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# Comparative Analysis of Hemostasis and Staple-Line Integrity between Medtronic Tri-Staple™ with Preloaded Buttress Material and the AEON™ Stapler in Bariatric Surgery

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## ABSTRACT

**Background and Objectives:** Haemostasis-related complications associated with Medtronic Tri-staple™ with preloaded buttress material and the novel, naked AEON™ gastrointestinal staplers have not been extensively studied in bariatric surgery. The study aimed to assess and compare the 30-day haemostasis-related complications between Medtronic Tri-staple™ and AEON™ GIA staplers.

**Methods:** A retrospective analysis was performed on data from patients who underwent primary or revision sleeve gastrectomy (SG) or the sleeve component of single anastomosis duodeno-ileal bypass with SG (SADI-S) in a private hospital in Australia between November 2021 and December 2022. The surgeries were performed by a single surgeon, using either Medtronic Tri-staple™ or AEON™ staplers.

**Results:** The analysis included 250 patients, with the first 125 consecutive patients receiving staple line using the Medtronic Tri-staple™ GIA stapler and the subsequent 125 patients receiving staple line using the AEON™ GIA stapler. Statistical analysis revealed no significant differences in the distribution of surgical procedures between the Medtronic and AEON groups. In the AEON group, there were statistically higher numbers of diabetics and former tobacco users, while other preoperative characteristics did not significantly differ between the two groups. The AEON group had a significantly longer mean operative time, while the length of hospital stay was significantly shorter. No intraoperative or 30-day complications, deaths, emergency room visits, readmissions, or reoperations were observed in either group.

**Conclusion:** The novel, naked AEON™ stapler demonstrated non-inferiority to the established Medtronic Tri-Staple™ with preloaded buttress material in achieving hemostasis and maintaining staple-line integrity in bariatric surgery.

**Key Words:** AEON™, GIA stapler, Medtronic Tri-Staple™, Reinforcement, SADI-S, SG.

## INTRODUCTION

Sleeve gastrectomy (SG) has emerged as the leading bariatric surgical procedure on a global scale, constituting approximately 60% of all bariatric procedures.[1] SG is widely acknowledged as the safest and most reliable among established bariatric techniques, serving as a versatile option for primary interventions and revision surgeries in patients experiencing inadequate weight loss or weight regain.[2,3] While traditionally performed in hospital settings, there has been a notable shift towards outpatient SG procedures in various parts of the world, including the United States and elsewhere.[4,5] This shift is driven by the inherent benefits of improved safety profiles, reduced postoperative hospital stays, cost-effectiveness, and enhanced convenience for both patients and surgeons.[4,5] Nevertheless, complications related to stapler usage remain a noteworthy concern, primarily manifesting within the initial postoperative week of SG cases.[6] Minimizing the incidence of these complications is of utmost importance, as it enables same-day discharge protocols and optimizes patient outcomes. Additionally, regardless of the surgical setting, maintaining low rates of stapler-related complications is pivotal in minimizing the

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overall financial burden associated with the procedure. By effectively reducing stapler-related complications, both inpatient and outpatient approaches to SG can enhance cost-efficiency while ensuring favorable patient outcomes.

Gastrointestinal anastomosis (GIA) staplers have revolutionized the landscape of surgical interventions, augmenting the precision and efficiency of gastrointestinal surgeries.[7] Of particular concern are hemostasis-related complications and staple-line integrity, which have profound implications for the safety and success of these procedures. Notably, the bariatric market has witnessed the emergence of novel stapler brands alongside well-established ones, presenting promising technological advancements.[8–10] While the surgical outcomes of established GIA staplers, such as Medtronic and Ethicon, have already been extensively investigated and demonstrated acceptable complication rates in SG,[11] the evaluation of the novel stapler brands is comparatively limited. One such relatively new GIA stapler, called "AEON™," by Lexington Medical Inc., has recently undergone limited investigation regarding its safety in bariatric procedures.[12–15] However, the existing literature exploring this specific stapler remains limited in scope and depth.

This study aims to address this gap in the literature by conducting a comprehensive analysis of the 30-day complication rates associated with Medtronic Tri-Staple™ with preloaded buttress material and the novel, naked AEON™ GIA staplers in the context of SG. By systematically comparing the hemostasis complication profiles of these staplers, we aim to provide valuable insights into their respective effectiveness and safety profiles in achieving optimal hemostasis during SGs.

## MATERIALS AND METHODS

A retrospective analysis was conducted on a cohort of 250 consecutively enrolled patients with obesity who underwent either primary or revision SG or the sleeve component of single anastomosis-duodeno-ileal bypass with SG (SADI-S) procedures. The surgeries included in the study were performed by a surgeon (FRACS) with a fellowship in Advanced Laparoscopic and Bariatric surgery with more than 14 years of experience. These surgeries took place in a private hospital from November 2021 to December 2022.

The eligibility criteria for this study included individuals aged 18 years and older, encompassing all sexes. Patients meeting absolute or relative contraindications with bariatric surgery were excluded.

In adherence to ethical guidelines, this study implemented rigorous anonymization protocols to ensure the complete exclusion of personal identifiers. Given the nature (retrospective chart review) of the data, formal approval from an ethics committee was not pursued, aligning with established guidelines. Nevertheless, a meticulous and comprehensive consent process was undertaken, wherein patients provided prospective written informed consent explicitly addressing the purpose of data collection for the study. Informed consent was obtained from patients, explicitly granting permission to collect their bariatric surgery and postoperative care information. Patients were apprised of the potential utilization of deidentified body mass index (BMI), anonymous blood test results, and nutritional data for comparative studies and potential publication in reputable medical journals. Notably, patients were assured that their identities would remain strictly confidential and not be disclosed in any subsequent publications. Emphasis was placed on informing patients of their rights to access their information, except in circumstances where legitimate restrictions might apply. This study demonstrated an unwavering commitment to prioritizing patient rights and privacy throughout the research process through strict adherence to ethical guidelines and robust patient consent protocols.

Prior to surgery, comprehensive individual evaluations were conducted in a clinical setting. A multidisciplinary team approach assessed and evaluated all prospective surgery patients, ensuring comprehensive preoperative evaluations.

Retrospective data collection was performed using a prospectively maintained database, focusing on baseline characteristics, intraoperative details, and 30-day postoperative outcomes. Patient demographics, including height, weight, and BMI, were recorded during the preoperative assessment. Comorbidity assessments, laboratory parameters, surgical history, and preoperative dietary restrictions were also documented.

During the operative assessment, weight and BMI measurements, American Society of Anesthesiology (ASA) grading, skin-to-skin time, estimated blood loss, intraoperative complications, surgical techniques employed, and instances of conversion to open surgery were meticulously recorded. All surgical procedures were performed laparoscopically, adhering to standardized perioperative and postoperative protocols.

Short-term complications occurring within the 30-day postoperative period were carefully reviewed and documented.

Weight-related parameters, including actual weight in kilograms and BMI in kilograms per square meter, were measured and recorded at specified time points. Nutritional values were assessed both preoperatively and postoperatively. Coexisting conditions, such as diabetes mellitus (DM), hypertension (HTN), and obstructive sleep apnea (OSA), were evaluated based on medication usage or positive sleep study results.

As part of this study, an extensive review of the existing literature on bariatric surgery was conducted to identify preoperative and intraoperative risk factors that have been consistently associated with hemostasis-related complications. A comprehensive list of established risk factors was compiled by synthesizing findings from various articles. The data collection process involved assessing the presence of these preoperative risk factors in both the Medtronic and AEON groups.

Continuous variables were summarized using means and standard deviations, while categorical variables were presented as frequencies and percentages. Statistical analyses were performed using scientific data analysis software, considering relevant statistical tests and *P*-values for hypothesis testing. Additionally, expert interpretations and clinical insights were incorporated to enhance the comprehensiveness of the analysis.

### Operative Technique

In the Medtronic group, the surgical technique for SG involved the resection of the greater omentum using a LigaSure device (Medtronic™, Mansfield, MA, USA). The gastric resection began 4 to 6 cm away from the pylorus, following the contour of the bougie, and concluded 1 to 2 cm off the angle of His. The initial two stapler firings employed 45 mm black Endo GIA™ reinforced Tristaples™ (Medtronic™, Mansfield, MA, USA), followed by subsequent firings using 60-mm black Endo GIA™ reinforced Tristaples™ (Medtronic Tri-Staple™, Mansfield, MA, USA). These staplers were selected with care to ensure secure closure and effective hemostasis along the staple line. As part of the surgical technique, 4 ml of TISSEEL (Baxter AG, Vienna, Austria) was applied as a hemostatic agent, sprayed along the staple line to enhance hemostasis.

In the AEON group, the greater omentum was dissected off the greater curve using Ligasure from 4 cm to 6 cm proximal to the pylorus all the way to the angle of HIS. A 36 Fr. bougie was positioned along the lesser curve and used for sizing. The first load was 60 mm black, preceded by a precompression period of 15 seconds. Subsequently, one 60-mm purple AEON™ (Bedford, MA, USA) staple load was fired across the antrum, following a precompression period of 15 seconds. Three Orange 60-mm AEON™ staple loads were fired along the bougie, each preceded by a precompression period of 15 seconds before firing the devices.

## RESULTS

Two-hundred and fifty patients were included in the final analysis, with 125 patients in both the Medtronic and AEON groups (**Table 1**). The distribution of surgical procedures for each group is presented in **Table 1** In the Medtronic group, 117 patients (93.6%) underwent primary surgery, while 8 patients (6.4%) underwent revision surgery (**Table 1**). Among the Medtronic group, 113 patients (90.4%) underwent SG, with 106 patients (84.8%) undergoing primary SG and 7 patients (5.6%) undergoing revision SG. In the AEON group, 118 patients (94.4%) underwent SG, with 112 patients (89.6%) undergoing primary SG and 4 patients (3.2%) undergoing revision SG. The SADI-S procedure was performed in 12 patients (9.6%) in the Medtronic group, with 11 patients (8.8%) undergoing primary SADI-S and 1 patient (0.8%) undergoing revision SADI-S. In the AEON group, eight patients (6.4%) underwent SADI-S, with six patients (4.8%) undergoing primary SADI-S and two patients (1.6%) undergoing revision SADI-S. Statistical analysis revealed no significant differences in the

**Table 1.**
Distribution of Surgical Procedures

| Variable | Medtronic Group (n [%]) | AEON Group (n [%]) | *P*-Value |
|---|---|---|---|
| Total | 125 | 125 | – |
| Primary | 117 (93.6%) | 119 (95.2%) | .783 |
| Revision | 8 (%) | 6 (%) | |
| SG | | | |
| Total | 113 (90.4%) | 118 (94.4%) | .473 |
| Primary | 106 (84.8%) | 112 (89.6%) | .508 |
| Revision | 7 (5.6%) | 4 (3.2%) | |
| SADI-S | | | |
| Total | 12 (9.6%) | 8 (6.4%) | .473 |
| Primary | 11 (8.8%) | 6 (4.8%) | .537 |
| Revision | 1 (.8%) | 2 (1.6%) | |

*Abbreviations:* SG, sleeve gastrectomy; SADI-S, single-anastomosis duodeno-ileal bypass with sleeve gastrectomy.

distribution of surgical procedures between the Medtronic and AEON groups (**Table 1**).

In the Medtronic group, the mean age was 38.9 ± 10.7 years, with a gender distribution of 19% males and 81% females (**Table 2**). The mean preoperative BMI was 41.2 ± 5.4 kg/m$^2$. Among the 125 patients in this group, 18.4%, 11.2%, and 6.4% were diagnosed with HTN, OSA, and DM, respectively. **Table 2** provides a comprehensive breakdown of the preoperative risk factors associated with intra- or postoperative bleeding.

In the AEON group, the mean age was 40 ± 10.4 years, with a gender distribution of 25% males and 75% females (**Table 2**). The mean preoperative BMI was 41.7 ± 5.9 kg/m$^2$. Among the 125 patients in this group, 19.2%, 13.6%, and 16.8% were diagnosed with HTN, OSA, and DM, respectively. **Table 2** provides a detailed breakdown of the preoperative risk factors associated with intra- or postoperative bleeding.

No statistically significant differences were observed in the preoperative characteristics between the Medtronic and AEON groups, as well as any of the preoperative risk factors associated with hemostasis-related complications, except for the total number of patients with DM and former tobacco users (**Table 2**). Notably, both DM ($P$ = .018) and former tobacco usage ($P$ = .008) were significantly higher in the AEON group.

The operative outcomes for both groups are presented in **Table 3**. All patients in the Medtronic group received

**Table 2.**
Characteristics and Operative Outcomes of Patients in the Study Groups

| Variable | Medtronic Group | AEON Group | *P*-Value |
|---|---|---|---|
| Total case | 250 | | – |
| N (no.) | 125 | 125 | |
| Primary surgery (no.) | 117 (93.6%) | 119 (95.2%) | .783 |
| Revision surgery (no.) | 8 (6.4%) | 6 (4.8%) | |
| Age (year)* | 38.9 ± 10.7 | 40 ± 10.4 | .411 |
| M/F (%) | 19/81 | 25/75 | .393 |
| Preoperative BMI (kg/m$^2$)* | 41.2 ± 5.4 | 41.7 ± 5.9 | .485 |
| High risk (no.) | 2 (1.6%) | 2 (1.6%) | – |
| **Baseline Obesity-Related Comorbidity/Risk Factor** | **Medtronic Group** | **AEON Group** | ***P*-Value** |
| HTN (no.) | 23 (18.4%) | 24 (19.2%) | 1.000 |
| OSA (no.) | 14 (11.2%) | 17 (13.6%) | .701 |
| DM (no.) | 8 (6.4%) | 21 (16.8%) | **.018** |
| NSAIDs (no.) | 9 (7.2%) | 11 (8.8%) | .816 |
| Liver disorder (no.) | 9 (7.2%) | 14 (11.2%) | .381 |
| Chronic steroid user (no.) | 4 (3.2%) | 2 (1.6%) | .679 |
| Anticoagulant user (no.) | 2 (1.6%) | 0 | .478 |
| Tobacco smoker (no.) | 11 (8.8%) | 14 (11.2%) | .673 |
| Former tobacco smoker (no.) | 27 (21.6%) | 47 (37.6%) | **.008** |
| Bleeding disorder (no.) | 2 (1.6%) | 2 (1.6%) | – |
| Abnormal serum albumin level (no.) | 0 | 0 (%) | – |
| History of DVT/PE (no.) | 5 (4%) | 3 (2.4%) | .719 |

*Value expressed as mean ± standard deviation.
*Abbreviations:* N, total patients; no., number; M, male; F, female; BMI, body mass index; HTN, hypertension; OSA, obstructive sleep apnea; DM, diabetes mellitus; NSAIDS, nonsteroidal anti-inflammatory drugs; DVT, deep vein thrombosis; PE, pulmonary embolism.

staple-line reinforcement through the use of preloaded buttress material in addition to the application of TISSEEL as a hemostatic agent. Conversely, in the AEON group, only 16.8% of the patients necessitated such reinforcement, as the AEON™ stapler does not include preloaded buttress material. Reinforcement with Seamgaurd was specifically used in patients with certain clinical conditions, such as type 1 diabetes, poorly controlled T2DM, known ischemic heart disease, cardiac failure, or those at high risk of postoperative bleeding due to prolonged anticoagulation. These decisions were made to address the increased potential for complications in these patient populations and to ensure optimal surgical outcomes. In each instance, both staplers underwent visual scrutiny, yielding no discernible complications. The median number of cartridges used during surgery was five for both the Medtronic group (range: 5 [5–7]) and the AEON group (range: 5 [4–7]). Stapler misfiring occurred in 2 cases and stapler malfunction in 2 cases within the Medtronic group, whereas no such events were observed in the AEON group. However, there was no statistically significant difference in the rates of stapler misfiring and malfunction between the two groups ($P = .478$). Leak tests were exclusively performed in high-risk patients, with 11 (8.8%) cases in the Medtronic group and 6 (4.8%) cases in the AEON group, showing no statistically significant difference. The mean operative skin-to-skin time was 30 ± 4.8 minutes for the Medtronic group and was significantly longer at 34.5 ± 4.9 minutes for the AEON group ($P < .001$). No intraoperative complications or deaths occurred in either group. The mean length of hospital stay was significantly shorter in the AEON group ($P = .039$) (1 ± .2 days) compared to the Medtronic group (1.1 ± .5 days).

The 30-day follow-up was completed for 100% of the patients in both groups, with no reports of emergency department visits, readmissions, reoperations, complications, or death (**Table 4**).

Preoperatively, the prevalence of patients exhibiting abnormal hemoglobin levels was 1.6% in the Medtronic group and 9.6% in the AEON group (**Table 5**). Notably, a statistically significant difference was observed between the two groups ($P = .014$). However, on postoperative day one, the proportion of patients with abnormal hemoglobin levels in the Medtronic group increased to 17.6%, while the AEON group had 27.6% of patients experiencing such abnormalities. Despite this observed disparity, the statistical analysis did not yield a significant difference between the groups ($P = .082$). Similarly, the analysis of hematocrit levels showed that preoperatively, only .8% of the patients in the Medtronic group and 4.8% in the AEON group had abnormal levels (**Table 5**). There was no statistically significant difference. On postoperative day one, 12% of the patients in the Medtronic group and 21.9% in the AEON group had abnormal hematocrit levels, but again, there was no statistically significant difference.

This study also conducted a $\chi^2$ test of independence to assess the association between abnormal hemostasis and staple-line integrity in bariatric surgery, comparing the

**Table 3.**
Operative Outcomes of Patients in the Study Groups

| Variable | Medtronic Group | AEON Group | *P*-Value |
|---|---|---|---|
| Reinforcement (no.) | 125 (100%) | 21 (16.8%) | **<.001** |
| Stapler cartridge (median [low range-upper range) | 5 (5–7) | 5 (4–7) | – |
| Stapler misfire (no.) | 2 (1.6%) | 0 | .478 |
| Stapler malfunction (no.) | 2 (1.6%) | 0 | .478 |
| Leak test (no.) | 11 (8.8%) | 6 (4.8%) | .315 |
| Operative time (skin-to-skin)* | 30 ± 4.8 | 34.5 ± 4.9 | **<.001** |
| Open conversion | 0 | 0 | – |
| Intraoperative complication (no.) | 0 | 0 | – |
| Death | 0 | 0 | – |
| Length of stay (day)* | 1.1 ± .5 | 1 ± .2 | **.039** |

*Value expressed as mean ± standard deviation.
*Abbreviations:* no., number.

**Table 4.**
30-Day Complications

| | 30-Day Readmission, Reoperation, and ER Visit | | |
|---|---|---|---|
| | Medtronic Group | AEON Group | *P*-Value |
| 30-day ER visit (event) | 0 | 0 | – |
| 30-day readmission (event) | 0 | 0 | – |
| 30-day reoperation (event) | 0 | 0 | – |
| 30-mortality | 0 | 0 | – |

| | Short-Term Complication | | | | | |
|---|---|---|---|---|---|---|
| | Medtronic | | | AEON | | |
| Complication (Event) | no. | % | Complication (Event) | no. | % | *P*-Value (Medtronic versus AEON [Pt]) |
| Follow-up | 125 | 100 | Follow-up | 125 | 100 | – |
| None | 0 | 0 | None | 0 | 0 | – |
| Total event | 0 | 0 | Total event (no.) | 0 | 0 | – |
| Total patient (no. [%]) | 0 | | Total patient (no. [%]) | 0 | | – |

*Abbreviations:* ER, emergency department; Pt, patient.

Medtronic Tristaple and novel AEON stapler. The analysis revealed that the relationship between staple-line bariatric procedures and abnormal hemostasis did not yield statistical significance at the $\alpha$ level .01. Specifically, the calculated $\chi^2$ statistic was 4.3642, based on a sample size of N = 248 participants, with 1 degree of freedom (df = 1) and an associated *P*-value of .0367. Power calculations were performed to determine the statistical power of the $\chi^2$ test. The power analysis was based on the aforementioned sample size of N = 248, a significance level of .01, and effect size (w) of .22, classified as a medium effect size. The resulting power of the test was calculated to be .81, corresponding to an 81% probability of correctly detecting an association if it indeed exists. Thus, the statistical power analysis demonstrated a reasonably high chance of identifying a true association between abnormal hemostasis and staple-line integrity using the data from **Table 5**.

## DISCUSSION

This study aimed to compare hemostasis-related complications and staple-line integrity between the established Medtronic Tri-Staple™ GIA stapler with preloaded buttress material and the novel, naked AEON™ GIA stapler in bariatric surgery, specifically SG or the sleeve component of SADI-S. The results of this study demonstrate that both staplers exhibit similar safety and efficacy in achieving hemostasis and maintaining staple-line integrity, with no significant differences observed in operative outcomes, 30-day complications, or postoperative hemoglobin and hematocrit levels. Notably, the study findings indicate that the AEON™ naked stapler is noninferior to the Medtronic Tri-Staple™ stapler with reinforcement and use of a hemostatic agent, highlighting the comparable performance of the AEON™ stapler without requiring additional reinforcement materials or hemostatic agent.

Assessing and comparing the rates of hemostasis-related complications between different stapler brands is crucial in bariatric surgery due to the potential adverse outcomes, increased healthcare costs, and extended hospital stays associated with these complications.[6] Improving the safety profiles of staplers and optimizing patient outcomes in bariatric procedures are important objectives. The evaluation of the AEON™ stapler's safety and efficacy compared to established staplers is particularly relevant due to its novel features and potential advantages in achieving hemostasis along the staple line.

The AEON™ stapler, a relatively new brand, incorporates three notable features through its S3 engineering framework, which revolutionized the field of surgical stapling.[16] Firstly, integrating multispeed gear, particularly the Thick Mode gear, reduces firing force, enabling superior staple formation and

**Table 5.**
Pre- and Postoperative Hemoglobin and Hematocrit

| Variable | Medtronic Group | | | | AEON Group | | | | *P*Value Medtronic versus AEON | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Preoperative | | Postoperative Day 1 | | Preoperative | | Postoperative Day 1 | | | |
| | Abn (No.) | Total (No.) | Abn (No.) | Total (No.) | Abn (No.) | Total (No.) | Abn (No.) | Total (No.) | Preoperative | Postoperative |
| Hemoglobin | | | | | | | | | | |
| Pt | 2 (1.6%) | 123 | 22 (17.6%) | 125 | 12 (9.6%) | 124 | 34 (27.6%) | 123 | **.014** | .082 |
| Normal range | Male: 138–172 (g/L) and Female: 121–151 (g/L) | | | | | | | | – | – |
| Hematocrit | | | | | | | | | | |
| Pt | 1 (.8%) | 123 | 15 (12%) | 125 | 6 (4.8%) | 124 | 27 (21.9%) | 123 | .128 | .055 |
| Normal range | Male: 41–50 (%) and Female: 36–48 (%) | | | | | | | | – | |

Data were presented as the number of patients with abnormal labs, preoperative and postoperative as well as mean ± SD.
*Abbreviations:* no., number; Abn, abnormal; Pt, patient; SD, standard deviation.

enhancing hemostatic capabilities, especially in challenging scenarios involving thick tissue. This feature proves beneficial for surgeons, including those with carpal tunnel issues, as it significantly eases staple firing on the wrist and fingers, providing added comfort and ergonomic advantages. Secondly, the AEON™ stapler's superior staple lines contribute to reduced bleeding and the formation of dried staple lines, indicating improved tissue sealing properties. These enhanced sealing properties can effectively negate the need for reinforcement or hemostatic agent, resulting in significant cost savings for the patient. Lastly, the incorporation of smooth articulation in the AEON™ stapler ensures precise positioning with a seamless range of motion, enabling accurate and efficient stapling in various surgical procedures. It is worth noting that the articulation in the AEON™ stapler provides a seamless range from 0 to 45 degrees, allowing for greater flexibility and adaptability during surgical maneuvers. In contrast, Medtronic has four preset articulation positions, not allowing full flexibility to position at any angle. This distinction highlights the advantage of the AEON™ stapler in providing a wider range of articulation options, further enhancing its usability and precision in surgical applications. These S3 engineering features of the AEON™ stapler offer distinct advantages and hold immense potential in optimizing surgical outcomes. Additionally, the AEON™ stapler offers the widest range of staple height offerings among all stapler brands, accommodating tissue thickness ranging from .75 mm to 4.0 mm. It also provides a comprehensive selection of anvils, including the proprietary AEON™ short tip designed to minimize tissue trauma associated with stapler blunting, ensuring versatility across a diverse range of clinical applications. Furthermore, the universal handle compatibility allows surgeons to utilize 30-mm, 45-mm, and 60-mm reloads within a single surgery, simplifying the procedure and streamlining instrument management.

The AEON™ stapler, a recent addition to the market, incorporates three distinct features through its S3 engineering framework, which have significantly impacted surgical stapling.[16] Firstly, the integration of a multispeed gear system, particularly the Thick Mode gear, reduces firing force, facilitating superior staple formation and enhancing hemostatic capabilities, particularly in challenging scenarios involving thick tissue. This feature provides notable benefits for surgeons, including those with carpal tunnel issues, by significantly reducing strain during staple firing, thereby enhancing comfort and ergonomics. Secondly, the AEON™ stapler's superior staple lines contribute to diminished bleeding and the formation of dried staple lines, indicative of improved tissue sealing properties. These enhanced sealing capabilities can

potentially eliminate the need for reinforcement or hemostatic agents, leading to substantial cost savings for patients. Lastly, the incorporation of smooth articulation in the AEON™ stapler ensures precise positioning with a seamless range of motion, facilitating accurate and efficient stapling across various surgical procedures. Notably, the articulation range of the AEON™ stapler spans from 0 to 45 degrees, allowing for enhanced flexibility and adaptability during surgical maneuvers, a feature not present in the Medtronic stapler which offers only four preset articulation positions. This distinction underscores the advantage of the AEON™ stapler in providing a broader range of articulation options, thereby enhancing its usability and precision in surgical applications. These S3 engineering features of the AEON™ stapler confer distinct advantages and hold significant potential in optimizing surgical outcomes. Additionally, the AEON™ stapler offers the widest range of staple height options among all stapler brands, accommodating tissue thicknesses ranging from .75 mm to 4.0 mm. It also provides a comprehensive selection of anvils, including the proprietary AEON™ short tip designed to minimize tissue trauma associated with staple blunting, ensuring versatility across a diverse range of clinical applications. Furthermore, the universal handle compatibility enables surgeons to utilize 30-mm, 45-mm, and 60-mm reloads within a single surgery, thereby simplifying the procedure and streamlining instrument management.

A limited number of studies have explored the outcomes related to the use of the AEON™ stapler, reflecting its relatively recent introduction compared to other well-established stapler devices.[12–15] When comparing our findings with previously published studies, we identified two relevant studies that investigated the use of different staplers in SG. Redmann et al. conducted a study comparing the AEON™ Endostapler to the Echelon Flex™ Powered Stapler.[12] Their findings revealed that the AEON™ Endostapler generated a significantly drier staple line and had a lower incidence and degree of staple line bleeding compared to the Echelon Flex™ stapler. It is important to note that their study primarily focused on intraoperative bleeding and the need for additional bleeding control methods. In contrast, our study did not specifically evaluate staple line bleeding as a primary outcome. Instead, we aimed to compare various surgical and postoperative outcomes between the Medtronic Tri-Staple™ and AEON™ staplers. Although we did not directly measure bleeding using visual analogue scale (VAS) scores, we did not observe any significant differences in intraoperative or postoperative bleeding between the two stapler groups. Another study by Raftopoulos et al. investigated two 6-row linear Endo staplers, the Medtronic Endo GIA™ Tristaple technology and the AEON™ Endostapler, in laparoscopic SG.[15] Their findings indicated that the AEON™ Endostapler group had significantly lower bleeding VAS scores in several laparoscopic and endoscopic images compared to the Medtronic group. This suggests that the AEON™ stapler may result in less intraoperative bleeding during SG. While our study did not directly measure bleeding using VAS scores, our results align with Raftopoulos et al.'s findings, as we did not observe any significant differences in intraoperative or postoperative bleeding between the Medtronic Tri-Staple™ and AEON™ stapler groups. It is worth noting that each study may have variations in methodologies, patient populations, and specific outcome measures, which could contribute to slight differences in the reported findings.

In the present study, the preoperative characteristics of patients in both the Medtronic and AEON groups were similar, indicating comparability in terms of baseline characteristics and comorbidities. Although there were significantly more patients with DM and former tobacco users in the AEON group, these differences did not appear to influence the occurrence of hemostasis-related complications or staple-line integrity issues. However, it is important to acknowledge that various confounding factors could influence these findings, and further investigations are warranted to explore potential associations between DM, tobacco usage, and stapler-related complications.

Furthermore, the surgeon possessed significant experience with the Medtronic Tristapler, renowned for its reinforced design and the prevalence of bleeding complications associated with its use. The decision to compare outcomes between a stapler equipped with preloaded buttress material and a naked stapler was intentional. Prior to this determination, an extensive review of bleeding-related literature pertaining to both AEON and Medtronic staplers was conducted. The favorable outcomes documented in these studies influenced the decision to forego reinforcement. However, despite promising findings associated with the AEON stapler in published literature, precautionary measures were taken in high-risk patients, whereby reinforcement was employed to ensure patient safety.

Operative outcomes, including staple-line reinforcement, misfiring, and malfunction, were compared between the two staplers in this study. Notably, the operative times were longer in the AEON group compared to the Medtronic group. The precompression period of 15 seconds before firing the AEON™ stapler, as described in the surgical

technique, may have contributed to the additional time needed to achieve hemostasis. In the Medtronic group, all patients received staple-line reinforcement through the use of preloaded buttress material, along with the hemostatic agent TISSEEL. Conversely, in the AEON group, only 16.8% of the patients required such reinforcement, indicating potentially superior sealing and hemostasis achieved with the AEON™ stapler. These findings strongly support the notion that AEON naked staples can be considered noninferior to the Medtronic stapler with reinforcement and the hemostatic agent TISSEEL.

Beyond the clinical implications, the cost-effectiveness associated with the AEON™ stapler deserves attention. The fact that only a small percentage of patients in the AEON group required staple-line reinforcement suggests that the use of AEON naked staples can significantly reduce the need for costly reinforcement materials, as well as the hemostatic agent TISSEEL. Considering the expenses incurred by reinforcement materials and hemostatic agents, the adoption of the AEON stapler offers a cost-effective alternative in comparison to the Medtronic stapler. By avoiding the additional costs associated with reinforcement materials and the hemostatic agent, healthcare facilities can potentially achieve notable cost savings without compromising patient outcomes. This economic advantage should be considered in the decision-making process, as it contributes to the overall value and feasibility of utilizing the AEON™ stapler in bariatric surgery. However, it is crucial to conduct further studies with larger sample sizes and comprehensive cost analyses to validate and consolidate the cost-effectiveness findings presented in this study. These investigations would strengthen the evidence base and provide more robust guidance for surgical decision-making processes.

It is important to note that the rates of staple misfiring and malfunction were low in both the AEON and Medtronic groups, with no significant difference observed. These results further support the notion that both staplers can be effectively used in bariatric surgery with minimal technical difficulties and complications, reaffirming the clinical reliability of the AEON stapler.

The length of hospital stay was significantly shorter in the AEON group, highlighting the potential advantages of the novel stapler in facilitating early recovery and discharge. This shorter duration of hospitalization can have positive implications, including improved patient satisfaction, reduced healthcare costs, and enhanced patient flow within healthcare facilities. However, it is important to consider various factors that may have influenced the length of hospital stay, including postoperative pain management, patient comorbidities, and institutional protocols. It is worth noting that both groups followed the same protocols, indicating that factors other than institutional protocols might have contributed to the shorter hospital stay in the AEON group.

The absence of intraoperative complications, deaths, emergency department visits, readmissions, and reoperations in both groups is a reassuring finding, suggesting the overall safety of the staplers in the studied population. This is consistent with previous studies on established stapler brands, such as Medtronic and Ethicon, which have demonstrated acceptable complication rates in bariatric surgery.11,17,1[8] The lack of significant differences in these outcomes further supports the comparable safety profiles of the Medtronic Tri-Staple™ and AEON™ staplers.

Postoperative hemoglobin and hematocrit levels were assessed as indicators of potential bleeding complications along the staple line.19,[20] Preoperatively, a statistically significant difference was observed between the Medtronic and AEON groups in terms of the prevalence of patients with abnormal hemoglobin levels, suggesting potential variations in patient characteristics or underlying factors. However, on the postoperative day one, both groups showed an increase in the proportion of patients with abnormal hemoglobin levels, and no significant difference was found between the groups. Similar trends were observed for hematocrit levels, with no statistically significant difference between the groups preoperatively or on postoperative day one. These findings suggest that the choice between Medtronic Tri-Staple™ and AEON™ staplers may not significantly impact postoperative hemoglobin and hematocrit levels. Both groups demonstrated comparable outcomes regarding these blood parameters, indicating similar rates of postoperative blood loss and hemostasis.

The findings of this study have important implications for clinical practice in bariatric surgery. The comparable safety and efficacy demonstrated by both the Medtronic Tri-Staple™ and AEON™ staplers provide surgeons with alternative options for achieving optimal staple-line integrity and hemostasis during SG and the sleeve component of SADI-S procedures. When selecting a stapler for bariatric surgery, surgeons must consider various factors, including stapler design, ease of use, cost, and institutional preferences. The results of this study suggest that both the Medtronic Tri-Staple™ and AEON™ staplers can be viable options in terms of safety and efficacy. However,

it is essential to note that this study focused specifically on SG and SADI-S procedures, and the findings may not be directly applicable to other bariatric procedures.

Acknowledgement of the limitations of this study is imperative. Firstly, the reliance on retrospective data analysis introduces inherent constraints due to potential biases and limitations in data availability and quality. Despite conscientious efforts to mitigate these limitations through meticulous data collection and analysis, the retrospective nature of the study imparts inherent drawbacks that can impact the accuracy and reliability of the findings. The implementation of prospective studies incorporating standardized data collection protocols would engender more robust evidence.

Additionally, the study's sample size may have been insufficient, thereby potentially compromising the statistical power and generalizability of the results. Augmenting the sample size would enhance the study's capacity to discern noteworthy distinctions between the Medtronic Tri-Staple™ and AEON™ GIA staplers, as well as fortify the external validity of the findings for the broader population undergoing SG.

It is crucial to acknowledge the considerable prior experience and familiarity of the surgeon with Medtronic Tri-Staple™, as they have been using them since 2012. This extended experience with Medtronic Tri-Staple™ might have provided an advantage to the Medtronic group, as the surgeon had been using these staplers for the past ten years before the study. On the other hand, the AEON group may have faced challenges associated with the learning curve of the newer stapler. It is important to recognize that this discrepancy in surgeon familiarity and experience with the two stapler brands could have influenced the outcomes and potentially introduced a bias in favor of Medtronic Tri-Staple™. In addition, it should be acknowledged that the study might have unintentionally overlooked the inclusion of preoperative risk factors for postoperative bleeding and other potential risk factors associated with stapler-related complications. Despite conducting thorough research and incorporating all available information, certain relevant risk factors may have been inadvertently omitted. Intraoperative leak tests were not routinely conducted during the cases, as it was not standard practice for the surgeon. However, given the favorable outcomes associated with both the AEON™ Endostapler and Medtronic Tri-Staple™, the decision was made based on existing literature suggesting significantly drier staple lines with these devices, reducing the necessity for additional measures such as intraoperative EGD.[12,15] Nonetheless, it is essential to acknowledge that this retrospective analysis may not capture all potential factors influencing outcomes, and prospective studies could provide more comprehensive evaluations.

Another potential limitation of this study is the disparity in the availability of preloaded buttress material between the Medtronic Tri-Staple™ and AEON™ staplers. The Medtronic Tri-Staple™ is equipped with preloaded buttress material, which augments the staple line's strength and stability. Conversely, the AEON™ stapler lacks this feature, leading to contrasting practices in buttress material usage between the two stapler brands. This discrepancy introduces the potential for bias in the study outcomes. The presence or absence of buttress material may influence the resilience and endurance of the staple line, thus affecting the likelihood of complications such as bleeding or leakage. Consequently, the outcomes associated with the Medtronic Tri-Staple™ may be subject to the supplementary support provided by the buttress material. Recognizing this limitation is essential, as it necessitates due consideration of the potential bias introduced by the presence or absence of buttress material when interpreting and comparing the findings of this investigation.

To comprehensively elucidate the comparative effectiveness and safety profiles of Medtronic Tri-Staple™ and AEON™ GIA staplers in SG procedures, future investigations should embrace larger sample sizes, prospective designs, and endeavors to account for surgeon experience and the effects of the learning curve. Moreover, a larger multicenter study with a more diverse patient population would provide further insights into the safety and efficacy of the Medtronic Tri-Staple™ and AEON™ staplers in bariatric surgery.

The findings from this study will contribute to the existing body of knowledge and assist surgeons in making evidence-based decisions regarding selecting GIA staplers, thereby enhancing patient outcomes and ensuring the cost-effectiveness of bariatric surgical procedures.

## CONCLUSIONS

In conclusion, this study establishes the noninferiority of the novel AEON™ stapler to the established Medtronic Tri-Staple™ in achieving hemostasis and maintaining staple-line integrity in bariatric surgery. The AEON™ stapler demonstrates improved hemostatic properties with its naked staple design, which compares favorably to Medtronic Tri-Staple™, incorporating buttress materials and tissue sealants. However, it is important to acknowledge that further research with larger sample sizes and longer follow-up periods is necessary to validate these findings and

investigate potential factors that may influence stapler performance in bariatric surgery.

In conclusion, our findings indicate that the novel AEON™ stapler is noninferior to the established Medtronic Tristaple™ in achieving hemostasis and maintaining staple-line integrity in bariatric surgery. However, we recognize the inherent biases of retrospective studies and acknowledge the limitations posed by our small sample size, which may constrain the breadth of our conclusions. It is imperative to note that definitive conclusions cannot be drawn from our study alone. Future research with larger sample sizes is essential to validate these findings and explore potential factors influencing stapler performance in bariatric surgery.

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