From science to practice:

Micro-invasive caries treatment with resin infiltration

In all areas of medicine, there has been a growing shift of focus dedicated to more preventative and early protective therapy options. With the development of its new cutting-edge technology, DMG intends to open up new possibilities within the world of dentistry with »Icon«.

Icon is based on the concept of caries infiltration whose development began at the Charité Berlin (Department of Operative Dentistry and Periodontology, chair: Prof. Dr. A. M. Kielbassa) and was continued at the University of Kiel (Clinic for Operative Dentistry and Periodontology, chair: Prof. Dr. Christoph Dörfer). In close cooperation with the two leading developers OA PD Dr. H. Meyer-Lückel and Dr. Sebastian Paris, DMG developed the means to deliver this new technology, resulting in the product »Icon«.

Since the year 2000, caries infiltration was first examined in vitro and then further developed and tested in the course of in situ and clinical studies. In this brochure you will find an overview of the available results and information on current studies illustrating the clinical efficacy of caries infiltration. To avoid misunderstandings ongoing studies are clearly marked.

We welcome you to see first-hand the many advantages of caries infiltration; whether it be based on the clinical results presented herein or via practical application of this innovative technology.

Dr. Susanne Effenberger
Scientific Affairs
Manager of Clinical Research

Dr. Dierk Lübbers
Manager Scientific Affairs
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Micro-invasive caries treatment with resin infiltration

Adj. Prof. Dr. Hendrik Meyer-Lückel, Dr. Sebastian Paris.

Even if a substantial decrease in caries has been observed in the past decades it still remains one of the most frequent dental diseases. The prevalence of preventive measures has contributed to curbing caries formation. And where this cannot be accomplished modern filling materials facilitate the restoration of cavities on a high medical as well as esthetic level. Unsolved, however, remains an adequate treatment approach for early approximal carious lesions and white spots on smooth surfaces.

Problem area – approximal caries
In today’s preventive-oriented dentistry fluoridation measures are aimed at inhibiting the formation of carious lesions. However, as soon as cavitation of the enamel surface is present invasive treatment methods are indicated which involve the removal of relatively large portions of healthy hard tissue. Especially for approximal caries the ratio of the caries and the healthy hard tissue needing to be removed is very unfavorable. Furthermore, due to the aging process of the filler materials the respective restorations must be renewed after varying periods of time.

Sealing as a solution?
An experimental therapy approach for approximal carious lesions is the surface treatment of the demineralized enamel structure with hardening resins similar to fissure sealing in the occlusal region. The objective of this limited invasive therapy is to arrest caries progression in a continuously existing cariogenic environment by obturating the diffusion paths for carbohydrates and organic acids. However, the application of resins in the approximal region can promote the formation of secondary caries due to remaining excess material. And subsequent periodontal irritations would have to be expected as well.

Pioneering solution: infiltration
Based on the described issues of sealing approximal lesions the current approaches to prevent caries progression have been further developed at the Charité in Berlin and the University of Kiel. The promising result: infiltration. For this method the hard tissue lost due to demineralization is replaced even to substantial lesion depths (up to 800 μm) with a low viscosity resin. This micro-invasive treatment method creates a diffusion barrier not on the surface but within the hard tissue thus stabilizing and blocking the caries. For approximal applications caries infiltration is indicated up to a maximum radiological lesion progression into the outer third of the dentine.

Vestibular application
As a positive side effect of the caries infiltration the treated enamel lesions lose their whitish opaque color and resemble healthy enamel more than untreated white spots. Thus, caries infiltration constitutes a much gentler treatment alternative for vestibular smooth surface lesions which are frequently observed after the removal of fixed orthodontic appliances and in patients with poor oral hygiene. This method therefore allows for a drastic improvement of the esthetic appearance of such lesions and a long-term caries arrest in only one visit.
Overview of ongoing studies

In vitro study
In vivo study
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In vitro studies
Sealing or infiltrating proximal and buccal lesions with resins might be a promising strategy to hamper further demineralization of carious lesions. Penetration abilities of commercially available adhesives have been studied priorly to the start of the present development using in vitro lesions. At first, visualization methods using confocal microscopy (CLSM) were developed to study penetration depths of the resins and the according lesion depths simultaneously. Lesion depth measurements were correlated with those of the gold standard (transversal microradiography). Subsequently, penetrating and caries inhibiting abilities of various commercially available adhesives were evaluated using in vitro lesions. To develop improved materials penetration coefficients (PC) of experimental monomer mixtures were determined. Subsequently, penetrating as well as caries inhibiting properties of these materials were compared using in vitro lesions.

Due to the compact surface layers of natural lesions resin penetration was shown to be hampered. Therefore, an etching procedure to erode the surface layer of these lesions was developed. Natural lesions etched with hydrochloric acid (15 %) for at least 90 s showed a reliable erosion of the surface that allowed improved penetration of the investigated adhesive. Subsequently, penetration depths of adhesives were compared with those of an infiltrant (PC > 50 cm/s). The validated measurements with CLSM revealed differences in penetration depths as well as the inhibition of lesion progression between several adhesives. Superior abilities to penetrate artificial lesions and to hamper lesion progression were observed for infiltrants compared to adhesives. Moreover, an experimental infiltrant revealed higher penetration depths than the adhesive. Clinical application to proximal surfaces could be accomplished by using separation and application tools developed for this purpose. On the basis of these promising preclinical results the clinical implementation of this so called micro-invasive therapy is advisable.
Evaluation of cavitations in proximal caries lesions at various magnification levels in vitro

Kielbassa AM', Paris S', Lussi A', Meyer-Lueckel H'.

1 Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
2 Department of Preventive, Restorative and Pediatric Dentistry, School of Dental Medicine, University of Bern, Switzerland

Objectives
The aim of this study was to evaluate the cavitation rate of proximal caries using different magnification aids in vitro.

Radiographs of 285 extracted teeth were taken and the proximal surfaces were graded to the criteria R0 (no radiolucency), R1 (radiolucency confined to the outer half of enamel), R2 (inner half of enamel) and R3 (outer half of dentin). Subsequently, the proximal surfaces were checked for the presence of cavitations with the naked eye (NE), by using 4.3 x magnification eyeglasses (ME), a stereo microscope (SM, 10 x) or a scanning electron microscope (SEM, up to 2000 x magnification). In surfaces with R3 caries, cavitations were visible in 56 of 59 cases with the naked eye. When using SEM, all surfaces revealed cavitations (100 %). Regarding the surfaces with R2 lesion, 36 of 46 cases showed cavitations (NE); the corresponding values were 39/46 (ME), 41/46 (SM), and 46/46 (SEM); in the latter, in most cases deep defects could be observed. With regard to R1 lesions, 36/60 (NE), 43/60 (ME), 45/60 (SM), and 58/60 (SEM) cases revealed cavitations. A breakdown of radiographically sound surfaces (R0) was present in some 10 % of the examined surfaces (24/261, NE; 33/261, SEM).

Conclusion
Cavitations (defined as breakdown of the surface) are present in significantly more cases than previously reported. This might be an explanation why even small radiolucencies tend to progress, albeit slowly. Thus, close follow-ups should strongly be recommended when considering a preventive treatment regimen with small radiolucencies.

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Resin infiltration of natural caries lesions


*Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany

Objectives

Infiltration of non-cavitated caries lesions with light-curing resins could lead to an arrest of lesion progression.

The aim of this study was to evaluate the penetration of a conventional adhesive into natural enamel caries after pre-treatment with two different etching gels in vitro. Extracted human molars and premolars showing proximal white spot lesions were cut across the lesions perpendicular to the surface. Corresponding lesion halves were etched for 120 sec with either 37% phosphoric acid gel (H₃PO₄) or 15% hydrochloric acid gel (HCl), and subsequently infiltrated with an adhesive. Specimens were observed by confocal microscopy. Mean penetration depths (SD) in the HCl group [58 (37) μm] were significantly increased compared with those of the H₃PO₄ group [18 (11) μm] (p < 0.001; Wilcoxon).

Conclusion

It can be concluded that etching with 15% hydrochloric acid gel is more suitable than 37% phosphoric acid gel as a pre-treatment for caries lesions intended to be infiltrated.

Aim

This study is used for development and verification of the caries infiltration treatment concept.

Source:


Illustration 1: Resin penetration into natural caries lesions after different erosion procedures. A: Deep resin penetration after etching with HCl. B: Incomplete removal of the surface layer after etching with H₃PO₄ results in very superficial resin penetration. (E = sound enamel, LB = lesion body, R = penetrated resin, S = lesion surface, SL = pseudointact surface layer).}

Illustration 2: Mean penetration depths of resin for various pre-treatments and histological lesion extensions (box and whisker plots with quartiles and medians, n = 10 per group). (C1 = caries extension into the outer half of enamel, C2 = caries extension into the inner half of enamel, C3 = caries extension into the outer half of dentin).
Surface layer erosion of natural caries lesions with phosphoric and hydrochloric acid gels in preparation for resin infiltration

Meyer-Lueckel H1, Paris S1, Kielbassa AM1.
1Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany

Objectives
The infiltration of proximal enamel lesions with low-viscosity light curing resins could be a viable approach to stop lesion progression. However, penetration of sealant might be hampered by the comparatively highly mineralized surface layers of natural lesions.

Therefore, the aim of this study was to compare the efficacy of three different etching gels in removing the surface layer in various etching times. Extracted human molars and premolars showing proximal white spot lesions were cut across the demineralized areas. Ninety-six lesions expected from visual examination to be confined to the outer enamel (C1) were selected. The cut surface and half of each lesion were varnished, thus serving as control. Subsequently, the lesions were etched with either phosphoric (37 %) or hydrochloric (5 or 15 %) acid gel for 30–120 s (n=8/group). Specimens were examined using confocal microscopy and transversal microradiography. Surface layer reduction was significantly increased in lesions etched with 15 % HCl gel for 90 and 120 s compared to those etched with H3 PO₄ gel for 30–120 s (p < 0.05). No significant differences regarding the depths of erosion in the lesions compared to sound enamel could be observed (p > 0.05).

Conclusion
An effective reduction in the surface layer of natural enamel caries can be achieved by etching with 15 % hydrochloric acid gel for 90–120 s.

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Influence of application frequency of an infiltrant on enamel lesions

Paris S1,2, Meyer-Lückel H1,2.
1Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
2Department of Operative Dentistry and Periodontology, Christian-Albrechts-University Kiel, Germany

Objectives
The aim of this study was to evaluate the application frequency of two experimental low viscous resins (infiltrants) on lesion progression and micro hardness of resin infiltrated artificial enamel lesions in vitro. Methods: Twenty-six bovine enamel specimens were demineralized (pH 4.95; 50 days) to prepare three windows of caries-like lesions. Two of these windows were etched with phosphoric acid (37 %) for 5 s, the third one served as control. Both etched lesion parts were treated with either one of two infiltrants (A: BisGMA 25 %, TEGDMA 75 %; B: BisGMA 20 %, TEGDMA 60 %, ethanol 20 %). The respective infiltrant was applied onto both windows (10 s), excessive material was removed and the material light cured (60 s). This procedure was repeated on one of the two windows of each specimen. Subsequently, lesions were cut in two halves, one being stored in the demineralizing solution for another 50 days, the other serving as baseline control. Lesion depths and mineral losses were evaluated by microradiography (n=13). Vickers hardness numbers (VHN) were assessed on cut surfaces 50 µm below the surface (n=9). Results: Control lesions of the baseline halves showed a mean (SD) mineral loss of 15.205 (1.820) vol. %×µm and a lesion depth of 357 (32) µm. Irrespective of the material control lesions as well as those being infiltrated once progressed significantly (t test, p < 0.05), whereas those being infiltrated twice revealed no significant progression (p > 0.05). Lesions being infiltrated twice [48 (17)] showed significantly higher VHN compared with those being infiltrated once [37 (16)], which were again significantly higher than those of the control lesions [7 (5)] (p < 0.05). No significant differences in micro hardness could be observed between the materials (p > 0.05).

Conclusion
Twice infiltration results in a hampered lesion progression and a gain in micro hardness in artificial lesions. This study was supported by Deutsche Forschungsgemeinschaft (PA 1508/1-1).

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Penetration coefficients of commercially available and experimental resins intended to infiltrate enamel carious lesions

Paris S1, Meyer-Lückel H1, Cölfen H2, Kielbassa AM1.
1 Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
2 Department of Colloid Chemistry, Max-Planck-Institute of Colloids and Interfaces, Golm, Germany

Objectives
Arresting of enamel lesions by infiltration with light-curing resins might be a treatment alternative of future micro-invasive dentistry. So far only commercially available adhesives and fissure sealants have been used to infiltrate enamel lesions. Since these products have been optimized for adhesive purposes, the aim of this study was to develop optimized resins for the infiltration of enamel lesions and to measure their physical properties.

The penetration coefficients (PCs) of five adhesives and a fissure sealant as well as 66 experimental composite resins were determined. To establish the resins’ PCs the viscosities, surface tensions and contact angles to bovine enamel were measured. For the commercially available products PCs from 4.0 to 278.9 cm/s were measured. Four of these materials showed a good correlation with penetration depths obtained in a previous study. Experimental resins showed PCs from 0.2 to 474.9 cm/s. The addition of ethanol significantly increased the PCs due to a decrease of viscosity and contact angle. Highest PCs were found for mixtures containing TEGDMA, HEMA and 20 % ethanol.

Conclusion
The knowledge about the PC of resins seems to be useful for the development of new materials optimized to infiltrate enamel lesions.

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Inhibition of lesion progression by the penetration of resins in vitro: influence of the application procedure

Mueller J¹, Meyer-Lueckel H¹, Paris S¹, Hopfenmueller W², Kielbassa AM¹.
¹Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
²Department of Medical Informatics, Biometry and Epidemiology, Campus Benjamin Franklin, Charité – University Medicine Berlin, Germany

Objectives
This study compared the progression of sealed early enamel lesions penetrated with a fissure sealant (Helioseal, Vivadent) or various adhesives (Heliobond, Excite, Vivadent; Resulcin, Merz; Solobond M, Voco; Prompt L-Pop, 3M-ESPE) after exposure to a demineralizing solution, in vitro.

From 27 bovine teeth, 54 enamel specimens were prepared and covered with nail varnish (control), thus obtaining three windows for treatment. After demineralization (pH 5.0; 14 days), two of the windows (A, B) were etched with phosphoric acid (20 %; 5 seconds); whereas, the third area served as the control (C). The specimens were divided randomly into six groups (n=9) and the material was applied (90 seconds) either once (A) or twice (B). Light-curing followed each application. Half of the area of each specimen window was then covered with nail varnish and the samples were again stored in the demineralizing solution (pH 5.0; 14 days). The specimens were cut perpendicular to the surface and both enamel slabs were studied after infiltration using a fluorescent, low viscous resin (VIRIN) and confocal microscopy (CLSM). Lesion depths were calculated (Image) from the surface to that point in the lesion where the grey values clearly changed to a darker grey. After demineralization mean lesion depths (SD) (14 days) were measured at 105 (21) micron. The second demineralization led to a mean progression of the lesion depths of 52 (31) %. Adper Prompt L-Pop and Solobond M could not significantly prevent lesion progression after a single application (p > 0.05; t-test); however, the second application of Solobond M significantly decreased lesion progression (p < 0.05; t-test). Helioseal, Heliobond, Resulcin Monobond and Excite showed significantly better inhibition of the demineralization compared to the other materials (p < 0.05; Bonferroni).

Conclusion
It can be concluded that the penetration of adhesives into early lesions inhibited a further demineralization in vitro.

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Progression of sealed early bovine enamel lesions under demineralizing conditions in vitro

Paris S¹, Meyer-Lueckel H¹, Mueller J¹, Hummel M², Kielbassa AM¹.
¹Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
²Institute of Pathology, Campus Benjamin Franklin, Charité – University Medicine Berlin, Germany

Objectives
The use of sealants for the infiltration of proximal enamel lesions could be a promising alternative to the common strategies of remineralization and operative treatment.

The aim of the present study was to compare the progression of sealed initial enamel lesions after exposure to a demineralizing solution in vitro. In each of 54 bovine enamel specimens three subsurface lesions were created. Two of the lesions were etched with phosphoric acid and sealed with either a fissure sealant or with various adhesives (1–5) for 15 s or 30 s, respectively, whereas one lesion remained as the untreated control. Subsequently, half of each specimen was covered with nail varnish (baseline) and the other half was re-exposed to a demineralizing solution for 14 days (experimental). The specimens were cut perpendicularly to the surface, infiltrated with a low-viscosity fluorescent resin and observed with a confocal laser scanning microscope (CLSM). For lesions sealed with the fissure sealant and adhesives 1–3, the progression of lesion depth (0–31 μm) was significantly decreased (p < 0.01; paired t-test) compared with the untreated control (57 μm). For the fissure sealant and adhesives 1 and 3 extended penetration times (30 s) resulted in significantly reduced lesion progression compared to 15 s.

Conclusion
It can be concluded that filling of the pores in early enamel lesions with the fissure sealant and adhesives 1–3 can inhibit further demineralization in vitro.

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Surface layer erosion of enamel caries lesions in primary teeth in preparation for resin infiltration

Paris S1, Meyer-Lueckel H1, Stiebritz M1, Kielbassa AM1.
1Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany

Objectives
Resin infiltration of enamel caries is a promising approach for arresting lesion progression. However, the relatively impermeable surface layer of natural enamel lesions hampers resin penetration into the lesion body and should thus be removed before infiltration. For permanent teeth hydrochloric acid has been shown to be suitable for surface layer erosion. Due to structural differences (e.g. aprismatic layer) between permanent and primary teeth, it is unclear whether this etching regimen can be transferred to the deciduous dentition. The aim of the present study was to evaluate the effect of etching the surface layer of natural white spot lesions in primary teeth using phosphoric and hydrochloric acid gels.

Extracted or exfoliated primary molars showing proximal white spot lesions were cut perpendicularly to the surface across the demineralizations and lesions confined to enamel were selected. The cut surfaces as well as parts of the lesions surfaces were varnished (control). Subsequently, corresponding lesion halves were etched with either 37 % phosphoric or 15 % hydrochloric acid gel for 30, 60, 90, and 120 s, respectively (n = 9). Specimens were observed using confocal microscopy and surface layer thicknesses in etched and protected lesion parts as well as erosion depths were measured. Etching with H3PO4 resulted in incomplete reduction of the surface layers in all groups [highest percentage reduction (SD) at 120 s: 54 (28) %]. In contrast, surface layers could be eroded nearly completely [99 (3) %] after etching with HCl for 120 s. Erosion was significantly increased after etching with HCl compared with H3PO4 (p < 0.05; Wilcoxon).

Conclusion
It can be concluded that the pseudointact surface layer of natural enamel lesions in primary teeth can be eroded reliably by etching with 15 % HCl gel for 120 s.

Supported by Deutsche Forschungsgemeinschaft (PA1508/1-1).

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Influence of different etching gels on the mineral content of initial enamel lesions in primary teeth

Meyer-Lueckel H1, Paris S1, Kielbassa AM1.
1Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany

Objectives
To achieve a penetration as deep as possible of low viscous resins (infiltrant) in natural lesions of permanent teeth, the erosion of the surface layer with hydrochloric acid gel (15 %) seems to be suitable. Due to anatomical differences primary teeth may behave different than permanent teeth.

The aim of this study was to evaluate the effect of etching with phosphoric or hydrochloric acid on the mineral content of initial enamel lesions in primary teeth. Extracted molars of primary teeth with proximal enamel caries were perpendicular cut into two halves. The cut surfaces, parts of the lesions and the sound enamel were covered with nail varnish (control). The halves were either treated with phosphoric acid (37 %) or hydrochloric acid (HCl, 15 %) for 30, 60, 90 or 120 s (n=8). The specimens were cut and analyzed by micro radiography. The mineral content of the upper 50 μm of the sound areas and the lesions and the depths of the highest mineral content was determined. ΔZ o,n, (standard deviation) was significantly higher after etching with HCl for 90 s [2.830 (800) vol. % x μm] and 120 s [3.040 (640)] than etching with Phosphoric acid [ 1.440 (270) resp. 1.550 (530)] (p < 0.05; adjusted paired t-test).

Conclusion
A treatment with HCl for 120 s lead to a complete erosion of the surface layer. This may have a positive influence on the penetration of the infiltrant. This study was supported by Deutsche Forschungsgemeinschaft (PA1 508/1-1).

Aim
This study is used for development and verification of the caries infiltration treatment concept.

Source:
Infiltration of natural caries lesions in primary teeth with experimental infiltrants in vitro

Paris S¹, Chatzidakis AJ², Meyer-Lückel H¹.
¹Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
²Department of Prosthodontics, Geriatrics and TMD, Charité – University Medicine Berlin, Germany

Objectives

Infiltration of carious enamel with low viscous light cured resins could be a promising treatment to arrest lesions. It is not clear yet whether this new procedure can be used also in primary teeth.

The aim of this study was to compare penetration depths of four experimental infiltrants with different composition and penetration coefficients (PK A: 63; B: 185; C: 204; D: 391 cm/s) in natural caries in primary teeth. The experimental infiltrants were made from TEGDMA (T), BisGMA (B) and Ethanol (E) in the mixing ratio (T:B:E) A: 75:25:0; B: 60:20:20; C: 100:0:0; D: 80:0:20. 52 exfoliated human primary teeth with natural proximal white spot lesions (ICDAS II: 2) were randomized in 4 groups. To remove the surface layer the lesions were etched for 120 s with 15 % Hydrochloric acid gel. The lesions were dried and the different infiltrants were applied to the surface. After a penetration time of 5 minutes excess was removed and the materials were cured with light. Subsequently the lesions were prepared for the measurement by CLSM with a fluorescent dye. Infiltrants C and D penetrated significantly deeper [Median (Q25, Q75)] [C: 257 (133, 413) µm; D: 283 (157, 449) µm] than the materials A [184 (98, 318) µm] and B [191 (99, 332) µm] p < 0.05; Mann-Whitney).

Conclusion

Non cavitated enamel caries lesions in primary teeth can nearly be completely infiltrated in vitro. Infiltrants with a high PK seem to be better suitable than those with low PK.

The study was supported by Deutsche Forschungsgemeinschaft (DFG) (PA 1508/1-1).

Aim

This study is used for development and verification of the caries infiltration treatment concept.

Source:

Illustration 1: Infiltrated lesion in a deciduous molar
Infiltration of natural caries lesions with monomer under simulated conditions of the oral cavity

Schneider H¹, Albert M¹, Busch M¹, Häfer M¹, Jentsch H¹.
¹Department of Conservative Dentistry and Periodontology, University of Leipzig, Leipzig, Germany

Objectives, Methods, Results
The infiltration of natural enamel caries lesions with resin («infiltrant») was to be assessed in vitro after setting of relative humidity (rH) to values according to an in-vivo treatment with or without rubber dam application. Hypothesis: With lower rH the penetration of the infiltrant is enhanced. Methods: n = 6 extracted human molars with enamel caries lesions, 2 cuts of each across the centre of lesions perpendicular to their surfaces (corresponding halves), 2 groups of lesion halves (G 1: rH 37 - 45 %, corr. to rubber dam application, control; G 2: rH 78 - 90 %, corr. to no rubber dam application; 27 - 30 °C each), covering cutted areas with nail varnish, infiltration with resin accord. to instruction (moist chamber, infiltrant, exp. charge, DMG GmbH, Hamburg, G), embedding of corresponding halves in Stycast, removal of nail varnish, preparation of specimens for scanning electron microscopy (SEM, 3 layers of each). Assessment criteria: percentage of resin penetration (area of penetrated resin:area of lesion, %), penetration depth, homogeneity of resin penetration (grades 1/2: homogeneous/inhomog.), residual surface layer (y/n). Statistics: Wilcoxon test, α = 0.0166, tendency: p < 0.08. Results: The hypothesis is not valid. The percentages of resin penetration between G 1 (26.9 ± 15.2 %) and G 2 (24.7 ± 16.1 %) were non-significantly different (p = 0.313), just as the penetration depths (G 1: 113.9 ± 65.6 µm, G 2: 90.6 ± 61.6 µm, p = 0.313), the penetration was more inhomogeneous in G 2 (4.0 ± 2.5) than in G 1 (2.8 ± 1.7, p = 0.063, sum of grades), residual surface layers were observed generally.

Conclusions
A lower rH (corr. to rubber dam application) seems not to enhance the resin penetration but seems to enhance its homogeneity. There is a potential for resin penetration and the removal of the residual surface layer. Investigations are in progress.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Schneider H. Infiltration of natural caries lesions with monomer under simulated conditions of the oral cavity. 2008, Date on file, DMG, Hamburg, Germany

Illustration 1+2: Enamel lesion after infiltration with resin (1, SEM), resin penetration in the lesion (2). Penetrated resin (R), residual surface layer (RL), non infiltrated areas (L), sound enamel (E).
In vitro color stability of infiltrated carious lesions

Luebbers D¹, Spieler-Husfeld K¹, Staude C¹, Effenberger S¹.
¹Scientific Affairs, DMG Dental-Material-GmbH, Hamburg, Germany

Objectives
Caries infiltration is a promising novel approach for the treatment of incipient lesions of smooth labial surfaces. Color stability of the infiltrated areas is the key factor for the long term clinical success. This study aimed to determine the color stability of infiltrated carious lesions subject to staining during the exposure to light irradiation (sun test).

24 artificial incipient lesions were created out of bovine incisors following a demineralization protocol. Specimens were subdivided in two groups (n=12): Group A served as a control and was stored in aqua dest. for 14 days. Group B underwent a sun test (exposure to Sunbeam radiation for 15 minutes, for 2’ in tap water and the remaining time of 23h43’ in aqua dest. for 14 consecutive days). To differentiate between extrinsic and intrinsic stain, specimens were polished after the last discoloration cycle using an electrical toothbrush (Oral-B, Vitality, Procter & Gamble, Schwalbach, Germany) and toothpaste (elmex, GABA, Lörrach, Germany). CIE L*a*b* values, were taken at four intervals: at baseline, 24 h after infiltration, after discoloration cycles and after final polishing. A small-area colorimeter was used. ΔL, Δa, Δb and ΔE values were calculated to determine the extent of color change. In this test no difference between the two groups could be detected. This corresponds to a ΔE value < 2.

Conclusion
Within the limitations of this test infiltrated artificial lesions are not sensitive to discoloration by sun light.

Aim
This study is used for verification of the product’s clinical performance.

Source:
DMG internal measurements, 2009, Data on file, DMG, Hamburg, Germany
In vitro resistance of resin infiltrated initial caries lesions (white spots) against tooth brush abrasion

Lohbauer U1, Ebert J1, Schubert EW1, Petschelt A1
1Dental clinic 1 – Conservative Dentistry and Periodontology, University hospital Erlangen, Germany

Objectives
To stop caries already in the initial stage a special infiltration method for the so called »white spots« has been developed. Porous enamel lesions are infiltrated with a light-cured resin. White spots can be found in proximal as well as in vestibular areas. Especially in vestibular areas the infiltrated areas are subject to abrasion. The resistance to tooth brushing is therefore very important for the longevity of the treatment.

Fresh extracted bovine teeth were prepared to get a smooth parallel area, which was subdivided in 4 areas (not treated–not brushed [1], not treated–brushed [2], demineralized–infiltrated–brushed [3], demineralised–brushed [4]). The areas 1 and 2 were protected against demineralization. The specimens (n = 8) were demineralized in a special demineralization solution (Buskes, Christoffersen et al. 1985) at pH-value of 4.95 for 30 days until lesions of about 200 µm were created. 2 demineralized areas were penetrated with the infiltrant twice according to the instructions for use. The abrasion tests were performed with a computer controlled tooth brush machine (Willitec, Munich, Germany). The abrasive medium was a commercial available tooth paste Elmex (Gaba, Lörrach), which was modified with an emulgator (Traganth). Standardized tooth brushes (Oral-B 40, medium hardness) with a brushing area of 184 mm² and a pressure of 1,9 N (ISO 14569-1) were used. An 8-shaped brushing procedure and a maximum of 10000 brushing cycles were chosen to avoid local build up of frames. The abraded enamel surfaces were observed with Confocal Laser Scanning Microscope (TCS SL, Leica, Bensheim) at a magnification of 200. The abraded surfaces 2, 3 and 4 were referenced to surface 1. The statistics were evaluated by Variance Analysis ANOVA (mod. LSD-Test, p < 0.05).

Results: Infiltrated lesions showed a slightly higher abrasion than sound enamel.

Conclusion
Infiltration reinforces artificial lesions with respect to abrasion resistance.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Surface roughness determination of a caries infiltrant resin

Burgess JO¹, Cakir D²
¹ UAB School of Dentistry, University of Alabama, Birmingham AL, USA

Objectives
Surface roughness can lead to excessive plaque accumulation, increased surface staining, and poor or less than optimal esthetics of the restored teeth. This in vitro study was designed to 1) determine the surface roughness of »caries infiltrant resin« after the application on enamel surface and to 2) compare surface roughness values of finished and unfinished surfaces and natural lesion to the values of sound enamel.

Freshly extracted molars were collected and polished using polishing caps and pumice to remove stains and tiny deposits of calculus. The teeth were then gently air-dried and visually examined using a 30x magnifying lens and overhead lamp for early white spot lesions in the plaque retentive areas. Only teeth with no cracks, restorations, forceps lesions or other developmental lesions were selected and divided into 4 groups (n=10), (A) Infiltrant with finished surface, (B) Infiltrant without surface treatment, (C) Natural enamel, (D) Carious enamel. The teeth specimens were then sectioned at the Cemento-enamel junctions, only the crowns were retained for purposes of this study. The crowns were further sectioned in to rectangular blocks with smooth surfaces and those blocks were then embedded in a putty material, in a way that ensured that the convex smooth tooth surfaces were as parallel to the scanning stage as possible. Through the entire procedure, the teeth hydration was maintained. The lesions were treated with Icon® kit for caries infiltration (DMG, Hamburg, Germany) according to manufacturer’s instructions. The samples were scanned using a 3-D non-contact surface profilometer (Proscan2000, Scantron, UK). Acceptable light intensity and depth were attained by adjusting the Z axis of the sensor. ISO standards were followed for cut-off and filter application on the scanned image. A surface filter of 133 was applied. Cut-offs of 0.4 on each side of the image were applied to give the final image analysis. The Ra mean X and Y surface readings were recorded and analyzed using ANOVA followed by Dunnets post-hoc test (p=0.05). The statistical analysis showed no significant differences in surface roughness between all 4 groups, for X and Y analysis (p>0.05).

Conclusion
Caries Infiltration does not lead to an increased surface roughness of infiltrated lesions compared to sound enamel.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Burgess JO, Cakir D. Surface Roughness Determination of a Caries Infiltrant Resin. Data on file. DMG; Hamburg, Germany

Illustration 1: Mean X values show no significant differences between all 4 groups

Illustration 2: Mean Y values show no significant differences between the all 4 groups
In vivo studies
Bitewing diagnosis and indications for proximal infiltration

The indications for the proximal infiltration include lesions with extension up to D1.

<table>
<thead>
<tr>
<th>Scores</th>
<th>Criteria</th>
</tr>
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<tbody>
<tr>
<td>E1</td>
<td>Radiolucency confined to the outer half of the enamel.</td>
</tr>
<tr>
<td>E2</td>
<td>Radiolucency in the inner half of the enamel including lesions extending up to but not beyond the enamel-dentin junction.</td>
</tr>
<tr>
<td>D1</td>
<td>Radiolucency in the dentin; broken enamel-dentin junction but up to the outer third of dentin.</td>
</tr>
<tr>
<td>D2</td>
<td>Radiolucency with obvious spread in the second third of the dentin</td>
</tr>
<tr>
<td>D3</td>
<td>Radiolucency with obvious spread in the inner third of the dentin</td>
</tr>
</tbody>
</table>

Radiographic scores to classify the depth of proximal carious lesions (based on: Mejäre et al. 1999)36

Illustration 1+2: Lesion extension illustrated radiographically

Source:
Progression of infiltrated artificial enamel caries lesions in situ

Paris S1,2, Meyer-Lückel H1,2.
1 Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
2 Department of Operative Dentistry and Periodontology, Christian-Albrechts-University Kiel, Germany

Objectives
The aim of the present study was to assess the efficacy of resin infiltration to prevent further demineralization in situ.

Two artificial enamel caries lesions were created in each of 40 bovine enamel specimens (demineralization solution, pH 4.95, 14 d). In the test group one of the lesions was etched for 5 s and subsequently infiltrated with a pre-product infiltrant (DMG) twice for 60 s. In a positive control group one lesion was superficially sealed with a fissure sealant (Clinpro Sealant, 3M Espe, Germany). The second lesion in each specimen served as untreated control. Specimens were embedded in intraoral appliances that were worn by six volunteers for 100 days. Plaque accumulation was promoted by protecting the specimen’s surface with a mesh and storing the appliances in 10 % sucrose solution (2×30 min/day). Specimens were analyzed using Transversal-Microradiography (TMR). Baseline lesion depths [mean (SD); LD=98 (19 µm) and mineral losses [ΔZ=2465 (472) vol. %×µm] did not differ significantly between various groups (p>0.05; paired t-test). After in situ phase untreated controls had progressed significantly [LD=206 (72) µm, ΔZ=6694 (2322) vol. %×µm; p<0.05]. In contrast, infiltrated [LD=99 (20) µm, ΔZ=2872 (527) vol. %×µm] and sealed [LD=97 (20) µm, ΔZ=2441 (667) vol. %×µm] lesions showed no significant progression (p>0.05).

Conclusion
It can be concluded that resin infiltration is efficacious in preventing further demineralization of enamel caries lesions under cariogenic conditions in situ.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Infiltration of proximal caries lesions in primary molars – Influence of the application time

Study planned, not yet published.

Mendes Soviero V1.
1Faculdade de Odontologia, Centro Biomédico, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, Brazil

Objectives
Several studies have observed promising results after sealing enamel lesions. In vitro studies have showed that artificial as well as natural caries lesions can be infiltrated by adhesives or fissure sealants. In addition, initial lesions in surfaces that are infiltrated with low viscosity resins became more resistant to further demineralization and lesion progression was hampered.

The aim of this, blinded clinical-laboratorial study is to evaluate the influence of the application time of the infiltration on the penetration depth of a low viscosity resin in proximal carious lesions in primary teeth. Individuals will be selected among children of the Pediatric Dental Clinic for dental treatment in the period of October of 2008 and June of 2009. Healthy children presenting at least one primary molar with proximal contact with the adjacent tooth will be considered eligible. Lesions will be identified by bitewing x-rays and scored with 2 or 3. Lesions will be randomly allocated to the three testing groups (A,B,C). At intervention the proximal surface will be cleaned with dental floss and water. After application of rubberdam, all lesions will be conditioned with 15 % HCl gel, cleaned and dried and infiltrated. The adjacent proximal surface will be protected with teflon tape during all the procedure. The lesions will be infiltrated with an infiltrant resin (DMG, Hamburg) for (A) 120 s, (B) 180 s and (C) 300 s. After the intervention, children will be followed up in monthly intervals until the teeth present natural mobility caused by the exfoliation process and can be extracted. After being extracted teeth will be cleaned of soft tissues and stored 0.1 % thymol solution. Penetration depth will be analyzed using CLSM and TWIM technique. Group assignments will be blinded. Statistical analysis will be performed with SPSS (SPSS Inc., Chicago, USA). Mean values of the penetration depth will be compared between groups. The level of significance is set at 5 %.

Status
First results will be obtained in November 2009.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Comparison of the radiological lesion progression of proximal caries after infiltration or standard therapy – 18 months follow-up

Study in progress, not yet published.

Paris S1,2, Meyer-Lückel H1,2.
1 Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
2 Department of Operative Dentistry and Periodontology, Christian-Albrechts-University Kiel, Germany

The aim of this study was to assess the efficacy of resin infiltration of proximal carious lesions with a low-viscous resin (infiltrant).

In 22 patients (informed consent, IRB approval) 29 pairs of proximal lesions with radiological extension inner half of enamel or outer third of dentin were selected. Lesions were randomly allocated to one of two treatment groups (split mouth design). In the effect group selected teeth were slightly separated with a flattened wedge. Subsequently, 15 % HCl-gel (pre-product; DMG, Hamburg) was applied onto the lesion surface for using a foil applicator and hereafter rinsed off with water spray. The lesion was dried with ethanol and an infiltrant (pre-product; DMG, Hamburg) was applied for using a foil applicator according to manufacturers instructions. After removing surplus material the resin was light-cured and applied for a second time. In the control group a placebo treatment was performed. All subjects received instructions for flossing and brushing with fluoridated toothpaste. After 18 month the subjects were examined by an investigator who was blinded with regard to treatment. Standardized x-rays were obtained and analyzed using digital subtraction radiography.

At baseline caries risk [mean (SD)] of included subjects was 40 (22) % (Cariogram 2.01). For follow up examination all 22 subjects could be recruited. No unwanted effects such as pain, loss of vitality or staining could be observed. In the control group one lesion was cavitated and one lesion had been restored by another dentist. In the effect group three lesions (10 %) and in the control group eleven lesions (38 %) showed progression (p<0.008; McNemar).

Infiltration of approximal carious lesions extending into inner half of enamel or outer third of dentin is an efficacious method to reduce lesion progression.

Aim
This study is used for verification of the product’s clinical performance.

Source:

Illustration 1+2: Representative bite wing x-ray using a customized, three-dimensionally supported film holder
Modern detection, assessment and treatment of initial approximal lesions – 12 months follow-up

Study in progress, not yet published.

Martignon S¹, Meyer-Lückel H ²³, Tellez M¹, Paris S ²³.
¹Caries Research Unit UNICA, Dental Faculty, Universidad El Bosque, Bogotá, Colombia,
²Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany
³Department of Operative Dentistry and Periodontology, Christian-Albrechts-University Kiel, Germany

The aim of this split mouth design study was to assess the efficacy of resin infiltration of approximal carious lesions. In each of 40 patients, three proximal lesions with radiographic extension around the enamel-dentin junction (E2) or in the outer third of the dentin (D1) were selected. Lesions were randomly allocated to one of three treatment groups and all three group teeth were separated using an orthodontic spacer over 24 h. According to the treatment group allocation teeth were treated: A. Infiltration using the Kit for Infiltration (DMG, Hamburg); B. Sealing using Prime Bond NT (Dentsply, USA), following manufacturer’s instructions for use; C. Control group: placebo treatment. All subjects received instructions for flossing. At 12 months, follow up examinations were conducted in 95 % of the sample by a blind examiner. Standardized x-rays were obtained and analyzed using digital subtraction radiography (Image Tool, UTHSCA, USA). At baseline subject’s caries risk was distributed as follows: 45 %-low; 30 %-moderate; 20 %-high; and 5 %-very high (Cariogram 2.01). No unwanted effects such as pain, loss of vitality or staining could be observed. Independent staging of x-rays showed little progression in all 3 groups. According to the radiographic-reading method, the pair-wise comparison showed progression in the following number of cases: 7(A); 17 (B) and 20 (C). Correspondent figures for the subtraction comparison were: 14(A), 29(B), and 28(C), respectively. Significant differences were observed in lesion progression between the 3 study groups (Infiltrant < Sealing < Control) pair wise reading (Stewart Maxwell χ²: less than 0.05) methods were used. No significant differences were observed when Rx independent reading was conducted.

The infiltration of proximal caries is an efficacious method to reduce lesion progression in vivo.

Status:
The radiographic follow up data after 12 months are available since February 2009.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Martignon S, Meyer-Lueckel H, Tellez M, Paris S. Radiographic comparison of lesion progression after infiltration, sealing and floss instructions in a high caries risk population – 12 months follow-up, Data on file. DMG Hamburg, Germany
Radiographic progression of infiltrated caries lesions in vivo

Study in progress, not yet published.

Peters MC1,2, Czajka-Jakubowska A2, Stopa N2, Bayne S1, Clarkson B1.
1 Department of Cariology, Restorative Dentistry and Endodontics, Department of Operative Dentistry, School of Dentistry, University of Michigan, Ann Arbor, MI, USA
2 Department of Conservative Dentistry and Periodontology, Marcinkowsky University of Medical Sciences, Poznan, Poland

Objectives
In vitro as well as in situ studies have shown that the infiltration of carious lesions is a novel and promising approach in the early, micro-invasive dental treatment options. In this method the compact surface layer of carious lesions is eroded by 15 % HCl gel. Subsequently a low viscous, light-cured resin (»Infiltrant«) is applied. This resin penetrates into the microporosities of the lesion and hampers after curing the progression of caries.

The micro-invasive treatment of caries lesions by resin infiltration may postpone invasive filling procedures more effective than other preventive approaches (mouth hygiene, topical fluoride application). In this prospective, randomized, controlled double blinded clinical trial, conducted in the split-mouth design, is evaluated whether infiltration leads to a hampered progression of lesions than the standard preventive measures. Follow-up visits are made after 12, 24 and 36 months after invention. The evaluation is done by blinded investigators.

At each follow-up visit a complete dental diagnosis is performed and the mouth hygiene is controlled. Standardized bitewing radiographs are taken. These radiographs are rated and compared with the initial radiographs by two trained and blinded investigators. Radiographs are digitalized and evaluated by digital subtraction radiography (DSR)-Software. A total of 45 patients will be enrolled in the study.

Status:
The first follow-up evaluation with radiographs (12 months) will be made in August 2010.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Sealing of proximal carious lesions in primary teeth with children

Study in progress, not yet published.

Ekstrand KR¹, Bakshandeh A¹.
¹ Københavns Universitet, Tandlægeskolen, København, Denmark

The aim of this split mouth design study was to assess the efficacy of resin infiltration versus fluoride treatment of early proximal carious lesions on deciduous molars. The study was undertaken in Nuuk in Greenland, where the majority of children are recognized by having very high caries progression rate (Pedersen et al., 2006). This, in spite of the fact that all children from the age of 0–18 years are enrolled in the Child Dental Health Service of Greenland, which focuses on prevention and it is free of charge. Initially, 48 children age around 7 years were selected, each having 2 or more proximal lesions on deciduous molar teeth with no or initial clinical signs of caries and radiological E1 to D1 lesion depth. Two lesions were randomly allocated to one of the two treatment regimes, resin infiltration (Kit for Infiltration, DMG, Hamburg, Germany) and Duraphat 2.26 % F- (GABA, Lörrach, Germany) -test lesion and only Duraphat 2.26 % F- (GABA, Lörrach, Germany) -control lesion.

The clinical ICDAS appearance of the selected lesions was recorded independently by two experienced clinicians before the treatments. If disagreement in ICDAS score was noted final score was obtained by consensus. Only 2 children refused the treatment and were excluded from the study. After one year the children were re-examined (n=42) clinically, and radiographs were taken (n=39). Two dentists one internal and one external scored the radiographs independently of each other using a 4 ranged scale. Intra- as well as Intra-reproducibility was expressed by unweighted Kappa. Baseline mean age of the children was 7.17(SD=0.68) and mean def was 8.1(SD 6.9). Clinically, 31 % of the test lesions versus 67 % of the control lesions had progressed (P<0.05). Radiographically, 24 % of the test lesions had progressed versus 63 % of the control lesions (P<0.05). The clinical and radiographical therapeutic effect of resin infiltration versus fluoride treatment after 1 year was both > 30 % and highly significant.

Resin infiltration seems promising in controlling lesion progression in proximal lesions on deciduous molar teeth.

Status
The results of the 1 year follow-up assessment are available since February 2009.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Ekstrand KE, Bakshandeh A. Radiographic comparison of lesion progression after infiltration, sealing and floss instructions in a higher caries risk population – 6 and 12 months follow-up. Data on file. DMG Hamburg, Germany.

Illustration 1: Clinical cavitations after 6 and 12 months
Clinical performance and color stability of infiltrated smooth surface lesions

Study in progress, not yet published.

Phark JH¹, Duarte S¹.
¹Department of Comprehensive Care, Case Western Reserve University, Cleveland, OH, USA

In incipient caries lesions the pores of enamel caries lesions provide diffusion pathways for acids and dissolved minerals. The aim of caries infiltration is to occlude these pores by infiltration with light-curing resins in order to block the diffusion of acids into the lesion body. In contrast to caries sealing, caries infiltration aims to occlude the pores within the lesion rather than placing a diffusion barrier on the lesion surface.

The aim of the controlled, randomized clinical trial in split-mouth design is to compare the efficacy of infiltration vs. fluoridation of vestibular incipient caries (white spot) lesions in premolars and canines shortly after removal of orthodontic brackets. 40 volunteers will be enrolled in this study according to eligibility criteria. Lesions will be randomly assigned to the test (infiltration) and control group (fluoridation regimen). Colorimetric determination of color changes and stability of lesions, evaluated by digital photographs and spectrophotometric analysis at baseline and after 6, 12, 18 and 24 months. For colorimetric/visual evaluation of the lesions digital images will be taken using a digital SLR camera system (Nikon D300, Nikon) and a spectrophotometer (Crystaleye, Nikon). The camera will be equipped with a 2 x magnification lens and a polarization filter. Imaging conditions will be controlled as much as possible to ensure optimum clarity and reproducibility. Illumination conditions and distance will be standardized for all sessions. Pictures will be taken in a room with controlled light conditions. The teeth will be illuminated with two lights, one from each side of the camera, also being equipped with polarization filters to avoid glare on the surface of the teeth due to illumination. Adequate light output will be constantly verified with a light meter. Before taking pictures the assigned teeth will be cleaned with pumice, rubber polishing cup and will be rinsed with water for 30 seconds. Pictures will be analyzed using an image analysis software. For evaluation of the color stability L*a*b* values of the lesion and the whole tooth will be obtained. Delta E values will be calculated and statistical evaluation will be performed using SPSS.

Status
First results will be available in October 2009.

Aim
This study is used for verification of the product’s clinical performance.

Source:
Infiltration concept – List of literature


- International Caries Detection and Assessment System Workshop, Baltimore 12-14th March 2005. Sponsored by the NIDCR, the ADA, and the IADR.


- Lang NP. Commonly used indices to assess oral hygiene and gingival and periodontal health and diseases.


Infiltration concept – List of literature


- Thylstrup A, Bille J, Qvist V. Radiographic and observed tissue changes in approximal caries lesions at the time of operative treatment. Caries Res 1986;20:75-84.


Icon – Practice-oriented product solutions for an innovative treatment method
DMG converted the scientific findings on caries infiltration into a user-friendly product for daily use at the dental office. Or more specifically: into intelligent product solutions for different applications.

Icon-proximal
With Icon-proximal DMG mastered the challenge to give dentists efficient access to critical proximal areas. Icon-proximal enables the treatment of approximal carious lesions with a maximum radiologically visible extent into the outer third of the dentine without drilling. A slight separation of the teeth is sufficient to apply the required materials directly to the desired area using a special Approximal-Tip made from ultra thin film. The result: a pleasant treatment for the patient with nearly no hard tissue loss or loss of the natural tooth shape. Icon-proximal is offered in clearly arranged treatment units. One unit contains all necessary materials for a successful infiltration treatment of two proximal lesions each in a patient. A user-friendly designed treatment tray ensures the proper execution of the work steps in the correct order.
Icon smooth surfaces
Other important areas of application for caries infiltration are incipient carious lesions on easily accessible smooth surfaces. These undesired cariogenic "white spots" can easily and efficiently be treated with Icon smooth surfaces. Icon smooth surfaces combines the cosmetic challenge with the medically sensible early arrest of carious lesions. Naturally, the product specifically developed for vestibular applications also offers the advantages of the user-friendly tray arrangement. Special Vestibular-Tips ensure the successful treatment of cariogenic white spots with maximum conservation of the hard tissue. The results impress after only one sitting.

Illustration 1: Vestibular-Tip
Illustration 2: Smooth surface treatment tray
Illustration 3: Packaging unit – Cube smooth surface
Authors

Prof. Dr. John O. Burgess, DDS, MSc

1971 – 1975 Dentistry, School of Dentistry, Emory University, USA
1980 – 1982 MSc in Biomedical Sciences, University of Texas Health Science Center, Houston, USA
1969 - 1990 Dentist at the US Air Force
1998 – 2006 Professor and Head, Department of Restorative Dentistry and Biomaterials, Vice Dean for Clinical Research, Louisiana State University Health Sciences Center-School of Dentistry, New Orleans, USA
since 2006 Professor and Head, Department of Prosthetic Dentistry, Vice Dean for Clinical Research, University of Alabama, Birmingham, USA

Dr. Deniz Cakir, DDS, MSc

1996 – 2002 Dentistry, Faculty of Dentistry, Ankara University, Ankara, Turkey
2002 – 2003 Private Dental Office, Bursa, Turkey
2003 – 2005 MSc Programme, School of Dentistry, University of Alabama, Birmingham, USA
since 2006 Research Coordinator, Department of Prosthetic Dentistry, School of Dentistry, University of Alabama, Birmingham, USA

Dr. Sillas Duarte, PhD

1987 – 1991 Dentistry, Universidade Araraquara, São Paulo, Brazil
1995 – 2002 Associate Professor, Department of Operative Dentistry, Clinic of Restorative Dentistry, Universidade Araraquara, São Paulo, Brazil
2002 – 2004 Visiting Associate Professor, Department of Operative Dentistry, Clinic of Restorative Dentistry, University of Minnesota, Minneapolis, MN, USA
2004 – 2007 Associate Professor, Department of Operative Dentistry, Clinic of Restorative Dentistry, Universidade Araraquara, São Paulo, Brazil
2007 Associate Professor, Department of Comprehensive Care, Dental School, Case Western Reserve University, Cleveland, OH, USA

Dr. med. dent. Susanne Effenberger

1993 – 1999 Dentistry, Georg-August-University of Göttingen, Germany
1999 – 2005 Assistant Professor, Department of Restorative and Preventive Dentistry, University of Hamburg, PhD, University of Hamburg, Germany
2005 Assistant Professor, Department of Restorative Dentistry, CVK, Charité – University Medicine Berlin, Germany
2006 – 2008 Professional Service Manager, Education/ Scientific Affairs, DMG, Hamburg, Germany
since 1/2008 Manager Clinical Research, Scientific Affairs, DMG, Hamburg, Germany
Prof. Dr. Kim Ekstrand, DDS, PhD

1978 – 1983 Dentistry, University of Copenhagen, Denmark
1985 – 1988 PhD in Dentistry, University of Copenhagen, Denmark
since 1992 Associate Professor, Dental School, University of Copenhagen, Denmark
1985 – 2002 Private Dental Office, Copenhagen, Denmark
1995 Visiting Professor, Guy’s Hospital, London, UK
2002 – 2003 Visiting Professor, Dundee Dental Hospital, UK

Prof. Dr. med. dent. Andrej M. Kielbassa

1984 – 1989 Dentistry, Philipps-University, Marburg, Germany
1990 PhD, Philipps-University, Marburg, Germany
1998 Habilitation, Albert-Ludwigs-University, Freiburg, Germany
1990 Private Dental Office
1990 – 1993 Assistant Professor Department of Pediatric Dentistry and Operative Dentistry, Philipps-University, Marburg, Germany
1993 – 1999 Senior Physician, Department of Operative Dentistry, Albert-Ludwigs-University, Freiburg, Germany
since 2000 Director, Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany

PD Dr. Ing. Ulrich Lohbauer

1991 – 1998 Materials Science, Graduate Engineer, University of Erlangen-Nuremberg, Germany
1998 – 2003 Assistant Professor, Dental Clinic 1, University of Erlangen-Nuremberg, Germany
2003 PhD, University of Erlangen-Nuremberg, Germany
since 2003 Director, Material Science, University of Erlangen-Nuremberg, Germany
2003 – 2004 Research Fellowship, Imperial College, London, UK
2006 Research Fellowship, University of Athens, Greece
2007 Habilitation, University of Erlangen-Nuremberg, Germany
2007 Academic Counsel, University of Erlangen-Nuremberg, Germany
| Authors |
|------------------|--------------------------------------------------|
| **Dr. rer. nat. Dierk Lübbers** |
| 1983 – 1989 Chemistry, University of Hamburg, Germany |
| 1989 – 1992 PhD, Institute of Technical and Macromolecular Chemistry, University of Hamburg, Germany |
| 1992 – 1997 Manager R&D Impression Materials and Adhesives, DMG, Hamburg, Germany |
| 1998 – 1999 Manager R&D Cements, Coltèn Whaledent AG, Altstätten, Switzerland |
| 1999 – 2007 Manager R&D Europe, Coltèn Whaledent AG, Altstätten, Switzerland |
| since 2007 Manager Scientific Affairs, DMG Hamburg, Germany |
| **Prof. Dr. Stefania Martignon, PhD** |
| 1985 – 1990 Dentistry, Universidad Javeriana, Bogotá, Colombia |
| 1993 – 1996 Specialisation in Pediatric Dentistry, Universidad El Bosque, Bogotá, Colombia |
| 1997 – 2000 Specialisation Academic Teaching, Universidad El Bosque, Bogotá, Colombia |
| 2001 – 2005 PhD in Dentistry, University of Copenhagen, Denmark |
| since 2006 Associate Professor, Director Caries Research Unit UNICA, Universidad El Bosque, Bogotá, Colombia |
| 2003 Member of the ICDAS Committee |
| **OA PD Dr. med. dent. Hendrik Meyer-Lückel** |
| 1992 – 1997 Dentistry, University of Gießen, Germany |
| 1997 – 1998 Assistant Professor, Department of Periodontology, University of Gießen, Germany |
| 1999 – 2000 Private Dental Office, Wetzlar, Germany |
| 2000 PhD, University of Freiburg, Germany |
| 2000 – 2008 Assistant Professor/Senior Physician (from 2001), Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany |
| 2008 Habilitation, Charité Berlin, Germany |
| since 11/2008 Associate Professor, Department of Operative Dentistry and Periodontology, Christian-Albrechts-University, Kiel, Germany |
| **Dr. med. dent. Jan Müller** |
| 1998 – 2004 Dentistry, »Freie« University of Berlin, Germany |
| 2005 PhD, »Freie« University of Berlin, Germany |
| since 2004 Assistant Professor, Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany |
| 2006 Winner VOCO Dental Challenge |
Dr. med. dent. Sebastian Paris

1998 – 2003 Dentistry, Charité Berlin, Germany

2004 – 2008 Assistant Professor, Department of Operative Dentistry and Periodontology, Charité – University Medicine Berlin, Germany

2005 PhD, Charité Berlin, Germany

2006 Research Fellowship, Deutsche Forschungsgemeinschaft, DFG

since 10/2008 Assistant Professor/ Lecturer, Department of Operative Dentistry and Periodontology, Christian-Albrechts-University, Kiel, Germany

Dr. med. dent. Jin-Ho Phark

1998 – 2003 Dentistry, Humboldt-University of Berlin, Germany

2006 PhD, Charité – University Medicine Berlin, Germany

2003–09/2006 Assistant Professor, Department of Operative Dentistry, CVK, Charité – University Medicine Berlin, Germany

since 10/2006 Associate Professor, Department of Comprehensive Care, Dental School, Case Western Reserve University, Cleveland, OH, USA

Prof. Dr. med. dent. Ulrich Schiffner

1975 – 1980 Dentistry, PhD, University of Hamburg, Germany

since 1982 Assistant Professor, Department of Restorative and Preventive Dentistry, University of Hamburg, PhD, University of Hamburg, Germany

1988 – 1992 Advisory Board, German Association for Operative Dentistry, (DGZ, Secretary)

since 2003 Director Section of Preventive Dentistry, Department of Restorative and Preventive Dentistry, University of Hamburg, PhD, University of Hamburg, Germany

2004 – 2008 President German Association of Pediatric Dentistry (DGK)

Dr. rer. nat. Hartmut Schneider

1971 – 1976 Physics, Karl-Marx-University of Leipzig, Germany

1976 – 1995 Assistant Professor, Section Bioscience, Department Cell Biology/ Regulation, University of Leipzig, Germany

1982 PhD, University of Leipzig, Germany

since 1995 Associate Professor, Department of Operative Dentistry and Periodontology, University of Leipzig, Germany
Authors

Prof. Dr. Vera Ligia Vieira Mendes Soviero, MSc, PhD
1987 – 1991  Dentistry, Universidade do Estado do Rio de Janeiro, Brazil
1994 – 1997  Master of Science in Pediatric Dentistry, Universidade Federal do Rio de Janeiro, Brazil
1997 – 1999  PhD in Pediatric Dentistry, Universidade Federal do Rio de Janeiro, Brazil
1997 – 1999  Assistant Professor, Dental School, Universidade Iguaçu, Brasilien
1998 – 2006  Assistant Professor, Dental School, Universidade Estácio de Sá, Brazil
since 1999  Associate Professor, Dental School, Universidade do Estado do Rio de Janeiro, Brazil

Katja Spieler-Husfeld
1990 – 1993  Chemical Laboratory Assistant, Beiersdorf AG, Hamburg, Germany
1993 – 1998  Development Laboratory „tesa“ labels/ Adhesive tapes, Beiersdorf AG, Hamburg, Germany
2000 – 2002  Chemical Development, DMG, Hamburg, Germany
2002 – 2004  Technical Development (Scale up), DMG, Hamburg, Germany
since 2004  Scientific Affairs, DMG, Hamburg, Germany

Christin Staude
1997 – 2001  Dental Technician Education, Dullek Dental Laboratory, Güstrow, Germany
2001  Dental Technician, Dullek Dental Laboratory, Güstrow, Germany
2001 – 2006  Dental Technology, Graduate Engineer, University of Applied Sciences, Osnabrück, Germany
since 2007  Scientific Affairs, DMG, Hamburg, Germany

Prof. Dr. Marisol Tellez, DDS, MPH, PhD
1993 – 1998  Dentistry, Universidad El Bosque, Bogotá, Colombia
2001  Pan American Health Organization, Division of Health Systems and Services Development, Washington, DC, USA
2001  Master of Public Health (MPH), University of Michigan, Ann Arbor, MI, USA
2003  GSI, Department, Department of Epidemiology, University of Michigan, Ann Arbor, MI, USA
2004  PhD, Epidemiologie, University of Michigan, Ann Arbor, MI, USA
2003 – 2006  Research Associate, Detroit Center for Research on Oral Health Disparities, University of Michigan, Ann Arbor, MI, USA
since 2006  Associate Professorin, Caries Research Unit UNICA, Universidad El Bosque, Bogotá, Kolumbien
since 2008  Academic Manager, Colgate Palmolive Bogotá, Kolumbien