

## **Dysplasia Detection in Barrett's Patients using the Optical Biopsy™ System**

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**BACKGROUND:** Detection of dysplasia within Barrett's esophagus is often difficult, yet early detection of dysplasia may result in improved outcomes. Random biopsy methods, as suggested by guidelines, are not often practiced due to their lack of sensitivity and their time consuming nature. Although optical methods have been previously described using laboratory equipment, we assessed the use of the Optical Biopsy™ System which employs a robust commercial laser-induced fluorescence (LIF) spectrophotometry system to distinguish between Barrett's metaplasia and low or high-grade dysplasia in Barrett's patients.

**METHODS:** Using a standardized biopsy protocol of 4 quadrant biopsies every 2 cm of visible columnar mucosa, multiple tissue samples were taken in established Barrett's patients. Immediately prior to physical biopsy, the SpectraScience Optical Biopsy™ System was used to collect spectral data. The Optical Biopsy™ Forceps used in this study combines a novel fiberoptic probe coaxially placed within the jaws of a standard biopsy forceps to facilitate both the collection of spectral data and the physical biopsy from the identical piece of tissue without the need for instrument exchange. The spectral data collected was correlated with the results of the pathologist's interpretation of the physical biopsy sample. A statistical tissue recognition algorithm was developed based on the spectral data/pathology correlation. The clinical data (excluding the training set) was retrospectively analyzed using the algorithm to determine the sensitivity and specificity of the Optical Biopsy™ System.

**RESULTS:** A total of 78 patients, with any length Barrett's esophagus, were enrolled into the trial with 774 optical biopsies taken. Physical biopsies revealed 268 specimens of Barrett's mucosa without dysplasia, 59 with low-grade dysplasia, and 11 with high-grade dysplasia. Applying the algorithm to the data set retrospectively, demonstrated a sensitivity of 90% and a specificity of 80% in distinguishing between low or high-grade dysplasia and non-dysplastic Barrett's epithelium. The algorithm will be further refined by numerous reruns through the data set to achieve spectral discriminator enhancements and subsequent improvement in sensitivity and specificity prior to further study.

**CONCLUSION:** The Optical Biopsy™ System can distinguish dysplastic Barrett's epithelium from Barrett's metaplasia with a high degree of sensitivity and specificity. Based upon these results, a prospective trial is scheduled to determine the clinical utility of using the Optical Biopsy™ System in surveillance endoscopy of Barrett's patients.

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