Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

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 retroscope," "cap-fitted," "cap-assisted," "transparent cap," "retroflexion," "cuff," "endoscope," "colonoscope," "detection," "wide-angle," and "full spectrum endoscope."

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BACKGROUND

Colon cancer is the second leading cause of cancer death in the United States.[1] Colonoscopy is widely considered to be the best screening modality for colon cancer and adenomatous polyps by most gastroenterologists.[2,3] Polyp detection rates depend on the proportion of the mucosal surface inspected and correlate with time dedicated to mucosal inspection during colonoscope withdrawal.[4-6] 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%).[7] The adenoma miss rate was 2% (95% CI, 0.3%-7.3%) for lesions $\geq$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.[8] Several devices and technologies have been developed with the objective of improving polyp detection.[9,10] Non-endoscopic methods such as CT colonography and mucosal enhancement techniques (eg, electronic chromoendoscopy) have been reviewed previously.[11,12] 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

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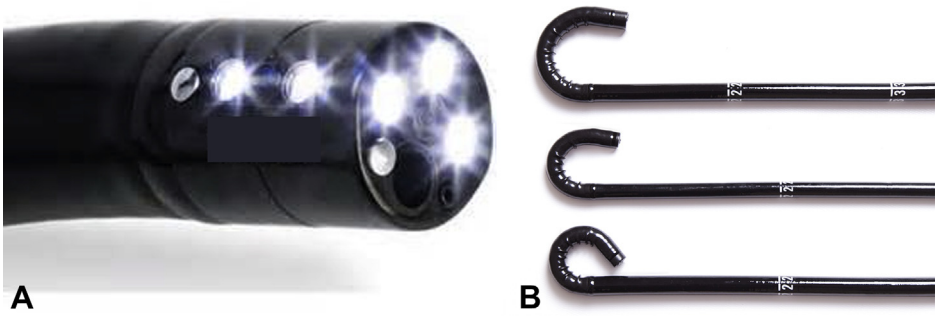

Figure 1. A, Full spectrum endoscope (Fuse, full-spectrum endoscopy; EndoChoice, Ga) with 330° field of view. **B,** Retroview colonoscope (Pentax, Montvale, NJ) with short turn radius (*bottom*) compared with a slim Pentax colonoscope (*middle*) and adult Pentax colonoscope (*top*).

TABLE 1. Colonoscope-based systems

Colonoscopy systems	Platform	Field of view	Mechanism	List price of colonoscope*
Wide angle	Olympus†	170°	Wider angle of view	$47,000
Fuse	EndoChoice‡	330°	Wider angle of view	$56,500
Retroview	Pentax§	140°	Short turning radius allows retroflexed withdrawal	$45,000

*This is the list price provided by the manufacturers for the colonoscope item only. Additional system requirements are not included in this cost.
†Olympus, Center Valley, Pa, USA.
‡Endochoice, Alpharetta, Ga, USA.
§Pentax, Montvale, NJ, USA.

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°. When "near focus" functionality is activated by a push button on the colonoscope, the field of view is 160°.

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° left-to-right field of view.[13] 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 gastroscope with 245° field of view also is available with this system. A pediatric-size colonoscope "slimscope," also having a 330-degree field of view, will soon be available (Endochoice, 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° to 232° angle lateral-backward viewing lens and a standard 140° angle forward viewing lens.[14] 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-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.[15] This is combined with a standard forward viewing withdrawal, which allows visualization of the distal aspects of colon folds and