorbs readily," he said. "In my experience, it is very well tolerated." Dr Torquati estimates that extra reinforcement, such as oversewing, is required in fewer than 1 in 20 of his cases. "An example might be very thick tissue close to the duodenum," he said. "We might also consider a clip for larger vessels when we see oozing, but these are uncommon situations." He added: "The combination of the buttressing material and the 3 rows of staples means it is rarely necessary to use additional reinforcement."

Reduced Bleeding[11,e]

The strength of the closure with Tri-Staple™ 2.0 reinforced reloads is reflected in a "solid" quality at the staple line, according to Dr Torquati. "When attempting to move tissue following closure, there was always a risk of bleeding in the absence of reinforcement. With Tri-Staple™ closures, there is less concern about pulling the tissue in order to move it into view," he said. "The reduction in intraoperative bleeding provides better visualization of the surgical field.[11,f] Less bleeding means less time clearing the field. Better visualization as a result of less bleeding allows me to ascertain during the procedure whether I am achieving a good staple formation."

Research indicates that buttressing (vs not buttressing) the staple line in bariatric surgery is associated with a 30% reduction in postoperative bleeding,[12] and Dr Torquati has found that his bleeding rate is at least as low as what has been reported in the literature since adopting the Tri-Staple™ 2.0 reinforced reloads. His leak rate is even lower.

"Leaks can be a more serious complication than bleeding, but they are rare," Dr Torquati said. In fact, he has had none in his series and attributes this absence of leaks to his reliance on staple line reinforcement. "We perform an endoscopy after every procedure to confirm the quality of the closure within the lumen of the stomach. We have consistently seen good hemostasis. I have not yet needed to perform additional steps on the basis of the endoscopic view," he said.

Smart Technology

The Tri-Staple™ 2.0 reinforced reload has a stepped cartridge face that provides gradual compression across tissue types. Many bariatric surgeons use the reload with the Signia™ stapler, which automatically adjusts speed to improve staple formation when forces increase in challenging applications (Figure 3).[13,14,g] Dr Torquati prefers

to staple without smart technology when demonstrating the fundamentals of closure to his fellows, but he is quick to recognize the advantages of using the technologies together. The Signia™ stapler is fully powered, and he likes the audible feedback and variable speed functions it offers. "With thicker tissue, it is helpful to close at a slower pace," he said. Manufacturer studies have found that adjusting the speed of firing in different tissue thicknesses can reduce the percentage of malformed staples.[13-15,g] Dr Torquati is also enthusiastic about the advantages of smart stapler technology for less experienced surgeons. "It's important to select the appropriate staple size. Staplers that help surgeons assess tissue thickness will be a big help for those developing skill in bariatric surgery," he said.[16,c]

Figure 3. Tri-Staple™ 2.0 reinforced reloads with the smart Signia™ stapler.

Conclusion

The progress in stapling technology for bariatric surgery has substantially reduced patient complications and improved the surgeon's experience.[6-8,12,a] Dr Torquati believes the Tri-Staple™ 2.0 reinforced reload features create procedural efficiencies,[a] provide adequate strength,[g,h] and permit the blood supply necessary for healing.[8,10,17,d] For him, strength at the closure line means less intraoperative bleeding and fewer postoperative complications.[11,18,f] Dr Torquati thus relies on the Tri-Staple™ 2.0 reinforced reload for weight loss surgery.

[a] Compared with an aftermarket buttress. Results based on a sample of 125 OR nurses and 125 surgeons.

[b] In vitro tensile strength compared with Seamguard™ at days 7 and 14.

[c] Bench test results may not necessarily be indicative of clinical performance.

[d] Compared with flat-faced cartridges with single-height staples.

[e] Compared with nonbuttressed reloads.

[f] Based on international consensus of an expert panel of bariatric surgeons.

[g] Preclinical results may not correlate with clinical performance in humans.

[h] Based on a benchtop comparison at 0 and 7 days in vivo (2 sample t-test: P=0.000 and 0.0007).

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