

TECHNICAL SUMMARY

FEASIBILITY TESTING & DEVELOPMENT OF ADAPTIVE FIRING™ TECHNOLOGY TO IMPROVE SURGICAL STAPLER PERFORMANCE.

In practice, surgeons face the challenge of firing staplers over variable tissue types, tissue qualities, perfusion levels, and disease conditions. To accommodate for variability they must select the correct staple size to ensure adequate compression of tissue and effective staple formation. Inadequate compression and staple formation can lead to adverse events, including:

- Compromised perfusion to the staple line¹
- Acute bleeding¹
- Staple line failure¹

Our research team is focused on overcoming challenges in stapling and advancing the performance of stapling technology. This includes widening the range of tissue applications to help surgeons cover greater variability in tissue and reduce the impact of mismatched staple sizing. Previously, our team identified the opportunity to redesign the staple cartridge interface. As a result, they developed Tri-Staple™ technology, a three-row, graduated cartridge design that evolved from the standard two-row flat, cartridge interface. This graduated, or stepped, cartridge design:

- Reduces the stress on tissues during compression²
- Allows more vessels to penetrate the compressed tissue to provide greater perfusion to the staple line³
- Widens the range of tissue applications in which the stapler can work effectively⁴⁻⁶

The move from stapling with a manual squeeze delivery to a powered stapling delivery has also facilitated further reduction in staple formation variability and the potential for stapling related complications.^{7,8} Powered stapling helps control and standardize the rate of firing across different users.⁷

Upon their introduction, powered staplers delivered staples at a fixed speed without regard to tissue properties. Our research team explored whether more consistent staple formation with stronger functional closure could be achieved by controlling the rate of stapling speeds in different tissue conditions.⁹ This inquiry led to the development of an algorithm called Adaptive Firing™ technology (AFT). AFT uses a strain gauge as an input to provide computer-assisted control of the motors when firing the Signia™ stapler.

EXPLORING THE POTENTIAL OF VARIABLE FIRING SPEEDS: STUDY DESIGN

In previous testing, our research team demonstrated that more fully formed “B”-shaped staples provide greater

holding strength.¹⁰ For this study, it was hypothesized that using different firing speeds in different tissue properties could help provide even stronger functional closure of the staples. The team reasoned that a stapler could provide more consistently formed and stronger holding staple lines if the device could:

- Accurately determine a tissue thickness range upon initial clamping
- Choose appropriate starting speed based on tissue feedback
- Adjust speed if tissue properties changed

To investigate feasibility of the hypothesis, the team designed a two-test series.⁹ The first step in determining when to adjust firing speeds — especially in more challenging, thick tissues — was to identify factors affecting stapling performance. The next step was to find out when firing speed should be adjusted to achieve the best results.

In each test series, the level of undercrimp of each staple was determined by the distance from the backspan to the closest tip of the staple (Figure 1). Staple malformations were identified as staples that are formed so that the staple leg is either straight or not completely formed into an arced position pointing towards the backspan (Figure 2).¹¹

Figure 1. Example of undercrimp measurement on a formed staple.

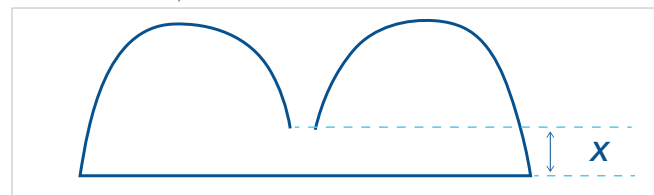
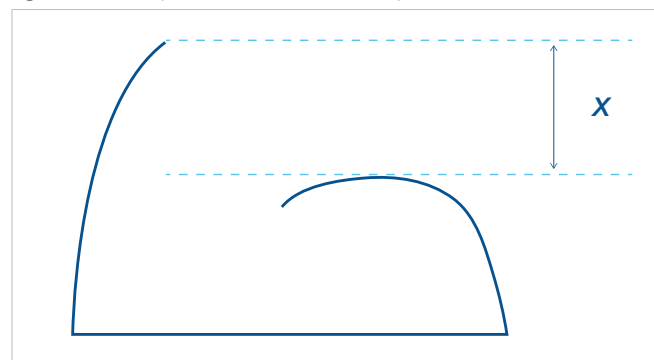


Figure 2. Example of a malformed staple.



TEST SERIES 1 — FEASIBILITY

To establish measurable parameters, researchers evaluated four variables to determine their impact on clamp forces, firing forces, and quality of staple formation during stapling.

TEST 1 METHODS AND MATERIALS

Four variables tested:

- Length of reload — 45 mm, 60 mm
- Wait time to fire — waiting 2 seconds, 15 seconds, or 60 seconds after clamp, before firing
- Tissue thickness range — average, thick, and extra-thick
- Firing speed — faster, medium, and slower

Test equipment:

- Instron 5965 electromechanical universal testing system
- Toveytron tissue calipers

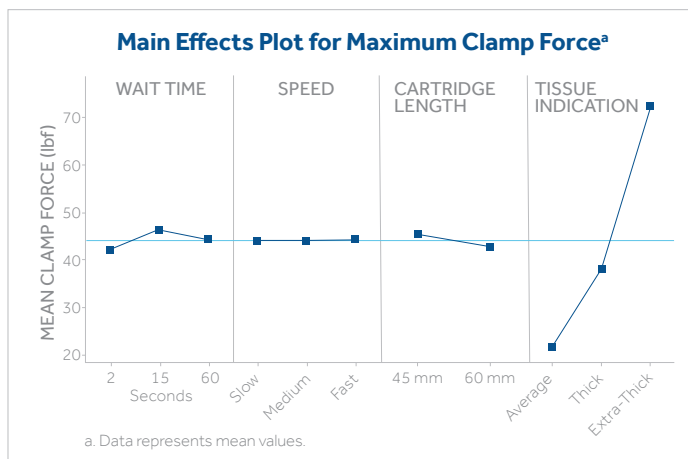
In this series, 162 purple Tri-Staple™ reloads (81 EGIA45 AMT and 81 EGIA60 AMT) were fired into premeasured *ex vivo* porcine stomach tissues. Responses included maximum clamp force, final clamp force, initial firing force, and maximum firing force. Values were taken from Instron data, and undercrimp and percentage of staple malformations were recorded.

TEST 1 RESULTS

Clamp Force†

The main finding was that initial clamp force was directly related to the tissue thickness being compressed by the stapler (Figure 3). Tissue thickness was the significant factor impacting clamp force.¹² Clamp forces were not different with short or longer lengths of reload. Neither speed nor wait time had an effect on clamp forces.

Figure 3. Maximum clamp force.

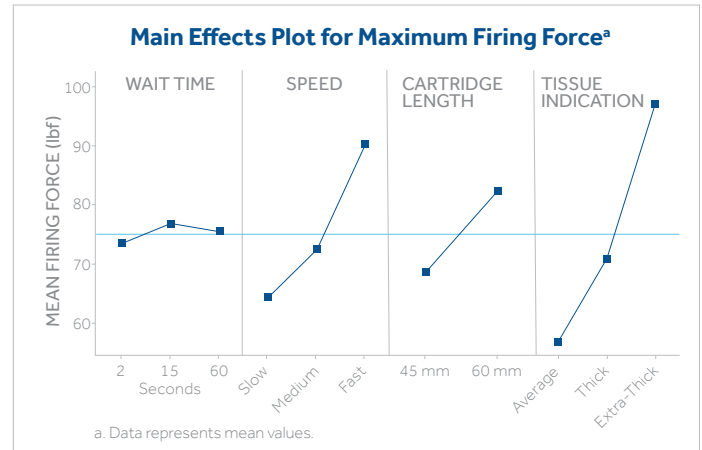


Firing Force

The main finding was that slower speeds reduced the forces — stress — on tissue during stapling (Figure 4). Firing speed and tissue thickness were the predominant factors affecting forces measured. Cartridge length impacted firing forces due

to additional firing distance; wait time had insignificant impact on firing forces.

Figure 4. Maximum firing force.



Staple Formation

The main finding was that faster firing speeds in thicker tissue created up to 84% more malformed staples and up to 38% more undercrimped staples (Figures 5,6).¹²

Figure 5. Slower firing speeds resulted in fewer malformed staples in thick tissues.¹²

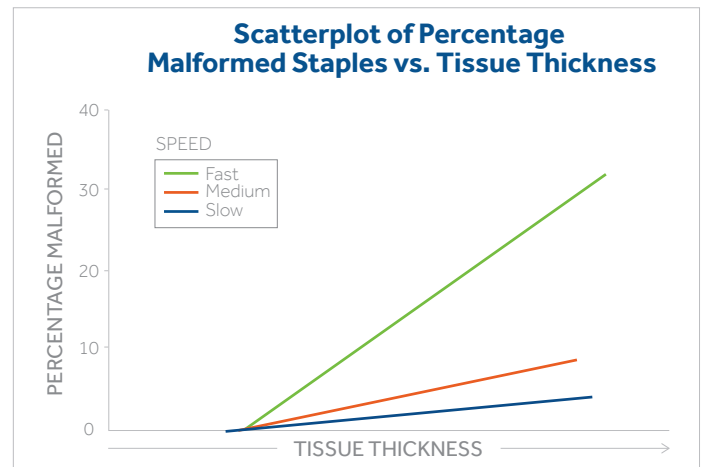
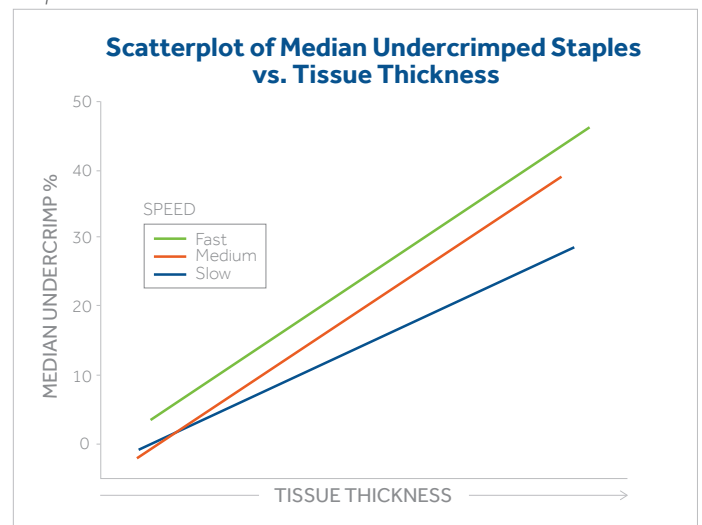


Figure 6. Slower firing speeds resulted in fewer undercrimped staples in thick tissues.¹²



†Clamp force measurement is the maximum force measured to clamp tissues; it does not continually measure the changing forces as tissues relax.

TEST SERIES 2 — VERIFICATION AND DEVELOPMENT

Test 1 identified that forces are directly related to tissue quality and speed of firing the stapler. It also identified that staple formation can be negatively impacted when firing occurs at a single fixed speed across different tissue thicknesses.⁹

Our researchers wanted to confirm these behaviors are applicable to all Tri-Staple™ technology reload staple sizes, in purple, tan, and black. Further, in their pursuit of achieving a greater number of properly formed B-shaped staples, they set out to determine parameters at which forces and speeds negatively impact staple formation when the stapler is fired in different tissue applications.

Based on Test 1 results, the team moved forward with a second test series to:

- Confirm that results for Test 1 purple reloads correlated to tan and black reload sizes
- Characterize clamp and firing forces in different tissue thicknesses to correlate tissue thickness ranges
- Understand the effect of firing speeds in different tissue properties with an aim of providing stronger functional closure of the staples by reducing the amount of malformed and undercrimped staples

TEST 2 MATERIALS AND METHODS

Variables tested:

- Length of reload — 60 mm
- Reload types — Tan, Purple, and Black (Tri-Staple™ technology AVM, AMT and AXT)
- Tissue thickness range — average, thick, and extra-thick
- Firing speed — faster, medium, and slower

Test equipment:

- Instron 5965 electromechanical universal testing system
- Toveytron tissue calipers

Testing focused on reload type, tissue thickness, and firing speed.[†] This series set up a total of 72 firings of 60 mm Tri-Staple™ AMT purple, 60 mm AVM Tri-Staple™ tan, and 60 mm AXT Tri-Staple™ black reloads in *ex vivo* porcine stomach. Responses included maximum clamp force and maximum firing force taken from Instron data. Level of undercrimped staples and percentage of staple malformations were recorded.

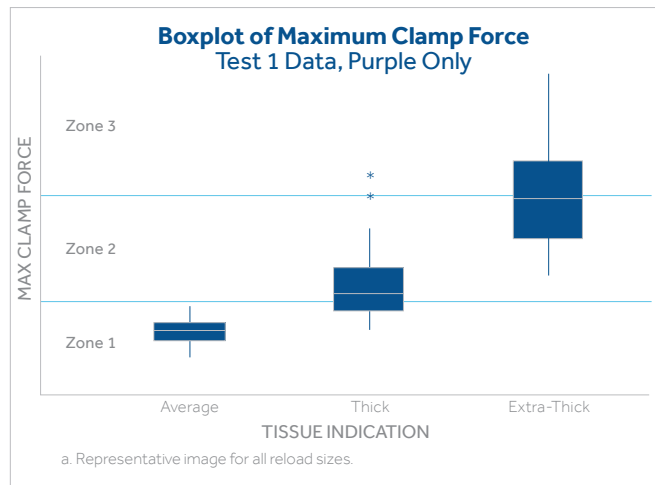
TEST 2 RESULTS

Force Measurements in Different Tissue Thicknesses

Firing data confirmed purple reloads correlated to tan and black reloads in Test 1 data. Increasing force measurements for clamp and fire were categorized into 3 different zones. These zones were determined by clamp forces and firing forces measured in different tissue thicknesses. Zones 1, 2, and 3 correlated to average, thick, and extra-thick tissues respectively. (Figure 7). Upon testing the accuracy of force measurements, statistical analysis found that:

- There is a 95% confidence^{12,‡} that upon initial clamping in average tissue thickness, the forces measured will be in zone 1
- There is a 95% confidence^{12,§} that upon initial clamping in thick tissues, the forces measured will be in zone 2 or 3

Figure 7. Ranges of clamp force.^{12,a}



EFFECT OF FIRING SPEED ON STAPLE FORMATION

Test 2 confirmed that firing speed impacted staple formation across tan, black, and purple reloads of all lengths. When firing at faster speeds in thicker tissues there was a greater probability of producing malformed and undercrimped staples (Tables 1,2).¹²

Table 1. Adjusting the speed of firing in different tissue thicknesses can reduce the percentage of malformed staples^{12,a} by up to 84%

Percent of malformed staples in each tissue thickness range ¹²			
Firing Speed	Average	Thick	Extra-Thick
Fast	0%	3%	25%
Medium	0%	0%	8%
Slow	0%	0%	4%

a. Actual calculation for reduction in malformed staples: $((25\% - 4\%) / 25\%) * 100 = 84\%$

Table 2. Adjusting the speed of firing in different tissue thicknesses can reduce the percentage of undercrimped staples^{12,a} by up to 38%

Percent of undercrimped staples in each tissue thickness range ¹²			
Firing Speed	Average	Thick	Extra-Thick
Fast	6%	21%	40%
Medium	2%	21%	31%
Slow	2%	7%	25%

a. Actual calculation for reduction in undercrimped staples: $((40\% - 25\%) / 40\%) * 100 = 38\%$

†Wait time and reload length were omitted since wait time and length of reload had insignificant impact on firing forces as seen in Test 1.

‡n = 64 purple and tan firings in average tissue thickness.

§n = 66 purple and tan firings in extra-thick tissue.

Relative Holding Strength

In previous testing, our research team demonstrated that more fully formed "B"-shaped staples provide greater holding strength of the staple line and that a greater number of undercrimped and malformed staples produced less secure staple lines.^{10,13} We applied a similar methodology to the staple formation results of Test 2 to determine the impact on staple line strength (Table 3).

Table 3. Adjusting the speed of firing in different tissue thicknesses can increase the strength of the staple line^{12,a} by up to 21%

Strength of staple line based on percentage of malformed and undercrimped staples in each tissue thickness range ¹²			
Firing Speed	Average	Thick	Extra-Thick
Fast	106.4 lbf	100.7 lbf	81.2 lbf
Medium	108.2 lbf	103.8 lbf	92.4 lbf
Slow	108.2 lbf	106.0 lbf	98.0 lbf

a. Actual calculation for increase in staple line strength: $((98 - 81.2)/81.2) * 100 = 21\%$

Effect of Speed on Force Applied to Tissue

Additional analysis of the force measurement data identified that slowing down the speed of fire can reduce the forces applied to tissues by up to 40% when firing in thicker, more variable tissues (Table 4).¹²

Table 4. Adjusting the speed of firing in different tissue thicknesses can reduce the forces applied to tissue^{12,a} by up to 40%

Forces measured in each tissue thickness range ¹²			
Firing Speed	Average	Thick	Extra-Thick
Fast	67 lbf	78 lbf	124 lbf
Medium	55 lbf	72 lbf	89 lbf
Slow	49 lbf	61 lbf	75 lbf

a. Actual calculation for increase in staple line strength: $((124 - 75)/124) * 100 = 40\%$

VALIDATION TESTING

For further validation, the research team conducted a third round of testing in freshly excised tissues and a separate series of *in vivo* testing. Both tests showed that the algorithm behaved consistently with initial results and supported earlier findings from Tests 1 and 2.⁵

DISCUSSION

Most commercially available powered staplers are designed to fire at a fixed speed.⁷ Our research team found that this method of stapling can produce inconsistent results that may provide a high rate of malformed and undercrimped staples,¹⁴ which may lead to less secure staple lines. This test series also demonstrated a reduction of stress on tissue (i.e., lower forces) and increased staple line strength (i.e., better formed "B"-shaped staples) when the rate of firing speed is controlled based on tissue properties.^{9,10}

Based on findings in this test series, an algorithm called Adaptive Firing™ technology (AFT) was developed. The algorithm uses the parameters identified in the test series to reduce the number of malformed and undercrimped staples fired in each staple line.⁹

CONCLUSIONS

By controlling the firing speed of a stapler in different tissue properties it is possible to deliver, with more consistency, properly formed B-shaped staples with stronger functional closure.⁹ This speed control creates a stronger holding staple line as compared to laparoscopic staplers that fire at one fixed speed.¹⁰ Furthermore, by measuring the force needed to clamp on tissues, AFT is able to determine average or thick tissues with 95% accuracy.¹²

This two-test series indicated that controlling the rate of fire in different tissue properties can improve stapling performance by^{9,11}:

- Reducing the amount of forces applied to tissues by up to 40%
- Creating a stronger functional closure of the staple line by reducing the amount of undercrimped staples by up to 38% and the number of malformed staples more than 80%
- Strengthening the staple line by more than 20%

This evidence supported the development of defining parameters for predictive zones of effective firing speeds in variable tissue thicknesses. Subsequent testing supported the development of the AFT algorithm for use in the Signia™ stapler, a computer-assisted stapler.

Given these findings, the practical application of AFT in the Signia™ stapling system may be expected to help surgeons deliver more consistent staple lines with stronger functional closure of the staples.^{5,9,14} As a result, they can achieve stronger holding staple lines when firing over different tissues as compared to staplers without AFT.^{6,10,14}

Force measurements are intended to provide informational feedback on tissue properties that correlate to the surgeon's tactile feel. Users should refer to the instructions for use for specific indications, contraindications, warning, precautions, and operating instructions.

Note: Testing was performed using animal tissue. Preclinical results may not correlate with performance in humans.

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