



NOT ALL THREATS
ARE EASY TO FIND.

WITH WATS^{3D}, DETECTING
BARRETT'S ESOPHAGUS AND
DYSPLASIA CAN BE.



WATS^{3D}
AI PLATFORM

Released September, 2019

WATS^{3D} is Included in the ASGE Standards of Practice Guidelines on the Screening and Surveillance of Barrett's Esophagus (BE).

GUIDELINE CLINICAL QUESTION:

“In patients with known or suspected BE, what is the role of WATS with computer-assisted 3-dimensional analysis (WATS-3D) in increasing the rate of dysplasia detection?”

ASGE RECOMMENDATION:

“In patients with known or suspected BE, we suggest using WATS-3D in addition to WLE with Seattle protocol biopsy sampling compared with WLE with Seattle protocol biopsy sampling alone.”

Published study in
Gastrointestinal Endoscopy

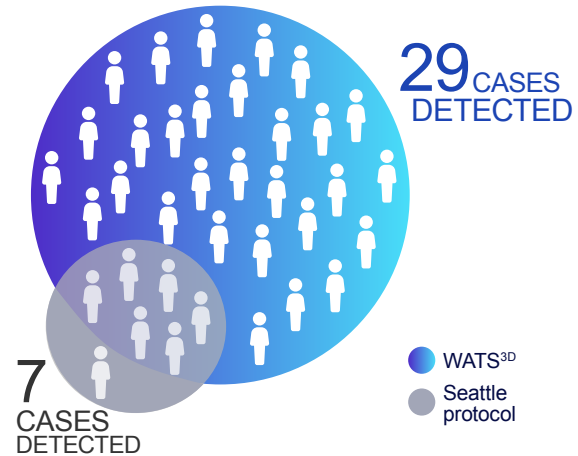
WATS^{3D} is ~4.2x more effective in detecting HGD/EAC than the Seattle protocol

STUDY DESIGN

- 16 major academic GI centers participated
- Double-blind, randomized, crossover study
- 160 high-risk patients undergoing BE surveillance
- WATS^{3D} and Seattle Protocol 4-quadrant FB every 1-2 cm

GIE STUDY RESULTS

WATS^{3D} detects more HGD/EAC



EAC=esophageal adenocarcinoma; FB=forceps biopsy; GI=gastrointestinal; HGD=high-grade dysplasia.

Vennalaganti PR, Eisen G, Falk GW, et al. Increased Detection of Barrett's Esophagus-Associated Neoplasia Using Wide Area Transepithelial Sampling in Conjunction with 4-Quadrant Forceps Biopsies: Final Results from a Multi-Center, Prospective, Randomized Trial. *Gastrointestinal Endoscopy*. <http://dx.doi.org/10.1016/j.gie.2017.07.039>

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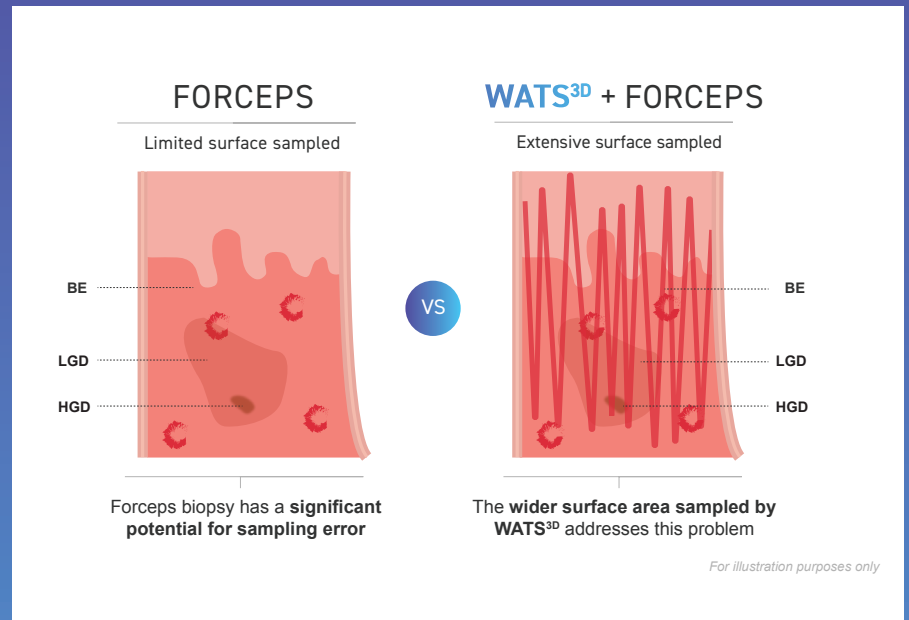
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The 3-in-1, guideline-included platform includes:

ENHANCED WIDE-AREA TISSUE SAMPLING

Finally, you can address the sampling limitations of random forceps biopsy

- Barrett's esophagus and dysplasia are often missed with 4-quadrant biopsies
- Wide area sampled by WATS^{3D} helps find abnormality located between forceps biopsy samples
- WATS^{3D} wider area sample sharply increases routine detection of Barrett's esophagus and dysplasia (see illustration)



“At the current time, endoscopists rely solely on taking small random forceps biopsies, at 1-2 cm intervals, leaving more than 96% of the endoscopically suspect area completely untested.”

— Prashanth R. Vennalaganti, MD
University of Kansas, School of Medicine,
Kansas City, KS

3D IMAGING WITH AI ANALYSIS

3D imaging yields critical diagnostic information — including the *en face* view of the gland

- If standard tissue sectioning were applied to a WATS sample, critical diagnostic information would be destroyed
- Analogous to a CAT scan, WATS^{3D} computer imaging synthesizes up to 50, 2D optical slices of each 3 micron focal plane into a single 3D image of the entire 150 micron thick specimen
- This computer synthesized WATS 3D image presents to the pathologist the *in vivo*, *en face* view of the gland — allowing for a definitive diagnosis of dysplasia in cases which may otherwise be reported as “indefinite”

How capturing the *en face* view of the gland helps to eliminate “Indefinite for Dysplasia” Reports:

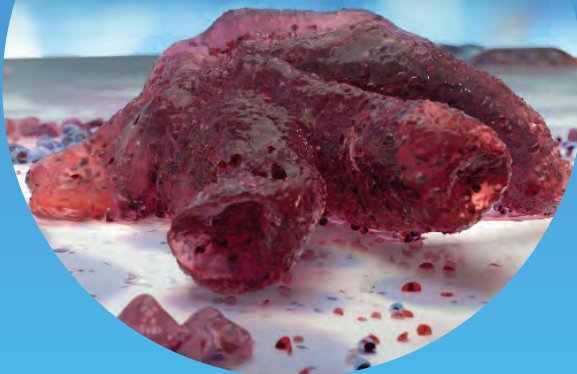


Non-dysplastic epithelium is characterized by a regular honeycomb pattern



Effacement of this honeycomb is a characteristic sign of dysplasia

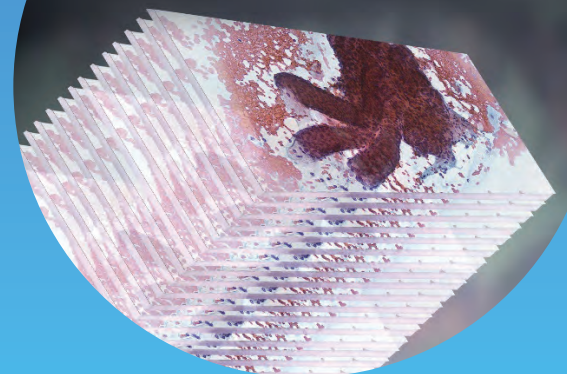
A WATS^{3D} sample is 50x thicker than a standard 3μ thick histopathology slide



“WATS^{3D} not only addresses the sampling error inherent in relying on random forceps biopsies, its three-dimensional computer-assisted analysis of the tissue sample provides the GI pathologist with diagnostic information that is not typically available using standard tissue based histopathology.”

— Robert D. Odze, MD, FRCPC

WATS^{3D} computer synthesis of 50, 2D “optical slices” forms an *in vivo* 3D image of the uncut glandular surface.



TEAM OF EXPERT PATHOLOGISTS

Computer assisted technology yields sharply higher inter-observer agreement among pathologists¹

- WATS^{3D} proprietary algorithm and neural network highlights the most suspicious areas on this computer synthesized image for consistent pathologist review

IMPROVED INTER-OBSERVER AGREEMENT WITH WATS^{3D}

Kappa values in the diagnosis of Barrett's esophagus and dysplasia

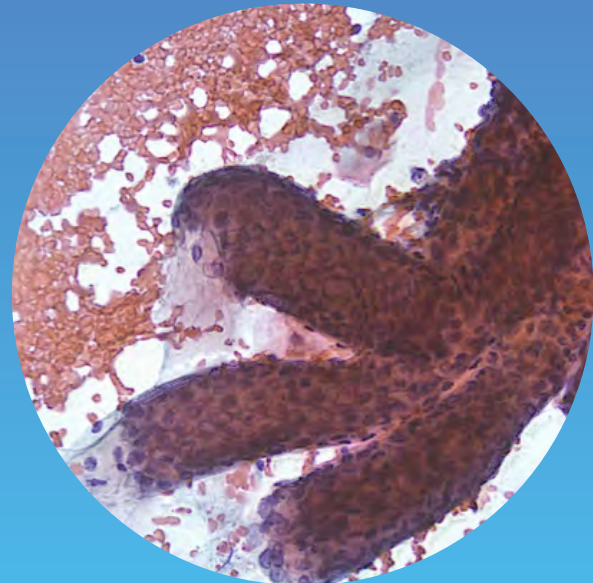
WATS^{3D} overall	.86
HGD	.95
Indefinite/LGD	.74
NDBE	.88

vs

Forceps biopsy	.30
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“These robust data demonstrate we have a tool that markedly improves our ability to detect dysplasia and cancer within Barrett’s well beyond the error-prone Seattle protocol.”

— Michael S. Smith, MD, MBA
Chief of Gastroenterology
and Hepatology,
Mount Sinai West and Mount Sinai
St. Luke’s Hospitals, NY



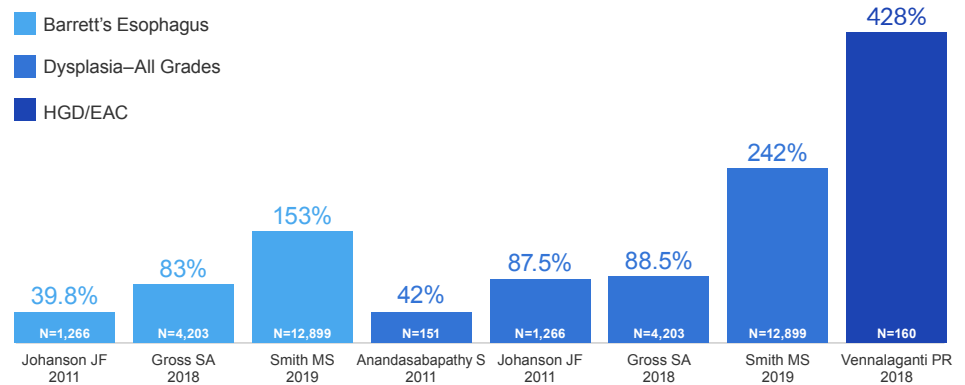
WITH POWERFUL CLINICAL EVIDENCE

WATS^{3D} increased detection of:

- Barrett's Esophagus by ~1.5x
- Dysplasia—All Grades by ~2.4x
- HGD/EAC by ~4.2x

ADDED DIAGNOSTIC YIELD OF WATS^{3D}

As an adjunct to forceps biopsy



“I see no reason why every academic and community gastroenterologist should not be using this rapidly performed, easily implemented procedure today to improve the diagnosis of Barrett's esophagus and dysplasia, so patients can be directed to appropriate endoscopic surveillance or therapy to prevent esophageal cancer.”

— Charles Lightdale, MD
Columbia University
Medical Center, New York

Overcome the Limitations of Forceps Biopsy — Start With Your Next Patient's EGD.

Call 845-777-7000 to schedule an in-person/virtual in-service consultation or visit www.WATS3D.AI for more information.



WATS^{3D}
AI PLATFORM

1. Vennalaganti PR, Kanakandi VN, Gross SA, et al. Inter-observer agreement among pathologists using wide-area transepithelial sampling with computer-assisted analysis in patients with Barrett's esophagus. *Am J Gastroenterol*. 2015;110(9):1257-1260.
2. Gross SA, Smith M, Ali R, Kaul V on behalf of US Collaborative WATS3D Study Group. Increased detection of Barrett's esophagus and esophageal dysplasia using transepithelial brush biopsy with three dimensional computer-assisted tissue analysis: a prospective multi-site community-based study. *United Eur Gastroenterol J*. 2015;3(5S):A103.
3. Ikononi EP, Bhuta R, Iorio N, et al. Transepithelial brush biopsies with computer-assisted 3-dimensional analysis markedly improve detection of Barrett's esophagus and dysplasia: interim analysis from a prospective multi-center community-based study. *Am J Gastroenterol*. 2015;110(Suppl 1):S728.
4. Johansen JF, Frakes J, Eisen D, et al. Computer-assisted analysis of abrasive transepithelial brush biopsies increases the effectiveness of esophageal screening: a multicenter prospective clinical trial by the EndoCDx Collaborative Group. *Dig Dis Sci*. 2011;56(3):767-772.
5. Vennalaganti PR, Eisen G, Falk GW, et al. Increased Detection of Barrett's Esophagus-Associated Neoplasia Using Wide Area Transepithelial Sampling in Conjunction with 4-Quadrant Forceps Biopsies: Final Results from a Multi-Center, Prospective, Randomized Trial. *Gastrointestinal Endoscopy*. <http://dx.doi.org/10.1016/j.gie.2017.07.039>.



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