A Novel Device for Improving Visualization in an Inadequately Prepared Colon

INTRODUCTION
Poor bowel preparation affects the completeness of the colonoscopy and can result in longer procedural times, missed adenomas, earlier repeat procedures, increased costs, and decreased patient satisfaction. The MOTUS GI Pure-Vu™ System (Tirat Carmel, Israel) has been designed to improve visualization in an inadequately prepared colon by facilitating intra-procedural cleaning. The primary aim was to rate adequate colon cleansing level as defined by a Boston Bowel Prep Score (BBPS), at baseline and after the use of Pure-Vu. The secondary endpoints were Pure-Vu usability via questionnaire and safety evaluation.

METHODS

Pure-Vu System
The system consists of a disposable single-use over-sleeve and a workstation controller. The disposable over-sleeve fits easily over standard colonoscopes without interfering with the working channel or the navigation or advancement of the colonoscope. The workstation controls the delivery of a novel irrigation mode via 4 jets and a regulated evacuation cycle that effectively removes considerable colon content and prevents potential clogging through an auto-purge function.

STUDY DESIGN
The Pure-Vu system was used in 35 procedures in swine (66% female) performed by 4 experienced gastroenterologists. In order to ensure an inadequate bowel preparation, the animals underwent a reduced preparation. Immediately after the procedure, physicians graded the cleanliness of the colon at baseline and after use of Pure-Vu as one segment using the Boston Bowel Prep Score and completed a questionnaire on the Pure-Vu usability. Following their colonoscopy, the animals were observed for 48 hours to ensure their full recovery and document any post-procedural adverse events.

Evaluation of Cleansing Level
The level of the cleansing was evaluated using Boston Bowel Prep Score (BBPS) at baseline and after use of Pure-Vu. The questionnaire included the following evaluation criteria:

1. General Ease of Use
2. Ease of Insertion into Rectum
3. Ease of Angulation (steering capability)
4. Torque Response
5. Ease of Advancement
6. Device Stiffness
7. Device Holding Force (weight, comfort)
8. Ease of Use Foot Pedals
9. Ease of Use Foot Buttons
10. Safety Evaluation

RESULTS

Cleansing Performance
The average BBPS score prior to the use of Pure-Vu was 0.5 with 86% of the animals being inadequately prepared (BBPS score <2) and the majority (60%) having a score of zero. Following the use of Pure-Vu 100% (30/30) of the animals had a BBPS score ≥ 2 (i.e., Excellent).

Figure 1. shows the distribution of BBPS scoring at baseline and after the use of Pure-Vu. The level of adequate bowel prep at baseline and after Pure-Vu use is shown in Figure 2.

Figure 1. % of Adequate Cleansing (BBPS ≥ 2) at Baseline & After Pure-Vu Use n=35

Evaluation of Safety
Adverse events were evaluated during and post-procedure for 48 hours. Any adverse events during the procedure were recorded per physician discretion. Following the procedure, the animals were observed for 48 hours to assess the effect of the procedure on their health.

Evaluation of Pure-Vu Usability
The usability of the Pure-Vu system was done via a questionnaire after each procedure. The questionnaire included the following evaluation criteria:

1. Unprepared colon segment with mucosa not seen because of solid stool that cannot be cleared
2. Prepared or clean segment seen for entire length of colon segment not well seen because of opaque liquid
3. Minor amount of residual stool, small fragments of stool and/or opaque liquid
4. Minor amount of residual stool, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen
5. Entire mucosa of colon segment seen with no residual stool, small fragments of stool and/or opaque liquid

The questionnaire included the following evaluation criteria:
1. General Ease of Use
2. Ease of Insertion into Rectum
3. Ease of Angulation (steering capability)
4. Torque Response
5. Ease of Advancement
6. Device Stiffness
7. Device Holding Force (weight, comfort)
8. Ease of Use Foot Pedals
9. Ease of Use Foot Buttons
10. Safety Evaluation

The physicians were satisfied with the Pure-Vu’s ease of advancement and navigation, stiffness, and torque response. They found Pure-Vu easy to use and intuitive to operate. The average score across all usability parameters assessed was 4.9 ± 0.5 (Figure 3). With the exception of the general ease of use assessment for one procedure (Animal 15P0889), all parameters were scored a ‘4’ (Good) or ‘5’ (Excellent).

Figure 3. Ease of Use

Safety
No adverse effects were noted and the study animals recovered and survived to their study time point in good health.

SUMMARY & CONCLUSIONS
The Pure-Vu System was safe with no adverse effects noted and study animals recovering and surviving to their study time point in good health. The Pure-Vu System was effective in cleansing inadequately prepared colons, improving the percentage of adequately prepared colons from 14% at baseline to 100% after use of Pure-Vu (p<0.001). The physicians were satisfied with the Pure-Vu’s ease of advancement and navigation, device stiffness, and torque response. They found Pure-Vu easy to use and intuitive to operate. Pure-Vu was found to be simple, safe and effective in cleansing inadequately prepared swine colons.

This technology may provide an opportunity to improve visualization of the mucosa in patients with poorly prepared colons and reduce the need for early repeat examinations, thereby improving patient satisfaction and reducing costs. The technology may also be very useful in patients that have difficulty with compliance to standard colonic preparation regimens.