# A One Year Double Blind Placebo Controlled Clinical Study to Assess Progression of Non-Cavitated Occlusal Caries Lesions in First Permanent Molars of Children Using Sugarless BasicBites® Soft Chew Confections

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**Abstract:**

**Objective:** The purpose of the present investigation, a double blind placebo controlled clinical study, was to assess progression of non-cavitated occlusal caries lesions in first permanent molars of children using sugarless soft chew confections (BasicBites®, Ortek Therapeutics, Roslyn, NY USA), containing arginine bicarbonate and calcium carbonate (AlkaGen Technology®, Ortek Therapeutics, Roslyn, NY USA).

**Methods:** Two hundred children from five elementary schools located in Sucre Municipality, Caracas, Venezuela were entered into this one-year clinical study, who showed the following: (i) age between 6 and 11 years (ii) erupted sound or non-cavitated occlusal caries lesions in their first permanent molars and (iii) some caries in their primary or permanent teeth. All children were examined visually by a single trained calibrated examiner, who used good artificial light, mirror and probe. All of the examinations were conducted under standardized conditions using dental unit facilities built into a mobile clinic. The children were randomly divided into two groups (A and B). Prior to initiation of the study, the protocol and pertinent documents were reviewed and approved by the Stony Brook University Institutional Review Board. Written informed consent to take part in this study was obtained from a parent or legal guardian.

Of the 200 children initially selected, 164 finished the experiment and provided complete data. These subjects generated 1,930 occlusal pits and fissures. Group A received sugar alcohol based soft chew confections (i.e. sugarless placebo) that did not contain arginine bicarbonate and calcium carbonate. Group B received sugar alcohol base soft chew confections (i.e. sugarless BasicBites®) that did contain arginine bicarbonate and calcium carbonate. One supervised confection was given at the school and one at home by the parents in the evening after brushing the teeth and before going to bed. Packaging, taste and appearance of both types of soft chew confections were identical. Both groups continued with their normal hygiene regimens, which included brushing the teeth throughout the study with commercially available 1450 ppm fluoride toothpaste.

**Results:** After totaling the number of sound, non-cavitated and cavitated lesions from the four molars at baseline and at 12 months for each experimental group, there were more non-cavitated carious lesions in Group B when compared to Group A. In contrast, there were more cavitated lesions in Group A when compared to Group B. Working with them as two separate groups, non-cavitated and cavitated, statistical comparison was done using the Fisher test. A statistically significant difference between the two groups was observed (Fisher-test p=0.03). A 42% reduction was found in the non-cavitated lesion progression in the permanent first molars in Group B (BasicBites®) compared to Group A (placebo) by the end of 12 months.

**Conclusion:** The results of this one-year clinical investigation demonstrates that a sugar free soft chew (BasicBites®) containing arginine bicarbonate and calcium carbonate is able to inhibit the progression of non-cavitated occlusal caries lesions in the first permanent molars of children.

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Conflict of interest: Dr. Israel Kleinberg, Distinguished Professor and Director of Translational Oral Biology at Stony Brook University, School of Dental Medicine serves on the Board of Directors of Ortek Therapeutics Inc. Dr. Ana Maria Acevedo is a Research Scientist at Stony Brook University, School of Dental Medicine. Drs. Kleinberg and Acevedo are two of the investigators who conducted this study and have a financial interest in Ortek Therapeutics. Therefore, neither Dr. Kleinberg nor Dr. Acevedo were involved in the recruitment of subjects, obtaining their consent or in performing any clinical evaluations in this study.