Chapter 2
Wide Angle Endoscopes and Accessory Devices to Improve the Field of View

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Introduction

Colonoscopy represents a widely established method for colorectal cancer (CRC) screening, given its ability to detect and remove precancerous lesions, namely adenomatous polyps [1, 2]. Interrupting adenoma-carcinoma sequence, increased colonoscopy utilization is possibly associated with the recently observed decline in the incidence of CRC and its earlier diagnosis [3, 4]. Despite the evidence regarding the effectiveness of colonoscopy, emerging data underline its imperfections. As shown in tandem colonoscopy studies, up to a quarter of polyps and adenomas are missed during colonoscopy, accounting for the development of interval cancer [5–7]. Several technical-, patient-, and endoscopist-related factors have been studied to explain variability in colonoscopy outcomes, which negatively influence the quality of the procedure [8–11].

It has been shown that important undetected lesions are often located in the right colon, on the proximal aspects of haustral folds, the area around the ileocecal valve and anatomical flexures. These sites are often hidden from the standard forward-viewing colonoscopes, which provide a 140–170° wide field of view, necessitating complex and time-consuming efforts for thorough mucosal examination.

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Mounting evidence suggests that improving colonoscope technology may result in lower adenoma miss rates and increased diagnostic yield. In order to broaden the field of mucosal view, integrated devices, wide-angle colonoscopes as well as accessory devices are being implemented. The former include the Third Eye® Retroscope® (Avantis Medical Systems, Sunnyvale, CA, USA), the Fuse® Full Spectrum Endoscopy® colonoscopy platform (EndoChoice, Inc., Alpharetta, GA, USA), the G-EYE™ balloon colonoscope (SMART Medical Systems Ltd, Ra'anana, Israel), and the Extra-Wide-Angle-View colonoscope (Olympus, Tokyo, Japan). Accessory devices include transparent caps and the Endocuff that are attached to the distal tip of the colonoscope. This chapter aims to highlight the aforementioned techniques and discuss current data related to their clinical use.

Wide Angle Colonoscopes

Third Eye® Retroscope®

The Third Eye® Retroscope® (TER; Avantis Medical Systems, Sunnyvale, CA, USA) represents a through-the-scope device that intends to enhance visualization behind the proximal aspects of colonic folds and anatomical flexures. It consists of a video processor and a flexible single-use catheter with a miniaturized video camera located in its tip (Fig. 2.1a). By achieving a 180° retroflexion (Fig. 2.1b), it enables detailed examination of the colon during withdrawal (Fig. 2.1c). The efficacy of TER was initially assessed by Triadafilopoulos et al. in three colon models with simulated polyps, both "obvious" and "hidden" [12]. Based on the results of this randomized, blind study, standard colonoscopy detected 12 % of polyps located on the proximal aspects of folds, while TER identified 81 % of them. In a follow-up pilot study by the same author and colleagues, TER detected four additional polyps (three hyperplastic and one adenoma), resulting in an increase in diagnostic yield as high as 11.8 % [13]. Of note, no adverse event was reported.

Accordingly, the diagnostic yield of TER was evaluated in two prospective, multicenter studies by DeMarco et al. and Waye et al. [14, 15]. In the former study, 27 additional polyps were found with TER leading to an increase of 14.8 % and 16 % in polyp and adenoma detection, respectively. Similarly, increases reached 13.2 % and 11 %, respectively, in the latter study. All changes were of statistical significance.

The TERRACE study is the sole randomized, back-to-back, multicenter study with respect to TER [8]. The authors reported that TER yielded a net additional detection rate of 29.8 % for all polyps and 23.2 % for adenomas, in the per protocol analysis. TER underperformed in patients undergoing screening colonoscopy as compared to those undergoing colonoscopy for surveillance or symptomatic evaluation. However, criticism has been raised regarding this study due to significant higher withdrawal time with TER in comparison with standard procedure. Nevertheless, in a post-hoc analysis by Siersema et al., that difference was not associated with the risk of missing adenomas [16].

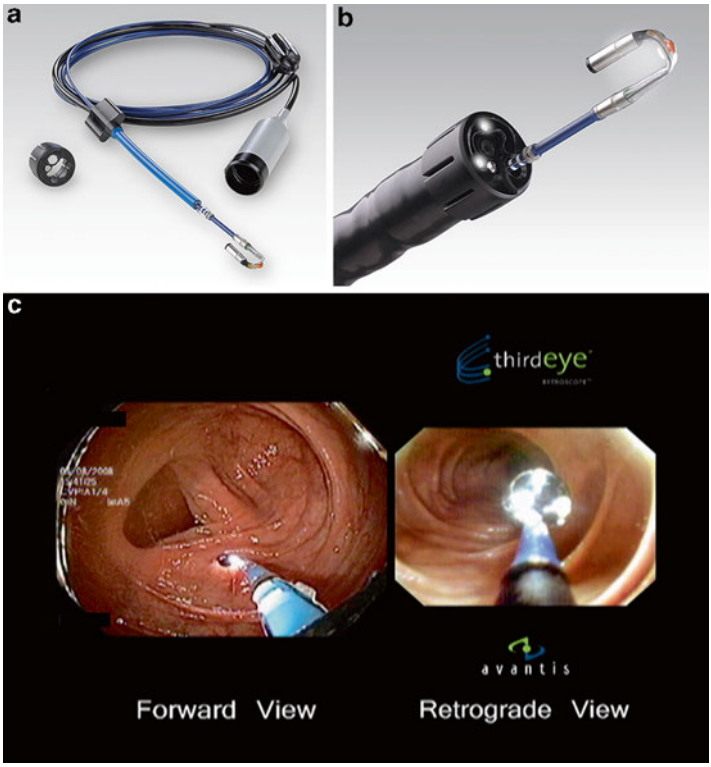

Fig. 2.1 Third Eye® Retroscope®: The devise (**a**), the devise through the endoscope; note its 180° retroflexion (**b**), and the endoscopic view (forward and retrograde) (**c**). With permission from Avantis Medical

Limitations of TER include an associated learning curve, significant cost, and blockage of the working channel preventing use of other devices unless removed. Obviously, a subsequent prolongation of the procedural time is expected.

The FUSE® System

The FUSE® system (EndoChoice, GA, USA) was recently developed as a new platform (Fig. 2.2a). It consists of a main control processor and a video colonoscope (168 cm working length, 12.8 mm outer diameter) with three imagers and LED groups located at the front and both sides of the flexible tip (Fig. 2.2b, c). Obtained images are displayed in three contiguous monitors (Fig. 2.2d), eventually achieving a 330° angle of colonic mucosa view (Fig. 2.2b). In that way, most of the "blind" areas of the colon become easily visualized.

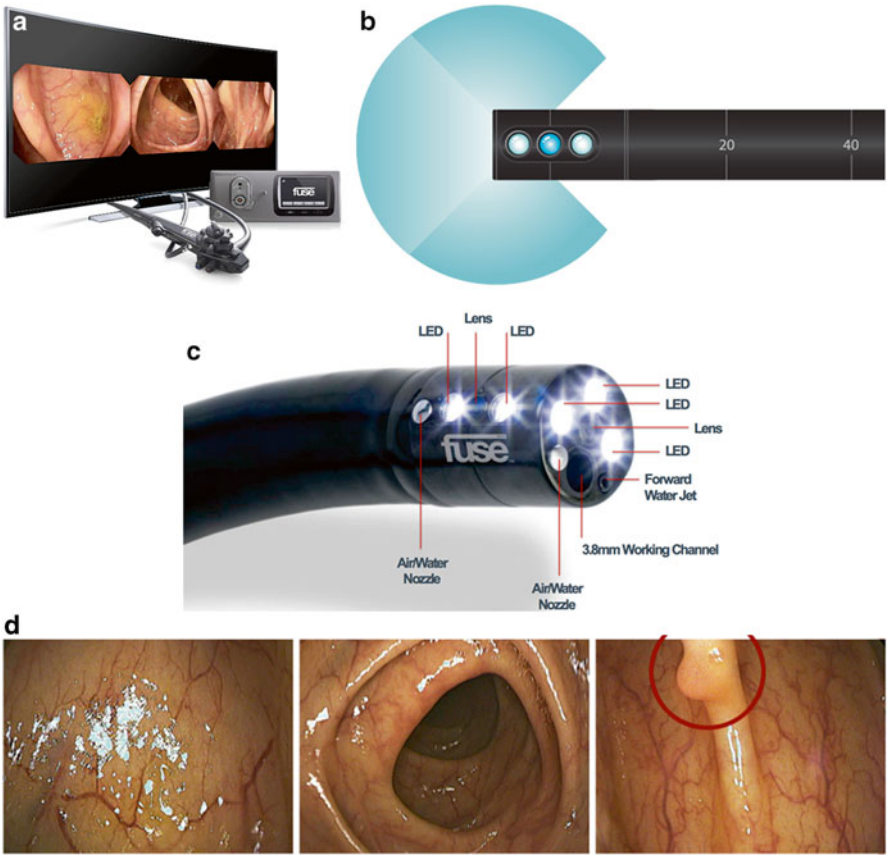

Fig. 2.2 The FUSE® system: Note, the system platform (including scope, processor, and monitor) (**a**), the system's three imagers, which provide a 330° angle view of the colonic mucosa (**b**), the LED groups at the front and sides of the scope's tip (**c**), and the endoscopic view on the three contiguous monitors (**d**). With permission from EndoChoice, Inc

Gralnek et al. reported in 2013 the first study that evaluated the FUSE® system [17]. It was a prospective, multicenter, non-randomized study in in vitro colon models with simulated polyps. As the results indicated, 85.7 % of the polyps were detected with the FUSE® platform compared to 52.9 % with the forward-viewing colonoscopy ($p < 0.001$). Simulated polyp detection rates were significantly higher with the FUSE® system in all colon segments. Interestingly, FUSE® colonoscopy identified significantly more "hidden" behind flexures and folds polyps (81.9 % versus 31.9 %).

A subsequent prospective, single-center study aimed to assess feasibility, usability, and safety of this novel colonoscopy platform in 50 adult subjects [18]. Reported cecal intubation rate was 100 % and time to cecum (minutes, mean ± SD) was 3.1 ± 1.5 min. Withdrawal time was 12.7 ± 4.4 min and total procedure time was 15.3 ± 4.6 min. In 44 % of the cases, 26 interventions were performed: 19 (73.1 %) biopsies and 7 (26.9 %) polypectomies. No acute or delayed adverse events were noticed. Both patients' and endoscopists' satisfaction were high.

An international, multicentre, randomized, tandem colonoscopy trial compared the adenoma miss rates of FUSE® colonoscopy with standard forward-viewing colonoscopy [19]. One hundred and ninety seven individuals were initially randomly assigned (1:1) to which procedure was done first. Per-lesion analysis in 185 patients showed that the adenoma miss rate was significantly lower with FUSE® colonoscopy than in the standard forward-viewing procedure: 7 % versus 41 % of adenomas were missed with FUSE® and standard colonoscopy, respectively ($p < 0.0001$). Standard forward-viewing colonoscopy missed 20 adenomas in 15 patients, three (15 %) of those being advanced. Full-spectrum endoscopy missed five adenomas (non-advanced) in five patients in whom an adenoma had already been found with first-pass standard forward-viewing examination. Five minor adverse events were reported, including vomiting, diarrhea, cystitis, gastroenteritis, and bleeding. The authors concluded that the FUSE® colonoscopy may enhance the efficacy of colorectal cancer screening and surveillance.

Very recently, Hassan and Gralnek demonstrated in a population-based program that, compared to standard colonoscopy, full-spectrum endoscopy appears to be more cost-effective for colon cancer screening and surveillance [20].

G-EYE™ Balloon Colonoscope

The G-EYE™ includes the G-EYE™ balloon colonoscope combined with the NaviAid™ SPARK²C inflation system. The G-EYE™ colonoscope integrates a reusable and inflatable by the endoscopist balloon onto its flexible tip (Fig. 2.3). The balloon has three intermediate pressure levels with a maximal inflation diameter reaching 60 mbar. By inflating the balloon after cecum intubation, flattening of

Fig. 2.3 G-EYE™ balloon colonoscope. With permission from Smart Medical Systems Ltd

haustral folds is achieved aiming to improve inspection and increase lesion detection. Additionally, it may also provide anchoring and stabilization of the colon during therapeutic interventions.

Hassan and colleagues compared the diagnostic yield of balloon-assisted colonoscopy versus that of standard colonoscopy in the detection of simulated polyps in a colon model [21]. G-EYE™ balloon colonoscope demonstrated significantly higher median polyp detection rate (91.7 % versus 45.8 %, $p < 0.0001$). This result was evident both in non-obscured and in obscured polyps.

In 2014, Gralnek et al. aimed to establish the safety and feasibility of this novel balloon-colonoscope in 50 patients referred for colonoscopy [22]. According to the results, two patients experienced minor adverse events (diarrhea, abdominal pain). Cecal intubation was achieved in all cases and mean times to reach the cecum, to withdrawal, the scope, as well as the mean time of the total procedure were 4.3, 7.4, and 16.5 min, respectively. Polyp and adenoma detection rates reached 53.2 % and 44.7 %, respectively, although most (79.5 %) of the findings were of diminutive size. The authors concluded that the studied system appears safe and feasible to use.

A multicenter, randomized, prospective, controlled study in 126 patients undergoing colonoscopy for screening/surveillance or diagnostic evaluation has been very recently published [23]. The adenoma detection and miss rates were compared between the two procedures. The adenoma miss rate of G-EYE™ balloon colonoscopy was significantly lower than that of standard colonoscopy (7.5 % versus 44.7 %; $p = 0.0002$). The detection of additional adenomas by balloon colonoscopy was also significant (81.0 %; $p = 0.0002$). Interestingly, the number of adenomas detected in the ascending colon by balloon colonoscopy was 41 % versus 14 % for standard colonoscopy. Given the significantly higher adenoma detection rate as well as the lower miss rate, the investigators suggested that balloon colonoscopy may increase the effectiveness of colorectal cancer screening and surveillance.

Extra-Wide-Angle-View Colonoscope

The Extra-Wide-Angle-View colonoscope (Olympus, Tokyo, Japan) has a 13.9-mm-tip diameter and a 144–232° lateral-backward viewing lens in addition to a 140° forward-viewing lens at the tip of the scope. Obtained views are presented simultaneously on a video monitor as a single image. This system aims to provide more extensive inspection of the colonic mucosa without any specific manipulations. To assess its diagnostic yield, Uraoka et al. conducted a simulated pilot study of two anatomic colorectal models, each prepared with eight polyps positioned in obvious locations and eight polyps hidden behind folds. Thirty-two endoscopists performed examinations on models by using the extra-wide-angle-view colonoscope and a standard colonoscope. The results indicated that the mean detection rate for all simulated polyps with the extra-wide-angle-view colonoscope was significantly higher than that of the standard colonoscope (68 % versus 51 %; $p < 0.0001$). In addition, the detection rate for “hidden” polyps was also significantly higher in the

extra-wide-angle-view colonoscope than in the standard colonoscope (61.7 % versus 46.9 %; $p = 0.0009$) [24].

Similarly, the same investigators presented in 2013 during the Digestive Disease Week a randomized trial comparing this novel colonoscope with a standard one, on the basis of polyp/adenoma detection. Nevertheless, the results showed no significant differences regarding polyp/adenoma detection rates between the two types of colonoscope. As an exception, the Extra-Wide-Angle-View colonoscope performed significantly better with respect to adenoma detection rate in the sigmoid colon, as compared to the standard scope (mean ADR 0.4 versus 0.2, $p = 0.04$).

Accessory Devices

Endocuff-Assisted Colonoscopy

The Endocuff (EC) is a recently developed attachable endoscopic cuff, which is approved for medical use in humans in order to improve the feasibility of colon polypectomy as well as visualization of the mucosa. The EC is a 2 cm long, flexible cuff with two rows of flexible, hinged wings (Fig. 2.4a) that flatten mucosal folds during scope withdrawal (Fig. 2.4b–d). Its first use was reported in 2012 for

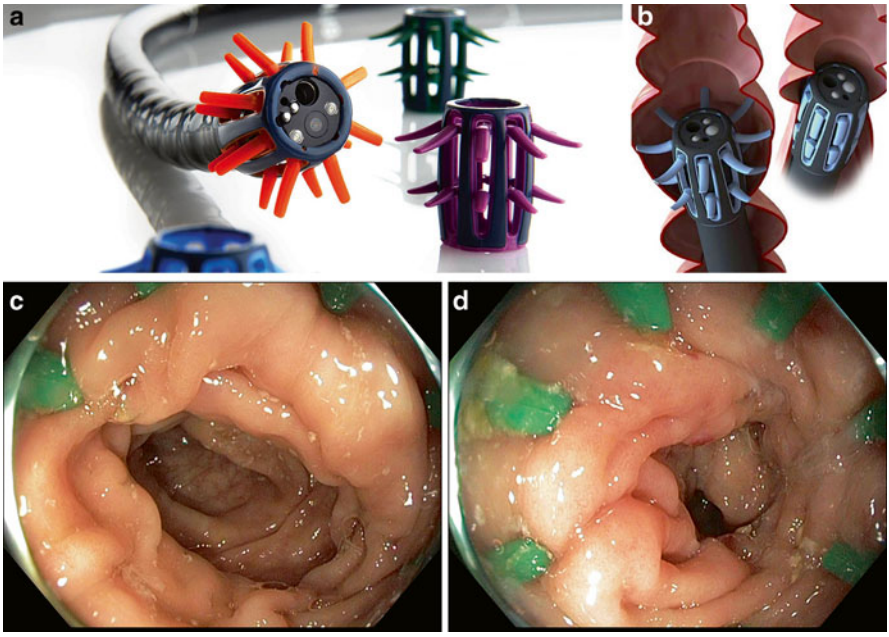

Fig. 2.4 Endocuff-assisted colonoscopy: Note, the device placed on the tip of the scope (**a**), the straightening of the colonic mucosal folds during scope withdrawal (**b**), and the endoscopic view with the device in place (**c**, **d**). With permission from Arc Medical Design Limited

complex polyp resections in the sigmoid colon [25]. Thereafter, a study in 50 patients assessed retrospectively the EC-assisted colonoscopy [26]. According to the results, the intubation rates of the cecum and terminal ileum were 98 % and 76 %, respectively. EC caused some minor superficial lesions in 30 % of the cases. In total, 80 polyps (36 adenomas, 9 advanced adenomas) were identified and the adenoma detection rate was 34 %, reaching 41 % in the screening group. Of note, 42 % of the adenomas were right-sided. The authors concluded that the EC is safe and may improve the adenoma detection rate and also facilitate polypectomy.

The first randomized controlled trial comparing EC-assisted versus standard colonoscopy (SC) was published in 2014 by Biecker and colleagues [27]. EC utilization did not influence the cecum or the ileum intubation rates. However, it did significantly increase the total procedure time. Polyp detection rates with EC-assisted and SC were 56 % and 42 %, respectively ($p = 0.001$). EC superiority regarding polyp detection was significantly evident in the sigmoid colon and the cecum for polyps sized less than 1 cm. In the EC group, the number of adenomas per patient increased significantly by 86 % ($p = 0.002$). No major complications were reported in both groups. As the investigators state, EC use is feasible and safe and leads to significantly higher polyp detection rates, especially for lesions located in the sigmoid colon. In that way, EC may improve the efficacy of colonoscopy and reduce the incidence of colorectal cancer.

Similarly, a recently published randomized prospective multicenter trial conducted at four academic units in Germany aimed to compare the adenoma detection rates (ADR) between EC-assisted and standard colonoscopy (SC) [28]. As indicated by the results, ADR significantly increased with EC (35.4 % versus 20.7 % $p < 0.0001$). Additionally, EC identified significantly more sessile polyps. Overall procedure time and withdrawal time did not differ. Cecum and ileum intubation rates were similar. No major adverse events occurred in both groups. In multivariate analysis, age (odds ratio [OR] 1.03; 95 % [CI] 1.01–1.05), male sex (OR 1.74; 95 % CI 1.10–2.73), withdrawal time (OR 1.16; 95 % CI 1.05–1.30), procedure time (OR 1.07; 95 % CI 1.04–1.10), colon cleanliness (OR 0.60; 95 % CI 0.39–0.94), and use of EC (OR 2.09; 95 % CI 1.34–3.27) were independent predictors of adenoma detection rates. As concluded, EC increases the ADR by 14.7 % (95 % CI 6.9–22.5 %) and is safe, effective, and easy to handle. It is supposed that EC might reduce the incidence of colorectal interval cancers.

Cap-Assisted Colonoscopy

In cap-assisted colonoscopy (CAC), a transparent cap is attached to the distal tip of the colonoscope. Originally, caps were designed to assist endoscopic mucosal resections, but they can also depress colonic folds improving visualization behind them. Several studies support that CAC reduces cecal intubation time and improves

cecal intubation rates for trainees [29–32]. Its beneficial effect may also account for cases in which standard colonoscopy (SC) was initially incomplete [33, 34].

Regarding CAC additive yield in terms of polyp/adenoma detection rates (PDR/ADR), available results are conflicting. In 2007, Kondo et al. found that PDR was significantly higher in the CAC group than in the no cap group (49.3 % versus 39.1 %, $p = 0.04$) [30]. Similarly, in a randomized trial including 420 subjects, the proportion of subjects with at least one adenoma was higher with CAC compared to SC (69 % versus 56 %, $p = 0.009$). CAC also detected a higher number of adenomas per subject (2.3 versus 1.4, $p < 0.001$) [31]. Moreover, a post-hoc analysis revealed that CAC offers a higher detection rate of significant serrated polyps when compared to SC [35]. Moreover, patients undergoing initial CAC had a significantly lower miss rate for all adenomas compared with that of patients undergoing regular colonoscopy (21 % versus 33 %, $p = 0.039$), according to a randomized tandem colonoscopy study published by Hewett and Rex [36].

On the other hand, several studies demonstrated that CAC does not increase PDR and ADR and thus has no efficacy [29, 33, 37, 38]. More detailed, a bi-centric randomized trial in 2012 demonstrated that CAC does not improve ADR, but does reduce cecal intubation time and the discomfort during the procedure [29]. The same outcomes were presented by Harada and colleagues, although more prominent in the expert endoscopists than in those with moderate experience [37]. In addition, Lee et al. reported that CAC should be reserved as a rescue method when cecal intubation fails, but it did not improve the initial cecal intubation rate and had a significantly lower ADR as compared to SC [33]. Finally, no significant differences in terms of cecal intubation time and PDR between CAC and SC were found in a 2010 single-center prospective randomized study [38].

Taking the above together, a meta-analysis by Ng and colleagues aimed to evaluate CAC with regard to cecum intubation time and PDR [39]. Accordingly, PDR with CAC was marginally higher than that of SC [relative risk (RR): 1.08; 95 % confidence interval (CI): 1.00–1.17]. In contrast, ADR showed no statistically significant difference. In subgroup analyses, a short cap (≤4 mm) was associated with improved PDR, whereas a long cap (≥7 mm) was associated with a shorter cecal intubation time. To sum up, CAC demonstrated incremental benefit over SC for polyp detection and shortened cecum intubation time. During the same year, a Cochrane meta-analysis suggested that cap utilization may give a marginally faster cecal intubation time compared with SC. It also proposed that there is an increased PDR and less pain with the cap. However, the authors feel that further randomized controlled trials in this area are needed to provide more clinically significant information regarding these issues [40].

A final remark regarding the new endoscopes and devices that were presented in this chapter has to do with their cost-effectiveness: One of the basic concerns whenever some new innovation is presented, should be if it can actually affect prognosis of patients [41]. As most of these new endoscopes and devices usually help us detect mostly small adenomas, their real-life clinical impact on patients' health should be always in focus. Thus, studies regarding change of patients' management, as well as the cost-effectiveness of such changes, should be especially welcome.

Conclusion

It is well-recognized that a considerable proportion of polyps and adenomas are missed during standard colonoscopy, especially when located in "hidden" aspects of the colonic surfaces. Recent tandem colonoscopy studies report miss rates reaching 25 % and even 40 % with standard and new endoscopic technologies, respectively. As a consequence, increasing cases of interval colorectal cancers appear, raising questions regarding the efficacy of colonoscopy as a protective means.

In this setting, several technological advances have been made in order to improve visualization of the colonic mucosa and therefore enhance colonoscopy's diagnostic yield. This goal is likely to be achieved by exciting emerging innovations, either directly concerning colonoscopes or related to accessories like those presented in this chapter. Although early results demonstrate the impressive potential of many of these endoscopic facilities, generalization of their use is still not recommended. Apart from their efficacy, concerns regarding costs and training demands should be taken into account. Undoubtedly, more well-designed studies assessing these issues are warranted, aiming to achieve evidence-based use of these technologies for early diagnosis and best management of colorectal neoplasia.

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