Comparison of standard forward-viewing mode versus ultrawide-viewing mode of a novel colonoscopy platform: a prospective, multicenter study in the detection of simulated polyps in an in vitro colon model (with video)

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Background: Although colonoscopy is the criterion standard for detecting colorectal adenomas and cancers, a significant percentage of adenomas are missed.

Objective: To compare forward-viewing with ultrawide-viewing colonoscopy in the detection of simulated colon polyps in an in vitro colon model.

Design: Prospective, multicenter.

Setting: Six endoscopy units (3 in the United States and 3 in Israel).

Patients: In vitro colon model with simulated colon polyps (n = 21 metallic beads).

Interventions: Detection of simulated colon polyps on colonoscope withdrawal.

Main Outcome Measurements: Incremental detection of simulated colon polyps and endoscopist evaluation of the usability, visibility, and maneuverability of ultrawide-viewing colonoscopy.

Results: On forward-viewing colonoscopy, the number of simulated polyps (mean ± standard deviation) detected per endoscopist was 11.1 ± 2.3 polyps, a 52.9% detection rate. Simulated polypl detection rates per colon segment were 3.0 ± 0.93 (60.0%) right colon, 2.4 ± 0.87 (48.0%) transverse colon, and 5.7 ± 1.5 (51.8%) left colon. On ultrawide-viewing colonoscopy, the simulated polypl detection rate per endoscopist significantly increased to 18.0 ± 1.98 polyps, an overall 85.7% polypl detection rate (P < .001). Simulated polypl detection rates were also significantly higher by using the ultrawide-viewing mode in each colon segment, 4.5 ± 0.65 polyps (90.0%) right colon, 4.0 ± 0.87 (80.0%) polyps transverse colon, and 9.6 ± 1.28 polyps (87.3%) left colon (all comparisons, P < .001). Importantly, the ultrawide-viewing mode detected significantly more “hidden” simulated polyps (81.9% vs 31.9%, P < .0001).

Limitations: Nonrandomized design, use of a colon model, and “simulated” colon polyps.

Conclusions: Ultrawide-view colonoscopy significantly improved simulated polyp detection in a colon model. Clinical studies in human subjects should be pursued to further evaluate this new endoscopic technology. (Gastrointest Endosc 2013;77:472-9.)

Abbreviations: MCU, main control unit; TER, third-eye retroscope.

DISCLOSURE: Drs Gralnek, Halpern, Siersma, Carr-Locke, Segol, and Suissa are consultants for Peer Medical Ltd. Dr Segol is the Medical Director of Peer Medical Ltd. This study was sponsored by Peer Medical Ltd, Caesaria, Israel.

This video can be viewed directly from the GIE website or by using the QR code and your mobile device. Download a free QR code scanner by searching “QR Scanner” in your mobile device’s app store.

Received September 30, 2012. Accepted December 13, 2012.

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Colonoscopy is the criterion standard for detecting colorectal adenomas and cancers.\(^1\)\(^-\)\(^4\) However, multiple studies, including a systematic review, have reported that a significant percentage of adenomas, approximately 25%, are missed during standard forward-viewing colonoscopy.\(^5\)\(^-\)\(^11\)

Aside from inadequate colon preparation, incomplete examinations (eg, failure to intubate the cecum), short withdrawal times, and patient-related factors, the primary reason for missing colorectal adenomas and cancers is poor visualization of the proximal aspect of colonic folds, anatomic flexures, and ileocecal valve area.\(^11\) These anatomic sites tend to be hidden from the standard forward-viewing colonoscope and can usually only be seen through manipulation of the colonoscope. This includes, in an effort to flatten out the folds and straighten the flexures, prolonged retroflexion of the colonoscope itself.\(^12\)\(^,\)\(^13\) However, because these maneuvers require additional time and technical skill and confer a limited patient risk, they may not always be performed or may be performed by using a less-than-optimal technique.

Thus, there is mounting evidence supporting the need to reduce the adenoma “miss rate” of standard forward-viewing colonoscopy by improving on current colonoscopy technology and its current visualization/optics limitations. Attempts to improve visualization capabilities during colonoscopy have been reported, including the use of adapted pediatric colonoscopes, prototype wide-angle colonoscopes, transparent caps fitted to the end of standard colonoscopes, and through-the-scope optical devices (eg, third-eye retroscope [TER]).\(^14\)\(^-\)\(^21\) Despite these innovations, our technological abilities remain incomplete or have not been user friendly or intuitive to the endoscopist.

The PeerScope System Model B colonoscope (developed by Peer Medical Ltd, Caesaria, Israel) is an adult, flexible colonoscope that allows the endoscopist to choose between 2 viewing modes with the press of a button: a standard 160-degree forward-viewing mode or a 300-degree or greater ultrawide viewing mode while maintaining standard colonoscope capabilities and maneuverability of full tip deflection (12.8-mm colonoscope outer diameter), working channel (3.8 mm), suction, and water jet irrigation. Thus, there is maintenance of the identical technical features of the current industry-standard, forward-viewing colonoscope. The ultrawide field of view is achieved by the use of 3 lenses and light-emitting diode groups positioned at the front and on the sides of the flexible tip of the colonoscope (Fig. 1). The video images are presented on 3 monitors (Fig. 2). The left, middle, and right video monitors correspond to the images transmitted from the left-sided, forward-facing, and right-sided lenses, respectively. The MCU serves as a control platform for the PeerScope System. The MCU is responsible for light-emitting diode illumination, endoscopic image acquisition and processing, video signal transfer, pneumatic control, and external accessories that interface with the platform.

Colonoscopy platform description

The PeerScope Colonoscopy Platform System (Peer Medical Ltd) comprises a video colonoscope and a main control unit (MCU). The PeerScope Model B colonoscope is an adult size (168-cm working length), flexible colonoscope intended for repeated clinical use (diagnostic visualization and therapeutic interventions). The PeerScope colonoscope allows the endoscopist to choose between 2 high-resolution viewing modes with the press of a button: a standard 160-degree forward-viewing mode or a 300-degree or greater ultrawide viewing mode while maintaining standard colonoscope capabilities and maneuverability of full tip deflection (12.8-mm colonoscope outer diameter), working channel (3.8 mm), suction, and water jet irrigation. Thus, there is maintenance of the identical technical features of the current industry-standard, forward-viewing colonoscope. The ultrawide field of view is achieved by the use of 3 lenses and light-emitting diode groups positioned at the front and on the sides of the flexible tip of the colonoscope (Fig. 1). The video images are presented on 3 monitors (Fig. 2). The left, middle, and right video monitors correspond to the images transmitted from the left-sided, forward-facing, and right-sided lenses, respectively. The MCU serves as a control platform for the PeerScope System. The MCU is responsible for light-emitting diode illumination, endoscopic image acquisition and processing, video signal transfer, pneumatic control, and external accessories that interface with the platform.

Colon model and colonoscopy procedures

The “in vitro” colon model used in this study was made of silicone and included colon anatomic structures: ileocecal valve, cecum, ascending colon, hepatic flexure, transverse colon, splenic flexure, descending colon, sigmoid colon, rectum, and anus (Fig. 3). A total of 21 simulated polyps (labeled a, b, c, and 1-18 in Figure 3B), metallic beads ranging in size (4-10 mm), shape, and color could be detected in 3 a priori–defined colonic segments: 5 simulated polyps located from the cecum to the hepatic flexure (defined as the right colon), 5 simulated polyps located in the transverse colon, and 11 simulated polyps attached to the colon model wall.

METHODS AND MATERIALS

This was a multicenter, prospective study whereby gastroenterologists, experienced in performing colonoscopy, were asked to complete a standard colonoscopy screening procedure in a medical facility procedure room by using a silicone colon model and to identify “simulated” colon polyps attached to the colon model wall.

Take-home Message

- Using a colon model and simulated colon polyps (metallic beads), we found that using forward-viewing colonoscopy yielded a 52.9% simulated polyp detection rate. In contrast, by using ultrawide-viewing colonoscopy, the simulated polyp detection rate significantly increased to 85.7%, a 32.8% higher detection rate (P < .001).
- These results suggest a true breakthrough in colonoscope imaging technology that may enhance the diagnostic yield (polyp and adenoma detection rates) of a colonoscopy when performed in human subjects. Those studies are eagerly awaited.

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located from the splenic flexure to the rectum (defined as the left colon) (Fig. 4; Video 1, available online at www.giejournal.org). In addition, we further defined the simulated polyps by difficulty of polyp location within the colon model. There were 10 simulated polyps that were “hidden” behind colonic folds or at flexures and 11 simulated polyps located in more obvious/visible locations in the colon.

Starting in the cecum, each endoscopist attempted to detect the simulated polyps on 2 separate colonoscope withdrawals: initially by using the forward-viewing mode (160-degree visualization) and then by using the ultrawide-viewing mode (≥300-degree visualization). All endoscopists were blinded to polyp quantity, size, and location and had no previous knowledge or use of the PeerScope colonoscopy platform. For each withdrawal, the endoscopists were instructed to use their “usual withdrawal technique” and were required to spend a minimum of 6 minutes, but no more than 10 minutes.22

**Primary and secondary study endpoints**

The primary study endpoint was the incremental detection of simulated colon polyps (per colon segment and for the entire colon) by using the ultrawide-viewing mode of the PeerScope System B compared with the standard forward-viewing mode. Secondary study endpoints included endoscopist subjective evaluation of the usability, visibility, and maneuverability of the PeerScope System B ultrawide-viewing mode. Specifically, we evaluated the subjective evaluation of the additional angle of view, incidence of difficulties in advancing or withdrawing the instrument, and manipulation of the instrument.

**Statistical analysis**

All measured variables and derived parameters were tabulated by descriptive statistics. Data summary tables were provided giving the sample size, arithmetic mean,
Figure 3. Colon model with schematic of 21 simulated colon polyps.
standard deviation, and median, minimum, and maximum for means of continuous variables. A paired t test was applied for testing differences between the 2 viewing modes for the number and percentage of polyps detected by each mode. All tests applied were 2 tailed, with \( P \leq 0.05 \) considered statistically significant. All data were analyzed by using the SAS version 9.1 for Windows (SAS Institute, Cary, NC).

**RESULTS**

In total, 37 endoscopists (32 male, 49.2 ± 8.7 years old, 16.7 ± 11.1 years in practice) participated at 6 centers located in the United States (\( n = 3 \)) and Israel (\( n = 3 \)). All 37 endoscopists (100%) successfully inserted and advanced the PeerScope System Model B colonoscope to the cecum. On colonoscope withdrawal by using the forward-viewing mode, the number of simulated polyps (mean ± standard deviation) detected per endoscopist was 11.1 ± 2.3 polyps, a 52.9% simulated polyp detection rate. Simulated polyp detection rates per colon segment were 3.0 ± 0.93 (60.0%) in the right colon, 2.4 ± 0.87 (48.0%) in the transverse colon, and 5.7 ± 1.5 (51.8%) in the left colon. In contrast, in the ultrawide-viewing mode, the simulated polyp detection rate per endoscopist significantly increased to 18.0 ± 1.98 polyps, representing an overall 85.7% polyp detection rate (\( P < .001 \)). Moreover, this is an incremental 6.9 more simulated polyps detected per endoscopist (a 62.2% improvement) and a 32.8% higher simulated polyp detection rate than observed in the forward-viewing mode (\( P < .001 \)). Moreover, when analyzing by colon segment, the simulated polyp detection rates were also significantly higher by using the ultrawide-viewing mode at 4.5 ± 0.65 polyps (90.0%) in the right colon, 4.0 ± 0.87 (80.0%) polyps in the transverse colon, and 9.6 ± 1.28 polyps (87.3%) in the left colon (all comparisons, \( P < .001 \) (Table 1).

Importantly, when we compared the detection rates of simulated polyps that were obvious (\( n = 11 \)) versus hidden (\( n = 10 \)) behind colonic folds or at flexures, we found that the simulated polyp detection rates were significantly higher for both types of polyps by using the ultrawide-viewing mode (Table 2). For the “obvious” located simulated polyps, the polyp detection rate was 86.7% by using...
the ultrawide-viewing mode versus 73.7% by using traditional forward-viewing mode (P < .0001). For the “hidden” simulated polyps, the polyp detection rate was 81.9% by using the ultrawide-viewing mode versus 31.9% by using the traditional forward-viewing mode (P < .0001).

**Endoscopist ratings of colonoscopy platform**

Subjective evaluation of the additional angle of view. In their subjective evaluation of the PeerScope colonoscope, 93.8% of the endoscopists reported that switching between the forward-viewing and the ultrawide-viewing modes was “intuitive,” and 87.5% deemed switching between viewing modes as “nonchallenging.” We also found that 100% of the endoscopists were confident in withdrawing the colonoscope when using the ultrawide-viewing mode, 100% positively evaluated the ultrawide-viewing mode with regard to its ability to detect simulated colon polyps, and 81.3% were confident in using accessory endoscopic tools (eg, snare, biopsy forceps) when using the ultrawide-viewing mode.

Moreover, no endoscopist reported any difficulties in advancing or withdrawing the PeerScope colonoscope. On a scale of 1 to 5, where 5 represented the highest level of confidence, we found that the “confidence level” of the endoscopists on colonoscope withdrawal and the “functionality” rating of the instrument were both high, mean scores of 4.7 ± 0.5 and 4.6 ± 0.5, respectively.

Instrument manipulation and use of endoscopic accessories. We found that 81.3% of the endoscopists were enthusiastic about the ability of the PeerScope colonoscope to improve their navigation and orientation abilities within the colon.

The insertion of endoscopic accessories (eg, biopsy forceps, snare) through the working channel and guiding them to the desired location was also highly rated. In total, 87.5% of the endoscopists answered positively on their ability to operate endoscopic accessories and 93.8% reported a positive benefit to the ultrawide-viewing mode in facilitating the operation and manipulation of endoscopic accessories. None of the colonoscopy procedures were aborted because of colonoscope malfunction or failure.

**DISCUSSION**

Multiple studies, in varied patient populations, have shown significant adenoma miss rates during forward-viewing, optical colonoscopy.5-11 Rex et al6 performed back-to-back colonoscopies on 183 patients and reported a 24% adenoma miss rate. This included miss rates of 27% for adenomas 5 mm or smaller, 13% for adenomas 6 to 9 mm, and even a 6% miss rate for adenomas 10 mm or larger. Moreover, adenoma miss rates varied widely even among senior endoscopists, ranging from 17% to 48%. The authors concluded that even experienced endoscopists with meticulous colonoscopy technique will miss a significant number of colorectal adenomas and that the study results demonstrated the need for improvements in colonoscopy technology.5 Van Rijn et al8 performed a systematic review of 6 studies, including 465 patients who underwent back-to-back, same-day colonoscopies and reported a pooled polyp miss rate of 22%. The adenoma miss rate was 2.1% for adenomas 10 mm or larger, 13% for adenomas 6 to 9 mm, and 26% for adenomas 1 to 5 mm. Moreover, in a recent prospective, multicenter European
study, Heresbach et al\textsuperscript{9} performed tandem colonoscopies in 286 patients and reported miss rates during the initial colonoscopy examination of 28% for all polyps and 20% for adenomas. Despite these data, endoscopists are still using colonoscope technology that has been in place for the past 40 years.

The most recent technological advancement in colonoscopy to be reported was the TER. The TER is an auxiliary, through-the-scope optical technology intended to detect polyps located in the proximal folds and at the anatomic flexures of the colon. In a pilot study, Triadafilopoulos and Li\textsuperscript{10} found 11.8% additional polyps (metallic beads imbedded in a colon model) behind colonic folds, hidden from a standard forward-viewing colonoscope. Subsequently, DeMarco et al\textsuperscript{10} and Waye et al\textsuperscript{11} conducted separate prospective, multicenter studies, involving 249 and 298 human subjects, respectively, evaluating the incremental colorectal polyp and adenoma detection rates comparing the TER with forward-viewing colonoscopy. Incremental polyp detection rates with the TER were 14.8% for all polyps and 16.0% for adenomas in the DeMarco et al study and 13.2% for all polyps and 11.0% for adenomas in the Waye et al\textsuperscript{11} study, all significantly higher polyp detection rates compared with forward-viewing colonoscopy. Moreover, DeMarco et al\textsuperscript{10} showed that adenoma detection rates increased to 25.0% after the endoscopists had used the TER in at least 15 procedures. In a prospective, randomized, international multicenter trial involving 4 European and 5 U.S. study sites and including 349 subjects, Leufkens et al\textsuperscript{10} demonstrated that by “per protocol analysis,” there was a net additional detection rate of 29.8% for all polyps and 23.2% for adenomas when using the TER. An intention-to-treat analysis was not performed because of limited subject enrollment. Moreover, the mean withdrawal time and total procedure time when using the TER were significantly longer.\textsuperscript{10}

Despite these intriguing findings, TER technology has an associated learning curve, may not be intuitive to use by endoscopists, requires the accessory channel of the colonoscope thus affecting the time needed for withdrawal/therapeutics (eg, polypectomy, biopsy), and has the associated costs of disposables. Thus, its true efficiency, practicality, and clinical use may be limited.

To reduce significantly the adenoma miss rate of standard forward-viewing colonoscopy, we must improve on current colonoscope technology with more advanced optics and wider angle visualization combined with a user-friendly, intuitive platform interface. In this study, we found that compared with the standard forward-viewing mode (160-degree visualization), the PeerScope Model B ultrawide-viewing colonoscope (\geq300-degree visualization) provided significantly higher rates of simulated polyp detection, both per colon segment and for the entire colon overall. Moreover, and importantly, endoscopists’ subjective assessment of the ultrawide-viewing mode was uniformly high, and its use was deemed intuitive.

The strengths of this study includes its prospective, multicenter, international design involving 37 experienced endoscopists who directly compared the 2 viewing modes on colonoscopy withdrawal. Importantly, we provide additional data that demonstrate that the ultrawide-viewing mode detected significantly more simulated polyps that were purposely “hidden” and located behind colonic folds or within flexures. The limitations include its nonrandomized design and the use of a colon model with “simulated” colon polyps using metallic beads. Despite these limitations, we believe that these impressive results suggest a true breakthrough in colonoscope imaging technology that will enhance the diagnostic yield (polyp and adenoma detection rates) of colonoscopy when performed in human subjects. These study results are very encouraging and are to be pursued in human subjects. Those data are anxiously awaited.

ACKNOWLEDGMENTS

We thank and acknowledge all of the participating endoscopists: Drs Abittan, Anikin, Asuncion, Bedmanrek, Bernstein, Bouch, Carr-Loake, Chowers, Cohen, Dekel, Dickstein, Fenster, Nascembeni Ferran, Halak, Halpern, Kadish, Karaban, Kamin, Khamyasi, Lachter, Lewis, Mardler, Milham, Milkes, Novelrudsky, Rattner, Santo, Scapa, Shapil, Shapira, Sloyer, Suissa, Talansky, Ugran, Yanay, Yassin, and Zeitan.

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