



## CASE STUDY: VLE for Pre-Treatment Planning

### PATIENT HISTORY

A 68 year old male being treated for short segment (1cm) Barrett's Esophagus (BE). During a prior exam, combination therapy for recurring non-dysplastic BE by Endoscopic Mucosal Resection (EMR) and Radiofrequency Ablation (RFA) was conducted. The intent for this procedure was to assess the treatment area, in part, using the NvisionVLE Imaging System, and to ablate any recurrence of disease.

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### PROCEDURE

#### ENDOSCOPIC EXAM

The EGD showed what appeared to be a very mild recurrence of intestinal metaplasia (IM) with approximately 1cm of BE islands scattered about the gastro-esophageal junction (GEJ): 40-39cm from incisors.

#### VLE

##### Volumetric Laser Endomicroscopy

- . A fiducial cautery mark was placed at the GEJ as a landmark to aid in the registration of the VLE image (Figure 1). Using the NvisionVLE Imaging System, the VLE scan was conducted and captured approximately 1cm below the top of the gastric folds, as well as about 5cm of the esophagus.
- . The BE islands could be seen in the VLE scan by virtue of correlative abnormal tissue. Additionally, 1cm distal to the GEJ, the VLE identified an area of glandular atypia with an irregular surface architecture that could not be appreciated under endoscopy. (Figures 2 and 3)
- . Biopsies were taken from the VLE-targeted areas.

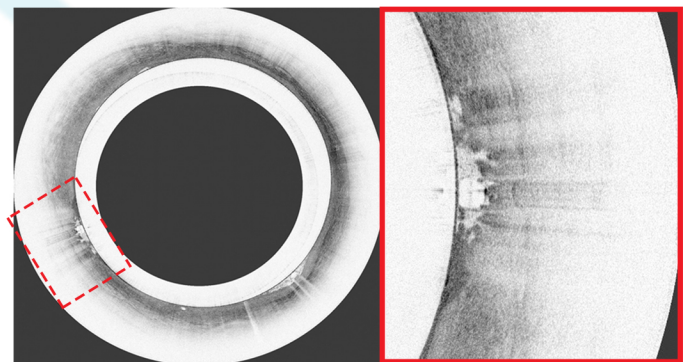


Figure 1: VLE image of the fiducial cautery mark

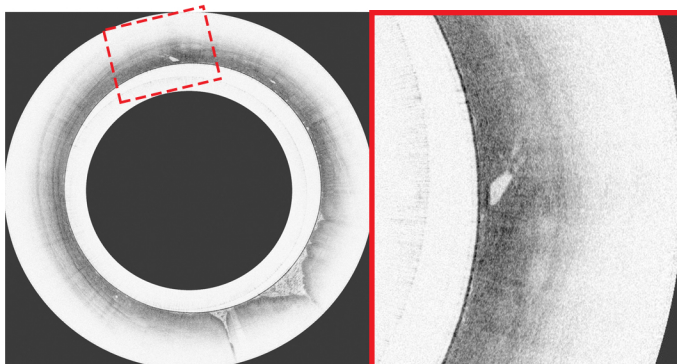


Figure 2: VLE image 1cm distal to the GEJ of glandular atypia and irregular surface architecture

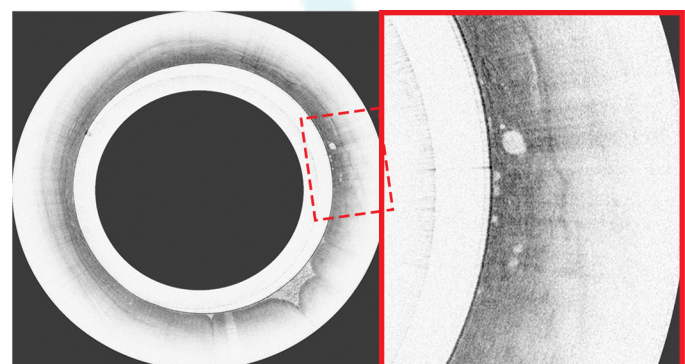


Figure 3: VLE image 1cm distal to the GEJ of glandular atypia and irregular surface architecture

## RESULTS

Biopsies taken from the VLE-targeted areas that were identified using Advanced OCT and sent for pathology came back **positive for focal High Grade Dysplasia (HGD)**.

## DISCUSSION

The intent of this procedure was to assess the prior treatment within the visibly diseased area, 1cm proximal to the GEJ. However, the NvisionVLE Imaging System uncovered areas of abnormality that were outside of the expected, and visibly diseased, region. This sub-squamous perspective identified these very suspicious regions that were sampled and pathologically confirmed to be focal HGD. This obviously had a dramatic and clinically important effect on the treatment algorithm for the patient. Although continued studies will be required to prove the broader impact of Advanced OCT in the management of Barrett's dysplasia, its impact on this particular patient is undeniable.



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*The NvisionVLE Imaging System is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization. The safety and effectiveness of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.*