



MEDICAL DEVICE DAILY

Digestive Disease Week *Colorectal cancer awareness driving colonoscopy advances*

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LOS ANGELES – The convergence of four separate societies all focused on treatments for alimentary tract conditions – the American Society for Gastrointestinal Endoscopy (Oak Brook, Illinois), the American Gastroenterological Association (Bethesda, Maryland), the Society for Surgery of the Alimentary Tract (Beverly, Massachusetts), and the American Association for the Study of Liver Diseases (Alexandria, Virginia) last week attracted throngs of professionals from around the world.

And they paid considerable attention to new colonoscopy systems – important, since aging “boomers,” coupled with the education of Americans by Katie Couric, TV news mega-star, on the importance of having a colonoscopy in order to prevent the second leading cause of cancer deaths, has driven the demand for colonoscopies beyond the point of capacity.

Projections from a survey of colorectal cancer screening practices by the National Cancer Institute (Bethesda, Maryland) estimate about 1.6 million screening examinations in the U.S. on an annual basis. Further analysis shows that even increasing the average number of colonoscopies per endoscopist from 21 to 32 procedures per month will not meet projected demand; thus, it is expected that substantial efficiencies must be found in the near future.

To meet this demand, several companies at DDW 2006 were exhibiting new products that advance colonoscopy speed and efficiency without compromising accuracy.

The phenomenon of looping, or a “bunching up” of the colonoscope, is inherent in conventional scopes since endoscopes are steered at the tip but have no steerability throughout the shaft, leaving the shaft able to loop back onto itself, requiring the operator to withdraw and readjust the scope. Besides eating up valuable procedure time, the forces produced by the looping produces considerable patient discomfort and thus requires sedation.

There were several new products at the meeting focused on shortening procedure time and lessening any pain to the patient, so that less sedation is needed.

Neoguide Systems (Los Gatos, California), which received its 510(k) clearance this past January, showed a newly developed, joy stick-operated handpiece, replacing the control wheels similar to most conventional scopes. This new ergonomic feature, coupled with a computerized, full-shaft scope advancement, should reduce procedure time by generating less operator fatigue, greater control and eliminate looping.

In a presentation titled, “Computer-Assisted Colonoscopy (The NeoGuide System): Results of the First Human Clinical Trial,” Jacques Van Dam, MD, of Stanford University Medical Center (Palo Alto, California), discussed the results of the first 10 human cases. He concluded that “even in difficult cases and under the operation of five different clinicians, the computer-assisted Neoguide system was able to perform colonoscopies safely and effectively, limiting loop formation.”

In an Endoscopic Technology Poster Session, he described an experiment that measured the forces transmitted to a laboratory model of a colon, comparing those using the Neoguide System with those using a conventional colonoscope. He was able to demonstrate that the forces on the colon using the computer-assisted colonoscope were significantly less than those of a conventional scope.

Smaller forces should translate into less pain, less sedation, and a quicker procedure time due to greater control of the movement of the scope and reduction in looping. USGI Medical (San Clemente, California) was showing its commercially-launched Shapelock endoscopic guide which received 510(k) clearance in 2004 for endoscopic access. And its Transport, a new multi-lumen steerable device in development for endoluminal and transluminal surgery, was cited several times in presentations on Natural Orifice Translumenal Endoscopic Surgery (NOTES).

Colonoscopies performed in U.S.	
Number of board-certified gastroenterologists in U.S.	11,044
Average number of colonoscopies per gastroenterologist per month	21
Current annual screening colonoscopies by gastroenterologists in U.S.	1.29 Million
Proportion of screening colonoscopy done by non-gastroenterologists	33%
Total number of colonoscopies performed	1.69 Million
<i>Source: Aliment Pharmacol Ther 20(5):507-515, 2004</i>	

Both devices have Shapelock capability, allowing easy advancement into the GI tract in their flexible state and then made rigid by activating the handle. In their rigid state the devices provide a stable platform through which to advance scopes and instruments. The ShapeLock guide has been shown to reduce painful looping in colonoscopy and facilitates access deep into the small bowel to areas typically unreachable by scopes alone.

GI View (Ramat Gan, Israel) demonstrated the Aer-OScope, an ultra-flexible, disposable colonoscope with what it terms a “breakthrough” propulsion and vision system.

Currently for diagnostic use only, an inflated scanning balloon self-advances the 360 degree camera up to the caecum in an average of 10 to 15 minutes. It is virtually impossible to produce looping because the cable attached to the balloon/camera is small and flexible, similar to that of a telephone cord. The self-advancement feature also allows it to be operated by less skilled personnel as well as lowering the forces commonly occurring with current methods, thus reducing pain and possibly sedation.

GI View said it expects CE marking in 2007, followed by FDA 510(k) clearance.

Spirus Medical (Stoughton, Massachusetts) has developed a spiral ridged disposable overtube which fits over a pediatric colonoscope and gently twists to advance the scope, providing easier advancement into the lumen, preventing looping and providing less patient discomfort. The company anticipates product launch soon for the lower GI tract.

Invendo Medical (Kissing, Germany) was demonstrating its computerized workstation that operates a small bending diameter colonoscope advanced through the colon using a proprietary inverted sleeve technology. Designed for single use, it has a biopsy channel for treatment and the company claims no sedation is required. It is CE-marked and commercialization is planned for 2007.

Interestingly, in the drive to advance the art of colonoscopy, many of the technologies designed to improve the procedure by eliminating looping are also the same technologies that behave well in NOTES, as is the case of Neoguide and USGI, in last week’s DDW report (*MedicalDevice Daily*, May 26, 2006).

Associated with neither colonoscopy nor NOTES, but definitely worth comment was the presence of cryoablation.

Susan Cho, MD, of St. Michael’s Hospital, University of Toronto, in a presentation titled “Endoscopic Cryotherapy for the Management of Gastric Antral Vascular Ectasia (GAVE): A Pilot Study,” described using cryotherapy as “so easy your grandmother could do it.”

Two companies with cryoablation technology were resent at the DDW meeting.

CSA Medical (Baltimore), whose debut took place here last week, has developed its Cryosprayablation (CSA) system that delivers a low pressure liquid nitrogen cryogen spray for endoscopic painting of the esophagus in order to prevent Barrett's disease, a precursor to esophageal cancer. The Polar Wand marketed by GI Supply (York, Pennsylvania) uses nitrous oxide as a compressed cryogen delivered through a catheter.

Both companies' catheters can be used with any endoscope, and both compete with

Barrx Medical (Sunnyvale, California), which was the new guy on the street last year with its 360 degree circumferential radio frequency ablation, photodynamic therapy, argon laser plasma coagulation, and conventional endoscopic mucosal resection techniques for treatment of esophageal lesions.