

**CONTROL ID:** 2111732

**TITLE:** Clinical Trial of the Canary System for proximal caries detection

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**ABSTRACT BODY:**

**Objectives:** Detecting initial caries on the proximal surfaces of teeth in an intact dentition is a problem in dental practice since radiograph has been shown to have poor sensitivity with this stage of caries lesions. The aim of this study was to investigate the efficacy of the Canary System (CS) to detect proximal caries in a clinical setting, comparing it with that of the bitewing radiography (BWR).

**Methods:** 30 subjects, age 18 years and above, were recruited from a mixed population of low, moderate, and high caries risk patients. BWR (by an oral radiologist) and the CS (by a trained clinician) were used to detect proximal caries lesions in these subjects. Teeth were separated by 48 hours insertion of rubber rings, and the proximal surfaces were examined by direct visual examination using ICDAS-II scoring system. The Sensitivity (se), specificity (sp), positive (ppv) and negative predictive (npv) values of the CS and BWR in detecting caries on proximal surfaces were calculated by evaluating each method alone against ICDAS-II system (used as bronze standard). The two methods were compared statistically using their Area Under the Receiver Operating Curve (AUC). The sensitivities and specificities were compared using a test of proportions and AUC values were compared using DeLong's method of nonparametric testing of AUC values.

**Results:** The se, sp, ppv and npv for the CS are Se: 0.92, Sp: 0.78, PPV: 0.89, NPV: 0.84, and for BWR are Se: 0.67, Sp: 0.54, PPV: 0.78, NPV: 0.40. The AUC of the Canary System (0.774) was statistically significantly higher than the AUC of the radiograph test (0.531,  $p < 0.001$ ).

**Conclusions:** This study demonstrated the efficacy of the Canary System in detecting proximal caries lesions to be greater than that of bitewing radiography. The Canary System can be a valuable clinical device for proximal caries diagnosis.

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**KEYWORDS:** Proximal caries, Canary System , Bitewing radiography .

**Support Funding Agency/Grant Number:**

**Financial Interest Disclosure:** NONE