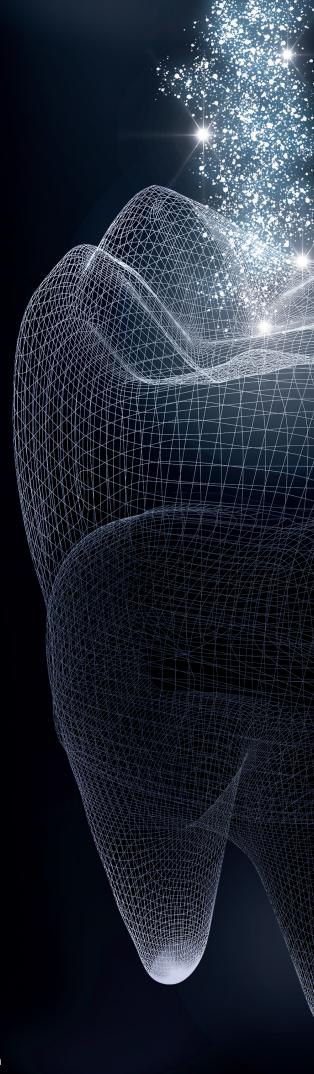
V VARDIS

BIOMIMETIC DENTAL SCIENCE

vvardis professional Clinical Booklet





AGENDA

- 1. Alkilzy M. et al., Self-assembling Peptide P11-4 and Fluoride for Regenerating Enamel. J Dent Res. 2018;97(2):148-154.
- 2. Bröseler F. et al., Randomised clinical trial investigating self-assembling peptide P11-4 in the treatment of early caries. Clin Oral Investig. 2020;24:123-132.
- Doberdoli D. et al., Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries. Sci Rep. 2020;10:4195.
- 4. Godenzi D. et al., Remineralizing potential of the biomimetic P11-4 self-assembling peptide on non-cavitated caries lesions. J Am Dent Assoc. 2023;28:S0002-8177(23)00416-6.
- 5. Jablonski-Momeni, A. et al. Impact of self-assembling peptides in remineralisation of artificial early enamel lesions adjacent to orthodontic brackets. Sci Rep. 2020;10,15132.
- 6. Keeper J. H.et al., Systematic review and meta-analysis on the effect of self-assembling peptide P11-4 on arrest, cavitation, and progression of initial caries lesions. J Am Dent Assoc. 2023;154:580-591.
- 7. Schlee M. et al., Clinical performance of self-assembling peptide P11 -4 in the treatment of initial proximal carious lesions: A practice-based case series. J Investig Clin Dent. 2018;9(1).
- 8. Welk, A. et al., Effect of self-assembling peptide P11-4 on orthodontic treatment-induced carious lesions. Sci Rep. 2020;10,6819.
- 9. Bilge K. et al., Effects of different remineralizing agents on color stability and surface characteristics of the teeth following vital bleaching. Microsc Res Tech. 2021;84:2206-2218.
- 10. Jablonski-Momeni A. et al., Randomised In Situ Clinical Trial Investigating Self-Assembling Peptide Matrix P11-4 in the Prevention of Artificial Caries Lesions. Orofac Orthop. 2014;75(3):175-90.
- 11. Magalhães G.A.P. et al., Effect of a Self-Assembly Peptide on Surface Roughness and Hardness of Bleached Enamel. J Funct Biomater. 2022;13:79.
- 12. Soares R. et al., Assessment of Enamel Remineralisation after treatment with four different remineralising agents: A Scanning Electron Microscopy (SEM) Study, J Clin Diagn Res. 2017;11(4):ZC136-ZC141.
- 13. Hill R. et al., An In Vitro Comparison of A Novel Self-Assembling Peptide Matrix Gel and Selected Desensitizing Toothpastes in Reducing Fluid Flow by Dentine Tubular Occlusion. J Dent Maxillofacial Res. 2020;3(1):1–11.
- 14. Schlee M. et al., Self-Assembling Peptide Matrix for Treatment of Dentin Hypersensitivity: A Randomized Controlled Clinical Trial. J Periodontol. 2018; 1–8.
- 15. Bommer C. et al., Hydroxyapatite and Self-Assembling Peptide Matrix for Non-Oxidizing Tooth Whitening. J Clin Dent. 2018;29(2):57-63.



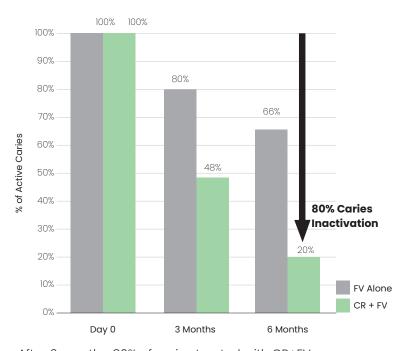


Significantly Superior Inactivation and Regression of Early Caries with the Combination of Curodont Repair (CR) and Fluoride Varnish (FV) Compared to FV Alone

RESULTS

After 6 months, treatment with Curodont Repair and Fluoride Varnish (CR+FV) showed significant and consistently greater caries regression than that seen after treatment with Fluoride Varnish (FV) alone, as per both objective (laser fluorescence) and subjective (Nyvad activity criteria)) assessments. CR+FV also resulted in significantly greater caries inactivation (80%) than that seen with FV alone (34%).

Caries Inactivation



After 6 months, 80% of caries treated with CR+FV became inactive as opposed to only 34% of those treated with FV alone, as assessed by Nyvad Caries Activity Criteria.

STUDY ESSENTIALS

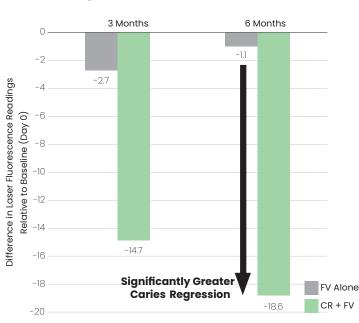


70 Children With Early Active Occlusal Caries on Erupting Permanent Molars



Randomized Single Blinded

Caries Regression



Greater decrease in laser fluorescence readings (assessed using DIAGNODent), signifying greater caries regression for treatment with CR+FV compared to FV alone.



6 Months



University of Greifswald, Germany

How can you use these results in your practice?

You can treat early, active caries in an easy, 8-10 minute, non-invasive, and pain-free protocol with CR. If needed, FV can be applied 5 minutes after CR. The combination of CR and FV leads to significantly higher arrest and regression of early caries than FV alone. Enamel regeneration with CR offers a predictable 'middle-ground' solution for early carious lesions that are frequently either left untreated ('wait-and-watch') or prematurely 'drilled-and-filled'.



Title: Self-assembling peptide P11-4 and fluoride for regenerating enamel*



Products Tested: • Curodont REPAIR + Fluoride Varnish (CR+FV)

• Fluoride Varnish (FV)



Scope & Methodology: The efficacy and safety of CR in combination with FV was compared with that of FV alone in producing regression of early carious lesions over a 6-month period. The assessments and techniques employed were as follows:

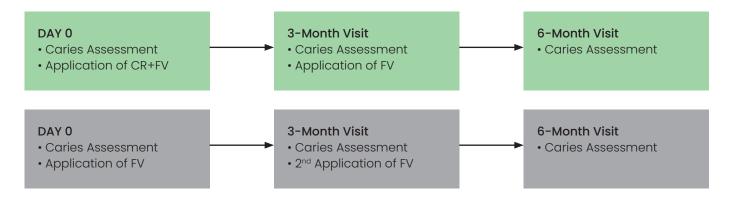
- Caries progression/regression: Laser fluorescence
- Caries activity: Nyvad Caries Activity



Study Participants: 70 children (age: 7-13 years) with active, occlusal, early carious lesions (ICDAS II score: 1-3) on first and second erupting permanent molars.



Procedure:





Conclusion: Biomimetic mineralization facilitated by CR in combination with FV is a simple, safe, and effective non-invasive treatment for early carious lesions and is superior to the present clinical gold standard of FV treatment alone in enhancing caries inactivation and regression.

*Reference

• Alkilzy M, Tarabaih A, Santamaria RM, Splieth CH. Self-assembling Peptide P11-4 and Fluoride for Regenerating Enamel. J Dent Res. 2018 Feb;97(2):148-154.

Supporting Studies

- Bröseler, F. et al (2019) "Randomised clinical trial investigating self-assembling peptide P11-4 in the treatment of early caries." Clin Oral Invest
- Brunton, PA., et al, (2013) "Treatment of early caries lesions using biomimetic self-assembling peptides a clinical safety trial" Brit Dent J, 2013, 215: E6
- Doberdoli, D. et al (2020) "Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries" Scientific Rep

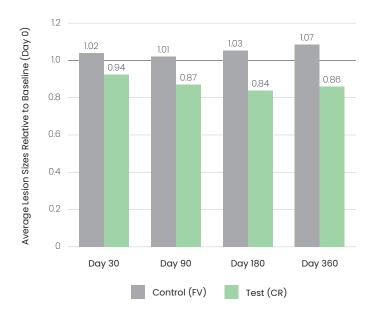


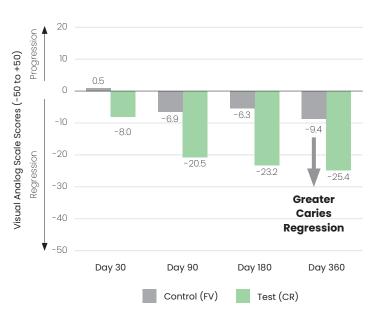


Significantly Greater Caries Regression with Curodont Repair (CR) than with Fluoride Varnish (FV)

RESULTS

On both objective (blinded morphometric assessment) and subjective (visual analog scale) assessments, the sizes of early carious lesions treated with CR decreased steadily (indicating caries regression) while lesions treated with FV remained stable, with a significant difference between the groups at all visits. The regression was majorly seen in the first 3 months after a single application of CR.





Blinded morphometric assessment revealed that relative to Day 0, the average sizes of lesions treated with CR steadily reduced while the sizes of those treated with FV remained stable, with a significant difference between the groups at all visits (P=0.001).

More rapid and greater decrease in VAS scores, indicating greater caries regression, seen in lesions treated with CR than in those treated with FV (VAS scale: Negative score: caries regression; '0': No change; Positive scores: caries progression).

STUDY ESSENTIALS



36 Patients with 88 Early Carious Lesions



Randomized, doubleblinded, controlled, splitmouth clinical trial



12 Months



Aachen, Germany

How can you use these results in your practice?

Once you detect an early, active carious lesion, a single application of CR is enough to enable its regression, which can be observed both visually and on radiographs. Due to a 'fan-shaped' arrangement of the new hydroxyapatite crystals as opposed to the parallel arrangement in natural enamel, the 'whitish appearance' of early buccal caries may reduce to a great extent but may not completely disappear. Thus, early detection and then immediate treatment using CR ensure the greatest probability caries regression and complete esthetic recovery.



Title: Randomized clinical trial investigating self-assembling peptide P11-4 in the treatment of early caries*



Products Tested: • Curodont REPAIR (CR)
• Fluoride Varnish (FV)



Scope & Methodology: The efficacy of CR in treating early buccal carious lesions was compared with that of the current gold standard FV over a 12-month period. Assessments were done at day 0, day 30, day 90, day 180, and day 360 using the following techniques:

- Change in white spot lesion size: Standardized photographs (morphometry)
- Caries progression/regression: Visual analog scale (VAS)

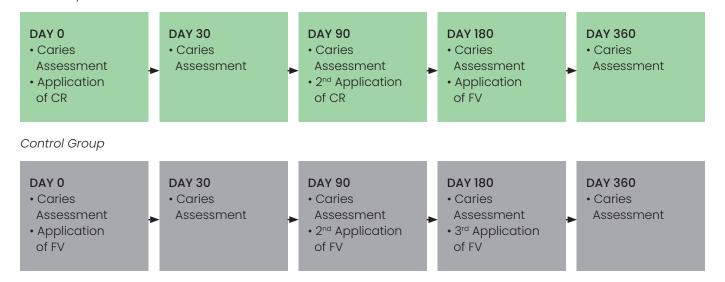


Study Participants: 36 participants (13-65 years), each having at least 2 teeth with early buccal caries. A total of 88 early carious lesions (44 tooth pairs) were studied.



Procedure: In each tooth pair, one tooth received treatment with CR (test) and the other, with FV (control).

Test Group





Conclusion: Biomimetic enamel regeneration enabled by CR is a non-invasive, painless, and quick treatment to promote regression of early carious lesions and is significantly superior to the current gold standard FV.

Reference

*Bröseler F, Tietmann C, Bommer C, Drechsel T, Heinzel-Gutenbrunner M, Jepsen S. Randomised clinical trial investigating self-assembling peptide P11-4 in the treatment of early caries. Clin Oral Investig. 2020;24:123-132

Supporting Studies

Doberdoli, D. et al (2020) "Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries" Scientifc Rep

² Alkilzy M, Tarabaih A, Santamaria RM, Splieth CH. Self-assembling Peptide P11-4 and Fluoride for Regenerating Enamel. J Dent Res. 2018 Feb;97(2):148-154.

³ Sedlakova Kondelova P., Mannaa A., Bommer C., Abdelaziz M., Daeniker L., di Bella E., Krejci I. Efficacy of P11-4 for the treatment of initial buccal caries: a randomized clinical trial. Sci Rep 2020;10:20211

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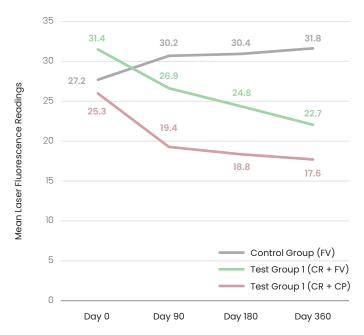


The Combination of Curodont Repair (CR) With a Twice Weekly Home Application of Curodont Protect (CP) is as Efficacious as the Combination of CR and Fluoride Varnish (FV) in Enabling Caries Regression and Inactivation

RESULTS

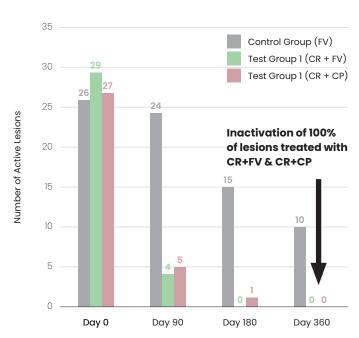
Treatment of early occlusal carious lesions with CR followed by a twice weekly home application of CP for one year led to greater caries regression and inactivation than the use of FV alone. This result was comparable to that demonstrated by the combination of CR and FV.

Caries Regression



Carious lesions treated with CR+FV and CR+CP showed a significant reduction in laser fluorescence values, indicating greater regression of caries, as compared to those treated with FV (p<0.0005), at every follow-up visit.

Caries Inactivation



According to assessment by Nyvad Caries Activity Criteria, by Day 360 all the carious lesions treated with CR+FV and CR+CP had become inactive.

STUDY ESSENTIALS



90 Children (6–15 Years) With Early Occlusal Caries



Randomized, Gold-Standard Controlled, Single Blinded Clinical Trial



12 Months



University Dentistry Clinical Center of Kosovo

How can you use these results in your practice?

You can treat early caries with CR in a non-invasive, painless, and drill free manner and have the patient follow a simple 2x/week home-use regimen of CP to achieve their arrest and regression. This combination arrests early caries as well as the combination of CR+FV does and leads to higher reminerlization of early caries than the combination of CR+FV.



Title: Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries*



Products/Treatments Tested: Control group - Fluoride varnish 7700 ppm (FV)

Test Group 1 - Curodont Repair (CR) + FV





Scope & Methodology: The efficacy of the combination of CR and CP in enabling caries regression and inactivation was compared to that of the combination of CR and FV and of FV alone over a 12-month period. Th following assessments were employed on Day 0, Day 90, Day 180, and Day 360:

- Caries progression/regression: Laser Fluorescence
- Caries activity: Nyvad Activity Criteria

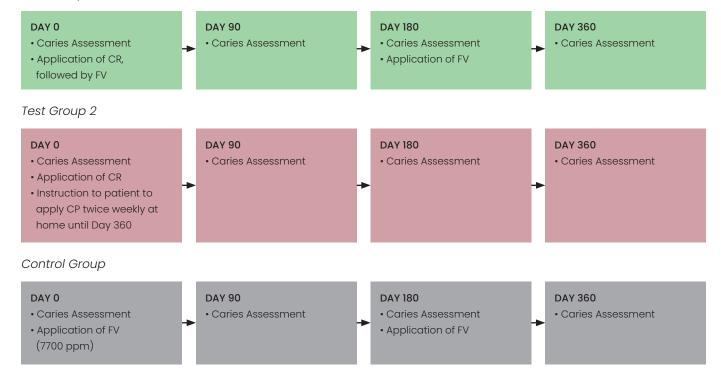


Study Participants: 90 participants (age: 6-15 years) with early, occlusal carious lesions (ICDAS II score 2 or 3) were randomly and equally allocated to study groups.



Procedure:

Test Group 1





Conclusion: The twice-weekly application of CP is as efficacious as FV in supporting the enamel-regenerative capacity of CR and can serve as its replacement. The self-assembling peptide technology in CR and CP can initiate regression of caries and not just its arrest/inactivation, predominantly seen with FV.

Reference

*Doberdoli D, Bommer C, Begzati A, Haliti F, Heinzel-Gutenbrunner M, Juric H. Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries. Sci Rep. 2020;10:4195.

Supporting Studies

- Bröseler F, Tietmann C, Bommer C, Drechsel T, Heinzel-Gutenbrunner M, Jepsen S. Randomised clinical trial investigating self-assembling peptide P11-4 in the treatment of early caries. Clin Oral Investig. 2020;24:123-132
- ² Alkilzy M, Tarabaih A, Santamaria RM, Splieth CH. Self-assembling Peptide P11-4 and Fluoride for Regenerating Enamel. J Dent Res. 2018 Feb;97(2):148-154.
- ³ Sedlakova Kondelova P., Mannaa A., Bommer C., Abdelaziz M., Daeniker L., di Bella E., Krejci I. Efficacy of P11-4 for the treatment of initial buccal caries: a randomized clinical trial. Sci Rep 2020;10:20211

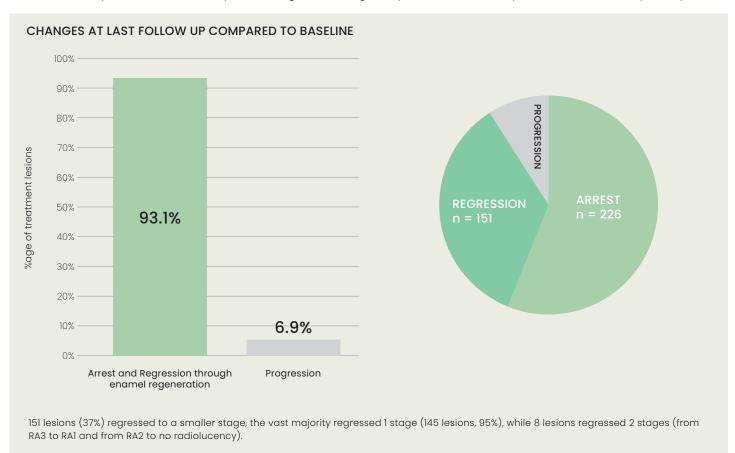




Curodont™ Repair (CR), followed by Curodont™ Protect (CP), leads to 93% success rate defined as arrest and regression of early (proximal) caries through enamel regeneration with up to 6 years clinical follow up

RESULTS

93% clinical success (377/405 lesions) in caries management was demonstrated in a retrospective cohort study in Switzerland involving 219 adolescents aged 10 -19 years. 405 early proximal-surface caries lesions treated with CR and followed up with CP were analyzed through bite-wing X-rays. Clinical follow up was obtained for up to 6 years.



STUDY ESSENTIALS



219 children aged 10 - 19 years



Retrospective cohort study



0.4 - 6 years



Schulzahnklinik, Chur, Switzerland

How can you use these results in your practice?

CR and CP are an ideal combination to treat initial caries lesions in children, remineralizing to the depth of the lesion over time. This treatment poses no risk and high regeneration benefit. The introduction of CR and CP in routine dental practice is clearly feasible and advantageous for both the clinic and the patient.



STUDY INFORMATION

Title: Remineralizing potential of the biomimetic P₁₁-4 self-assembling peptide on noncavitated caries lesions



Treatments Tested: Curodont™ Repair (CR) and Curodont™ Protect (CP)



Scope & Methodology:

Caries lesions in permanent teeth treated with monomeric (CR) and polymeric (CP) P¹¹–4 self-assembling peptide from May 2015 through October 2020 were retrospectively analyzed at lesion and child levels by means of bite-wing radiography for changes in stage and cavitation.



Study participants:

Adolescents 10-19 years having a baseline radiograph showing at least 1 proximal initial caries lesion belonging to RA1, RA2, RA3 or RB4 stage [according to the International Caries Classification and Management System (ICCMS)].



RA1

RA2



RA3



RB4

Radiolucency in the outer 1/2 of enamel

Radiolucency in the inner 1/2 of enamel

Radiolucency limited to the outer 1/3 of dentin

Radiolucency reaching the middle 1/3 of dentin, non-cavitated

INTERVENTIONS:

The caries lesions were pre-treated as per the manufacturer's recommended protocol before CR application into the interdental space. CR was allowed to diffuse and self-assemble for 5 minutes before CP was applied. The patient was instructed not to rinse, eat, or drink for 1 hour after treatment. CP was provided for self-administration once per week.

OUTCOMES:

Primary outcomes: the change in stage

Secondary outcomes: cavitation and restoration

COMPARISONS:

Uncontrolled



Conclusion: A one-time application of CR followed by the at-home use of CP can prevent the progression of over 90% of early caries, through arrest and regression, in real-life clinical settings.

References

Godenzi D, Bommer C, Heinzel-Gutenbrunner M, Keeper JH, Peters K. Remineralizing potential of the biomimetic P11-4 self-assembling peptide on noncavitated caries lesions. J Am Dent Assoc. 2023 Aug 28:S0002-8177(23)00416-6.

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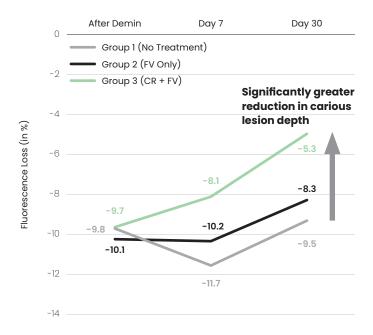
BIOMIMETIC DENTAL SCIENCE

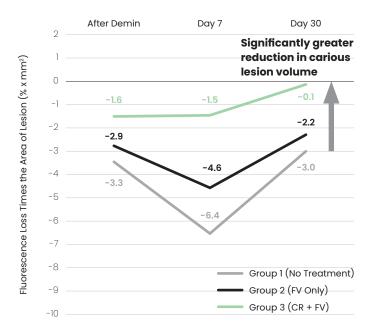


Significantly Superior Remineralization of Early Caries Adjacent to Fixed Orthodontic Brackets with the Combination of Curodont Repair (CR) and Fluoride Varnish (FV) Compared to FV Alone

RESULTS

A single application of CR followed by FV led to higher remineralization in demineralized areas adjacent to orthodontic brackets than did a single application of FV and the administration of no treatment in the short term (30 days). This was demonstrated by a significantly higher reduction in both lesion depth and volume after treatment with CR+FV.





The fluorescence loss with group 3 (CR+FV) was significantly lower than the other groups on both Days 7 and 30 (P = 0.00001), indicating significantly greater reduction in lesion depth.

The fluorescence loss times area with group 3 (CR+FV) was significantly lower than the other groups on both Days 7 and 30 (P < 0.000001), indicating significantly greater reduction in lesion volume.

STUDY ESSENTIALS



In-vitro Study



30 Days



Philipps-University of Marburg, Germany

How can you use these results in your practice?

Patients undergoing fixed orthodontic therapy are at a high risk of developing caries due to difficulty in maintaining good oral hygiene. These caries, in the form of white spot lesions, can even develop a month into the treatment. With CR, you can treat these lesions as soon as they are detected during orthodontic follow-up appointments every 4-6 weeks. CR can be used even while the brackets are still in place and it does not affect the bond strength of the orthodontic adhesive. This enables you to actively manage early caries in the course of the treatment rather than having to address these esthetically unappealing lesions after debonding of the brackets.



Title: Impact of self-assembling peptides in remineralization of artificial early enamel lesions adjacent to orthodontic brackets*



Products/Treatments Tested: Group 1 – No treatment

Group 2 – Fluoride varnish 22,600 ppm (FV) alone

Group 3 - Curodont Repair (CR) + FV



Scope & Methodology: The ability of the combination of CR + FV to remineralize early caries adjacent to orthodontic brackets was compared to that of FV alone and to no treatment. The remineralization was assessed using *Quantitative Light-induced Fluorescence (QLF)*. The fluorescence of enamel reflects its mineral content. The loss of minerals (as in caries) is indicated by a fluorescence loss. Conversely, when the mineral content increases (as in remineralization), the fluorescence loss reduces. The following QLF measurements were made after demineralization and on Day 7 and Day 30 after administration of the treatments:

- 1. Fluorescence loss (in %): Indicative of carious lesion depth
- 2. Fluorescence loss times area (% x mm²): Indicative of carious lesion volume



Procedure: Buccal surfaces of extracted teeth were prepared as follows:



Green patterned segment: Intact enamel

Red patterned segment: Demineralized enamel (caries)

Middle segment: Fixed with an orthodontic bracket in the center and then subjected to different remineralization agents after demineralization

The samples were grouped as follows depending on the remineralization agents used:

Group 1 (Negative control): No treatment

Group 2 (Positive control): Single application of FV

Group 3 (Test group): CR + FV (FV applied 5 minutes after CR)

After treatment administration, all samples were stored in a remineralizing solution.



Conclusion: A single application of CR followed by FV remineralizes artificial carious lesions by a significantly greater extent compared to a one-time use of FV in the short term (30 days). This combination can be used in patients undergoing fixed multi-bracket orthodontic therapy.

Reference

*Jablonski-Momeni, A, Nothelfer, R, Morawietz, M. et al. Impact of self-assembling peptides in remineralisation of artificial early enamel lesions adjacent to orthodontic brackets. Sci Rep 10, 15132 (2020)

Supporting Studies

- l Alkilzy M, Tarabaih A, Santamaria RM, Splieth CH. Self-assembling Peptide P11-4 and Fluoride for Regenerating Enamel. J Dent Res. 2018 Feb;97(2):148-154.
- ² Sedlakova Kondelova P., Mannaa A., Bommer C., Abdelaziz M., Daeniker L., di Bella E., Krejci I. Efficacy of P11-4 for the treatment of initial buccal caries: a randomized clinical trial. Sci Rep 2020;10:20211
- ³ Bröseler F, Tietmann C, Bommer C, Drechsel T, Heinzel-Gutenbrunner M, Jepsen S. Randomised clinical trial investigating self-assembling peptide P11-4 in the treatment of early caries. Clin Oral Investig. 2020;24:123-132
- ⁴Doberdoli D, Bommer C, Begzati A, Haliti F, Heinzel-Gutenbrunner M, Juric H. Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries. Sci Rep. 2020;10:4195.



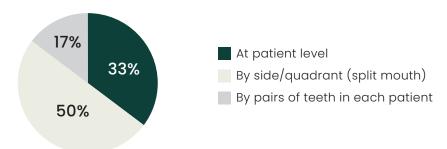


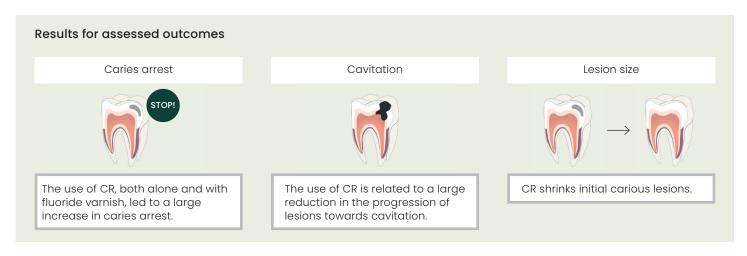
Curodont Repair (CR) leads to arrest and shrinkage of early caries lesions.

RESULTS

The systematic review and meta-analysis of 6 randomized controlled trials (RCTs) found that CR is a promising treatment for initial carious lesions. In total, the outcomes for 132 carious lesions treated with CR were assessed and compared with a parallel group.

Randomization in included studies





No studies reported any adverse esthetic change, such as discoloration or staining.

STUDY ESSENTIALS



6 RCTs in systematic review 5 RCTs combined for meta-analysis

How can you use these results in your practice?

- CR is proven to be a viable treatment option for early caries that not only arrests initial caries but also prevents cavitation and reduces the sizes of lesions.
- This easy and quick treatment can be performed by dentists and hygienists and can be done within 10 minutes with no associated adverse effects.



STUDY INFORMATION

Title: Systematic review and meta-analysis on the effect of self-assembling peptide P_{11} -4 on arrest, cavitation, and progression of initial caries lesions*



Products/Treatments Tested:

Curodont REPAIR (CR)



Scope & Methodology:

A literature search on PubMed and EMBASE identified 193 relevant articles. Articles compliant with the criteria developed by the ADA Center for Evidence-Based Dentistry were included in this study.

INCLUSION CRITERIA:

Patient of any age with initial, non-cavitated carious lesions in at Participants:

least 1 permanent tooth

Topical application of CR Intervention:

Comparisons: Placebo, fluoride varnish, or no intervention

OUTCOMES ON WHICH RESULTS WERE REPORTED:

Primary outcomes:

- Caries arrest
- Cavitation (including restoration)

Secondary outcomes:

- Decrease in merged ICDAS scores
- Lesion size by radiography or digital photography (continuous measures)



Conclusion: This systematic review and meta-analysis provides evidence that CR is effective for arresting initial, non-cavitated caries lesions and reducing lesion size. CR is a valuable addition to the pharmacopeia for the most common disease in humans, caries.

*Keeper JH, Kibbe LJ, Thakkar-Samtani M, Heaton LJ, Desrosiers C, Vela K, Amaechi BT, Jablonski-Momeni A, Young DA, MacLean J, Weyant RJ, Zandona AF, Sohn W, Pitts N, Frantsve-Hawley J. Systematic review and meta-analysis on the effect of self-assembling peptide P11-4 on arrest, cavitation, and progression of initial caries lesions. J Am Dent Assoc. 2023;154:580-591.e11.

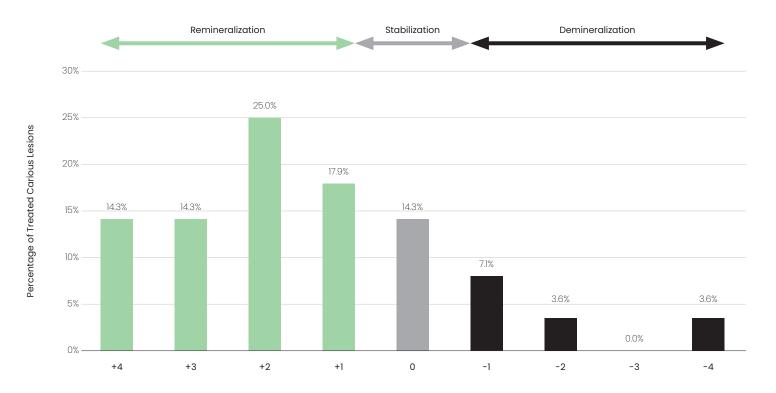




Curodont Repair (CR) Leads to Regression of Initial Carious Lesions Evident on Radiographic Assessments

RESULTS

Twelve months after treatment of initial proximal carious lesions with CR, a predominant shift toward caries regression was seen with the combined assessment of clinical radiographs and digital subtraction radiography (DSR) images, demonstrating total or partial regression in over 70% of lesions.



Over 70% of the lesions were judged as being remineralizing after 1 year of treatment with CR as per the cumulative scores attributed to the lesions on standardized clinical radiographs and DSR images.

STUDY ESSENTIALS



26 Patients with 35 Initial Carious Lesions on Proximal Tooth Surfaces



Practice-based, Uncontrolled, Prospective Case Series



12 Months



Forchheim, Germany

How can you use these results in your practice?

You can use CR to treat early carious lesions, including those on proximal surfaces, in a non-invasive and painless manner. Patients can be recalled at 4-6 months to assess caries regression on intra-oral radiohraphs. This is seen as the reduction in lesion depth. Treatment with CR can prevent the need for invasive restorations in the future.



Title: Clinical Performance of Self-Assembling Peptide P11-4 in the Treatment of Initial Proximal Carious Lesions: A Practice-Based Case Series*



Products Tested: Curodont Repair (CR)



Scope & Methodology: The clinical performance of CR in remineralizing non-cavitated proximal initial carious lesions over a 12-month period was assessed using standardized radiographs and by digital subtraction radiography. The evaluations were done by two blinded assessors by giving scores as follows:

- i. Remineralizing lesion: +1
- ii. Unchanged lesion: 0
- iii. Demineralizing lesion: -1

The scores attributed to a lesion by the two assessors were added and the cumulative score was used to judge it as remineralizing, stabilized or demineralizing.



Study Participants: 26 adults with 35 proximal non-cavitated carious lesions.



Procedure: On Day 0, standardized radiographs of the proximal initial carious lesions were shot before treating them with CR and the patients were asked to maintain good oral hygiene. On Day 360, the radiographic assessments were repeated to compare them with the pre-treatment radiographs.



Conclusion: Treatment with self-assembling peptide P11-4 in CR can lead to regression of early non-cavitated proximal carious lesions. The treatment might delay or ultimately avoid restorative treatments.

Reference

*Schlee M, Schad T, Koch JH, Cattin PC, Rathe F. Clinical performance of self-assembling peptide P11 -4 in the treatment of initial proximal carious lesions: A practice-based case series. J Investig Clin Dent. 2018 Feb;9(1).

Supporting Studies

- ¹ Bröseler F, Tietmann C, Bommer C, Drechsel T, Heinzel-Gutenbrunner M, Jepsen S. Randomised clinical trial investigating self-assembling peptide P11-4 in the treatment of early caries. Clin Oral Investig. 2020;24:123-132
- ² Alkilzy M, Tarabaih A, Santamaria RM, Splieth CH. Self-assembling Peptide P11-4 and Fluoride for Regenerating Enamel. J Dent Res. 2018 Feb;97(2):148-154.
- ³ Sedlakova Kondelova P., Mannaa A., Bommer C., Abdelaziz M., Daeniker L., di Bella E., Krejci I. Efficacy of P11-4 for the treatment of initial buccal caries: a randomized clinical trial. Sci Rep 2020;10:20211
- ⁴ Doberdoli D, Bommer C, Begzati A, Haliti F, Heinzel-Gutenbrunner M, Juric H. Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries. Sci Rep. 2020;10:4195.



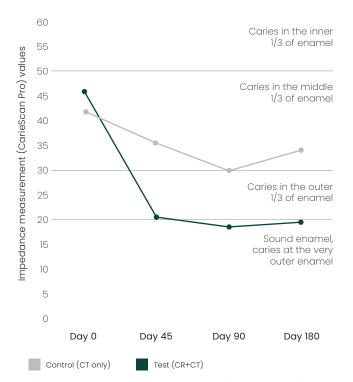


Significantly greater regression of orthodontic treatment-induced early caries with Curodont™ Repair (CR) than with conventional treatment (CT)

RESULTS

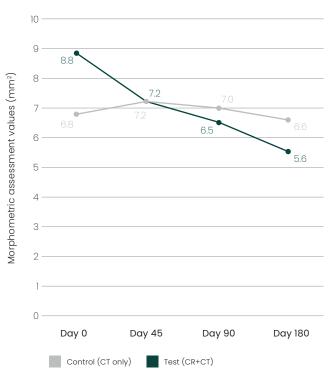
On impedance measurement and morphometric assessment (in mm²), early caries treated with CR, followed by CT with fluoride-based professional prophylaxis paste and home care toothpaste, demonstrated significantly greater regression than those receiving CT only. The greater reduction in impedance values confirmed that CR regenerates the mineral structure of enamel in the lesion body and not just on the surface.

CARIES REGRESSION



Significantly greater caries regression at all follow-up visits for lesions in the test group, than those in the control group (P<0.01). At day 180, the caries had regressed into the very outer enamel. (responses adjusted for baseline values).

LESION SIZE REDUCTION



Sizes of lesions in the test group, reduced significantly (P=0.004) more than that of those in the control group, at the end of 6 months (responses adjusted for baseline values).

STUDY ESSENTIALS



23 patients



Randomized, treatmentcontrolled, split-mouth, clinical trial



6 Months



How can you use these results in your practice?

- Patients undergoing fixed orthodontic therapy are at a high risk of caries.
- · CR can treat early carious lesions, as soon as they are identified, without the need to debond the brackets.



STUDY INFORMATION

Title: Effect of self-assembling peptide P11-4 on orthodontic-treatment induced carious lesions*



Treatments Tested:

- **Test**: Curodont[™] Repair (CR), followed by conventional treatment (CT) with fluoride-based professional prophylaxis paste and home care toothpaste
- Control: CT only



Scope & Methodology:

The efficacy of CR in treating post-orthodontic early buccal caries lesions was compared with CT over a 6-month period. Assessments were done at day 0, day 45, day 90, and day 180 using the following techniques:

Impedance measurement, using CarieScan Pro (Orangedental, Germany)

Measurement values used (per manufacturer):

- 0 = sound
- II. 1-20 = Sound enamel, caries at the very outer enamel
- III. 21-30 = caries in the outer 1/3 of the enamel
- IV. 31-50 = caries in the middle 1/3 of the enamel
- 51-90 =caries in the inner 1/3 of the enamel
- 91-99 = caries at the dentine enamel junction
- VII. 100 = established dentine caries



Study participants:

Morphometric assessment (size of WSL in mm²), using Shadepilot (Degudent, Germany)

23 patients (average age: 15.4 years), each having at least 2 teeth with active buccal surface caries after removal of fixed orthodontic appliances.



Procedure:

Two days after debonding, one tooth in each tooth pair received treatment with CR + CT (test) and the other, only CT(control).

Test group:

2 days before baseline	Day 0 (Baseline)	Day 45	Day 90	Day 180
• Debonding	Oral prophylaxis Caries assessment Application of CR	Oral prophylaxis Caries assessment	Oral prophylaxis Caries assessment	Oral prophylaxis Caries assessment

Control group:

2 days before baseline	Day 0 (Baseline)	Day 45	Day 90	Day 180
• Debonding	Oral prophylaxis Caries assessment			



Conclusion: The treatment of post-orthodontic early caries with CR leads to superior regression and reduction in lesion size compared with CT only with fluoride-based professional prophylaxis paste and home care toothpaste.

References

- Welk, A., Ratzmann, A., Reich, M. et al. Effect of self-assembling peptide P11-4 on orthodontic treatment-induced carious lesions. Sci Rep 10, 6819 (2020).
- 1. Doberdoli, D. et al (2020) "Randomized Clinical Trial investigating Self-Assembling Peptide P11-4 for Treatment of Early Occlusal Caries" Scientific Rep 2. Alkilzy M, Tarabaih A, Santamaria RM, Splieth CH. Self-assembling Peptide P11-4 and Fluoride for Regenerating Enamel. J Dent Res. 2018 Feb;97(2):148-154. 3. Sedlakova Kondelova P, Mannaa A., Bommer C., Abdelaziz M., Daeniker L., di Bella E., Krejci I. Efficacy of P11-4 for the treatment of initial buccal caries: a randomized clinical trial. Sci Rep 2020;10:20211



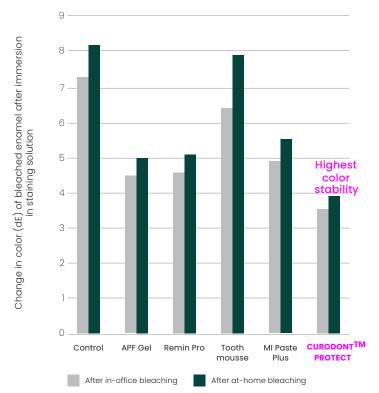


Superior remineralization and maintenance of color stability of bleached enamel with Curodont™ Protect (CP) than with common remineralization agents

RESULTS

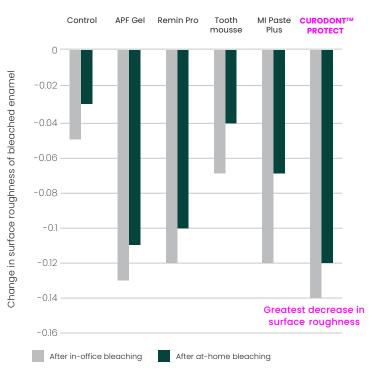
While all remineralization agents reduced post-bleaching surface roughness significantly, the greatest decrease in surface roughness, after both in-office and at-home bleaching, was seen after a twice-weekly application of CP for 14 days. In addition, the application of CP also resulted in the lowest change in the color of bleached enamel after immersion in a staining coffee solution.

COLOR STABILITY



CP demonstrated the least change in color (dE), therefore most color stability, of bleached enamel as compared to other remineralization agents.

REDUCTION IN SURFACE ROUGHNESS



CP demonstrated the greatest reduction in surface roughness post bleaching as compared to other remineralization agents.

STUDY ESSENTIALS



96 human incisor teeth (n=8/group)



In-vitro study



14 days



Firat University, Turkey

How can you use these results in your practice?

- Peroxide-based bleaching can lead to a degree of demineralization manifesting as increased surface roughness and consequently, increased susceptibility to staining.
- CP can be used immediately after in-office bleaching and concurrently with at-home bleaching to restore surface smoothness and maintain color stability of bleached teeth.



Title: Effects of different remineralizing agents on color stability and surface characteristics of the teeth following vital bleaching*

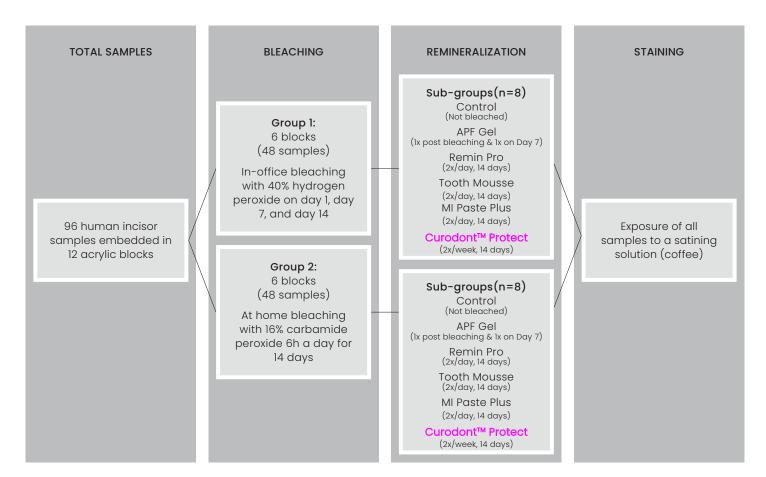


Treatments Tested: 1.

- 1. Acidulated Phosphate Fluoride (APF) gel
- 2. Remin Pro (1450 PPM sodium fluoride + hydroxyapatite)
- 3. Tooth Mousse (Casein Phosphopeptide- Amorphous Calcium Phosphate; CPP-ACP)
- 4. MI Paste Plus (CPP-ACP with 900 PPM sodium fluoride; CPP-ACPF)
- Curodont™ Protect (Self-assembling peptide P11-4 + Calcium, Phosphate, 900 PPM sodium monofluorophosphate)



Scope & Methodology: The following experimental procedure was used:



Assessments done:

- Measurement of color change (dE); using a contact spectrophotometer: (a) At baseline, (b) after bleaching,
- (c) after immersion in staining solution following the remineralization process
- Surface roughness; using a contact-type profilometer: (a) At baseline, (b) after bleaching, (c) after remineralization



Conclusion: CP can be used twice weekly after peroxide-based bleaching to reduce surface roughness due to its superior remineralizing effect and to prevent discoloration, thereby providing colour stability.

References

*Bilge K, Kiliç V. Effects of different remineralizing agents on color stability and surface characteristics of the teeth following vital bleaching. Microsc Res Tech.2021;84:2206-2218. Supporting studies:

Supporting studies.

1. Magalhäes GAP, Fraga MAA, de Souza Araújo IJ, Pacheco RR, Correr AB, Puppin-Rontani RM. Effect of a Self-Assembly Peptide on Surface Roughness and Hardness of Bleached Enamel. J Funct Biomater. 2022;13:79



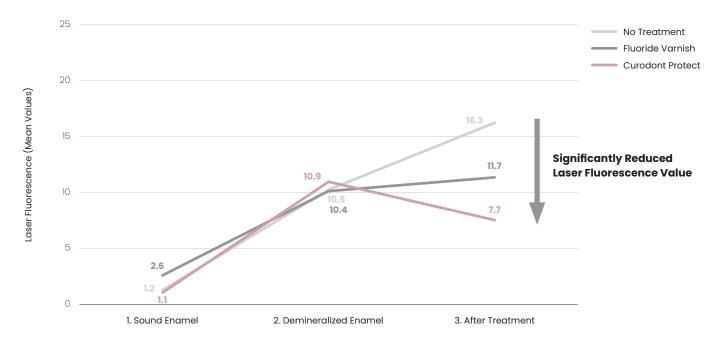


Curodont Protect protects from the onset and progress of demineralization and remineralizes early carious lesions

RESULTS

Curodont Protect has a clinical beneficial effect in caries prevention and proved to be useful in preventing the progression of initial demineralisation, especially around orthodontic brackets. Curodont Protect demonstrated superior remineralisation potential compared to the present gold standard of fluoride varnish alone.

Laser Fluorescence Changes Linked to Demineralization and Remineralization Process



After demineralisation, the fluorescence values of all specimens increase, indicating "enamel lesions". Curodont Protect demonstrates the highest remineralisation potential, inducing the biggest decrease in the fluorescence value, towards that of sound enamel.

STUDY ESSENTIALS









How can you use these results in your practice?

You can use Curodont Protect in-office and instruct the patient on its home-use for three benefits: (i) protection from the onset of caries, (ii) protection from the progress of initial demineralization, and (iii) a degree of remineralization. This is especially advantageous in patients with a high caries risk, where fluoride alone might not be sufficient, such as those with fixed orthodontic appliances. The clinical benefit of Curodont Protect due to its remineralizing ability has also been demonstrated previously in vitro.^{1,2}



Title: Randomised In Situ Clinical Trial Investigating Self-Assembling Peptide Matrix P11-4 in the Prevention of Artificial Caries Lesions*



Products Tested: • Curodont Protect

• Fluoride Varnish (FV)



Scope & Methodology: The objective of this clinical study was to investigate the efficacy of Curodont Protect in combination with daily oral hygiene, in remineralising artificial initial demineralisation and to compare its caries prevention efficacy to the application of fluoride. Volunteers had bovine specimens (half including orthodontic brackets) placed on the buccal aspects of mandibular appliances. Specimens included internal sound enamel control and a demineralised control. This study was divided into three phases. Each phase lasted 4 weeks, with three types of treatments: A) no treatment; B) treatment with FV once at the start; C) treatment with Curodont Protect once at the start and then twice a week application by the volunteers. Each 4 weeks treatment was followed by a one-week washout. Assessment techniques:

- Laser fluorescence values
- Micro-CT analysis



Study Participants: 9 volunteers with specimens (sound enamel and demineralised control) placed on the buccal aspects of mandibular appliances.



Procedure:

- Volunteers given the appliances (worn 24h/day, removed only for eating/brushing)
 Group A: No treatment
 - Group B: application of FV only once at the start
 - Group C: 1st application of Curodont Protect
- Volunteers to brush their teeth twice daily
- Appliances to be cleaned separately with same method
- Group C:
 Curodont Protect
 applied twice a
 week x 4 weeks
 by the volunteers
 at home
- Washout phase (1 week): volunteer did not wear the appliance

New appliances handed to volunteers for the next treatment phase



Conclusion: The study demonstrated the ability of Curodont Protect to prevent caries and remineralise enamel around orthodontic brackets. Curodont Protect, in combination with daily oral hygiene, showed higher efficacy in remineralising artificial initial demineralisation, compared to daily oral hygiene alone and also compared to the application of fluoride varnish and daily oral hygiene.

*Reference

Jablonski-Momeni A, Korbmacher-Steiner H., Heinzel-Gutenbrunner M., Jablonski B., Jaquet W. and Bottenberg P., J. Orofac Orthop. 2014 May;75(3):175-90. Supporting Studies

- 1. Ceci, M. et al. Effect of self- assembling peptide p11-4 on enamel erosion: AFM and SEM studies. Scanning. 38, 344-351 (2016).
- 2. Soares et al. Assessment of enamel remineralisation after treatment with four different remineralising agents: A Scanning Electron Microscopy (SEM) Study. J. Clin. Diagn. Res. 11, ZC136–ZC141 (2017).

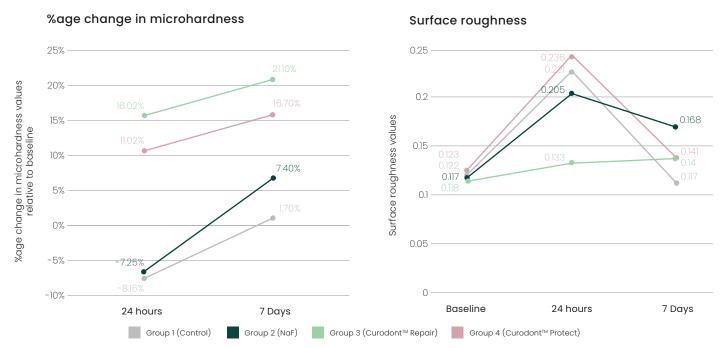
VVARDIS SWITZERLAND BIOMIMETIC DENTAL SCIENCE



Greater increase in surface hardness and faster recovery of surface smoothness of bleached enamel with Curodont™ Repair and Curodont™ Protect than with fluoride (NaF)

RESULTS

At 24 hours and 7 days, Curodont™ Repair and Curodont™ Protect led to significant increases in enamel microhardness compared to baseline values (sound enamel). After 24 hours, bleached enamel samples treated with Curodont™ Repair showed surface roughness values lower than all other groups and closest to the baseline value of sound enamel.



Higher and constant increases in surface microhardness relative to baseline with Curodont™ Repair and Curodont™ Protect.

Recovery of surface smoothness towards baseline values with all groups with Curodont Repair showing the fastest recovery.

STUDY ESSENTIALS







Brazil

Randomized in-vitro study

How can you use these results in your practice?

- Peroxide-based bleaching can lead to a degree of mineral loss from the enamel, manifesting as increased surface roughness and decreased surface microhardness.
- Self-assembling peptide (P11-4) based products, used immediately after bleaching, restore surface smoothness quicker than fluoride and increase surface microhardness significantly more than fluoride. Additionally, early carious lesions detected before or after bleaching can also be treated with Curodont™ Repair, followed by Curodont™ Protect for home-based use for surface remineralization.



STUDY INFORMATION

Title: Effect of Self-Assembly Peptide on surface roughness and hardness of bleached enamel

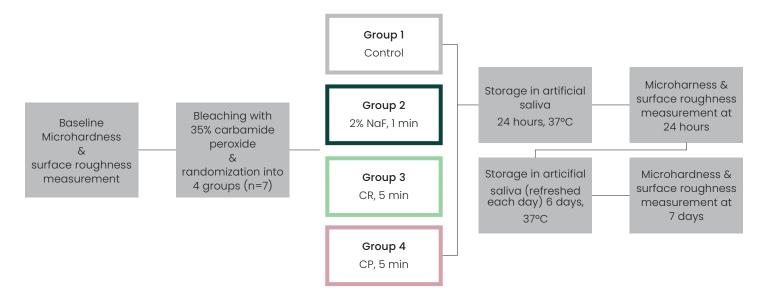


Treatments Tested: Group 1: Control (No remineralization agent following bleaching)

Group 2: 2% sodium fluoride (NaF) following bleaching Group 3: Curodont™ Repair (CR) following bleaching Group 4: Curodont™ Protect (CP) following bleaching



Scope & Methodology: 28 bovine enamel samples were selected for the following experimental procedure:



After each treatment (NaF, CR, and CP), the samples were exposed to a supersaturated solution of calcium and phosphate ions for 1 min.

The assessments performed were:

- Measurement of microhardness: Knoop Microhardness analysis to determine the Knoop Hardness Number (KHN)
- Surface Roughness: Using SurfCorder SE 1700, a surface roughness measurement instrument



Conclusion: The reduction in enamel surface microhardness and increase in surface roughness, resulting from demineralization consequent to peroxide-based bleaching, can be managed with self-assembling peptide-based products.

References

*Magalhães GAP, Fraga MAA, de Souza Araújo IJ, Pacheco RR, Correr AB, Puppin-Rontani RM. Effect of a Self-Assembly Peptide on Surface Roughness and Hardness of Bleached Enamel. J Funct Biomater. 2022;13:79

1. Bilge K, Kılıç V. Effects of different remineralizing agents on color stability and surface characteristics of the teeth following vital bleaching. Microsc Res Tech. 2021;84:2206-2218.

2021,04.2200-2210.

2. Soares, R. et al (2017) "Assessment of Enamel Remineralisation After Treatment with Four Different Remineralising Agents: A Scanning Electron Microscopy (SEM) Study" J Clin Diagn Res Vol-11(4): ZC136-ZC141



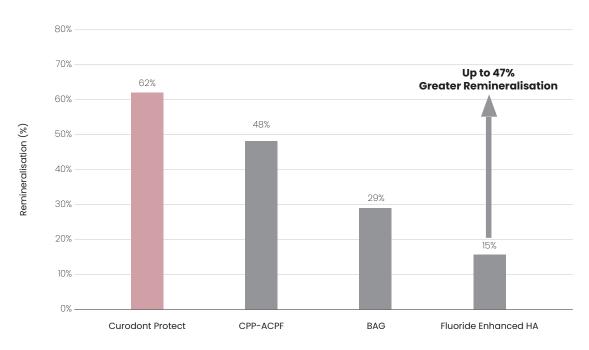


Curodont Protect increases the surface microhardness of demineralized enamel significantly better than competing products

RESULTS

Curodont Protect demonstrate to effectively and significantly remineralize enamel lesions as compared to other test agents: Casein phosphopeptide amorphous calcium phosphate fluoride (CPP-ACPF), Bioactive glass (BAG) and Fluoride enhanced hydroxyapatite (Fluoride enhanced HA). Curodont Protect raised Surface Microhardness to a level where no significant difference to the sound control samples could be found.

Surface Microhardness Analysis



STUDY ESSENTIALS







In Vitro Study



30 Days



Goa, India

How can you use these results in your practice?

One of the manifestations of demineralization is the reduction in the surface hardness of enamel. You can use Curodont Protect in-office and instruct the patient on its home-use to increase the surface hardness of demineralized enamel to a level comparable to that of sound enamel. Most 'remineralizing' products increase the concentration of calcium and phosphate ions in the vicinity of enamel (such as CPP-ACP and BAG) or make the enamel more resistant to dissolution (such as fluoride-based products). Curodont Protect combines the benefits of calcium, phosphpate, and fluoride with the regenerative capacity of the self-assembling peptide technology and thus remineralizes up to 47% more than competing products.



Title: Assessment of Enamel Remineralisation After Treatment with Four Different Remineralising Agents: A Scanning Electron Microscopy (SEM) Study*



Products Tested: • Curodont Protect

- Casein Phosphopeptide Amorphous Calcium Phosphate Fluoride (CPP-ACPF)
- Bioactive Glass (BAG)
- Fluoride Enhanced Hydroxyapatite (Fluoride enhanced HA)

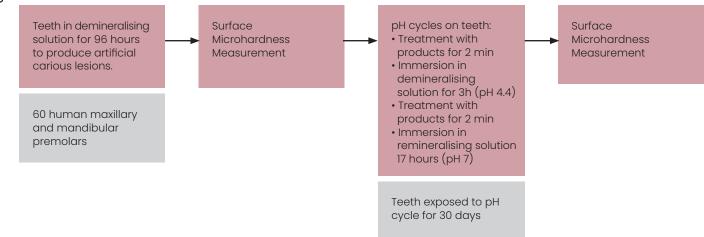


Scope & Methodology: This in vitro study was designed to evaluate the remineralising capacity of 4 remineralization agents on artificial enamel lesions, through Surface Microhardness (SMH) analysis, tested in a pH cycling model over 30 days.



Samples: 60 human maxillary and mandibular premolars extracted for orthodontic treatment. Teeth with any visible or detectable caries, restorations, hypoplastic lesions, stains, cracks and white spot lesions were excluded from the study.

Procedure:





Conclusion: Curodont Protect demonstrated promising results by effectively and significantly remineralizing the enamel lesions as compared to other test agents based on Fluoride or BAG.

*Reference

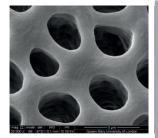




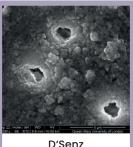
Effective and superior occlusion of dentine tubules for the treatment of dentine hypersensitivity using Curodont™ D'Senz

RESULTS

D'senz demonstrated greater reduction in the number of open tubules compared to the other desensitizing toothpastes, with a significant reduction in both the number and the diameter of the open dentine tubules, which was evident for all the treated samples.

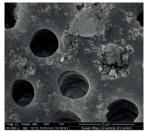


Untreated

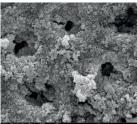




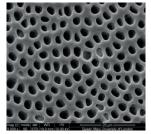
Pro-Argin and Calcium Carbonate toothpaste



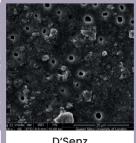
Calcium phosphosilicate and Bioactive Glass toothpaste



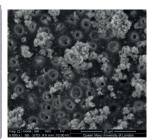
Strontium Acetate based toothpaste



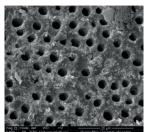
Untreated



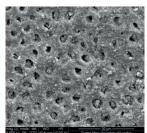
D'Senz



Pro-Argin and Calcium Carbonate toothpaste



Calcium phosphosilicate and Bioactive Glass toothpaste



Strontium Acetate based toothpaste

STUDY ESSENTIALS



20 Dentin Discs (5 discs x 4 groups)



In vitro study



London, UK

IMPLICATION FOR PRACTICE

Curodont™ D'Senz ability in occluding the dentine tubules makes it an effective desensitizing product for the treatment of dentine hypersensitivity.



Title: An In Vitro Comparison of A Novel Self-Assembling Peptide Matrix Gel and Selected Desensitizing Toothpastes in Reducing Fluid Flow by Dentine Tubular Occlusion*



- Products Tested: Curodont D'SENZ gel
 - Pro-Argin (5% Arginine) and Calcium Carbonate toothpaste
 - Calcium phosphosilicate and (Novamin) Bioactive Glass toothpaste
 - Strontium Acetate based toothpaste



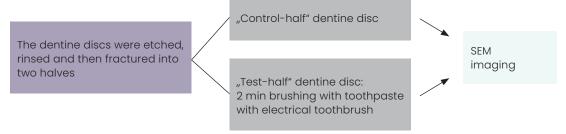
Scope & Methodology: Mid-coronal dentine discs with a thickness of 1 mm were sectioned from caries-free human molars. The discs were etched with 6% citric acid for 2 minutes, halved and subjected to a 2-minute brushing with D'senz and three selected desensitizing toothpastes. The ability of the desensitizing gel and toothpastes to occlude the dentine tubules was assessed and compared before and after brushing using Scanning Electron Microscopy (SEM).



Samples: 20 Dentin discs from mandibular & maxillary molars (5 discs for each of the 4 tested groups).



Procedure:





Conclusion: The results suggest that Curodont D'Senz is effective in blocking the dentine tubules and may therefore have the potential to be an effective desensitizing product for the treatment of Dentine Hypersensitivity.



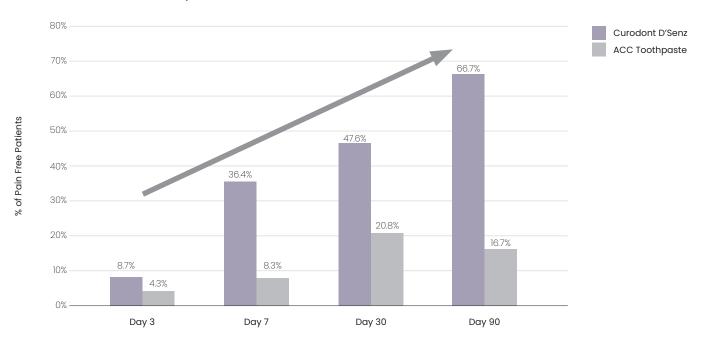


Curodont D'Senz provides rapid and lasting relief from dentin hypersensitivity

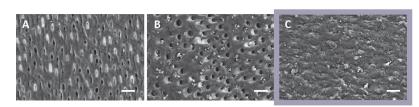
RESULTS

Curodont D'Senz resulted in higher patient satisfaction at day 7, with higher number of pain-free patients at day 7 and day 90. In parallel, SEM images of tooth discs treated with Curodont D'Senz show complete coverage of the dentin tubules, compared with those treated with 8% arginine and calcium carbonate [ACC] toothpaste, where tubules were still partially exposed.

VRS Assessment (Verbal Response Scale)



SEM Images (Tooth Discs)



- A. No Treatment: Tubules Exposed
- B. ACC Toothpaste: Tubules Still Partially Exposed
- C. Curodont D'Senz: No Tubules Exposed

STUDY ESSENTIALS



50 Participants



Randomized, Monocentric, Clinical Study



90 Days



Forchheim, Germany

How can you use these results in your practice?

You can use Curodont D'Senz in-office and instruct the patient on its home-use for rapid and lasting relief from sensitivity due to various causes such as exposed dentin due to periodontal disease, post-peroxide-based whitening, MIH, etc. It can also be used on sensitive teeth before a tooth whitening or hygiene appointment to make the appointments more bearable.

Title: Self-Assembling Peptide Matrix for Treatment of Dentin Hypersensitivity: A Randomized Controlled Clinical Trial*



Products Tested: • Curodont D'Senz

• 8% arginine and calcium carbonate [ACC] toothpaste



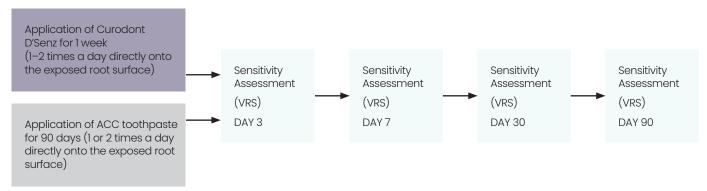
Scope & Methodology: The objective of this clinical study was to evaluate the efficacy and safety of Curodont D'Senz in the treatment of dentin hypersensitivity compared to the established therapy with 8% arginine and calcium carbonate [ACC] toothpaste. The assessment was carries using Verbal Response Scale (VRS). In parallel, tubules exposure was assessed using SEM images of bovine incisor tooth discs treated with the products.



Study Participants: 50 patients with history of supportive periodontal therapy.



Procedure:





Conclusion: The new therapeutic regimen using Curodont D'Senz resulted in greater patient satisfaction and provided relief far beyond its period of use and the VRS scores indicated continuous pain relief beyond its application, until the end of the trial at day 90.



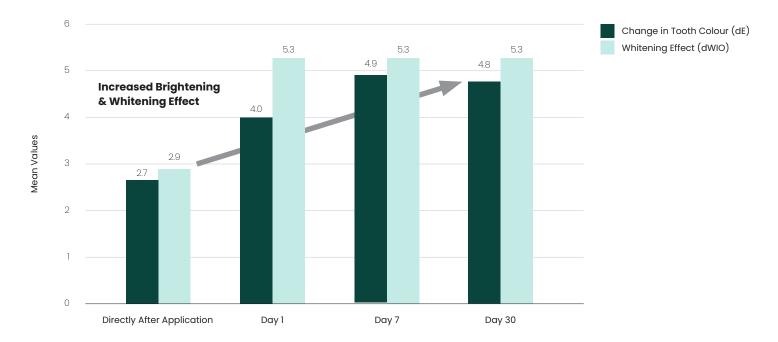


The New White Enamel serum leads to significant brightening and whitening of teeth

RESULTS

The New White Enamel serum showed significant and visible whitening effect after one application, increasing throughout the first week of home application and remaining stable for 30 days.

L*a*b Measurement Differences (Vita Easyshade) Relative to Baseline



Subject's Questionnaire



STUDY ESSENTIALS





Clinical Study



Holzkirchen,

Germany

How can you use these results in your practice?

You can use the New White Enamel serum as an agent for tooth brightening and a gentle, natural whitening, without any sensitivity or gingival irritation. Alternatively, it can be used as a post-peroxide-bleaching booster/enhancer to provide a natural-looking finish to the bleached teeth. For patients in whom peroxide-based bleaching is contraindicated, the New White Enamel serum provides a safe and effective option for enhancing dental esthetics.



Title: Hydroxyapatite and Self-Assembling Peptide Matrix for Non-Oxidizing Tooth Whitening*



Products Tested: New White Enamel serum (Self-Assembling Peptide Matrix and Hydroxyapatite)



Scope & Methodology: The objective of the clinical study was to evaluate the tooth whitening efficacy and safety of the novel New White Enamel serum. For each subject, six teeth, the maxillary incisors and canines were measured throughout the study and assessed relative to baseline for tooth color L*a*b measurements (Vita Easyshade) and Vita Bleachedguide 3D-Master (Vita, Bad Säckingen, Germany) and via a subject questionnaire.



Study Participants: 40 subjects recruited from a daily general dental practice.



Procedure:





Conclusion: The combination of Self-Assembling Peptide Matrix and hydroxyapatite (HA) particles) in the New White Enamel serum caused optical whitening based on diffuse reflection by the HA particles on the tooth surface. The results verified that the New White Enamel serum remained on the tooth surface and acted as a temporary adhesive to attach the white, light-scattering HA particles to the tooth surface. The whitening effect and its magnitude was observed both in vitro and in vivo.