

# The Aer-O-Scope™ Colonoscope System is Safe and Effective for Colonoscopy in Humans

Gluck Nathan M.D. Ph.D.<sup>1,2</sup>, Melhem Alaa M.D.<sup>1,2</sup>, Halpern Zamir M.D.<sup>1,2</sup>, Mergener, Klaus M.D.<sup>3</sup>, Goldfarb, Sharon<sup>4</sup> and Santo Erwin M.D.<sup>1,2</sup>

<sup>1</sup>Tel Aviv Medical Center, Tel-Aviv, Israel. <sup>2</sup>Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel.

<sup>3</sup>Digestive Health Specialists, Tacoma, WA, United States. <sup>4</sup>GI View Ltd, Ramat Gan, Israel.



## Background:

The self-propelled, disposable Aer-O-Scope™ Colonoscope (AOS) with 360° view is designed to enhance visualization as well as minimize risk for perforation and infection transmission, while shortening operator training time associated with conventional colonoscopy (CC) (Figures 1, 2 and 3).



Figure 1. Disposable Aer-O-Scope™ Disposable Scanner.

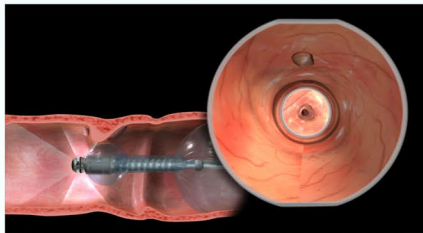


Figure 2. Aer-O-Scope™ visualization of a colonic polyp (rendering). Right: single-screen combined on colonoscopy monitor includes front view (inner section) and panoramic OMNI views (outer section). Left: total field of view with Aer-O-Scope™.

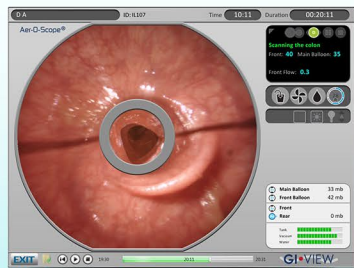


Figure 3. Visualization system: Front and 360° OMNI views.

## Objective:

Testing the AOS for efficacy and safety.

**Design:** Single center, prospective study with AOS immediately followed by CC.

**Setting:** Gastroenterology unit at tertiary care hospital.

**Patients:** Adults presenting for colorectal cancer screening. Initial patients necessary for AOS operators to achieve proficiency made up the "training cohort". Subsequent enrolled patients made up the "study cohort".

**Interventions:** AOS was performed to the cecum, where anatomic landmarks were photographed and distinctive mucosal suction-marks made. During AOS withdrawal, polyps were recorded and similarly marked. At second-pass CC, any potential mucosal damage and suction-marks from the AOS, as well as polyps, were recorded (Figures 4 and 5).



Figure 4. Colonic polyp as visualized in the Aer-O-Scope™ OMNI View.

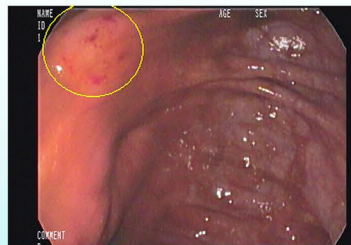


Figure 5. Aer-O-Scope™ distinctive suction mark as seen on conventional colonoscopy screen.

**Main Outcome Measurements:** 1) AOS cecal intubation rates, confirmed by anatomic landmarks and/or residual marks seen at subsequent CC. 2) Frequency and severity of adverse events and mucosal damage with AOS.

Secondary Endpoints: 1) Subjective procedure-proficiency, evaluated by physician-operator based on training cohort 2) Documenting pathologies visualized with AOS.

## Results:

56/58 enrolled patients completed the study. Proficiency with AOS was attained after 8-10 procedures. Cecal intubation was successful in 98.2% (55/56 subjects, 95%CI 90.4-99.9%), including 100% (95%CI 90.7-100%) of study cohort and 94.4% (95%CI 72.7-99.9%) of training cohort.

Table 1. Aer-O-Scope™ Cecal Intubation & Safety Results

Number of training procedures per physician (Training Cohort)	10 ; 8
Total number of Aer-O-Scope™ procedures (Study Cohort)	40
Number of procedures not counted (poor prep)	2
Total number of confirmed cecal intubations	38
Average cecal intubation time	10min.
Cecal intubation success rate	100%

No significant adverse events, immediate or delayed, in all procedures

Cecal intubation was confirmed by second-pass CC in 52/55 (94.5%) patients (Table 1). No mucosal damage or adverse events were reported. AOS detected 87.5% of polyps seen in tandem CC, including all polyps >5mm.

## Conclusions:

AOS was highly successful and safe in attaining complete colonic intubation, a prerequisite for effective colorectal cancer screening in humans.

Contact: nathang@tlvmc.gov.il