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

S.H. Abrams\textsuperscript{a} K. Sivagurunathan\textsuperscript{a}, R. J. Jeon\textsuperscript{a}, J.D. Silvertown\textsuperscript{a}, A. Hellen\textsuperscript{a}, A. Mandelis\textsuperscript{a}, W.M.P. Hellen\textsuperscript{b}, G. I. Elman\textsuperscript{b}, B.T. Amaechi\textsuperscript{c} and Y. Finer\textsuperscript{d}

\textsuperscript{a} Quantum Dental Technologies, Toronto, Ontario, Canada;
\textsuperscript{b} Cliffcrest Dental Office, Scarborough, Ontario, Canada;
\textsuperscript{c} Department of Comprehensive Dentistry, University of Texas Health Science Center at San Antonio, Texas, USA
\textsuperscript{d} Faculty of Dentistry, University of Toronto, Canada
The Life Cycle of Tooth Decay

Healthy Tooth

Early Enamel Decay

Demineralization

Remineralization

Remineralization Therapies

The Canary System Scan

X-Ray, Drill Fill & Bill
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 (Photothermal Radiometry)
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 (Luminescence)
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
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

<table>
<thead>
<tr>
<th>1-Patient Number</th>
<th>300</th>
<th>EDIT-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Clinical Situation</td>
<td>NA</td>
<td>EDIT-2</td>
</tr>
<tr>
<td>3-Tooth Number</td>
<td>11</td>
<td>EDIT-3</td>
</tr>
<tr>
<td>4-Tooth Surface</td>
<td>NA</td>
<td>EDIT-4</td>
</tr>
<tr>
<td>5-ICDAS and Scan Area</td>
<td>00</td>
<td>EDIT-5</td>
</tr>
</tbody>
</table>

[Image of a tooth with a lesion]

[Buttons: Repeat, Confirm]
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:

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Canary Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Hz</td>
<td>16 ± 8</td>
</tr>
<tr>
<td>5 Hz</td>
<td>8 ± 4</td>
</tr>
</tbody>
</table>
Case Study #1: Sound Enamel

Max Canary Number

Visit #1  Visit #2: 2 Months  Visit #3: 3 Months  Visit #3: 6 Months

ICDAS: 00  ICDAS: 00  ICDAS: 00  ICDAS: 00

Patient Assessment Visit

ICDAS: 00

ICDAS: 00

ICDAS: 00

ICDAS: 00

2Hz
5Hz
Case Study #2: Occlusal Caries

Graph showing the Max Canary Number for Visit #1 and Visit #2: 2 Months, comparing 2 Hz and 5 Hz.

Patient Assessment Visit

ICDAS: 02
Case Study #3: Remineralization

Graph showing Canine Number over visits with 2 Hz and 5 Hz treatments. The graph shows a downward trend over the visits.

Patient Assessment Visit:
- Visit #1: ICDAS 02
- Visit #2: 2 Months, ICDAS 02
- Visit #3: 4 Months, ICDAS 02
- Visit #4: 6 Months, ICDAS 02
Case Study #4: Remineralization

Graph showing the change in Canary Number over time for different visits:
- Visit #1
- Visit #2: 2 Months
- Visit #3: 3 Months
- Visit #4: 5 Months

Graph lines:
- Blue line labeled 2Hz
- Red line labeled 5Hz

Images of patient assessment visits:
- Visit #1: ICDAS: 02
- Visit #2: 2 Months: ICDAS: 02
- Visit #3: 3 Months: ICDAS: 02
- Visit #4: 5 Months: ICDAS: 02
Case Study #5: Remineralization

Canary Number

Visit #1: 2Hz
Visit #2: 6 Months 5Hz
Visit #3: 9 Months

ICDAS: 01

Patient Assessment Visit
Case Study #6: Proximal Caries Detection

![Graph showing Canary Number over time with 2Hz and 5Hz lines, and images of teeth at different assessment visits with ICDAS: 00.]
Case Study #7: Lesion Detection

ICDAS: 03

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-evaluation of current treatment plans
  – 4. Detect lesions at the point of restoration
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
Thank You!

by Quantum Dental Technologies