

Effect of Curodont™ Repair in Patients with Proximal Carious Lesions: Uncontrolled, Non-Interventional Study – intermediate report

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1 abstract

The prevalence of caries on the proximal tooth surface is high and the interdental location of the lesion a challenging site for treatment. In this study patients with early proximal caries (E1 and E2) are treated with the regenerative product Curodont™ Repair. It contains P11-4, a self-assembling-peptide (SAP), that is applied as a solution onto the lesion surface. P11-4 then diffuses into the subsurface body of the early carious lesion where it forms a 3-D fibril network. In the process of a few months Ca²⁺ and PO₄³⁻ ions, excessively present in the patient's saliva, attach to the nucleation sites of the P11-4-network and induce formation of *de novo* hydroxyapatite (HA) crystals [1]. The aim of the present study is to evaluate the efficacy of Curodont™ Repair in respect to regenerating enamel in patients with early proximal caries.

2 material and method

25 patients with an early, untreated, proximal carious lesion (E1 and E2) are enrolled in this prospective study and treated with a single Curodont™ Repair application. Follow-ups are 6 (D₁₈₀) and 12 months (D₃₆₅) after treatment (D₀). Assessments on each visit are:

- VAS progression & size (visual analogue scale, -50 mm to +50 mm)
- standardised x-ray

3 results

The study is on-going. 10 patients (19-59 years old, 5 male, 5 female) with 6 months (D₁₈₀) data were available for interim analysis and assessed by investigators (figure 1-3).

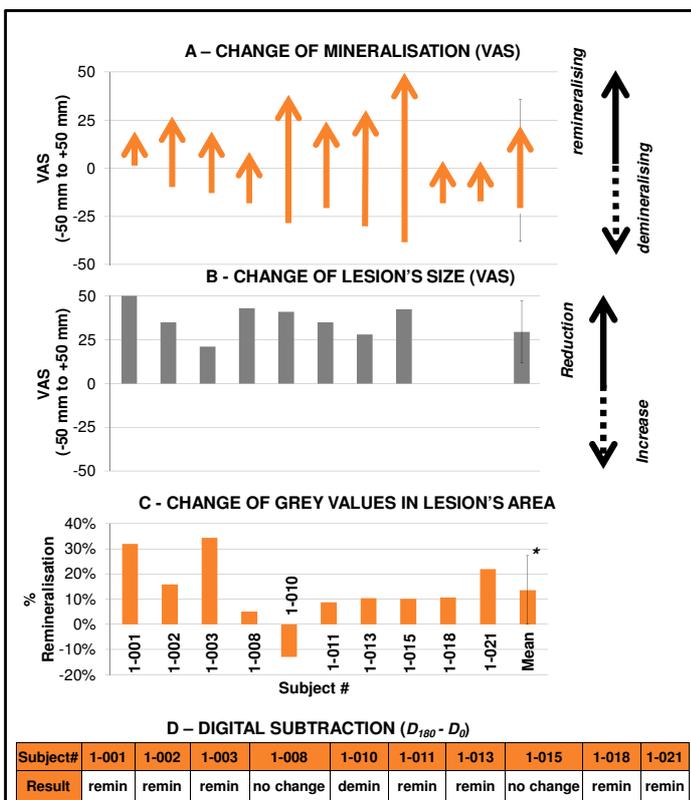


Figure 1:
A - lesion's progression (VAS): Δ remineralisation from D₀ to D₁₈₀. 10/10 lesion's were assessed as «remineralising» (Δ mean_{remin} = 41.7mm ± 24.9).
 Note: D₀ according to patient's history and caries risk profile.
B - lesion's size from from D₀ to D₁₈₀ (VAS): 8/10 lesions were assessed as «reduction in lesion size» (VAS_{mean} = -29.5mm ± 17.6), 2/10 as «unchanged».
C - change of grey values in lesion's area from D₀ to D₁₈₀: 9/10 lesions showed remineralisation (mean_{remin} = 13.7% ± 13.6, p=0.011* (significant)).
D - Digital subtraction x-rays (D₁₈₀ - D₀): 7/10 lesions showed remineralisation, 2/10 «no change», 1/10 demineralisation.
 Note: white pixels in lesion's area: remineralisation; black pixels: demineralisation; greyish appearance: no change

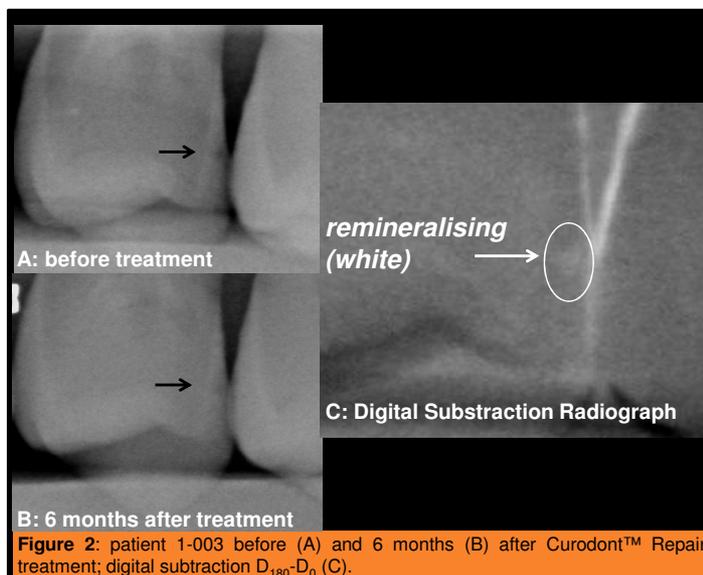


Figure 2: patient 1-003 before (A) and 6 months (B) after Curodont™ Repair treatment; digital subtraction D₁₈₀-D₀ (C).

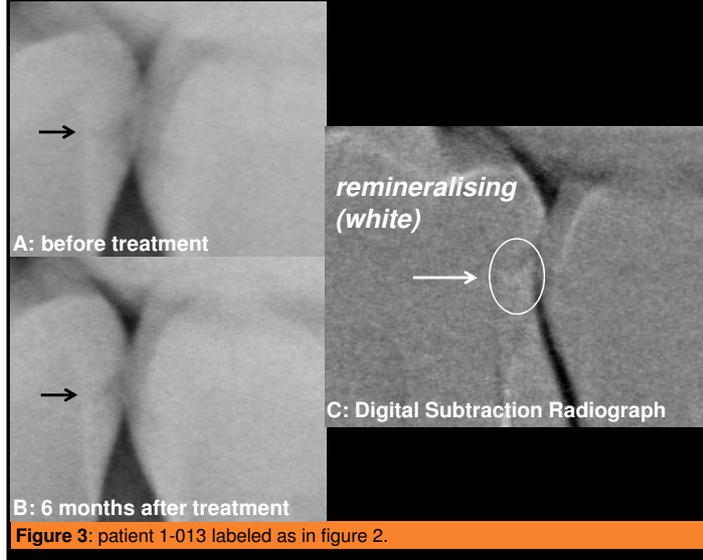


Figure 3: patient 1-013 labeled as in figure 2.

4 discussion

Preliminary results of 10 patients with 6 months follow-up demonstrate *in-depth* remineralisation of the lesion after treatment with Curodont™ Repair. Digital subtraction analysis demonstrated increased remineralisation within the subsurface lesions and was confirmed by clinical assessment supporting the biomimetic mineralisation approach first presented by Kirkham et al. [1]. So far 6 months data of the first 10 patients are promising - nevertheless, more data is needed to show the long-term-effect of the treatment.

5 conclusion

Biomimetic mineralisation with Curodont™ Repair is a painless, tooth-preserving, biological treatment for *in-depth* remineralisation that seems to be a promising approach for the treatment of early, progressing, interdental carious lesions. In respect to the challenging interdental treatment site, its application is convenient and fast.

literature

[1] Kirkham et al., 2007: «Self-assembling Peptide Scaffolds Promote Enamel Remineralization».