Clinical Evaluation of an Enhanced White Light and Fluorescence Device for Early Detection of Caries Lesions

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Abstract

• **Objective:** Sensitivity of a device based on Fluorescence Imaging with Reflectance Enhancement (FIRE) in detecting a potential incipient lesion (PIL) was compared with visual examination to demonstrate non-inferiority to it.

• **Methods:** Visual examination (VE) and an investigational device (ID) were used to detect PIL (actual incipient caries [AIC] and hypomineralization). Seventeen subjects satisfied data analysis criteria. Two-hundred and seventy-seven AIC and 367 hypomineralizations reached VE consensus. Ground truth was generated from consensus VE results and image information from enhanced white light (eWL) and FIRE images. Data from VE and ID in Still Image (IDSM) and Video (IDVM) modes were evaluated against ground truth.

• **Results:** Overall sensitivity of VE, IDSM, and IDVM evaluated against ground truth were 0.94, 0.884, and 0.848, respectively, for Actual Incipient Caries (AIC) detection, and 0.95, 0.916, and 0.883, respectively, for PIL detection. Sensitivity of ID in both modes was > 90% that of VE, thus demonstrating non-inferiority of IDSM and IDVM to VE.

• **Conclusion:** The investigated eWL and fluorescence device is clinically effective and at least as good as expert VE in detecting PIL. An enhanced white light device with FIRE technology can be used, in Video or Still Image Detection modes, as an aid to caries diagnosis.

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