NinePoint MEDICAL

VLE IMAGE ATLAS

VLE-TO-HISTOPATHOLOGY IMAGE CORRELATIONS

NINEPOINT MEDICAL DEVELOPS OPTICAL TECHNOLOGIES THAT PRODUCE HIGH-RESOLUTION, VOLUMETRIC IMAGES AT AND BELOW THE MUCOSAL SURFACE.

NvisionVLE® Imaging System
with Real-time Targeting™

INDICATIONS FOR USE

The NvisionVLE® Imaging System with Real-time Targeting™ 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, and may be used to mark areas of tissue.

The NvisionVLE® Imaging System with Real-time Targeting™ is intended to provide an image of the tissue microstructure. 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.

The following histological correlation slides are a compilation of data from a Clinical Trial Agreement between NinePoint Medical and the Academische Medisch Centrum (AMC) of Amsterdam, NL, which resulted in the following publications:

- Swager A, Bergman J et al., **Volumetric laser endomicroscopy in Barrett's esophagus: a feasibility study on histological correlation.** *Diseases of the Esophagus*, August 2016
- Swager A, Bergman J et al., **Identification of Volumetric Laser Endomicroscopy features predictive for early neoplasia in Barrett's esophagus using high-quality histological correlation.** *Gastrointestinal Endoscopy*, May 2017

We would like to sincerely thank the following individuals for acquiring and analyzing much of the histological correlation data presented here: A.F. Swager MD, W. Curvers MD, J.J.G.H.M. Bergman MD PhD, R. Odze MD and G. Lauwers MD

Accompanying in vivo VLE example images were acquired as part of NinePoint Medical Clinical Study #13_02.

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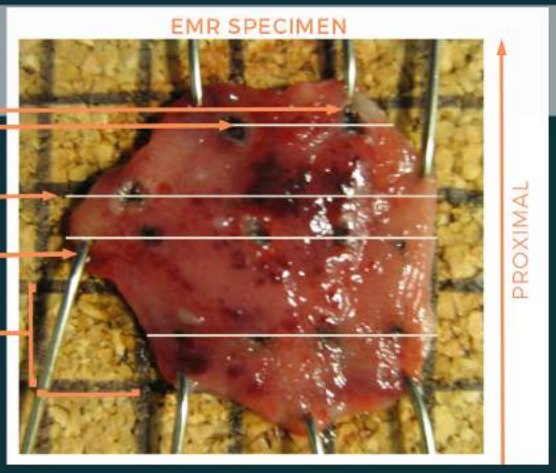
METHODOLOGY



1. Identification of lesion for EMR under WLE and NBI
2. In-vivo VLE scan is performed
3. Lesion is marked in-vivo using electrocautery at the lateral margins
4. Lesion is resected endoscopically using cap and snare technique
5. Ex-vivo specimen is pinned to cork with gridlines in same orientation that it was scanned in-vivo VLE (distal to proximal)
6. Additional markers are applied to the specimen using india ink to yield additional matches
7. Specimen is placed in ex-vivo scanning fixture and VLE scan is performed
8. Extensive histological sectioning of EMR sample, being careful to cut through markers
9. The histological sections were matched back to the VLE images by identifying at least two fiducial marks on each image. This ensures a one-to-one match between the histology and the VLE

RESULTS

30 patients imaged with VLE
Yielding 86 VLE / Histology matches

EAC	20
HGD	8
LGD	19
NDBE	21
SQUAMOUS	6
GASTRIC	12

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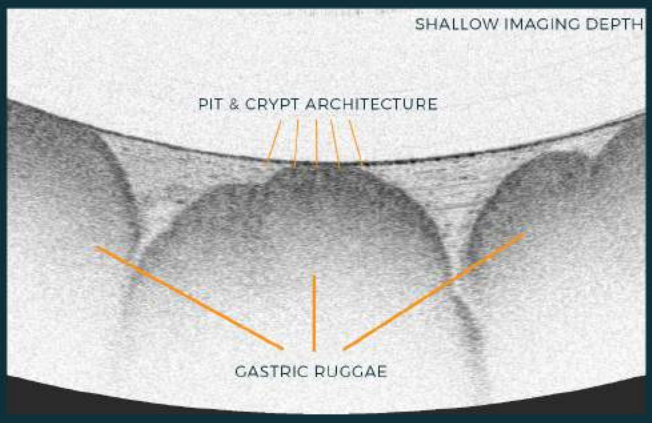
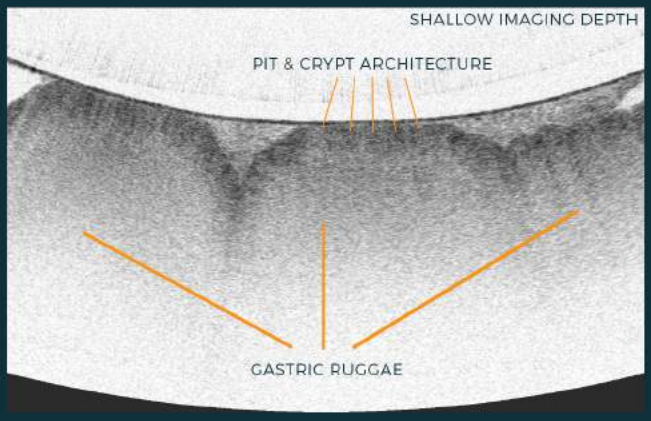
GASTRIC

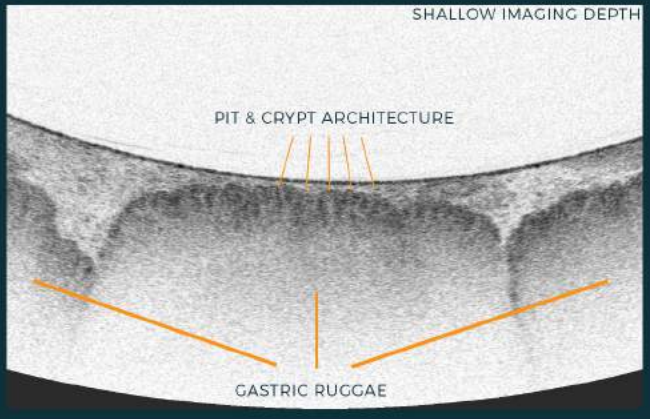
VLE Features of Gastric Cardia:
* Vertical pit & crypt architecture
* High surface reflectivity
* Shallow Imaging Depth

GASTRIC

IN VIVO VLE EXAMPLES







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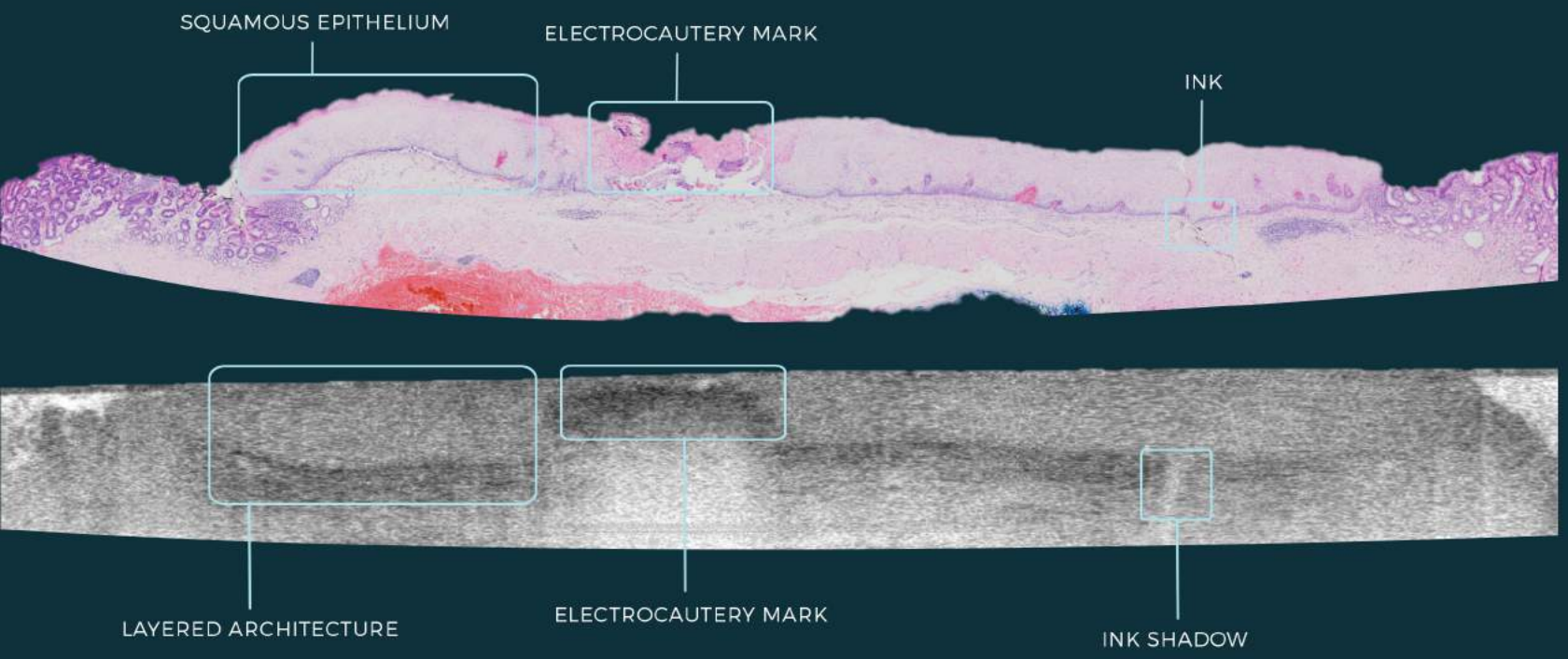
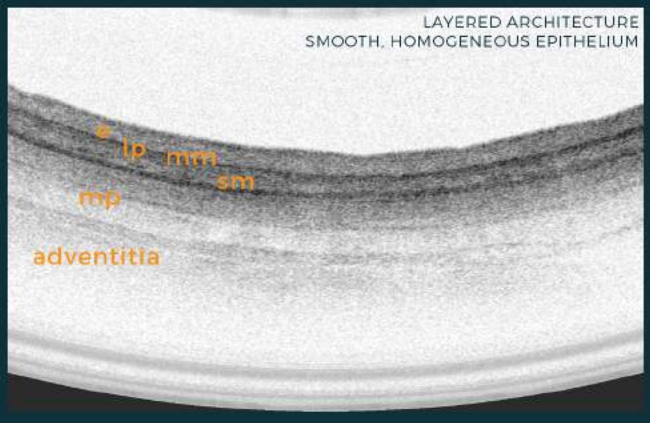
SQUAMOUS

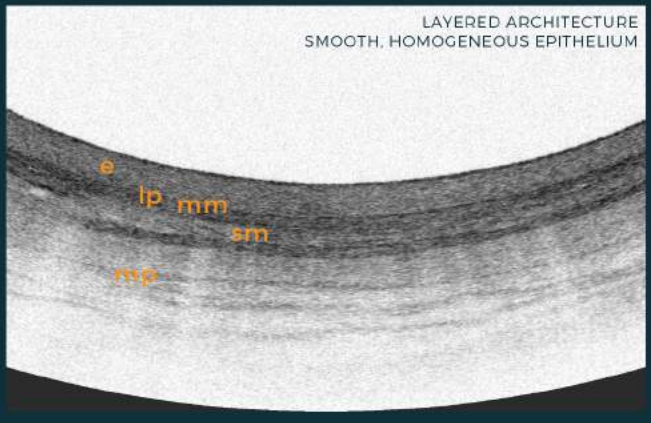


VLE Features of of Squamous Mucosa:
* Layered architecture without glands in epithelium

SQUAMOUS

IN VIVO VLE EXAMPLES





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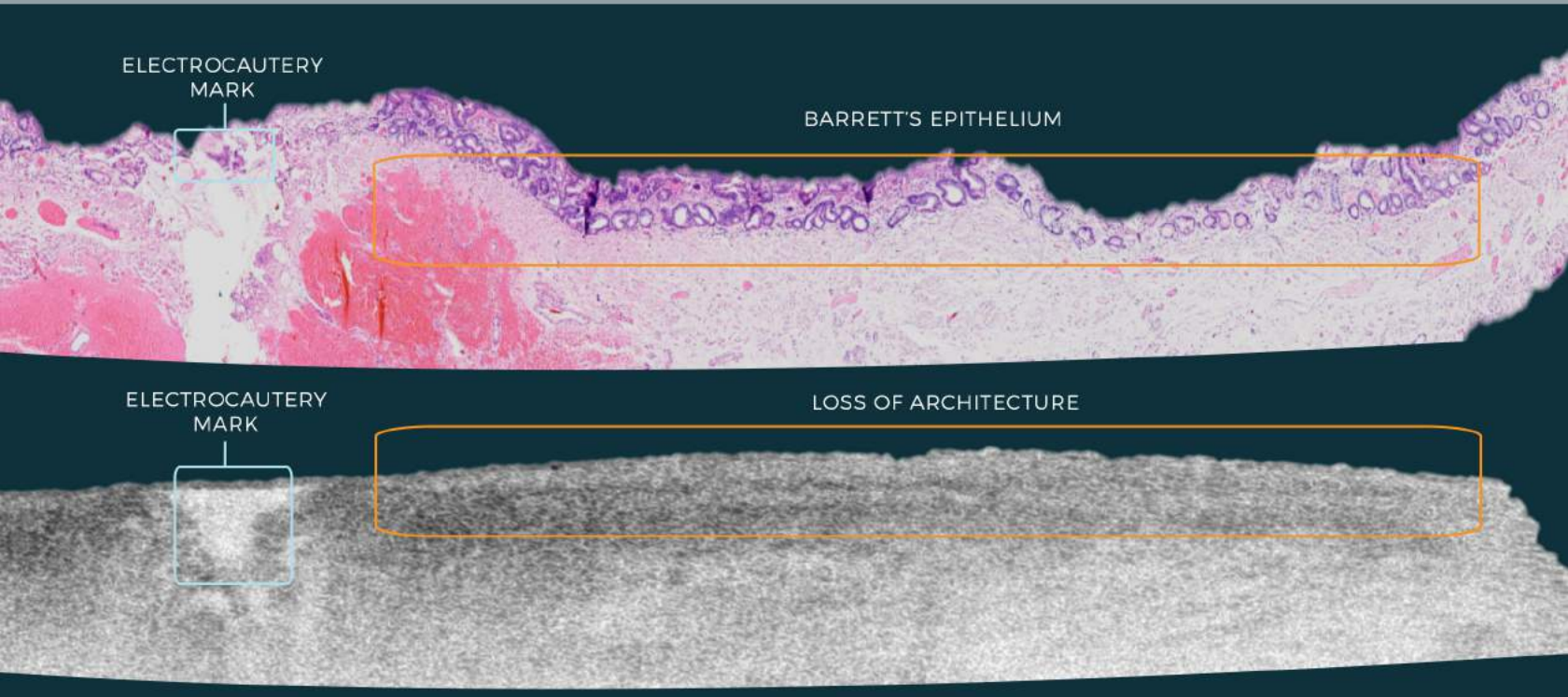
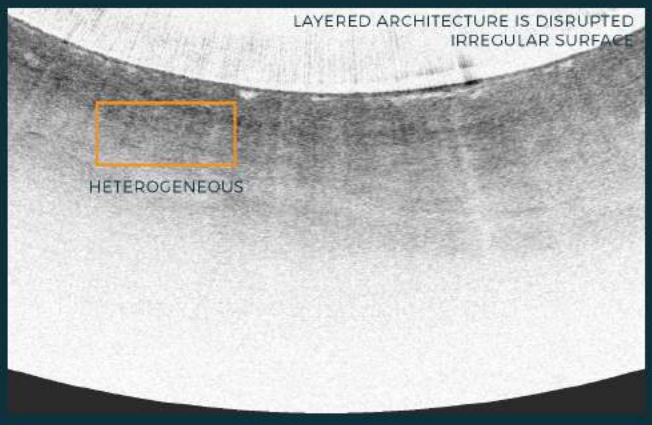
BARRETT'S

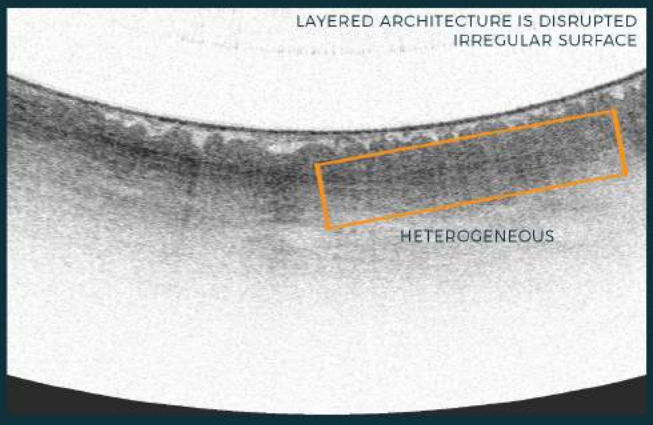


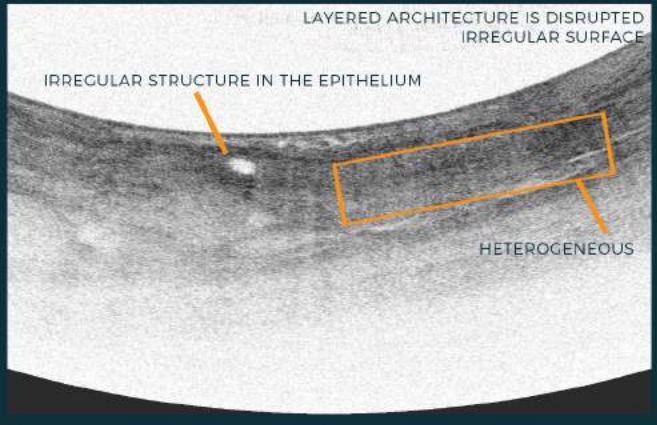
VLE Features of Barrett's Mucosa:
* Irregular surface
* Heterogeneous scattering

PATHOLOGY*: BARRETT'S

IN VIVO VLE EXAMPLES







* INDICATES PATIENT'S HIGHEST GRADE PATHOLOGY

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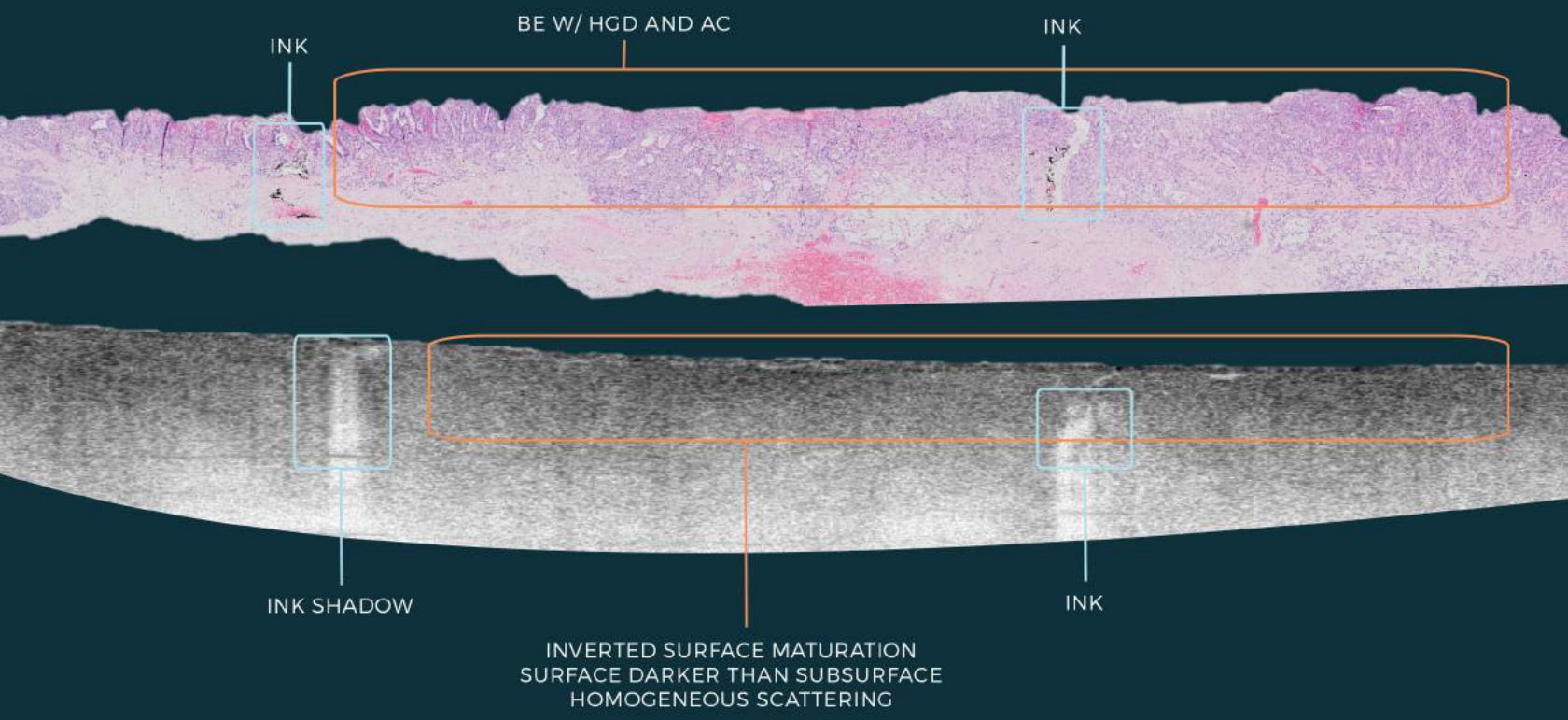
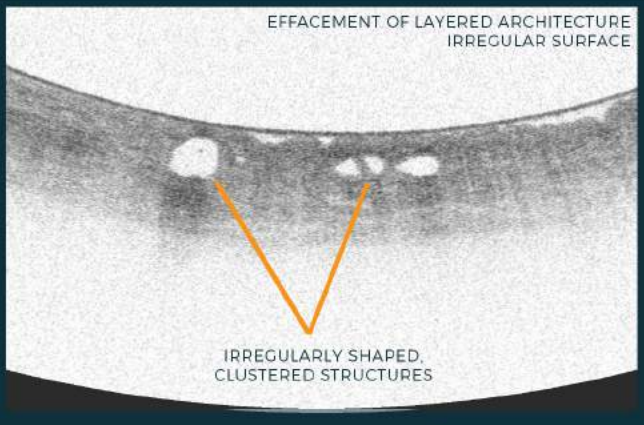
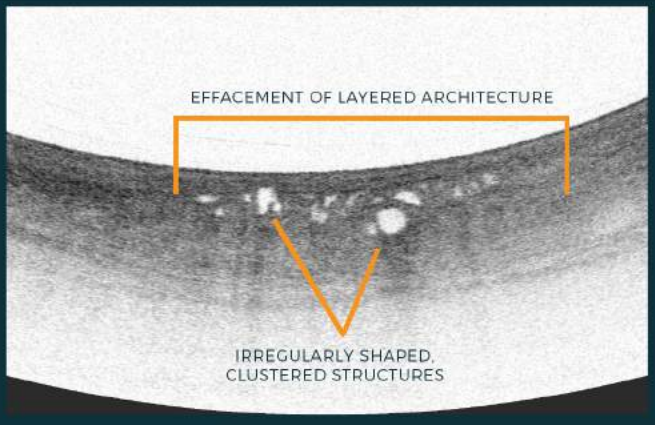
HIGH GRADE DYSPLASIA / CANCER

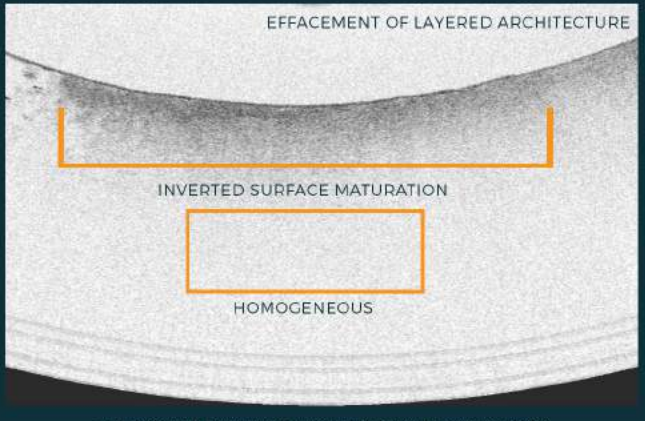


PATHOLOGY*: HIGH-GRADE DYSPLASIA / CANCER

IN VIVO VLE EXAMPLES







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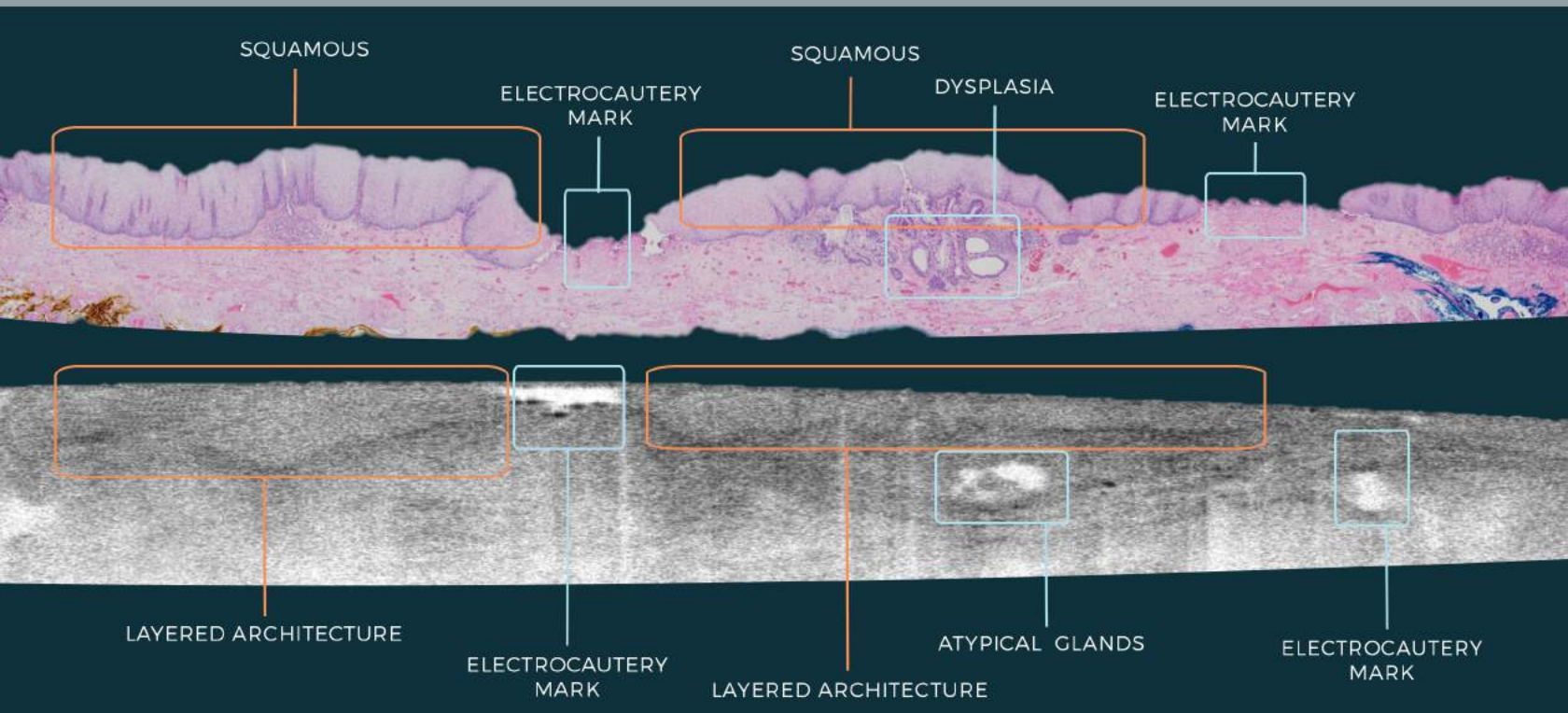
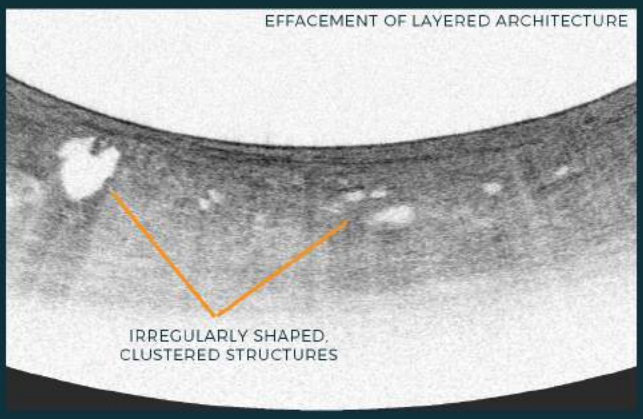
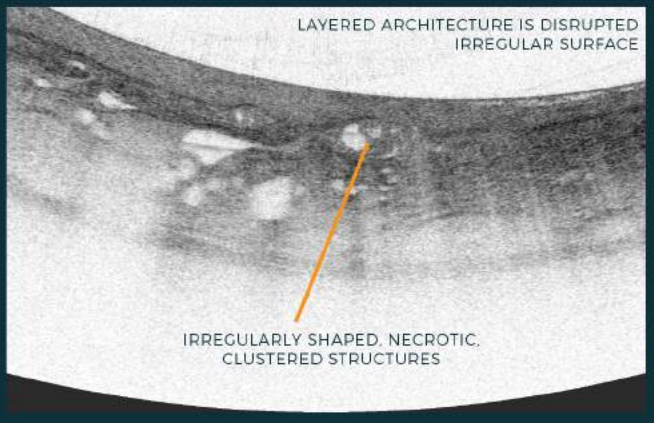
DYSPLASIA

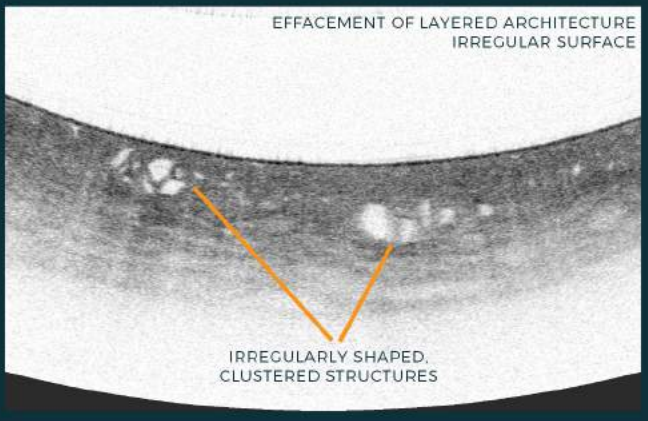


PATHOLOGY*: DYSPLASIA

IN VIVO VLE EXAMPLES







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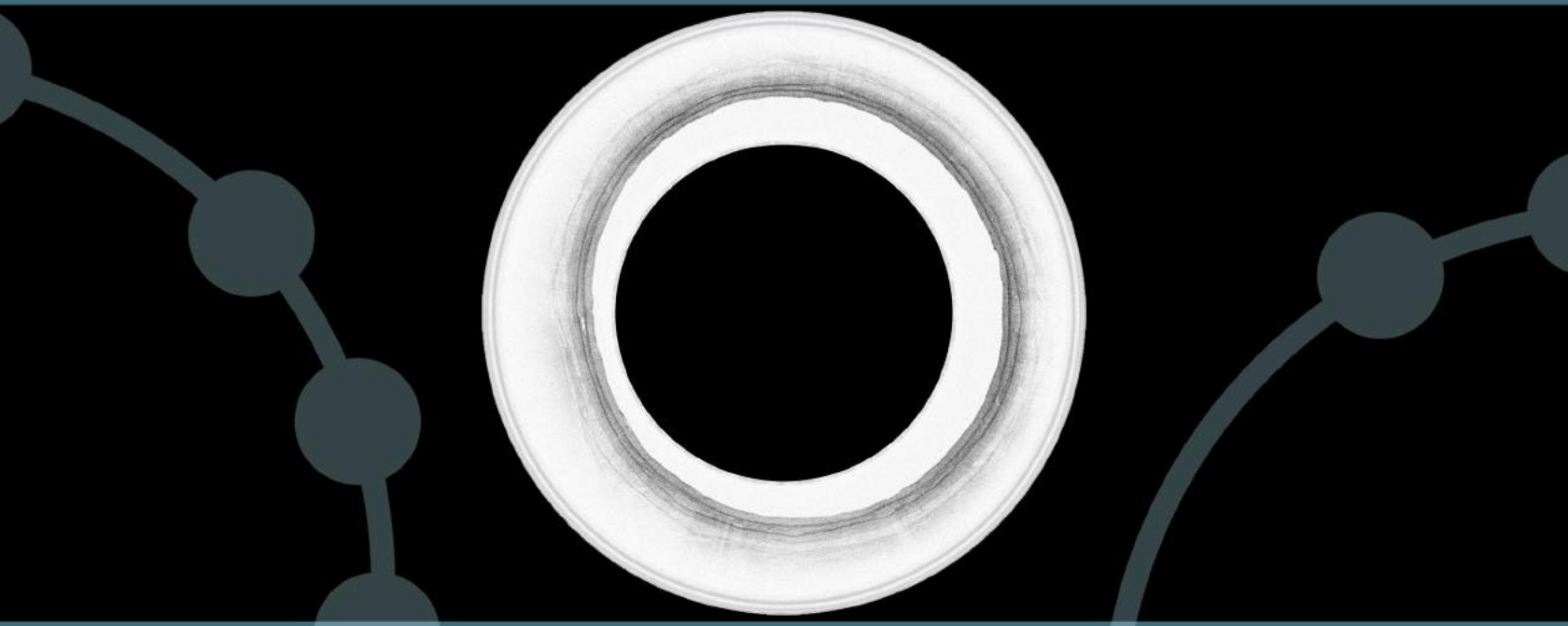

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