

## **Development of a Low-cost, Automated Multimodal Mobile Detection of Oral Cancer (mDOC) Imaging System**

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Oral squamous cell carcinoma, commonly known as oral cancer, is frequently diagnosed at an advanced stage despite it often being preceded by clinically visible precursors and the ease of direct visual examination of the oral cavity. Oral cancer precursors designated as oral potentially malignant disorders (OPMDs) are oral mucosal lesions (OML) with an increased risk of developing into OSCC. Frontline health care providers (i.e., primary care physicians, nurse practitioners, community dentists, and dental hygienists) are often the first to see patients with OML but lack the training and expertise needed to recognize and distinguish OPMDs from their benign mimics. There is an unmet clinical need for screening tools to assist front-line providers in determining which patients should be referred to an oral cancer specialist for evaluation. This study reports the development and evaluation of the mobile Detection of Oral Cancer (mDOC) imaging system and an automated algorithm that generates a referral recommendation from mDOC images. The mDOC imaging system is a smartphone-based autofluorescence and white light imaging tool that captures images of the OML. A multimodal image classification algorithm was developed to automatically generate a recommendation of “Refer” or “Do Not Refer” from mDOC images, using expert clinical referral decision as the ground truth label. Data were collected from a total of 406 oral sites in 29 healthy volunteers and 120 patients. An automated referral algorithm was developed using cross-validation methods on 80% of the dataset, then retrained and evaluated on a separate holdout test set. Automated referral decisions generated in the holdout test set had a sensitivity of 93.9% and a specificity of 72.4% with respect to expert clinical referral decisions. The mDOC system has the potential to be utilized in community physicians’ and dentists’ offices to help identify patients who need further evaluation by an oral cancer specialist.