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Diagnosing Esophageal Cancer More Accurately: Interview with Mark Rutenberg, CEO of CDx Diagnostics

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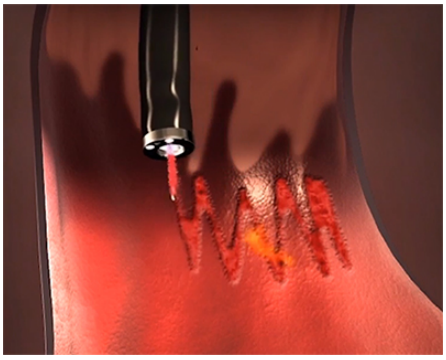


Cancer of the esophagus is often related to chronic heartburn, something patients too often end up ignoring. The onset of the potentially deadly disease can be detected, though, given good enough imaging and regular screenings. The imaging component, that we're particularly interested in, relies on physicians to take biopsies of random bits of the esophageal tissue and to then examine it under the microscope. Since precancerous cells are spread out randomly, it is very easy to miss the development of cancer.

CDx Diagnostics has developed a technology that allows physicians to take more comprehensive samples and to have them analyzed like never before. We spoke with Mark Rutenberg, the Founder and CEO of CDx Diagnostics to find out more about the company's WATS3D system that can perform volumetric scans on thick samples that come from the entire depth of the epithelium.

Medgadget: *Please describe the current diagnostic process of detecting cancer and pre-cancerous growths within the esophagus?*

Mark Rutenberg, Founder and Chief Executive Officer, CDx Diagnostics: Patients with chronic heartburn receive an upper endoscopy to search for precancerous (dysplastic) cells. If detected these precancerous cells can then be easily removed or destroyed without surgery during a follow-up endoscopy procedure known as ablation. This prevents esophageal cancer, the most rapidly growing cancer in the US, before it can actually start. This is similar to what happens when precancerous

polyps are discovered and removed during a routine colonoscopy preventing colon cancer before it can start. The problem in the esophagus is that areas that may harbor dysplastic cells are very small, highly focal, and usually invisible. In contrast to the colon in the esophagus there are no polyps or any other visible sign to tell the gastroenterologist where the precancerous cells may be located. Endoscopists use a small forceps to take random samples that end up testing less than 5% of the esophagus and as a result much precancerous disease is missed allowing esophageal cancer to develop. I have had GI's tell me that they feel like they work for the TSA but can only screen 5% of the passengers on the plane.

Medgadget: *How does WATS3D system compare to this?*

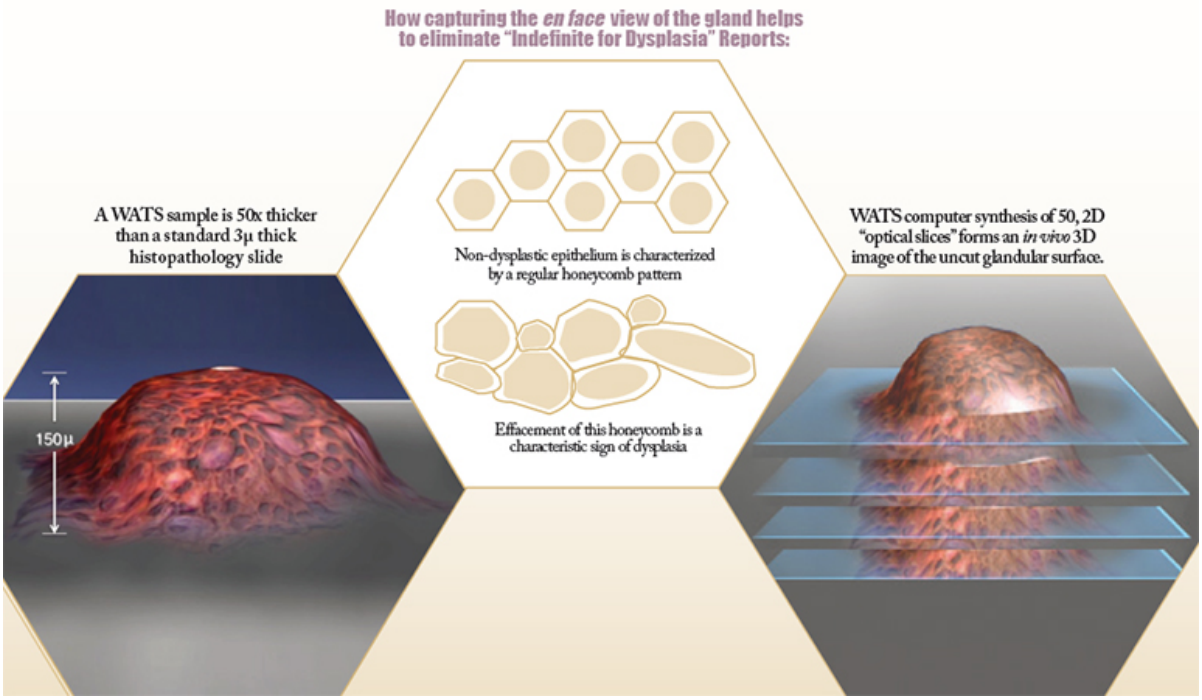
Rutenberg: WATS uses a specially designed biopsy brush to sample a much wider area of the esophagus.

Medgadget: *Why does it require a large tissue sample?*

Rutenberg: Unlike standard superficial cell sampling which works well in other body sites like the cervical Pap smear, in the esophagus and the rest of the GI tract, you need to sample the full 500 micron thickness of the epithelium in order to be able to rule out the presence of precancerous cells. This is called "transepithelial" sampling. The problem was that after taking a wide area transepithelial sample (this is what "WAT"S stands for) the sample deposited on the microscope is 50X thicker than a standard forceps biopsy slice and cannot be evaluated by a standard 2D microscope. That is why we invested over $80M to develop the WATS3D imaging system used by laboratories that evaluate WATS specimens.

Medgadget: *Can a pathologist examine individual cells in 3D?*

Rutenberg: Using the WATS3D system, yes.



***Medgadget**: What is the specificity and sensitivity of your testing?*

Rutenberg: The specificity is close to 100% because the images provided by the WATS3D system are probative, i.e. they can be confirmed by any pathologist using standard diagnostic criteria. Sensitivity is unknown because even with WATS the entire esophagus is not tested. Therefore the metric used is "added detection yield", i.e. how much more disease detection is added by adding WATS to standard random forceps biopsy. The answer is 250% for low grade dysplasia and 450% for the most dangerous but mist difficult to find high grade dysplasia.

***Medgadget**: How did you teach the system what a suspicious cell looks like?*

Rutenberg: We trained a neural network with thousands of examples of normal and abnormal cells.

***Medgadget**: Does the system improve its ability to detect potentially diseased cells?*

Rutenberg: Yes, using periodic neural network training updates.

***Medgadget**: What is the regulatory status of your services?*

Rutenberg: The WATS biopsy brush is distributed under a 510K clearance. Use of the 3D analysis system is regulated as a laboratory procedure.