

Aer-O-Scope™, a Self-Propelled Pneumatic Colonoscope, is Superior to Conventional Colonoscopy in Polyp Detection

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Background

The Aer-O-Scope™ Colonoscope is a new disposable, self-propelled colonoscope with a novel optical system designed to maximize visualization of the entire colonic mucosa including behind haustral folds. This is achieved by using a circumferential (OMNI) 360° panoramic viewer allowing visualization both to the front and to the rear of the optical imaging capsule. A conventional front view is also provided. Both views are projected simultaneously on a single screen.



Figure 1. Disposable Aer-O-Scope scanner with optical imaging head; soft multi-lumen supply cable and two balloons for propulsion

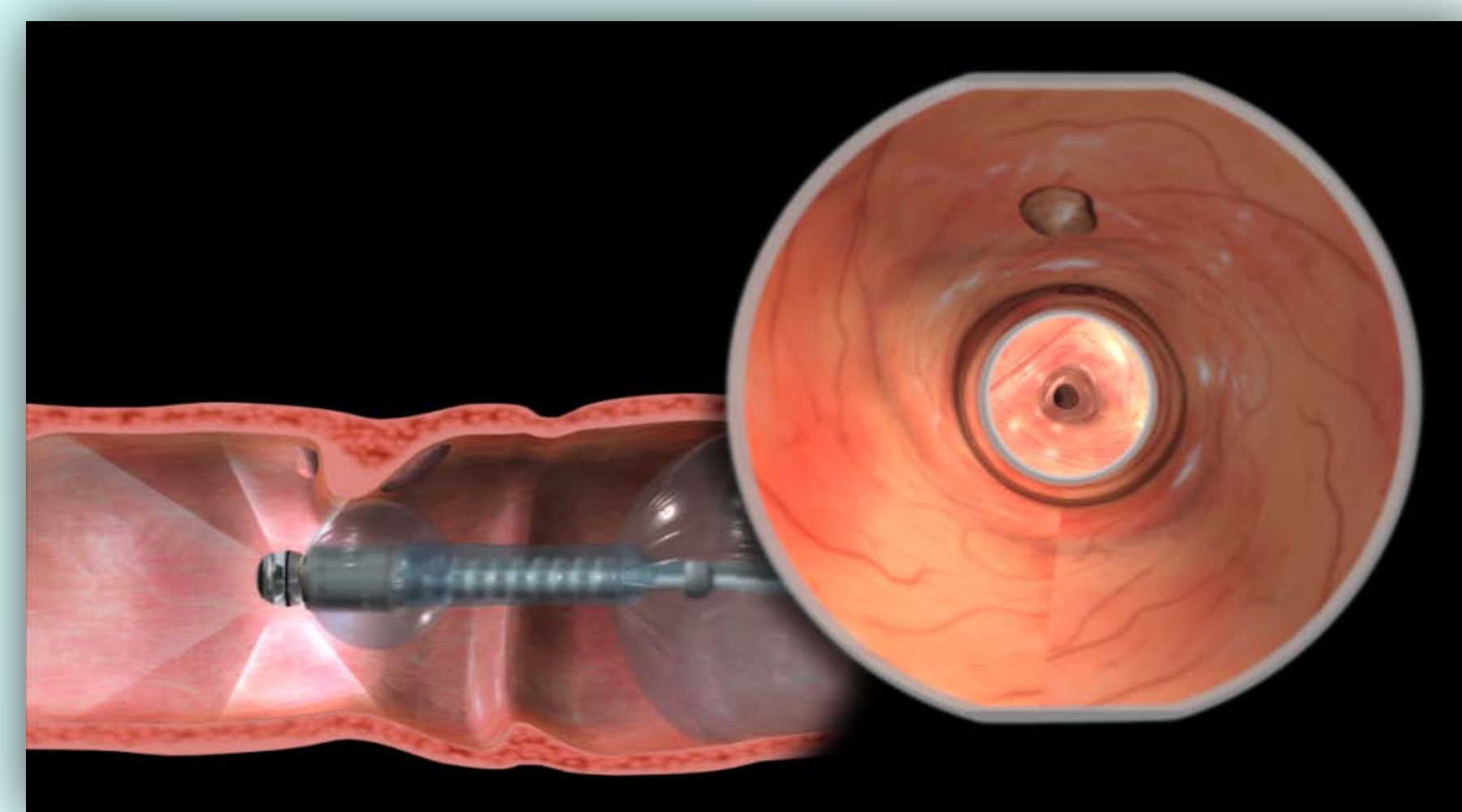


Figure 2. Aer-O-Scope visualization of a colonic polyp (rendering). Right: Single-screen combined on colonoscopy monitor includes front view (inner section) and panoramic OMNI views (outer section). Left: Total field of view with Aer-O-Scope.

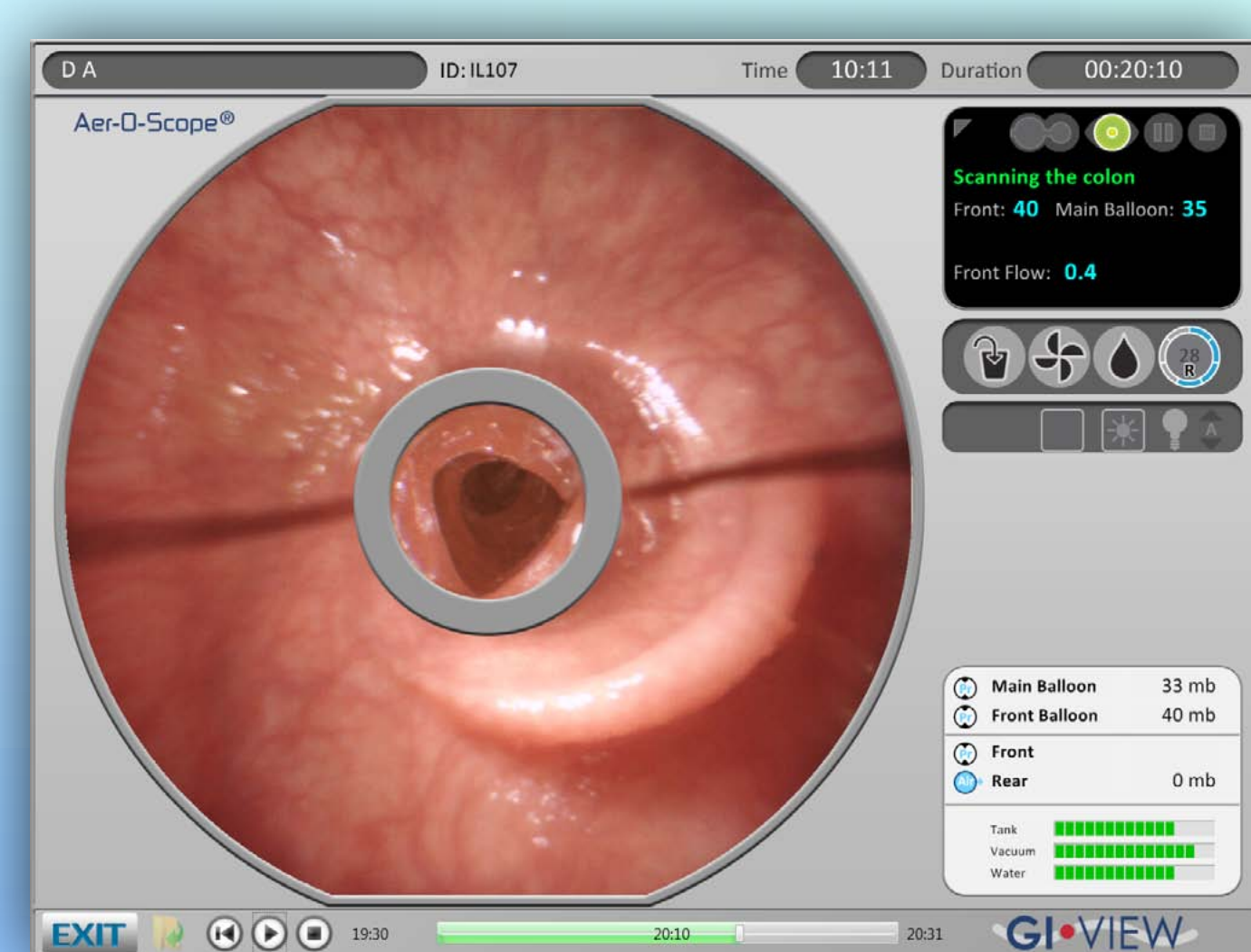


Figure 3. Visualization system: 360° OMNI and front views.

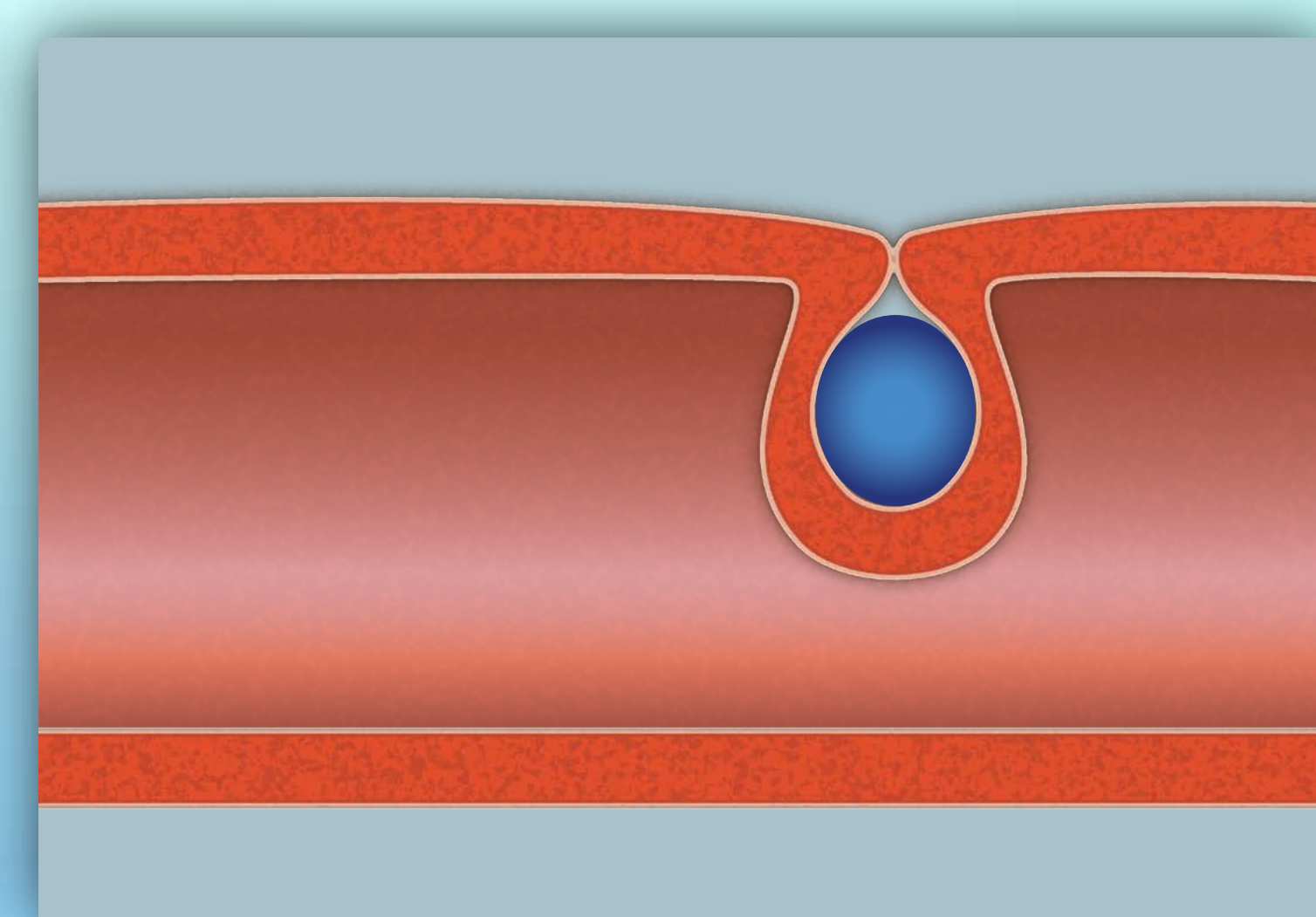


Figure 4. Pseudo-Polyp.

Aims

To assess the Aer-O-Scope colonoscopy for safety, ease of operation and the ability to identify pre-created pathologies in an *in vivo* swine model in comparison to standard colonoscopy.

Methods

Swine colons were surgically legated at a depth of 100-120cm and colored beads were sewn distally to the ligation (Figures 4, 5 & 6).

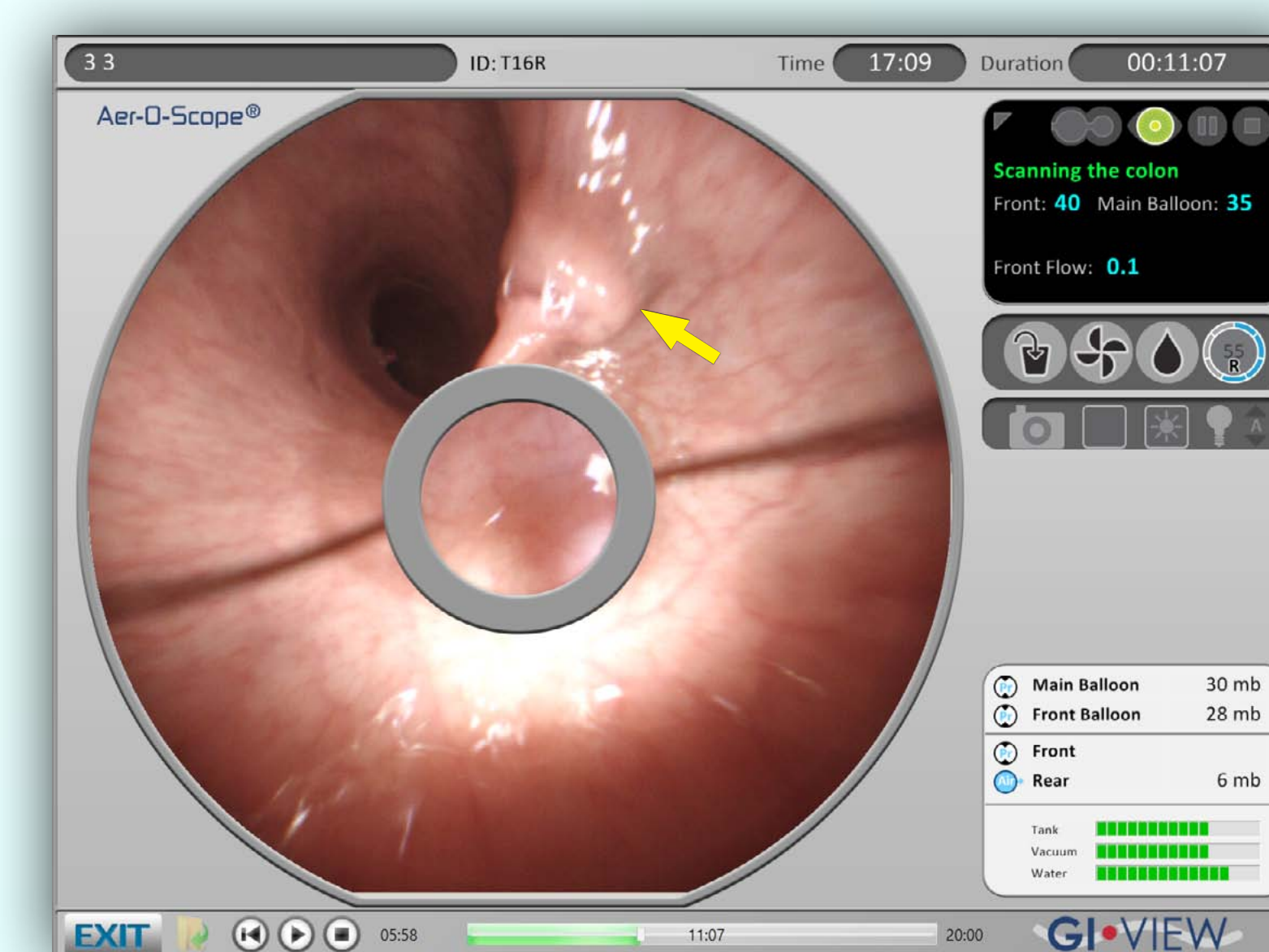


Figure 5. Aer-O-Scope Colonoscope System Single-screen display. Pseudo polyp seen in OMNI view.

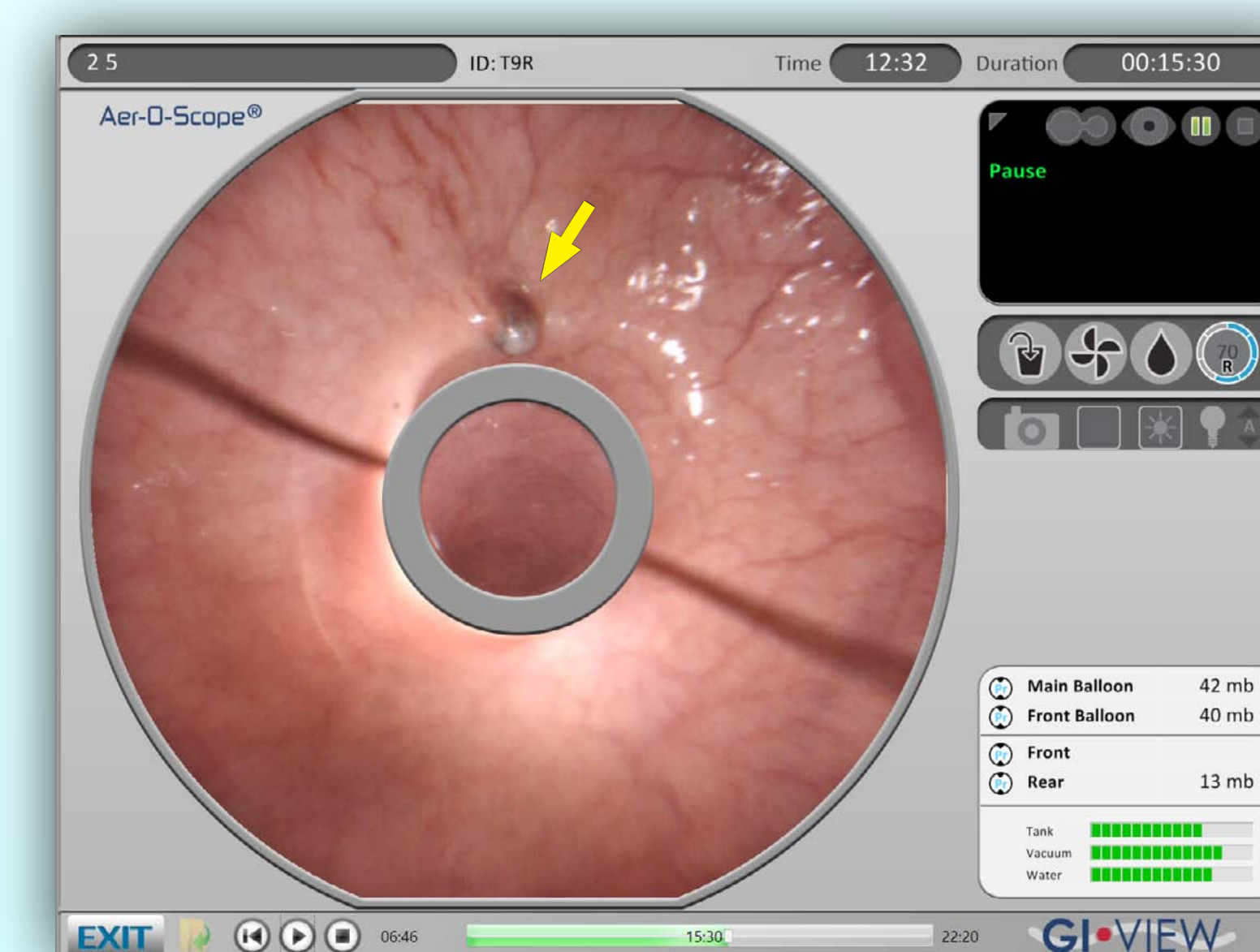


Figure 6. Aer-O-Scope Colonoscope System Single-screen display. Pseudo polyp seen in OMNI view.

Two physicians underwent a short Aer-O-Scope colonoscopy training session and were then randomized to perform in tandem a total of 3 Aer-O-Scope colonoscopies and 2 colonoscopies to the depth of ligation on each of 12 swine. Aer-O-Scope colonoscopy was performed first in half of the animals. The sequence of all other procedures was randomized. Physicians were blinded to number, size, shape and color of beads. Pigs, physicians and scope tower were randomly alternated between procedure rooms to maintain physician blindness and objectivity. Viewed lesions were documented. Procedures videos were interpreted offline by 2 independent blinded physicians who could repeatedly review segments.

Results

Safety and ease of operation

Training physicians to operate the Aer-O-Scope Colonoscope system and visualize pathologies using the unique visualization system was completed in under half a day. Intubation of the full length of the studied colonic segment was achieved in all cases with no complications.

Visualization

94.9% (259/273) of all implanted pathologies were visualized in real-time by the Aer-O-Scope Colonoscope as compared to 86.8% (158/182) with the conventional colonoscope ($p=0.002$). Miss rates of implanted pathologies >6 mm were 2.6% for Aer-O-Scope colonoscopy and 10.5% for conventional

colonoscopy ($p=0.022$). Miss rates for implanted pathologies <6 mm were 6.9% and 15.1%, respectively ($p=0.031$). The average agreement rate of Aer-O-Scope colonoscopy with conventional colonoscopy for implanted pathology detection or miss was 88.3%. These results demonstrate superiority of Aer-O-Scope Colonoscope over the conventional colonoscope for the visualization of implanted pathologies (Table 1 and Figure 7).

Adding offline video review results to live endoscopy results maintained a statistically significant advantage for Aer-O-Scope colonoscopy in detection of implanted pathologies of both size subgroups (see Table 2).

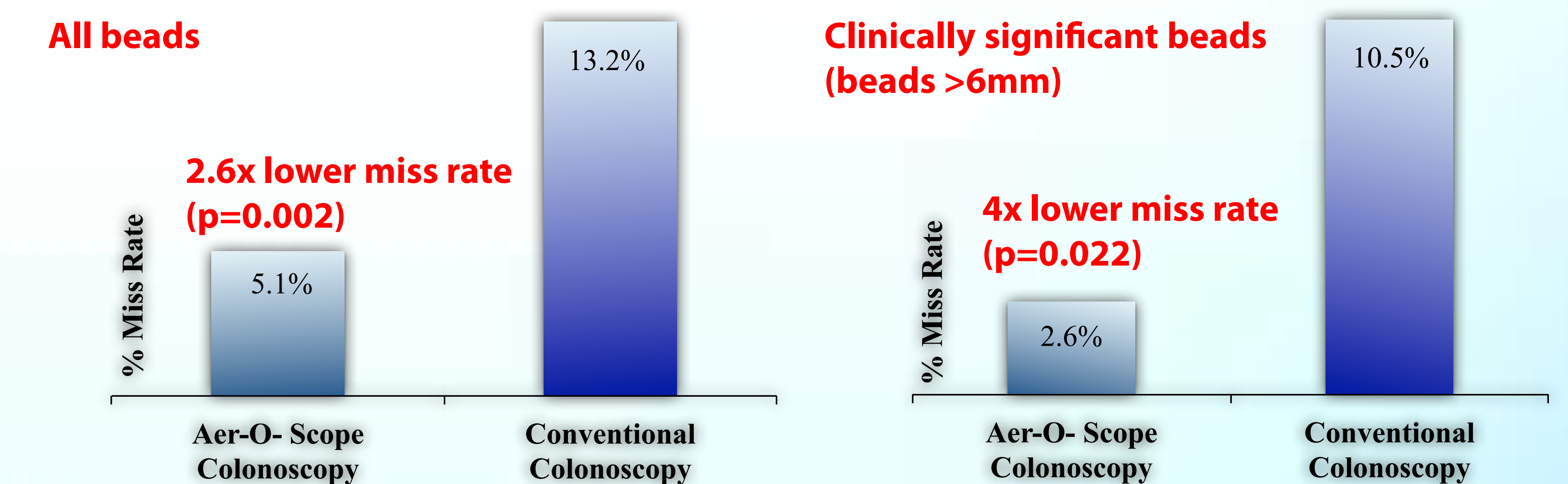


Figure 7. Superior Visualization of Aer-O-Scope Colonoscopy vs. Conventional Colonoscopy in Detecting 453 Implanted Pathologies (Beads).

Table 1. Real-Time Results

	Colonoscopy Type	Beads Implanted (Total Beads × no. of Procedures)	% Beads Visualized (Number of Beads)	% Miss Rate	Pearson χ^2 P-Value
Overall implanted beads	Aer-O-Scope	273	94.9 (259)	5.1	0.002
	Conventional	182	86.8 (158)	13.2	
Beads ≥ 6 mm	Aer-O-Scope	114	97.4 (111)	2.6	0.022
	Conventional	76	89.5 (68)	10.5	
Beads < 6 mm	Aer-O-Scope	159	93.1 (148)	6.9	0.031
	Conventional	106	84.9 (90)	15.1	

Table 2. Combined Results Real-Time and Off-Line

	Colonoscopy Type	Beads Implanted (Total Beads × no. of Procedures)	% Beads Visualized (Number of Beads)	% Miss Rate	Pearson χ^2 P-Value
Overall implanted beads	Aer-O-Scope	546	95.2 (520)	4.8	<0.001
	Conventional	364	88.7 (323)	11.3	
Beads ≥ 6 mm	Aer-O-Scope	228	97.8 (223)	2.2	0.016
	Conventional	152	92.8 (141)	7.2	
Beads < 6 mm	Aer-O-Scope	318	93.4 (297)	6.6	0.004
	Conventional	182	85.8 (212)	14.2	

Conclusions

Aer-O-Scope colonoscopy is an easily mastered and safe system that proved equal or superior to conventional colonoscopy in detecting colonic pathologies, an advantage that was particularly striking in real-time detection of lesions of clinically significant dimensions.

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