

Research Report

Treatment of occlusal caries with REGENAMEL® and Fluoride

Authors

University of Greifswald
Department of Preventive and Pediatric Dentistry
17475 Greifswald, Germany

Mohammad Alkilzy, Ahmad Tarabaih, Christian Splieth



WILD REGENAMEL®

Treatment of occlusal caries with REGENAMEL® and Fluoride

Safety, application and clinical effect of REGENAMEL®* in children with early occlusal caries

Summary

Occlusal surfaces of erupting permanent molars are highly prone to caries. The self-assembling peptide (P11-4) has been proven to enhance biomimetic mineralization of early carious lesions.

The aim of this study was to evaluate safety, clinical applicability and effect of using P11-4 (REGENAMEL®) in non-invasive treatment of early occlusal lesions.

Method

70 patients (28 females, mean age 10.03 years \pm 2.7, dft 2.8 \pm 3.1, DMFT 1.3 \pm 2.5) with early occlusal lesions (ICDAS-II:1-3) on first or second permanent molars at eruption were allocated in this randomized, controlled, single blinded post-marketing study either to test

(REGENAMEL® and Duraphat®) or control (Duraphat®). Safety and applicability was evaluated using dentist's / patient's questionnaires about adverse events, difficulties of application and satisfaction with the procedure. Lesions were assessed at baseline and recalls after 3 and 6 months regarding clinical status (ICDAS-II), caries activity and DIAGNODent. At every recall fluoride varnish was applied and patients received oral health instructions.

Results

Preliminary data showed good patient acceptance for REGENAMEL®. Investigators considered the application as much easier as a composite filling or even a fissure sealant. In all cases, no adverse events or allergic reactions have been observed after application.

Study size

Control group:
35 treated with Duraphat® (Fluoride 22,000 ppm)

Test group:
35 treated with REGENAMEL® and Duraphat®

Main Selection criteria

- 1) Occlusal caries (ICDAS 1 or 2) on a freshly erupted molar
- 2) No need for imminent interventional treatment
- 3) Informed consent of parent / guardian and patient

Study design

Randomised, assessor blinded, gold standard controlled clinical trial

Diagnostic

DIAGNODent; ICDAS-II activity status (visual)

* REGENAMEL® is a registered Trademark of Dr. Wild & Co. AG, Switzerland. Study was conducted in Germany with material marketed as CURODONT™ REPAIR.

Treatment protocol

- 1) Professional dental hygiene treatment
- 2) 2% Sodium-Hypochloride (20 s),
to remove the pellicle
- 3) Etching Gel (35% Phosphoric Acid; 20 s)
to remove amorphous mineral from the pores
to the subsurface lesion
- 4) Neutralising with water (20 s)
- 5) Test group:
Application of REGENAMEL®, (3–5 min)
- 6) Test- and control group:
Application of Duraphat®

Follow-up procedure

Follow-up D90 (Additional application of Duraphat®)

Follow-up D180 (Last visit)

Result

Criteria	Duraphat®	REGENAMEL® & Duraphat®
DIAGNODent change D ₀ to D ₉₀	-2.7	-14.7 (p=0.0274)
to D ₁₈₀	-1.1	-18.6 (p=0.0112)
Caries activity	D ₀ : 100 % D ₉₀ : 80 % D ₁₈₀ : 66 %	D ₀ : 100 % D ₉₀ : 48 % (OR=18.1; p=0.0015) D ₁₈₀ : 20 % (OR=13.0; p<0.0005)

Conclusion

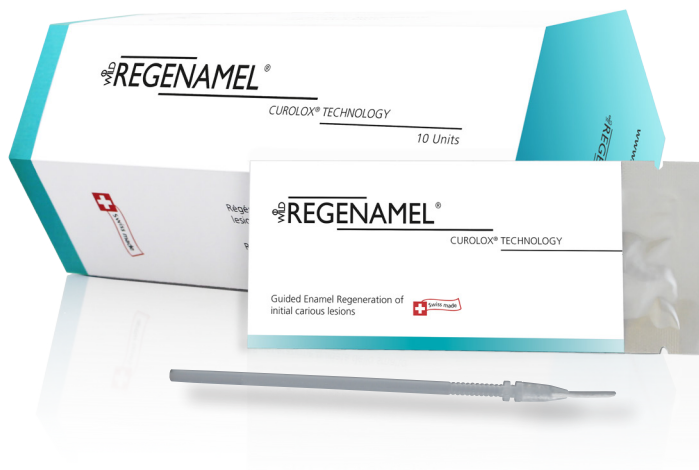
Duraphat® was effective in stopping the progression of caries. However, the additional treatment of REGENAMEL® (followed by Duraphat®), led to a significant decrease in lesion progression and its activity.

Literature

Alkilzy et al. (2014): 61st ORCA, July 2–5, 2014, Greifswald, Germany; Caries Research, (2014), Abstract #61
Alkilzy et al. (2015): 62nd ORCA, July 1-4, 2015, Brussels, Belgium; Caries Research, (2015), Abstract #30

WILD REGENAMEL®

Natural filling of initial carious lesions
and similar defects



For further information,
please visit our Website:

www.wild-pharma.com



Dr. Wild & Co. AG | Hofackerstrasse 8 | 4132 Muttenz
www.wild-pharma.com | info@wild-pharma.com

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