Research Report

Treatment of occlusal caries with REGENAMEL® and Fluoride

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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 ±2.7, dft 2.8 ±3.1, DMFT 1.3 ±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®

Study design

Randomised, accessor blinded, gold standard controlled clinical trial

Diagnostic

DIAGNOdent; ICDAS-II activity status (visual)

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

* 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®

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and similar defects

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