Multi-center study evaluating safety and effectiveness of the Canary System

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Objective: A multi-center, non-blinded study was conducted to evaluate the safety and effectiveness of The Canary System. The primary objective of the present study (QDT-201) was to establish how The Canary System detects and monitors tooth decay in vivo in a wide range of clinical scenarios seen in a typical dental practice. The secondary objectives of this study were to: 1) Develop a treatment scale that correlates to lesion size; 2) Explore the ability of the investigational device to detect caries and erosion lesions; and 3) Monitor changes in lesion size in response to various remineralization therapies.

Methods: 150 subjects (18 years and older) from four dental clinics and who have been patients of the clinics for more than 6 months were enrolled in the study. The study procedures were conducted as part of normal clinical practice. The Canary System responds to different clinical conditions by generating a Canary Number (CN). The CNs were recorded from various clinical conditions such as healthy surfaces, white and brown spots, early caries, hidden caries, interproximal caries and demineralized and remineralized tooth surfaces.

Results: PTR-amplitude and PTR-phase in the CN contributed to detect near-surface and subsurface lesions, while LUM-amplitude and LUM-phase contributed to detect near-surface lesions, thus enabling the device to detect both types of lesions with varying CNs. Similar to QDT's first investigational study (QDT-101), no adverse events or soft or hard tissue trauma were observed. The CN correlated with severity of decay and the type, size and nature of the lesion. In addition, The Canary System was able to track lesion activity over time after exposure to different remineralization agents.

Conclusion: The present investigational study (QDT-201) corroborated and extended our findings from QDT-101, that The Canary System is safe and can discriminate between healthy and carious tooth surfaces.

Keywords: Cariology, Clinical trials, Demineralization/Remineralization, Diagnosis and Preventive dentistry

Presenting author's disclosure statement: The Presenter currently holds the position of President & Founder of Quantum Dental Technologies, the developers of The Canary System.

See more of: Cariology: Detection and Caries Removal
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