Title: Comparing Traditional Forward-Viewing Colonoscopy with "Full Spectrum Endoscopy": A Randomized, Multicenter Tandem Colonoscopy Study – The Fuse Study

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Background: Colonoscopy is the "gold standard" for detecting adenomas and colorectal cancer (CRC). Yet, a significant percentage of adenomas (upwards of 31%) can be missed using a traditional forward-viewing (TFV) colonoscope (140o to 170o maximum viewing angle). This is primarily due to inadequate visualization of the proximal aspect of colonic folds and flexures.

Aims: To determine adenoma miss rates and additional 'adenoma find rates' for TFV and Fuse colonoscopy during same-day, back-to-back tandem colonoscopy.

Methods: In a multicenter, international study (3 sites Israel, 1 site The Netherlands, 2 sites USA), subjects (ages 18-70 years) referred for CRC screening, polyp surveillance or diagnostic evaluation were randomly assigned (concealed allocation, computer-generated block design) to undergo same day back-to-back colonoscopy starting with either a TFV colonoscope (Olympus 160 or 180 series) or the FUSE colonoscope. The same endoscopist performed both examinations. The primary study endpoint was adenoma miss rates. Other endpoints included additional 'adenoma find rates', polyp miss rates, additional 'polyp find rates', time to cecal intubation, withdrawal time, total procedure time, and adverse events (AE). Per study protocol, all polyps identified by the endoscopist were removed.

Results: From January 2012 to March 2013 we enrolled 197 subjects, 12 subjects were excluded due to inability to reach the cecum, poor prep, or a protocol violation, thus n=185 subjects (101 female (54.6%) / 84 male (45.4%); mean age 55.8 ± 9.7 years) completed back-to-back tandem colonoscopies and are included for analysis. Indications for colonoscopy were: CRC screening n=103 (55.7%), polyp surveillance n=36 (19.5%), and diagnostic evaluation n=46 (24.9%).

In 88 subjects with TFV first, 28 adenomas were detected while Fuse yielded 20 additional adenomas, an adenoma miss rate of 41.7% (20/48) by TFV. In the 97 subjects undergoing FUSE first, 61 adenomas were detected, while TFV yielded 5 additional adenomas, an adenoma miss rate of 7.6% ($p<0.0001$). The incremental adenoma find rate with FUSE was 71.4% (20/28) and 5/61 (8.2%) with TFV ($p<0.0001$). Median times to cecum for TFV and FUSE were 5.1 and 4.8 min (p=NS), withdrawal times 5.6 and 6.2 min ($P<0.0001$) and procedure times 12.2 and 14.5 min ($p<0.001$), respectively. TFV found adenomas in 24 patients when used first, follow-up FUSE colonoscopy found additional adenomas in 15 of those same patients and in 5 more patients in whom no adenomas were found by TFV. FUSE found adenomas in 29 patients when used first, follow-up TFV colonoscopy found an additional adenoma in five of those same patients and in no patients in whom no adenomas were found by FUSE. The study was not powered to provide a per patient analysis of adenoma detection rates. One patient was hospitalized for colitis, while 6 minor AEs were observed (vomiting, diarrhea, cystitis, gastroenteritis, bleeding and colitis).

Conclusions - As compared to traditional forward viewing colonoscopy, we found a significantly higher adenoma miss rate for TFV compared to FUSE colonoscopy. Moreover, we observed significantly higher additional 'adenoma find rates' using FUSE colonoscopy. These results appear to demonstrate an important advancement in colonoscopy imaging technology.

1. Gralnek IM et al. Comparison of standard forward viewing mode versus ultra-wide viewing mode of a novel colonoscopy platform: a prospective, multicenter study in the detection of simulated polyps in an *in vitro* colon model. *Gastrointest Endosc 2013, in press.*

2. Gralnek IM et al. A prospective cohort study evaluating a novel colonoscopy platform featuring "full spectrum endoscopy™". *Endoscopy 2013, in press.*

Study Type:
Tandem, Randomized Comparison of Traditional Forward Viewing (TFV) Endoscope and Fuse™ Endoscope

P-Value
p<0.0001

Lead Physicians
Gralnek, Siersema, Rex

Number of Patients **185**

Results

When TFV Was Used First:

Adenomas Found by TFV Endoscopes **28**

ADDITIONAL Adenomas Found by Fuse™ **20**

Results

When Fuse™ Was Used First:

Adenomas Found by Fuse™ Endoscope **61**

ADDITIONAL Adenomas Found by TFV **5**

ENDOCHOICE®

42% **Miss Rate with TFV endoscope**

8% **Miss Rate with Fuse™ endoscope**

71% **Incremental adenoma find rate with Fuse™**

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Full Spectrum Endoscopy

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