Enamel demineralization prevention by eight treatments in full-banded orthodontic patients

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OBJECTIVE: Document clinical performance of eight treatments in enamel demineralization prevention.

METHODS: Practice-based, controlled clinical trial. 328 patients (95% completed), 9-18yrs, 56% male, none users of fluoride (F) supplements or F-water, all users of OTC-F dentifrice, all full-banded-orthodontic cases. Assigned randomly to 8 groups: daily (1)Xylitol gum-tablets-dentifrice (Epic) 6gm/day; F-2x/day (2)Clinpro5000 ppmF; (3) PreviDent5000 ppmF Plus or Booster; (4) MI-Paste-Plus amorphous calcium phosphate+900ppmF; treatment each 6-8 weeks (5) HealOzone 2100ppm O3-gas 1min/arch; (6) VarnishAmerica 5%NaF- varnish all tooth surfaces; combined (7) VarnishAmerica-PreviDent5000; control (8) patient’s own OTC-F dentifrice and regimen. Before banding and each 6-8 weeks recorded: saliva pH and flow rate, oral hygiene, compliance, ATPase activity, foods eaten, full-color close-up images of all anterior and pre-molar teeth. Demineralization defined by visual appearance (none, light-to-moderate, severe) and quantified/tooth (ImagePro-Plus, MediaCybernetics) on clinical photographs before, 7days post-debanding, 1yr after treatment discontinued. Statistics: Generalized linear mixed models; teeth clustered by patient.

RESULTS:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Estimated Average Percent Demineralization</th>
<th>Subsets</th>
</tr>
</thead>
<tbody>
<tr>
<td>PreviDent5000</td>
<td>11 ±0.9</td>
<td></td>
</tr>
<tr>
<td>VarnishAmerica</td>
<td>14 ±1.1</td>
<td></td>
</tr>
<tr>
<td>CONTROL</td>
<td>15 ±1.1</td>
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</tr>
<tr>
<td>HealOzone</td>
<td>16 ±1.2</td>
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<tr>
<td>VarnishAmerica-PreviDent5000</td>
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</tr>
<tr>
<td>Clinpro5000</td>
<td>19 ±1.3</td>
<td></td>
</tr>
<tr>
<td>MI-Paste-Plus</td>
<td>19 ±1.3</td>
<td></td>
</tr>
<tr>
<td>Xylitol</td>
<td>21 ±1.2</td>
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</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Estimated Percent Teeth with NO Demin</th>
<th>Subsets</th>
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<tbody>
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<td>HealOzone</td>
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<tr>
<td>MI-Paste-Plus</td>
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<tr>
<td>Xylitol</td>
<td>5 ±1.3</td>
<td></td>
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</tbody>
</table>

PreviDent5000 Plus and Booster not different; both had significantly less demineralization. Demineralization exceeding Control: Clinpro5000, MI-Paste-Plus, Xylitol. All patients had visually apparent demineralization. Only 5-23% of teeth within the 8 groups had no visible demineralization.

Demineralization predictors: treatment (<0.000), tooth location (<0.000), time in orthodontics (<0.000), age (<0.000), hygiene (0.013), before-study F-supplement duration (0.014). Post-treatment natural resolution of demineralization not related to treatment (0.489), but to demineralization severity and tooth location (both <0.000).

CONCLUSION: All treatments tested failed to prevent all enamel demineralization in any one patient or treatment group.
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QUESTION
What happens if products claiming enamel remineralization are subjected to real-life natural accelerated demineralization?

STUDY OUTCOME
Only 1 of 7 treatments showed significantly less demineralization than the Control group where subjects used their habitual oral hygiene regimen & own commercial OTC 1000 ppm F dentifrice. These data indicate:
1. Six of the treatments prevented no more visible enamel demineralization than Crest, Colgate, Aquafresh, Aim, etc.
2. Excellent oral hygiene did not eliminate all demineralization.
3. Claims of efficacy in the presence of visible oral biofilm not confirmed.
4. Commercial products promoted for enamel remineralization need real-life testing before market release.

RESULTS
(Demineralization quantified [ImagePro plus software; Media Cybernetics] on clinical image of each tooth 6 days post debond & statistically analyzed.)

Only PreviDent 5000 had statistically less demineralization.

PATIENT PROFILE
gender = 56% male; 44% female
age = mean 12.3y; range 12-19y
systemic F = 27% of subjects
habitual use OTC F dentifrice = 99% of subjects
oral hygiene grade = mean fair (2.3 in 4.0 scale)
saliva pH = mean 7.2; range 6.0-8.0
saliva flow 1ml/min = 74%
added sugar in diet = high (esp breakfast cereals)
socio-economic = middle class working white
FOCUS ON: Tooth Preparation Disinfection

Rella Christensen, PhD, reviews how clinical microbiology identified 5% glutaraldehyde/35% HEMA is an excellent tooth preparation disinfectant.

Q: Why disinfect a tooth preparation?
A: Many of the same organisms cultured from within carious lesions remain in the finished prep. During removal of the infected dentin, clinicians inadvertently spread organisms and drive them into surrounding uninfected dentin, where they can remain viable. Clinicians have reported for years the presence of caries later found under their carefully placed restorations—on the pulp floor. Although they attribute post-treatment caries on axial walls and at margins to leakage, gross caries on the pulp floor only has been more difficult to explain. Our research, using sterile-field organism collection during restorative dentistry procedures in dental practices in 6 US states, shows repeatedly the presence of the same viable organisms in the final prep as those cultured throughout the lesion. Other sterile-field work we have performed removing sealants and various types of restorative materials shows microbes can survive and continue to destroy tooth structure even though surfaces have received acid-etch/resin restorative procedures such as sealants, cements, direct placement resins, or silver amalgam. From this work, we have concluded that burying microbes under restorative materials does not necessarily inactivate them; however, it does slow their progress.

Q: Is tooth prep disinfection a new idea?
A: No. G. V. Black recommended silver nitrate to treat final preparations before silver amalgam placement. His recommendation was followed for decades until the early 1960s, when patients objected to the permanent dark gray-black silver nitrate stain within their teeth. Since at that time no alternative chemicals were proposed, tooth preparation disinfection disappeared along with the silver nitrate use. When later research on postoperative sensitivity showed photographs of microbes within dentinal tubules, use of disinfectants on tooth preparations was revived. Today, several different chemicals are marketed for this purpose, ie, sodium hypochlorite, chlorhexidine, and quaternary ammonium compounds such as benzalkonium chloride.

Q: Is there an ideal product or formulation for this procedure?
A: Our lab has conducted in-depth studies on disinfectants since 1985 and has detailed data on performance and properties of more than 180 different formulations. Our in vivo studies of tooth responses to various chemicals began in...
1980. We put these 2 information bases together to try to identify a tooth preparation disinfectant ideally suited to fulfill the following criteria: (1) rapid, broad spectrum kill; (2) resistant to neutralization by the many components within the cut dentin such as bacteria, saliva, blood, food debris, old dental materials, gingival tissue, crevicular fluid, etc; (3) compatibility with resin-based dental materials; (4) good wetting and penetration into dentin; (5) proven non-irritating to vital teeth; and (6) used commonly throughout the world in dentistry for many years.

By systematic elimination using the above 6 criteria, we selected GIUMA Desensitizer (Heraeus Kulzer) with a chemical composition of 5% glutaraldehyde/35% hydroxyethyl methacrylate (HEMA) for in vivo testing. It has performed exceedingly well with virtually no negative postoperative sequelae, and 3 added benefits: (1) it desensitizes very well, (2) it modestly increases bond strengths, and (3) it modestly enhances longevity of bonds. Several other companies now sell this same formulation—MicroPrime G by Danville Materials, G5 by CLINICIANS CHOICE, GluSense by Centrix, etc.

The 5% glutaraldehyde/35% HEMA formulation has been used continuously in the oral cavity for more than 25 years worldwide—first as the primer in Gluma Adhesive (Bayer) and then as GIUMA Desensitizer and finally in the several newer brand names listed above. This is not a new chemistry in dentistry. We have simply suggested an additional use for which it is particularly well suited.

Q: What are important points to consider when using these products?

A: Contact time is critical. The 2 one-minute applications allow chemical penetration into the smear layer and dentinal tubules to produce excellent microbe kill. Thorough kill is desirable to prevent the microbes from multiplying and resuming activity. A qualified dental assistant can apply the disinfectant to the tooth while the dentist performs a hygiene check or other procedure.

Restricting the application to tooth surfaces is also important to consider. Soft-tissue contact causes chemical burn. Application should be under magnification and headlamp, with controlled painting of all surfaces of the preparation up to the cavosurface margin. Use standard personal protection items for clinicians and patients.

For now, restrict use to resin-based products. We have data to support trouble-free use with resin-based restoratives, cements, and sealants, including RMGI, but we have not yet tested use with conventional GI restoratives or GI cements.

Q: Are there situations where you would not disinfect a preparation?

A: No. Based on the information in question one, it appears disinfection of all tooth preparations is desirable. Contrary to what some have stated, we are learning that microbes within teeth can remain viable and active unless deliberately killed.
FOCUS ON: Caries Arrest

Rella Christensen, RDH, PhD, discusses what it takes to stop a developing carious lesion.

Q: Can progression of a carious lesion be stopped clinically without cutting the tooth?
A: Yes, if the following critical factors are in place: (1) patient dedication to sustained maintenance of a low-sugar diet, excellent oral hygiene, and management of saliva flow rate (ie, non-caffeine-related factors in low saliva flow rate can be medication side effects and/or inadequate fluid intake); and (2) patient access to a dental office to allow daily clearance of the patient's biofilm accumulation in these critical areas.

Q: Does placement of dental restorative material arrest caries?
A: Yes and no. Virtually millions of individual teeth have had the caries process arrested by excision of the carious material and placement of a dental restorative material. However, if factors that resulted in the original lesion are allowed to continue, other lesions can subsequently develop in the same oral cavity—and many times, on a tooth just recently treated. Repeated episodes of carious lesions have caused great frustration to patients, dentists, dental educators, and third party payment organizations. Unfortunately, dental caries is a disease clinically treated vigorously while patients continue known causes.

Dental caries is a microbe driven disease. During the past 11 years, a series of in vivo caries microbiology studies performed by TRAC Research show clearly that the microbes must be controlled before attempting to strengthen and/or repair the tooth, if recurring disease is to be prevented.

Q: Do various commercial products now being dispensed by clinicians to patients help arrest carious lesions already in progress?
A: There is no commercial product that can, by itself, arrest an ongoing carious lesion. In other words, there is no “magic formula.” In 2016, there is no way around the fact that the patient will need to control dietary choices, oral hygiene, and saliva flow in order to control the microbes driving the caries process. Unfortunately, when clinicians dispense products it can imply to patients that the products can solve their caries problem without their making changes in their habits and choices. The products can raise false expectations and divert attention from the changes necessary. For clinicians, the croush of typical patient days and the apathy of patients toward changes have bred a reliance on dispensing products they hope will help, perhaps without putting enough emphasis on the critical necessity for changes in diet and oral hygiene. Unfortunately, very few of the currently available products have been subjected to clinical validation using real-world test protocols before market release. By manipulating claims, it is relatively easy to market products with very little evidence of efficacy.

Q: Can a carious lesion arrested by changes in diet, oral hygiene, and saliva flow rate be remineralized?
A: The answer depends on how the patient and dentist define the term “remineralized.” Patients and dental clinicians tend to think when a tooth is “remineralized” it means the defect, such as an opaque white area or a cavitation, will disappear, and the surface will be returned to its previous perfect condition. We have seen this only in cases of very initial white spot demineralization. It does not occur with a visually apparent cavitated lesion or a severe white spot lesion. However, it is possible to cause certain ions to be deposited within a carious defect and technically call this remineralization, without making any visual change to the site. Although some have reported that lesions treated with fluoride ions develop surface layers that are more resistant to re-infection, we have not found this to be the case clinically. Our work shows that when a high-sugar diet and poor oral hygiene return, enamel remineralization returns to the same locations that once may have appeared to remineralize visually.

Q: Does fluoride help prevent caries from occurring in the first place?
A: Yes. Habitual thorough oral hygiene using a fluoride-containing dentifrice along with control of sugar intake and saliva flow, plus use of sealants, can virtually prevent dental caries. Fluoride has a well-established and validated record of aiding in prevention of dental caries. But clinicians and patients need to understand that while fluoride can lower the caries rate, habitual good oral practices also need to be in place. TRAC Research clinical studies have demonstrated the usefulness of PrevioForte and Colgate for prevention of caries and hyper-sensitivity in particularly susceptible patients. When used as a dentifrice just before bed to brush thoroughly and expectorate, but abstain from water rinsing, it can be very helpful.

Q: Do the new “risk assessment” techniques help?
A: Yes, if the patient is (1) truthful, (2) willing to change patterns that increase risk for dental caries, and (3) willing to undergo regular monitoring. If these three points are not present, caries arrest and prevention cannot be accomplished using the risk assessment approach. Unfortunately, often patients find it embarrassing to reveal their actual habits and choices, and are not truthful in providing the essential caries risk information. In addition, clinicians must be alert to the fact that risk factors can change abruptly as significant personal changes occur such as divorce, moving to a new locality, incarceration, deployment, etc. Therefore, risk categorization must be reviewed and revised frequently. It is not prudent to place an individual into a low-risk category and assume that person will maintain that level forever. Furthermore, we must be careful not to let risk categorization deny helpful preventive treatments to patients in the low risk group. If we categorize patients, we then have the responsibility to review their health status regularly to assure we don’t miss changes. Realistically, getting patients to comply with regular exams can be challenging. Therefore, office recall programs need to be vigorous.

Q: Does the future hold promise for caries arrest and remineralization?
A: Yes. A lot of very intelligent scientists are working in these areas. Dental clinicians, the dental industry, third party payment organizations, and patients all have high interest in these areas. The problem is patients want to enjoy sugars, poor oral hygiene habits, and multiple medications without worrying about teeth! But definitely the best is yet to come in both caries arrest and tooth remineralization.

Rella Christensen, RDH, PhD

Dr. Christensen currently leads TRAC Research Laboratory which is devoted to clinical research in oral microbiology and dental restorative concepts. TRAC Research is part of the non-profit educational Clinicians Report Foundation (formerly CPA) which she directed for 27 years. Through her career, she has taught at the undergraduate and graduate levels, authored many research abstracts and reports, and received numerous honors. She has performed research within the practices of hundreds of dentists and their teams seeking best patient treatments. She can be reached via email at rela@tracresearch.org.
FOCUS ON: Silver Diamine Fluoride

Rella Christensen, PhD, discusses the use of silver diamine fluoride for trauma-free caries treatment.

Q: Who needs to know about silver diamine fluoride (SDF), and why?
A: Anyone who cares for the health of people of any age needs to become acquainted with SDF (eg, dental/medical clinicians, school nurses, daycare for children and adults, social workers) because: (1) US clinicians are using SDF for caries patients of all ages to prevent pain, delay progression, and lower biofilm accumulation. SDF needs no injection, handpiece, or dentist (it can generally be applied by personnel who apply fluoride); (2) published randomized controlled clinical trials report caries prevention using one annual application of SDF is superior to fluoride varnish using 4 annual applications—for children and elders; (3) SDF can improve caries treatment outcomes in difficult access areas (ie, furcations); (4) SDF hardens soft dentin and enamel and desensitizes, making subsequent restorative procedures easier for the dentist and patient; (5) slowing caries progression with SDF buys time for patients struggling to modify poor habits involving diet, oral hygiene, saliva flow, and dental treatment fear; and (6) offices not offering SDF may find some patients going elsewhere to receive it.

Q: Has SDF always been available, or is it new?
A: SDF is relatively new to the United States (FDA clearance, 2014; commercial product, 2015; CDT code D354, 2016), but it was used extensively in Japan for 80-plus years for caries arrest. It was brought to the United States by dentists seeking trauma-free, inexpensive ways to stop or delay dental caries in children and vulnerable populations.

Q: How does SDF arrest dental caries?
A: SDF kills microbes and hardens damaged tooth structure. SDF sold in the United States (brand name: Advantage Arrest) is composed of 25% silver, 8% ammonia, 5% fluoride, and 65% water. Antimicrobial activity comes mostly from the silver ions and tooth mineralization from the high concentration of fluoride ions. Ammonia is present mainly to stabilize the solution by holding ions in suspension, but it also temporarily raises pH in local areas. Numerous SDF clinical applications and chemistry were defined 45 years ago by Japanese researchers (Yamada R, Nishino M, Yoshida S, et al. J Osaka Univ Dent Sch. 1972;21:21-20).

Q: Are there disadvantages to SDF?
A: The most obvious disadvantage is, once dried, it leaves a permanent brown-black stain on demineralized tooth structure, fabrics, and clinical furnishings, and a transient black stain on oral soft tissues and skin. Patients and/or guardians need to be informed. The manufacturer (Elevate Oral Care) suggests using an informed consent that contains photographs of treated teeth. Although some clinicians feel strongly that caries arrest is far more important than oral aesthetics, this is a decision for each patient and/or guardian. Critical points in informed consent include communicating treatment options along with the advantages and disadvantages, risks, and costs of each, and what will happen if no treatment is performed. Stain can be covered subsequently with tooth colored resin-modified glass ionomer, glass ionomer, or resin restorative material. Another option is use of potassium iodide saturated solution immediately after SDF application to lighten the stain.

Other disadvantages include unpleasant odor and taste, and can be minimized by placing a small amount of toothpaste on an untreated tooth. Data are lacking on longevity of the treatment. TRAC Research's very early microbial data indicate some microbes in deeper layers survive 3 SDF treatments performed at one-week intervals, indicating SDF may not be able to stop lesion progression, but instead delay progression. Also, others have reported that every lesion has not been stopped by SDF; in these cases, the dentin remains unstained and soft. However, even with this, clinical studies show SDF outperforms anything else currently used for the same purposes.

Q: What are some indications and contraindications of SDF?
A: As suggested by the University of California San Francisco Dental School Paradigm Shift Committee, indications are: (1) extreme caries risk (particularly in very young or very old), (2) difficult management cases (behavior or medical problems), (3) difficult access treatment areas (furcations and margins), (4) more lesions than treatable in one visit, and (5) access to care problems (humanitarian and bedridden). Contraindications are: (1) silver allergy, (2) presence of open or sore areas on oral soft tissues, (3) if patient and/or guardian object to tooth discoloration in spite of possibility to cover later with tooth colored materials, and (4) pregnancy (if potassium iodide is planned to minimize dark stain).

Q: What are the clinical procedure steps?
A: Step 1—If possible, gently remove heavy biofilm with Starbrush (Ultradent Products) in low-speed handpiece and rinse. Step 2—Isolate and dry. Step 3—Place a small amount of SDF directly onto lesion(s) using smallest (black handle) Microbrush (Dentaur). Precise placement avoids inadvertent staining. Step 4—Allow SDF to dry at least one minute (longer, if possible), then remove excess with cotton ball. Optional step to minimize staining: apply saturated solution of potassium iodide using smallest Microbrush, wait 10 seconds, repeat until no white precipitate appears.) Step 5—Water rinse. Step 6—Repeat all steps 3 times at approximately one-week intervals.

Q: What is the future of SDF caries treatment?
A: SDF for caries arrest is an attempt to slow lesion progression and prevent pain while avoiding patient fear and lowering costs. SDF is meeting these goals in most patients of all ages. A nontooth-staining chemical would be preferred by most clinicians, but the stain has proven useful to accurately identify location of lesions (SDF does not stain healthy tooth structure). SDF use in the United States is gaining momentum, particularly with pediatric, public health, and humanitarian clinicians. If SDF replaces fluoride varnish, it will gain routine use in general dentistry throughout the United States, with the stain identifying caries missed by radiographs.

Dr. Christensen leads TRAC Research Laboratory at Clinicians Report Foundation. She can be reached via the email address rella@bracecontrol.org.
Enamel Remineralization Products: How helpful are they?

Gordon’s Clinical Observations: Remineralization of tooth structure has been a long-time goal in the profession. Based on laboratory studies and manufacturer claims, some optimistically predict that cutting teeth will soon be outdated. However, on hearing practitioner experiences with remineralization, TRAC Research conducted a practice-based trial to determine if remineralizing products were effective. The results will frustrate you.

Remineralization is a “hot” word in dental caries treatment in 2015. Practitioners are being advised to remineralize lesions rather than excavate. In their eagerness to provide solutions for patients, clinicians often use treatments that lack real-world clinical research. This has resulted in considerable expense to patients and embarrassment to clinicians when little or no benefit was realized. This report summarizes findings from a practice-based 5-year clinical study of six products that claim to remineralize enamel. The research question asked: Can products claiming enamel remineralization prevent or slow demineralization that often develops during orthodontic treatment when optimal oral hygiene is difficult?

1. Products tested and how they were used; description of patients; data collection methods

A. Products and use-regimen (listed alphabetically by brand name)
   - Clinpro 5000: 5000 ppm fluoride (F) dentifrice plus tricalcium phosphate; used nightly before retiring without water rinsing after use.
   - Epic Tablets, Gum, Dentifrice: Combined provided xylitol at ≥ 6 gm/day; used throughout the day every day.
   - HealOzone: 2100 ppm ozone gas applied in special trays 1 minute per arch; output confirmed then applied professionally every 6–8 weeks.
   - MI Paste Plus: Amorphous calcium phosphate plus 900 ppm F; applied on fingertip after brushing with 1000 ppm F dentifrice nightly.
   - VarnishAmerica: 5% sodium fluoride varnish (22,600 ppm F); applied professionally to all surfaces of all teeth every 6–8 weeks.
   - VarnishAmerica and PreviDent 5000: Combination of the products described immediately above and below this line.
   - Positive Control: PreviDent 5000 (Booster and Plus forms) – 5000 ppm sodium fluoride dentifrice; used same as Clinpro 5000 above.
   - Negative Control: Patient used own OTC dentifrice (1000 ppm F), toothbrush, brushing methods, and brushing frequency.

B. Patients who needed full banded treatment in an orthodontic practice in Springville, Utah, USA
   - 328 patients 9–18 years scheduled for full band orthodontic treatment
   - 56% male; 44% female
   - 12.3 years mean age

C. Data collection methods

Patients assigned randomly to 8 groups. Before banding and each 6–8 weeks recorded: compliance to assigned treatment, saliva pH and flow rate, oral hygiene grade, ATPase activity, foods eaten, full-color close-up images of all anterior and pre-molar teeth.

Demineralization defined by visual appearance as None, Light-to-Moderate, or Severe and quantified per tooth using ImagePro plus software by MediaCybernetics by outlining each tooth and areas within that showed severe and/or light-moderate demineralization. Software counted pixels within each polygon on images made before treatment, 6 days post-deband, 1yr after treatment. Analyzed >25,000 images.

Statistics: Generalized linear mixed models; teeth clustered by patient.

Continued on page 2
Enamel Remineralization Products: How helpful are they?  (Continued from page 1)

2. Results

A. **None** of the patients treated completed orthodontic treatment without any demineralization. See graph below.
B. Clinical images, count data, and statistical analyses all showed widespread visually apparent demineralization, with all treatments used.
C. Strong demineralization predictors were treatment, tooth location, time in ortho treatment, patient age, and oral hygiene.

**Interpretation of graph:**

A. The PreviDent 5000 group had a statistically higher percentage of teeth with no demineralization (23%) after debanding. This means 77% of the teeth had demineralization. **Is this limited result good enough?**

B. The other 6 treatments were no better or worse than the negative control patients who used their own 1000 ppm OTC F dentifrice (Crest, Colgate, Aquafresh, Aim) and toothbrush when and how they chose.

3. Important Observations

A. **Terms ARREST** and **REMINERALIZE** need to be separated in clinicians’ minds. **Caries arrest** is possible when: (1) oral hygiene is thorough, (2) dietary sugars are limited, and (3) impaired saliva flow is corrected or treated. **Enamel demineralization** that is visibly and tactilely porous (dull appearance and rough to light touch) **never** returns to its original state. Sometimes appearance of very early demineralization can be reversed if surfaces are kept scrupulously clean over time, but they return in the same locations if poor habits return, demonstrating that the surfaces were never truly remineralized.

B. **Nightly use of PreviDent 5000 Plus or Booster showed best results.** However, many teeth in this group (77%) showed clearly visible signs of demineralization. Clinicians and patients want 100% effectiveness, and no treatment available can yet meet this goal.

C. **TRAC Research microbiology testing shows microorganisms must be controlled before attempting to strengthen and/or repair the tooth.** Responsibility for microorganism control belongs solely to the patient who must improve oral hygiene and limit sugar intake.

D. Ethically, clinical studies using real-life regimen should be conducted to show efficacy before a product is released to market.

**TRAC Conclusions:**

Dental caries is a microbe driven disease essentially self-induced by poor oral hygiene and excessive intake of sugar. Remineralizing products tested did not alter microbe activity, and use was expensive, time consuming, and ineffective. However, PreviDent 5000 dentifrice used nightly resulted, to a limited extent, in fewer teeth with severe demineralization and statistically more teeth with no demineralization after orthodontic treatment. The other 6 treatments tested showed results no better than the negative control. These data indicate the need to rethink use of current products claiming enamel remineralization.

**What is CR?**

**HOW DOES CR FUNCTION?**

Each year, CR tests in excess of 750 different product brands, performing about 20,000 field evaluations. CR tests all types of dental products, including materials, devices, and equipment, plus techniques. Worldwide, products are purchased from distributors, secured from companies, and sent to CR by clinicians, inventors, and patients. There is no charge for product evaluations. Testing combines the efforts of 450 clinicians in 19 countries who volunteer their time and expertise, and 40 on-site scientists, engineers, and support staff. Products are subjected at least two levels of CR’s unique three-tiered evaluation process that consists of:

1. **Clinical field trials** where new products are incorporated into routine use in a variety of dental practices and compared by clinicians to products and methods they use routinely.
2. **Controlled clinical tests** where new products are used and compared under rigorously controlled conditions, and patients are paid for their time as study participants.
3. **Laboratory tests** where physical and chemical properties of new products are compared to standard products.

**WHY CR?**

CR was founded in 1976 by clinicians who believed practitioners could confirm efficacy and clinical usefulness of new products and avoid both the experimentation on patients and failures in the closet. With this purpose in mind, CR was organized as a unique volunteer purpose of testing all types of dental products and disseminating results to colleagues throughout the world.

**WHO FUNDS CR?**

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Gordon and Paul’s Clinical Bottom Line: It is well known that current dental radiographs, analog or digital, do not show the exact extent of dental caries. Occlusal caries must be relatively large to show definitively on typical bite-wing or periapical radiographs. This is a major void in the profession. Several new methods now on the market identify caries well, and can be used to augment radiographs. However, current caries detection products identify either occlusal or proximal caries, but none identify both reliably and accurately. The TRAC Research division of CR has performed extensive evaluations to verify the clinical effectiveness of the four products in this research report.

When was the last time you had a patient become hostile when you indicated caries needing treatment or the last time you wondered how to convince a patient that his choices and habits had to change to improve his oral health? Would it help if a neutral team member had technology that showed the patient real-time images of his teeth that identified and highlighted carious areas? Several newer caries detection instruments have this capability. Whether you plan to try to remineralize, seal, or excavate a carious lesion, correct detection is still a critical goal. This report summarizes results of work by the TRAC Research team using four systems which detected initial carious lesions accurately in vivo with no false positives in all 75 teeth scheduled for clinical treatment.

New Caries Detection Systems: Reliable and Accurate

<table>
<thead>
<tr>
<th>System</th>
<th>Retail list price</th>
<th>Accuracy of diagnosis</th>
<th>Ease and speed of use</th>
<th>Tabulates results of exam</th>
<th>Possible to use for remineralization monitoring</th>
<th>Easily transfers to major practice management software</th>
<th>Necessary pre-treatment of teeth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Logicon</td>
<td>$1995</td>
<td>Excellent</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>2. CarieScan Pro</td>
<td>$2995</td>
<td>Excellent</td>
<td>No*</td>
<td>Yes</td>
<td>No</td>
<td>Yes/Yes†</td>
<td>No/Yes†</td>
</tr>
<tr>
<td>3. SoproLIFE</td>
<td>$6470</td>
<td>Good</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes/No</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Spectra</td>
<td>$4995</td>
<td>Good</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No/Yes</td>
<td>Yes/Yes†</td>
</tr>
</tbody>
</table>

* Device not designed for this use  † No/Yes: FDA wording restrictions defining number readout preclude this use in the U.S.
Yes = Definition of numbers displayed outside U.S. give clear indication of caries severity

Main Features Summary:
1. **Logicon**: Can monitor tooth density change due to both des- and remineralization on interproximal surfaces displayed by digital radiographs, but its use is restricted currently to the Kodak RVG system only (Carestream).
2. **CarieScan Pro**: Easiest and fastest to use and tabulates results of the exam in several different forms, but does not display a real-time image of the patient’s tooth during the exam.
3. **SoproLIFE**: The same cored handpiece contains an excellent intraoral camera plus a caries detector. This allows the patient to view the tooth clinically first then with the detector colors superimposed, but the reddish coloration indicating caries is subtle and requires a darkened operatory and some experience to learn to see it on a monitor screen quickly.
4. **Spectra**: Corded handpiece has controls that allow display of caries location and severity. This display is quickly and easily understood by both patients and clinicians, but this device does not have intraoral camera capability to view the tooth as it appears clinically.
New Caries Detection Systems: Reliable and Accurate (Continued from page 1)

Methods

Each patient's bitewing radiographs made on the Kodak RVG system were enhanced, subjected to Logicon software for interproximal caries detection, and saved. The three other caries detection systems were then used in the oral cavity clinically one at a time for detection of initial occlusal caries, and the data were saved. Carious lesions were excavated, cultured (aerobic and anaerobic) and photographed during each step of sequential removal of initial enamel, deep enamel, initial dentin, deep dentin, and final prep to validate the caries detection data from the four systems.

How the Systems Detect and Display Caries and What Interferes with Accurate Detection

A. Interproximal Caries Detection Systems (1 system is listed)

1. Logicon: Analyzes grayscale (4096 shades of gray currently), recognizes caries patterns, and compares to a library of 600 teeth to identify healthy and carious tooth structure on digital bitewing radiographs made on Kodak RVG equipment. The pictures below show computer screen images of data presented for viewing by the clinician and patient, plus clinical images of the teeth during the excavation to prove the system's analysis. Conditions that commonly interfere with detection by this system are: overlapped proximal surfaces, restorations on proximal surfaces, concave proximal surfaces, or artificial radiolucencies caused by some holders.

B. Occlusal Caries Detection Systems (3 systems are listed alphabetically by brand name)

1. CarieScan Pro: Low voltage current is directed through the tooth (note lip hook in image below) to evaluate mineral density. A numerical value between 0 and 100 is displayed on the instrument along with color-coded lights. No zeroing is required because the tooth is compared to a library of over 2000 sites to identify healthy and carious tooth structure. No clinical tooth image is displayed, but data can be transferred by Bluetooth to proprietary software called RemoteView which both displays and tabulates the examination data in colored graphics (one example is shown at right). Conditions that commonly interfere with detection include restored sites, excess saliva, and over drying.
New Caries Detection Systems: Reliable and Accurate (Continued from page 2)

How the Systems Detect and Display Caries and What Interferes with Accurate Detection (Continued)

B. Occlusal Caries Detection (Continued)

2. SoproLIFE: The same handpiece emits white light for intraoral camera imaging or 450 nm LED blue light for caries detection. Conditions that commonly interfere with detection include restored sites, stained surfaces, and calculus in fissures. Also too much light in the operatory during the analysis can impede perception.

3. Spectra: Handpiece emits 405 nm LED blue light to show porphyrin metabolites from cariogenic bacteria, and Analysis Mode gives color-coded map and numbers indicating lesion location and severity \((\text{ingress into tooth})\). Conditions that commonly interfere with detection are restored sites and calculus in fissures.

How the Four Caries Detectors can Improve Patient Treatment

1. Three of the four systems detect initial \textit{occlusal caries} reliably and accurately. Up until now, this has not been possible using traditional methods such as radiographs and visual/tactile examination.
2. Data generated by all four systems helps to dispel patient doubts about legitimacy of caries diagnosis.
3. All four systems give patients a clear understanding of their caries status.
4. Three of the four systems allow patients to see the relative severity of the lesions which enables them to share in decisions on if and when to excavate. Caries severity is not determined easily by the SoproLIFE.
5. All four systems can provide printouts for patients to carry home to consider their oral health status in the privacy of their home.
6. Accurate caries detection followed by lesion monitoring over time to determine lesion arrest, progress, or regress can give patients the opportunity to change habits and choices to conserve irreplaceable tooth structure.

\textit{Note: Detection is not a reason to excavate. The dentist and patient must consider past caries experience, lesion size and location, oral hygiene, saliva flow rate, diet, etc. in making a decision on treatment.}

Conclusions: All four caries detection systems reported have performed well and better than all previous products in rigorous trials of their accuracy in multiple real-world clinical environments. Because they differ substantially in design, output, and features, clinicians must study the chart above to identify features they need most. Only the Logicon detects \textit{interproximal lesions} reliably and accurately. The other three systems detect \textit{occlusal lesions} equally reliably and accurately. Their ability to detect and record initial \textit{occlusal caries} marks a significant first for dentistry which warrants consideration for routine use by clinicians. Although today there is debate on how to manage initial carious lesions, dental clinicians’ responsibility to detect and record caries accurately has not changed.
SEALANTS
A procedure worth revisiting

You can improve the success rates of the sealants you place. Here are a few tips, including using an assistant, magnification, disinfection – and charging accordingly.

Pit and fissure sealant use has been urged and researched actively for over 30 years,¹² yet dentists’ enthusiasm for the procedure has been only moderate, and pits and fissures remain the most common site of dental caries.³ Why?

One clinician summed up his sealant experiences humorously stating that the kids act as though he is killing them, the parents act as though he is ripping them off, and if a sealed tooth develops caries he becomes a confirmed criminal in the eyes of both the child and parent! Why would sealed teeth develop caries?

- Are we applying sealants after carious lesions have progressed too far?
- Are we failing to achieve a seal between the uncut acid etched enamel and sealant?
- Are we underestimating the pathogenic potential of the organic plug that generally remains at the base of pits and fissures?
- Are we expecting more than is possible from a thin layer of resin on active occlusal surfaces?

It’s anatomical

Observant clinicians have been writing about susceptibility of pits and fissures to carious lesions for years (see Figure 1) and suggesting conservative excavation and insertion of restorative material.⁴⁻⁷ However, widespread use of these recommendations never occurred. Hesitancy of clinicians to cut virgin teeth and costs to the patient in the absence of frank disease were probable deterrents. With the advent of acid etch-resin adhesive dentistry in 1955,⁸ treatment of pits and fissures prophylactically without cutting into virgin teeth became possible, and minimally invasive dentistry was born. However, resin-based sealants have not yielded the expected public health impact. Why not?

Figure 1. These images show four different human teeth sectioned longitudinally to expose fissure anatomy internally. Image A shows pink sealant over a caries free fissure with ideal anatomy, while B shows white sealant over a caries free defective fissure filled with organic debris and microorganisms. C and D show how fissures with novel anatomy can be susceptible to decalcification (C) and develop into carious lesions penetrating into dentin (D).

Updated from February 2007 Dental Products Report
Pits and fissures in human teeth predispose them to dental caries. Calcification of tooth buds begins at cusp tips and proceeds downward towards the eventual pits and fissures. Often, there is incomplete enamel closure where the calcifying planes meet. This allows openings that penetrate to dentin (See Figure 2). Another problem is the inability to clear dental plaque daily at the base of pits and fissures. Figure 3 shows scanning electron microscope images of plaque within the pits and fissures of teeth that appear clinically “clean”. Restricted visual access in the most posterior areas of the oral cavity compounds both of these problems.

The problem is us
I submit that sealant placement as it is practiced in the U.S. today is inherently flawed due to the desire for sealants to be a fast, easy, inexpensive procedure. Staff personnel are expected to work without an assistant to achieve and maintain a dry field and visual access on young children’s most posterior teeth – and they are expected to obtain a seal in the presence of debris at the base of the pits and fissures! Furthermore, many view sealants as a fix for questionable borderline teeth where it is impossible to confirm absence of carious lesions. They hope the sealant will “arrest” caries, if present. Yet clinicians removing sealants see that caries can, and do, progress under sealants. In a study we reported in 2001, 10 subjects 22-29 years of age gave permission to replace sealants placed 10+ years earlier by 25 different private practices in 21 U.S. states where they were patients as children. We found 147 of 159 teeth (92%) had carious lesions under the sealants, and 42 of the 147 lesions (29%) were unusually large. Only 12 of the 159 teeth (8%) remained caries free at 10+ years after sealants were placed.

How long should a sealant be expected to protect against dental caries? Sealant life expectancy has not been defined. Although partial loss of sealants has been described in most clinical sealant studies, replacement frequency recommendations are nonexistent, and studies have not reported on the effectiveness of repaired sealants.

The high percentage of carious lesions under the unsupervised sealants in our young adult subjects indicates several important points. First, sealants need close surveillance, second, sealants often do not arrest caries, and third, sealants do not serve indefinitely. The study also suggests that sealant placement may be more demanding technically than acknowledged. To be successful in preventing the ingress of microorganisms, an excellent adhesive bond of resin to tooth is needed. Achieving this on a child’s most posterior partially erupted teeth where rubber dam isolation is impossible requires time, patience, and skill—generally more so than for a Class 1 restoration. Yet the average reimbursement for sealant placement in a molar is $38, while a Class 1 restoration in the same tooth is $120 in the U.S. 11 Perhaps it is time to review the value of caries prevention vs. caries treatment.

Originally, sealant placement was taught as a procedure for recently erupted teeth that were known to be caries free. See Figure 4. However, because placement at this stage was difficult and time consuming, and the teeth were not always available at the ideal time, treatment quickly moved to application on fully erupted teeth. Today some researchers suggest people of any age could be sealant candidates. 12-14 However, when sealing fully erupted teeth inadvertent sealing of carious lesions raises questions that have never been answered fully. Although researchers have reported sealing arrests caries, 15-18 clinicians have observed otherwise.

Figure 2. Image A shows tooth buds from a human fetus after staining with alizarin red S dye to discriminate calcified from non-calcified tissue. Note that calcification starts at cusp tips (left bud) and moves downward (middle bud) and coalesces to form the fissures (right bud). Image B shows areas in fissures of a fully formed extracted human tooth where the enamel did not fuse fully in the fissures, leaving holes that penetrate to dentin.

Figure 3. Scanning electron microscope images show how fissures of teeth in situ retain dental plaque. Tooth fissures are never totally free of dental plaque because there is no homecare instrument or method that penetrates completely. Air polishers or light air abrasion are the most conservative ways to clean fissures thoroughly before sealant placement.

Figure 4. Image A shows a tooth that has erupted to a stage ideal for sealing, with its entire occlusal surface exposed and no carious lesions present. Image B shows a tooth with the distal still covered by operculum tissue, which challenges thorough cleaning and isolation during sealant placement. This tooth should receive fluoride varnish at two month intervals until it is ready for sealant.
The critical clinical questions are: (1) What can we do to improve sealant placement? and (2) How can we improve remuneration for the time and effort required?

To improve sealant placement I suggest the following steps:

1. Obtain an assistant. If cost is prohibitive, hire and train a teenager to come after school, and schedule sealants only when the assistant is present.
2. Watch patients nearing 6 and 12 years of age carefully for tooth eruption, and seal after the teeth have cleared the soft tissue while they are caries free (See Figure 4). If operculum is retained for an extended time, apply fluoride varnish every other month until the teeth can be cleaned well and sealed. (All four molars may not be available for sealant at the same time.)
3. Isolate well and clean pits and fissures thoroughly using an air polisher. Use sodium-free abrasive (Cavitron Jet-Fresh by Dentsply Preventive) for better flavor (See Figure 5). If caries is suspected, use air abrasion or an erbium laser to explore and remove caries.
4. If a young child will not tolerate the air polisher, isolate well and clean the pits and fissures as thoroughly as possible using water only on a special small brush that fits a latch attachment (See Figure 6, ICB Brush by Ultradent).
5. Remove isolation and rinse thoroughly using the spray mode on the air/water syringe while simultaneously evacuating.
6. When air polishing is used, an extra acid etch application step is required to neutralize the basic pH of the abrasive powder before acid etching for sealant retention. (The sodium-free Jet-Fresh powder also has a basic pH.) Neutralize by placing acid etchant onto the teeth under treatment and leaving it in place just long enough for the rapid bubbling of the acid-base reaction to cease. DO NOT allow the acid to contact surfaces that will not be sealed. (Use of magnification is more than helpful—it is mandatory to control the chemicals used with sealants.) Rinse again thoroughly as described in Step 5 above.
7. Isolate well and dry thoroughly.
8. Disinfect all pits and fissures well using a 5% glutaraldehyde/HEMA based desensitizer for two 60-second applications. (Gluma Desensitizer by Kulzer, MicroPrime G by Danville). Remove residual liquid with high velocity suction. DO NOT rinse and DO NOT allow the glutaraldehyde to contact soft tissue.
9. Apply an adhesive directly over the damp glutaraldehyde/HEMA surface and spread it to a thin coating using a gentle stream of air.
10. Apply the sealant, exercising care to keep it within the pits and fissures. Remember to seal all the buccal grooves, plus distal lingual grooves on upper molars.
11. Check occlusion, and adjust if needed.
12. Plan to MONITOR the sealants forever with the same zeal given to restorations. At recalls, apply fluoride varnish to sealant treated teeth. (Thin resin on occlusal surfaces is subject to cracking and breaking away. I would not repair broken sealants. Instead remove the residual resin and replace the sealant using the steps above.)

To improve remuneration for more careful sealant placement I suggest the fee be related to the time used clinically. A flat fee makes no sense when the time needed can vary dramatically, depending on the patient’s cooperation.

Conclusion
In conclusion, I believe we can do a better job placing and monitoring sealants. Several steps have been suggested above that are not generally performed. They include routine use of an assistant and magnification; when possible, sealing teeth when newly erupted and caries free; routine use of an air polisher (and air abrasion if caries is suspected); use of a potent disinfectant (5% glutaraldehyde/HEMA) followed by an adhesive before sealant placement; applying fluoride varnish at recalls; and monitoring forever to the same degree that restorations are monitored. Consider your sealants to be a “preventive barrier” that you must keep intact!

Figure 5. Cavitron Jet-Fresh by Dentsply Preventive is a sodium-free abrasive made for air polishers. Its aluminum tri-hydroxide abrasive eliminates the sharp taste of the conventional sodium bicarbonate.

Figure 6. The InterCoronal Brush (ICB Brush) by Ultradent is specially designed to fit slow speed latch attachments. Its small size and short fine bristles can be used to clean pits and fissures in young children who may not allow air polisher use. (However, an air polisher provides optimum cleaning.)
References:


