

Research Report

Treatment of buccal caries with REGENAMEL® – GUIDED ENAMEL REGENERATION

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WILD REGENAMEL®

Treatment of buccal caries with REGENAMEL® – GUIDED ENAMEL REGENERATION

Introduction

The aim of this study was to evaluate the biomimetic mineralization induced by REGENAMEL® (P11-4) in comparison to a fluoride varnish (Duraphat®) in a prospective, randomised, controlled, split-mouth study design.

Materials and Methods

35 subjects (N) with a total of 45 tooth pairs (n) showing initial buccal carious lesions were included in this randomised, controlled, split-mouth trial. The study teeth's white spot lesions (WSL) were randomly allocated to the test (REGENAMEL®) and control (Duraphat®) group and followed up to 1 year (D360). Standardised photographs of study teeth were taken by the investigators

of the study teeth before the treatment (D0) as well as 30 (D30), 90 (D90), 180 (D180) and 360 (D360) days after the treatment. All WSL were morphometrically evaluated on calibrated pictures by a blinded, external assessor.

Results

First evaluation showed significant differences between the test and control group over all study time points. The 95 % Confidence Interval (95 % CI) showed a sustainable decrease in the size of the WSL over a period of one year for the REGENAMEL® group whereas the fluoride control group showed a stabilisation in the size of the WSL.

Study design

Randomised, gold-standard controlled, assessor and patient blinded, split-mouth clinical trial

Study design

35 subjects (N) with a total of 45 study teeth pairs (n): One tooth of each pair was randomly assigned to the test group (REGENAMEL®, P11-4), the other to the control group (Duraphat®, 22'600 ppm fluoride).

Main selection criteria

Inclusion:

- Two buccal carious lesions which do not require invasive intervention
- Willing to keep good oral hygiene throughout the study
- Age \geq 10 years and \leq 65 years

Exclusion:

- Secondary carious lesion on same tooth surface
- Carious lesions due to orthodontic treatment
- Enamel aberration and evidence of tooth erosion
- Abnormality in salivary flow (i.e. due to medication, xerostomia)

Diagnostics

- Standardised pictures taken before the treatment (D0) and 30 (D30), 90 (D90), 180 (D180) and 360 (D360) days after the treatment
- Morphometric evaluation of WSL on the basis of standardised and colour-calibrated pictures by a blinded, external assessor

Results

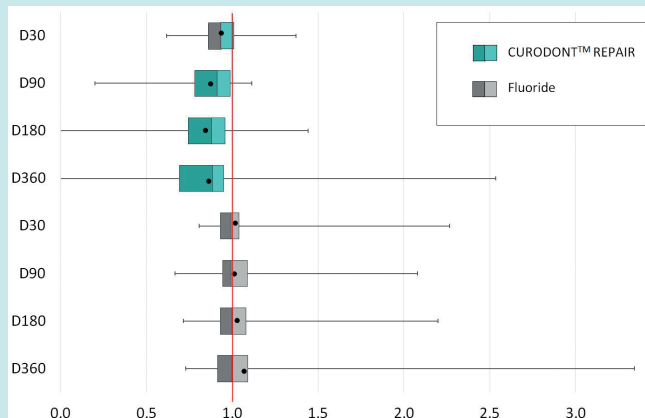


Chart 1: Tukey's plot showing the change in size of white spot lesions over time (N=35; n=45; box: interquartile range; vertical line in the box: median; black bullet: mean; whiskers: range of distribution; green: REGENAMEL® group; grey: fluoride group).

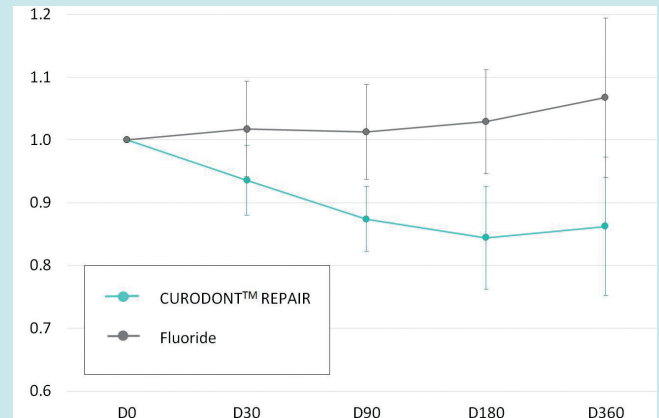


Chart 2: Plot showing mean size (bullets) and 95 % confidence interval (whiskers) of the white spot lesions over time (N=35; n=45)

Treatment

Test – REGENAMEL®

- Professional dental cleaning of study lesions
- 2 % NaOCl (20 sec)
- 35 % Phosphoric acid (20 sec)
- Thorough rinsing with water (20 sec) and air-drying of study lesions
- Application of REGENAMEL® (3–5 min)
- D180: Application of fluoride varnish

Control – Duraphat® at D0; D90 and D180:

- Application according to manufacturer's instructions

Follow-ups

- D30
- D90 (test group: Curodont Repair respectively control group: fluoride application)
- D180 (test and control group: fluoride application)
- D360

Conclusion

Guided Enamel Regeneration by REGENAMEL® leads to a decrease in the size of the white spot lesions within a 6-month period.

Literature

- Bröseler, F. et al. (2013): 6th ConsEuro, May 9-11, 2013, Paris, France, Clin Oral Invest 17(2013): 1055
- Bröseler, F. et al. (2015): Deutscher Zahnärztetag, November 6-7, 2015, Frankfurt am Main, Germany; <http://www.dtz.de/kurzvortraege.php>
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WILD REGENAMEL®

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and similar defects



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www.wild-dental.com

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