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Study Summary

Detection of Colorectal Adenomas with Texture and Color Enhancement Imaging

A Multicenter Observational Study

Digestive Endoscopy. 2022 Nov 18. doi: 10.1111/den.14480. Sakamoto T, Ikematsu H, Tamai N, et al.

Conclusion

Our study indicates that texture and color enhancement imaging improves the detection of colorectal neoplastic lesions. However, prospective randomized trials are required to confirm these findings.

Objective

To evaluate the efficacy of texture and color enhancement imaging (TXI™ technology), which allows the acquisition of brighter images with enhanced color and surface structure in colorectal polyp detection compared to white light imaging (WLI).

Design

Retrospective cohort study (Evidence level 2b*, according to Oxford Center Evidence based Medicine (2009)).

Outcomes

Mean number of adenomas detected per procedure (MAP), adenoma detection rate (ADR), ascending colonic adenoma miss rate (Ac-AMR) and Flat Polyp Detection Rate.

Colonoscopy

- The EVIS X1™ endoscopy system was used consisting of: CV-1500 video system center, new colonoscope (CF-EZ1500DI), or conventional endoscope (CF-HQ290ECI, CF-HQ290I, CF-HQ290ZI, PCF-H290TI, PCF-H290ZI, or GIF-H290T).
- The colonoscopy was performed only in tertiary centers in Japan.

Participant Characteristics

- Patients who underwent colonoscopy with repeated ascending colon observation using TXI technology and WLI between August 2020 and January 2021 were identified in three institutions.
- A total of 1043 lesions from 470 patients were included.
- The two groups (TXI technology and WLI group) were comparable in terms of their demographic characteristics such as age and sex.

*The level is lower than an RCT and higher than a case control study/case series.

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- Indications included both screening and non-screening. The number of screening colonoscopies was smaller 58 (24.5%) in the TXI™ technology group than in the WLI group 84 (36.1%), and more colonoscopies were performed for pretreatment workups in the TXI technology group 44 (18.6%) than in the WLI group 21 (9.0%).
- Colonoscopy procedural characteristics such as withdrawal time were similar in both groups.

Results

- The MAP, ADR, and Ac-AMR in TXI technology and WLI were 1.5 (95% confidence interval 1.3-1.6) vs. 1.0 (0.9-1.1), 58.2% (51.7-64.6%) vs. 46.8% (40.2-53.4%), and 17.9% (12.1-25.2%) vs. 28.2% (20.0-37.6%), respectively. (Figure 1)
- Significant differences were observed in the multivariate regression model with MAP as the objective variable (odds ratio in lesion units) for the use of TXI technology mode (1.4; 95% CI 1.2–1.6%; $P < 0.001$), older age (1.0; 1.0–1.0%, $P < 0.001$), smoking history (1.3; 1.1–1.5%, $P = 0.010$), longer withdrawal time (1.1; 1.0–1.1%, $P < 0.001$), and the use of new endoscope (1.5; 1.2–1.9%, $P < 0.001$).
- Significant differences were observed in the multivariate regression model with ADR as the objective variable (odds ratio in case units) for the use of the TXI technology mode (1.5; 1.0–2.3%, $P = 0.044$), older age (1.0; 1.0–1.1%, $P < 0.001$), longer withdrawal time (1.1; 1.0–1.1%, $P = 0.040$), and the use of new endoscope (1.7; 1.1–2.7%, $P = 0.025$).
- No intraprocedural bleeding was observed. Bleeding occurred after endoscopic submucosal dissection in one patient (0.6%) in the WLI group. During or after the procedure, there were no perforations, cardiopulmonary complications, anaphylaxis, or other complications.

Note

- This is the first clinical study to directly compare the detection of colorectal polyps between TXI technology and WLI.
- The study has the following limitations:
  - There may have been a selection bias because this observational study retrospectively selected patients.
  - There may have been a diagnostic bias that resulted in careful observation with TXI technology, which is expected to detect more polyps since the mode used was not blinded.
  - The choice of endoscope or observation mode was left to the endoscopist's discretion, which may have affected patient selection.
  - The study was conducted only in tertiary centers in Japan and may not reflect the environment in community hospitals.

Disclaimer

This study was assessing the impact of the TXI technology which is 510(k) cleared in the United States as part of the CV-1500 video system center but utilized colonoscopes (290 and 1500 series) which are not available in the United States. There is no time established as to when or if these products will be available in these markets, including the United States. The safety and effectiveness for these products and/or the use of some of these products has not yet been established in the United States market.

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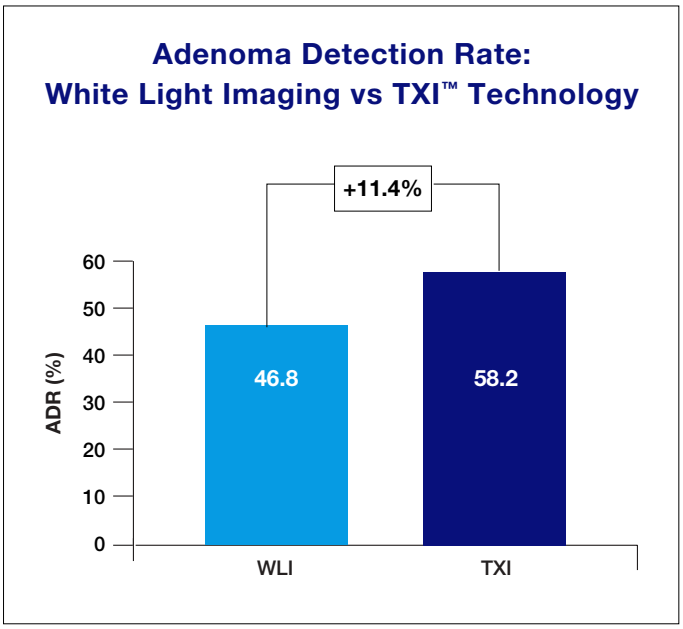
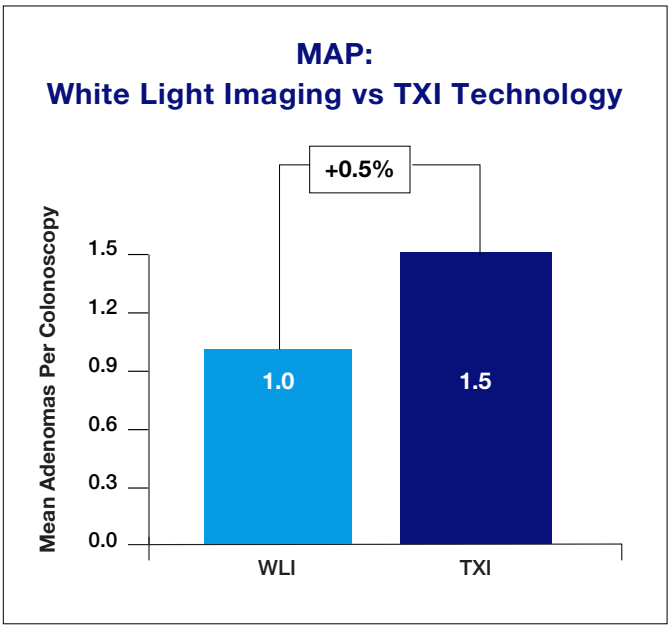
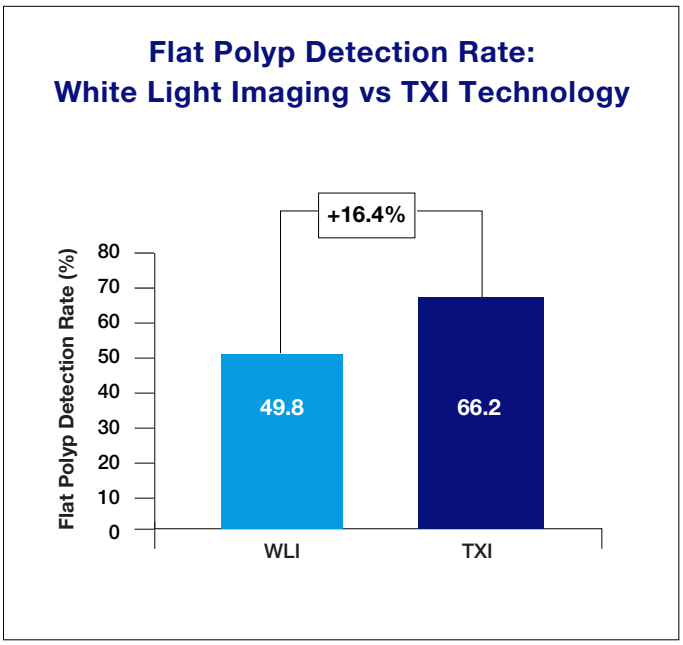
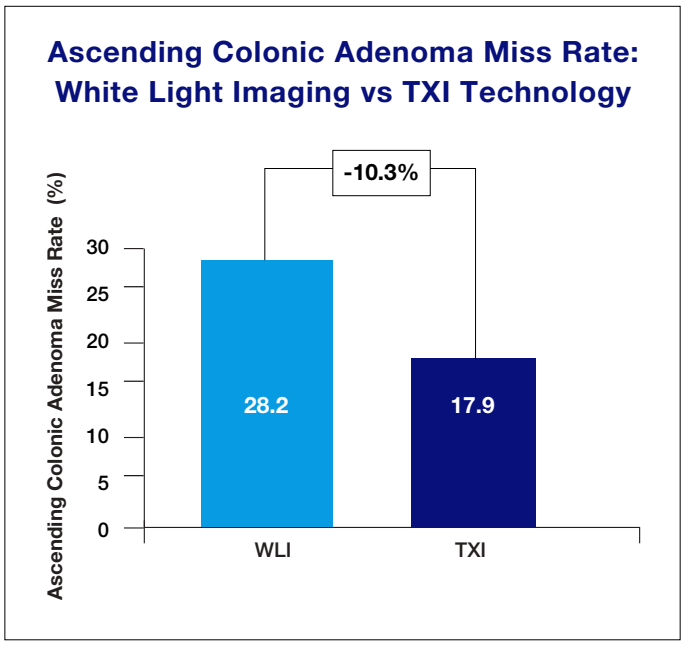
Figure 1 Outcomes









TXI technology is not intended to replace histopathological sampling as a means of diagnosis.

OLYMPUS AMERICA INC.
3500 Corporate Parkway, PO Box 610, Center Valley, PA 18034

For more information, contact your Olympus sales representative or call 800-848-9024.
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