

Research Report

Treatment of buccal caries with CURODONT™ REPAIR. Summary of three randomised controlled trials.

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Clinical effect of CURODONT™ REPAIR in treatment of buccal caries

Introduction

Buccal surfaces are known to develop caries, especially in conjunction with orthodontic brackets. The self-assembling peptide (SAP P11-4) has been proven to enhance biomimetic mineralisation of early carious lesions.

The aim of these randomised controlled trials (RCTs) was to evaluate the safety and clinical effect of using SAP P11-4 (CURODONT™ REPAIR) in non-invasive treatment of buccal caries, either directly after debonding (RCT 3) or independently of orthodontic treatment (RCT 1 & 2).

Method

RCT 1: 37 subjects (13–36 years) with 90 early carious lesions (not after orthodontic debonding) were included in this randomised controlled blinded split-mouth study. Test lesions received CURODONT™ REPAIR on days 0 and 90, while control lesions received fluoride varnish (Duraphat® 22,600 ppm fluoride) on days 0 and 90. All lesions received fluoride varnish on day 180. Follow-up until day 360. Morphometric assessment of lesion size, microcavity progression on standardised clinical photographs and subjective investigator assessment [1].

RCT 2: 44 subjects (average 27.1 years) with 88 early carious lesions (not after orthodontic debonding) were included in this randomised controlled quadruple-blinded split-mouth study with sequential design. Test lesions received CURODONT™

REPAIR on day 0 and fluoride varnish on day 90, while control lesions received placebo on day 90 and fluoride varnish (Duraphat® 22,600 ppm fluoride) on day 90. Evaluation: Morphometric assessment of lesion size on standardised clinical photographs and subjective investigator assessment [2].

RCT 3: 23 subjects with 46 early carious lesions were included directly after debonding of orthodontic brackets in this randomised controlled blinded split-mouth study. Test lesions received CURODONT™ REPAIR on day 0, control lesions received no special treatment. Morphometric assessment of lesion size by Shadepilot and progression of caries by CarieScan [3].

Results

Combined data from the three RCTs showed superior white spot lesion (WSL) regression (-16% to -19% non-orthodontic WSLs, -33% orthodontic WSLs) when treated with CURODONT™ REPAIR compared to fluoride varnish (+3 to -3% non-orthodontic WSLs) and placebo (-7% non-orthodontic WSLs, -24% orthodontic WSLs).

Orthodontic WSLs treated with CURODONT™ REPAIR showed superior regression compared to placebo according to CarieScan (change in value: -30 vs -10) and non-orthodontic WSLs with microcavities exhibited less microcavity growth over 1 year when treated with SAP P11-4 (+29% vs +88%).

Combined study size

- 89 teeth treated with fluoride varnish (Duraphat® 22,000 ppm fluoride)
- 112 teeth treated with CURODONT™ REPAIR
- 67 teeth treated with placebo/no treatment

Main selection criteria

- Buccal caries after debonding (RCT 3) or not after debonding (RCT 1 & 2)
- No need for imminent interventional treatment
- Informed consent of patient/guardian

Study design

- RCT 1: Randomised gold-standard controlled blinded split-mouth study
- RCT 2: Randomised gold-standard and placebo-controlled quadruple-blinded split-mouth study
- RCT 3: Randomised placebo-controlled blinded split-mouth study

Diagnostic

- RCT 1–3: WSL size on standardised photographs (RCT 1 & 2) or by Shadepilot (RCT 3)
- RCT 1: Microcavity progression
- RCT 1 & 2: Investigator assessment of progression
- RCT 3: Caries progression by CarieScan

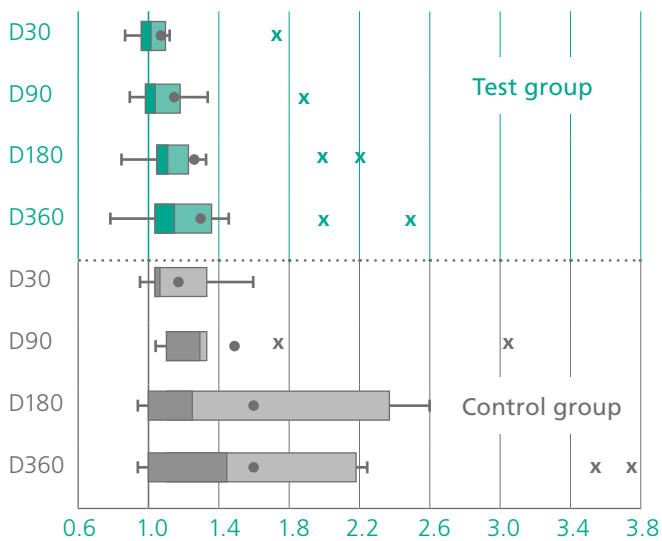
Follow-up

- RCT 1: Days 30, 90, 180 and 360
- RCT 2: Days 30, 90, 180 and 270
- RCT 3: Days 45, 90 and 180

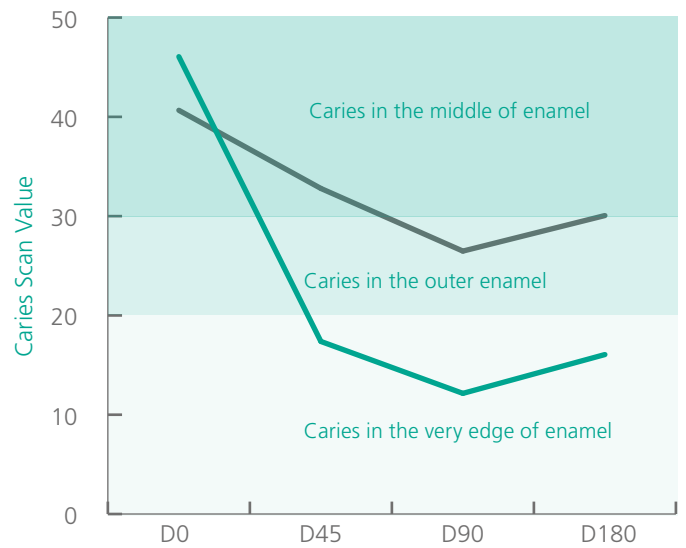
Surrogate – regression of WSL size (RCT 1–3)

Comparison	From Study	Change in Lesion Size (SD)		p-Value
		SAP P11-4	Control	
SAP P11-4 vs placebo (non-orthodontic)	RCT 2	-19 %	-7 %	>0.01
SAP P11-4 vs placebo (orthodontic)	RCT 3	-33 %	-24 %	tbd
SAP P11-4 vs fluoride varnish	RCT 1 & 2	(-16 %) – (-19 %)	(+3 %) – (-3 %)	>0.01
SAP P11-4 + fluoride varnish vs fluoride varnish	RCT 2	-20 %	-4 %	0.003

Microcavity progression (RCT 1)



Regression of caries according to CarieScan (RCT 3)



Conclusion

WSLs show a spontaneous regression after debonding of an orthodontic bracket, which can be enhanced with CURODONT™ REPAIR treatment. When non-orthodontic buccal white spots are treated, neither placebo nor fluoride varnish show a significant WSL reduction. Treatment with CURODONT™ REPAIR leads to a noticeable WSL reduction, indicating remission of the caries, which was also monitored by a caries diagnostic and resulted in less progression of cavities, indicating a higher clinical success rate.

Literature

1. Brösel, F., et al., Behandlung primär kariöser Schmelzläsionen mittels selbstorganisierender Peptide – erste Daten einer kontrollierten klinischen Studie, in Deutscher Zahnärztetag 2015. 2015: Frankfurt am Main, Germany.
2. Manna, A., et al., RCT Investigating the Efficacy of Self-Assembling Peptide for Early Caries, in IADR. 2018: London, GB.
3. Ratzmann, A., et al. Evaluation von «CURODONT™ REPAIR» in der Initialkariestherapie nach Multibracketbehandlung. in 91. Jahrestagung der DGKFO. 2018. Bremen, Germany.