The Science of Stapling: Staple Form

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ABSTRACT

Surgical stapling has evolved significantly over time, with the primary goal of improving patient outcomes. This study describes the technological advancements in surgical stapling from the perspective of staple and cartridge design, assessing the impact of staple design when it changes from the traditional B form (also known as 2D staple form) to a three-dimensional form (known as 3D staple form). The change in configuration helps compress a larger surface area of the tissue. The 3D configuration is designed to optimize compression not only underneath each staple but also across staples and multiple staple lines, including both stapled and unstapled regions of the tissue. By achieving more evenly distributed compression throughout the staple line, there is potential for reduced leak paths. The study demonstrates that the 3D staple form in surgical stapling results in more evenly distributed compression. In the future, this advanced technology should seamlessly integrate into emerging systems such as the surgical robot, enabling continued progress in surgical instrumentation and ultimately in surgical care.

INTRODUCTION

Ever since their invention in 1908, surgical staplers have been utilized as a means of "mechanical suturing" to effectively divide hollow organs and establish anastomoses in a sterile manner.[1] Surgical staplers are used in virtually all surgical disciplines and have become the gold standard for tissue approximation and hemostasis while preserving tissue structure and viability.

Present manufacturing techniques and innovative engineering solutions help ensure the consistent development and delivery of high-quality products. Surgical staplers are used in a wide range of surgeries and are specialized for specific purposes. There are several established categories of staplers: circular, linear, linear cutting, and skin staplers, as well as newer variations suitable for minimally invasive surgery.[2] Each category has multiple commercial models, each with unique features. The applications for these instruments are extensive and diverse, and recent design developments have further expanded and improved their capabilities.

Hümér Hültl, a Hungarian surgeon, developed the first stapler in 1908. This stapler weighed 8 pounds and required a long time to assemble and load, making it difficult to place on tissue due to its size.[3] Hültl's stapler consisted of more than 100 parts and had to be assembled right before surgery. Once the stapler had been fired, it had to be returned to the manufacturer to be reloaded.[4] The stapler applied two rows of wires; however, the tissues between the rows had to be cut manually.

In recent years, stapling applications have been further expanded and improved due to advancements in instrument design. Modern stapling devices are significantly lighter, enabling a more consistent staple line, fewer technical failures, and easier construction of anastomosis in difficult locations.[5] Conventional staple cartridges typically consist of a flat-faced surface with staples of a single height. To optimize a device's interaction with tissue and its stability during stapling, manufacturers have introduced various solutions that involve altering the length of the staple line or modifying the surface of the cartridge.[6]

The Echelon™ stapler (Ethicon Inc., Cincinnati, Ohio) reloads entail small bumps on the cartridge face, known as Gripping Surface Technology (GST), which helps engage tissue and minimize distal and lateral tissue movement during compression and firing.[5,7,8] Tissue movement may compromise the integrity of the staple line and necessitate intervention for surgical complications such as bleeding and leaks. Previous literature has associated GST with fewer intraoperative staple line interventions, decreased hemostasis-related complications, and reduced hospital costs.[5,7-11]

To fully understand the advancements in stapler technology, it is important to discuss the scientific principles involved in designing staples. Surgical staple innovation has undergone extensive research and development to ensure optimal performance and efficacy, as staple line integrity is critical in creating a completely sealed transection line.

Factors such as staple size, shape, material, and placement have all been studied and refined to achieve the desired outcomes in surgical procedures.[5,10,12-17] The aim is to create staples that securely hold tissues together while minimizing trauma, promoting efficient healing, and reducing the risk of complications.[18] Key factors that may affect clinical outcomes include tissue properties, which may vary from organ to organ, and the biomechanics of tissue interacting with the staple. One of the biomechanical variables to consider when apposing tissue together is the degree of compression applied to the tissue by the staple.[19] The optimal amount of compression largely depends on the type and mechanical properties of the tissue itself.[20] As the tissue becomes less compressible, an increased amount of pressure needs to be applied by the staple to ensure the desired closed staple height is obtained, providing adequate compression to hold tissue together without causing bleeding, leaking, or tearing.[18]

Another factor to consider is choosing the appropriate staple height to avoid a mismatch between the staple height and tissue thickness. This discrepancy can lead to leakage due to necrosis or poor apposition. Stapler cartridges are available with closed B-shaped staples of different heights, ranging from 1mm to 2.3mm, and these cartridges are color-coded based on the staple height.

If the height of the closed staple is too high, it may not adequately oppose the tissues and could result in leakage, bleeding, and/or dehiscence. On the other hand, selecting a staple height that is too low can cause problems such as ischemia and serosal shearing, which may result in leakage or necrosis. Most endoscopic and open staplers have at least three staple heights available to secure tissue. To achieve this, most surgical staplers bend each staple, resulting in a B-shaped staple form. However, malformed staples can occur due to the staple leg bending inappropriately, which is influenced by several tissue/stapler characteristics such as tissue thickness, tissue viscosity, staple height, and type of staple metal.

In recent years, stapling technology has progressed from innovating on the stapler cartridge and staple height to the design of the staple shape itself. This article discusses the evolution in the design of the staple, moving from a conventional two-dimensional (2D) "B" form to a three-dimensional (3D) shape (Fig. 1). The 3D form is designed to occupy more space in the staple line,

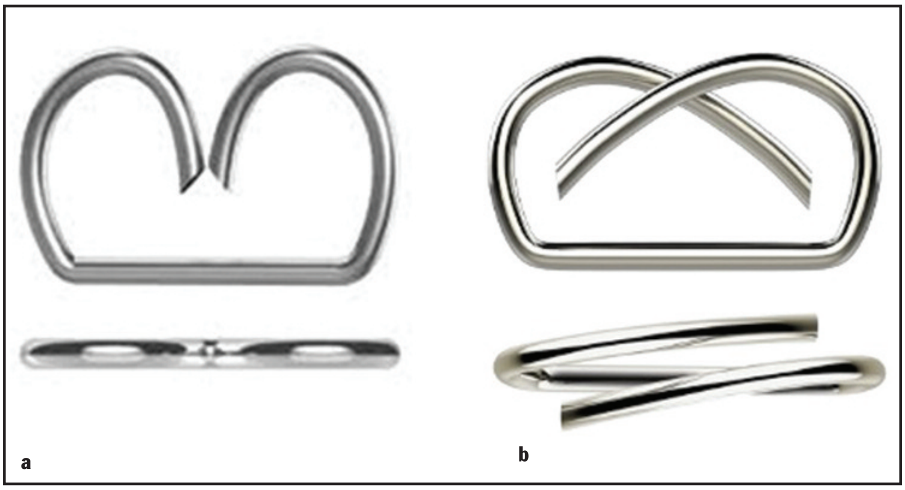

Figure 1. A 2D staple (a) and a 3D staple (b).

providing more even compression and reducing leak pathways. The benefits of the 3D form, compared to standard 2D staples, were evaluated by measuring the variability in the compression profile along the staple line and the onset pressure of leakage.

MATERIALS AND METHODS

Staples and staplers

The staples used are made of Ti3Al2.5V titanium wire, which contains small amounts of aluminum and vanadium in addition to titanium. This titanium alloy has been shown to be suitable for permanent implantation. Staples were deployed using state-of-the-art linear and circular staplers at the time of the study.

Compression profile

To gain a better understanding of the biomechanics of staple interaction with tissue and to optimize staple design parameters, a comparison of the pressure distribution profiles of 2D and 3D staples was performed. To accomplish this, we fired the staples into a foam specimen with consistent properties using staplers capable of delivering either 2D- or 3D-shaped staples. The staple heights were kept constant at 1.5mm to ensure that the mean pressure applied underneath the staple was comparable, regardless of staple form.

A cross-linked polyolefin foam (3.2mm thick) from Sekisui Voltek (Coldwater, Michigan) was used as a medium to monitor compression because it allowed for the quantifiable and comparable measurement of pressure, thanks to its constant material properties. The staples fired into the foam specimen were scanned using a Keyence Laser microscope (TL2505) with a VR-3000 3D Measurement System from Keyence Corporation of America (Itasca, Illinois). The scan of the staple line captured the compression profile on one side of the foam. By inputting the material properties of the foam, the compression data was then translated into pressure values. The resulting pressure output, as presented in Figure 2, was used to compare the two staple forms. The same test method was employed to collect data on 3D and 2D form staples using different types of stapling devices (circular and linear staplers).

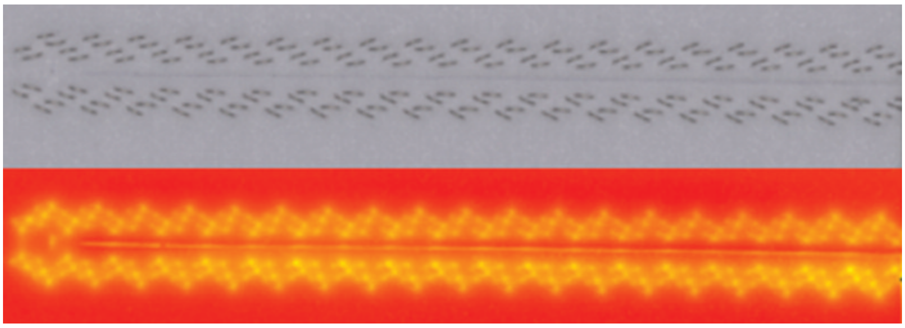

Figure 2. The sample optical (upper) and compression (lower) images for a linear stapler using 3D staples. Compression is the product of mechanical force on tissue over time, influenced by tissue properties like thickness, ability to stretch and shape, and viscoelasticity. Firing on properly compressed tissue reduces the chance of malformed staples.

Leak pressure testing

This test method was used to evaluate the leak onset pressure of staple lines created using either 3D or 2D staples. Staple lines were created using a circular or linear stapler that deploys either 3D or 2D staples in excised porcine colon tissue of a specific thickness. Excised porcine tissue is considered an appropriate medium for this test because it introduces natural variation due to the biomechanical properties of tissue and its interaction with the device and staple itself. Crossing staple lines were not considered in this test to limit the failure mode to only one staple line that has either 3D or 2D staples.

The stapler was closed on the tissue, compressed for 15 seconds, and then fired according to the specific device's instructions for use. The tissue specimen was then loaded onto a computer-controlled pressurizing fixture that allows fluid to be injected directly into the specimen at a ramp rate of 0.3mmHg per second initially and then held at a high-pressure threshold afterwards. The specimen is tested either to failure (i.e., the onset of a leak at the staple line) or to a sustained high-pressure threshold that is considerably higher than the physiological pressure at which a leak may occur. Either the high pressure (for a non-failed specimen) or the actual leak onset pressure (for a specimen tested until failure) below the high-pressure threshold is recorded for each specimen.

Statistical comparisons for continuous variables were performed with parametric or non-parametric tests depending on the distribution of the data, as described in the Results section below. Comparisons of proportions were performed using Fisher's Exact test. All statistical tests used a significance level (alpha) of 0.05.

RESULTS

Compression profile

Comparison of the pressure distribution profiles of 3D and 2D staples was conducted in two steps: (1) determination of the variability of pressure underneath each staple and (2) determination of the variability of pressure for the entire staple line. This methodology allowed for a direct comparison of the pressure distribution profiles between different staple designs.

A fixed staple area footprint was created around each staple, with the width and height of the footprint dependent on the type of stapling device deploying the staple line. To ensure a direct comparison, the fixed staple area footprint was kept the same for both 3D and 2D staple forms for a particular stapling device. This means that the fixed staple footprint for a 2D staple form on a circular stapler is the same as that for a 3D staple form on a circular stapler. Similarly, the fixed staple area footprint for a linear cutter for both 2D and 3D staple forms was kept constant.

The scanned profile of the specimen was then converted into actual pressure values using the constant properties of foam with the LS Dyna software (Ansys, Inc. Canonsburg, Pennsylvania). To assess the even distribution of pressure underneath each staple, the standard deviation of pressure was utilized. Standard deviations were calculated for individual staples and entire staple lines, encompassing the pressure profile under both the stapled and unstapled areas. This calculation allowed for a direct comparison between staple lines (either linear or circular) that have multiple 3D- or 2D-formed staples.

Thick or poorly compressed tissue can cause tissue movement and trauma during firing. The greater the deflection

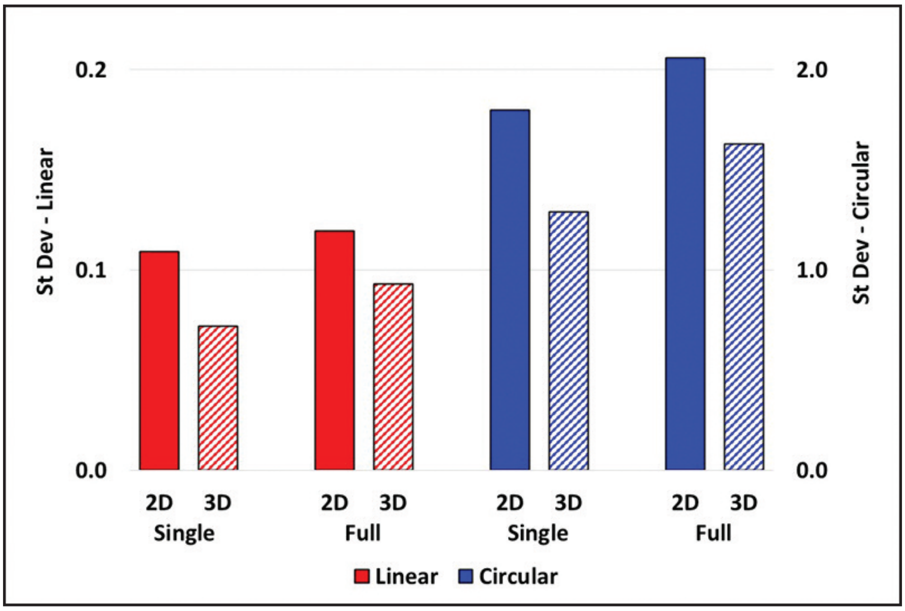

Figure 3. Variability in closed staple pressure for linear (red) and circular (blue) staplers, single staples and full staple lines, and 2D (solid) and 3D (hatched) staples.

Table I
Variability of compression pressure for circular and linear staples calculated for individual staples and over the entire staple line

Stapler type	Comparison	2D staple	3D staple	p-value
Circular	Single staple	1.80	1.29	<0.001
Circular	Full staple line	2.06	1.63	<0.001
Linear	Single staple	0.109	0.072	<0.001
Linear	Full staple line	0.119	0.093	<0.001

Pressures are given in relative pressure units

Table II
Leak onset pressure and proportion of leaks below a critical value for circular and linear staplers

Stapler type	Comparison	2D staple	3D staple	p-value
Circular	Median leak onset pressure	26mmHg	33mmHg	<0.001
Circular	Leak rate below 30mmHg	79% (23/29)	31% (9/29)	<0.001
Linear	Median leak onset pressure	23mmHg	37mmHg	<0.001
Linear	Leak rate below 30mmHg	53% (19/36)	28% (10/36)	0.025

of the anvil, the longer the staple legs must travel, which can potentially affect the ability of staple legs to hit the anvil pockets. In circular staplers, the variability in compression pressure for single staples was 28% lower for 3D staples compared to 2D staples. For the entire staple line, it was 21% lower (Table I, Fig. 3). In linear staplers, the variability in compression pressure for single staples was 34% lower for 3D staples compared to 2D staples. For the entire staple line, it was 22% lower (Fig. 3).

Leak onset at the staple line

The leak onset pressure data was recorded as either the actual leak onset pressure for specimens that failed before reaching the high-pressure threshold or the high-pressure threshold itself for specimens that did not present a leak. Since the test was conducted using excised porcine tissue to introduce natural variation in tissue biomechanical properties, the cumulative device failure rate against a target pressure value was used as a method of comparison. This helped to ensure that the rate of failure was impacted only by the type of staple line and not solely by the biphasic and elastic nature of excised tissue. The cumulative number of device failures was noted against a threshold of 30mmHg.[21]

In the case of circular staplers, 3D staples demonstrated a 27% higher median leak onset pressure and a 61% lower rate of leaks below 30mmHg compared to 2D staples (Table II). Similarly, for linear staplers, 3D staples exhibited a 61% higher median leak onset pressure and a 47% lower rate of leaks below 30mmHg than 2D staples (Fig. 4).

DISCUSSION

Anastomotic leaks are a feared complication in general, bariatric, thoracic, and colorectal surgery, leading to increased morbidity and mortality, the need for further invasive interventions, including reoperation, extended hospital stays, and increased healthcare costs across the board. One study involving 239,350 patients undergoing colorectal surgery and 62,292 patients undergoing bariatric surgery demonstrated that in patients with an anastomotic leak, the length of stay was increased by 12 and 15 days, respectively, with an additional cost of over $30,000 for hospitalization compared to patients who did not experience a leak.[22] Other publications support the increased length of stay and costs related to anastomotic leaks.[23-27] In addition, a recent study showed that anastomotic leaks are associated with a substantial impact on the environment.[28] By recognizing and implementing measures, such as the use of 3D staples in surgical staplers, to decrease the occurrence of anastomotic leaks, hospitals and healthcare systems can not only enhance patient outcomes but also move closer to achieving economic and environmental sustainability.

Staples with the 3D configuration have

been used in numerous surgical staplers throughout the years. In a randomized study comparing 3D/3-row linear staplers with 2D/2-row staplers in gastrointestinal surgery, the 3D stapler exhibited an 88% lower rate of anastomotic bleeding (p=0.006) and a 25% shorter hospital stay (p<0.05), with no cases of anastomotic dehiscence observed.[29] In a matched comparison of 3D/3-row and 2D/2-row linear staplers in ileocolic anastomoses, the 3D stapler demonstrated a 69% lower rate of reoperation (p<0.05), with no instances of anastomotic leakage or bleeding detected.[30]

In a retrospective review of the use of 3D staples in a powered circular stapler for left-sided anastomotic reconstruction, no leaks were observed (0/17), and perfusion as monitored via indocyanine green did not appear to be affected by the 3D staple line.[31] In a prospective evaluation of a powered circular stapler with 3D staples in colorectal surgery, there were no positive intraoperative leak tests and a low (1.8%) rate of postoperative anastomotic leaks that were deemed to be device related.[32] The results of this study were compared, in a propensity score-matched adjusted indirect comparison, to manual circular staplers with 2D staples, which produced a higher (6.9%) rate of leakage.[33] In left-sided colorectal anastomosis analyzed via propensity score-matched comparison, leakage was observed in 11.8% of the 2D manual stapler cases; whereas, only 1.7% of those in the 3D powered stapler group experienced a leak.[34] Four more recent studies in colorectal anastomosis confirm this trend,[35-38] with rates of leakage ranging from 0.0% to 6.1% for 3D staples, and 4.2% to 14.3% for 2D staples. We calculated the relative decrease of leaks for 3D staples compared to 2D staples in these four studies to range from 31% to 100%. The authors of the studies were not able to identify whether any benefit in patient morbidity was specifically associated with the staple configuration. However, they observed low leak rates and lower rates of reoperations when a stapler with a 3D configuration was used over conventional 2D staplers.

In this study, we presented two tests that compared the performance of 3D staples to the standard 2D form and investigated the physical properties that could potentially account for the observed clinical benefits. First, the compression profile generated by 3D staples has been shown to be more consistent than that of 2D staples in both linear and circular staplers. This uniformity in pressure ensures adequate tissue apposition without interfering with perfusion. Secondly, the seals formed by 3D staples are stronger, characterized by higher leak onset pressures, and are less likely to leak at typical physiological pressures. Because the 3D staples occupy a wider region compared to 2D staples when formed, the pathways for leakage are reduced (Fig. 5). The reduced leakage

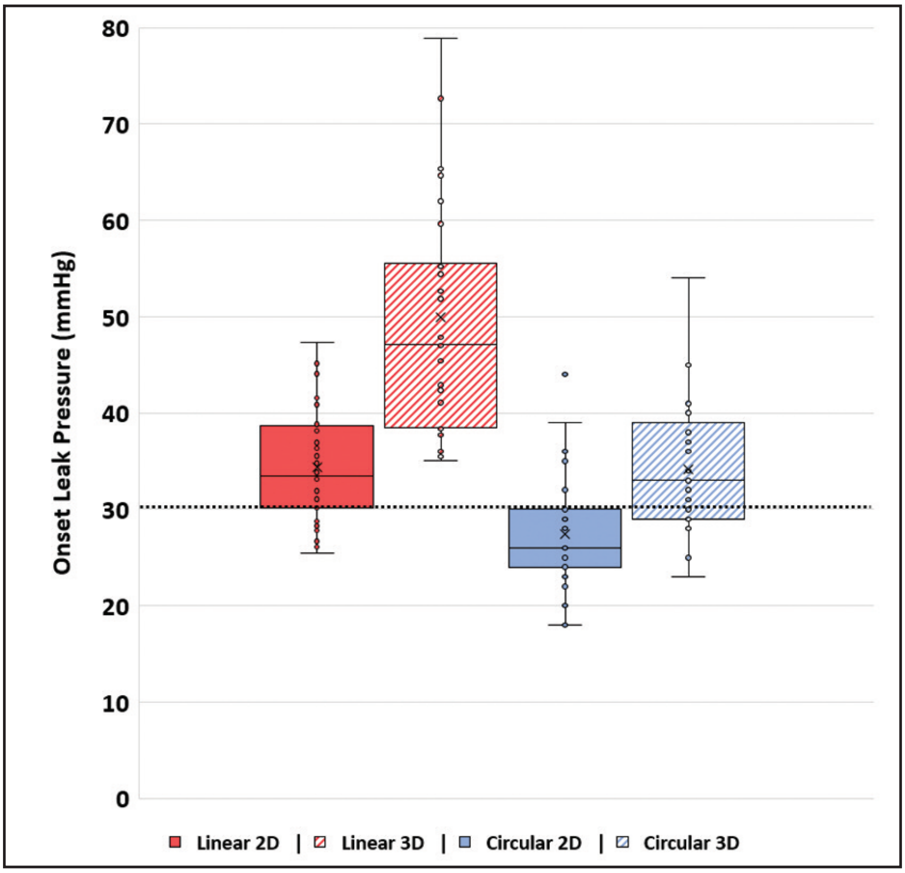

Figure 4. Onset leak pressure for linear (red) and circular (blue) staplers for 2D (solid) and 3D (hatched) staples.

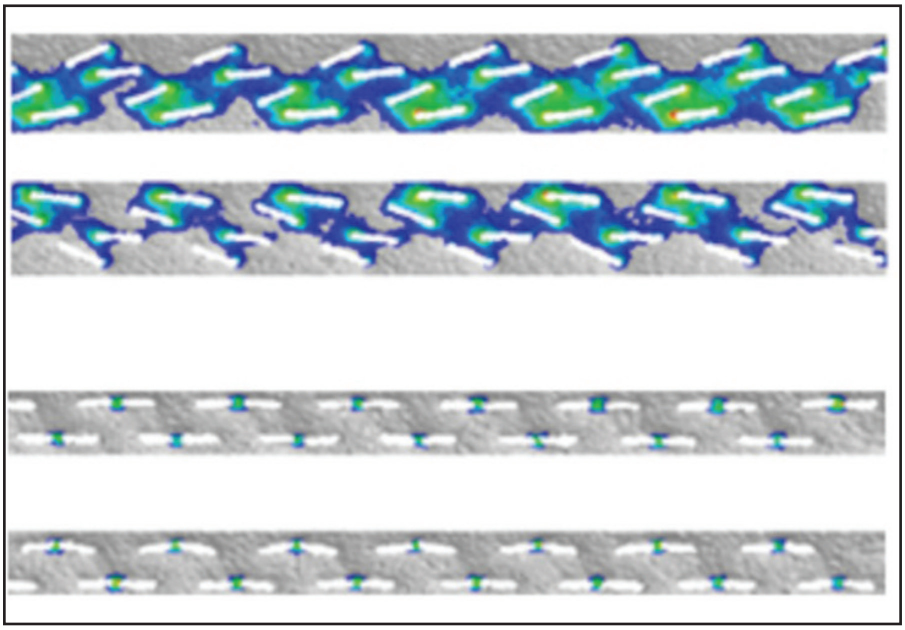

Figure 5. Leak path plot at 20 psi for 3D staples (above) and 2D staples (below). Blue and green areas represent pathways of higher resistance to flow.

pathways are believed to be responsible for the higher leak onset pressures observed in this study.

The results of the compression distribution analysis demonstrate that a 3D staple line provides more evenly distributed compression underneath the staple and across the entire staple line. A staple line with less variation between and across the staples ensures that low-pressure areas are not formed in the unstapled region of the tissue, minimizing the formation of potential leak paths. Based on the principles of fluid flow, it is known that fluid tends to follow the path of least resistance due to the difference in energy states created. A region that is more evenly compressed, spreading over a much larger surface area, is less likely to develop leaks than a region with rapid changes in compression over the same surface area.

The 3D staple configuration and offsetting of the staple legs provide a more even compression of tissue.[21] This benefit is in addition to the advantages of atraumatic Gripping Surface Technology (GST), which has been shown to provide gentler handling with a reduction in compressive forces on tissue.[5] The GST consists of small bumps extending from the driver wells, ensuring that the cartridge is not flat. These bumps are intended to engage with the tissue and minimize distal and lateral tissue movement during stapler compression and firing. The use of staplers with GST has been associated with lower total hospital costs, intraoperative blood loss, and reduced usage of hemostatic materials.[11]

There are limitations to this study. Although using foam as a medium provides benefits in terms of controlling pressure measurement consistency and eliminating noise in data analysis, it can be argued that these data cannot be fully extrapolated to tissue. Additionally, while both arms of this study achieved statistical significance, the sample sizes were relatively small.

The evolution of surgery has led to the widespread adoption of mechanical stapling as a recognized alternative to suturing. As surgical techniques have advanced in recent decades, the focus of research and development has shifted from making devices easier to use (manual versus power-driven) and reducing user errors to developing technologies that interact with tissue more effectively.

While patient factors contributing to the risk of a leak must be addressed on a clinical level, improvements in stapler technology have the potential to decrease the rate of anastomotic leaks from a technical standpoint. The introduction of a 3D staple design is an example of a technological advancement that has improved the overall impact of staple designs. With a staple line that has adequate staple height and 3D staple form, the desired compression is not only imparted at the staple line but is also well-distributed in the regions surrounding each staple. This study demonstrates the mechanical advantage of 3D staples, paving the way for further investigation into how this technology impacts clinical outcomes.

CONCLUSION

In this study, we found that the 3D staple form provides even and consistent compression which may support fewer leak pathways at the staple line. As surgery has evolved, mechanical stapling has become standard practice and a recognized alternative to suturing. With advanced surgical techniques developed in the last few decades, the focus of research and development has shifted from making devices easier to use (manual versus power-driven) and reducing user errors to developing technology that directly interacts with tissue itself.

Continued technological advancements, such as 3D stapling technology, that directly work with tissue interaction are the path to continued growth and innovation in the field of medical technologies. Therefore, continued research and development in this area is essential for further improving the outcomes of surgical procedures. In the future, this advanced technology should seamlessly integrate into emerging systems, such as the surgical robot, and enable continued progress in surgical instrumentation and, ultimately, surgical care. STI

AUTHORS' DISCLOSURES

All authors are employees of Ethicon, Inc., a manufacturer of surgical staplers.

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