

Devices to improve colon polyp detection

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, performing a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the Committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through March 2010 for articles related to endoscopy in patients with "colon polyps" by using the key words "colon polyp," "colon adenoma," and "colon neoplasm" paired with "colonoscopy," "third eye retroscope," "cap-fitted," "cap-assisted," "transparent cap," "retroflexion," "endoscope," "colonoscopy," "detection," and "wide-angle."

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BACKGROUND

Colon cancer is the second leading cause of cancer death in the United States.¹ Colonoscopy is used to

screen for colon cancer and adenomatous polyps.^{2,3} Polyp detection rates depend on the proportion of mucosal surface inspected and have been correlated with the time dedicated to inspection during colonoscopy withdrawal.⁴ A significant number of polyps are missed during colonoscopy, and in a review of studies using back-to-back colonoscopy design, the pooled miss rate for all polyps was reported to be 22% (95% CI, 19%-26%).⁵ The adenoma miss rate was 2% for lesions 10 mm or larger (95% CI, 0.3%-7.3%), 13% for lesions 5 to 10 mm (95% CI, 8%-18%) and 26% for lesions 1 to 5 mm (95% CI, 27%-35%).

To improve polyp detection rates, various devices and methods have been used.^{6,7} Nonendoscopic methods such as CT colonography and mucosal enhancement techniques including chromoendoscopy and electronic mucosal enhancement (eg, narrow-band imaging and multi-band imaging) have recently been reviewed.⁸⁻¹⁰ This review describes endoscopic technologies designed to improve colon polyp detection by increasing mucosal surface area inspection, including wide-angle lens and cap-fitted colonoscopy, and a through-the-scope retrograde viewing device.

TECHNICAL CONSIDERATIONS

The wide-angle lens colonoscopes (CF-H180AL/I and CF-Q180AL/I; Olympus Medical Systems, Center Valley, Pa) are similar in design to standard colonoscopes with the exception of a 170-degree field of view lens replacing the standard 140-degree field of view. To increase the depth of the visual field, the light aperture in the distal lens assembly is reduced, which, in turn, decreases the amount of light passing through the iris onto the charge-coupled device. Because additional light is needed to illuminate a larger field of view, the wide-angle colonoscopy incorporates 3 light bundles instead of 2. At the working tip of the endoscope, the light sources are directed slightly outward from the center axis to help illuminate this wider field of view.

Endoscopic caps are transparent, single-use attachments initially designed as mucosectomy assist devices but have been used as a means to manipulate and deflect mucosal folds allowing visualization of their proximal aspects. They are placed on the distal tip of the colonoscopy to maintain a suitable distance from the mucosa based on the instrument's depth of view. The caps come in various sizes to fit the tip diameter of different endo-

TABLE 1. Devices to improve colon polyp detection

Cap-fitted colonoscopy	Outer diameter, mm	Cap length: working distance, mm	Price
Disposable distal attachments			\$321 (package of 10)
D-201-10704	11.35	4	
D-201-11304	11.8	4	
D-201-11804	12.4	4	
D-201-12704	13.4	4	
D-201-13404	14.0	4	
D-201-14304	15.0	4	
D-201-15004	15.7	4	
Disposable distal attachments for magnification endoscopes			\$321 (package of 10)
D-201-11802	12.1	2 and 3	
D-201-12402	12.7	2 and 3	
D-201-16403	16.7	2 and 3	
Wide-angle colonoscopes (170-degree field of view)			
CF-H180AL/I	12.8		\$40,000
CF-Q180AL/I	12.8		\$36,000
Third Eye Retroscope			
Disposable catheter	3.5		\$350
Disposable colonoscope polarizing filter cap			\$25
Video processor			\$20,000

scopes (Table 1). A side hole is present on some models that allows for drainage of fluid that may accumulate within the cap during the procedure. An appropriately sized cap is attached manually to the tip of the colonoscope without lubrication and may be further secured with elastic medical tape to avoid dislodgment during the procedure. While attaching the cap, the colonoscope is held close to the distal end to minimize applying force to the bending section. If there is resistance when mounting the device, water-soluble lubricant can be used. The cap is advanced onto the tip of the colonoscope until it reaches the alignment line and rotated until the side drainage hole is adjacent to the objective lens.

The through-the-scope retrograde viewing device (Third Eye Retroscope [TER]; Avantis Medical Systems, Inc, Sunnyvale, Calif) consists of 3 parts: the retroscope, a cap with a polarizing filter, and a dedicated video processor. The retroscope contains a complementary metal oxide semiconductor camera and light-emitting diode light source on a 3.5-mm braided polyether block amide flexible catheter. This optical system provides a 135-degree

field of view of the colon. The distal tip of the TER is retroflexed 180 degrees when in its natural configuration. This distal flexed portion of the TER is manually straightened to place it through the working channel of a colonoscope. When the TER exits the working channel, it assumes its natural flexed position and provides a retrograde view of the colon. The cap contains a locking mechanism to secure the TER in the viewing position, extended 42 mm from the colonoscope tip. It also has a polarizing filter to prevent the colonoscope's light from blinding the retroscope's image. Because of differences in the configuration of their tips, each model of colonoscope requires a specific cap model. The TER and the cap are single-use devices. The video processor displays side-by-side video images of the colonoscope's forward view and the TER's retrograde view on a wide-screen monitor. Video and still images can be captured and interfaced with an electronic medical record. The system is compatible with colonoscopes with a working channel 3.7 mm in diameter or larger. A model-specific cap must be placed on the tip of the colonoscope before insertion. Washing and suctioning of the colonic

contents should be performed during colonoscopy insertion because when the TER is in place during withdrawal, there is reduced suctioning capacity. Once the cecum is reached, the retroscope is placed through the working channel of the colonoscope. On exiting the colonoscope, the tip of the TER automatically bends 180 degrees assuming a "J" shape. The device is rotated into position, allowing its lens to be cleaned by the colonoscope's auxiliary channel water jet. The TER is then withdrawn and locked in position by engaging the cap-locking mechanism. When a polyp is encountered, the TER needs to be temporarily removed to pass the polypectomy instrument through the colonoscope working channel.

INDICATIONS AND EFFICACY

Wide-angle colonoscopes are designed to increase the field of view during endoscopy and, therefore, potentially increase the examined surface area including areas immediately adjacent to the colonoscope and behind mucosal folds. An initial randomized, controlled, tandem study examined polyp detection rates with a prototype 210-degree field of view lens colonoscope.¹¹ The study was performed in 2 phases; in the first phase, 50 patients underwent back-to-back same-day colonoscopy by a single examiner with a standard and wide-angle colonoscope. Although the miss rate for polyps was higher with the standard colonoscope (31% vs 20%, $P = .046$), there was no significant difference in adenoma detection rate. A second tandem study compared polyp and adenoma detection rates by using standard and 170-degree angle of view colonoscopes.¹² There was no difference demonstrated in polyp or adenoma detection rates in 50 examined patients. A more recent randomized, controlled trial was performed in which 8 endoscopists at 2 institutions compared the 170-degree field of view colonoscope with the standard colonoscope in 710 patients.¹³ There was no difference in the adenoma detection rates.

The feasibility of cap attachments to improve polyp detection was initially evaluated in a randomized trial of 140 patients divided into 2 groups: cap-fitted colonoscopy and standard colonoscopy.¹⁴ The average number of detected lesions per patient was statistically higher in the cap-fitted colonoscopy group (0.86 ± 0.96 vs 0.58 ± 0.81 , $P < .05$). Most of the large trials evaluating cap-assisted colonoscopy were primarily designed to evaluate the success and the speed of full colonoscopy with and without a cap. In 1 randomized trial of 684 patients, 2 types of caps (2- and 4-mm length caps) were compared with standard colonoscopy.¹⁵ The polyp detection rate was significantly higher in the long-cap group compared with the no-cap group (49.3% vs 39.1%, $P = .04$). A preliminary report of a randomized, controlled trial of 2500 patients found a higher polyp detection rate in cap-fitted colonoscopy relative to the standard technique (47% vs 42.6%, $P = .03$), but there was no difference in detection of polyps larger

than 10 mm. A retractable cap device was examined in a trial of 835 patients.¹⁶ The cap was extended from the tip of the colonoscope by injection of air up to the maximum cap length of 7 mm. Cap-fitted colonoscopy found significantly more adenomas (205 vs 150, $P = .04$). Sixty patients with adenoma initially detected on standard colonoscopy without a cap were rerandomized for repeat colonoscopy in 3 months, and cap-fitted colonoscopy revealed 20% more adenomas than the initial procedure compared with 4% with a standard colonoscopy ($P = .029$). Most recently, in a randomized trial of 592 patients, there was no difference seen between polyp detection rates with and without the cap (43% vs 42.4%) including polyps 5 mm and smaller (37.9% vs 37.1%).¹⁷ In the largest published to date study, including 1000 patients randomized to cap-fitted or standard colonoscopy, there was a decreased adenoma detection rate demonstrated in the cap-fitted group (30.5% vs 37.5%, $P = .0018$).¹⁸ Two other small studies reported mixed results, 1 showing benefit of cap-fitted colonoscopy in detecting small polyps, whereas the other found no benefit.^{19,20} Taken together, the results of cap-fitted colonoscopy have been mixed, and the benefit in polyp detection appears to be marginal.

The TER system received U.S. Food and Drug Administration 510(k) clearance as a device designed to provide retrograde illumination and visualization of the colon to enhance polyp detection during colonoscopy. The TER was initially evaluated in a bench model with simulated colon polyps.²¹ Although there was no significant difference in the detection rate of simulated polyps placed in nonobscured locations, the TER demonstrated a greater detection rate for polyps placed on proximal aspect of folds compared with standard methods without the device (81% vs 12%; $P = .00001$). An additional study used CT colonography software to simulate colonoscopic examination of the mucosal surface with and without the TER.²² The simulated addition of the TER to a colonoscope with 140-degree field of view improved surface area visualization from 87% to 99%. In this simulation, a 170-degree field of view colonoscope alone examined 92% of the surface area. A pilot study of 24 patients examining the safety and efficacy of the TER demonstrated an increase in polyp detection rate by 11.8%.²³ A larger study in 288 patients of whom 249 completed the study was reported recently.²⁴ Fourteen endoscopists at 8 U.S. centers detected 257 polyps and 136 adenomas during a standard colonoscopy. Use of the TER resulted in the detection of an additional 34 polyps (a 13.2% increase) and an additional 15 adenomas (an 11% increase), both of which were statistically significant ($P < .01$). Adenoma detection increased by 4.1% in the left side of the colon and 14.9% in the right side of the colon. In 8 of the patients (3%), the only polyp found was detected by the TER. The TER improved the detection rate of polyps 6 mm or larger by 18% and polyps 10 mm or larger by 31%. The detection rate of adenomas 6 mm or larger was increased by 25% and adenomas 10 mm or

larger by 33%. Another recent open-label, prospective study of 298 patients examined polyp and adenoma detection rates and procedure times by experienced endoscopists who had not previously used the device.²⁵ Twenty-seven additional polyps were found by using the TER, resulting in a 14.8% increase in polyp detection ($P < .001$), whereas 16 additional adenomas (16%) were detected ($P < .001$). The TER increased detection of adenomas 6 mm or larger by 23% and adenomas 10 mm or larger by 19%. Preliminary results of a trial randomizing 343 subjects to same-day back-to-back colonoscopies using the TER on initial colonoscopy or the second examination revealed a net benefit of a 22% improved adenoma detection by using the TER.²⁶

EASE OF USE

The wide-angle colonoscope with 170-degree field of view was evaluated in a tandem study of 50 patients and was found to significantly reduce both insertion and withdrawal time compared with the standard colonoscope.¹² Similarly, a prototype colonoscope with the convex 210-degree angle of view lens that projects from the tip of the colonoscope resulted in a shorter withdrawal time relative to the standard colonoscope, but flat polyps were more often missed because of a fish-eye distortion in the center of the visual field. Also, frequent washing of the lens was required because of the increased protrusion of the lens from the tip of the instrument compared with the standard colonoscope. Finally, a randomized trial of the wide-angle (170-degree) versus standard colonoscope demonstrated significantly shorter withdrawal time for the wide-angle instrument, although the 30-second difference was of questionable clinical significance.¹³

Several trials have examined the impact of caps on the ability to perform colonoscopy. In early trials, cap-fitted colonoscopy did not differ from standard colonoscopy with regard to the rate of cecal and terminal ileal intubation, procedure time, or patient comfort.^{14,19,20} Several subsequent larger trials suggested cap-fitted techniques may facilitate colonoscopy completion. One trial of 684 patients included only trainees with experience in performing fewer than 1000 procedures. An experienced attending colonoscopist with more than 3000 performed procedures supervised the trainees and replaced them if the cecum was not reached within 15 minutes. Cecal intubation time was significantly shorter in the cap-fitted group, and subgroup analysis demonstrated that the overall trainee cecal intubation rate was higher in female and older patients.¹⁵ The results suggested that the 4-mm cap was useful in the angulated colon by helping to move the colon folds away and maintaining orientation by keeping distance between the lens and the mucosa. This finding was not seen with the shorter 2-mm cap. However, in another large randomized trial of 592 patients, the 2-mm cap reduced patient discomfort and shortened the cecal

intubation time, particularly for experienced endoscopists.¹⁷ Cap-fitted colonoscopy was used to repeat the procedure in 100 patients with difficult colonoscopies, defined as the inability to pass the sigmoid colon within 20 minutes or failure to reach the cecum. It was found to be a successful rescue method in 96% of examinations.²⁷ This result was also seen in the most recent randomized trial of 1000 patients in which the cecal intubation and total colonoscopy times were shorter in the cap-fitted colonoscopy group.¹⁸ In this study, cecal intubation failed in 46 patients, and they were crossed over to the alternative technique; cap-fitted colonoscopy demonstrated a higher rescue cecal intubation rate compared with standard colonoscopy (67% vs 21%, $P = .003$). Retroflexion in the rectum has been noted to be difficult with the attached cap.¹⁹ Problems created by the decreased field of view (tunnel vision) using this technique or difficulties performing polypectomy through the device have not been reported. The accumulation of debris in the instrument can be alleviated by irrigation and gentle pressing of the cap side hole against the tissue to allow drainage.

There have been reports of technical difficulties in some of the TER studies. Three patients were excluded in the TER pilot study because of colonoscope compatibility issues including the inability to pass the catheter through the colonoscope's working channel, kinking, and insufficient locking onto the cap.²³ In a recently published trial of 288 patients, 13 patients were withdrawn because of device-related reasons that were not further specified.²⁴ In another recent trial of 328 patients, a single patient was withdrawn because an incorrect cap was placed on the colonoscope.²⁵ The image quality is inferior to that of high-resolution forward-viewing colonoscopes, and a period of adjustment may be necessary to acclimate to the side-by-side viewing of images with different directional orientations. Residual glare from the colonoscope's light source was reported to be a minor distraction by 2 of 6 endoscopists in the anatomic model study.²¹ Other disadvantages are the need to remove the catheter when a polyp is encountered to insert polypectomy instruments. Also, with the device in the accessory channel, there are partial occlusion of the suction channel and an impaired ability to aspirate luminal contents. Therefore, thorough cleaning of debris during colonoscope insertion is recommended. The use of a 2-channel colonoscope could help avoid this inconvenience. There is also the potential for the loss of elasticity of the TER tip with repeated straightening of the tip if several insertions and withdrawals are required, and this may impair its ability to assume the retroflexed position. The removal of the catheter to perform polypectomy adds time to the procedure, which was 22 ± 11 minutes (range 7-47 minutes) on average in the pilot trial.²³ However, the subsequent larger trial reported improved average colonoscope withdrawal time of 10.9 minutes.²⁵ This latter trial examined endoscopists' learning curve by having each endoscopist examine 20 patients

divided in quartiles according to the order of procedures. The colonoscope withdrawal time decreased from 10.6 to 9.2 minutes between the first and fourth quartiles ($P = .044$) and total procedure time from 25.8 to 22.6 minutes ($P = .046$). When comparing the first and fourth quartiles, polyp detection rates were the same, whereas adenoma detection rates increased from 15% to 25%, although this difference did not reach statistical significance.

SAFETY

The wide-angle colonoscopes are similar in their design to standard instruments. Therefore, no additional safety issues are expected, and none have been reported in clinical trials.

Although it has been suggested that caps may facilitate colonoscope insertion, the relatively firm attachment protruding from the tip of the colonoscope has the potential to cause injury or perforation. However, none of the trials reported any adverse events with the exception of 1 fatal colonic perforation, which took place after a prolonged standard colonoscopy followed by cap-fitted colonoscopy.²⁷

There are no reported safety issues with the TER device. The catheter is flexible, and, if used as recommended during colonoscope withdrawal and advanced carefully while the tip of the colonoscope is positioned away from the mucosa, the device is unlikely to result in any tissue injury. The theoretical concern regarding the catheter becoming caught in a fold or diverticulum has not been reported. In a recently reported trial, 3 patients were withdrawn because of potential risk factors including colitis, polyposis, and severe diverticulosis.²⁵

FINANCIAL

The costs of devices to improve colon polyp detection are included in Table 1. There are no unique CPT* codes for these devices. Theoretically, extra reimbursement for the practice expense of the cap device could be negotiated with payers individually, if they could be persuaded of its value and based on invoice cost, similar to how some facilities negotiate pass-through on certain high-cost accessories. Similarly, if a payer was persuaded that the TER yield justifies its costs, per-use calculations would be a reasonable negotiating tool, and a 44799 unlisted code, intestine, might be reported with the procedure report and description of device and per-use cost attached to the claim.

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RESEARCH AGENDA

Considering the relative ease of use and low cost, large randomized trials investigating cap-fitted colonoscopy should be explored with an emphasis on comparative analysis evaluating the efficacy and cost-effectiveness with alternative techniques such as the TER. Several aspects of the TER deserve further study and refinement, including the device image quality and glare reduction. Randomized trials comparing colonoscopy with and without the TER device in tandem will be required to determine the efficacy, safety, and necessary training requirements for this novel technique. Furthermore, the cost-effectiveness of TER use will need to be explored, particularly given the putative improved diagnostic yield paired with an anticipated increase in procedure time and cost to perform colonoscopy. A randomized trial evaluating polyp detection rates with the TER and standard colonoscopy after controlling for withdrawal times, inspection techniques, and colon preparation would be useful.

SUMMARY

Based on the current data, wide-angle colonoscopy does not appear to improve polyp or adenoma detection rate. Results for cap-fitted colonoscopy related to polyp detection are mixed, but an adjunctive benefit may be facilitation of cecal intubation. The TER is a promising tool in assisting standard colonoscopy to improve visualization of colonic areas otherwise difficult to access. At this point, published experience is limited and further studies are necessary to define its utility in everyday practice.

DISCLOSURE

No financial relationships relevant to this publication were disclosed.

Abbreviation: TER, Third Eye Retroscope.

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This document is a product of the ASGE Technology Assessment

Committee. This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.