Endoscopes and devices to improve colon polyp detection

The American Society for Gastrointestinal Endoscopy (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, with a MEDLINE literature search to identify pertinent clinical studies on the topic, and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events 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 2014 for articles related to endoscopy in patients with colon polyps by using the keywords “colon polyp,” “colon adenoma,” and “colon neoplasm” paired with “colonoscopy,” “third eye retroflexion,” “cap-fitted,” “cap-assisted,” “transparent cap,” “retroflexion,” “cuff,” “endoscope,” “colonoscopy,” “detection,” “wide-angle,” and “full spectrum endoscope.”

Endoscopes and devices to improve colon polyp detection to be the best screening modality for colon cancer and adenomatous polyps by most gastroenterologists. Polyp detection rates depend on the proportion of the mucosal surface inspected and correlate with time dedicated to mucosal inspection during colonoscope withdrawal. A significant number of polyps are missed during colonoscopy, and in a review of studies that used back-to-back and/or tandem colonoscopy design, the pooled miss rate for all polyps was reported to be 22% (95% confidence interval [CI], 19%-26%). The adenoma miss rate was 2% (95% CI, 0.3%-7.3%) for lesions ≥10 mm, 13% (95% CI, 8%-18%) for lesions 5 to 10 mm, and 26% (95% CI, 27%-35%) for lesions 1 to 5 mm in size.

Some polyps may be located on the proximal aspect of colon folds and may therefore be difficult to visualize during standard colonoscopy. A simulation study that used CT colonography suggested that 13.4% of the colon surface area was not visualized during standard colonoscopy. Several devices and technologies have been developed with the objective of improving polyp detection. Non-endoscopic methods such as CT colonography and mucosal enhancement techniques (e.g., electronic chro- mocystoscopy) have been reviewed previously. This review describes endoscopes and endoscopic devices designed to improve colon polyp detection by increasing mucosal surface area visualization.

TECHNICAL CONSIDERATIONS

Endoscopes that increase mucosal visualization

Wide-angle colonoscopes. Standard colonoscopes have a 140° field of view (EC-530HL; Fujifilm Corporation, Tokyo, Japan. EC-3890K; Pentax, Montvale, NJ, USA. CF-Q160L/I/S, Olympus Medical Systems, Center Valley, Pa, USA). Colonoscopes currently manufactured by Olympus (CF-H180AL/I, CF-Q180AL/I, and CF-HQ190; Olympus Medical Systems, Center Valley, Pa) are similar in design to earlier generation colonoscopes, with the exception of having a wider 170° field of view lens. 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. 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, wide-angle

BACKGROUND

Colon cancer is the second leading cause of cancer death in the United States. Colonoscopy is widely considered

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Colonoscopes incorporate 3 light bundles instead of the standard 2 bundles. 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. The latest generation of Olympus colonoscopes (CF-HQ190) provides in the normal setting a field of view of \(170^\circ\). When “near focus” functionality is activated by a push button on the colonoscope, the field of view is \(160^\circ\).

**Colonoscopes with multiple lenses.** A new endoscopy platform (Fuse, full-spectrum endoscopy; EndoChoice, Alpharetta, Ga) incorporates 3 camera lenses that provide 3 separate images that together provide a \(330^\circ\) left-to-right field of view. This endoscope system uses light-emitting diode (LED)–based lighting, thereby freeing up space in the colonoscope shaft typically occupied by traditional light-carrying fiberoptics. This allows for the insertion of optics for the 3 cameras, without increasing the overall endoscope diameter. The dimensions and specifications of the colonoscope are otherwise similar to other standard adult colonoscopy systems. Three LED-based lights are located on the tip of the colonoscope and 2 on each side of the shaft. One lens is located at the tip of the instrument, providing the forward view, and 1 lens is positioned on each side of the shaft, near the tip of the instrument to allow side viewing images (Fig. 1, Table 1). This colonoscope requires a dedicated processor and light source and has its own image management system. The viewing station has 3 independent monitors for the forward, left-sided, and right-sided views. A gastroscopy with \(245^\circ\) field of view also is available with this system. A pediatric-size colonoscope “slimscope,” also having a \(330^\circ\) degree field of view, will soon be available (Endo-choice, Alpharetta, Ga). Magnification and image enhancement similar to narrow-band imaging (NBI, Olympus, Center Valley, Pa), i-SCAN (Pentax, Montvale, NJ), or flexible spectral Imaging Colour Enhancement (FICE, Fujifilm Corporation, Tokyo, Japan) is not currently available with the Fuse system.

An Olympus colonoscope prototype has a combination of a \(144^\circ\) to \(232^\circ\) angle lateral-backward viewing lens and a standard \(140^\circ\) angle forward viewing lens. The images from the 2 cameras are fused as a single image for viewing. The colonoscope tip is 13.9 mm in diameter and has standard working channels. The prototype is compatible with a standard 180 series Olympus processor. The Olympus prototype colonoscope is currently not marketed in the United States.

**Short turn radius colonoscope.** A Pentax colonoscope (Retroview; Pentax, Montvale, NJ) has the standard \(140^\circ\) degree field of view but has a short turn radius that facilitates easy retroflexion in the right side of the colon and potentially withdrawal through most or all of the colon in full retroflexion, thereby allowing visualization of the proximal aspects of colon folds and flexures. This is combined with a standard forward viewing withdrawal, which allows visualization of the distal aspects of colon folds and

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**TABLE 1. Colonoscopy-based systems**

<table>
<thead>
<tr>
<th>Colonoscopy systems</th>
<th>Platform</th>
<th>Field of view</th>
<th>Mechanism</th>
<th>List price of colonoscope*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wide angle</td>
<td>Olympus(^y)</td>
<td>(170^\circ)</td>
<td>Wider angle of view</td>
<td>$47,000</td>
</tr>
<tr>
<td>Fuse</td>
<td>EndoChoice(^z)</td>
<td>(330^\circ)</td>
<td>Wider angle of view</td>
<td>$56,500</td>
</tr>
<tr>
<td>Retroview</td>
<td>Pentax(^x)</td>
<td>(140^\circ)</td>
<td>Short turning radius allows retroflexed withdrawal</td>
<td>$45,000</td>
</tr>
</tbody>
</table>

*This is the list price provided by the manufacturers for the colonoscope item only. Additional system requirements are not included in this cost.

\(^y\)Olympus, Center Valley, Pa, USA.

\(^z\)Endochoice, Alpharetta, Ga, USA.

\(^x\)Pentax, Montvale, NJ, USA.

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Figure 1. A, Full spectrum endoscope (Fuse, full-spectrum endoscopy; EndoChoice, Ga) with \(330^\circ\) field of view. B, Retroview colonoscope (Pentax, Montvale, NJ) with short turn radius (bottom) compared with a slim Pentax colonoscope (middle) and adult Pentax colonoscope (top).
flexures. The maximum width of the colonoscope between the shaft and retroflexed tip in the fully deflected position is 40 mm, compared with a distance of 52 mm for a standard Pentax slim colonoscope. The colonoscope allows for a 210° tip deflection in the upward direction compared with a 180° tip deflection for the standard Pentax slim colonoscope (Fig. 1). The colonoscope is compatible with standard Pentax processors. The Retroview colonoscope is currently commercially available in the United States.

**Accessory devices**

**Transparent caps.** Endoscopic caps are transparent, single-use attachments initially designed as mucosectomy assist devices, but they also have been used as a means to manipulate and deflect colon folds, thereby allowing visualization of their proximal aspects. They are placed on the distal tip of the colonoscope to maintain a suitable distance from the mucosa, based on the instrument’s depth of view. The caps come in various sizes, designed to fit the tip diameter of different endoscopes (Table 2). A side hole is present on some cap models that allows for drainage of fluid that may accumulate within the cap during the procedure. The cap is advanced onto the tip of the colonoscope until it reaches the alignment line and is rotated until the side drainage hole is adjacent to the objective lens. The cap then may be used to deflect folds and inspect the mucosa on the proximal aspect by the use of tip deflection.

**Endocuff.** The Endocuff (Arc Medical Design Ltd, Leeds, England) is a single-use device16 composed of a soft, radiopaque, cylindrical, non-latex, biocompatible, polymer sleeve with slender flexible projections (Fig. 2B). The cylindrical cuff is approximately 23 mm long, with an approximate diameter of 17 mm when the projections are flush with the device and a maximal diameter of approximately 35 mm with the projections fully extended. It is available in 4 color-coded variations, each with specific sizes designed to fit all commonly available colonoscopes. The flexible projections are arranged circumferentially in 2 rows of 8 and emerge from linearly arranged gaps on the shaft of the device. The device slides onto the distal tip of the colonoscope shaft until it is flush with the tip of the instrument. The Endocuff may be moistened with water for easier placement. Although the device is mounted onto the colonoscope in a manner similar to that of a cap, the distal portion of the device does not extend beyond the tip of the colonoscope. The hinged projections on the device are compressed flush with the colonoscope during insertion. On withdrawal, traction on the mucosa causes the flexible projections to extend radially, which serves to manipulate the colon folds for inspection of the proximal aspects of folds. The projections may allow the colonoscope to maintain a more central position within the colon lumen. The cuff also may provide some traction to maintain colonoscope position during loop reduction, to avoid rapid slippage around turns and flexures, and to maintain colonoscope stability during instrumentation.

**EndoRings.** The EndoRings (EndoRings; Endo-Aid, Caesarea, Israel) is a single-use device17 composed of a series of 3 clear silicone discs or rings positioned sequentially on a cylindrical cuff (Fig. 2C), which slides onto the distal tip of the colonoscope. The rings are 50 mm in diameter in the extended native state and collapse to a cone-like configuration with a diameter of approximately 22 mm when deflected by mucosal traction during insertion or withdrawal. The rings are flexible and will deflect in opposite directions during colonoscope insertion and withdrawal. The proximal-most circular ring has wide fenestrations, whereas the distal rings, situated closer to the tip of the colonoscope, have narrow slits. These rings engage and mechanically stretch the mucosa and colon folds during colonoscopy. The rings also provide some traction to maintain position during loop reduction, to decrease slippage, and to maintain stability during instrumentation.

**G-Eye.** The G-Eye system (G-Eye Endoscope; Smart Medical Systems Ltd, Ra-anana, Israel) is composed of a cylindrical balloon that is integrated into the distal portion of the colonoscope shaft.18,19 An accompanying dedicated balloon inflation system (NaviAid Spark2C Inflation System; Smart Medical Systems Ltd) operated by a foot pedal allows for balloon inflation to a low, moderate, or high pressure. The balloon is in the deflated state during colonoscope insertion and can be inflated to low or moderate pressures during colonoscope withdrawal from the cecum. The inflated balloon induces the colon folds to flatten immediately downstream from the colonoscope optics, thereby improving inspection of the upstream aspect of colon folds during withdrawal. Adjusting the inflation pressure of the balloon to a higher setting may serve to stabilize the position of the endoscope tip. Safety mechanisms regulate the balloon pressure, providing compensation for changes in colon diameter, thereby avoiding excessive pressure on the colon wall.

Because the G-Eye balloon is permanently integrated into the colonoscope at the distal tip, it can undergo reprocessing and/or high-level disinfection along with the colonoscope. It is compatible with standard colonoscopy systems and may be purchased via some manufacturers of endoscopy systems or integrated into previously purchased endoscopy systems by Smart Medical Systems. This system is not yet available in the United States. Pentax Medical integrates the G-Eye system into its G-Eye HD+ line of colonoscopes, which are marketed in Europe.

**Third Eye Panoramic Device.** The original through-the-scope retrograde viewing device (Third Eye RetroScope [TER], Avantis Medical Systems, Inc, Sunnyvale, Calif) was made up of a complementary metal oxide semiconductor camera and LED light source on a 3.5-mm braided polyether block amide flexible catheter, designed to provide a retrograde view of the colon. This system did not gain widespread acceptance because of issues
including cost of the disposable TER devices, inability to suction because of the presence of the device in the colonoscope working channel, and potentially, loss of visualization of detected polyps when the device was removed to allow insertion of a polypectomy device. This device is no longer marketed.

To address some of these issues, the company has developed a Third Eye Panoramic (TEP) device camera (Avantis Medical Systems) that attaches to the distal tip of colonoscopes and provides a 330° field of view while freeing up the working channel of the colonoscope. The device has just received 510 K clearance from the FDA. This device is compatible with any standard colonoscopy system but does require purchase of a separate video processor. The TEP device is designed to be reused up to 25 times (personal communication, manufacturer). The device incorporates two side-viewing complementary metal-oxide-semiconductor (CMOS) video chips with adjacent LEDs to provide illumination. A catheter connects the camera portion to the video processor and carries the transmission wires as well as an air and/or water channel. The video monitor provides the forward view image

<table>
<thead>
<tr>
<th>Accessory device</th>
<th>Manufacturer (distributor)</th>
<th>Mechanism</th>
<th>Single vs multiple use</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cap*</td>
<td>Olympus</td>
<td>Protruding cap flattens colon folds</td>
<td>Single</td>
<td>$254.51 for a box of 10</td>
</tr>
<tr>
<td>Endocuff*</td>
<td>Arc Medical (Medivators)</td>
<td>Hinged projections flatten and spread mucosa and folds</td>
<td>Single</td>
<td>$320 for a box of 8</td>
</tr>
<tr>
<td>EndoRings</td>
<td>EndoAid</td>
<td>Sequential rings flatten and spread mucosa and folds</td>
<td>Single</td>
<td>$25-$30</td>
</tr>
<tr>
<td>G-Eye</td>
<td>Smart Medical Systems</td>
<td>Inflatable balloon flattens and spreads mucosa and folds</td>
<td>Multiple, can be reprocessed</td>
<td>Not yet available in the United States</td>
</tr>
<tr>
<td>Third Eye Panoramic</td>
<td>Avantis**</td>
<td>Accessory clip-on camera increases field of view</td>
<td>Proposed multiple use (≥ 25 times)</td>
<td>Not yet available in the United States</td>
</tr>
</tbody>
</table>

*Available in different sizes to fit specific colonoscopes.
| Olympus, Center Valley, Pa. |
| Arc Medical (Medivators) Leeds, England. |
| EndoAid, Caesarea, Israel. |
| Smart Medical Systems, Ra-anana, Israel. |
| **Avantis, Sunnyvale, Ca. |

**Figure 2.** A, Cap. B, Endocuff. C, EndoRings. D, G-Eye balloon. E, Third Eye Panoramic device.
generated by the colonoscope, with flanking images on each side from the left-sided and right-sided TEP device cameras. The image output from the device is high definition (1080 p).

INDICATIONS AND EFFICACY

Endoscope-based systems

A tandem colonoscopy study including 50 patients compared polyp miss rates by using colonoscopes with standard 140° angle of view and wide-angle 170° angle of view.\(^\text{21}\) No difference was demonstrated in polyp miss rates between the standard and wide-angle colonoscopes. A randomized, controlled trial was performed in which 8 endoscopists at 2 institutions compared the 170° field of view colonoscope with the standard colonoscope in 710 patients. No difference in adenoma detection rate (ADR) was demonstrated between the standard and wide-angle colonoscopes.\(^\text{22}\) A further trial that randomized 693 patients to colonoscopy with either a standard view colonoscope or a high-definition, wide-angle, 170° colonoscope did not demonstrate any difference in detection of polyps, adenomas, flat adenomas, or hyperplastic polyps with the two systems.\(^\text{23}\) The current data therefore suggest that wide-angle colonoscopes do not have a significant impact on improving the detection of polyps.

The Fuse colonoscope with the 330° angle view of the colon was initially studied in a pilot trial including 50 patients, which demonstrated the ability to perform colonoscopy and therapeutic maneuvers.\(^\text{24}\) A recent international, multicenter trial randomizing 197 patients to colonoscopy with either the Fuse colonoscope or a standard colonoscope initially, followed by tandem colonoscopy by using the other colonoscope, demonstrated a significantly lower adenoma miss rate in patients undergoing colonoscopy with a Fuse colonoscope compared with those undergoing standard forward viewing colonoscopy (7% vs 41%; \(P < .0001\)).\(^\text{25}\) In patients undergoing initial standard colonoscopy, missed adenomas that were subsequently detected by the tandem Fuse colonoscopy led to a shortening of the recommended post-polypectomy surveillance interval in 8 patients.

The Olympus prototype colonoscope with the combination forward and lateral and/or backward-looking lenses and the Pentax Retroview colonoscope have to date only been evaluated in colon model studies. The Olympus prototype extra wide-angle colonoscope demonstrated a higher detection rate for simulated polyps in colon models. In a study with 32 endoscopists and a colon model with both obvious and hidden simulated polyps, the mean simulated polyp detection rate was significantly higher with the prototype colonoscope than with a standard colonoscope (68% vs 51%; \(P < .0001\)).\(^\text{14}\)

Another study evaluated the performance of the Pentax Retroview colonoscope by using colon models with simulated polyps placed in both easy to visualize locations (21% of polyps) as well as in difficult to visualize locations proximal to colon folds and flexures (79% of polyps). This study demonstrated that a combination approach with withdrawal in both forward and retroflexed views was feasible and enabled a higher detection rate for all simulated polyps, compared with a standard Pentax slim colonoscope that used traditional forward-viewing withdrawal only (94% vs 32%; \(P < .0001\)).\(^\text{15}\)

Accessory devices

Data on the efficacy of cap-assisted colonoscopy in improving ADRs at colonoscopy has been mixed, with some studies indicating a minor benefit,\(^\text{26-30}\) whereas other studies have indicated no benefit.\(^\text{31-33}\) Meta-analyses of randomized, controlled studies on cap-assisted colonoscopy demonstrate only a marginal benefit of cap-assisted colonoscopy, with a relative risk of 1.08 for polyp detection (95% CI, 1.00-1.17) in an analysis of 16 randomized, controlled trials\(^\text{34}\) and an odds ratio of 1.13 (\(P = .030\)) noted in an analysis of 12 studies.\(^\text{35}\) A Cochrane systematic review also favored using cap-assisted colonoscopy for increasing polyp detection rates, although the lack of comparable data made the meta-analysis not feasible. Taken together, the results of cap-fitted colonoscopy have been mixed, and improvement in polyp detection appears to be marginal.

The initial experience with Endocuff-assisted colonoscopy in 50 patients analyzed retrospectively demonstrated a 34% ADR.\(^\text{15}\) A two-center prospective study randomized 498 patients to undergo standard or Endocuff-assisted colonoscopy. The median number of polyps detected per colonoscopy was significantly higher with Endocuff-assisted colonoscopy compared to standard colonoscopy (2.00 [IQR 1-4] vs 1.00 [IQR 1-2.25], \(P = .002\)).\(^\text{36}\) A retrospective, multicenter study published only in abstract form indicated a higher ADR in patients undergoing Endocuff-assisted colonoscopy compared with standard colonoscopy (46.6% vs 30.0%; \(P = .002\)), a higher detection rate for specifically right-sided adenomas (32.1% vs 18.3%; \(P = .004\)), and a higher average of adenomas per colonoscopy (0.8 vs 0.38; \(P = < .001\)).\(^\text{52}\)

The EndoRings have been investigated in a tandem colonoscopy study randomizing 126 patients to either initial standard colonoscopy followed by EndoRings-assisted colonoscopy or initial EndoRings-assisted colonoscopy followed by standard colonoscopy. The interim results have been reported in abstract form with 66 patients of the 126 expected enrollment. The adenoma miss rate was 15% in the initial EndoRings-assisted colonoscopy group versus 48% in the initial standard colonoscopy group (\(p < 0.01\)).\(^\text{17}\)

In a multicenter, retrospective study of 50 patients undergoing colonoscopy with the G-Eye balloon device, an ADR of 44.7% was noted.\(^\text{19}\) A prospective cohort study of 177 patients published only in abstract form indicated a
superior ADR with G-Eye-assisted colonoscopy, compared with conventional colonoscopy (37.5% vs 25.3%). In a randomized, tandem colonoscopy study published only in abstract form, the first pass ADR was 40.4% for G-Eye-assisted colonoscopy and 25.9% for standard colonoscopy, and 3 additional patients were found to have polyps on second pass with G-Eye, with no additional patients on second pass found by conventional colonoscopy.

Accessory camera devices

The ability of the previously available TER to detect polyps hidden on the proximal aspect of colon folds was initially demonstrated in a bench model by using simulated polyps and a simulation model based on CT colonography software. Several clinical studies have indicated improved polyp detection with TER-assisted colonoscopy, compared with standard colonoscopy, including a randomized, tandem-colonoscopy trial with 395 participants that indicated a 23% improved ADR associated with the TER compared with standard colonoscopy. A pilot feasibility trial enrolling 25 participants by using the next generation TER compared with standard colonoscopy and 25.9% for standard colonoscopy, including 50 patients. In the randomized trial, the cecum was not reached in 1 of 96 patients with the initial forward viewing colonoscopy and in 2 of 101 patients with the initial Fuse colonoscopy. No significant difference was noted for time to cecum for the Fuse colonoscopy compared with standard colonoscopes in the randomized trial.

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. A more recent meta-analysis of 14 studies indicated that the cecal intubation time with cap-assisted colonoscopy was shorter than that of standard colonoscopy by a mean of 48 seconds. Cap-assisted colonoscopy also may facilitate polypectomy, particularly of polyps located on the proximal aspects of colon folds and also by stabilizing the position of the colonoscope. The field of view may be restricted in cap-assisted colonoscopy, because the cap projects in front of the colonoscope lens. Potential problems created by the decreased field of view (tunnel vision) with cap-assisted colonoscopy or difficulties performing polypectomy through the device have not been reported. Retroflexion in the rectum has been noted to be more difficult with the attached cap.

In the initial experience with Endocuff, there was a 98% cecal intubation rate, with a mean cecal intubation time of 6 minutes and a 76% ileal intubation rate. Cecal intubation rates and times are therefore comparable to those observed with standard colonoscopy. The relatively low ileal intubation rate may be related to the wider diameter of the endoscope tip, which may impair easy advancement of the colonoscope through the ileocecal valve. Polypectomy may be easier because of the improved visualization and stability offered by the Endocuff. A short learning curve approximated to only 4 procedures was noted for use of the device to improve visualization of the proximal aspect of colon folds.

There have been reports of technical difficulties in some of the TER studies including inability to pass the catheter through the working channel, kinking, and insufficient locking onto the cap. As mentioned previously, based on issues of the occupancy of the working channel and position of the camera for the TER device, the next generation TEP is proposed to have an improved ease of use. The TEP device was studied in a feasibility trial of 25 patients without any noted restrictions on colonoscope mobility, tip deflection, or retroflexion.

Ease of use

Insertion times to the cecum with the 170° field of view colonoscope were comparable with those for the 140° field of view colonoscope. A 100% cecal intubation rate was noted with the Fuse colonoscope in a pilot feasibility trial including 50 patients. In the randomized trial, the cecum was not reached in 1 of 96 patients with the initial forward viewing colonoscopy and in 2 of 101 patients with the initial Fuse colonoscopy. No significant difference was noted for time to cecum for the Fuse colonoscopy compared with standard colonoscopies in the randomized trial.

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SAFETY

Studies with the Fuse colonoscope reported no serious adverse events. Minor adverse events including vomiting, cystitis, gastroenteritis, and bleeding were reported in the initial Fuse colonoscopy group, and diarrhea was reported in the initial standard colonoscopy group. 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 one fatal colon perforation, which took place after a prolonged standard colonoscopy followed by cap-fitted colonoscopy.

Superficial mucosal scratches, presumably from the slender projections, have been reported in 25% to 30% of patients undergoing Endocuff-assisted colonoscopy. There were no perforations reported with Endocuff, despite 26% of the patients in the initial experience of 50 patients having diverticulosis. No dislodgements of the device were noted.

There were no adverse events reported in the trial with EndoRings.

In the initial study with G-Eye, 2 minor adverse events were reported—abdominal pain and diarrhea. No adverse events were reported with G-Eye in the prospective cohort study or the randomized tandem colonoscopy study. There are no reported safety issues with the previously available TER device. The next generation TEP device was
studied in a feasibility trial of 25 patients, and no adverse events were reported in this small study.20

FINANCIAL CONSIDERATIONS

The costs of devices to improve colon polyp detection are shown in Table 1. There are no unique CPT1 codes for these devices. Endoscopy-based systems have no additional costs “per colonoscopy,” whereas the add-on devices will add a cost burden to each procedure. Theoretically, extra reimbursement for the practice expense of these devices could be negotiated with payers individually.

FUTURE RESEARCH

Many of these endoscopes and devices show promise in improving adenoma detection, but additional, large, randomized trials will be required to determine whether the improved ADR remains true in broader practices and whether use of these endoscopes and devices in everyday practice is cost effective and clinically warranted. More robust clinical data are needed for the Pentax Retrowview colonoscope and for devices including EndoRings, Endocuff, G-Eye, and the TEP system.

SUMMARY

Wide-angle colonoscopy does not appear to improve adenoma detection, based on the current data. The full-spectrum endoscope improves adenoma detection but requires additional study. Improvement in adenoma detection with cap-fitted colonoscopy is marginal. The Pentax Retrowview colonoscope and the next generation of accessory devices including the Endocuff, EndoRings, G-Eye balloon, and TEP demonstrate initial potential and promise but will require further evaluation in larger studies.

DISCLOSURES

V. Konda received a grant from Olympus and an honorarium from Mauna Kea Technologies. J.H. Hwang does consulting for US Endoscopy and Covidien. B. Abu Dayyab received research support from Apollo Endosurgery, Aspire Bariatrics, and C-3 Dynamic. S. Banerjee has a research grant pending from Pentax. All other authors disclosed no financial relationships relevant to this publication.

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Abbreviations: ADR, adenoma detection rate; LED, light-emitting diode; TEP, Third Eye Panoramic; TER, Third Eye Retroscope.


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