Innovating to Improve Patient Outcomes:
Surgeon, Device, and Tissue Interactions

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Tissue and Surgical Stapler Considerations In Laparoscopic Bariatric Procedures

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Introduction

As bariatric procedures evolve, it is clear that surgeons are using laparoscopic stapling devices in a wide range of tissue thicknesses when performing sleeve gastrectomies and bariatric-related revisional surgery.[1,2] Over the years, stapling enhancements have been made to better accommodate the variety of applications encountered in surgery.[3] Despite these advancements, however, surgeons must possess a comprehensive understanding of tissue and device interaction.

Stapling, Tissue Compressibility, Tissue Thickness

Although surgical stapling has become commonplace in today's bariatric procedures,[1] it should be recognized that there are important considerations between tissue and device interaction that can affect staple line outcomes. When considering thicker tissue applications such as those encountered in bariatric surgery, delivery of compression to the tissue before the stapler is fired (pre-compression) is desired to minimize tissue trauma and maximize staple line performance.[4,5]

As tissue is biphasic, consisting of both solid and liquid properties, compression applied over time prior to firing the stapler allows for tissue to exudate fluid, which in turn reduces stress on the tissue during the firing stroke. When tissue is forcefully compressed, it elongates—a phenomenon called "tissue creep"—which can adversely affect staple line integrity. Rapid compression also can contribute to shearing of the tissue and/or malformed staples. However, with pre-compression, tissue is permitted to reach a point of "stress relaxation" resulting in a reduction in the amount of force required to maintain the tissue displacement.[4]

According to Randal S. Baker, MD, assistant professor of surgery, Michigan State University, Grand Rapids, "optimal stapling consists of allowing adequate time for tissue compression and creep while not producing excessive tensile stress." When sufficient time is allotted for compression, a surgeon should be able to consistently deliver a staple line with uniform staple formation. Previous findings have shown that an applied pressure of 8 g/mm^2 is essential for optimal stapling.[4] It also has been shown that applying pre-compression to tissue, especially as it relates to thicker tissue such as gastric tissue, for 15 seconds increases the staple line performance.[4,5]

Adequate tissue compression and proper staple cartridge selection are a function of and are influenced by the thickness of the tissue being stapled. In a study of 50 patients undergoing vertical sleeve gastrectomy, Elariny and colleagues[1] found that stomach wall thickness varied considerably, with the thickest area occurring near the pylorus, the thinnest area at the proximal end near the esophageal juncture, and thinner along the greater curvature (Figure 1).[1]

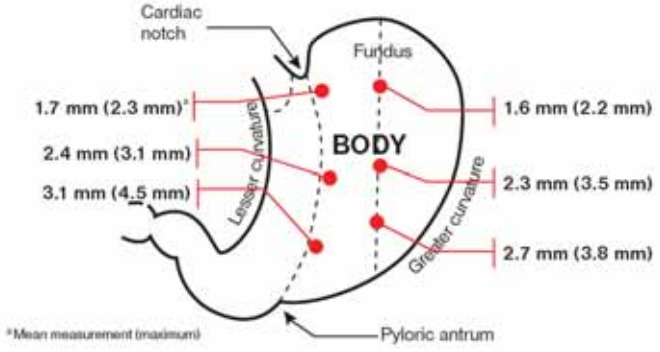

Figure 1. Diagram of the stomach showing tissue thickness measured on excised gastric specimens of obese patients.

Adapted from Elariny H, et al. Tissue thickness of human stomach measured on excised gastric specimens from obese patients. *Surg Technol Int.* 2005;14:119-124.

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It is important to remember that the fundamental expectation of any surgical stapler is to provide tissue approximation and hemostasis without causing ischemia or tearing of the tissue.[6] Thus, it is critical for surgeons to carefully select the appropriate staple cartridge to accommodate the associated tissue thickness being stapled. Due to the various tissue thicknesses encountered in bariatric surgery, various staple cartridges are available that range from thin tissue to thick tissue indications. Typically, the staple cartridge options are gray, white, blue, gold, and green, which represent the staple cartridge color as arranged from smallest to largest in closed staple height dimensions, respectively.

"If you select an undersized cartridge, you increase the risk for inadequate staple formation or excessive tissue compression," said Dr. Baker. "Also, if you use an undersized cartridge and begin near the prepyloric area, you have a good chance of causing shear forces or tearing and ripping of that tissue which will increase the risk for complications. If you're up by the angle of His, you have to be careful not to incorporate the esophagus to avoid complications. If the esophageal tissue is incorporated into the staple line, the consequences can be catastrophic."

Thick stomach tissue requires the use of staples with wider diameters that form longer leg lengths.[4] A comparison study conducted by EES in a porcine gastric model showed that the EES ECHELON FLEX™ (Figure 2) had significantly fewer malformed staples[a] (79% fewer in 4-mm-thick stomach tissue and 62% fewer in 5-mm-thick stomach tissue) when compared with the ENDO GIA®.[7] This study demonstrates that pre-compression applied over time and appropriate staple cartridge selection (in this study a green cartridge was used) are crucial in improving staple line performance in extremely thick tissue.[7]

"We need to continually remind ourselves that each staple cartridge is designed for a specific tissue thickness," added C. Joe Northup, MD, FACS, medical director, Mercy Healthy Weight Solutions, Cincinnati, Ohio. "Selecting the appropriate cartridge is critical to the outcome of the surgical procedure. If the tissue thickness exceeds the cartridge specifications or is thinner than the recommended range, you can end up with serious complications."

Figure 2. ECHELON FLEX™ ENDOPATH® Stapler.

Image courtesy of Ethicon Endo-Surgery.

Complications Associated With Surgery

Strictures and staple-line leaks are the most frequently occurring complications associated with gastric surgery. Early and late anastomotic strictures have been observed in 2% to 6% of laparoscopic cases.[8]

Anastomotic leaks have the potential to cause peritonitis, septic shock, multiorgan failure, and death.[4] Previously reported in approximately 2% to 5% of laparoscopy cases,[2] additional series have reported lower incidences of 0.2% and 0.1% using the same or similar stapling techniques.[2,9] Surgeon experience is cited as a key component of successful patient outcomes.

"Leaks have many different causes," said Dr. Northup. "Ischemic and mechanical/tissue causes make up the 2 major categories. Ischemic leaks are often more delayed following the procedures and are less common. Leaks caused by mechanical/tissue factors, such as those that might occur as a result of selecting the wrong staple load, are the most common. These typically occur within the first 24 to 36 hours of the procedure."

In either case, however, the leak is a consequence of staple-line failure. "Staple-line failure emphasizes the need to create the strongest staple line possible from the beginning," says Dr. Baker. "It will take approximately 6 weeks for the wound-healing process to enter the fibrosis phase. At that point, the wound tissue will have gained enough strength to withstand any mechanical/tissue forces."

[a] Malformed staples are determined by the count of malformed staple legs divided by 2. Thick tissue is defined as 3-mm to 5-mm as measured with an 8 g/mm^2 thickness measuring device. Study conducted by Ethicon Endo-Surgery in a porcine model. Data on file. ECHELON FLEX™ 60 with Green Cartridge (88 staples per cartridge) vs. ENDO GIA® Universal with 60-mm Green Roticulator™ (90 staples per cartridge).

Tissue bunching at the crotch of the stapler also must be avoided as it can lead to poor staple formation and inadequate tissue acquisition. Surgeons also must monitor for and remove any "migratory crotch staples" (Figure 3).[4]

"The crotch staple is a staple caught by the blade of the endocutter and advanced up to the newly formed crotch," said Dr. Baker. "It can occur following the first firing of the device and usually appears as the blade catches a staple in the crossover area and carries it to the newly formed crotch. If the crotch staple is not removed, there is a greater chance of tissue damage as well as a stapler misfire. A misfire can cause the stapler to lock when firing is attempted. This happens when the staple driver hits the crotch staple and experiences excessive force as the staple is dislodged from its position."

Education

Drs. Baker and Northup agree that education on tissue and stapling device interaction can help reduce the occurrence of these complications and improve patient outcomes. Clinical experience remains the major determinant in successful patient outcomes, as is understanding the full functionality of currently available surgical staplers. "Most surgeons learn to use staplers during their training, but they don't have a thorough understanding of the science that forms the basis for stapler use and cartridge selection, under what circumstances they function optimally, and when caution—depending on tissue type—is needed," said Dr. Baker. Surgeons should thoroughly review the instructions for use with all new stapling devices, even if they have experience with other models.

Conclusion

When used appropriately, surgical staplers are essential devices that can provide improved outcomes in laparoscopic procedures by reducing operative time, length of hospital stay, and anastomotic leaks.[10] EES is committed to collaborative innovation by working with surgeons to optimize the interaction of surgeon, tissue, and device. An understanding of the interaction between human tissue and the device will enable surgeons to optimize care and outcomes in bariatric surgery.

Figure 3. Migratory crotch staple.

Reprinted with permission from Baker RS, et al. The science of stapling and leaks. *Obes Surg.* 2004;14(10):1290-1298.

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