Treatment of occlusal caries with CURODONT™ REPAIR and Fluoride

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Safety, application and clinical effect of CURODONT™ REPAIR 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 (CURODONT™ REPAIR) 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 (CURODONT™ REPAIR 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 CURODONT™ REPAIR. 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 CURODONT™ REPAIR 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, accessor blinded, gold standard controlled clinical trial

Diagnostic

DIAGNOdent; ICDAS-II activity status (visual)
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 CURODONT™ REPAIR, (3–5 min)
6) Test- and control grup: Application of Duraphat®

Follow-up procedure
Follow-up D90 (Additional application of Duraphat®)
Follow-up D180 (Last visit)

Result

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Duraphat®</th>
<th>CURODONT™ REPAIR &amp; Duraphat®</th>
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</thead>
<tbody>
<tr>
<td>DIAGNOdent change D₀ to D₉₀</td>
<td>-4.4</td>
<td>-13.0 (p=0.06)</td>
</tr>
<tr>
<td>to D₁₈₀</td>
<td>-1.1</td>
<td>-18.6 (p=0.005)</td>
</tr>
<tr>
<td>Caries activity</td>
<td>D₀: 97%</td>
<td>D₀: 100%</td>
</tr>
<tr>
<td>D₉₀: 80%</td>
<td>D₉₀: 46% (OR=4.7; p=0.02)</td>
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<tr>
<td>D₁₈₀: 65%</td>
<td>D₁₈₀: 20% (OR=7.6; p&lt;0.001)</td>
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</tbody>
</table>

Conclusion

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

Literature

www.credentis.com; www.curodont.com
Natural filling of initial carious lesions and similar defects

Regenerating tooth gel for intensive prophylaxis

For further information, please visit our Website:

www.curodont.com