DIRECTIONAL STAPLING TECHNOLOGY:
IMPROVED RELIABILITY IN STAPLE FORMATION

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INTRODUCTION

Directional Stapling Technology provides improved staple formation and enhanced security in tissue closure as shown by the study published in January 2005 on the DST Series™ TA™ instruments. The purpose of the second research study discussed in this white paper was to document in an in vivo study that the Directional Stapling Technology produces similar results with the DST Series™ GIA™ stapler.

MATERIALS AND METHODS

STAPLERS

The staplers involved in this study placed two double staggered rows of titanium staples and simultaneously cut and divided the tissue between the two double rows. Staplers of this type are classified by the length of the staple line created (60, 80, 100mm) and the length of the staple leg (2.5, 3.8, 4.8mm). In this study, staplers providing an 80mm length with 3.8mm length staple legs prior to closure were used. The staplers were obtained from commercial sources. The staplers evaluated were:

- The Autosuture™ DST Series GIA™ 80-3.8mm (U.S. Surgical, Norwalk, CT)
- Proximate™ TLC™ 75 blue (3.85mm) (Ethicon, Inc., Somerville, NJ)

These staplers are for single patient use and can be reloaded 7 times. In this study, no instrument was used more than four times.
**EXPERIMENTAL DESIGN**

Sixteen, non-surviving canines (17-27kg) of both sexes were used to evaluate the performance of each of the two types of staplers. Each type of stapler was fired in parallel 50mm apart along the greater curvature of the canine stomach, creating test segments. The order of firing was randomized to minimize anatomical bias. Each test segment was excised, and a special clamp applied across the open end of the test segment, and down the center, isolating each staple line for testing. Each staple line was independently quantitated for resistance to fluid leakage, staple geometry and staple twist. All results were analyzed for statistically significant (p ≤ 0.05) differences.

**RESISTANCE TO LEAKAGE**

The thickness of stomach tissue was measured with a spring-loaded caliper. Each stomach received a minimum of one firing (two staple lines) from each type of stapler across both walls of the stomach (Figure 1). All plications were transverse and 70mm in length. After firing the first staple line, the other type of stapler was used to plicate the stomach again 50mm lateral to the first plication. This created “test pockets” of stomach tissue sealed on the lateral edges by the staple lines. These “test pockets” were excised from the stomach and used to quantify the pressure required to cause water leakage. The open end and center of the “test pocket” was clamped and an infusion pump with an in-line pressure monitor was used to independently fill each half of the test pocket through an 18 gauge needle. Thus each staple line was tested independently. Colored water was infused at a rate that resulted in a 25mm Hg increase in pressure every 30 seconds. Failure was recorded as the pressure which resulted in steady leakage.

Figure 1: Schematic of ex vivo testing in canine stomach tissue.
FORMED STAPLE GEOMETRY AND TWIST

Following leakage testing, each staple line was excised from the test pocket and placed in sulfuric acid to dissolve the tissue. Each staple was recovered and 4 parameters of formation were quantitated, as well as twist (Figure 2):

- maximum gap
- minimum gap
- delta gap = (max gap – min gap)
- average gap = (max gap + min gap)/2
- twist

STAPLE FORMATION MEASUREMENT DEFINITIONS

Maximum Gap: Measurement of the gap between the staple leg furthest 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 height of the tip of the farthest leg out of the plane of the staple backspan.

RESULTS

RESISTANCE TO FLUID LEAKAGE

The mean thickness of stomach tissue in this study was 3.48 ± 0.51mm. The study involved 16 dogs but 17 firings of each type of stapler was accomplished. In the 17 firings, there were 3 incidents of non-formed staples with Proximate™ TLC™ staplers and 2 incidents of non-formed staples with Autosuture™ staplers. There was 1 incident of technical error in the testing of a test pocket stapled with an Autosuture™ stapler. Thus, 14 test segments were analyzed for each type of stapler.

When the test segments of stomach were infused with water, the mean pressure at which continuous fluid leakage occurred was 16% higher with Autosuture™ DST Series™ staples (223 ± 72mm Hg) than with Proximate™ staples (193 ± 100mm Hg) (Figure 3). These mean values were not statistically different.

Figure 3: The pressure required to cause water to leak through the staple line of the stomach segment was quantified.
FORMED STAPLE GEOMETRY

The geometry of 631 formed Autosuture™ DST Series™ staples and 566 formed Proximate™ staples were quantified. The mean values for maximum gap, minimum gap, and average gap were significantly smaller (p<0.001) for the Autosuture™ DST Series™ staples than for the Proximate™ staples (Table 1, 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.

Figure 4: After formation in stomach tissue, the staples were collected and the gap dimensions were quantified and their mean values reported.

STAPLE TWIST

The magnitude of staple twist in the Autosuture™ DST Series™ staples was significantly (p<0.001) smaller than that produced with the Proximate™ staples (0.116 ± 0.161mm vs. 0.357 ± 0.282mm) (Figure 5).

Figure 5: After formation in stomach tissue, the staples were collected and the magnitude of staple leg twist was quantified and reported as the mean value.

DISCUSSION

STAPLE FORMATION

The DST Series™ GIA™ staples closed more completely and twisted less than the Proximate™ TLC™ staples. For the DST Series™ GIA™ staples, the mean distance of the staple legs from the backsan was 1.26mm, while that distance for the Proximate™ TLC™ staples was significantly (p=0.001) larger at 1.60mm. The mean value of twist for the Proximate™ TLC™ staples (0.357mm) was three times the magnitude of that for the DST Series™ GIA™ staples (0.116mm).

The clinical significance of these differences has not been documented but may result in improved security.

LEAK RESISTANCE

The 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 223mm Hg to steadily leak. This resistance to fluid leakage was greater than that provided by Proximate™ TLC™ staples (193mm Hg), as reported in the “Results” Section.
**CONCLUSION**

Consistent with the results from the first study on Directional Stapling Technology in the DST Series™ TA™ stapler, this second study confirms that Directional Stapling Technology translates into improved staple formation with the DST Series™ GIA™, as indicated by the reduced gaps and twist in staple geometry and the increased resistance to leakage.

<table>
<thead>
<tr>
<th>Staple Type</th>
<th>Mean Value (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MAX. GAP</td>
</tr>
<tr>
<td>Autosuture™ DST</td>
<td>1.41 ± 0.86(^1)</td>
</tr>
<tr>
<td>Series™ proximate™</td>
<td>1.70 ± 0.89</td>
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</tbody>
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**TABLE 1**: Geometry of staples formed in stomach tissue.

\(^1\)These values for the Autosuture™ staples were significantly (p<0.001) smaller than those for the Proximate™ staples.

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