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A novel colonoscope with an extra-wide field of view increases polyp detection rate compared with standard colonoscope: Prospective model-based trial

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ABSTRACT

Background and study aims Colonoscopy, the gold standard for early detection of colorectal cancer, may miss polyps especially those hidden behind folds. This prospective study compared polyp detection and performance of a novel colonoscope with extra-wide field of view (EFOV) of 230 degrees (partially retrograde) to a standard colonoscope (SC, 170 degrees) in a colon model.

Patients and methods A 3 D printed colon model was used featuring 12 polyps placed throughout different colon segments, with several located on the proximal side of haustral folds. Endoscopists were instructed to identify polyps, first inserting the SC immediately followed by the EFOV device, and to place a snare to simulate a polypectomy. A standardized survey was used to record operator impressions.

Results Twenty-nine experienced endoscopists participated in this study. On average, 5.3 vs 9.6 polyps were detected with the standard and EFOV colonoscopes, respectively ($P < 0.001$). Five of 29 operators (17.2%) detected all 12 polyps with the EFOV device, whereas no operator detected all polyps with the SC. The success rate for snare placement was 100% for both endoscopes with similar times (mean of 14 vs 15 seconds for SC and EFOV, respectively). EFOV handling and optical performance were rated as equally good or better by all endoscopists.

Conclusions Use of a colonoscope with novel optics significantly improved polyp detection compared with a standard colonoscope in this non-randomized model-based study, with favorable performance and usability ratings for the EFOV instrument. Clinical studies are needed to confirm these encouraging preliminary results.

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer death [1], despite the increased use of colonoscopy in CRC screening programs [2]. Colonoscopy is currently considered the gold standard for detecting and removing premalignant colorectal lesions. Although it is an effective method, lesions can be missed during colonoscopy [3], increasing the risk of post-colonoscopy interval cancer [4]. Data from the United States indicate that an estimated 55% of post-colonoscopy CRC is due to missed neoplastic lesions at the index colonoscopy [5]. This risk is inversely correlated with the adenoma detection rate (ADR), an important quality parameter in colonoscopy [6, 7]. From a technical standpoint, one of the main weaknesses

is the limited field of view of current colonoscopes and the fact that polyps can be hidden behind folds and in tight bends.

In recent years, multiple developments have been introduced to overcome these limitations, mainly by mechanically flattening the folds and improving the viewing and imaging modalities [8, 9]. Several studies have been performed with advanced viewing colonoscopes, offering improved detection of lesions hidden behind folds [10] and showing a significant increase in ADR compared with standard colonoscopy [11, 12]. However, these devices have never gained widespread acceptance, partly due to the time-consuming process of viewing multiple images, presence of distortions making them unsuitable for interventions, and their overall lack of user-friendliness.

Recently, a novel colonoscope with an extra-wide 230-degree (partially retrograde) field of view has been developed to bridge the gap between improved visibility, image quality, and ease of use in daily clinical practice. The goal is to maintain current features and parameters of colonoscopy, such as withdrawal time, image quality, working channel, stiffness, and compatibility with current platforms. In addition, operator and patient comfort should not be compromised. The objective of this study was to compare the polyp detection rate (PDR) and performance of this novel 230-degree (partially retrograde) extra-wide field of view colonoscope with a standard 170-degree colonoscope in a colon model.

Methods

Study design and participants

This was a prospective study conducted in a closed room during a live endoscopy event (Endo Club North, Hamburg, Germany, November 3 and 4, 2023). Operators were recruited on a voluntary basis, without regard to gender, age, nationality, place of employment, or position, as long as there were in clinical practice and had performed more than 200 colonoscopies. After instruction, participants were asked to perform back-to-back colonoscopies in a silicone colon model, by using a standard colonoscope (SC) first, followed immediately by the novel extended field of view (EFOV) instrument. While withdrawing the endoscope, each endoscopist was asked to identify simulated polyps, which were counted according to dedicated markers placed within the model. Withdrawal time was limited to 4 minutes with regular announcements of the remaining time. If the distal end of the model was not reached, the participant was asked to remain at the last polyp seen. Lesions not identified were counted as missed. All endoscopists were blinded to the number, size, and location of the polyps.

After each colonoscopy, when the withdrawal time had expired or the endoscope reached the end of the model, the endoscopist was asked to place a snare around the most distal polyp detected to simulate a polypectomy. Time was stopped during each placement.

▶ **Fig. 1** Close-up of the tip of the endoscope with the slightly protruding lens providing the wide field of view image.

▶ **Table 1** Specification for colonoscopes used in the study.

Items		Standard scope: EC38-i20c	EFOV scope: EC38-i20cW
Image sensor		CMOS	
Direction of view		0°	0°
Field of view		170°	230°
Depth of field		2–100 mm	
Tip angulation	Up/down	210°/180°	180°/180°
	Right/left	160°/160°	
Forward water jet		Yes	
Working length		1500 mm	
Adjustable stiffness		Yes	

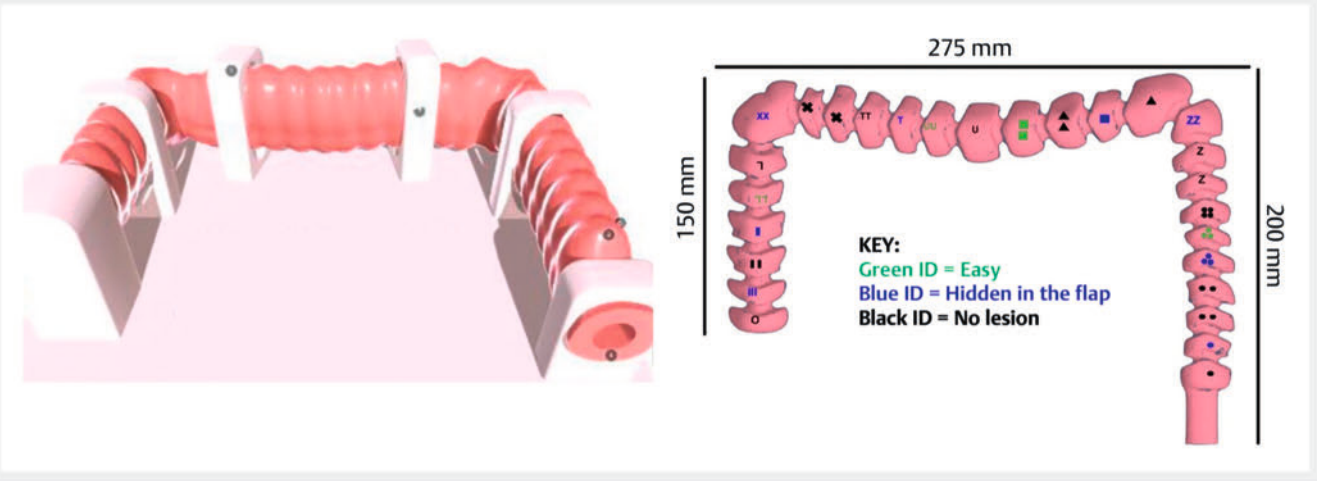
EFOV, extended field of view.

Endoscopist feedback

The endoscopists shared their experience about performing colonoscopies (number of colonoscopies performed) and completed a standardized survey to record their impressions of snare handling, optical performance, maneuverability, potential impact on polyp detection, and endoscope intubation of the new versus the standard endoscope. All ratings were ranked on a 1 to 5 Likert scale, where 1 meant unacceptable/strongly disagree, 2 difficult/disagree, 3 neutral/acceptable, 4 good/agree, and 5 excellent/strongly agree.

Novel colonoscope

At first glance, the novel colonoscope (EC38-i20cW, PENTAX Medical) looks like a standard device, but the fish-eye lens is curved and protrudes from the end of the endoscope, providing a partially retrograde view of 230 degrees (▶ **Fig. 1**). ▶ **Table 1** shows the specifications for the novel colonoscope compared with the standard device (EC38-i20c, PENTAX Medical).



▶ **Fig. 2** Colon model in a U-shape (left), simulating 12 obvious and hidden polyps at the different segments (right).

Pentax Medical Video Processor EPK-i8020c, called INSPIRA, Hoya Corporation, Japan, was used as the processor. This product provides illumination for the endoscopes, processes the image signal from the solid-state image sensor mounted on the distal end of the endoscope, and outputs the observation image to the monitor. Brightness, color balance, and other characteristics of the displayed image can be adjusted using the control buttons on the product. Due to the novel endoscope's advanced imaging chip and LED on the tip illumination, its color, contrast, and resolution differ from those of the standard colonoscope (SC).

To simulate a polypectomy, a disposable polypectomy snare (StellaLoop) with a loop width of 10 mm was used in both procedures (SC, EFOV). Times for each were recorded.

Colon model

A 3 D printed silicon model of a colon was commissioned specifically for this study from Lazarus 3 D, Albany, Oregon, United States (▶ **Fig. 2**). The model is 62 cm long and simulates ascending, transverse, and descending colonic segments. It contains 12 sessile polyps ranging in size from 4 mm to 7.5 mm, placed throughout the colon, with four easy-to-find polyps located on the distal, more central side of the folds ("obvious") and eight polyps located on the proximal side of the haustral folds ("hidden").

For screening procedures, professional societies consider withdrawal time as an important quality parameter. Therefore, a colonoscope should be withdrawn in 6 minutes or longer [13, 14]. The colon model for this study was about 50% shorter; therefore, we determined that withdrawal time should be at least 3 minutes. For the purpose of this study, we decided on a maximum withdrawal time of 4 minutes to allow the operators to get used to the artificial environment, but also to mimic the daily clinical routine with limited time windows per patient.

Study outcomes

The primary outcome was performance of the EFOV compared with the SC based on number of simulated polyps detected in a colon model with both instruments. Secondary outcomes included withdrawal time for both endoscopes, with a time limit of ≤ 4 minutes. In addition, success rate and time to place a snare around the most distal polyp detected were evaluated. At the end of the study, subjective impressions were collected from each endoscopist were collected, such as for endoscope/snare handling, optical performance, and maneuverability.

Sample size calculation

Using a two-sample paired *t*-test, based on a 50% PDR with SC (i. e., 6 of 12 polyps), an assumed difference of two detected polyps (8 of 12 or about 67% PDR) with EFOV and a standard deviation (SD) of the number of detected polyps of three, resulted in a sample size of 21 endoscopists with a two-sided significance level of 0.05 and 80% power. Adjustment for nonparametric Wilcoxon signed-rank test based on Pitman Efficiency [15] resulted in about 30 endoscopists to detect at least the assumed difference regarding the number of detected polyps.

Study analysis

Variables and derived parameters are reported by using descriptive statistics. Data summary tables are provided with sample size, minimum, maximum, arithmetic mean, median, and SD with 95% confidence intervals (CIs) for continuous variables. Due to the limited number of polyps to be detected, a two-sided Wilcoxon signed-rank test (non-parametric test) was used to test differences between EFOV and SC for the number of simulated polyps detected (primary endpoint). Separate descriptive data and (descriptive) Wilcoxon signed-rank tests were also performed for the number of obvious and hidden polyps detected.

Other secondary endpoints included detection rates for SC and EFOV and their difference (including 95% CIs). Withdrawal time was used as measured; if the maximum time for a colonoscopy was reached without stopping the procedure, withdrawal time was censored at the maximum time for a colonoscopy. All data were analyzed by using SAS (SAS Institute, Cary, North Carolina, United States).

▶ **Table 2** Polyp detection per segment and overall.

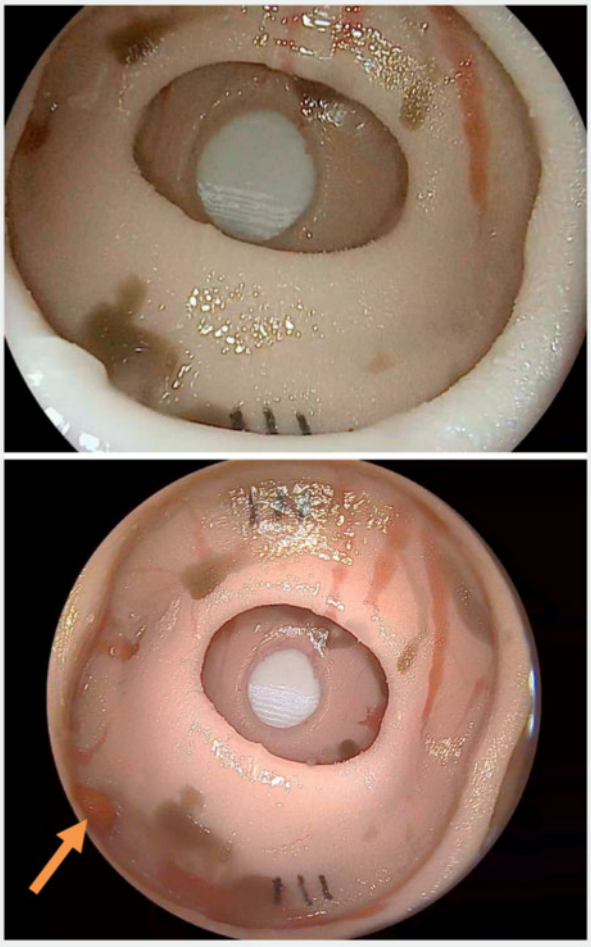
Colon segment	Detected polyps with SC mean ± SD (%)	Detected polyps with EFOV mean ± SD (%)	*P* value
Right colon	1.55 ± 0.95 (39)	3.10 ± 1.01 (78)	< 0.0001
Transverse	2.69 ± 1.0 (67)	3.69 ± 0.6 (92)	< 0.0001
Left colon	1.03 ± 0.57 (26)	2.76 ± 1.06 (69)	< 0.0001
Entire colon	5.28 ± 1.53 (44)	9.55 ± 2.05 (80)	< 0.0001

EFOV, extended field of view; SC, standard colonoscope.

▶ **Table 3** Polyps detected per endoscopist.

Polyps detected by 29 endoscopists	Using SC; n = (%)	Using EFOV; n = (%)	*P* value
All 4 obvious	15 (51.72%)	26 (89.66%)	0.0015
All 8 hidden	0 (0%)	5 (17.24%)	0.0193
All 12, incl. 8 hidden	0 (0%)	5 (17.24%)	0.0193

EFOV, extended field of view; SC, standard colonoscope.



▶ **Fig. 3** Image views recorded with the standard endoscope (left) versus EFOV endoscope (right). During withdrawal without rotation, a hidden polyp in segment III is visualized by the EFOV device only.

Results

A total of 29 experienced endoscopists, 25 male (86%) with a mean age of 50 years (± 11 SD), participated in this trial; 90% of them had performed > 1,000 colonoscopies during their careers and none had performed fewer than 200. Half of them, 15 participants (52%), reported a personal ADR of 34.6% (± 7.7 SD), while others did not recall this information.

Using the SC, an average of 5.3 polyps (95% CI 4.69–5.86) were detected, compared with 9.6 polyps (95% CI 8.77–10.33) when using the EFOV colonoscope ($P < 0.001$) (▶ **Table 2**). The median difference in the number of polyps detected by the same endoscopist between SC and EFOV was 4, ranging from 1 to 8 ($P < 0.001$ for Wilcoxon signed-rank test). Regarding the PDR, the mean PDR with the SC was 44% (95% CI 0.39–0.49), whereas the colonoscopies using the EFOV instrument reached 80% (95% CI 0.73–0.86), yielding a significant increase of 36%.

Five of 29 operators (17.2%) detected all 12 polyps with the EFOV endoscope, whereas none spotted all polyps with the SC (▶ **Table 3**). The maximum number of polyps detected with the SC was nine (75%).

The maximum achievable number of polyps based on 29 endoscopists was 116 for obvious and 232 for hidden polyps. Of all obvious polyps, 85% were detected with the SC compared with 97% with the EFOV endoscope ($P < 0.0001$) (▶ **Table 3**). Polyps located on the proximal side of the haustral folds were also more frequently identified with the EFOV endoscope, resulting in a 48% increase in detection (54/232 (23%) and 165/232 (71%) with the SC and EFOV, respectively). ▶ **Fig. 3** shows the view of polyps during withdrawal of each colonoscope.

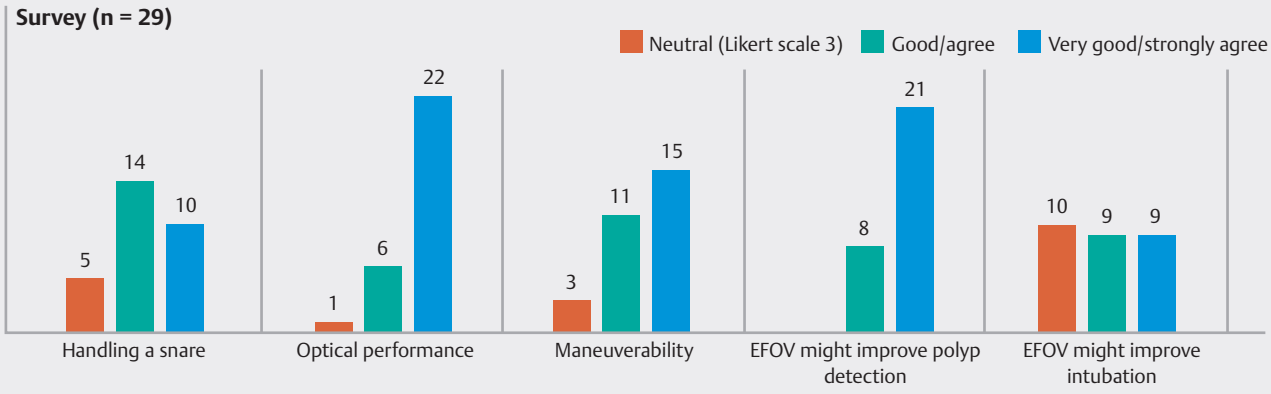
Withdrawal times (quantiles) with SC compared with EFOV was 3.1 and 2.1 minutes, respectively. With the SC, 31% of the operators finished evaluation of the model in less than 4 minutes, while with EFOV, the complete withdrawal rate was 93% (95% CI 80%-99%) within the 4-minute timeframe.

Simulating polypectomy

The success rateforf snare placement was 100% for both endoscopes with similar times (mean of 14 seconds vs 15 seconds for SC and EFOV, respectively).

Endoscopist subjective ratings

Handling, optical performance, and maneuverability of the EFOV colonoscope were consistently rated as equal to or better than the SC by all endoscopists (▶ **Fig. 4**). Notably, none of the users assigned ratings lower than 3.



▶ **Fig. 4** Individual ranking of the operators based on a Likert scale of 1 to 5.

▶ **Table 4** Overall number of obvious and hidden polyps detected by the endoscopists using both scopes.

	Number of polyps detected with SC (%)	Number of polyps detected with EFOV (%)	P value
Obvious polyps: n = 4; in total achievable: 116	99/116 (85%)	112/116 (97%)	0.0029
Hidden polyps: n = 8; in total achievable: 232	54/232 (23%)	165/232 (71%)	< 0.0001

EFOV, extended field of view; SC, standard colonoscope.

Discussion

Efforts to mitigate the problem of adenoma miss rates in routine colorectal cancer screening have led to several technological advances. Real-time artificial intelligence or so-called computer-aided detection systems can assist the operator in identifying abnormalities, but are dependent on the equipment, i. e., the field of view of each colonoscope [16]. Other technologies include mechanically flattened folds and enhanced viewing and imaging modalities, which have initially demonstrated significant increases in ADR compared with conventional colonoscopes [9, 11, 12, 17]. However, these instruments have never gained widespread acceptance or are no longer commercially available (e. g., FUSE and EWAVE). One contributing factor has been the display method. Simultaneous inspection of images from multiple cameras proved time-consuming and lacked ease of use. The same disadvantages arise when using additional monitors. Furthermore, presence of peripheral distortion was perceived as cumbersome, i. e., during interventions, whereas the requirement for additional gadgets is inconvenient and costly. Recognizing these challenges, there is a clear need for a new device with an expanded field of view that remains user-friendly.

In this study, endoscopists utilized a colonoscope featuring innovative optics. The novel device presents a single but wider optics configuration with a 230-degree extra-wide field of view, displayed on the same monitor commonly used in the procedure. Results from the model-based study demonstrated a significant improvement in polyp detection over the standard device (▶ **Table 2** and ▶ **Table 3**), applicable for both obvious and hidden polyps. The low detection rate for even obvious polyps in the SC group maybe partially explained by the rigidity of the model and unavailability of suction and flushing. In addition, spots simulating stool remnants in the model seemed to be disturbing to some users. Withdrawal times and time required to place a snare when simulating polypectomy were comparable between both instruments. This suggests that the new device is easy to use and does not require extensive training, yet excels in visualizing more polyps, especially those hidden behind folds (▶ **Table 3** and ▶ **Table 4**). Subjective ratings from operators indicated that the novel colonoscope is promising, with good handling and maneuverability during procedures. Despite the limitation of using water for lens cleaning during this study setting to prevent silicone oil beading up in the model and hindering polyp detection, operators expressed confidence that the new device would improve outcomes such as ADR.

Strengths of this trial include the variety of operators who volunteered and were recruited spontaneously during their attendance at an endoscopy conference. All 29 endoscopists were experienced in performing colonoscopy and used both scopes in a standardized approach within a unique 3D-printed model. The trial imposed constraints such as a maximum 4-minute withdrawal time, matching each polyp according to a special marker, and simulating polypectomy without time limits. These standardized conditions enhance the comparability of results, even if real-world scenarios may differ due to variations in patient anatomies and other parameters in clinical practice.

Although a colon model is a popular method for initial testing [18, 19, 20], the trial's reliance on a colon model with simulated polyps and its design were limiting factors. In addition, the non-randomized order of scope use may have influenced polyp detection rates at subsequent colonoscopies, as endoscopists might have recalled some polyps from the initial round. Despite regular announcements of time and endoscope position, not all of the operators were able to complete the colonoscopy within the allotted 4-minute time frame (31% versus 93% with SC and EFOV devices, respectively). One reason for this may be that participants needed more time to get used to the model during their first colonoscopy conducted with an SC. Polyps located in uninspected segments of the colon due to incomplete withdrawal were calculated as missed, which may have disadvantaged the SC. On the other hand, counting missed polyps in unexamined areas of the colon is close to clinical practice and, therefore, is considered a reasonable way to account for missed lesions due to incomplete withdrawal. Furthermore, significant differences in endoscope handling are unlikely because both instruments are based on the same insertion technology. One indicator of comparable handling was snare placement, which was similarly effective in time and success rate with both endoscopes. However, studies in humans are needed to gain deeper insights.

Conclusions

In conclusion, use of a novel colonoscope with an EFOV (230 degrees) resulted in a significant improvement in PDRs compared with a SC in this non-randomized model-based trial. The EFOV instrument received favorable ratings for its performance and usability, with no reported issues of distortion or prolonged learning curve. Clinical studies are needed to confirm these encouraging preliminary results.

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Conflict of Interest

H.N. has received a consultancy fee from Pentax Europe. T.N. has received a consultancy fee from Pentax Europe. A.S. has no conflicts of interest.

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