

Endocuff[®]-assisted colonoscopy increases polyp detection rate: a simulated randomized study involving an anatomic colorectal model and 32 international endoscopists

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Abstract

Background The undetected colonic lesions behind the folds and flexures are a major factor contributing to the adenoma miss rate.

Objective To assess the efficacy of Endocuff[®], a special attachment was fixed at the distal tip of a colonoscope, for the polyp detection. This soft accessory is composed of a plastic cap surrounded by flexible finger-like projections on the lateral sides of the cap that make holding of the folds during scope withdrawal easier.

Design This was a simulated pilot study with one anatomic colorectal model, containing 13 polyps positioned in obvious locations and behind the folds. Thirty-two endoscopists (16 Japanese and 16 foreign visitors) with different levels of experience performed examinations on the model in a randomized order by using Endocuff[®]-assisted colonoscopy (EAC) and standard colonoscope (SC).

Main outcome measurements To assess the detection rate of polyps and the feasibility of $Endocuff^{(R)}$ insertion.

Results EAC detected significantly more polyps than SC with 9.9 versus 7.5 mean lesions (p = 0.03), respectively, comparing the 16 first colonoscopies in each group. Endocuff[®] was useful independent of the level of experience of the participants. After crossover, EAC in second position allowed an additional detection of 1.8 polyps compared with SC (p = 0.001). After adjustment on experience, time

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of detection, and order of colonoscopy, EAC over-detected 1.2 polyps (p = 0.0037). The insertion time (p = 0.99) was identical. There was no difference in the mean time of polyp detection between EAC and SC groups (p = 0.520). *Limitations* This was not a clinical study. The stiffness of the folds in the colonic model was higher than in the human large bowel.

Conclusion EAC was associated with a higher polyp detection rate. Even in such relatively stiff anatomic model, it was easier to spread out the colonic mucosa between the folds using this cap. This study provides an additional argument for the routine application of this easy-to-use accessory to improve polyp detection.

Keywords General endoscopy · Training endoscopy · Colorectal cancer

Colonoscopy is the gold standard for adenoma detection as it allows a reduction in the invasive colon cancer incidence [1]. Nevertheless, this technique is not perfect, and we miss a significant part of superficial neoplasia between 15 and 28 % [2–4]. There are several reasons which could explain these overlooked lesions such as quality of bowel preparation, level of sedation, and endoscopist skills, but the inability to observe all the colonic mucosa because of large colonic folds and bowel movements is probably one of the main. Techniques including cap-fitted colonoscopy and right colon retroflexion have shown their benefit to improve adenoma detection rate [5, 6]. Different accessories have also been developed to increase the colon field of view like large-angle colonoscope as Endochoice® FUSE [7] or Olympus 210° scopes [8]. Nevertheless, such dedicated scopes will be expensive, and their incorporation into routine practice will probably be slow. A simpler accessory called Endocuff[®] (Arc Medical design Ltd, Leeds,

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England) was recently developed. This is a special device attached to the tip of standard colonoscopes designed to improve the adenoma detection rate and the control of the scope. All around this attachment are several floppy fingerlike projections which allow unfolding of the colon mucosa during the withdrawal without preventing scope insertion. This distal attachment has shown its safety and its effectiveness in clinical screening [9, 10], and the aim of the present study was to confirm its polyp detection potential from the first use of this device on a colon model.

Methods

Technical details of Endocuff[®] attachment

Endocuff[®] is a Communauté Européenne-certified and Food and Drug administration-approved device for colonoscopy (Fig. 1C). It is available in four different sizes, and it is therefore compatible with most standard

colonoscopes. The flexible arms are arranged in two rows of eight and emerge from gaps in the body of the device. The arms move independently from each other in a passive way when in contact with colonic mucosa. In contrast to cap-assisted colonoscopy, the distal end of the Endocuff[®] does not extend beyond the tip of the colonoscope. The suction and the working channel of the colonoscope are not impaired by this device [9].

Anatomic colon model (Fig. 1)

A commercially available colon model (CM 15, Kyoto Kagaku co., Kyoto, Japan) dedicated for colonoscopy training was prepared. This model was already used for comparative works and for colonoscopy training [8, 11]. Different difficulty levels of insertion were available changing the fixation points of the colon. We chose the most difficult level allowing a complete shortening technique for a Japanese expert before the study. In this model, 13 pins of metals were regularly distributed from the



Fig. 1 Materials and procedure example. A Colon model. B Procedure ongoing. C Endocuff[®] attachment. D Polyp simulated by metal pins. E Endocuff[®] unfolding of the colonic wall (*orange* finger-like

projections). **F** Polyp detected between the folds thanks to Endocuff[®] projections (*orange*) (Color figure online)

cecum to the recto-sigmoid junction and simulated the polyps. These pins were round in shape and of metal color and different sizes which made it difficult to identify each individual polyp during the withdrawal. A gel was first introduced in the model to allow smooth movement of the scope. The main advantage of this model was to have very clear polyps represented by metal pins which allowed easy polyp detection as soon as the area was explored. This was intended to reduce the bias of inter-observer variation in polyp recognition even if a polyp was exposed during colonoscopy examination.

Study design (Fig. 2)

This was a simulated prospective comparative study. Each participant performed two successive back-to-back colonoscopies on the same colon model, and they were blinded with the other participants' findings. The participants never used Endocuff[®] accessory before the study. Both procedures were performed with normal colonoscope with 140° field of view (Olympus HQ-260, Tokyo, Japan) and alternatively with and without the Endocuff[®] attachment. The sequence of the colonoscopy with or without distal attachment was randomized before the procedure with envelopes. In the sequence 1, the randomization corresponded to standard colonoscopy (SC) performed first followed by Endocuff[®]-assisted colonoscopy (EAC). The opposite sequence corresponded to group 2 (EAC and then SC). Randomization was performed independently for each of the three groups of endoscopists: group A: eight Japanese staff doctors expert in colonoscopy, group B: eight Japanese residents or chief residents with moderate-to-high experience and group C: 16 non-Japanese endoscopists with different experiences who were visitors in the National Cancer center Hospital (NCCH) for at least 1 week. Finally, 16 doctors followed the sequence 1 and 16 the sequence 2 (Fig. 2). All the non-Japanese doctors were endoscopists performing routine colonoscopy currently in their own unit and visiting NCCH for a ESD-learning fellowship consecutively. For each endoscopist, experience was reported as follows: limited experience (<5 years experience and <500 colonoscopies), medium experience (between 5 and 10 years experience, and between 500 and 1000 colonoscopies), high experience (more than 10 years experience or more than 1000 colonoscopies), and expert (more than 10 years and more than 1000 colonoscopies). We also recorded age, sex, and country of origin for each participant.

Procedures

After randomization, each of the participants performed the first colonoscopy according to the randomized order. They inserted the scope to the cecum. Time of insertion (from anus to cecum) and loop formation were reported. If no loop appeared, we considered it as a success of shortening technique insertion. Participants withdrew at their usual speed describing every polyp they detected. Retroflexion was not allowed in the cecum and in the rectum since it was quite impossible on this model and can damage the colonic wall. One external observer verified the detection and counted the total number of polyps described. Precise location of the polyps was not considered because usual



landmarks like hepatic or splenic flexure were not visible in the model, and precise identification of each simulated polyp was not clear. Total time of withdrawal was also recorded and corresponds to polyp detection time. The detection time per polyp corresponds to the time of detection divided by the number of polyps detected during the withdrawal.

Then, immediately after first colonoscopy, the same participant did the second colonoscopy with or without Endocuff[®] according to the randomization and followed exactly the same sequence as previously described. Every participant was finally asked about the easiness of insertion of the EAC compared with that of SC with a semiquantitative verbal scale from 0 (very difficult) to 10 (as easy as SC) for a subjective evaluation. All the data were reported prospectively on a report form.

Outcomes

The main outcome was the polyp detection with each of the two techniques. We also assessed the easiness of the procedure with or without Endocuff[®] attachment.

Statistical analysis

Quantitative variables were described using mean, standard deviation (SD), and range. Qualitative values were tabulated, and percentages were calculated. The frequencies and the continuous variables were compared using the Fisher's test and the Student's t test when appropriate. According to the design, three different analyses were performed: First, we compared only the 32 first procedures before the crossover; second, we analyzed all 64 colonoscopies without considering the order of the procedures nor the repeated measurement structure of the study; lastly, we analyzed the data using linear mixed-effect models in order to take into account the fact that each endoscopist performed two colonoscopies. Indeed, because endoscopists have various levels of experience, colonoscopies performed by the same individual are likely to yield similar results, while colonoscopies performed by different individuals may exhibit more variability. Therefore, a correct assessment of the difference between endoscopic techniques should account for this inter-endoscopist variability by including a normal random effect at the endoscopist level. p values lower than or equal to 0.05 were considered to be statistically significant. For the comparison of three groups, we used Bonferroni's correction method when appropriate. Statistical analysis was performed with SPSS 20.0 (SPSS inc., Chicago, Illinois, USA) and R 3.1.1 (R project, 2014) when appropriate.

Results

Endoscopists

Thirty-two endoscopists were enrolled in the study from May 2014 to September 2014. Eight Japanese expert doctors (7 males, 1 female, mean age 41.5, rank 36-49, SD 4.8) who performed more than 1000 colonoscopies each composed the group A. Eight Japanese residents and chief residents (1 female, 7 males, mean age 34, rank 31-37, SD 2.1) composed the group B, and 16 non-Japanese doctors (11 males, 5 females, mean age: 37.9, rank 26-54, SD 7.7) visiting NCCH composed the group C coming from China (n = 2), France (n = 1), Hungary (n = 1), Russia (n = 4), Spain (n = 2), Taiwan (n = 2), UK (n = 2), and USA (n = 1). All group A doctors were experts with more than 10 years of experience who performed more than 1000 colonoscopies each. In the group B, endoscopic experience was distributed as follow: 0 experts (with more than 10 years and more than 1000 colonoscopies), 4 highly experienced (with more than 10 years or more than 1000 colonoscopies), 3 with medium experience (between 5 and 10 years or/and between 500 and 1000 colonoscopies), and 1 with limited experience (<5 years and <500 colonoscopies). Experience in the group C was distributed as follow: five experts, five high-experience doctors, four with medium experience, and two with limited experience.

Insertion

All of them successfully reached the cecum with and without Endocuff[®]; hence all 64 colonoscopies were completed. The mean time of cecal intubation was 131.1 s (rank 41–386, SD 82.0; Table 1). It was similar to the two groups with, respectively, 131.0 s for EAC (rank 45–378, SD 78.0) and 131.3 s (rank 41–386, SD 82.8) for SC (p = 0.99). During 64 colonoscopies, sigmoid loop was formed in three cases (4.7 %), two using Endocuff[®] (6.2 %) and one without (3.1 %) (p = 0.562). The three failures of shortening technique occurred in group C (n = 2) and group B (n = 1). According to the experience, cecal intubation was significantly shorter in the expert group than in the two other groups with 84.9 (group A, SD 38.8), 134.8 (group B, SD 77.4, p = 0.008), and 152.5 s (group C, SD 72.6, p = 0.001), respectively.

According to the difficulty evaluation, subjective score of the easiness of Endocuff insertion compared with SC insertion was in average 8.2 on a 0 (very difficult) to 10 (as easy as SC) scale (SD 2.2).

 Table 1
 Comparative results
 between EAC and SC including only the first position colonoscopy (32 colonoscopies)

	EAC	SC	Statistics, p value
Loop	2/16	1/16	0.237
Insertion time	134.2 (SD 65.5)	157.4 (SD 89.1)	0.418
Total number of polyps detected	158	120	0.003
Average polyps detected	9.9	7.5	0.003
	76.9 % (SD 2.0)	57.7 % (SD 2.1)	
Detection time	550.8 (SD 255.4)	358.4 (SD 142.4)	0.013
Detection time/polyp (seconds/polyp)	54.8 (SD 19.7)	48.8 (SD 17.3)	0.376

Detection

First colonoscopy results (Table 1; Fig. 2)

In this part, we considered only 32 first colonoscopies (16 EAC and 16 SC) before the crossover (Fig. 2, Line 1st). EAC detected more polyps than SC with 158 and 120 lesions, respectively, (p = 0.03). The average number of polyps was 9.9 (76.1 %) for EAC and 7.5 (57.7 %) for SC (p = 0.03). Time of detection was significantly longer in EAC group with 550.8 (254-1200, SD 55.4) versus 358.4 s $(165-757, SD \ 142.4) \ (p = 0.013), \text{ but per polyp detection}$ time was not significantly different with 55.8 s/polyp (EAC) versus 48.9 s/polyp (SC) (p = 0.376), respectively. The mean insertion times were not different in EAC [134.2 s (64-270, SD 65.5)] and SC groups [157.4 s (54-255, SD 89.1)] (p = 0.418).

All 64 colonoscopies results (Table 2; Fig. 2)

Totally, 309 polyps were detected by EAC versus 264 by SC with significant superiority (p = 0.02). Considering all 64 colonoscopies (Fig. 2, Lines first and second), among 13 polyps simulated, the mean number of polyps detected was 8.9 (68.5 %, rank 4-13, SD 2.4). Regardless of the Surg Endosc (2016) 30:288-295

randomized order, colonoscopy with Endocuff[®] detected significantly (p = 0.02) more polyps than SC with an average number of 9.6 polyps (73.7 %, rank 6-13, SD 2.1) versus 8.3 polyps (63.5 %, rank 4-13, SD 2.6), respectively. When EAC was performed in the second position, first SC and EAC detected an average number of 7.6 and 9.4 polyps, respectively, (p = 0.001). In other words, the mean number of new polyps detected by EAC was 1.8 (rank - 1 to 5, SD 1.9) corresponding to polyps overlooked by first SC (p = 0.001). In the opposite strategy, first EAC and second SC detected a mean number of 9.9 and 8.9, respectively, (p = 0.127). In other words, second SC detected an average 1 less polyp (range -8 to 2, SD 2.6) than the first EAC (p = 0.127). That means that the first EAC detected one more polyps than the second standard one even if the operator remembered the lesions.

Comparison of the three groups A, B, and C (Table 3)

The group of experts (group A) detected more polyps with EAC with a mean number of 9.1 (rank 7-13, SD 2.5) versus 7.8 (rank 4–12, SD 2.4) with SC (p = 0.515). In the group of Japanese residents and chief residents (group B), a respective number of 10.3 polyps were detected (rank 9-12, SD 1.3) with EAC versus 9.4 (rank 7-12, SD 2.2)

Table 2	Comparative	results	between	EAC	and	SC	including	the	64	colonoscopies
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	EAC	SC	Statistics, p value
Loop	2/32	1/32	0.562
Insertion time	131.0 (SD 78.0)	131.3 (SD 82.8)	0.986
Total number of polyps detected	309	264	0.019
Average	9.6	8.25	0.019
polyps detected	73.7 % (SD 2.1)	63.5 % (SD 2.6)	
Second colonoscopy benefit vs first one	+1.8* (SD 1.9)	-1** (SD 2.6)	p = 0.001, p = 0.127
Detection time	465.8 (SD 229.4)	431.8 (SD 214.6)	0.520
Detection time/polyp (seconds/polyp)	47.6 (SD 19.9)	53.4 (SD 24.8)	0.299

polyps detected by first colonoscopy (EAC or SC)

EAC Endocuff[®]-assisted colonoscopy, SC Standard colonoscopy, NA Not applicable

* First colonoscopy was a standard one and the second was an Endocuff assisted one

** First colonoscopy was a Endocuff assisted one and the second was a standard one

Table 3 Comparative results in each group depending on origin and experience of participants

	Group A (eight doctors)		Group B (eight do	ctors)	Group C (16 doctors)		
	EAC	SC	EAC	SC	EAC	SC	
Loop	0	0	0	1	2	0	
Insertion Time (seconds)	81.2 (SD 40.1)	88.5 (SD 39.9)	142.8 (SD 105.9)	126.8 (SD 111.2)	149.9 (SD 69.3)	155 (SD 78.0)	
Average number of polyps detected	9.1	7.8	10.3	9.4	9.6	7.9	
	70.0 % (SD 2.5)	60.0 % (SD 2.4)	79.2 % (SD 1.3)	72.3 % (SD 2.2)	73.8 % (SD 2.3)	60.8 % (SD 2.8)	
Benefit of Second colonoscopy	2	-0.8	1.25	-0.5	2.1	-1.3	
Detection time (seconds)	449.6 (SD 166.7)	417.4 (SD 180.9)	450.5 (SD 232.3)	385.4 (SD 450.5)	474.7 (SD 289.4)	451.6 (SD 266.7)	
Easiness of EAC versus SC	8.3 (SD 2.4)		8.6 (SD 3.2)		8.1 (SD 1.7)		

Easiness was evaluated by verbal scale from 0 very difficult EAC compared with SC to 10 easy as SC. Group A: Japanese experts; Group B: Japanese residents and chief residents; Group C: Foreign visitors

EAC Endocuff®-assisted colonoscopy, SC Standard colonoscopy

with SC (p = 0.114). In the non-Japanese doctors group (group C), EAC was also more effective with 9.6 polyps detected (rank 7–13, SD 2.3) versus 7.9 polyps seen (rank 4–13, SD 2.8) with SC (p = 0.392).

Considering the total number of polyps detected (both EAC and SC), no difference appeared between three groups with 8.4 (SD 2.4), 9.8 (SD 1.8), and 8.7 (SD 2.7) polyps seen for group A, B, and C, respectively (p > 0.1). Considering only EAC, group B detected more polyps than group A (p = 0.013, significant) and group C (p = 0.02, not significant according to Bonferroni's correction). No difference existed between group A and C (p = 0.478).

Time of detection during withdrawal was not significantly different (p = 0.520) between EAC and SC with 465.8 s (rank 176–1200, SD 229.4) versus 432.8 (rank 165–1080, SD 214.6), respectively. Nevertheless, the number of polyps diagnosed by EAC was higher so the mean time of detection per polyp was 47.6 s/polyp (SD 19.9) in EAC group versus 53.4 s/polyp (SD 24.8) in SC group with no significant difference (p = 0.299).

Group C composed of non-Japanese doctors spent more time (463.1 s) on detection compared with group B (417.9 s) (p = 0.022) and group A (p = 0.065) but without significant difference using Bonferroni's correction method.

Mixed-effect model analysis

This model includes a weighting of the results according to the colonoscopy order (first or second position), the group of experience (A, B, or C), and the detection time. After this weighting, the second position colonoscopy over-detected 0.47 polyps compared with first one whatever the technique used. Using this mixed-effect model, the number of polyps detected by EAC was significantly superior to SC with 9.9 and 7.5 polyps (p = 0.0015), respectively. In this model, times of detection were not significantly longer in EAC group (459.8 s) compared with SC group (425.2 s; p = 0.14). Considering the per polyp time of detection, the EAC time/polyp (53.4 s, SD 4.0) was shorter than the SC time/polyp (59.4 s, SD 7.5) without significant difference (p = 0.145).

Polyp detection and time of detection were not significantly different comparing the three groups in this mixed-effect model analysis. After taking into account the time of detection, the group of experience and the order of the procedures, it was found that EAC allowed on average the detection of 1.20 more polyps than SC (95 % CI [0.46; 1.95]; p = 0.0037).

Discussion

The main result of this study is a significant increase in number of polyps detected with EAC, with a mean number of 2.4 polyps (32 %) over-diagnosed by this method compared with SC. This result was obtained comparing only the first colonoscopies performed before the cross-over. However, the time of detection during EAC was longer than SC (p = 0.013) which could lead to a bias for the EAC polyp detection rate. Nevertheless, this difference disappeared when the detection time per polyp (p = 0.376) was included in the analysis. In fact, EAC over-detected 2.4 polyps, which may partially explain longer detection time to describe each of these polyps during the withdrawal.

In all 64 colonoscopies, EAC detected significantly more polyps than SC [73.7 % sensitivity compared with

63.5 % in SC (p = 0.002)] with similar times of detection in both groups. Moreover, when EAC was performed as a second examination, it allowed an average significant additional detection of 1.8 polyps (p = 0.001). SC performed as a second examination diagnosed 1 polyp less than first EAC, but the difference was not significant probably because operators remembered the polyps detected by first EAC and thus searched those lesions. The same result was shown in all three groups independent of the level of experience and the origin of each participant. Finally, we found similar results in the mixed-effect model analysis to confirm the higher detection rate of EAC (9.9 versus 7.5, p = 0.0015). Taking into account the inter-endoscopist variability, after adjusting for the order of the colonoscopies, the group of experience, and the time of detection, we confirmed the higher detection rate of EAC with 1.20 more polyps detected compared with SC (p = 0.0037).

This study also showed the easiness and the usefulness of Endocuff[®] irrespective of the level of experience of the doctors from beginners to experts. Experts had significantly shorter times of insertion, but the detection rates were not different. Polyp detection time was not significantly different between three groups. Shortening technique was possible in this model, and most of the physicians could insert the scope without loop formation. There was no difference in loop formation between Japanese and non-Japanese doctors. EAC did not increase the difficulty of insertion since time of insertion and loop formation was the same with or without this attachment. These results were accomplished from the start demonstrating that Endocuff[®] is "user friendly" without learning curve. The verbal evaluation of Endocuff[®] confirmed a subjective easiness of 8.2 score on a 0-10 scale where 10 was the SC difficulty.

The use of such plastic model allows an indirect study of the proportion of the examined colorectal mucosa. Since the metal pins simulated the polyps, their detection was not difficult if the area had been correctly visualized. It is likely that the detection of the polyps in this model was probably linked to the percentage of the examined colonic mucosa. Additionally, enhanced polyp detection allowed by Endocuff[®] is an indirect argument to prove that this device permits a better exploration of colonic surface by enabling us to see behind the folds. Furthermore, this model is probably stiffer than human colon reducing Endocuff[®]'s ability to unfold the colonic wall, and we can stipulate it will be even more effective in clinical practice.

Endocuff[®] is an interesting option to increase adenoma detection rate with a relatively simple and cheap technique [9, 10, 12]. Other devices have shown their benefits, for example FUSE (Endochoice, GA, USA). This dedicated scope with three cameras allows a 330° angle of view and showed a significant benefit of adenoma detection [7, 13]. Different devices like the Third Eye Retroscope (Avantis

Medical Systems, California, USA) [14, 15] or extra-wideangle Olympus[®] 210° scopes (Olympus[®] co., Tokyo, Japan) [8] can also be used to increase the detection rate. Nevertheless, those kinds of tools are expensive and not commonly used. The distal attachment like Endocuff[®] can be adapted to any conventional scope making easier its initial spreading. Another option could be the retroflexed examination of the ascending colon routinely [16] using dedicated soft pediatric colonoscope with short bending, but the risk of perforation of such procedure in general practice is not clearly known [17]. Furthermore, Endocuff[®] attachment showed its benefit in stabilizing the scope in the colon and thus making easier removal of the lesions in difficult locations [18]. Comparative studies between these different modalities should be undertaken to evaluate further benefits of such dedicated scopes compared with Endocuff[®].

The first limitation of our study is that it is not a clinical trial but a simulated study on an anatomical plastic model. Nevertheless, the polyps were always at the same location, and colon shape was the same for every participant giving it a more reproducible situation than a clinical trial. Even if all participants did not have the same experience, the use of back-to-back colonoscopies allowed every participant to be his own control in comparing EAC and SC.

The second limitation is the design with back-to-back colonoscopies but without resection of the polyps. To reduce this bias, we did the first comparison including only first 32 procedures before the crossover with a bias of participants. The second comparison included all the 64 procedures, and finally the use of mixed-effect model allowed us to adjust the results with the order of the colonoscopy and the time of detection. Both analyses showed a significant benefit of Endocuff[®] in increasing polyp detection. Additionally, design of our study allowed us to evaluate the impact of the second colonoscopy on the polyp detection rate. In this analysis, EAC performed in a second position increased significantly the detection rate. In the opposite strategy, since operators remembered the polyps seen with first EAC, the number of polyps detected by second SC was inferior to EAC but not significantly.

The third limitation was the difficulty to precisely recognize each polyp in our model, and we were not able to describe which lesions were more detected using Endocuff[®]. It would be valuable to determine the exact situations where Endocuff[®] is most useful.

Conclusion

Endocuff[®]-assisted colonoscopy (EAC) increased significantly polyp detection during withdrawal on this anatomical colon model. This increased potential was apparent from the first use of the device without previous experience. Even in this relatively stiff anatomical model with large folds, the benefits of unfolding the mucosa and inspecting between the folds were clear. This study is an additional argument for the benefits of such simple accessory to improve polyp detection.

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