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The Canary System®



□ Pulses of laser light (660 nm) are shone on the tooth and the laser light is converted to four signals during a 5 second scan: 1) The strength of the converted heat (PTR Amplitude); 2) The time delay of the converted heat to reach the surface (PTR Phase); 3) The strength of the converted luminescent light (LUM Amplitude); 4) The time delay of the converted luminescent light (LUM phase).

□ The Canary Number is created from an algorithm combining these four signals and is directly linked to the status of the enamel or root surface crystal structure. Changes in the tooth microstructure, due to caries, causes corresponding changes in the optical and thermal properties of the tooth and the resultant PTR-LUM response.

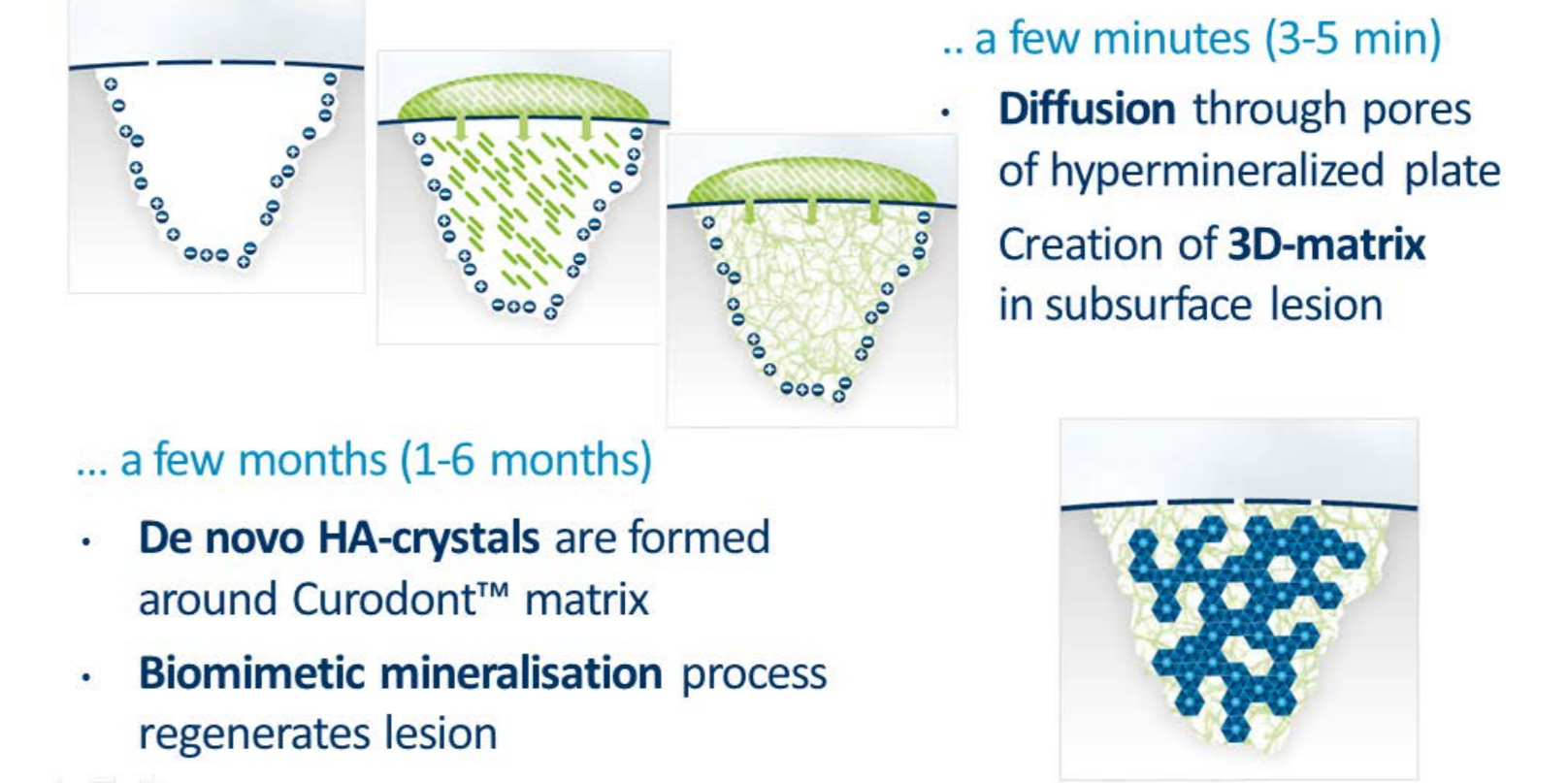
The Canary Lab



□ Using the same PTR-LUM technology as The Canary System, The Canary Lab outputs four images of a selected region of interest (ROI): 1) Camera image of the sample measured with the red box delineating the measurement area; 2) The Canary Lab image, which overlays the colour-coded Canary Numbers over the camera image, the Canary Scale, and average and standard deviations of the Canary Number; 3) The autoscaled image, which enhances the contrast of the Canary Lab image. To enhance the contrast, the software generates its own scale based on the highest and lowest Canary Numbers in the acquired ROI; 4) The pixelated version of the Canary Lab image.

Curodont™ Repair

Mechanism of Action



□ Curodont™ Repair is used for the treatment of early caries. It stops the demineralization process, and induces regeneration in form of in-depth remineralization and therefore helps to avoid invasive restorative treatment.

□ Curodont™ Repair includes a self-assembling peptide, that diffuses into the caries lesion body, forming a 3D matrix, around which, new hydroxyapatite crystals form (remineralization).

Objectives

□ This *in vitro* study evaluated the ability of: 1) The Canary System® and The Canary Lab to detect natural early caries on smooth surfaces; 2) Curodont™ Repair (Credentis AG, Windisch, Switzerland) to induce in-depth remineralization of enamel structure in natural early caries; and 3) The Canary System and Canary Lab to detect and monitor remineralization of teeth treated with Curodont™ Repair.

Materials & Methods

□ Fifteen extracted human teeth with natural early caries lesions on smooth surfaces were selected. Teeth were randomly assigned to three experimental groups (5 teeth/group): (1) Treatment Group (teeth treated with CR), (2) Control Group (teeth were left untreated), and (3) Placebo Group (teeth were treated with CR placebo).

□ Prior to treatment, sound and carious sites on one smooth surface of each tooth were selected and scanned with CS (baseline). A total of 102 sound and 84 carious sites were scanned using CS with three repeat measurements taken per site. A region ≤6mm x 6mm on each smooth surface of interest was scanned using CL (baseline). A total of 305 sound sites and 936 carious sites were scanned using CL.

□ CR was applied to Treatment Group and CR placebo was applied to Placebo Group. All examination sites were re-scanned with CS and CL after CR application (Day 0).

□ All ten teeth were stored in remineralization solution. The same sites were scanned with CS and CL after 7, 14, 30, and 50 days of remineralization.

□ For both CS and CL, A time series plot will be produced to show mean Canary Numbers of the four categories of samples (1) Sound sites on all Control Samples; 2) Carious sites on all Control Samples; 3) Sound sites on all Treated Samples; 4) Carious Sites on all Treated Samples) as functions of treatment time.

□ Polarized Light Microscopy (PLM) was performed at University of Texas in San Antonio as validation.

□ Statistically significant differences in Canary Numbers (CN) compared to baseline will be determined by Related-Samples Wilcoxon Signed Rank Test ($p < 0.05$).

Results

Representative Control Tooth

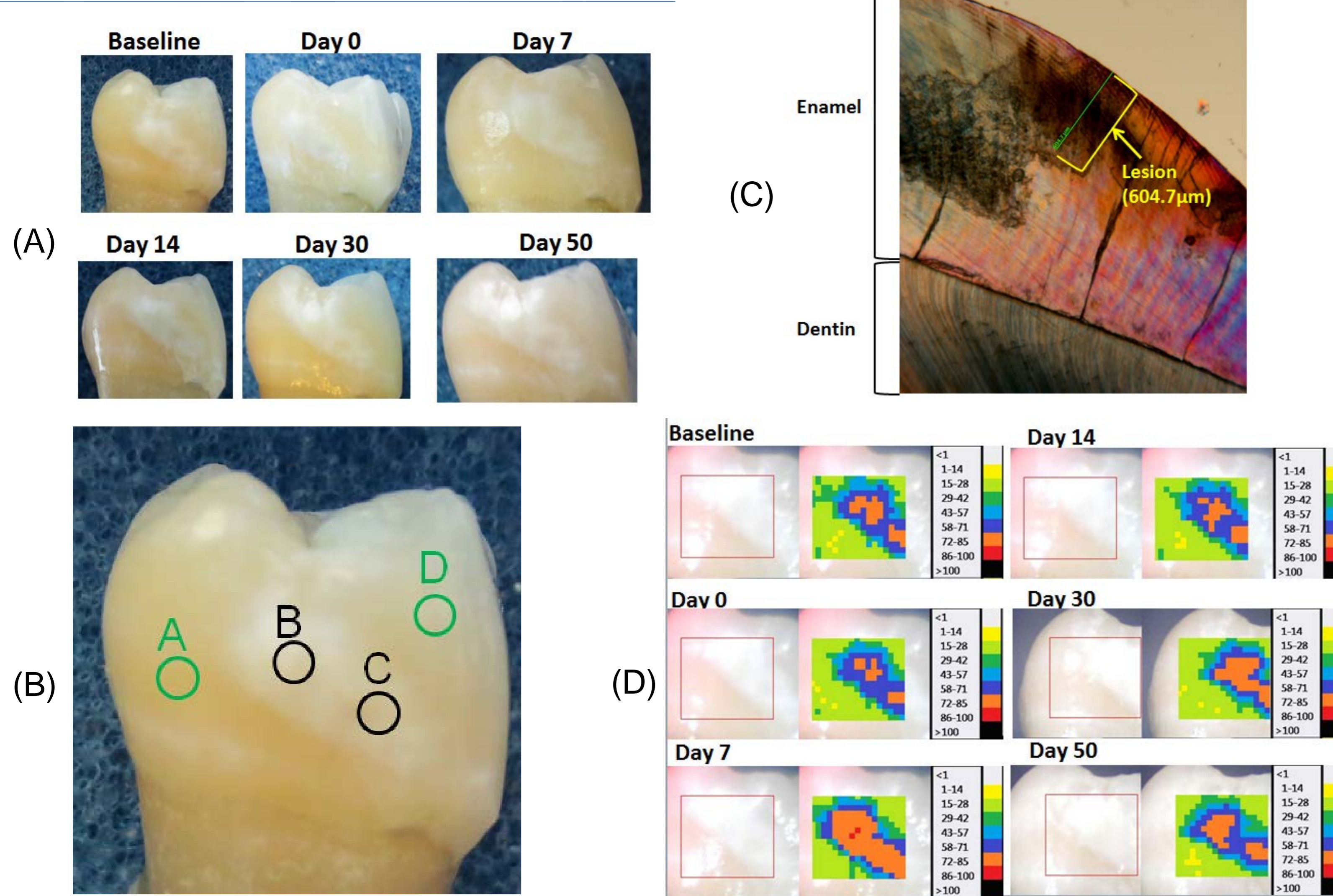


Figure 1. (A) Visually, the tooth surface did not change significantly in appearance over the treatment period. (B) CN of sound sites are outlined by green circles, and carious sites are outlined by black circles. (C) PLM image of examination site B at Day 50. (D) Canary Lab images of tooth were comparable throughout treatment period.

Representative Treated Tooth

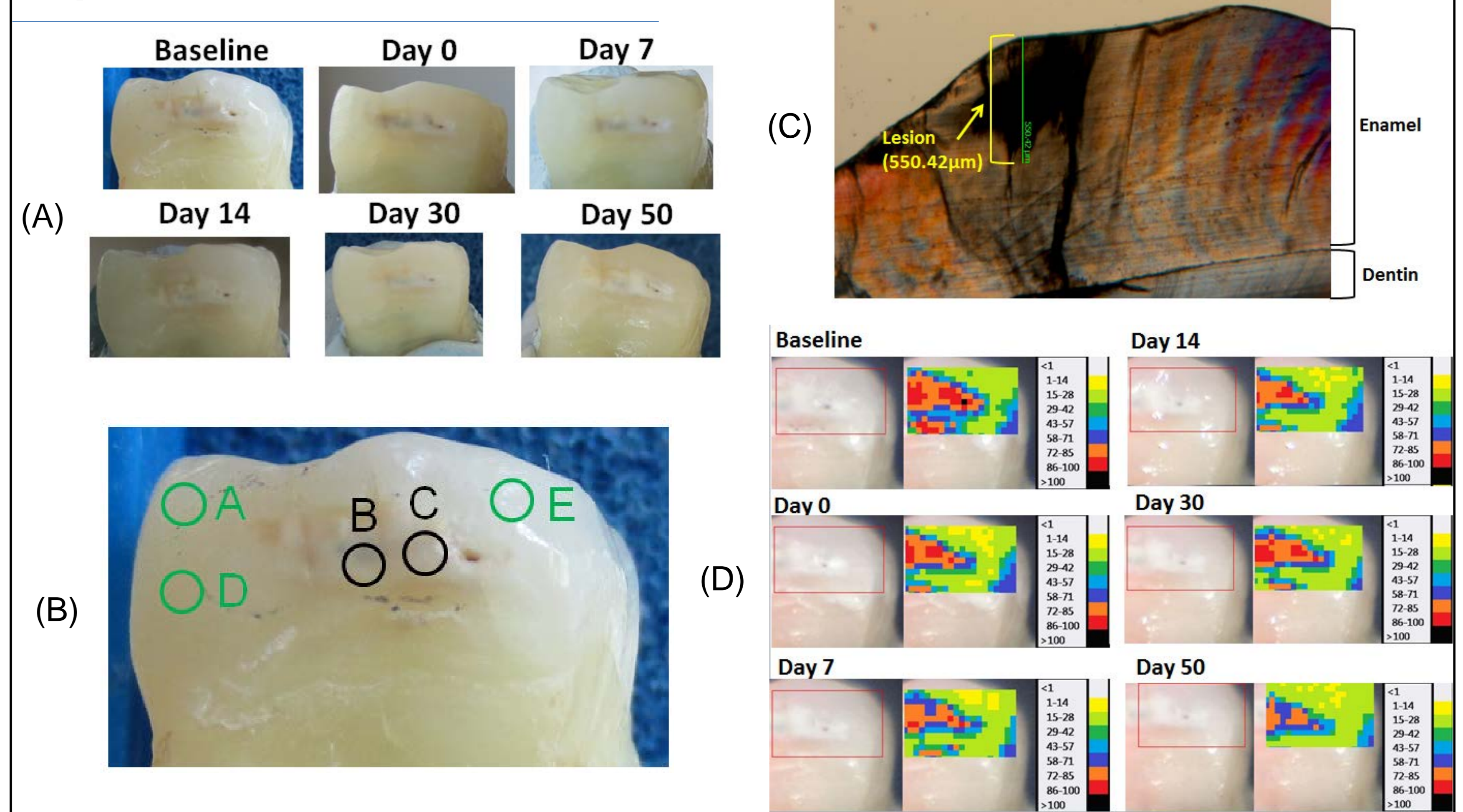


Figure 2. (A) Visually, the tooth surface did not change significantly in appearance over the treatment period. (B) CN of sound sites are outlined by green circles, and carious sites are outlined by black circles. (C) PLM image of examination site B at Day 50. (D) Canary Lab images of tooth, Remineralization of the treated tooth structures were reflected in the Canary Lab images by the fact that colors representing higher Canary Numbers were replaced with colors representing lower Canary Numbers.

Findings –The Canary System

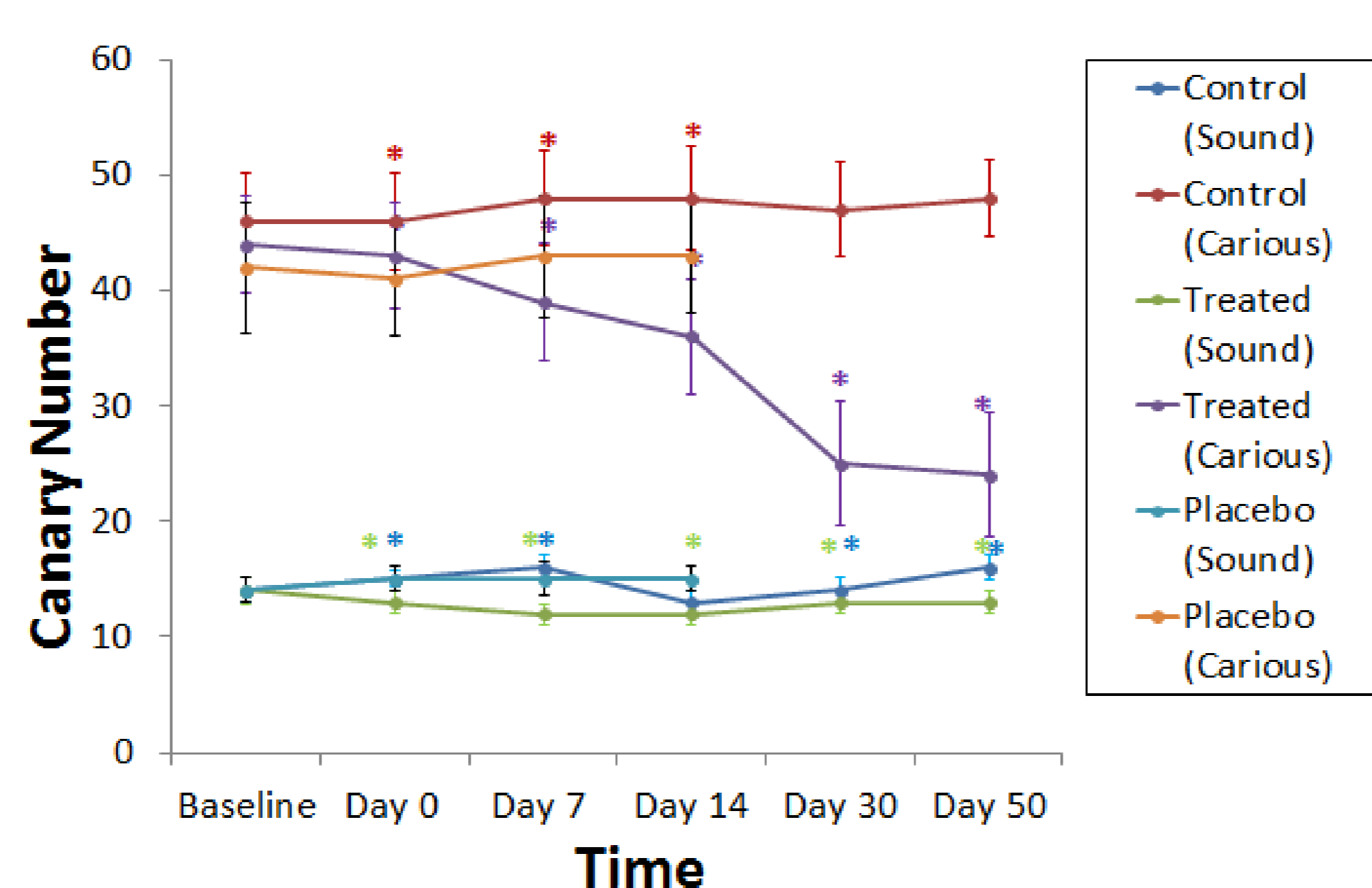
- PLM validation showed that in the:
 - Control Group (Sound Sites), 100% ($n = 30/30$) of the examination sites were found to be sound.
 - Control Group (Cariou Sites), 100% ($n = 27/27$) of the examination sites were found to be enamel caries.
 - Treatment Group (Sound Sites), 93% ($n = 39/42$) of the examination site were found to be sound, and 7% ($n = 3/42$) to be enamel caries.
 - Treatment Group (Cariou Sites), 100% ($n = 30/30$) of the examination sites were found to be enamel caries.

□ Average Canary Number (CN) of carious sites on treated samples decreased significantly (Related-Samples Wilcoxon Signed Rank Test; $p < 0.05$) from 44 at baseline to 24 after 50 days of remineralization.

□ No significant decreases in average CN of carious sites on control samples were observed.

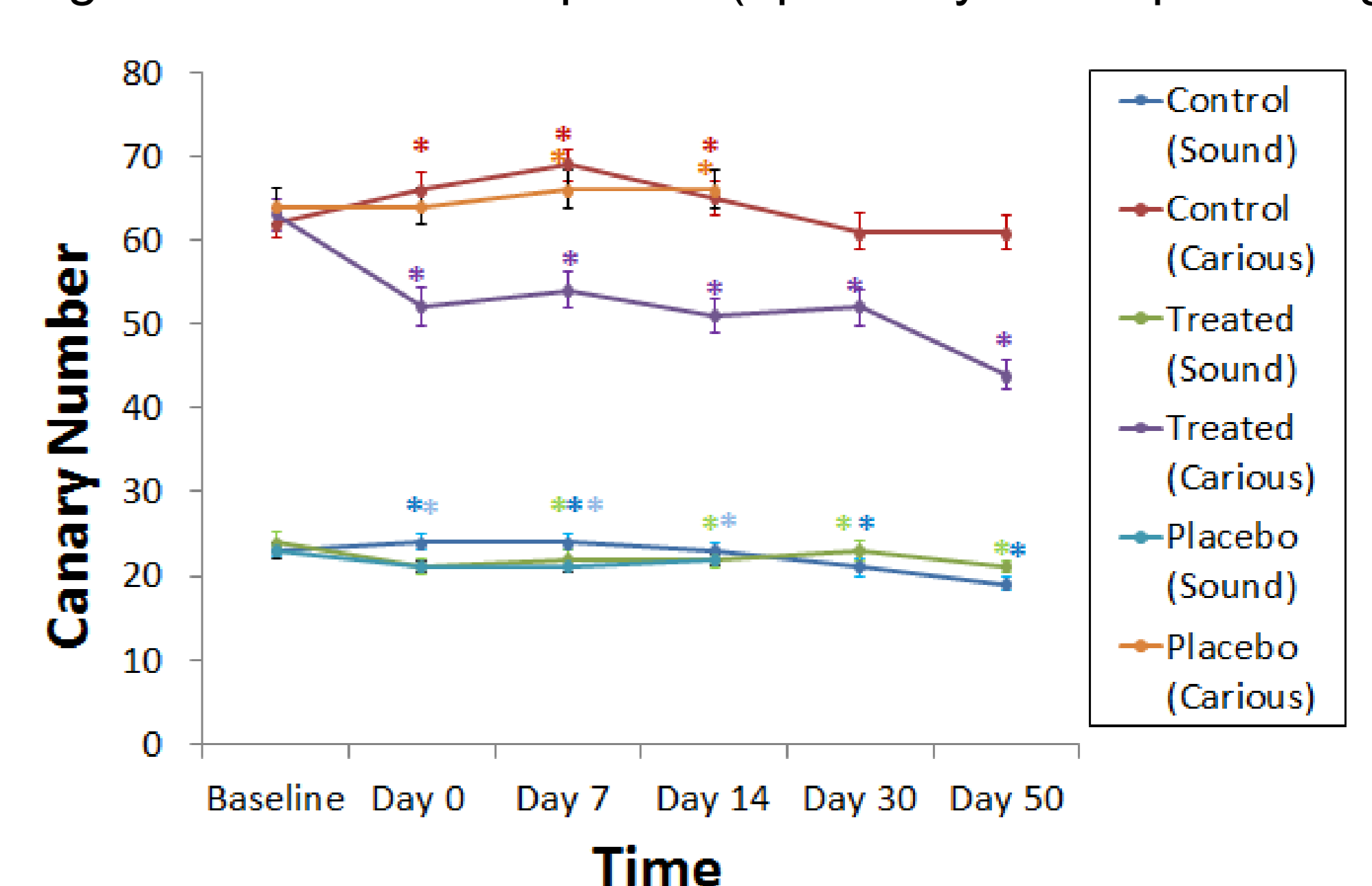
□ No significant decrease in average CN of carious sites on placebo samples were observed up to Day 14 of remineralization treatment.

□ Average Canary Numbers of sound sites of all three sample groups < 20 throughout the treatment period (up to Day 14 for placebo group).



Findings –The Canary Lab

- Average Canary Number (CN) of carious sites on treated samples decreased significantly from 63 at baseline to 44 after 50 days of remineralization.
- In contrast, no significant decreases in average CN of carious sites on control samples were observed throughout treatment period of 50 days.
- No significant decrease in average CN of carious sites on placebo samples were observed up to Day 14 of remineralization treatment.
- Average Canary Numbers of sound sites of all three sample groups ≤ 24 throughout the treatment period (up to Day 14 for placebo group).



Conclusions

- This study demonstrated the potential of The Canary System and Canary Lab to detect natural early carious lesions on smooth surfaces and monitor remineralization of caries lesion treated with Curodont Repair.
- Placebo group study is still under progress but has shown no remineralisation up to day 14.

