

A prospective cohort study evaluating a novel colonoscopy platform featuring full-spectrum endoscopy*

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Background and study aims: Although colonoscopy is the criterion standard for detecting colorectal adenomas and cancers, a significant percentage of adenomas are missed with this technique. We aimed to establish the feasibility, usability, and safety of a novel colonoscopy platform featuring full-spectrum endoscopy (FUSE).

Patients and methods: This was a prospective, single-center pilot and feasibility study. In total, 50 individuals, ages 18–70 years, underwent colonoscopy featuring FUSE (up to 330° field of view) for colorectal cancer screening, polyp surveillance, or diagnostic evaluation. Study end points included success of cecal intubation, time to cecal intubation, withdrawal time, total procedure time, success of therapeutic interventions, adverse events, and endoscopists' subjective evaluation of FUSE.

Results: Cecal intubation was achieved in 50/50 individuals (100%). Time to cecum (minutes, mean±SD) was 3.1±1.5 minutes, withdrawal time 12.7±4.4 minutes, and total procedure time 15.3±4.6 minutes. In 22/50 cases (44%), 26 therapeutic interventions were performed: 19 (73.1%) biopsies and 7 (26.9%) polypectomies. No acute or delayed adverse events were observed. Patient satisfaction and endoscopist subjective evaluation were high.

Conclusions: A colonoscopy platform featuring full-spectrum endoscopy appears feasible, usable, and safe. These results represent an important advance in colonoscopy imaging technology and should be further pursued in comparative human studies.

Introduction

Colonoscopy is the gold standard for detecting colorectal adenomas and cancers [1–4]. However, a number of clinical trials and a systematic review have reported that a significant percentage of adenomas (approximately 20%–40%) are missed during traditional colonoscopy [5–11]. The primary reason for missing colorectal adenomas and cancers is poor visualization of the proximal aspect of colonic folds, anatomic flexures, and the ileocecal valve area [11]. These anatomic sites tend to be hidden from the forward-viewing colonoscope and can only be seen through scope manipulation by the endoscopist (e.g., prolonged retroflexion of the colonoscope tip) [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 using 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 upon current colonoscope technology—specifically, its field of view and the current limitations of its optics. Attempts at improving visualization capabilities during colonoscopy have been reported and include 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 (e.g., Third Eye Retroscope) [14–21]. Despite these innovations, the technological abilities of colonoscopes remain incomplete, or have not been user friendly or intuitive to use by the endoscopist.

We recently reported the results of a prospective multicenter study comparing forward-viewing with full-spectrum endoscopy (FUSE) colonoscopy

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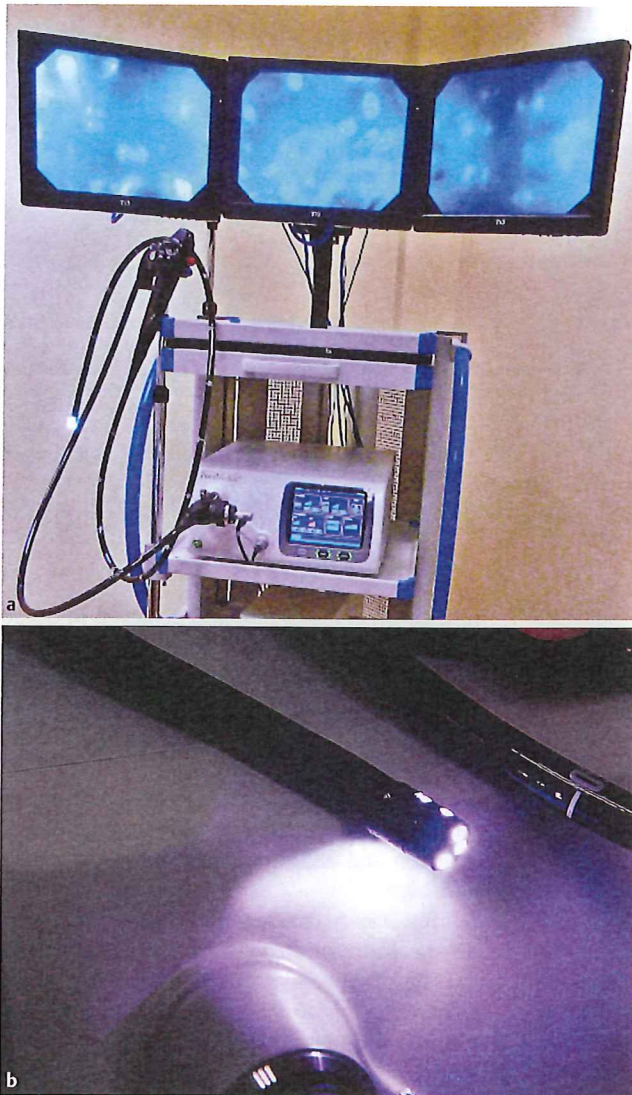


Fig. 1 a Full-spectrum endoscopy (FUSE) colonoscopy platform (Full Spectrum Endoscopy; EndoChoice, Alpharetta, Georgia, USA) with monitors. b Colonoscope and main control unit.

py in the detection of simulated colon polyps (metallic beads) in an in vitro colon model [22]. We found significantly higher rates of detection of simulated polyps with FUSE, both per colon seg-

ment and overall throughout the entire colon (85.7% vs. 52.9% detection rate, $P < 0.001$). Importantly, FUSE also detected significantly more purposely “hidden” simulated polyps (81.9% vs. 31.9%, $P < 0.0001$).

The aim of this prospective cohort study was to establish the feasibility, usability, and safety of a novel colonoscopy platform featuring FUSE in human subjects.

Methods and materials

We performed a prospective cohort study in which gastroenterologists who were experienced in performing colonoscopy evaluated the feasibility, usability, and safety of a novel colonoscopy platform featuring FUSE in human subjects (ages 18–70 years) referred for colorectal cancer screening, polyp surveillance, or diagnostic evaluation. We excluded individuals with a history of colonic resection, inflammatory bowel disease, polyposis syndrome, suspected colonic stricture, suspected acute diverticulitis or toxic megacolon, or radiation therapy to the abdomen or pelvis. The participating endoscopists ($n = 7$) had no prior clinical experience using this prototype colonoscopy platform.

Colonoscopy platform

The FUSE colonoscopy platform (Full Spectrum Endoscopy; EndoChoice, Alpharetta, Georgia, USA) comprises a video colonoscope and a main control unit (MCU) (Fig. 1). The FUSE colonoscope is an adult-size (168 cm working length), flexible colonoscope intended for repeated clinical use (diagnostic visualization and therapeutic interventions). It allows the endoscopist to choose between two high-resolution viewing modes with the press of a button—a standard 160° forward-viewing mode and an up to 330° “full spectrum” mode—while maintaining standard colonoscope capabilities and maneuverability of full tip deflection (scope outer diameter 12.8 mm), working channel (3.8 mm), air or CO₂ insufflation options, suction, and forward water jet irrigation. Thus, the FUSE colonoscope maintains identical technical features to the current industry-standard, forward-viewing colonoscopes (Table 1). Full-spectrum viewing is achieved by the use of three lenses/imagers and groups of light-emitting diodes (LEDs) positioned at the front and on the sides of the flexible tip of the colonoscope (Fig. 2). The video images are presented to the endoscopist on three contiguous monitors (Fig. 1a). The left, middle, and right video monitors correspond

Table 1 Comparison of technical specifications of commercially available colonoscopes.

Manufacturer	Olympus	Olympus	Pentax	Fujinon	EndoChoice
Model	CF-H180	CF-HQ190	EC-3890LI HD	EC-450HL5	FUSE
Outer diameter	12.8 mm	12.8 mm	13.2 mm	12.8 mm	12.8 mm
Distal tip diameter	13.9 mm	13.2 mm	–	12.8 mm	13.9 mm
Working channel	3.7 mm	3.7 mm	3.8 mm	3.8 mm	3.8 mm
Water jet	Yes	Yes	Yes	Yes	Yes
Working length	168 cm	165 cm	170 cm	169 cm	168 cm
Tip angulation up/down	180°/180°	180°/180°	180°/180°	180°/180°	180°/180°
Tip angulation right/left	160°/160°	160°/160°	160°/160°	160°/160°	160°/160°
Illumination source	2 light guides	2 light guides	2 light guides	2 light guides	7 LEDs
Field of view (degrees)	170°	170°	140°	140°	160° (forward lens FOV) 330° degrees (FUSE FOV)
Type of imager	CCD	CCD	CCD	CCD	CCD

FOV, field of view; FUSE, full-spectrum endoscopy; CCD, charge-coupled device; LED, light-emitting diode.

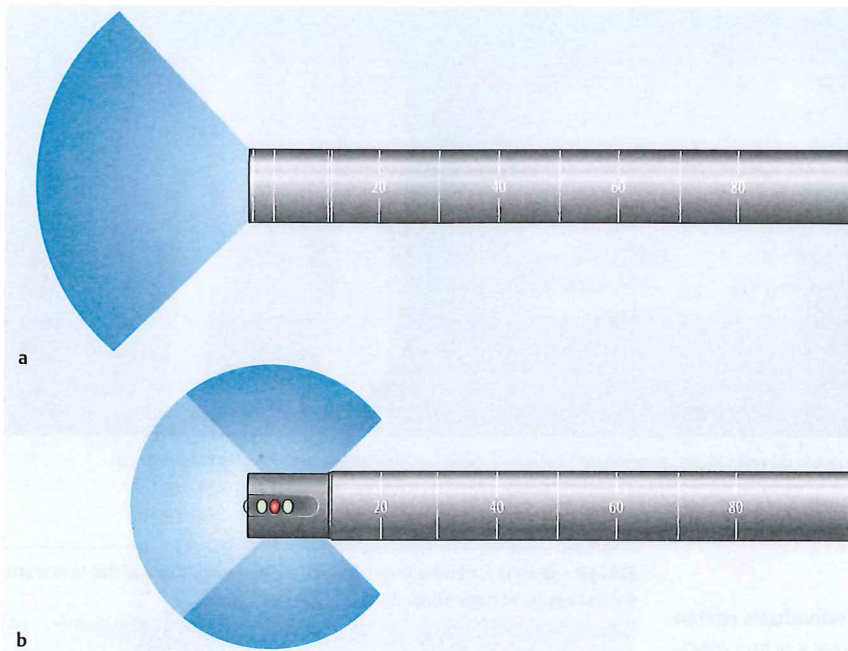


Fig. 2 a Field of view with a traditional forward-viewing colonoscope. b Field of view with a full-spectrum colonoscope.

with the colonic images transmitted from the left-sided, forward-facing, and right-sided lenses respectively (● **Video 1**). The MCU serves as a control platform for the FUSE colonoscopy system. The MCU is responsible for LED illumination, endoscopic image acquisition and processing, video signal transfer, insufflation/water irrigation control, and external accessories that interface with the platform.

Colonoscopy examination

All subjects underwent standard colonoscopy preparation using either a polyethylene-glycol-based solution or a sodium picosulfate preparation, all commercially available and approved for use in Israel. Choice of colon preparation was at the discretion of the endoscopist. Conscious sedation was delivered by the endoscopist and achieved using a combination of midazolam, fentanyl, and propofol. The intention with each colonoscopy examination was to reach and intubate the cecum. Intubation of the terminal ileum was optional and at the discretion of the endoscopist. Upon colonoscope withdrawal, the endoscopist was instructed to use his or her “usual withdrawal technique” but was required to spend a minimum of 6 minutes withdrawing and examining the colon [23]. Insertion time, withdrawal time, and total procedure time were all recorded using a stopwatch during the colonoscopy procedure. The stopwatch was stopped for polypectomy or diagnostic biopsy and then restarted after completion of these interventions. Retroflexion of the colonoscope in the rectum was performed in each subject. Biopsies and/or polypectomies were performed on an as-needed basis (● **Fig. 3**).

Study end points

The primary end point of this pilot and feasibility study was cecal intubation; additional end points included time to cecal intuba-

tion, withdrawal time, total procedure time, success of diagnostic and therapeutic interventions, adverse events, and endoscopists' subjective evaluation of the FUSE technique. Telephone follow-up of patients was performed by a research assistant 24 hours after the procedure to assess for any possible delayed adverse events and to evaluate patient satisfaction with the colonoscopy procedure. Patient satisfaction was captured by single yes/no question asking if the patient was satisfied with the colonoscopy examination. In addition, using a 5-point Likert rating scale, we assessed the endoscopists' subjective evaluation of the usability, field of view, and maneuverability of the FUSE colonoscopy platform. This rating scale offered the following answer options: unacceptable, difficult, acceptable, good, and excellent. Specifically, we assessed the subjective evaluation of FUSE in terms of the incidence of difficulties in advancing or withdrawing the instrument, ease of manipulation of the instrument, and ease of use of endoscopic accessories through the working channel. Endoscopists completed their subjective evaluations immediately following each colonoscopy examination.

This study was performed according to the guidelines approved by the Elisha Hospital Helsinki committee on 4 April 2011, and informed written consent was obtained from all subjects. This study was registered at clinicaltrials.gov (identifier: NCT01483040) before the first subject was enrolled.

Statistical analysis

All measured variables and derived parameters were tabulated by descriptive statistics. Data summary tables were provided giving sample size, arithmetic mean, standard deviation, median, minimum, and maximum for means of continuous variables. A paired *t* test was applied for testing differences between the two viewing modes for the number and percentage of polyps detected by each mode. We calculated 95% confidence intervals (CI) where appropriate, using a binomial proportion for one-way tables. All tests applied were two-tailed, with a *P* of 0.05 or less considered to be statistically significant. All data were analyzed using the SAS version 9.1 for Windows (SAS Institute, Cary, North Carolina, USA).

Video 1

Traditional forward-viewing colonoscopy transitioning to full-spectrum view.

online content including video sequences viewable at:
www.thieme-connect.de

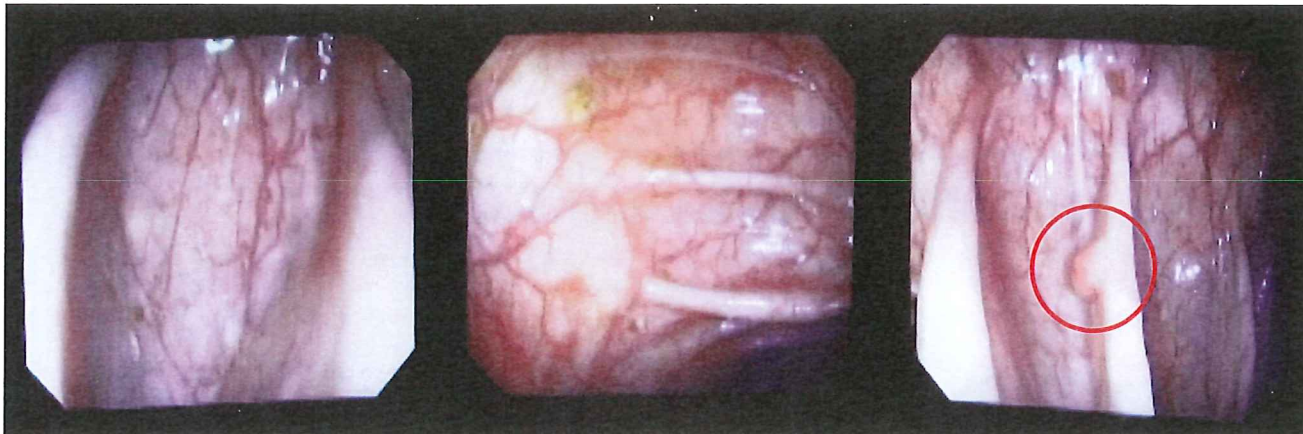


Fig. 3 Full-spectrum endoscopy demonstrating sessile polyp on right video monitor, not detected using traditional forward-viewing colonoscopy.

Results

From 22 September to 9 November 2011, 50 individuals (mean age \pm SD, 53.1 \pm 13.7 years, 56% male) meeting our a priori specified inclusion and exclusion criteria were enrolled at the Gastrointestinal Endoscopy Unit at Elisha Hospital, Haifa, Israel. A 50/50 (100%) success rate in cecal intubation was achieved using FUSE. Time to reach the cecum (mean \pm SD) was 3.1 \pm 1.5 minutes (range 1–8 minutes), and colonoscopy withdrawal time was 12.7 \pm 4.4 minutes. Total procedure time was 15.3 \pm 4.6 minutes (range 5.9–28.0 minutes) (Table 2; Videos 2 and 3). As per choice of the endoscopist, in 23/50 individuals (46%) the terminal ileum was intubated. Furthermore, in 22/50 cases (44%) 26 diagnostic and/or therapeutic interventions were performed: 19/26 biopsies (73.1%), 4/26 “cold” snare polypectomies (15.4%), and 3/26 “hot” snare polypectomies using bipolar coagulation (11.5%). Overall, a 100% success rate was achieved with use of biopsy forceps ($n=19$) and snare polypectomies ($n=7$). We did not observe acute or delayed adverse events (“delayed” was defined as more than 24 hours after colonoscopy), and patient satisfaction was uniformly high when patients were contacted 24 hours following the colonoscopy procedure.

Endoscopists’ subjective evaluation of the FUSE mode demonstrated 92% and 100% satisfaction in ease of scope advancement and maneuverability, respectively. Tool insertion through the working channel and performance of biopsy/polypectomy were rated by the endoscopists as “excellent” in 100% of cases. The benefit of FUSE was reported as “highly significant” (94%) or “significant” (6%) (Table 3).

Discussion

Multiple studies, in varying patient populations, have shown significant adenoma miss rates with the use of current industry-standard, forward-viewing optical colonoscopes [5–11]. For example, Rex et al. performed back-to-back colonoscopies in 183

Table 2 Results for end points of pilot and feasibility study of full-spectrum endoscopy in 50 patients undergoing colonoscopy.

	Minutes, mean \pm SD
Time to cecal intubation	3.1 \pm 1.5
Withdrawal time	12.7 \pm 4.4
Total procedure time	15.3 \pm 4.6

Table 3 Qualitative assessment by seven endoscopists of full-spectrum endoscopy used for colonoscopy in 50 patients, in 22 of whom therapeutic interventions were performed.

Qualitative aspect	Rated excellent/good, %
General ease of use	100
Ease of scope advancement	92/6
Ease of scope maneuverability	100
Quality of side views	94/6
Image quality (overall)	90/10
Air insufflation quality	94/2
Lens irrigation (front)	98/2
Lens irrigation (sides)	90/4
Suction quality	90/6
Ability to insert tool into working channel (22 patients)	100
Ability to biopsy/polypectomy (22 patients)	100

patients and reported a 24% adenoma miss rate. This included miss rates of 27% for adenomas 5 mm in size or smaller, 13% for adenomas 6–9 mm in size, and even a 6% miss rate for adenomas that were 10 mm or larger. High adenoma miss rates ranging from 17% to 48% were also reported among well-experienced endoscopists. The authors concluded that even experienced endoscopists with a meticulous colonoscopy technique can miss a significant number of colorectal adenomas, and suggested that the study results demonstrated “the need for improvements in colonoscopy technology” [6]. Van Rijn et al. performed a syste-

Video 2

Cecal intubation with ileocecal valve seen en face in left full-spectrum endoscopy video monitor.

online content including video sequences viewable at: www.thieme-connect.de

Video 3

Sessile polyp seen only on right full-spectrum endoscopy video monitor.

online content including video sequences viewable at: www.thieme-connect.de

matic review of six studies including 465 patients who underwent back-to-back, same-day colonoscopies, and reported a pooled miss rate for polyps of 22%. The adenoma miss rate was 2.1% for adenomas sized 10 mm or larger, 13% for adenomas sized 6–9 mm, and 26% for adenomas sized 1–5 mm [8]. In a recent European prospective multicenter study, Heresbach et al. performed tandem colonoscopies in 286 patients and reported miss rates during the initial colonoscopy examination of 28% for all polyps and 20% for adenomas [9]. Despite these data, endoscopists are still using forward-viewing colonoscopy technology that has been in place for the past four decades and is still considered the standard for polyp detection and removal.

The most recent technological advance in colonoscopy to be reported is the Third Eye Retroscope (TER). The TER is an auxiliary through-the-scope optical technology intended to detect polyps located on the proximal side of colonic folds and at the anatomic flexures. Triadafilopoulos et al. found 11.8% additional “polyps” (metallic beads imbedded in a colon model) behind colonic folds, hidden from a standard forward-viewing colonoscopy [18]. DeMarco et al. and Waye et al. conducted separate prospective multicenter studies involving 249 and 298 human subjects respectively, evaluating the incremental colorectal polyp and adenoma detection rates comparing TER to forward-viewing colonoscopy [20, 21]. Incremental polyp detection rates with the TER were 14.8% for all polyps and 16.0% for adenomas in the study by DeMarco et al. and 13.2% for all polyps and 11.0% for adenomas in the study by Waye et al. Both these polyp detection rates were significantly higher than with forward-viewing colonoscopy. Moreover, DeMarco et al. showed that adenoma detection rates increased even further, to 25.0%, after the endoscopists had used the TER in at least 15 procedures [20, 21]. In an international prospective, randomized, multicenter trial involving 49 subjects, Leufkens et al. demonstrated that the “per protocol” net additional detection with TER was 29.8% for all polyps and 23.2% for adenomas [10]. However, mean withdrawal time and total procedure time when using TER were slightly, but significantly, longer [10].

Despite these provocative findings and increased polyp detection rates, there are several drawbacks to using TER technology. As stated above, there is a learning curve and endoscopists may not find the TER technology intuitive to use. Moreover, this technology is probe-based, requiring the accessory channel of the colonoscope, and thus impacting upon the time needed for scope withdrawal and therapeutic interventions (e.g., polypectomy, biopsy). The TER technology also has associated costs of disposables. Therefore, its true efficiency, practicality, and clinical use in the hands of community gastroenterologists may be limited.

In order to reduce significantly the adenoma “miss rate” of standard forward-viewing colonoscopy, therefore, we must improve upon current colonoscopy technology with more advanced optics and wider-angle visualization combined with a user-friendly, intuitive platform interface. In this present study, we found that a prototype colonoscope with FUSE demonstrated a 100% success rate in cecal intubation and in diagnostic and therapeutic interventions, had very efficient colonoscopy procedure times (time to cecum, withdrawal time, total procedure time), and was safe to use. Moreover, endoscopists’ subjective evaluation of FUSE was uniformly “excellent” or “good.” Using FUSE, we also found that the drivability of the colonoscope on insertion provided much better visualization of the colonic lumen. We subjectively observed that essentially no more blind corners were encountered

at colonic flexures, and this appears to have translated into a very efficient mean time to reach the cecum.

The strengths of this pilot and feasibility study include its prospective design and the a priori defined outcome measurements. The limitations include that it was nonrandomized with no comparison to forward-viewing colonoscopy, and had a limited sample size and a limited number of participating endoscopists. The limited sample size and number of endoscopists may restrict the generalizability of the endoscopists’ subjective assessment of this technology and any reliable quantification of a learning curve. Despite these limitations, we believe these results suggest an important and significant advance in colonoscopy imaging technology that will improve the diagnostic yield (polyp and adenoma detection rates) of colonoscopy. Moreover, this technology is easy to use, intuitive to the endoscopist, and time efficient.

In conclusion, these pilot study results are encouraging and will be further pursued in human subjects, with comparison to standard forward-viewing colonoscopy in a back-to-back, tandem design. If the results of this planned clinical trial indeed show significantly reduced miss rates for polyps, and particularly adenomas, we believe that colonoscopy with FUSE has the potential to significantly improve the efficacy of colorectal cancer screening and surveillance colonoscopy.

Competing interests: This study was funded in part by PeerMedical Ltd, Caesaria, Israel (now EndoChoice, Alpharetta, Georgia, USA). Professors Gralnek, Siersema, and Halpern, and Drs. Carr-Locke, Segol, and Suissa were consultants for PeerMedical Ltd during the conduct of this study.

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