

Effect of Curodont™ Repair in Patients with Buccal Carious Lesions:

A Mono-centre, Single-blinded, Randomised, Controlled Split-mouth Study – intermediate report

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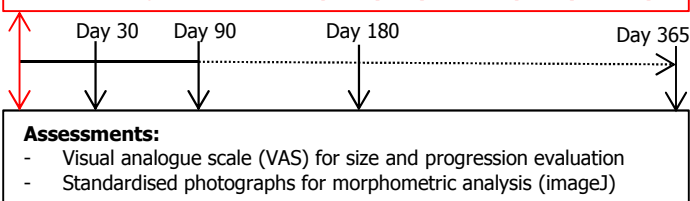
1 Abstract

Fluoride containing agents are universally accepted for the treatment of early carious lesions. However, fluoride's mechanism of action is only topical [1] within a reach of a few μm into enamel respectively into the subsurface carious lesion. Non-cavitated enamel carious lesions extend up to 400 μm in depth. Curodont™ Repair contains the self-assembling peptide (SAP) P11-4 that diffuses deeply into the subsurface body of the carious lesion where it forms a 3-dimensional matrix. Ca^{2+} and PO_4^{3-} ions, the components of enamel, are sufficiently available from the patients' saliva and attach to the matrix, inducing *de-novo* formation of hydroxyapatite (HAP) crystals [2]. The aim of the present study is to evaluate the remineralisation efficacy of Curodont™ Repair in respect to a fluoride varnish in patients with early buccal carious lesions.

2 Material & Method

25 patients with at least two early buccal carious lesions (arrested or progressive) are enrolled in this prospective, randomised, single-blinded, controlled split-mouth study. All study patients agreed to participate by signing an informed consent. The study is approved by an ethical committee.

Treatment Day 0: Curodont Repair (test) vs. Duraphat (control)



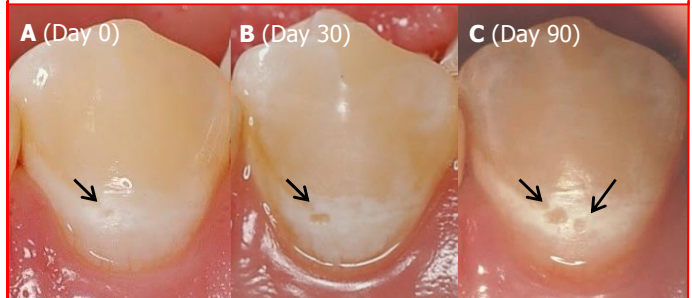
3 Results

7 Patients, 2 at D30 and 5 at D90 follow-up (13-30 years old; 3 male and 4 female) were assessed. The VAS shows for both groups "remineralisation" and "reduction in size of lesion" (data not shown). Blinded morphometric analysis (table 1) showed a significant difference in size ($p=0.042^*$) for Curodont™ Repair (mean = 20.2 % reduction) compared to Duraphat® (mean = 15.2 % increase); figure 1 and 2.

Table 1: preliminary results: subject information and results for morphometry (% change in lesion size compared to D0; a positive figure corresponds to an increase of lesion's size and a negative figure to a decrease in size.

Subject #	Tooth	MORPHOMETRY - % CHANGE IN SIZE			
		Day 30		Day 90	
		Curodont™ Repair	Duraphat®	Curodont™ Repair	Duraphat®
1-007	25/14	-3.4	0.1	-25.8	2.1
1-017	34/35	-3.1	1.9	-10.9	0.3
1-012	16/26	-16.9	2.6	-26.3	-5.0
1-013	34/35	-32.0	-13.9	-45.9	-2.7
1-002	13/23	-1.8	64.3	1.1	97.7
	14/24	8.9	-8.8	-13.7	-0.9
1-016	12/13	7.1	-2.0		
	21/22	5.0	-3.8		
1-003	34/45	-4.3	61.4		
	35	-22.5			
	Mean	-6.3	11.3	-20.2	15.3
	Std. Dev.	±13.4	±29.7	±16.2	±40.5
	T-test (p)	0.163		0.042* (*significant)	

Duraphat® (control)



Curodont™ Repair (test)



Figure 1: patient 1-013 - tooth 35 (Duraphat®, A-C) and tooth 34 (Curodont™ Repair, D-F); picture before (A,D), 1 month (B,E) and 3 months (C,F) after treatment. Note that tooth 35 (control) shows an increase in cavity's size and number and tooth 34 (test) remineralisation at D90 (C, F) compared to D0 (A, D).

Duraphat® (control)

Curodont™ Repair (test)



Figure 2: patient 1-003 - tooth 45 (Duraphat®, A-B) and tooth 35 (Curodont™ Repair, C-D); picture before (A,C) and 1 month (B,D) after treatment. Note that tooth 45 (control) shows further demineralisation whereas tooth 35 (test) shows remineralisation at D30 (B, D) compared to D0 (A, C).

4 Discussion & Conclusion

Interim results (5 patients D90; 2 patients D30) indicate a superior remineralisation of the white spot lesions for Curodont™ Repair compared to Duraphat®. Fluoride's anti-caries effect is predominantly in biofilm and the top enamel layer [1], whereas SAPs diffuse into the subsurface body of the carious lesion where, indicated by *in vitro* data, the formed matrix induces formation of *de-novo* hydroxyapatite crystals [2]. So far, the early data of the Curodont™ REPAIR group are promising. However, additional and long-term data from a larger pool of patients is needed to confirm the outcome presented and test whether the combined effect of fluoridation and a biomimic mineralisation are additional or even complementary.

Literature

- [1] Lussi et al., 2012: Fluoride – Wirkungsmechanismen und Empfehlungen für deren Gebrauch
 [2] Kirkham et al., 2007: Self-assembling Peptide Scaffolds Promote Enamel Remineralization

