

The Development of Capsule Endoscopy

Introduction

Much has been written about the exciting invention less than a decade ago of the first swallowable video capsule (wireless capsule endoscope) by Gavriel Iddan, DSc, first human ingestion of the prototype by Paul Swain, MD (1), our subsequent development of the first commercially-available video capsule, the M2A® (Given Imaging, Ltd, Yokneam, Israel), and the emergence of capsule endoscopy (CE) as a first-line diagnostic tool. Prior to the invention of CE, the small intestine was endoscopy's last frontier; it could not be internally visualized directly or in entirety by any method. The introduction of CE also represented the first major technological innovation in GI diagnostic medicine since the flexible endoscope more than 30 years before. Today, the benefits of high-quality CE imaging and analysis are well-documented in hundreds of peer-review articles, abstracts and presentations (2-4) (Figure 1).

According to *Wireless Capsule Endoscopy*, "novel would correctly describe the capsule endoscope, but hardly seems adequate to characterize the brilliantly conceived and executed advance that this device represents. In a complete break with all prior endoscopes, consisting in modern times of pushed tube-shaped fiberoptic devices with a video chip at the tip, the capsule endoscopy – about the size of a vitamin pill – is simply swallowed. *Paradigm shift* is another abused term, but it may not be far off the mark in describing the change in thinking about endoscopy that has occurred as a result of the introduction of the capsule endoscope" (5).

The journey of capsule endoscopy in such a short time and its impact on healthcare has been truly amazing. Further milestone developments have been incorporated into daily use in GI clinics worldwide—including advanced software designed to improve reading efficiency (6), next-generation video capsules for the small bowel (from the initial M2A to the PillCam™ SB), esophageal capsule endoscopy (ECE) with the PillCam™ ESO (launched to market in 2004) (Figures 2 - 7), and additional capsules for visualizing the colon (Figures 8-24) and stomach are already under development and in initial clinical trials. Significant FDA clearances were received, opening doors for new applications of CE. These include the AGILE™ Patency System (May 2006) (Figure 5) which tests functional patency prior to PillCam capsule endoscopy; and for pediatric small bowel applications in children over 10 years old (FDA clearance January 2004). And there is now international data on CE for even younger children (2,7,8)

Capsule endoscopy is the technology through which we learned that the prevalence and malignancy rates for small bowel tumors (SBT) are much higher than previously reported (9,10); and that early use of CE can lead to earlier diagnoses and reduced costs, and hopefully prevent cancer (11). Special needs patients, such as those with implanted pacemakers and defibrillators, can also benefit from valuable new published data and case reports (12,13). And for both patients and physicians, the best news of all is that recent data demonstrate that capsule endoscopy findings can result in definitive diagnosis, as well as changes in patient management that lead to improved patient outcomes (3,9,14-17).

In addition to these new developments, new clinical practice models have also emerged—such as satellite/remote CE—which can expand the range of CE practices to reach more patients. Recent studies on new practice models include feasibility and cost-analysis for remote CE (18) as well as clinical results for satellite CE applications in the emergency department for imaging small bowel (19) as well as the esophagus (20), particularly for emergency screening of acute bleeding. Remote initialization for Data Recorders (Figure 6) (via standard RAPID® software from version 4.1 and up) is expected to further streamline this model, improving efficiency and cost-effectiveness. And a new handheld device, RAPID Access™ (Figure 7) that enables real-time viewing of PillCam images is currently on the path to introduction to market. With built-in remote initialization, this device can increase the flexibility of all clinical practice models. It seems that every day, CE research delves into more possibilities for different configurations responding to specific needs of GI physicians and patients.

At this time, hundreds of thousands of patients worldwide have benefited from PillCam capsule endoscopy. At Digestive Disease Week® (DDW) 2006, there were eighty-seven oral and poster presentations covering capsule endoscopy, including initial data on competitive video capsules. CE generates an ongoing flow of valuable GI studies, resulting in hundreds of peer-reviewed publications by physicians and scientists, as well as patents and intellectual properties by corporate entities and inventors. Acceptance and validation of new indications result in improved reimbursement, which, in turn, results in growing coverage of patients and advanced medical practice being delivered to more and more patients all over the globe.

Using evidence-based methodology, the American Society for Gastrointestinal Endoscopy (ASGE) provides its Guideline publications to physicians on appropriate use of endoscopic technologies. The recent Guideline "ASGE

Figure 3: PillCam™ SB video capsule for visualizing small bowel mucosa.



Figure 4: PillCam™ ESO video capsule for visualizing the esophagus mucosa.



Figure 5: AGILE™ Patency capsule which tests functional patency prior to PillCam capsule endoscopy.



Figure 6: Data Recorder device, together with standard RAPID software version 4.1 and up, enables remote initialization, which can increase the flexibility of clinical practice models including satellite/remote CE.



Figure 12: Transverse colon.



Figure 13: Transverse colon.



Figure 14: Descending colon.



Figure 15: Descending colon.

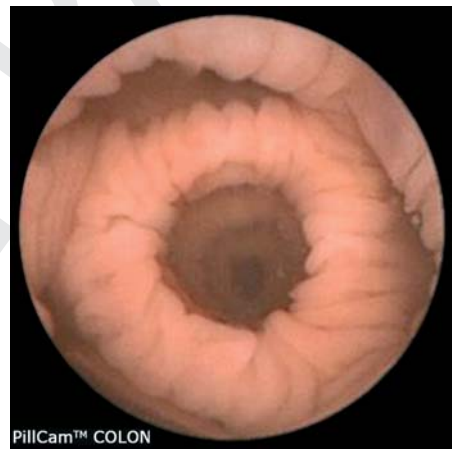


Figure 16: Rectum.



Figure 17: Rectum.

