IMPROVING HEMOSTASIS IN SLEEVE GASTRECTOMY: A RANDOMIZED CLINICAL TRIAL COMPARING STAPLERS

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Introduction

Staple line bleeding can be a major intraoperative complication during laparoscopic sleeve gastrectomy, requiring reinforcing interventions that may diminish the integrity of the staple line and put patients at risk for postoperative hemorrhage or leak. The risk of bleeding is commonly mitigated using buttressing, oversewing or fibrin glue to reinforce the staple line, however, these bleeding control methods are costly, often redundant, and may result in further complications. [1-3] For this reason, it is necessary to produce a drier stapler line that leads to less staple line manipulation. The primary goal of this prospective study is to assess staple line bleeding of the AEON™ Endostapler against the Echelon Flex™ Powered Stapler for use in laparoscopic sleeve gastrectomy.

Methods

Sixty consecutive laparoscopic sleeve gastrectomy procedures were performed by three surgeons; 30 sleeves using the AEON™ Endostapler on THICK MODE and 30 using the Echelon Flex™ Powered Stapler with pulse technique. Stapler performance was measured by incidence and degree of staple line bleeding. Images of the first firing and fundus were taken with the laparoscope 10 seconds after the final firing. Images were evaluated by a third-party blinded evaluator and given a "bleeding score," a qualitative measure of intra-operative staple-line bleeding (1 = no bleeding to 5 = profuse bleeding) (**Fig. 1**).

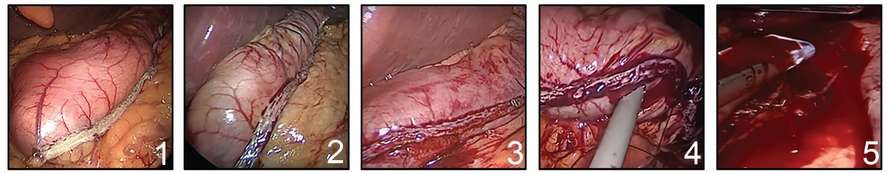


Fig. 1. Bleeding severity scale. 1: No bleeding at staple line; 2: Minimal bleeding at staple line; 3: Moderate bleeding at staple line; 4: Excessive bleeding at staple line; 5: Profuse bleeding at staple line.

Results

The AEON™ Endostapler demonstrated a lower mean (± S.E.M) "bleeding score" versus the Echelon Flex™ (2.1 ± 0.1 vs. 2.6 ± 0.1; p = 0.01) (**Table 2**). The AEON™ Endostapler had 15 cases (50%) with no bleeding at the fundus; the Echelon Flex™ had 7 cases (23%) with no bleeding at the fundus. The AEON™ Endostapler had 0 cases (0%) with profuse bleeding; the Echelon Flex™ had 2 cases (7%) with profuse bleeding (**Table 3**).

Table 1.
Comparison of patient demographics

Variable	*AEON™*	*Echelon Flex™*	*Total*
Patients	30	30	60
Age, y	46 ± 11	45 ± 11	46 ± 11
Sex (male/female)	12 (40%) / 18 (60%)	5 (17%) / 25 (83%)	17 (28%) / 43 (72%)
BMI, kg/m²	44 ± 6	46 ± 7	45 ± 7

Data are expressed as mean ± SD or n (%)

Table 2.
Comparison of intraoperative stapler bleeding scores

Outcome measure	*AEON™*	*Echelon Flex™*	*P Value*
Overall bleeding score	2.1 ± 0.1	2.6 ± 0.1	**0.01**
Fundus bleeding score	1.6 ± 0.1	2.3 ± 0.2	**0.001**
First firing bleeding score	2.6 ± 0.2	2.8 ± 0.2	0.49

Data are expressed as mean ± SEM

Conclusion

The AEON™ Endostapler is shown to be a significantly drier alternative to the Echelon Flex™ Powered Stapler. Stapler choice is a factor in producing a drier stapler line and in decreasing the need for other bleeding control methods.

Table 3.
Cases with and without staple line bleeding

	AEON™	*Echelon Flex™*
Cases with no bleeding at the fundus	15 (50%)	7 (23%)
Cases with no bleeding over the entire staple line	3 (10%)	1 (3%)
Cases with profuse bleeding	0 (0%)	2 (7%)

Data are expressed as n (%)

References

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