Multi-center study evaluating safety and effectiveness of 'The Canary System': An Interim Analysis

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The Life Cycle of Tooth Decay

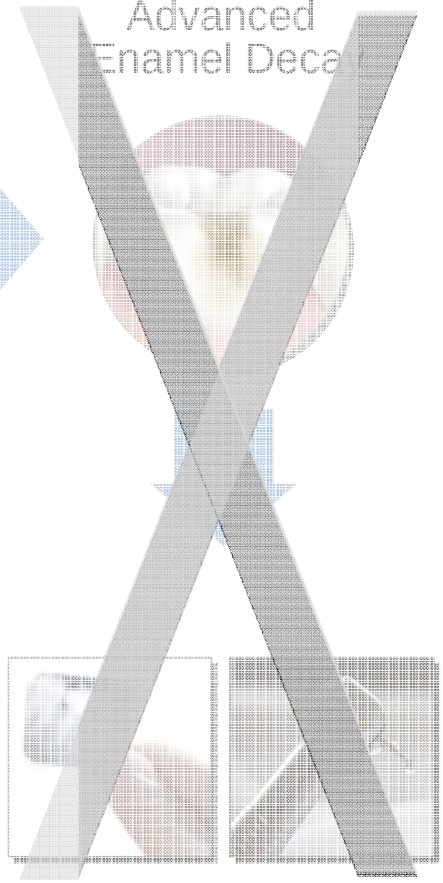
Healthy Tooth

Demineralization

Remineralization

Early Enamel Decay

Advanced Enamel Decay



X-Ray, Drill Fill & Bill

The Canary System Scan

Remineralization Therapies

First Investigational Trial

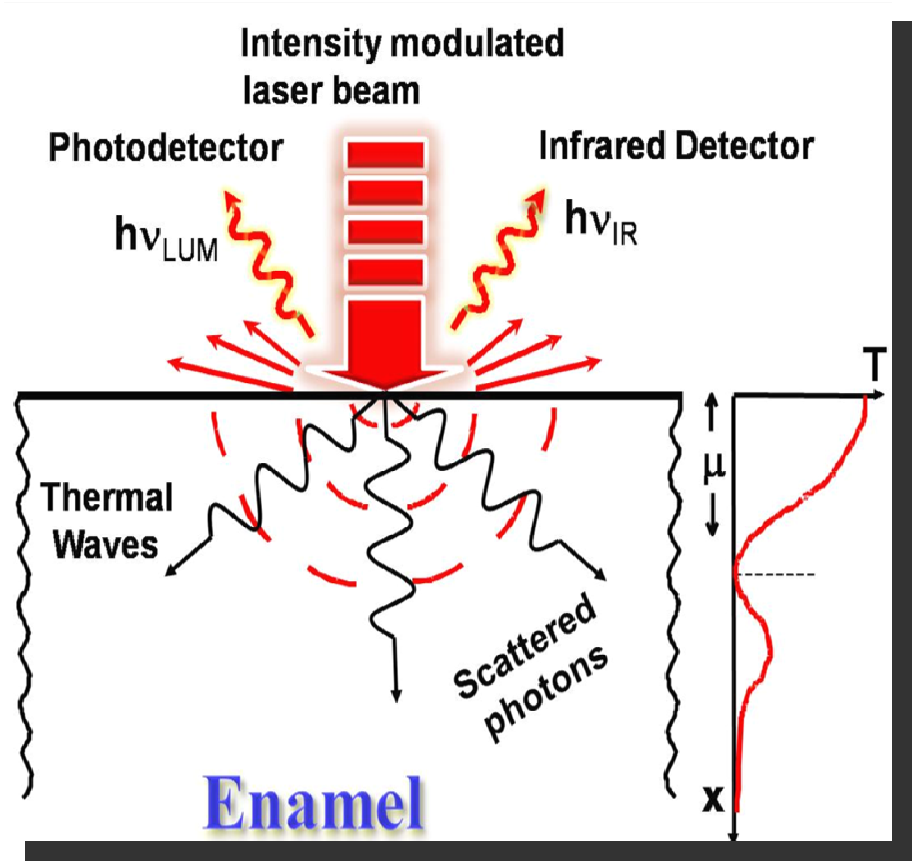
- Health Canada approved clinical trial
  - Completed December 2009 under supervision of AXON
  - Trial involved 50 patients and focused primarily on device safety

Principal Findings:

- No signal difference between wet or dry tooth surfaces
  - No need to isolate teeth
- Surface stain did not deteriorate the PTR-LUM signal
- Able to detect brown spots and carious lesions on visible tooth surfaces
- No safety issues

The Canary System technology:

Photothermal Radiometry (PTR) and Luminescence (LUM)



PTR (**P**hotot**t**hermal **R**adiometry)

The generated IR signals, resulting from radiation absorption and non-radiative energy conversion, carry subsurface information in the form of a temperature depth integral. The frequency dependence of the penetration depth of thermal waves makes it possible to perform depth profiling.

LUM (**lum**inescence)

based on radiative energy conversion and relaxation. LUM is limited by the optical scattering process of the incident light inside the tooth.

The Canary Number

- The Canary algorithm is the core function that takes PTR-LUM amplitudes and phases and converts to a numerical scale:

  - PTR Amplitude
  - PTR Phase
  - LUM Amplitude
  - LUM Phase

Canary Number

Purpose and Objectives

- A multi-center study to evaluate the safety and effectiveness of 'The Canary System' in adults (n = 150 volunteers)
  - 4 dental clinics around the Greater Toronto Area.
  - Not randomized
  - 1 Screening Visit; Multiple Assessment & Follow-Up Visits

- Evaluating the safety and effectiveness of 'The Canary System' in 4 categories:
  - Category 1: Sound enamel/root surfaces;
  - Category 2: Lesions (WSL & Brown spots);
  - Category 3: Remineralization of caries lesions
  - Category 4: Secondary caries and restoration of lesions

Protocol Overview

- **Informed Consent** Form

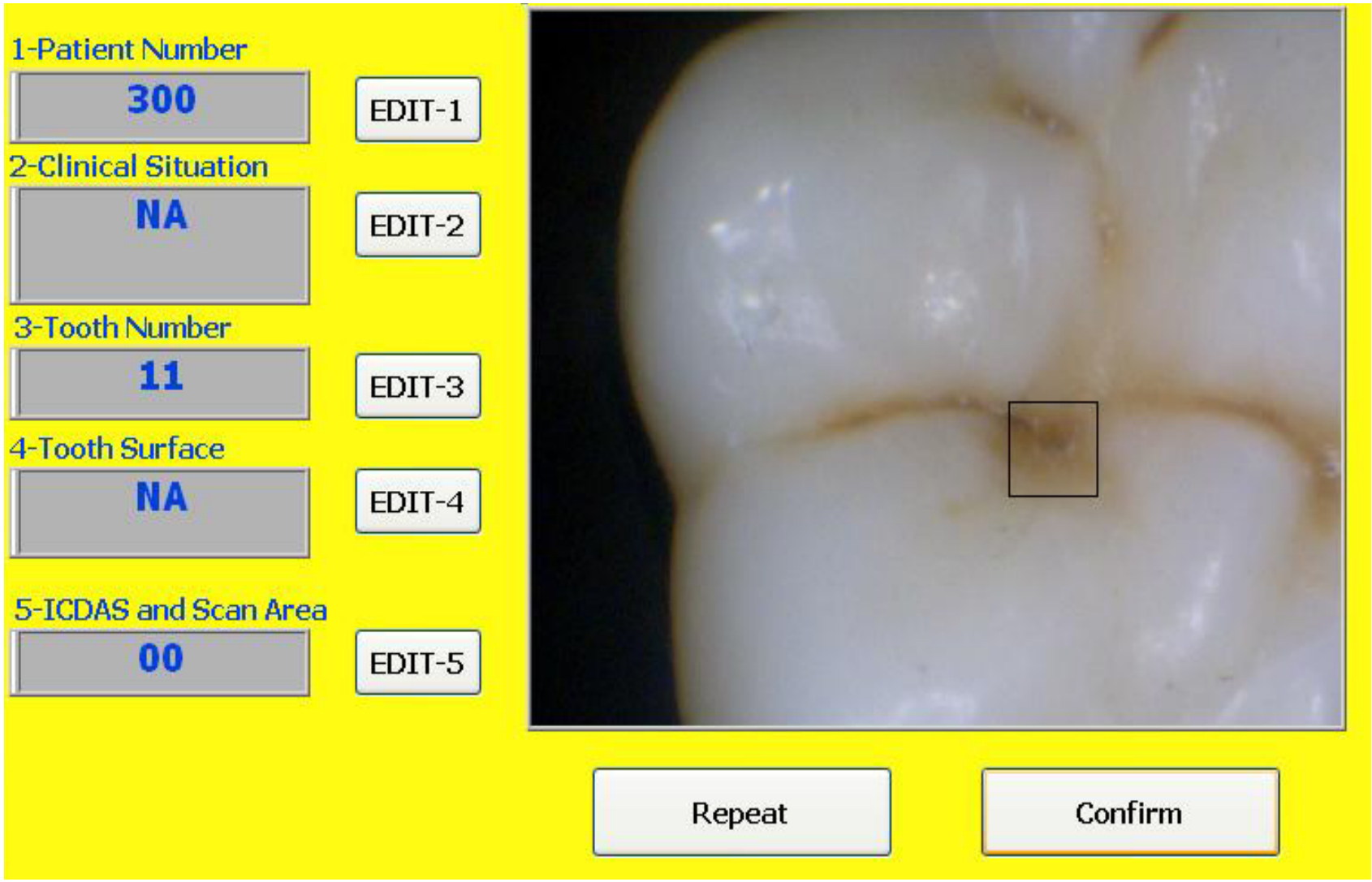
- **Screening Visit** to assess eligibility and Risk Assessment
  - 18+ yrs;
  - Registered patient at the clinic for ≥ 6 months at the time of initial visit;
  - Full adult dentition, or a minimum of two natural teeth and a minimum of one healthy tooth surface;
  - Speak and read English

- **Assessment Visit** to assess subjects using 'The Canary System'
  - **Quick Scan:** 5 measurements @ 2 Hz + 5 measurements @ 5 Hz
  - **Detailed Scan:** Point scan at 2, 5, 20, 200 Hz.

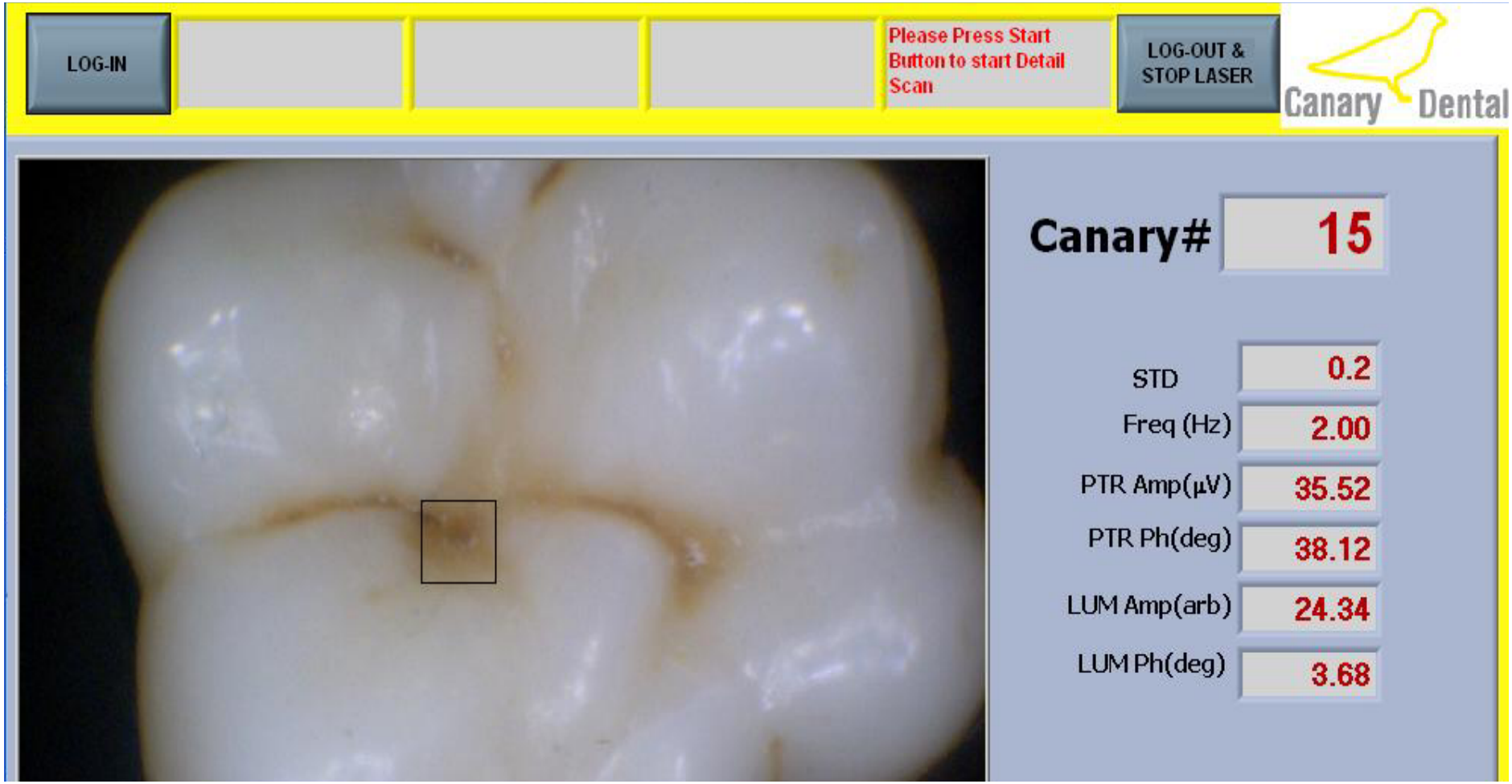
- **Follow-up Phone Call** to assess subject safety (minimum of 24 hours post-scan)

The Canary- Clinical Trial System

Methods: Clinical Trial Software



Methods: Clinical Trial Software



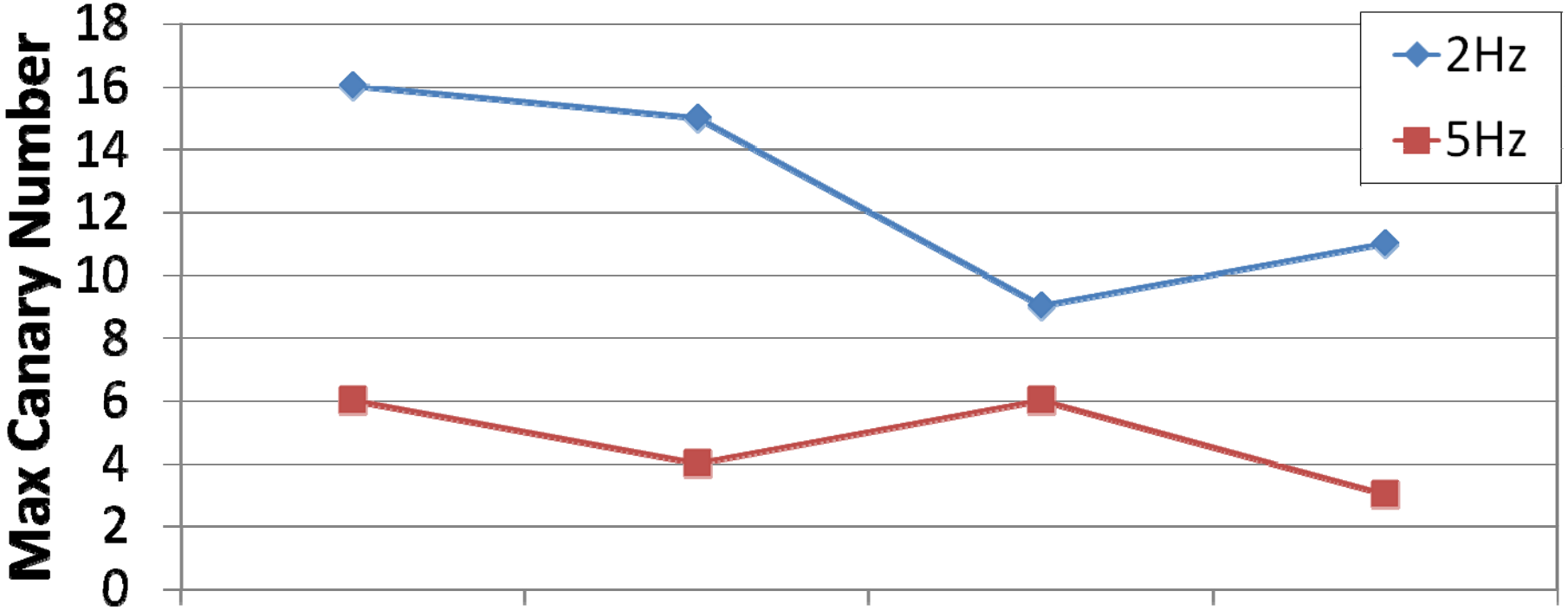
Interim Results

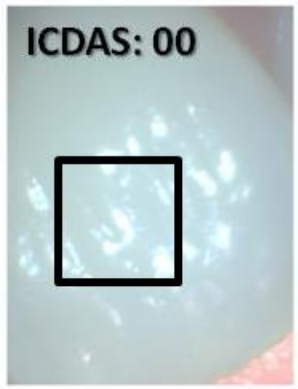
- Interim examination of enrolled patients (n = 85) has revealed no adverse events

- Examination of sound enamel surfaces (n = 210) produced Canary Numbers:

Frequency	Canary Number
2 Hz	16 ± 8
5 Hz	8 ± 4

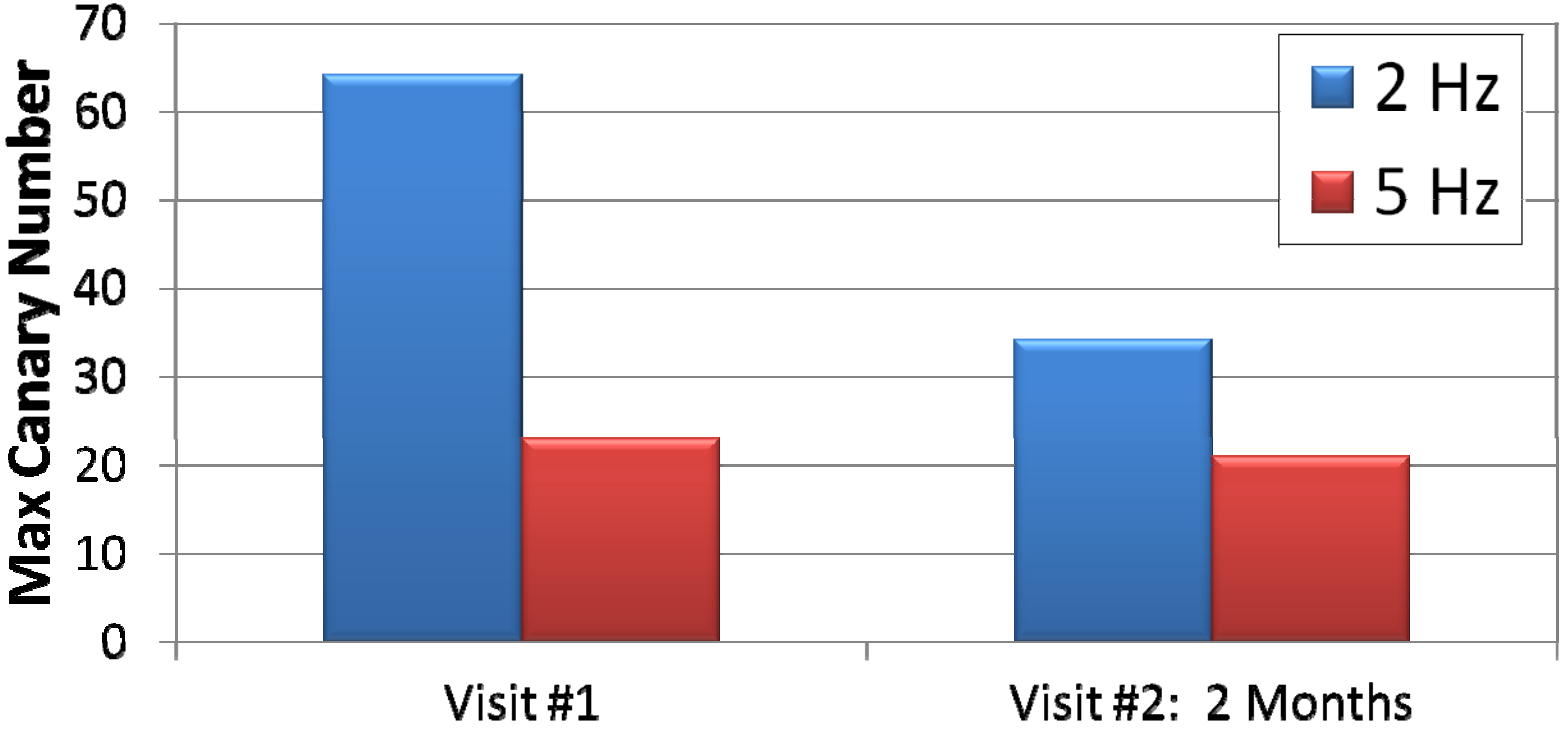
Case Study #1: Sound Enamel

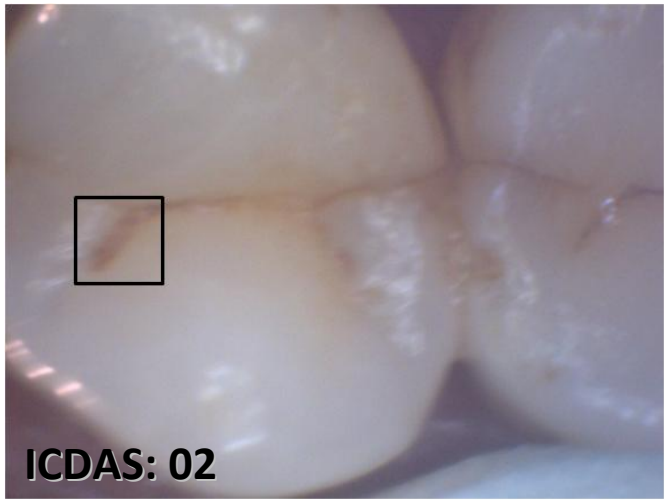


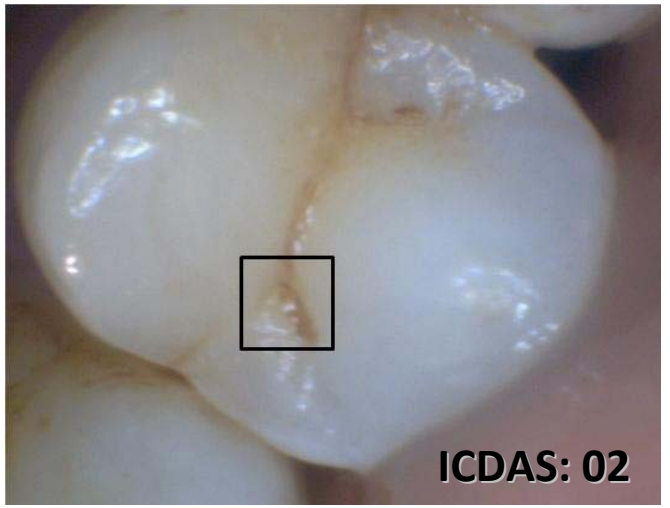


Patient Assessment Visit

Case Study #2: Occlusal Caries

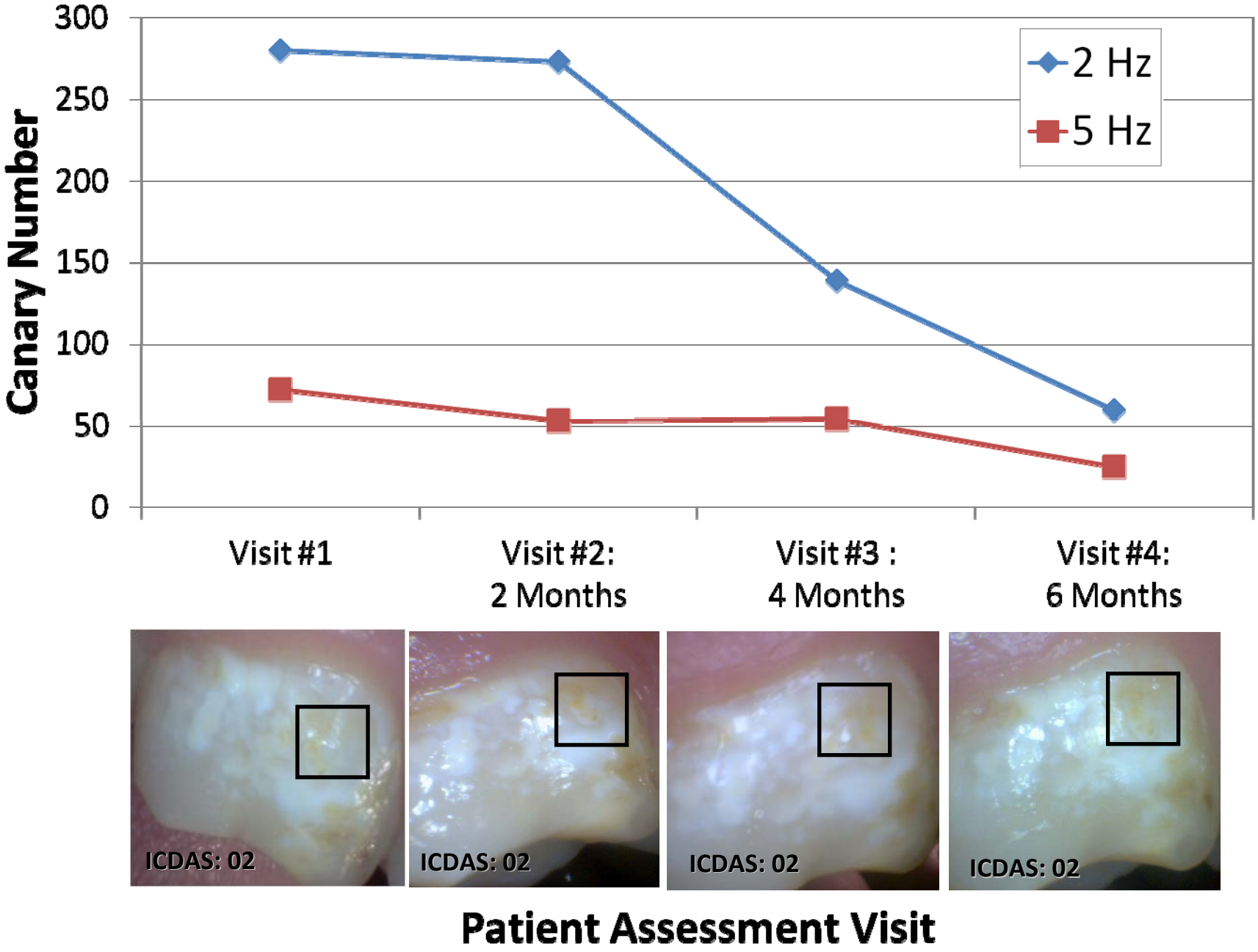




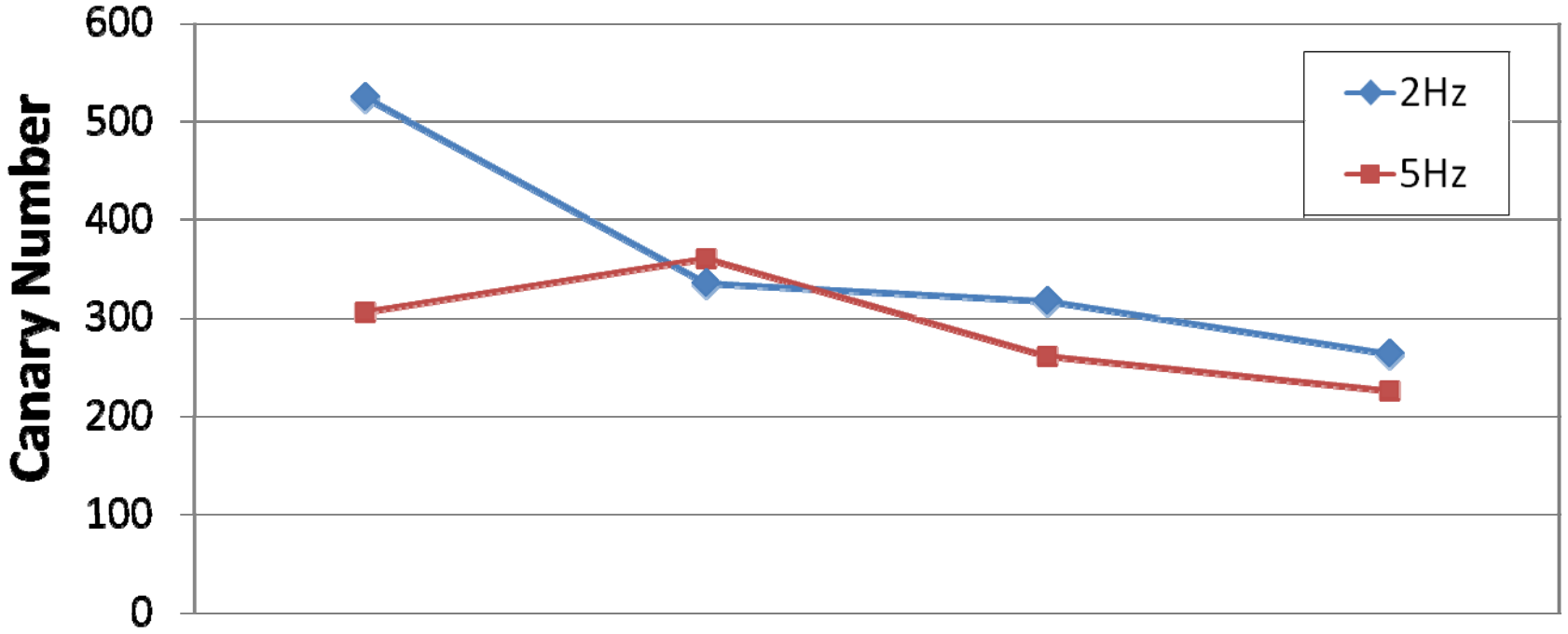


Patient Assessment Visit

Case Study #3: Remineralization



Case Study #4: Remineralization

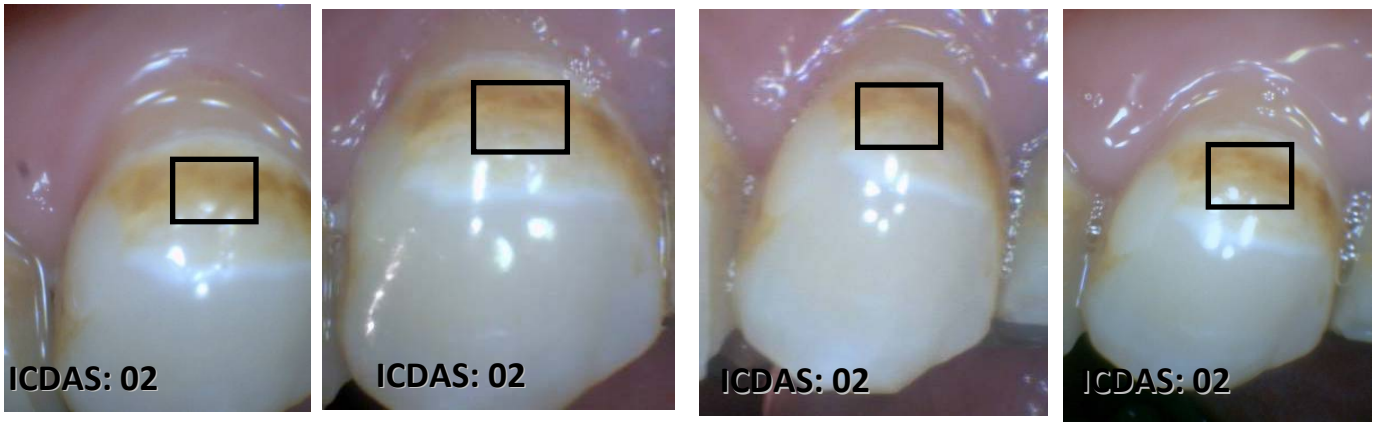


Visit #1

Visit #2:
2 Months

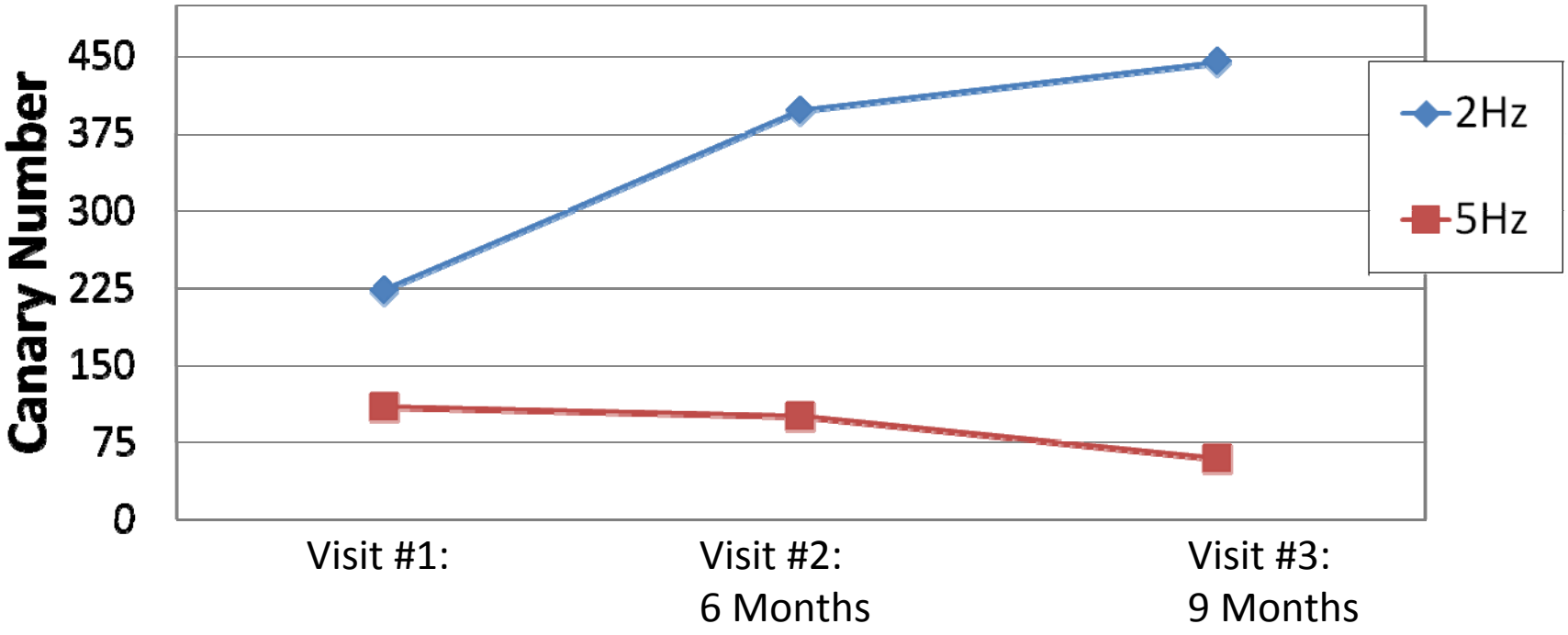
Visit #3:
3 Months

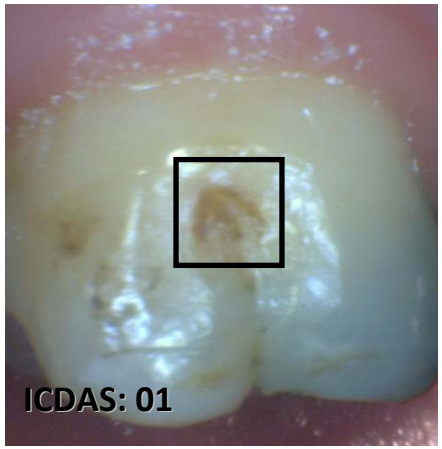
Visit #4:
5 Months

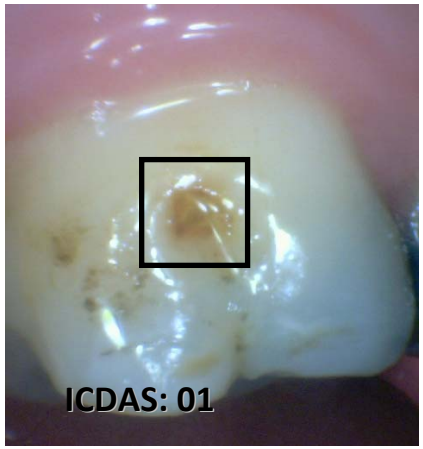


Patient Assessment Visit

Case Study #5: Remineralization

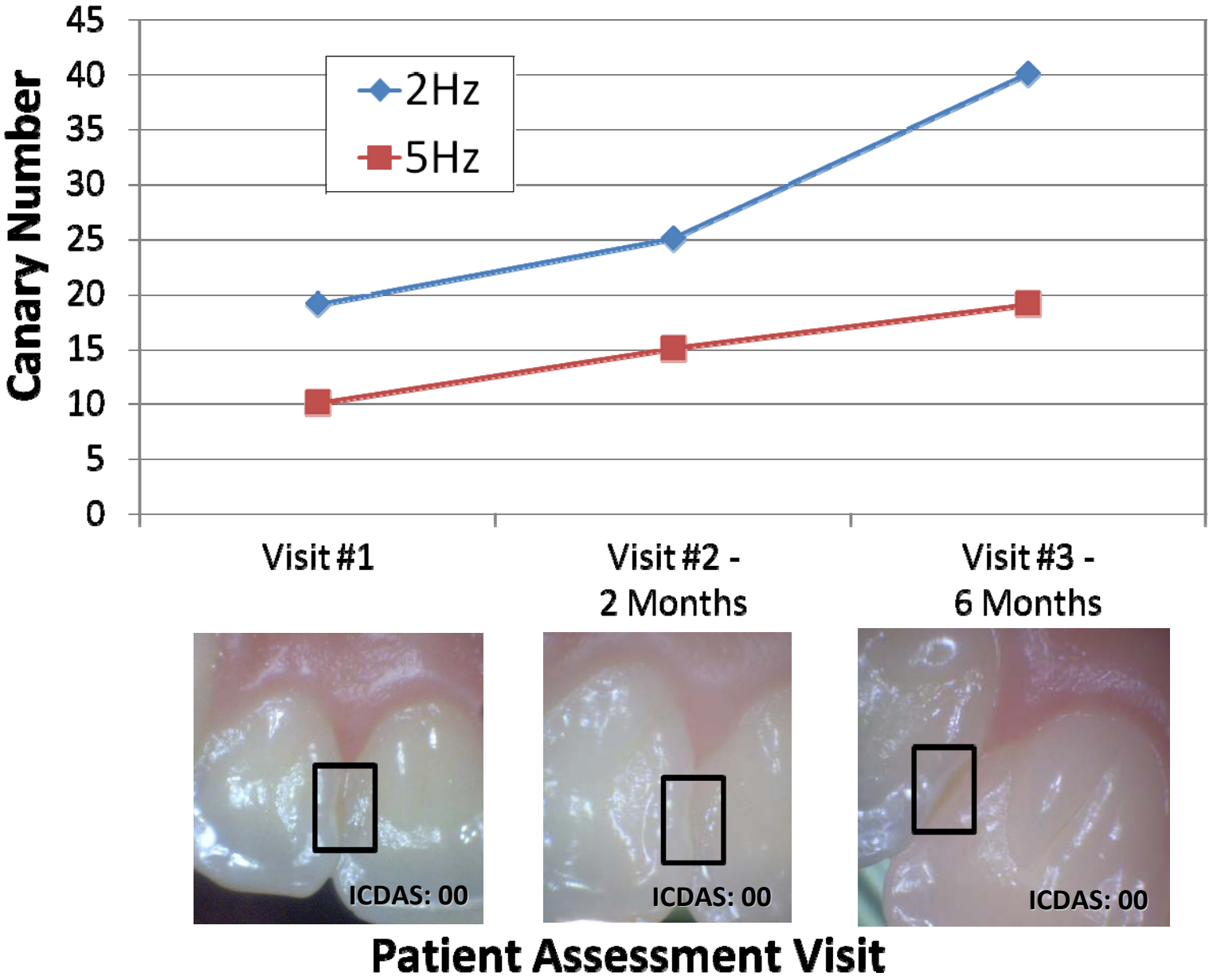




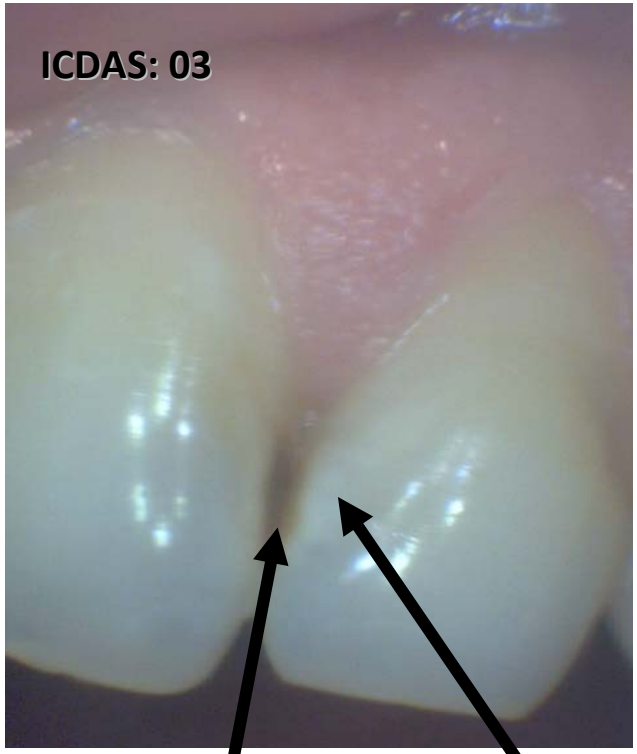


Patient Assessment Visit

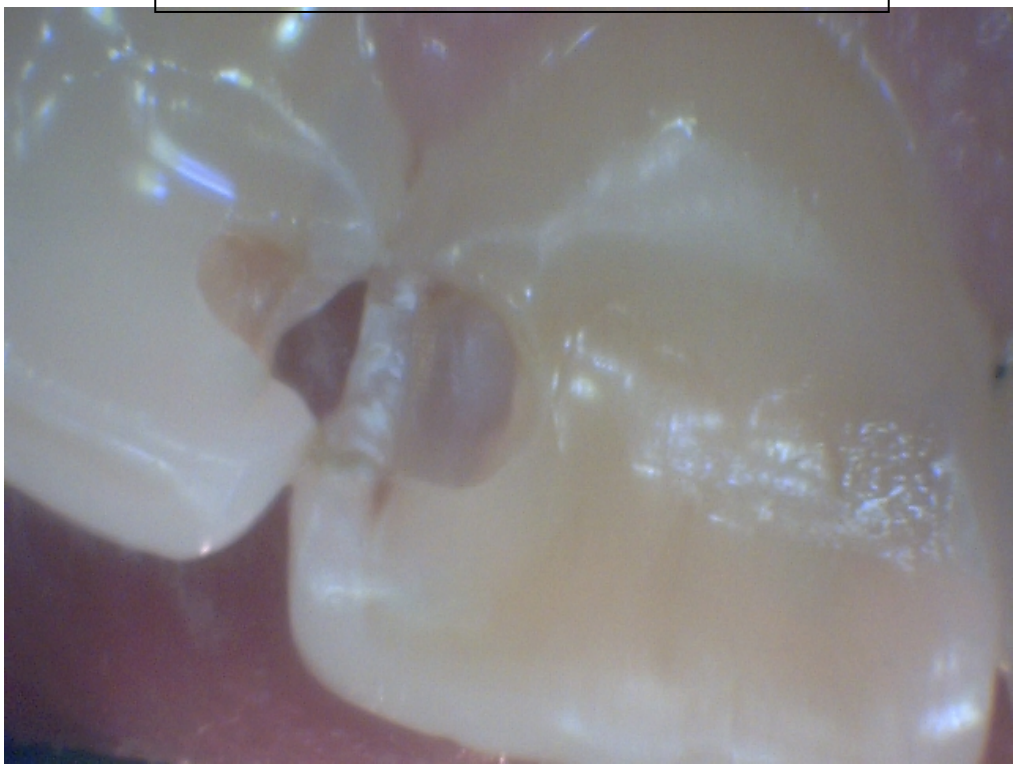
Case Study #6: Proximal Caries Detection



Case Study #7: Lesion Detection



Lingual View of Lesion



2 Hz = **228**
5 Hz = **73**

2 Hz = **161**
5 Hz = **26**

Interim Conclusions and Future Directions

- From the **interim case study data** 'The Canary System' was able to:
  - 1. Differentiate between sound and demineralized enamel
  - 2. Detect incipient lesions (WSL or Brown spots)
  - 3. Monitor the effectiveness of remineralization programs
    - Allowed for the re-evalution of current treatment plans
  - 4. Detect lesions at the point of restoration
  - 5. Detect and monitor lesions on smooth-surface enamel, occlusal enamel and proximal surfaces.

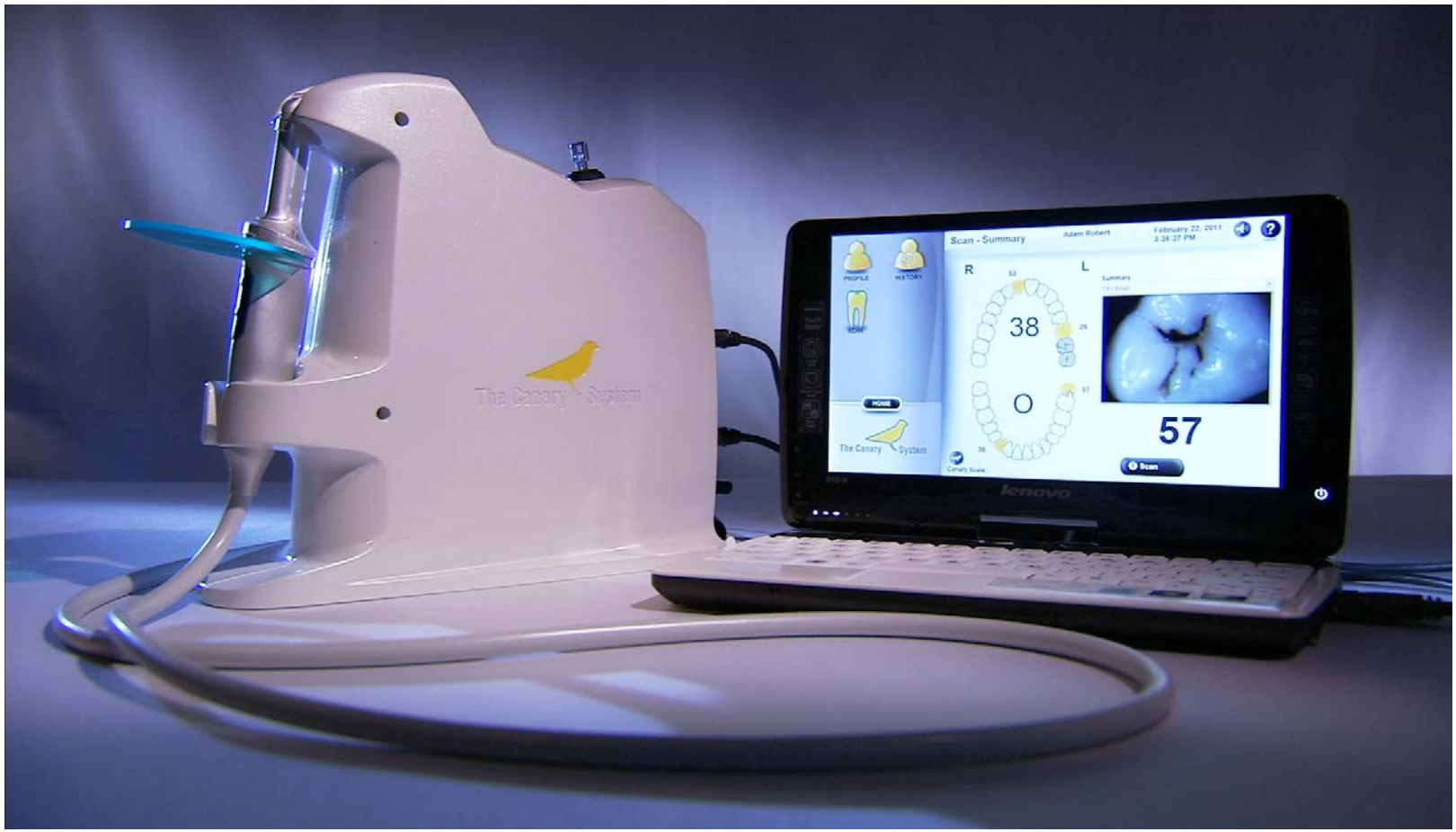
Future Objectives Toward Study Completion

- Inter and Intra-examiner reproducibility
  - ICDAS and Canary System reproducibility

- In the remainder of the study the following clinical situations will be analyzed:
  - Root dentin/cementum surface detection
  - Secondary caries, lesion restoration, sealants
  - Enamel hypoplasias and Fluorosis *

Future Objectives Toward Study Completion

- Health Canada approval to introduce clinical unit on new patients enrolled in clinical trial



The Canary System

by Quantum Dental Technologies

Thank You!