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The Science of Stapling and Leaks

Randal S. Baker, MD, FACS; James Foote, MD; Paul Kemmeter, MD; Randall Brady, PA-C; Todd Vroegop, PA-C; Matt Serveld, PA-C

Michigan Medical Center for Health Excellence, Grand Rapids, MI, USA

Staple-line leaks represent an unwanted, yet seemingly unavoidable, complication of stapling associated with bariatric surgery. Although, "folk legends" abound as to precluding leaks, little has been written based on basic research and understanding of stapling mechanics. This article reviews the history of stapling and discusses the implications of understanding the biomechanics of stapling living tissue. Finally, three leak studies evaluating ways to optimize staple-line strength are presented, and a large bariatric clinical series is reviewed.

Key words: Staple line, morbid obesity, bariatric surgery, staple line reinforcement, cartridge selection, buttressing, stapling mechanics

"Diseases desperate grown; By desperate appliances are relieved"
William Shakespeare
Hamlet, 1600

Background

Staple-line leaks have long represented a feared nemesis of gastric and bowel surgery. Bariatric operations including Roux-en-Y gastric bypass (RYGBP) and duodenal switch (DS) procedures have thus represented an ideal breeding ground for the nemesis, as formation of staple-lines is essential to the procedures. Since the dawn of modern staplers, surgeons have been confronted with the dilemma of decreasing staple-line bleeding, yet avoiding leaks. Various methods have been employed to accomplish "optimal" staple-line formation, including undersizing cartridge selection, oversewing staple-lines, and utilizing staple-line buttressing material. The laparoscopic era has also influenced this arena, as there has been more of a move to undersize cartridge selection of endocutters, in an attempt to decrease oozing which is more evident with video magnification.

Inextricably drawn to this by our clinical experience involving over 1,700 bariatric operations, we noted a dearth of basic scientific data on this topic, yet we encountered an excess of deeply held practices and traditions not always based on good data. The purpose of this article is to review the history of modern mechanical staplers and present basic stapling biomechanics involved in stapling living tissue. Additionally, the data from three studies examining the factors associated with leaks and our clinical experience will be presented to help understand and avoid staple-line leaks.

History

The origins of the modern stapling apparatus hail back to the 1800s. Dr. Henroz, a Belgium surgeon, developed a device, which he tested on dogs to allow approximation of everted tissues from two bowel segments. Other surgeons, including Drs. Travers, Lembert, and Denans, also began to study and develop similar devices, primarily for use in bowel surgery.

Dr. John Murphy from Chicago developed a novel anastomotic ring originally designed for cholecystoduodenostomies, which then came to be used for bowel and gastric anastomoses.

In the early 1900s, many of the basic principles of mechanical stapling began to emerge as more surgeons tested and developed staplers. Humer Hultl in Budapest with the help of Victor Fischer created a stapler used to close the stomach during gastrectomies. Ahead of his time, Hultl recognized and

Reprint requests to: Randal S. Baker, MD, MMPC, 4100 Lake Drive SE, Suite B01, Grand Rapids, MI 49546, USA. Fax: (616) 974-4444; e-mail: rbaker@mmpc.com

focused on tissue compression, use of metallic B-shaped staples, and use of two staggered staple-lines in his instrument. The stapler, however, was found to be too heavy and bulky, and as a result, Aladar von Petz, another Hungarian surgeon, developed a light and easy-to-use version. This stapler was more readily adopted by other surgeons, despite the fact that the double staggered staple-line was unfortunately omitted.

Dr. H. Friedrich came up with the concept of creating cartridges that allowed the stapler to be used several times. This stapler did feature simultaneous tissue compression and staple firing but did not use the staggered staple formation so necessary for creating ideal staple-lines.

The next major phase of stapler development occurred in the USSR after the end of World War II. The war resulted in a significant decline in the number of surgeons, which further exacerbated the Russian health-care crisis. This led to the development of the Scienticfic Institute for Surgical Devices and Instruments. This institute studied and then developed stapling instruments that served as the precursors of today's modern staplers. These instruments incorporated a double linear row of staples and the ability to simultaneously cut between two sets of double rows. These staplers allowed inadequately trained surgeons to carry out standard surgical procedures in emergencies, thus partially alleviating the surgical health-care crisis.

An American surgeon, Dr. Mark Ravitch, visited Kiev and observed a Russian surgeon operating with a stapler on the lung. As a result, Dr. Ravitch studied the Russian products and then developed a completely new series of American instruments incorporating new innovations such as reusable staplers with sterilized preloaded cartridges, staplers which could deliver different lengths of staple-lines and a circular stapler capable of delivering a double row of staggered staples. Thus began the era of modern mechanical staplers.[1]

Clinical Conundrum

Shortly after experiencing our first staple-line leak, we initiated an intense investigation into literature related to staple-line leaks and began to review manufacture's "information for use" (IFU) statements for each stapler that we were using. This in turn resulted in meeting with the stapler manufactures to obtain answers to remaining stapler questions.

The manufacturer's IFU literature provides practitioners with specific recommendations on what staple to use based on tissue thickness. The U.S. Surgical IFU states in regard to their blue cartridge, "Do not use the ENDO GIA UNIVERSAL 3.5-mm staples on any tissue that compresses to less than 1.5-mm thickness or any tissue that cannot comfortably compress to 2.0 mm or on the aorta".[2] Ethicon's IFU states, regarding use of their blue cartridge, "Do not use the instrument with blue reload on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily to below 1.5 mm".[3]

These IFUs set a standard that requires the surgeons as users of these devices to understand thickness and compression properties of the tissues on which we operate. In our clinical experience of over 1,700 cases and 13,000 staple firings, we cannot often declare with confidence that we know the thickness of the gastric, small bowel, or mesenteric tissue upon which we work. Nor can we comment accurately on what constitutes "comfortably compressed" tissues or a precise delineation of normal versus "excessive force". In addition, if we are held to thickness measurements of the tissues, at what pressure do we measure the thickness? Finally, does thickness vary in a given stomach such that different cartridge selection should be considered?

The use of staple-line buttressing is also purported to decrease staple-line leaks. How does the thickness of the buttress itself influence the stapling process? The IFU for one buttressing material states, "Selection of staple size should reflect the thickness of reinforcement such that the total thickness falls within the recommended range for the stapler (see stapler instructions for use)".[4]

Investigations

As a result of this, we pursued related information and initiated studies to help answer questions in areas where little literature could be found. Three studies were undertaken to evaluate how to achieve the strongest staple-lines, by measuring pouch pressure upon inducing leaks. The first study was performed using a porcine model and evaluated the use and placement of ePTFE staple buttressing material. The second study was performed on cadaveric stomachs and evaluated the use of buttressing materials, variation of stomach thickness, use of oversewing staple-lines, and contribution of 3-row vs 2-row staple-lines. The final porcine study evaluated choice of cartridge (blue vs green) and use of bioabsorbable buttressing material. Finally, basic biomechanical principles of stapling living tissue and our clinical experience involving over 1,700 patients are reviewed.

Staple-line leaks often lead to peritonitis, septic shock, multisystem organ failure and at times death. Even "minor" leaks, where the patient shows little or no physiologic signs/symptoms of sepsis, can lead to protracted recovery courses. Differentiation of leaks is essential when attempting to compare data and work to decrease the incidence of leaks. Anastomotic leaks may or may not involve the staple-lines dependent upon the method of surgery used. Unfortunately, many papers on this topic do not delineate the type of leak encountered. Some report only anastomotic leaks and do not include information as to whether a staple device was involved in the reported leaks. A MEDLINE search was conducted using the key words: *leaks, gastric bypass,* and *bariatric surgery,* and identified 32 studies representing 11,605 cases. In this series, leak percentages were reported from 0.3% to 8.3% (Table 1). In their classic study evaluating open vs laparoscopic RYGBP, Nguyen et al[37] included 3,464 cases and reported leak rates of 1.68% for open RYGBP and 2.05% for laparoscopic RYGBP.

Since presenting our abstracts in Spain[38,39] and Japan[40] at the 2003 and 2004 IFSO (International Federation for the Surgery of Obesity) Conferences, our office has been barraged with calls from surgeons around the country who struggle with staple-line leaks, asking for advice on how to best preclude them.

It is presumed that with experience in both open and laparoscopic RYGBP, a given surgeon's leak-rate is likely to improve. However, given the potential devastating outcomes from a leak, it is our duty and the duty of all surgeons entering into the arena of bariatric surgery to educate themselves and utilize appropriate methods to decrease this problem and the associated learning curve.

Etiology of Leaks

The causes of staple-line leaks are many, and we believe that they fall into two main categories: *Mechanical/Tissue causes* and *Ischemic causes*. In both instances, the intraluminal pressure exceeds the strength of the tissue and the staple-line, resulting in a leak. Classic ischemic leaks are described to occur 5-7 days postoperatively when the wound

Table 1. Leak statistics from MedLine search

Reference	Surgery Type	No. of Patients	Leak Rate (%)
S. Smith et al (2004)[5]	L/ORYGBP	779	1.3
J. Kelly et al (2203)[6]	LRYGBP	188	1.6
Flancbaum et al (2003)[7]	ORYGBP	634	1.1
Gouge et al (2003)[8]	LRYGBP	158	1.3
Schwartz et al (2003)[9]	LRYGBP	600	0.8
Liu et al (2003)[10]	ORYGBP	480	1.7
Champion et al (2003)[11]	LRYGBP	100	1.0
Jones et al (2003)[12]	LRYGBP	201	4.5
Shope et al (2003)[13]	LRYGBP	61	3.3
Calmes et al (2003)[14]	LRYGBP	107	4.6
Schmidt et al (2002)[15]	LRYGBP	300	1.3
McCarty et al (2002)[16]	LRYGBP	100	3.0
Schauer et al (2002)[17]	LRYGBP	463	3.0 major 2.8 minor
Gould et al (2002)[18]	LRYBGP (hand asst.)	30.	2.3
Watts et al (2002)[19]	L/ORYGBP	72	8.3
Gagne et al (2002)[20]	LRYGBP	116	1.9
DeMaria et al (2002)[21]	LRYGBP	281	4.9
Sabry et al (2002)[22]	LRYGBP	90	5.6
Livingston et al (2002)[23]	ORYGBP	1067	1.4
Rutledge (2001)[24]	MiniGBP	1274	1.6
Morino et al (2001)[25]	ORYGBP	55	3.6
Nguyen et al (2002)[26]	LRYGBP	155	1.9
Higa et al (2000)[27]	LRYGBP	1500	0.3
Heniford et al (2000)[28]	LRYGBP	48	2.1
Clark et al (2000)[29]	LRYGBP	500	2.2
Balsiger et al (2000)[30]	ORYGBP	191	0.5
Fobi et al (1998)[31]	ORYGBP	705	1.3
Zapas et al (1998)[32]	ORYGBP	212	6.1
MacLean et al (1993)[33]	ORYGBP	106	5.6
Sugerman et al (1989)[34]	ORYGBP	182	1.6
Linner et al (1982)[35]	ORYGBP	174	0.6
Griffin et al (1981)[36]	ORYGBP	402	5.5
Average Leak Rate			**2.77**

healing is between the inflammatory and fibrosis phases. Upon reviewing the literature and our clinical experience, we noted that the vast majority of leaks occurred in the first 2 days following surgery. On reoperation, we did not see evidence of ischemia but instead found evidence of staple-line failure in well-perfused tissue. We therefore believe that most leaks are due to mechanical/tissue issues and that true ischemic leaks are rare.

Stapling Biomechanics

The various staple cartridges are designed for different tissue thicknesses to allow for hemostasis, tissue apposition while avoiding significant ischemia and tissue destruction. Human tissues are considered biphasic because of their solid and liquid components. The intra- and extra-cellular fluid components influence the tissue, so that elongation (tissue creep) occurs when crushing force is applied. When subjected to an applied displacement, stress relaxation occurs (i.e. a reduction in the amount of force required to maintain the applied displacement). At some point, increasing compression will produce excess tissue shear or tensile stress that results in tearing of tissues. The phenomena of tissue creep, stress relaxation, and shear stress are dependent upon one common factor – **time**. Optimal stapling then would consist of allowing adequate time for tissue compression and creep while not producing excessive tensile stress.[41]

Upon intense questioning of the representatives from the major endocutter manufacturers, we were able to ascertain that the industry standard for optimal pressure used to measure tissue thickness for stapling is 8 grams per millimeter squared (8 g/m^2). This standard is derived from the work conducted by the Russians at the Scientific Institute for Surgical Devices and Instruments. Russian researcher G.V. Astafiev reported this standard in the article "Investigation of Processes Relating to Tissue Compression in Suturing and Stapling Apparatus" back in 1967.[42] It was after we had Astafiev's text translated from Russian into English that we found that this was indeed the pivotal paper defining today's industry standard. This reference details an experimental investigation of stapling devices for determining optimal healing conditions. Earlier publications had demonstrated that too much pressure applied by clamping or clipping at the wound edges had adverse effects on healing. The author, therefore, conducted more than 500 tests in four sessions to derive the optimal compression needed to achieve tissue apposition and hemostasis while avoiding tissue injury. The first session of firings showed that no significant bleeding was noted when the stapler pressure was set to 8 g/m^2. The second session of firings focused on the effects to tissue after application of the optimal pressure derived from the first session of firings. Histological sectioning to evaluate the consequences of tissue trauma and its effects on tissue healing were addressed. The optimal pressures were found to be 8 g/m^2 for gastric tissue and 6 g/m^2 for the esophagus and the intestines. The results demonstrated that optimal pressure when applied, caused good apposition and negligent structural modifications with no long-term tissue disruption or aggravation. Specifically, the stomach tests showed more tissue trauma when higher pressures were applied than the esophagus or intestines. The researchers concluded that gastric tissue was less elastic and more prone to tissue stress if too high a pressure was applied.[42]

Studies

Taking this information we began to design our studies to help evaluate the best way to decrease leaks by achieving strong staple-lines. We designed a model to make small gastric pouches that could be forced to the point of leaking. Oversewing, cartridge selection, use of buttress material (non-absorbable and absorbable) and use of multiple-row staple-lines could all then be tested for their affect on staple-line leaks.

Leak testing was accomplished on porcine and fresh frozen cadaveric stomach models. Various endocutters were used from the two major manufacturers (Ethicon and US Surgical). Staple-lines were drawn using a template, and stomach thickness was measured. For testing purposes two consecutive staple-lines were used in conjunction with bowel clamps to stimulate a gastric pouch (Figure 1). Once constructed, blue dye was infused into the pouch

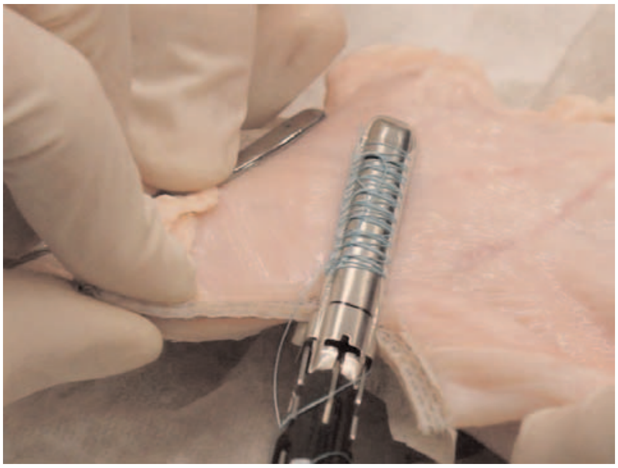

Figure 1. Creation of gastric pouches for pressure testing.

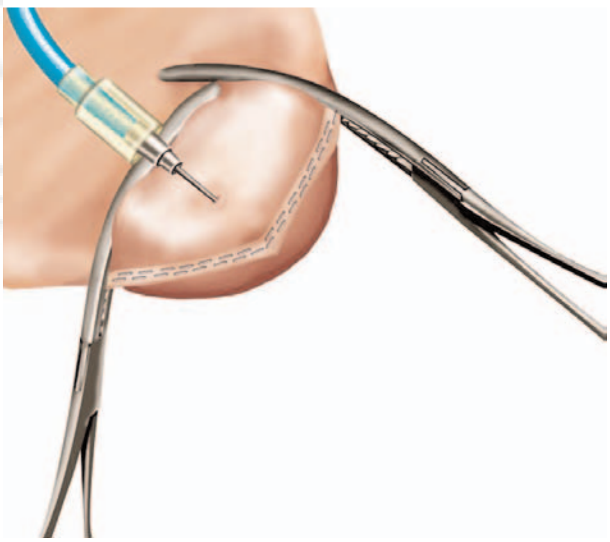

Figure 2. Pouch model used to test leak pressures.

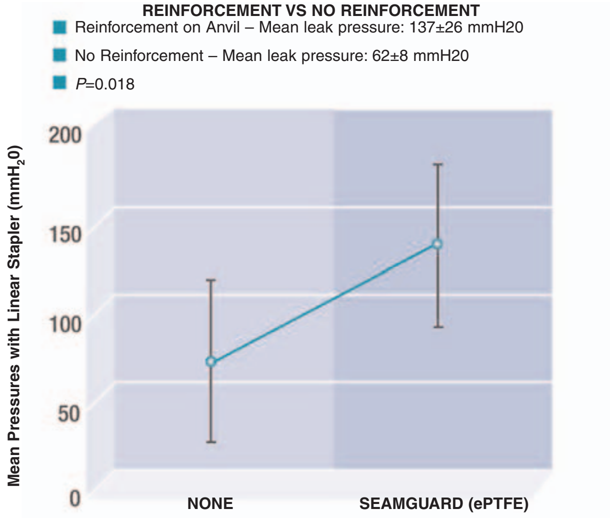

Figure 3. Mean leak pressures with and without reinforcement.

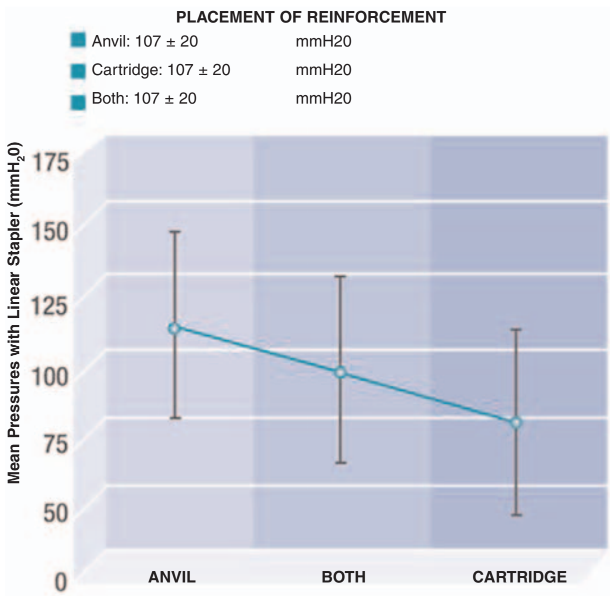

Figure 4. Mean leak pressures related to placement of reinforcement on endocutters.

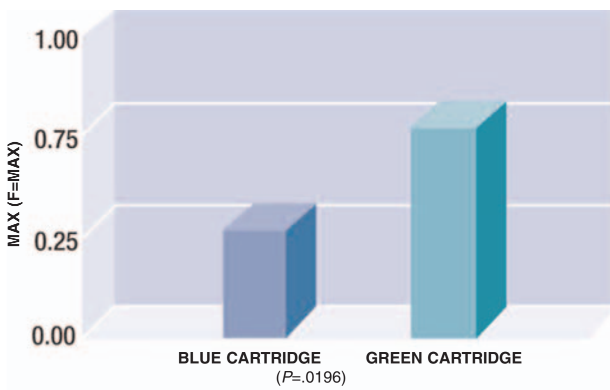

Figure 5. Percent of times that the pouches created with Seamguard® (bioabsorbable) buttressing reached the maximum system pressure and did not leak.

with the assistance of an 18-gauge needle, a submersible pump, and a regulator, and pressures were measured with a digital pressure gauge. Pressures were noted during dye infusion, with the final pressure recorded when the dye was noted to first leak from the staple-line (Figure 2).

The first porcine stomach model study revealed that reinforced staple-lines were significantly stronger than non-reinforced style-lines using non-absorbable ePTFE (Figure 3) In addition, a positive trend existed in favor of the use of buttress material placed on the anvil alone versus the cartridge alone or on both sides (Figure 4).

The cadaveric stomach model revealed the following: 1) Buttress material (ePTFE) again significantly increased the pressure required to cause staple-line leakage (P=0.002). 2) Stomach thickness was shown to vary significantly even in the same stomach (0.3 to 3.73 mm). 3) Full-thickness oversewing of staple-lines significantly weakened all staple-lines (P=0.015). 4) Three-row vs two-row staple-lines exhibited no significant difference during leak pressure testing (P=0.848).

The third study involved the porcine stomach model to evaluate cartridge selection and a new bioabsorbable staple-line reinforcement material (W. L. Gore and Associates). Reinforced staple-lines were again significantly more resilient than non-reinforced staple-lines for blue or green loads.

Despite the fact that the exact infusion pump/pressure gauge system was used in the previous studies, during this study the maximal achievable pressure was reached without evidence of a leak in both green and blue staple-lines with reinforcement (Figure 5). The green staple-lines were significantly stronger than the blue (P=0.02).

Applying these studies to our clinical situation, we were able to decrease our leak-rate from 1% to <0.3%.

Final Discussion

Staple size must be selected appropriately for the tissue on which it is to be used. This is necessary to allow for proper staple formation while in turn achieving optimal staple-line strength and tissue compression. Under-sizing staple cartridge increases the risk for inadequate staple formation or can lead to excessive tissue compression, which exceeds the tissue's tensile strength, leading to tearing and perforation. Figure 6A depicts ripped tissue after purposeful creation with undersized staples. Note, the tissue fracture present because of excessive tensile force. Figure 6B illustrates incomplete staple formation when a blue cartridge is used on thick gastric tissue. Note that the first portion of the staple-line appears adequately formed. However, follow the staple-line distally toward the crotch, noting the widening of the tissue resulting from incomplete staple-leg formation.

Green load cartridges should be used on thick stomach because they are designed to be stronger (wider diameter) and form longer leg lengths (Figure 7)

Full-thickness oversewing past a fixed staple-line may increase the risk of tearing at the point of suture penetration in the distended gastric pouch (Figure 8). This effect is not likely to be significant in low-pressure areas.

Staple-line buttressing in our studies always significantly increased staple-line strength and should be considered in an attempt to decrease leaks.

Great care must be used in firing the endocutters. Bunching of tissue at the crotch of the stapler must be avoided.

When using these devices to create a long staple-line, the surgeon must watch for and remove the "migratory crotch staple". This occurs after the first firing and often appears as the blade catches a staple in the crossover area and carries it to the newly formed crotch (Figure 9). Failure to note and remove this staple may result in a staple misfire. If left in place, the "crotch staple" can cause the stapler to lock when firing is attempted. A wedge band bypass failure can also occur when the staple driver hits the crotch staple secondary to excessive force and dislodges from its track. This results in staple formation on one side and slicing open of the tissue on the opposite side.

Finally, care must be taken while firing the stapler near the angle of His. Migration of the stapler with incorporation of the esophagus can weaken the staple-line because of the weaker nature of esophageal tissue. Bunching of fundus or a thick fundus can also lead to leaks if inadequate staple formation or tissue shearing occurs.

Figure 6A. Undersized cartridge on thick gastric tissue.

Figure 6B. Incomplete staple-line formation from thick stomach.

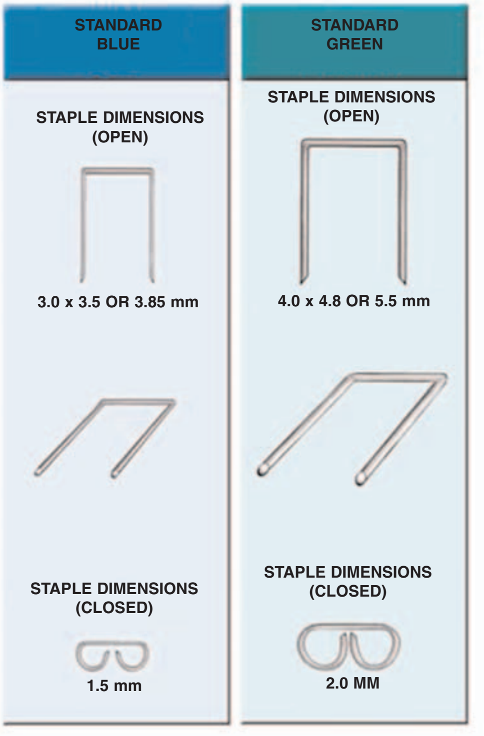

Figure 7. Green staples have larger diameter and longer leg length.

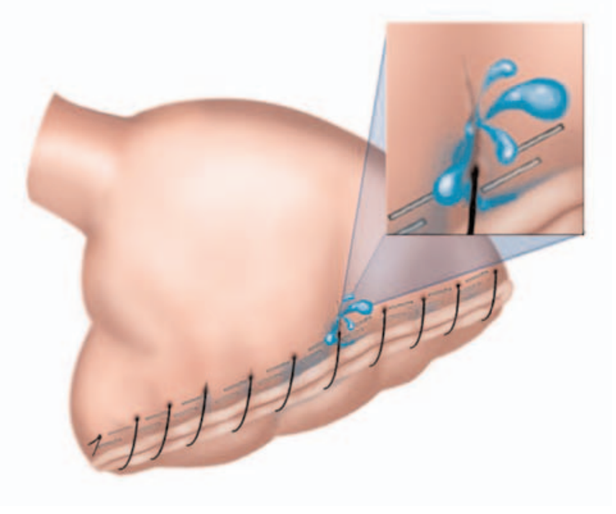

Figure 8. Oversewing causing leaks when the pouch is distended and suture bowstrings and tears tissue.

Figure 9. Migratory crotch staple.

Conclusion

The ultimate goal in staple formation is to produce mechanically sound staple-lines, which can withstand pertinent pressure forces until the tissue response endows significant strength over time. This formation must achieve adequate staple formation and yet avoid tearing the tissue.

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