

# Results of Prospective Clinical Trial : “Evaluation of the AEON Endoscopic Powered Stapling System in Primary Sleeve Gastrectomy”

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OF HEALTH SCIENCES



# Disclosures

- Principal investigator of the trial sponsored by Lexington Medical

# Emerging Trends and Challenges

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- The number of laparoscopic stapler manufacturers is growing.
- New technologies are implemented by industry to make surgery safer, more ergonomic, faster.
- Most of improvements are carefully designed in laboratories, but lack of clinical trials still exist.

# Product Background

- Lexington Medical is a Boston-based surgical stapler manufacturer.
- 2018: AEON manual stapler was launched globally and successfully adopted with 10 peer reviewed studies and abstracts to-date.
- 2024: AEON powered stapler received FDA clearance and launched globally.
- AEON Powered Stapler: Integrated intelligence with tissue sensing to adjust firing speed in response to real-time tissue thickness readings.
  - 7 firing speeds | 1,000 tissue thickness readings per second

Manual AEON Handle



Powered AEON Handle



# First-In-Man Trial

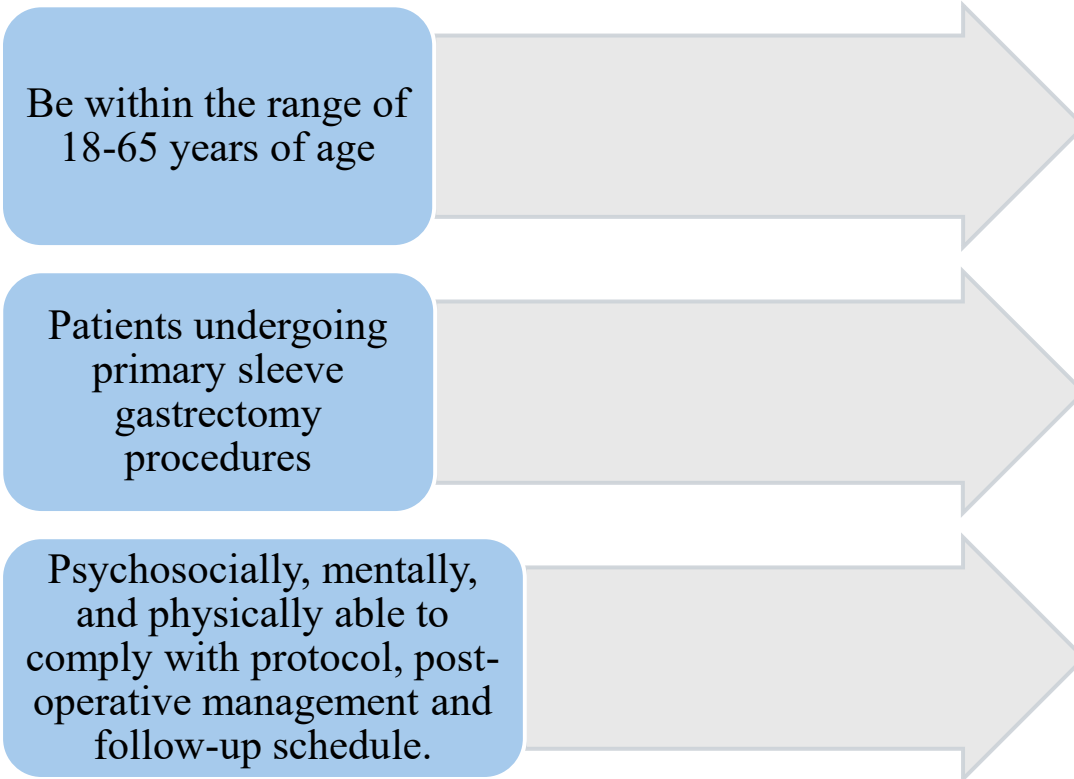
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- Overview: This is the First-in-Man study of AEON Powered Stapler following successful pre-clinical testing.
- Hypothesis: The AEON Powered Stapling System can enhance consistency and stability during firing, reduce tissue trauma, improve hemostasis, and decrease postoperative complications.
- Design: Prospective, single-arm, single-center study to evaluate the clinical outcomes of patients undergoing primary sleeve gastrectomy procedures using AEON Powered Stapling System.
- Clinical Trial Registration: [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT06474637) 2024.01.30  
**ClinicalTrials.gov ID** NCT06474637.



## Inclusion criteria



## Exclusion criteria

1. Prior bariatric surgery procedure or major GI surgery via open approach.
2. Sleeve gastrectomy procedure that is planned to be performed via open approach
3. Patients receiving anticoagulant medication(s)
4. Severe heart disease or lung problems
5. Known sensitivity to implant materials
6. Evidence of active (systemic or localized) infection at time of surgery
7. Women who are pregnant or planning to get pregnant in the next 12 months
8. Recent history of known alcohol and/or narcotic abuse
9. Investigational drug or device use within 30 days
10. Any other factors that may contribute, based on professional judgement of the treating surgeon, to the subject being a poor candidate for the study

Trial sample size – 50 patients

# Data collection

## **Baseline evaluation**

Medical History and Demographic Data :

- Demographic data
- Medical history, including comorbidities
- Physical examination (height, weight, previous surgeries)
- Pregnancy Test Result (as applicable)
- Quality of life questionnaires 36-Item Short Form Health Survey (SF-36)

# Data collection

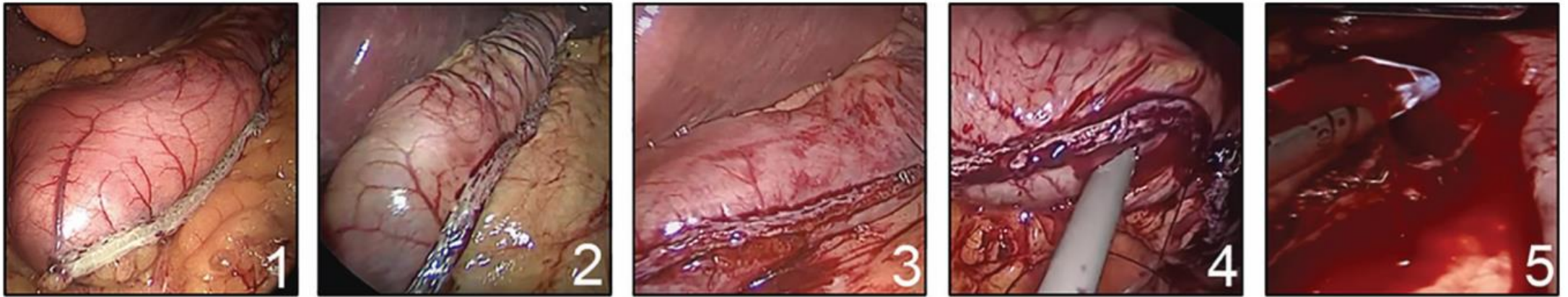
## Operative and Postoperative Course

- Device information :
  - Handle Lot Number
  - Staple Reloads :
    - Reload Size
    - Quantity Used
- Duration of procedure (operative time)
- Estimated blood loss (ml)
- Staple line bleeding : Bleeding severity scale from Redmann et al.
- Staple line leaks
- Intra-operative adverse events including but not limited to:
  - Staple line bleeding requiring blood transfusion
  - Staple line bleeding requiring revision surgery
  - Staple line leak requiring revision surgery
  - Conversion from laparoscopic to open surgery
- Hospital Stay Duration

# Data collection

## Staple line bleeding evaluation

- The hemostatic appearance of the sleeve gastrectomy staple line was analyzed using a visual analogue score (VAS), graded from 1 to 5 based on bleeding observed at the staple line 10 seconds after completion of resection



*Bleeding Severity Scale from Redmann J.G. et al., 2020*

VAS Bleeding Severity Scale for hemostasis evaluation. 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.

# Data collection

## 3-Week Follow-Up

Clinical Assessment :

- Subject compliance with postoperative care instructions
- Any procedure related, or device related adverse events since discharge from the hospital/clinic
- Weight loss (kg)
- Pain level
- Dysphagia
- Nausea
- Quality of life questionnaire 36-ItemShortFormHealthSurvey(SF-36)

# Results 45 patients

## Demographics and Surgery details

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- We present interim results of 45 consecutive patients who have completed the 3 weeks follow up.

|   |                                   |
|---|-----------------------------------|
| <b>Sample Size (n)</b>                          | 45 (44 female, 1 male)            |
| <b>Mean age (years)</b>                         | 38.24 ± 7.693                     |
| <b>Mean preoperative BMI (kg/m<sup>2</sup>)</b> | 35.92 ± 3.76                      |
| <b>Mean procedure time (minutes)</b>            | 59.8 ± 9.79                       |
| <b>Mean reload qty / per procedure</b>          | 5.91 ± 0.63 (median 6, range 5-7) |
| <b>Mean 45mm reload qty / procedure</b>         | 1.62 ± 0.58 (median 2, range 1-3) |
| <b>Mean 60mm reload qty / procedure</b>         | 4.29 ± 0.51 (median 4, range 3-5) |

# Results 50 patients

## Demographics and Surgery details

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- We present the final results of 50 patients who have completed the 3 weeks follow up.

|   |                                   |
|---|-----------------------------------|
| <b>Sample Size (n)</b>                          | 50 (49 female, 1 male)            |
| <b>Mean age (years)</b>                         | 38.5 ± 7.41                       |
| <b>Mean preoperative BMI (kg/m<sup>2</sup>)</b> | 35.78 ± 3.68                      |
| <b>Mean procedure time (minutes)</b>            | 58.72 ± 10.19                     |
| <b>Mean reload qty / per procedure</b>          | 5.9 ± 0.61 (median 6, range 5-7)  |
| <b>Mean 45mm reload qty / procedure</b>         | 1.64 ± 0.56 (median 2, range 1-3) |
| <b>Mean 60mm reload qty / procedure</b>         | 4.26 ± 0.48 (median 4, range 3-5) |

# Results 45 patients

## Intraoperative and Postoperative Outcomes

- 
- No intraoperative or postoperative complications were observed during the study.

|   |                     |
|---|---------------------|
| <b>Pain score 4 hours post-surgery (0-10 scale)</b>                               | <b>3.16 ± 1.93</b>  |
| <b>Pain score, post-op day 1 (0-10 scale)</b>                                     | <b>2.38 ± 1.28</b>  |
| <b>Pain score, post-op day 2 (0-10 scale)</b>                                     | <b>1.6 ± 1.05</b>   |
| <b>Blood Emesis</b>   | <b>0</b>            |
| <b>Postoperative Leak</b>   | <b>0</b>            |
| <b>Blood Transfusion</b>  | <b>0</b>            |
| <b>Hb (g/L) delta at recovery (the difference comparing to preoperative test)</b> | <b>9.16 ± 5.99</b>  |
| <b>Hb (g/L) delta, preop to post-op day 1</b>                                     | <b>12.84 ± 6.44</b> |
| <b>Hb (g/L) delta, preop to post-op day 2</b>                                     | <b>16.16 ± 8.67</b> |
| <b>Weight loss at 3-week follow-up (kg)</b>                                       | <b>8.49 ± 2.15</b>  |
| <b>Analgesics use days</b>  | <b>3.51 ± 2.20</b>  |
| <b>VAS Bleeding Severity Results</b>  | <b>1.04 ± 0.208</b> |

# Results 50 patients

## Intraoperative and Postoperative Outcomes

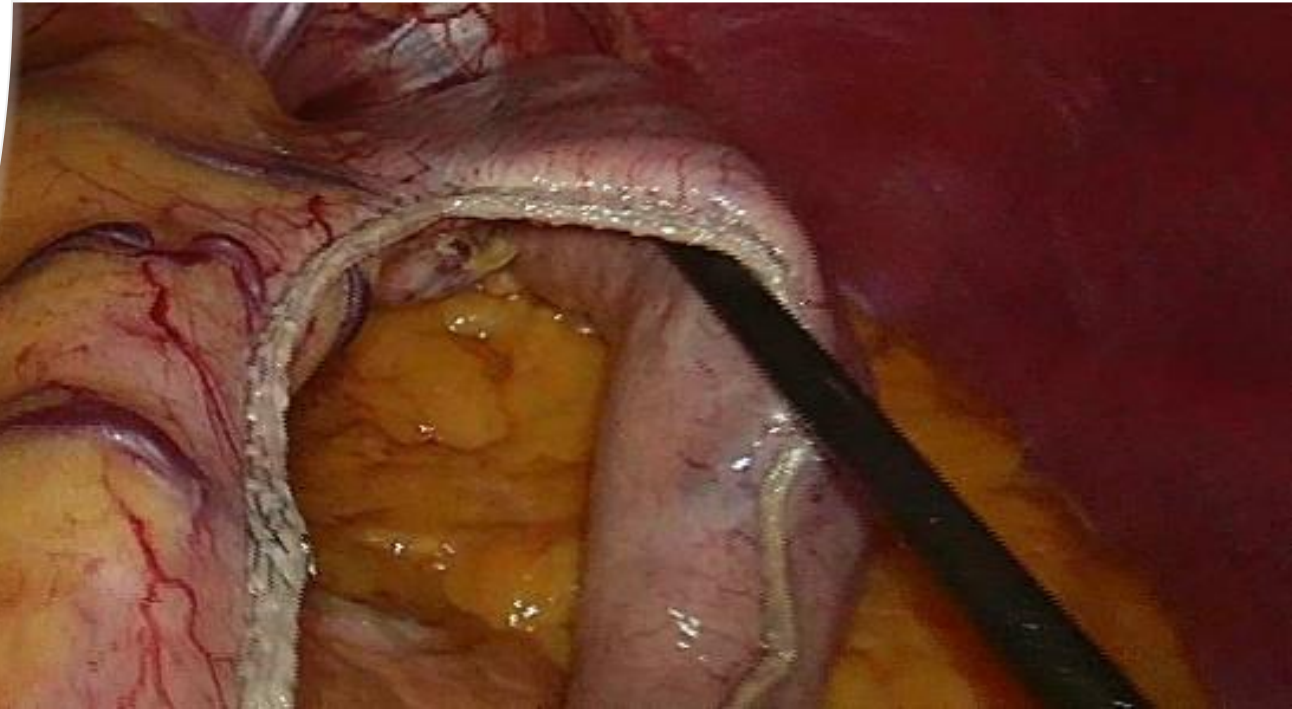
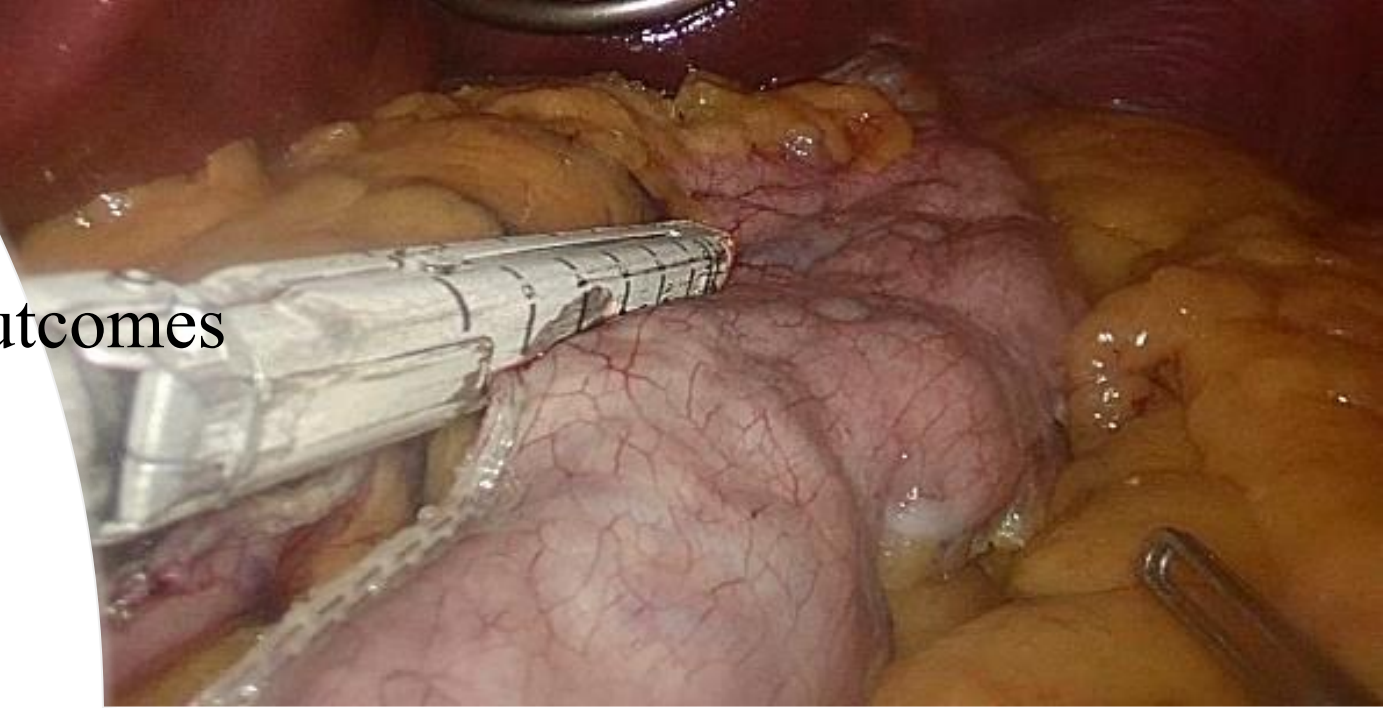
- 
- No intraoperative or postoperative complications were observed during the study.

|   |                     |
|---|---------------------|
| <b>Pain score 4 hours post-surgery (0-10 scale)</b>                               | <b>3.24 ± 1.85</b>  |
| <b>Pain score, post-op day 1 (0-10 scale)</b>                                     | <b>2.34 ± 1.23</b>  |
| <b>Pain score, post-op day 2 (0-10 scale)</b>                                     | <b>1.5 ± 1.05</b>   |
| <b>Blood Emesis</b>   | <b>0</b>            |
| <b>Postoperative Leak</b>   | <b>0</b>            |
| <b>Blood Transfusion</b>  | <b>0</b>            |
| <b>Hb (g/L) delta at recovery (the difference comparing to preoperative test)</b> | <b>8.90 ± 5.85</b>  |
| <b>Hb (g/L) delta, preop to post-op day 1</b>                                     | <b>12.76 ± 6.36</b> |
| <b>Hb (g/L) delta, preop to post-op day 2</b>                                     | <b>16.24 ± 8.35</b> |
| <b>Weight loss at 3-week follow-up (kg)</b>                                       | <b>8.4 ± 2.07</b>   |
| <b>Analgesics use days</b>  | <b>3.62 ± 2.15</b>  |
| <b>VAS Bleeding Severity Results</b>  | <b>1.04 ± 0.19</b>  |

# Results

## Intraoperative and Postoperative Outcomes

- Bleeding Severity Scores were  $1.04 \pm 0.19$  on a 1 – 5 scale for 50 cases, indicating the staple line following completion of resection was nearly free from bleeding.



# Discussion

With AEON Powered Stapling System **Bleeding Severity Scores were  $1.04 \pm 0.19$**  on a 1 – 5 scale, indicating the staple line following completion of resection was nearly free from bleeding.

RESEARCH ARTICLE

JLS

## Improving Hemostasis in Sleeve Gastrectomy With Alternative Stapler

James G. Redmann, MD, Thomas E. Lavin, MD, Matthew S. French, MD, Toby D. Broussard, MD, Maxime Lapointe-Gagner, BSc

**Table 2.**

Comparison of Intraoperative Stapler Bleeding Scores

| Outcome Measure             | AEON™     | Echelon Flex™ | <i>p</i> -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 ± standard error of the mean.

Obesity Surgery  
<https://doi.org/10.1007/s11695-022-06240-4>



NEW CONCEPT



## Prospective Randomized Comparison of Linear Endostaplers During Laparoscopic Sleeve Gastrectomy

Yannis Raftopoulos<sup>1</sup> · Shruthi Rajkumar<sup>1</sup> · Elana Davidson<sup>1</sup> · Pavlos Pappasavas<sup>2</sup>

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**Table 6** Staple-line bleeding VAS scores in relation to type of Endostapler

| Parameter           | AEON        | MTS         | <i>p</i> |
|---------------------|-------------|-------------|----------|
| Laparoscopic images |             |             |          |
| Pre-pyloric         | 1.70 ± 0.70 | 2.36 ± 0.76 | .0007*   |
| Incisura            | 1.53 ± 0.62 | 1.80 ± 0.66 | 0.11     |
| Mid-sleeve          | 1.46 ± 0.62 | 1.86 ± 0.68 | 0.0196*  |
| Proximal sleeve     | 1.60 ± 0.77 | 2.0 ± 0.83  | 0.0387*  |
| GEJ                 | 1.43 ± 0.67 | 1.86 ± 0.77 | 0.0140*  |

# Conclusions

- The first-in-man clinical study of the AEON Powered Stapling System has demonstrated the device's safety and effectiveness in performing primary sleeve gastrectomy procedures.
- The first clinical results were notably excellent, particularly in relation to intraoperative and postoperative staple-line bleeding.

# Conclusions

- Our hypothesis that the stapler's intelligent functionality, its capability to detect tissue thickness and adjust firing speed to facilitate precise dissection, played a role in minimizing tissue trauma and achieving superior hemostasis.
- Design of further complex research towards “zero anastomotic complications” probably should involve aspects of developing stapler that best promotes healing, but also deeper understanding how stapling devices function biologically.

# Discussion 2

- Recent increase in numbers of laparoscopic staplers manufacturers raises a question of stapler influence on surgery results again.
- Do surgeons have guidelines for evaluating quality standards for new staplers?
- Do we need the guidelines?