

A New Device For Achieving Adequate Bowel Prep In Poorly Prepped Patients Receiving A Reduced Pre-Procedural Preparation.

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INTRODUCTION

Colonoscopy is the gold standard for evaluating the colon and an effective bowel preparation is essential to perform a quality colonoscopy. Inadequate preparation, estimated as many as 25% of colonoscopy procedures, results in increased rates of missed lesions, earlier repeat procedures, prolonged colonoscopy duration, reduced patient satisfaction and increased costs.

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 Pure-Vu system consists of a disposable single-use over-sleeve and a supporting workstation controller. The disposable over-sleeve fits easily on standard colonoscopes and does not interfere with the working channel or the navigation and advancement of the colonoscope. The workstation, through a series of peristaltic pumps activated by foot pedals, delivers a unique irrigation medium of air and water that creates a pulsed vortex inside the colon to break up fecal matter while simultaneously evacuating the colon content.

Pure-Vu System



METHODS

Fifty procedures from two clinical sites using identical protocols, Carmel Medical Center in Haifa, Israel (n=9) and San Rafael Hospital in Cadiz, Spain (n=41), used the Pure-Vu System in partially prepped patients receiving a colonoscopy for screening, diagnostic or surveillance. The preparation used to ensure an inadequately prepped colon included a spill dose of two tablets of 5mg Bisacodyl / Laxadin, diet restrictions (no dried fruit, seeds or nuts) starting 2 days before the procedure and a 24 or 18 hour clear liquid diet prior to the colonoscopy. At 2 and 14 days post procedure a telephone follow-up was conducted to assess patient well-being and capture any adverse events. The study endpoints were: (1) improvement of colon cleansing level as per the Boston Bowel Preparation Scoring (BBPS) when comparing before and after Pure-Vu use, (2) Pure-Vu usability via questionnaire and (3) safety.

Evaluation of Cleansing Level

The level of the cleansing was evaluated by using the Boston Bowel Preparation Scale definitions.¹ An adequate colon cleansing level was defined by a BBPS ≥ 2 for each segment.

Evaluation of Pure-Vu Usability

THE QUESTIONNAIRE INCLUDED THE FOLLOWING EVALUATION CRITERIA:

1. General Ease of Use	3. Ease of Angulation (steering capability)	5. Device Stiffness
2. Ease of Insertion into Rectum	4. Ease of Advancement	6. Device Holding Force (weight, comfort)

RESULTS

Fifty subjects (64% males) are included in this analysis. The subject's age ranged from 26-73 years with an average BMI of 26.6

The reason for colonoscopy is summarized in the table below:

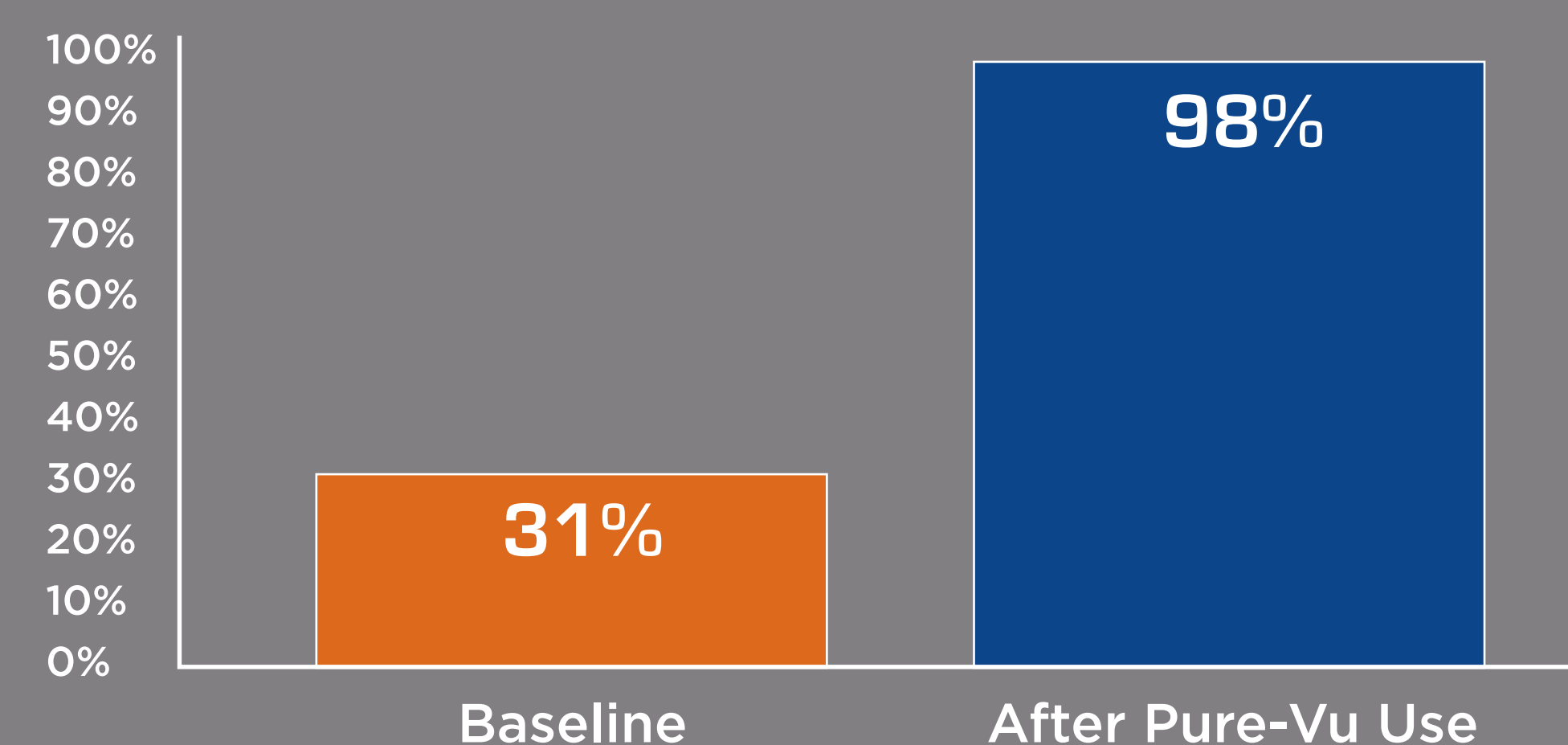
REASON FOR REFERRAL	# PATIENTS	% PATIENTS
CRC Screening	22	44%
Family History	10	20%
Rectal Bleeding	6	12%
Constipation	6	12%
Poly Surveillance	4	8%
Diarrhea	3	6%
Abdominal Pains	2	4%
Iron Def. ASmenia	2	4%
IBS Like	1	2%

One patient was excluded from the cleansing efficacy and usability analysis due to patient non-compliance with the pre-procedural prep regimen. The safety analysis was done based on the entire study population (n=50).

The Pure-Vu significantly increased the number of subjects with an adequate cleansing level (BBPS ≥ 2 for each colon segment). The rate of adequate cleansing rate improved from (15/49) 31% at baseline to (48/49) 98% after use of Pure-Vu (p<0.001). Due to a convoluted anatomy in one patient, the colonoscope was unable to reach and therefore clean the cecum.

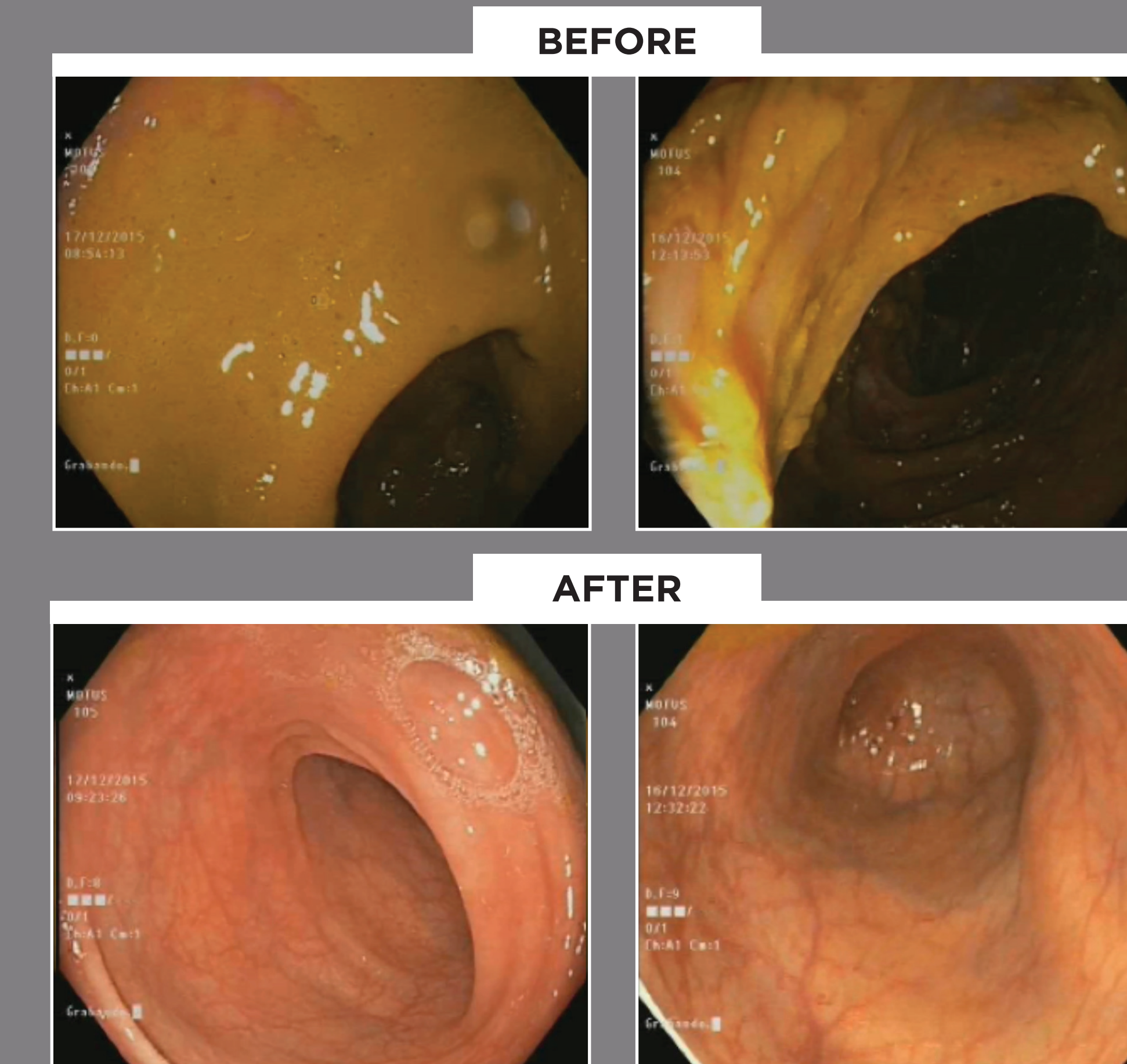
% of Adequate Cleansing

(BBPS ≥ 2 in each colon segment at Baseline & After Pure-Vu Use n=49)

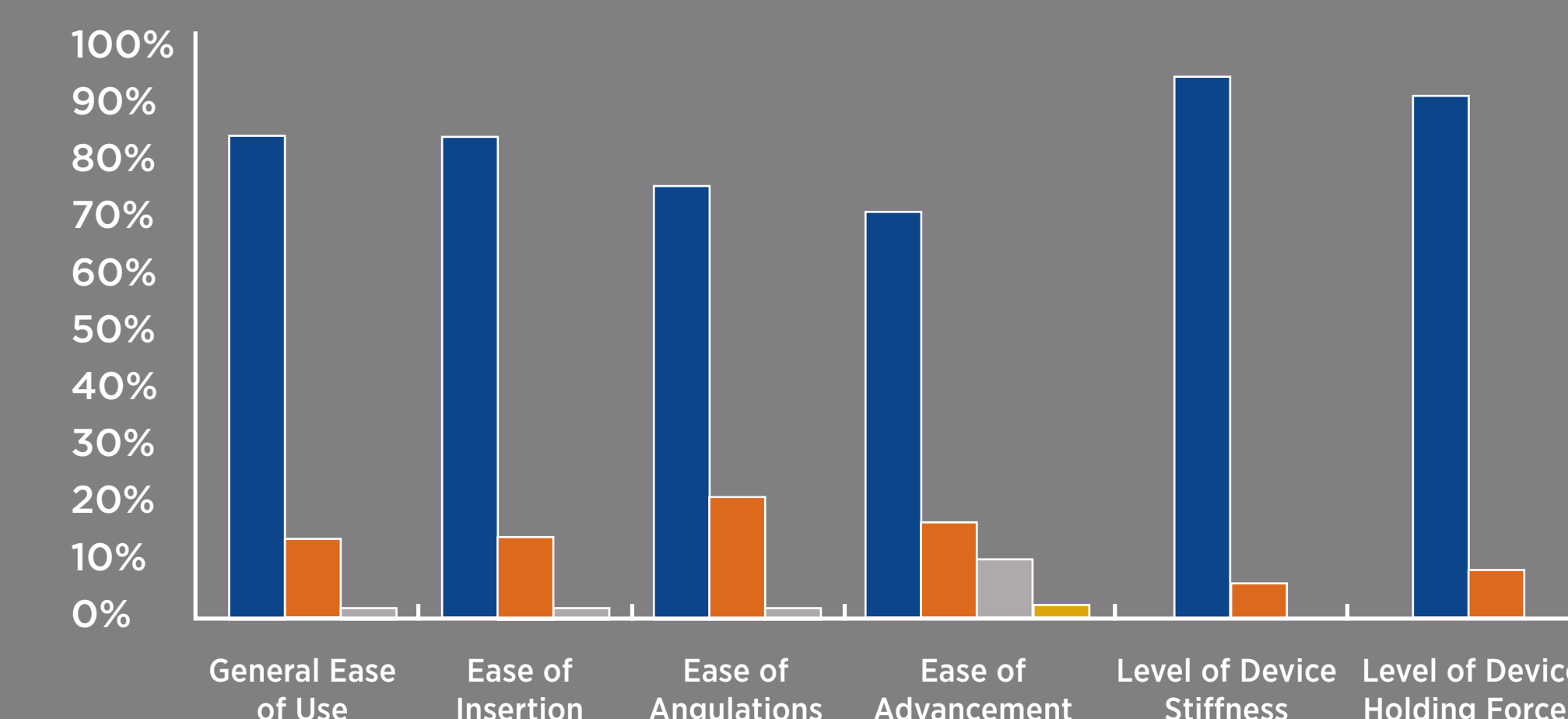


- The mean and standard deviation of the post-treatment BBPS score was 2.96 ± 0.29.
- The cecum was reached successfully in 48/49 (98%, CI 95% [89%, 100%]) of the cases.

The following are representative images of colon cleansing levels at baseline and after Pure-Vu use.



The physicians were satisfied with the device's ease of advancement and found it easy to use and intuitive to operate.



In one case the ease of advancement was defined as unacceptable due to a convoluted colon anatomy.

Legend: Good Or Excellent (Blue), Acceptable (Orange), Difficult (Grey), Unacceptable (Yellow)

No serious adverse events were reported.

CONCLUSIONS

The Pure-Vu System was found to be simple, safe and effective in cleaning inadequately prepared colons to an adequate level for a thorough exam. Based upon these early results the device is expected to have a role in subjects with an inadequately prepared colon which may help to improve overall quality of colonoscopy, reduce the need to cancel or repeat colonoscopy procedures and improve patient satisfaction especially in those patients that have difficulty tolerating current prep regimens.

REFERENCE:

¹Lai E.J. et al., "The Boston Bowel Preparation Scale: A valid and reliable instrument for colonoscopy-oriented research", *Gastrointestinal Endosc.*, 2009; 69(3 Pt 2): 620-625.