Signia™ with Tri-Staple™ vs Intuitive Surgical SureForm™* Stapler

Comparative Preclinical Evaluation

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Introduction

The adoption of robotic surgery has profoundly transformed the landscape of surgical interventions, offering enhanced precision, dexterity, and visualization to surgeons across various specialties. With an increasing emphasis on advancing minimally invasive techniques, the integration of robotic platforms has increased specifically within the bariatric and metabolic surgery (MBS) space – most recently at 30% utilization of the total procedures performed.[1]

This abstract seeks to compare and evaluate the Signia™ Powered Stapler with Tri-Staple™ and Intuitive's SureForm™* stapler, two cutting-edge devices designed for minimally invasive surgical applications, with a focus on their performance, features, and potential impact on patient care.

Background

In this context, the significance of advanced surgical staplers cannot be overstated, as they play a pivotal role in ensuring secure tissue approximation and hemostasis during robotic-assisted procedures.

The following test methodologies follow industry standardized best practices for evaluating intraoperative preclinical performance of surgical staplers. While these results cannot be directly linked to clinical outcomes, they are valuable to assessing relative preclinical differences between surgical staplers.

Figures 1 and 2 are comparative images of Tri-Staple™ and SureForm™ staple lines fired in equivalent thickness of tissue (ex-vivo porcine stomach).

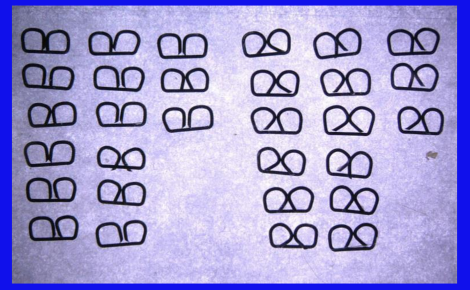
Figure 1. Tri-Staple™ Black fired in indicated tissue (2.9mm)

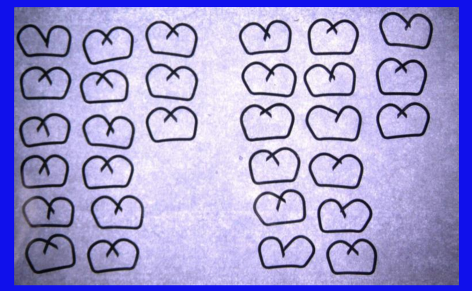
Figure 2. SureForm™* Black fired in indicated tissue (2.9mm)

Methods

Acute Hemostasis

Acute hemostasis is evaluated categorically using a modified Likert scale, with the value assigned based on the trained observer's judgement regarding level of blood loss following deployment of a staple line.[2]

Rank and definition		
	0	No bleeding at tissue site
	1	Staple line shows pinpoint bleeds
	2	Staple line is wet ≤ 50%
	3	Staple line is fully wet ≥ 50%
	4	Staple line is actively oozing


Figure 3. Score 0


Figure 4. Score 1


Figure 5. Score 2


Figure 6. Score 3

Staple Line Integrity – Leak Pressure

Leak testing assesses the ability of a staple line to resist leakage following surgical resection and repair. Leak testing is performed using a pressure-controlled inflation system and fresh ex-vivo porcine tissue.[3]

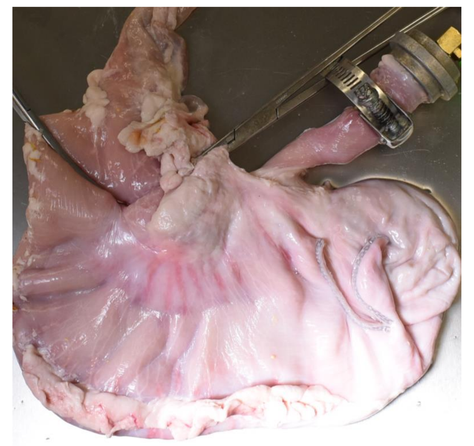
Figure 7. Leak Testing Setup (ex-vivo porcine stomach)


Figure 8. Example of a leak in the staple line

Preclinical Results

Staple Formation – Mechanical Performance

3,539 staples were fired, measured and analyzed. Staples were fired in indicated in-vivo and ex-vivo porcine stomach, small bowel, colon, and lung tissues.

Signia™ with Tri-Staple™ provides **better staple formation** [closure] across staple sizes compared to SureForm™*.[†,4] p-value = 0.00.

Acute Hemostasis – Intraoperative Performance

118 staple lines were fired (59 SureForm™* White, 59 Tri-Staple™ Tan), in indicated in-vivo porcine small bowel. Staple line hemostasis was assessed 10mins after firing.

Signia™ with Tri-Staple™ Tan staple lines are **37% less likely to bleed** compared to SureForm™* White staple lines.[†,4] p-value 0.061.

Leak Pressure – Intraoperative Performance

30 Signia™ Black staple lines and 16 SureForm™* Black staple lines were fired in indicated ex-vivo porcine stomach tissue. The maximum leak pressure resistance was measured and recorded.

Signia™ with Tri-Staple™ Black staple lines can **withstand 20% greater leak pressure** compared to SureForm™* Black staple lines.[†,4] p-value = 0.036.

Conclusion

Signia™ with Tri-Staple™ technology demonstrated superior performance in preclinical staple formation, acute hemostasis, and leak pressure testing when compared to the SureForm™* stapler. Clinicians should consider the clinical outcomes of each device as they make decisions and expand robotic-assisted surgery in MBS when clinically indicated and accessible.

References:
1. Benjamin Clapp, Jaime Ponce, John Corbett, Omar M. Ghanem, Marina Kurian, Ann M. Rogers, Richard M. Peterson, Teresa LaMasters, Wayne J. English, American Society for Metabolic and Bariatric Surgery 2022 estimate of metabolic and bariatric procedures performed in the United States, Surgery for Obesity and Related Diseases, Volume 20, Issue 5, 2024, Pages 425-431, ISSN 1550-7289, https://doi.org/10.1016/j.soard.2024.01.012.
2. Siegel J, Cummings J, Clymer J. Reproducible, repeatable and clinically-relevant hemostasis scoring. Journal of Advances in Medical and Pharmaceutical Sciences. 2014;1(1):30-39. doi:10.9734/jamps/2014/11653
3. Strassner H, Caulk A, Reher N, Petrescu S, Vasanji A. Evaluating performance of Circular Staplers using comparative test methods for evidence-based surgery. Surgical Innovation. 2023;30(5):576-585. doi:10.1177/15533506231166447
4. Based on Internal Test Report RE00498029

† Preclinical results may not correlate with clinical performance in humans.

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