DIRECTIONAL STAPLING TECHNOLOGY:
IMPROVED RELIABILITY IN STAPLE FORMATION

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INTRODUCTION

Metal staples have been used successfully for decades to provide secure, hemostatic closure of tissue margins prior to surgical resection. In almost all cases, the two or three rows of staggered staples penetrate the full-thickness of both layers of tissue and are formed by the stapling device into a perfectly aligned “B” shape that securely and hemostatically seals the tissue margins at the resection site. However, in certain situations where the tissue thickness exceeds the limits of the selected staple, or the tissue is difficult to penetrate due to calcification, fibrosis, etc., the staple may not form the perfect, fully closed and aligned “B” shape. In these situations the tissue margin may not be as secure as it would be otherwise.

Autosuture has critically analyzed this event and has made improvements in the design of its staplers and the staples to improve the accurate formation of the staple in difficult tissue. This system is called Directional Stapling Technology. The DST Series™ staplers use a redesigned staple wire, that is supposed to sit more securely on the anvil and bend more consistently and reliably in the desired plane, and a new platform in the stapler designed to provide a more secure path to direct the staple legs during their deformation into a closed staple.

The purpose of this study was to document in both in vitro and in vivo studies that the DST Series™ TA™ stapler produces more reliable and secure staple formation.

MATERIALS AND METHODS

STAPLERS

Staplers are classified by the length of staple line created (30, 45, or 60mm) and the length of the staple leg (2.0, 2.5, 3.5, or 4.8mm). In this study staplers providing a 60mm length with 4.8mm length staple legs prior to closure were used. The staplers were obtained from commercial sources. The staplers evaluated were:

- Autosuture™ DST Series™ TA™ 60-4.8
- U.S. Surgical, Norwalk, CT
- Proximate™ TX™ 60 green (4.8)
- Ethicon, Inc., Somerville, NJ
EXPERIMENTAL DESIGN

Twenty, non-surviving canines (15-23kg) of both sexes were used to evaluate the performance of 31 staplers of each of the two types. Each stapler was used to create a wedge-shaped segment across the stomach. A stapler of each type was used on each stomach and the results analyzed as paired data. The position on the stomach, where each type of stapler was used, was randomized to minimize anatomical bias. Each plicated wedge test segment was excised and quantitated for resistance to fluid leakage and staple geometry. All results were analyzed for statistically significant (p < 0.05) differences.

In a separate in vitro study the staples were measured for their magnitude of twist following formation in foam pads.

RESISTANCE TO LEAKAGE

Each stomach received two or four wedge-shaped plications of both walls of the stomach (Figure 1). All plications were transverse and 6cm in length. After firing the first staple line, another staple cartridge was placed in the same stapler and used to plicate the stomach again 5cm lateral to the first plication. This created a plicated wedge of stomach tissue sealed on each lateral edge by the staple lines. This “test wedge” was excised from the stomach and used to quantify the pressure required to cause water leakage. An infusion pump with an in-line pressure monitor was used to fill the test pocket through an 18 gauge needle. Colored water was infused at a rate that resulted in a 25mmHg increase in pressure every 30 seconds. Failure was recorded as the pressure which resulted in steady leakage.

FORMED STAPLE GEOMETRY

Following leakage testing, the first staple line placed was excised from the test sample and placed in sulfuric acid to dissolve the tissue. Each staple was recovered and four parameters of formation were quantitated (Figure 2):

- maximum gap
- minimum gap
- delta gap = (max gap – min gap)
- average gap = (max gap + min gap)/2
STAPLE TWIST
A twisted staple is a formed staple that has one or both of its legs formed outside the plane of the backspan. The twist is defined as the distance from the tip of the farthest leg to the staple backspan (Figure 2). The staples were formed by firing the staplers into six pads of foam and then excising the formed staples and quantifying the magnitude of twist of each staple.

RESULTS

RESISTANCE TO FLUID LEAKAGE
When the isolated wedge segments of stomach were infused with water, the mean pressure at which continuous fluid leakage occurred was significantly (p=0.04) higher with Autosuture™ staples (443 ± 133mmHg) than with Proximate™ staples (385 ± 156mmHg) (n=31) (Figure 3).

FORMED STAPLE GEOMETRY
The geometry of 636 formed Autosuture™ staples and 591 formed Proximate™ staples were quantified. These staples were obtained from the stomach tissue used in the previously described in vivo tests. Because the results were not normally distributed, the results are presented as the median values.

The median values for maximum gap, minimum gap, and average gap were significantly (p < 0.01) smaller for the Autosuture™ DST Series™ staples than for the Proximate™ staples (Table 1 and Figure 4). However, the delta gap measurement which represents consistency of staple formation within each staple was not significantly different, thus indicating that both staple types are formed consistently.

STAPLE TWIST
The median value of staple twist for 549 Autosuture™ DST Series™ staples was 0.3149mm (range = 0.0939 - 0.5334mm). This value was significantly (p = 0.003) less than the median value of the Proximate™ staples of 0.5486mm (range = 0.1168 - 0.8305mm) (Figure 5).
DISCUSSION

The use of staples to isolate and secure tissue during surgery is effective and efficient. The keys to a successful outcome are the proper selection of staple length for the thickness of tissue being closed and the proper mechanical formation of the staples. The issue of proper staple length is learned through personal experience or from recommendations of previous users. The issue of reliable staple formation has been addressed in this study.

Directional Stapling Technology has been developed by Autosuture to improve the reproducibility of optimum staple formation. DST Series™ staples are no longer round; they have been made rectangular so that they lay more securely on the flat anvil. The formation platform has been redesigned to more precisely direct the path of the staple legs as they are being deformed upward into the final “B” shape.

The precision of staple formation can be critically judged by how perfectly the two legs of the staple are deformed in the same plane. A perfectly formed staple will lie completely flat on a flat surface. If the staple does not lie perfectly flat, then one or both legs are twisted out of the plane of the staple’s backspan (Figure 2). The median value of twist for the Proximate™ staples (0.5486mm) was almost twice the magnitude of that for the DST Series™ staples (0.3149mm).

The DST Series™ staples also closed more completely than the Proximate™ staples. For the DST Series™ staples, the median distance of the staple legs from the backspan was 0.3962mm, while that distance for the Proximate™ staples was significantly (p=0.003) larger at 0.6833mm. The clinical significance of this difference has not been documented but may result in improved security.

The enhanced security of the DST Series™ staples was documented by measuring the resistance of the closed tissue to leakage. Closure of stomach tissue with DST Series™ staples resulted in a staple line that required a mean water pressure of 443mmHg to steadily leak. This resistance to fluid leakage was significantly (p=0.04) greater than that provided by Proximate™ staples (385mmHg).
CONCLUSION

The Directional Stapling Technology in the DST Series™ TA™ 60 4.8 stapler has improved the reproducibility of optimum staple formation as shown by the reduced gaps and twist, which translates into improved security (resistance to fluid leakage) during surgical resection.

<table>
<thead>
<tr>
<th>Staple Type</th>
<th>Median Value (mm $10^{-3}$)</th>
<th>MAX. GAP$^1$</th>
<th>MIN. GAP$^1$</th>
<th>DELTA GAP</th>
<th>AVG. GAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autosuture™ DST Series™</td>
<td>485 307 178 396</td>
<td>485</td>
<td>307</td>
<td>178</td>
<td>396</td>
</tr>
<tr>
<td>Proximate™</td>
<td>787 2 600 2 188 683</td>
<td>787$^2$</td>
<td>600$^2$</td>
<td>188</td>
<td>683$^2$</td>
</tr>
</tbody>
</table>

$^1$ The gap is the distance from the tip of the formed staple leg to the backspan (Figure 2).
$^2$ These median values for the Autosuture™ DST Series™ staples were significantly ($p < 0.01$) smaller than those for the Proximate™ staples.
Staple Formation
Measurement Definitions

Maximum Gap:
Measurement of the gap between the staple leg farthest from the backspan to the backspan.

Minimum Gap:
Measurement of the gap between the staple leg closest to the backspan to the backspan.

Delta Gap:
The difference in measurement between maximum gap and minimum gap.

Average Gap:
The average difference in measurement between maximum gap and minimum gap.

Twist:
The distance from the tip of the farthest leg to the staple backspan.

FIGURE 2: Measurements Conducted on Formed Staples

FIGURE 3. Resistance to Leakage
The pressure required to cause water to leak through the staple line of the stomach segment was quantified.

FIGURE 4. Staple Geometry
After formation in stomach tissue, the staples were collected and the gap dimensions were quantified and their median values reported.

FIGURE 5. Twisted Staples
Staples formed in foam were collected and the magnitude of staple leg twist was quantified and reported as the median value.