OLYMPUS

## Study Summary

# Texture and Color Enhancing Imaging Versus High-Definition White Light Endoscopy for Detection of Colorectal Neoplasia

### A Randomized. Trial

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Antonelli G, Bevivino G, Pecere S, et al.


## Conclusion

In a randomized trial, TXI™ technology increased Adenoma Detection Rate (ADR) and Adenomas Per Colonoscopy (APC) among unselected patients undergoing colonoscopy for various indications. TXI technology increased detection of polyps <10mm in size, both in the proximal and in the distal colon, and may help to increase colonoscopy quality indicators.


## Objective

To assess the efficacy of TXI technology in detection of colorectal neoplasia.

## Design

International, multicenter randomized trial (Evidence Level 2, according to Oxford Center Evidence based Medicine (2011))

## Outcomes

ADR was significantly higher in the TXI technology group (221/375, 58.9%) versus WLI group (159/372, 42.7%; adjusted RR:1.38 [95%CI:1.20-1.59]).

## Colonoscopy

- All procedures were performed by experienced endoscopists (>2000 screening colonoscopies) in five participating centres (2 Italy, 2 Germany and 1 Japan).
- All procedures were performed with high-definition Olympus 190, 290, 1100, or 1500 series scopes with or without magnification with a CV-1500 Video Processor System Center (Olympus,Tokyo, Japan).

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### Participant Characteristics

- The target population included >40 years-old subjects undergoing colonoscopy for primary CRC screening or postpolypectomy surveillance, as well as for work-up following FIT positivity (cut-off=20 μg Hb/g faeces) or for symptoms/signs.
- Patients were excluded in case of personal history of colorectal cancer (CRC), or inflammatory bowel disease (IBD), previous colonic resection, antithrombotic therapy precluding polyp resection, or lack of informed written consent.
- The study cohort was represented by 747 (men: 50.2%, mean age 62.3 ± 9.5 years) randomized patients. Of these, 375 were allocated in the TXI technology arm, and 372 in the white light imaging (WLI) arm; no difference in clinical indications between the 2 arms was found.

### Results

- ADR was significantly higher in the TXI technology group (221/375, 58.9%) versus WLI group (159/372, 42.7%; adjusted RR:1.38 [95%CI:1.20-1.59]). This was significant both for ≤5mm (RR:1.42 [1.16-1.73]) and 6-9mm (RR:1.36 [1.01-1.83]) adenomas.
- A higher proportion of both polypoid (151/375, 40.3% vs. 104/372, 28%; RR:1.43 [1.17-1.75]) and non-polypoid adenomas (136/375, 36.3% vs. 102/372, 27.4%; RR:1.30 [1.05-1.61]) and both proximal (143/375 [38.1%] vs 111/372 [29.8%], RR, 1.28 [1.05-1.57]) and distal (144/375 [38.4%] vs 98/372 [26.3%], RR, 1.46 [1.18-1.80]) lesions were found in the TXI technology group.
- APC was higher in the TXI technology group (1.36 ±1.79 vs 0.89 ±1.35; incident rate ratio, 1.53 [1.25-1.88]).

### Note

- This RCT evaluates the detection of colorectal polyps between TXI technology and WLI.
- The study has the following limitations:
  - Both 1000 and 190/290 series endoscopes, all high-definition- and TXI technology-capable, but with differences in image quality.
  - A “new-technology bias”, where the impact of a newly introduced technology is overinflated in the first studies evaluating it.
  - The study was largely performed in an enriched-disease population since many patients were post-FIT colonoscopies among the organized screening programs, leading to an ADR of the control group that was higher than expected.

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## 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.

## Graphical Results

**Figure 1**

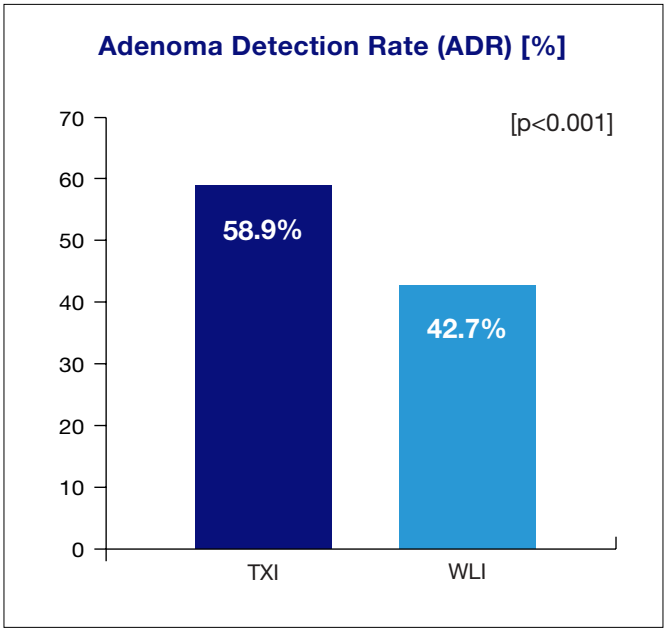
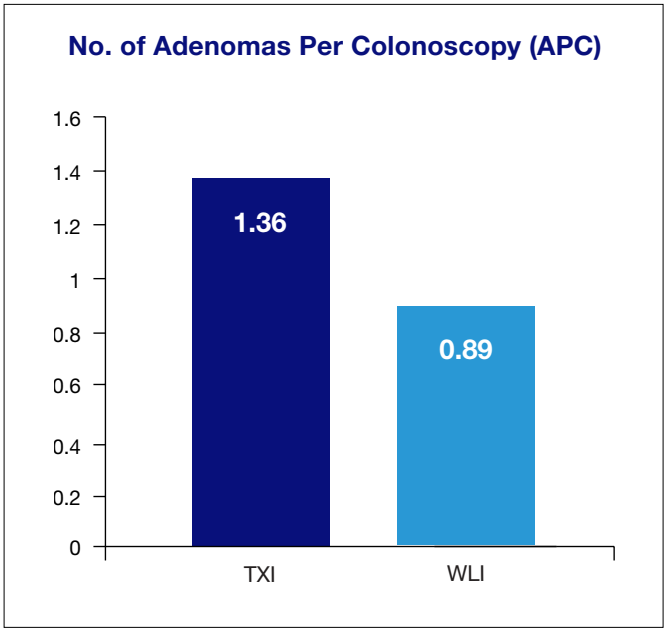



**Figure 2**




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

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

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www.medical.olympusamerica.com

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