

# A Novel Balloon-Colonoscope for Increased Polyp Detection Rate – Results of a Randomized Tandem Study\*

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**Introduction:** Approximately 30% of polyps are missed during Standard Colonoscopy (SC), e.g., due to polyps hidden behind colon folds and flexures. This work explores a novel device and technique for increasing polyp and adenoma detection during colonoscopy. It employs a unique balloon-colonoscope (G-EYE™ Endoscope, Smart Medical Systems Ltd., Ra'anana, Israel), comprising a standard colonoscope having a reprocessable, permanently integrated balloon at its distal tip. The G-EYE balloon-colonoscope does not require pre-procedure preparation, mounting or use of any single-use accessory. Balloon pressure is controlled through a unique inflation system providing pre-determined, user-selectable, anchoring and intermediate (low) pressure levels. The aim of this study is to compare the additional diagnostic yield of G-EYE colonoscopy with that of standard colonoscopy.

**Methods:** This is a multicenter, randomized, tandem study. Patients referred to colonoscopy for screening, surveillance or diagnostic workup, were randomized into two groups. Group A underwent SC followed by G-EYE Colonoscopy; group B underwent G-EYE colonoscopy followed by SC. During the G-EYE colonoscopy, the endoscope is inserted with the balloon deflated until the cecum is reached. Then, the balloon is inflated to intermediate pressure and the G-EYE colonoscope is withdrawn, thus straightening intestinal folds, smoothening colon topography and improving colon visibility. All polyps detected were removed.

**Results:** Study enrolment plan included 126 randomized patients, with 106 actually enrolled (54 in group A, 52 in group B) and 20 excluded, mostly due to insufficient bowel preparation. In group A, SC detected 30 polyps and 21 adenomas, and the following G-EYE colonoscopy detected 30 additional polyps (100% additional detection) and 17 adenomas (81% additional detection). In group B, G-EYE colonoscopy detected 51 polyps and 37 adenomas, and the following SC detected 3 additional polyps (5.6% miss-rate) and 3 adenomas (7.5% miss-rate). The resulting G-EYE colonoscopy ratio of additional detection to miss-rate, relative to SC, was 17.9 for polyps and 10.8 for adenomas. In addition, polyp and adenoma detection rates (PDR and ADR) were observed. SC first-pass PDR and ADR were 37.0% (20/54) and 25.9% (14/54), respectively, and respective G-EYE colonoscopy first-pass PDR and ADR were 53.8% (28/52) and 40.4% (21/52). G-EYE colonoscopy PDR was 45% higher than PDR of SC, and G-EYE colonoscopy ADR was 56% higher than the SC ADR. In the second-pass procedure, G-EYE colonoscopy detected polyps in 8 new patients and adenomas in 3 new patients. Second-pass SC did not detect polyps or adenomas in any new patients. Insertion times of SC and G-EYE colonoscopy were similar, with 100% cecum reach in both techniques. No adverse events occurred.

**Conclusion:** G-EYE colonoscopy using the G-EYE™ endoscope and withdrawal technique is safe, easy to use, exhibits a substantially higher polyp and adenoma detection yield compared with standard colonoscopy ( $p < 0.001$ ), and presents significant reduction in miss-rate during colonoscopy. In addition, G-EYE colonoscopy demonstrated increase in PDR and ADR relative to standard colonoscopy, which should be further investigated.

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\* Presentation Abstract, 2013 UEGW (Abstract # OP286)

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