

Comparison of a new PillCam™ SB2 video capsule versus the standard PillCam™ SB for detection of small bowel disease

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Background: Capsule endoscopy is the procedure of choice for many suspected small bowel diseases. PillCam™ small bowel (SB), has a high diagnostic yield. No improvements have been made on its optics since its introduction in 2002.

Aim: To compare the diagnostic yield and quality of visualization of PillCam™ SB with that of a new small bowel endoscope (PillCam™ SB2) which has a larger angle of view and upgraded visual attributes.

Methods: Twenty patients were randomized to undergo capsule enteroscopy with PillCam™ SB and PillCam™ SB2 a week apart.

Results: Both procedures had a comparable diagnostic yield. However images from PillCam™ SB2 were found to be significantly better in regards of homogenous light exposure ($P < 0.001$), sharpness and resolution ($P < 0.001$), depth of view ($P < 0.005$), and overall impression ($P < 0.0001$).

Conclusion: PillCam™ SB2 appears to be superior to the original PillCam™ SB in regard to quality of images obtained.

Keywords: small bowel, capsule endoscopy, image quality, resolution

Introduction

Capsule endoscopy (CE) is an important new diagnostic tool for the examination of the small bowel.^{1,2} The noninvasiveness of the procedure and sensitivity for the detection of small bowel bleeding, tumors, nonsteroidal anti-inflammatory drug-induced damage, Crohn's disease, etc, has ensured its wide acceptability. However since the commercial availability of CE in 2002 there have been no new developments in improving the performance of the capsule by Given Imaging (PillCam™ SB; Yokneam, Israel).

PillCam™ SB2 is a new video capsule which is the same size as the previous model PillCam™ SB. They differ only in certain details as listed in Table 1. PillCam™ SB2 has an angle of view of 156°, as compared to the PillCam™ SB's 140° angle of view. The wider angle of view is purported to cover more than double the visualized mucosal surface area at a working distance of 4.5 mm from the dome of the capsule (Figure 1, Table 2). The entire circumferences of the intestinal folds can be visualized and better tunnel vision is obtained (Figures 2, 3). Improved optics of the PillCam™ SB2 capsule, which includes a three-lens system, an automatic light exposure sensor and new sophisticated algorithms for processing of the digital information provided by the photo sensitive chip are purported to produce images with uniform exposure to light as observed during video play. This provides a perceived higher image resolution during review with better sharpness of the mucosal detail, as well as an increase in the depth of view. The latter is due to an algorithm on the photo sensitive chip which elongates the exposure time if the scenery is at a distance from the dome and would

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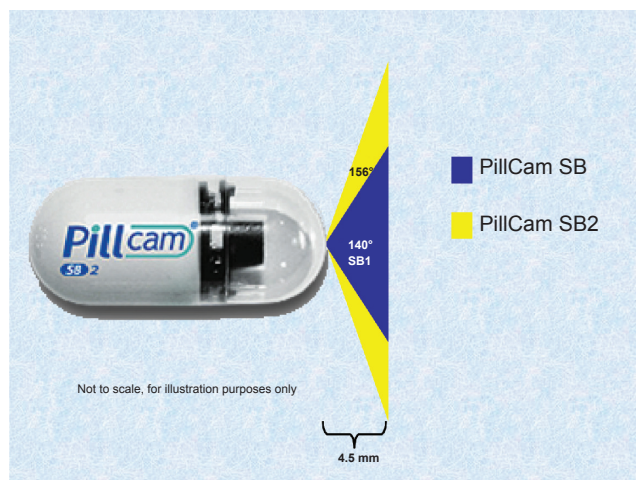
Table 1 Optical properties of PillCam™ SB versus PillCam™ SB2

SB	SB2
Single lens	Three lenses
Standard light control	Advanced automatic light control
Angle of view 140°	Angle of view 156°

otherwise appear dark. It also controls the analog gain applied to each image as a function of the exposure time. The end result is a brighter image of the regions located at a distance from the dome. This increases the effective depth-of-view visible by the capsule. The aim of this study was to assess the possible visual superiority of PillCam™ SB2 over that of PillCam™ SB in regards of diagnostic accuracy and quality of visual images.

Methods

After obtaining approval by the Internal Review Board committee of Bikur Holim Hospital, twenty-one patients requiring examination by capsule endoscopy for suspected small bowel disease were enrolled at a single hospital gastroenterology outpatient clinic. One patient was disqualified due to protocol violation. The remaining 10 male and 10 female patients underwent the studies. Their ages ranged from 10 to 86, average age 33 years. None had contraindications to PillCam™ ingestion such as dysphagia, pregnancy, clinical suspicion for small bowel obstruction or pacemaker implantation. Fourteen patients underwent the study for suspected or established inflammatory bowel disease, four patients for suspected celiac disease, and two for occult gastrointestinal bleeding.

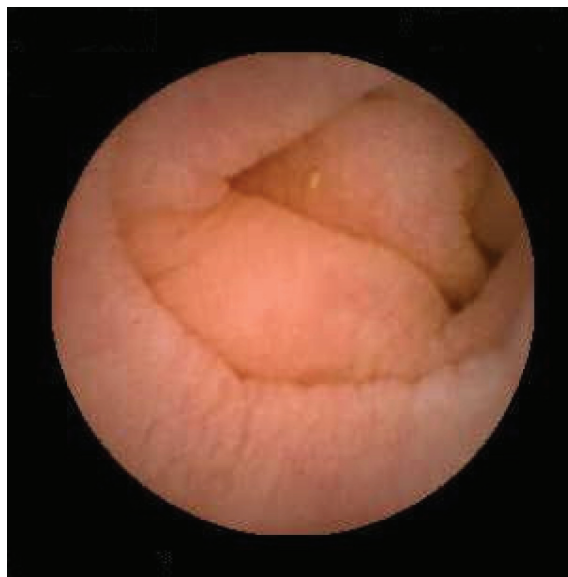
**Figure 1** Illustration of new optical features.**Table 2** Effect of wider angle of view on area covered by imaging lens at 4.5 mm from dome of capsule

PillCam™	Reference working distance (mm)	Angle of view	Coverage area [mm ²]	Coverage increase %
SB	4.5	140	500	n/a
SB2	4.5	156	1,100	120

Patients were randomized to ingest one of the two different video capsules a week apart. 45 ml of Na-P taken 12 hours prior to ingestion was used for bowel cleansing. Patients fasted for at least 12 hours prior to capsule ingestion while only ingestion of water was allowed after 6 PM prior to the ingestion. Following ingestion of the PillCam™ endoscope patients were permitted only to drink water for the next four hours at which time regular meals could be taken. The antenna array and Data 2 recorder were removed after eight hours.

All patients gave written informed consent to these studies.

The two videos were reviewed separately using a Given Workstation installed with RAPID® 5 version software. The quality of the images, findings and final diagnosis from each PillCam™ SB or SB2 capsule video were recorded and compared. 15 sets of the best pictures of gross pathology or unmistakably identical anatomical locations (ie, ulcers, flat mucosa, papilla of Vater, second part of duodenum) were

**Figure 2** Image from a Celiac patient taken by PillCam™ SB demonstrating three Kerkring folds, incomplete visualization of circumference and a partial tunnel view.

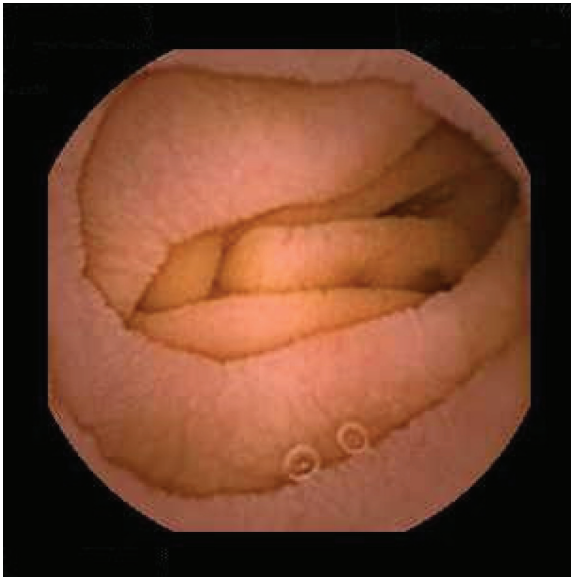


Figure 3 Same location as in Figure 2 using PillCam™ SB2 demonstrating five Kerkring folds, complete visualization of circumference of second fold and a full tunnel view. This picture is also sharper due to the improved optics.

chosen from each study. These sets of images were shown blindly and randomly for comparison to two independent viewers, who were then asked to choose the picture which was superior in reference to the following four parameters: 1) homogenous light exposure, 2) resolution and sharpness, 3) depth of view, and 4) overall assessment.

The image of the SB2 capsule is overtly different from the standard SB capsule. The picture of the SB2 capsule is always larger than the picture of standard SB capsule. In order to minimize bias, the images of the SB2 capsule were down-sized by encircling them with a black frame in which the wider view of the PillCam™ SB2 was reduced to adjust it to the size and shape of standard PillCam™ SB. This measure was to the disadvantage of PillCam™ SB2, but without these adjustments a fair comparison could not be made.

Statistics

Nonparametric signed rank test (Wilcoxon test) was performed on each tested parameter in order to compare between SB and SB2 image quality. The parameters were reviewed independently by two separate reviewers who provided a

Table 3 Illumination

Illumination	Viewer 1		Viewer 2		Total
	#SB2	%SB2	#SB2	%SB2	
	13	87%	12	80%	15
P value	<0.001		<0.001		

Table 4 Resolution

Resolution	Viewer 1		Viewer 2		Total
	#SB2	%SB2	#SB2	%SB2	
	13	87%	12	80%	15
P value	<0.001		<0.001		

score for each set of PillCam™ SB photographs, based on their impression, for the following parameters: Illumination, Resolution, Depth of view, and Overall impression.

Results

There were no significant differences ($p > 0.05$) in the diagnostic yield between the two capsules (PillCam™ SB2 58% and PillCam™ SB 53%). All diagnoses made by standard PillCam™ SB were also made by PillCam™ SB2, including five patients with Crohn’s disease, one Celiac disease, two arteriovenous malformation, and 10 normal examinations. PillCam™ SB2 showed erosive duodenitis in one patient, which standard PillCam™ SB did not and the papilla of Vater was seen more frequently (five times with PillCam™ SB2, and only once with PillCam™ SB), but there were no significant diagnostic differences between the two methods.

With reference to picture quality, the two independent readers were in strong agreement regarding all four parameters throughout the entire test set (15 paired pictures in total). Both reported either that PillCam™ SB2 image quality was superior to that of PillCam™ SB, or in some cases that neither PillCam™ provided a clear advantage regarding image quality.

Not a single case was reported in which a PillCam™ SB image scored higher than a PillCam™ SB2 image.

Based on the physicians’ assessment, Tables 3 to 6 summarize the number of cases in which image quality of PillCam™ SB2 was scored superior to that of PillCam™ SB. The statistic parameter (P value) of each event is presented. Cases not reported below represent the paired sets in which no clear advantage was reported for either SB or SB2 image. For example, with regard to illumination, the first viewer reported 13 cases of SB2 superiority; the remaining two cases were considered a draw. For the same parameter, the

Table 5 Depth of view

Depth of view	Viewer 1		Viewer 2		Total
	#SB2	%SB2	#SB2	%SB2	
	9	64%	15	100%	15
P value	<0.005		<0.001		

Table 6 Overall impression

Overall impression	Viewer 1		Viewer 2		Total
	#SB2	%SB2	#SB2	%SB2	
	15	100%	15	100%	15
P value	<0.0001		<0.0001		

second viewer reported 12 cases in which SB2 was superior, leaving three cases as a draw.

In conclusion, PillCam™ SB2 was found to be significantly better than PillCam™ SB in the following four categories: 1) homogenous light exposure in 12 or 13 out of 15 comparisons ($P < 0.001$), representative pictures are shown in Figures 4 and 5; 2) sharpness and resolution in 12 or 13 out of 15 ($P < 0.001$), representative pictures are shown in Figure 6 and 7; 3) depth of view in 9 or 14 out of 15 ($P < 0.005$); and 4) overall impression in 15 out of 15 ($P < 0.0001$).

In all cases, the P values are statistically significant.

Both PillCam™ capsules safely passed through the GI tract and were naturally excreted without causing complications or discomfort to the patients.

Discussion

This study shows that the new PillCam™ SB2 did not produce a statistically greater diagnostic yield than PillCam™ SB, although more findings were recorded with PillCam™ SB2. Nevertheless the enlarged area



Figure 5 Same area as in Figure 4, using PillCam™ SB2, demonstrating homogeneous light exposure of the image.

covered by PillCam™ SB2 and the improved optical quality parameters demonstrate that this device, with regard to visual quality of the images, is significantly more advanced.

Similar to our observation, in a comparative study, Seitz and colleagues³ noticed that the lack of an automatic light exposure element in the standard PillCam™ capsule led to compromised picture quality as compared to the Olympus EndoCapsule. The authors commented that “landscape”

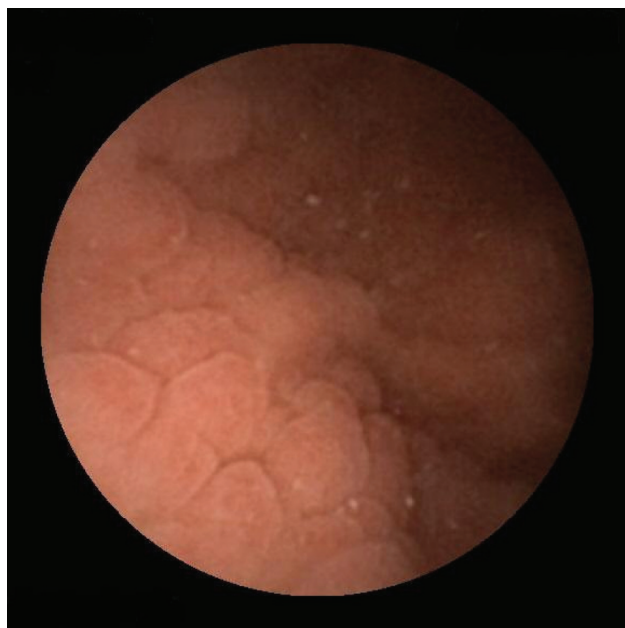


Figure 4 Gastric polyps visualized by PillCam™ SB. Nonhomogeneous light exposure, right side underexposed.

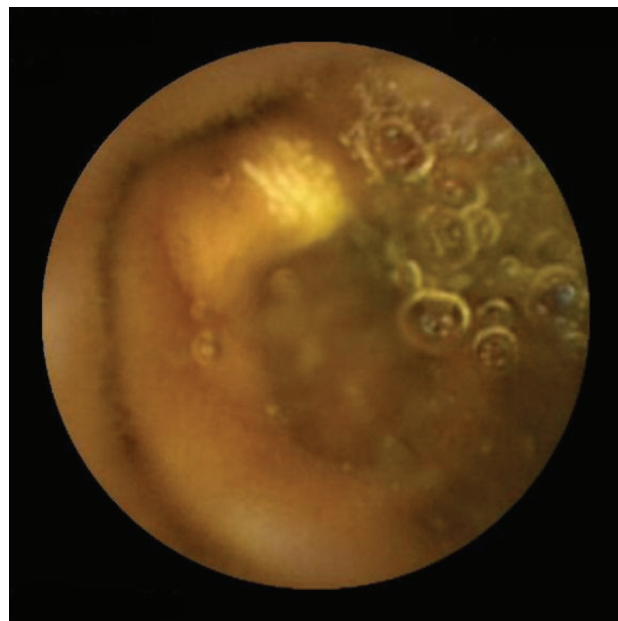


Figure 6 Lymphangiectasia depicted by PillCam™ SB. Blurry view.



Figure 7 Same location as in Figure 6, using PillCam SB2, demonstrating sharp image of lymphangiectasia and good resolution (see villi).

patterns, folds, polypoid lesions, and discoloration were good with both systems, but the lack of automatic light exposure in the PillCam™ capsule compromised the picture quality as compared to the Olympus EndoCapsule.³ As in our study neither device had a diagnostic advantage. In another comparative study Cave and colleagues⁴ examined the performance of the EndoCapsule as compared to standard PillCam™ SB in 51 patients with occult gastrointestinal

bleeding. The PillCam™ SB studies were read with the older Rapid3 version software. Again, overall image quality was judged to be superior for the Olympus EndoCapsule as measured by a Likert score, yet an improved diagnostic performance was not evident.⁴ Our findings are thus in good agreement with those of other investigators that improved quality of images does not necessarily yield better diagnostic results.

In summary, the improved optical characteristics of PillCam™ SB2 carry a diagnostic yield which is at least equal to that of the standard PillCam™ SB capsule. The overall image quality of PillCam™ SB2 is significantly superior.

Disclosure

The authors report no conflicts of interest in this work. We are indebted to Hagit Efrath for her assistance in the statistical evaluation of our results.

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