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ENAMEL DEMINERALIZATION AROUND BONDED ORTHDONTIC APPLIANCES USING RESIN COATINGS

by

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A THESIS

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ENAMEL DEMINERALIZATION AROUND BONDED ORTHODONTIC APPLIANCES USING RESIN COATINGS

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CLINICAL DENTISTRY

ABSTRACT

Introduction: Orthodontists work to achieve a favorable esthetic and functional result, only to have the outcome tainted by the presence of demineralization upon appliance removal. The presence of WSL's is a disappointment to both orthodontists and patients. Several products have been developed to prevent this unfortunate damage to tooth structure, including "Opalseal" and "Ortho-coat". Opalseal is a 38% filled primer that releases and recharges fluoride. Ortho-coat is a fluoride releasing, light cure, hydrophilic resin that coats both the bracket and tooth surface preventing decalcification. The aim of this study was to investigate the barrier effect of Opalseal and Ortho-coat compared to both a fluoride varnish group and a control group. **Methods:** Utilizing fifty-four human central incisors, the teeth were divided into four groups to receive treatment with the following materials: Opalseal (Ultradent, South Jordan, UT), Ortho-coat (Pulpdent Corporation, Watertown, MA), Cavity Shield (OMNII Oral Pharmaceuticals, West Palm Beach, Fla.), and a control using Transbond XT (3M Unitek, St. Paul, MN). The groups of teeth were treated with the corresponding material following manufacturer's instructions and the bonding of an orthodontic button was incorporated into the procedure. The teeth were then subjected to 10K thermocycles and treated for 48hrs with 3.8ph demineralization solution. Each tooth was then sectioned and imaged

using a digital microscope (Keyence VHX 600 Series) at 100x magnification. The depth of demineralization was measured for all groups using two separate distances from the edge of the orthodontic button corresponding to the center of both the treated enamel zone and the untreated enamel zone. The results were statistically analyzed using a mixed model ANOVA ($p<0.05$). **Results:** Control, Varnish, Opalseal, and Ortho-coat showed no statistically significant differences for protection of the treated enamel zone. The opalseal group showed more demineralization in the untreated enamel zone. **Conclusions:** There was no difference in demineralization around bonded orthodontic appliances between the groups. There was no difference in the groups relative to the control for the untreated enamel indicating that no fluoride releasing benefit was seen.

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LIST OF ABBREVIATIONS

PPM	parts per million
RMGIC	resin-modified glass ionomer cement
WSL	white spot lesion
LED	light emitting diode
SBS	shear bond strength

INTRODUCTION

Patients are prompted to seek orthodontic care for a myriad of different reasons. Evaluation forms are full of chief complaints such as misalignment of teeth, deep bite, underbite, overbite, gap, teeth don't fit together, front teeth stick out, want straight teeth, and the list could go on and on. And just as patients present with many different concerns, there are many different ways to evaluate the result of the treatment that orthodontists give these patients. The most weight on this list is given to function and esthetics.

In Andrews' study of 120 casts of non-orthodontic patients with normal occlusion, he listed the characteristics that these cases shared and called them the "six keys to normal occlusion." These keys are molar relationship, crown angulation, crown inclination, rotations, spaces, and occlusal plane. He concluded that we have an excellent example of "natures best" and that in the absence of uncontrollable abnormalities these principles should be the goal.[66] These keys have guided many orthodontists to what they feel is a stable and functionally acceptable result. Yet some orthodontist's believe that function has been overemphasized and that occlusion's role in function and temperomandibular disease has been overstated. This is no more evident in the field of gnathology, which is considered "the science that treats the biology of the masticatory mechanism as a whole." Rinchuse and Kandasamy concluded in their article "the view that occlusion and condyle position are the primary causes of TMD, and that diagnoses and treatments should be based on these notions, has been discredited."[67]

Simultaneously there has been a patient shift in concern for esthetics. Sarver

and Ackerman explored this paradigm shift stating that "throughout most of the 20th century, the idea persisted that occlusion was the primary objective of orthodontic treatment, with esthetics playing only a secondary role." They concluded that as the role of esthetics continues to grow, new ways to evaluate the parameters that make up a good smile and face will need to be developed as measuring cephalograms alone is outdated.[68]

As smile esthetics moves up the list of patient priorities, nothing threatens meeting this expectation more than unsightly damaged enamel that can be present at appliance removal. These white spot lesions (WSLs) are due to acid demineralization of enamel by cariogenic bacteria.[69] This damaged enamel shows up most frequently as a white, opaque area outlining the site of bracket bonding. Prevention of these lesions during the course of orthodontic treatment is an overwhelming concern for orthodontists as they are unaesthetic, unhealthy and potentially irreversible.[6] Many preventative regimens have been examined in an attempt to minimize the formation of these WSLs. For example, the caries inhibiting effect of fluoride toothpaste has been firmly established and the preventative effect increases with increased fluoride concentration and frequency.[70] The effects of fluoride gels and varnishes has also been investigated and their benefits documented extensively. [16, 71] The unfortunate part about these treatments is that they require compliance, which is a the initial oral hygiene problem and also a large impediment to quality orthodontic care. Geiger and colleagues found that among the 101 patients, the degree of compliance with the home care preventive protocol was judged to be poor in 52.5%, partial in 20.8% and 26.7% were rated excellent.[8]

Considering that cooperation is always part of the equation, new methods of prevention have been developed in an attempt to prevent WSLs that don't require patient effort. Fluoride varnishes have been used but require multiple in-office visits and also leave an unpleasant yellowish discoloration on teeth. Antimicrobial, selenium and fluoride-releasing ligatures have also been developed to help prevent enamel demineralization. However, Wiltshire and colleagues stated that on the basis of their study, it was doubtful that fluoride-impregnated elastomeric ligature ties would be able to significantly inhibit enamel demineralization during orthodontics with plaque present around the brackets.[29] The non-compliant products that show the most promise in prevention are current commercially developed resins.
Ultradent developed Opalseal which is a 38% filled resin applied under brackets that releases fluoride and recharges fluoride with uptake. Orthocoat was developed by Pulpdent and is a fluoride releasing, light cure resin that coats both the bracket and the tooth, prevents food and bacteria from collecting around and under brackets, and prevents decalcification and staining. There are no studies in the current literature in which these products are tested together.

Purpose of this Study

The purpose of this study is to compare, *in vitro*, the barrier effect of Opalseal, Ortho-coat, fluoride varnish and our transbond xt control on the inhibition of enamel demineralization.

Figure 1. Clinical example of before (top) and after (bottom) treatment in a patient exhibiting severe enamel demineralization.

White Spot Lesions and Orthodontics

Decalcification of tooth structure surrounding orthodontic appliances is unfortunately a prevalent iatrogenic effect of orthodontic treatment. Gorelick has reported an increase in white spots in 50% of patients after orthodontic treatment.[5] Patients begin treatment with a well-aligned, esthetic result in mind and are often dissatisfied with the lesions that remain after appliance removal. Just as dental caries is a multifactorial disease, demineralization is a complex process involving the loss of tooth structure resulting in an altered surface appearance. Dental caries is a state of imbalance between demineralization and remineralization.[2] Brackets, archwires, ligatures, and other orthodontic appliances confound the use of conventional oral-hygiene methods which can result in substantial plaque accumulation around appliances at the level of tooth structure. This creates a cariogenic challenge on what would normally be smooth, caries-resistant tooth surfaces. Many different treatment regimens have been developed to limit the formation of white spot lesions. Fluoride is the basis for a majority of these regimens.

Unfortunately some courses of therapy require patient cooperation so clinicians have searched for methods that remain in their control. Chadwick et al concluded in a systematic review that the use of topical fluorides in addition to fluoride toothpaste appeared to reduce the incidence of decalcification in patients undergoing orthodontic treatment with fixed appliances. They also found that none of the various preparations studied appeared to be superior and that it was not possible to recommend which of the various schedules provided the greatest protection.[17] Although, Farhadian concluded

that one topical application of high concentration fluoride varnish could decrease enamel lesion depth around bonded brackets by 40% for three months and found it a highly advisable course of treatment in susceptible and uncooperative patients.[24] Great promise in the war on demineralization has been seen in the area of resin materials. In a 2006 study using bovine teeth, Paris et al found that lesions coated with a resin sealant showed almost no progression even in artificially carious conditions. This gave promise that sealing therapy may be a strategy to arrest lesions in less-compliant patients.[51]

A study by Hu and Featherstone compared fluoride varnish with Pro Seal (Reliance Orthodontics, Itasca, IL), which is a filled, light-cured sealant. They found that the teeth sealed with Pro Seal had what looked like a normal enamel profile at all points, indicating almost complete inhibition of demineralization. They also found that the fluoride varnish group had 30% less demineralization than the control group but more than the filled resin group. Compliance with fluoride as a solution to this problem of demineralization was also discussed as a hindrance. Coincidentally, Pro Seal was also found to effectively resist toothbrush abrasion meaning longer protection if a non-compliant patient suddenly started brushing.[75]

There has also been research aimed at how to address demineralization lesions once they have begun formation. One technique incorporates the use of acid to erode the surface layer of demineralized enamel in preparation for resin infiltration. The use of low viscosity resins to fill lesions has been shown to be a viable option for halting lesion progression. Unfortunately, the highly mineralized enamel surface layer of these lesions has been thought to decrease penetration of the resin. Meyer-Lueckel et

al conducted a study of using commercially available phosphoric acid and two experimental hydrochloric acid gels to prepare the enamel for infiltration with the unfilled resin. They found that a 90-120sec etch with hydrochloric acid gel led to an almost complete removal of the surface layer without lesion damage that could potentially cause cavitation. Phosphoric acid gel was found to be an insufficient enamel preparation material.[52]

Demineralization Process

Extensive research has shown us that dental caries is a multifactorial process involving food particles acquired in the diet, bacteria in dental plaque and the tooth surface.[76] Mutans streptococci (including Streptococcus mutans and S sobrinus) and lactobacilli have been identified as most associated with the caries process. These organisms, which thrive in an acidic environment, colonize the tooth surface and metabolize fermentable carbohydrates to form glucans and lactic acid. The model described by Harris and Garcia-Godoy illustrates the complex chemical and physical events that are initiated once the pH drops in the presence of the production of these acids.[77] As the pH level decreases, the plaque fluid that is normally supersaturated with calcium and phosphate gradually loses the saturation of these valuable minerals. A critical pH of approximately 5.5 is reached and acids are able to diffuse through the acquired pellicle to reach the enamel surface. These acids, that include lactic, acetic, propionic and formic acid, have the capability to dissolve the calcium phosphate mineral of tooth enamel or dentin. This is demineralization, or the loss of minerals.[10]

Featherstone stated that the acids diffuse through plaque and into porous enamel and dissociate to produce hydrogen ions as they penetrate. These hydrogen ions have the capacity to dissolve the mineral of tooth structure, thereby releasing calcium and phosphate into solution that diffuse out of the tooth. But as these minerals diffuse out of the tooth they redeposit the mineral and produce what appears as an intact surface layer.

The outset of this process has been described by Ogaard and colleagues and subdivided into two unique initial stages.[12] The first is surface softening which is characterized by the loss of "interprismatic substance" and is most exaggerated at the outer enamel surface. Remineralization will occur more readily in this phase due to the ability of the ions to penetrate the outer surface layer.[13] The next is categorized as the subsurface lesion where mineral content is lost at the deeper part of the enamel but is still covered by a relatively intact mineral rich layer. This has also been described in its earliest stages as an incipient lesion. It is first observed as a sub-surface white spot lesion due to the fact that mineral loss changes the refractive index optical property the eye perceives when compared to the intact and translucent surrounding enamel.
This entire process is a dynamic continuous cycle with the balance shifting to and fro between demineralization and remineralization. If the demineralization process continues unabated the lesion will progress into an overt or frank lesion.

Decalcification Prevalence in Orthodontic Patients

Fixed orthodontic appliances pose serious hygiene concerns, especially in non-

compliant patients. The increased plaque retention afforded by these appliances can lead to both white spot lesion formation and gingival inflammation. A 1971 study by Zachrisson and colleagues showed that there is a definite linear, positive correlation between white spot lesion development and bacterial plaque accumulation in orthodontic patients.[78]

Numerous studies have reported the incidence of demineralization in orthodontic patients as anywhere from 2%-96%.[1,3,5,6,8] A longitudinal study by Zachrisson and Zachrisson showed that 89% showed signs of demineralization after treatment and Ogaard showed that only 4% of patients were without WSLs five years after treatment.[6,78] Gorelick and colleagues performed a study examining 2,211 debonded teeth after orthodontic treatment in which there was no preventative fluoride program other than routine toothpaste. They showed that 49.6% of patients had white spot formation on at least one tooth but that only 10.8% had WSLs. They reported that there was a large variation in the number of white spots per patient which confirms the large range of incidence seen in the literature.[5] Boersma et al performed a study in which 97% of their patients displayed lesions after treatment.[79]

The demineralization process has been shown to transpire in only four weeks, which can be the time between appointments for most orthodontists. [2, 7] Alexander, O'Reily and Geiger all found that lesions can appear in patients in this one month window of time. And the location of these lesions within the arch is another point of interest. Mizrahi published two studies evaluating this phenomenon. In 1982 he stated that the majority of demineralization following orthodontic treatment occurred in the cervical and middle thirds of the facial surface of the teeth.[80] Next, in a study

published in 1983, he found that the greatest prevalence of demineralization was seen in the maxillary and mandibular molars followed by the maxillary incisors ranking as the second most affected.[9] Other sites commonly affected are the cervical margins of teeth, loose molar bands and the resin enamel junction.[7] And as stated earlier, white spot lesions can be seen up to five years after treatment demonstrating their ability to resist remineralization.

Decreasing Decalcification in Orthodontic Patients

Manual Products

The difficulty in maintaining oral hygiene with fixed appliances is greatly increased and failure to do so can increase patients risk for decalicification, caries and periodontal disease.[78] Approximately 20% to 30% of adolescents do not adequately remove plaque while undergoing orthodontic care.[4] And taking into account that orthodontic treatment can persist for two or more years, a rigid plaque control program is indispensable.[12] It is imperative that oral hygiene education be presented at the beginning of treatment and reinforce at every visit by verifying that the patient can remove plaque when problems arise. Mechanical plaque removal is the essential first step that has to be achieved by daily brushing and flossing. Proper use of a manual toothbrush may be sufficient, but most clinicians recommend a powered toothbrush, which removes plaque more effectively.[4,13-15] Wilcoxon found that counterrotational power toothbrushes are superior to manual toothbrushes in removing dental plaque from patients with fixed orthodontic appliances.[14] Ho and

Niederman found that the Sonicare toothbrush was significantly more effective in supragingival plaque removal and also at reducing gram negative bacteria count than the manual toothbrush.[15] Although these products have been proven to aid orthodontic patients in maintaining good oral hygiene, proper use and compliance are necessities in seeing results.

Fluoride

Mechanism of action

The compliance issues associated with the use of manual products have forced clinicians to seek alternate methods of preventing demineralization. Fluoride has long been utilized as a supplement to manual products and plays a critical role in orthodontics. The regular use of fluoride by a patient in orthodontic treatment has been shown to decrease the prevalence of demineralization.[6, 16, 17] Reductions of dental caries by 40-70% was the result of widespread fluoridation of public water supplies in many communities across the country.[10] The three key characteristics of fluoride that make it so effective are its abilities to inhibit demineralization, inhibit bacterial metabolism and enhance remineralization.

Sound tooth enamel contains approximately 20-100ppm fluoride levels depending on the amount of fluoride available during tooth development. Patients developing in fluoridated communities are usually on the high end of this scale. And although these fluoride levels are inherent to tooth structure, investigators have shown that fluoride in solution is much more effective at preventing demineralization than that existing in the crystalline structure of enamel.[10] Systemic fluoride is incorporated

into enamel by combining with hydroxyapatite to form fluoroapatite which is stronger and more resistant to dissolution.[81]

Another capability of fluoride is to inhibit the enzyme enolase thereby limiting bacterial metabolism. Enolase is a bacterial enzyme necessary for the breakdown of carbohydrates into pyruvic acid. Fluoride combines with hydrogen to penetrate the cell wall and once inside it dissociates again and the free fluoride acidifies the bacterial cell and disrupting enolase. Fluoride also competes with bacteria for the binding sites on enamel to prevent adhesion to the tooth.[82]

Perhaps the most important characteristic of fluoride is its ability to enhance remineralization. As saliva bathes tooth structure with its supersaturated chemical mixture of calcium and phosphate, fluoride acts to speed up this process by absorbing to the surface and attracting calcium ions.[10] These ions are then able to form a new structure between hydroxyapatite and fluorapatite which is stronger and more acid-resistant that the previous enamel. Remineralization can occur in saliva alone but Arends and ten Cate found a twofold rate increase in the presence of 1ppm fluoride ion.[83]

Fluoride can help place high-caries risk patients into an equilibrium that will favor remineralization. And although fluoride in the drinking water has been shown to reduce dental caries, it doesn't eradicate the problem. Jeansonne and Feagin concluded that the action of fluoride in the presence of acid in their study indicated that popular commercial beverages may serve as excellent vehicles for fluoridation.[84] Because even the slightest changes in this equilibrium prove effective, a variety of fluoride delivery systems have developed over the years to help dentists in the fight against decay.

Fluoride Products

Reports have suggested that topical fluoride in the form of toothpastes, gels, rinses and fluoride varnishes might reduce or eliminate decalcification during fixed orthodontic treatment.[17] But fluoride can exist in many different forms and delivery methods. Some common preparations include stannous fluoride, sodium fluoride, amine fluoride, and acidulated phosphofluoride. The contemporary delivery methods include rinses, gels and solutions.

A fluoride rinse is one of the most easily accessible forms of fluoride outside of drinking water and normal dentifrice use. Unfortunately, it is a self-administered product and is thus related to patient compliance which is a significant problem in the patients who need it the most.[8] Geiger and colleagues found that despite educational efforts and a free supply of rinse, only 13% of patients complied fully with its use suggesting the need for motivation and improved compliance with this product. They also found that there was a statistically significant dose response effect between the frequency of rinsing and incidence of white spots regardless of oral hygiene status. However, regardless of compliance issues, they also demonstrated a 25% reduction in the number of patients exhibiting white spot lesions during the use of this rinsing program.

Fluoride varnish as a topical delivery method has been used extensively in the prevention of demineralization around orthodontic brackets.[7] This is mostly due to the compliance issues that have been seen with toothbrushing, flossing and rinsing. The benefits of a professionally applied fluoride varnish regimen are that it doesn't require patient compliance and allows the orthodontist to choose his appliances without

worrying about the release of fluoride inherent in certain bonding systems.[85] The orthodontist can bond with resin instead of a fluoride releasing glass ionomer system thereby avoiding a sacrifice in bond strength. Another benefit of fluoride varnish is the delivery method that allows increased exposure time of the enamel to the fluoride. Brudevold and colleagues showed that the efficiency of topical fluoride applications was directly related to the exposure period of the enamel.[86] In a study by Farhadian and colleagues designed to evaluate the short term effect of topical fluoride in-vivo, they found that one application can decrease enamel lesion depth by 40% for 3 months.[24] The literature has shown that varnish can be beneficial as a preventive adjunct in reducing demineralization around orthodontic brackets.

Another common fluoride delivery method is the gel. Comparing reports about fluoride toothpaste alone versus toothpaste with an additional topical fluoride strongly suggest that additional topical fluorides offer greater protection against decalcification.[17] Alexander and Ripa stated that self-applied topical fluoride preparations are indicated in orthodontic treatment and may very well represent the standard of care in the orthodontic community. They found that subjects who used either gel after brushing with toothpaste at bedtime or the dentifrice twice daily, showed significantly fewer areas of demineralization than those adding fluoride rinse at bedtime.[11] Stratemann and Shannon found that only 2% of patients on a fluoride gel regimen developed white spot lesions while 58% of patients without fluoride developed lesions.[87] A couple of popular fluoride gel products are Prevident 5000 and MI Paste. Prevident has 5000ppm fluoride as has been shown in one study to be superior to products containing 1100 ppm fluoride.[88] MI paste has the active ingredient CPP-ACP, which is a complex of casein phosphopeptides and amorphous

calcium phosphate, and has been shown effective in reducing mean lesion depth integrated with a paste.[89] The only disadvantage of the gels is that it has been shown that 15-20% of patients develop mild staining after 3-6 months of use.[4] Although, this side effect doesn't outweigh the inherent benefit of preventing decalcification for orthodontic patients.

Bonding systems incorporating fluoride

In reaction to the increasing problem of white spot lesions, orthodontic adhesives have been developed that release fluoride in order to increase tip the balance toward remineralization in teeth that are facing a cariogenic challenge. This is a popular fluoride releasing system that dismisses the compliance issue as fluoride is released at the site of bonding of fixed orthodontic appliances. Fluoride releasing cement systems include glass ionomers, composite resins and resin-modified glass ionomers.

The benefit of glass ionomer cements is that not only do they release fluoride, they also absorb topically applied fluorides in order that they recharge and release over longer periods of time.[90] Fluoride is released gradually, usually more readily in low pH environments and also releases at the site of bonding which is the closest to the site of demineralization. The disadvantage of glass ionomer cements is that they have been shown to have lower bond strengths and higher rates of bond failure than resin cements.[25] Composite resins have been combined with glass ionomers in pursuit of greater bond strength and fluoride release. Resin-modified glass ionomer cements (RMGIC) were developed to overcome moisture sensitivity problems of composites

and low bond strength of glass ionomers while still possessing qualities of fluoride release, chemical bond to enamel and adhesion in a wet field.[91] This type of bonding agent has been shown to significantly prevent the development of demineralization. Sudjalim and colleagues found that while the use of RMGIC's significantly reduced enamel demineralization when compared with composite resin controls, there was concern regarding the reduction in shear and tensile bond strength.[27]

Enamel coatings and sealants

Enamel sealants have shown recent promise in the fight against demineralization during orthodontic treatment. Sealant placement has been thought to increase bond strength, protect against demineralization and protect etched enamel. Chemical cure sealants have been shown to be ineffective due to their inability to completely seal smooth enamel surfaces. This is due to the oxygen inhibition of polymerization when the sealant is in contact with air in a thin layer and only islands of cured sealant remain where resin pooling occurs.[92] One way to quantify these resins is the degree of conversion, or the percentage of bonds that are reacting. Craig found that while chemical cure systems have a 35% conversion in the air inhibited layer, light-initiated polymerization has around 80%.[93] However, the unfilled or lightly filled light-cured sealant hasn't been shown to provide more protection than the chemically cured due to mechanical toothbrush abrasion and acid attack intraorally.[94] More recently, highly filled light cure cements have been shown to be effective in reduction of enamel demineralization and also to be resistant to abrasion from toothbrushing.[95] Hu and Featherstone also found that this highly filled cement didn't

affect shear bond strength of adhesive precoated metal brackets.[94]

New materials

Ortho-coat™

Ortho-coat™ (Pulpdent Corporation) is a fluoride releasing, light cure resin that coats the bracket and tooth. It incorporates Pulpdent's bis-GMA-free Embrace Technology, which is a patented, hydrophilic resin technology that behaves favorably in a moist environment. Ortho-coat integrates with the tooth structure and is noted for its ability to prevent microleakage. The product can be used with both light cure and chemical cure adhesives. For light cure adhesives, Ortho-coat can be applied immediately after bracket placement and cured for 20 seconds or it applied at subsequent orthodontic visits by etching the bracket margin and enamel and placing. When using with chemical cure adhesives and placing the material after initial bonding, the air-inhibited layer must be removed with a dry cotton pellet or alcohol. Tuncer and colleagues performed a study evaluating the effect of Ortho-coat application on bond strength when used with two different self-etching primers. They found that the application of enamel-protective resin didn't affect the bond strength of orthodontic brackets to enamel with a self-etching primer.[96] Abdelnaby and Al-Wakeel studied the bond strength and microleakage properties of Ortho-coat when used with transbond xt. They found that curing the resin coat and adhesive simultaneously showed an increase in shear bond strength (SBS) that was not significant, but curing the resin and adhesive separately exhibited a significant increase. It was also shown that Ortho-coat applied in either protocol produced a

significant reduction in microleakage probably due to the barrier around the bracket and adhesive edges.[97]

Opalseal

Opalseal is a fluoride releasing and recharging light cured primer that is 38% filled with substantial glass ionomer plus nano-fillers and is compatible with any bonding system. Opal Seal is used when bonding orthodontic appliances to etched enamel and the use of a UV "black" light will make the sealant illuminate showing that the resin containing fluoride is present. Opalseal is applied by etching the tooth surface, rinsing and applying a thin layer of opalseal. It is then cured for 5 seconds to avoid bracket skating on placement and then the bracket is cured per manufacturer's instructions. There is no current literature available evaluating either the bond strength or demineralization inhibiting properties of opalseal.

Present Study

Bonded resins have been shown to be effective in reducing enamel demineralization during orthodontic treatment.[(51, 94, 95, 97)] No reports have been conducted to compare Ortho-coat and Opalseal with a fluoride varnish and control. The specific aim of this study was to compare, *in vitro*, the barrier effect of Opalseal, Ortho-coat, fluoride varnish and our Transbond xt control on the inhibition of enamel demineralization.

MATERIALS AND METHODS

Study Design

Forty extracted human central incisor teeth were collected and stored in a 10% solution of sodium hypochlorite. Approximately one month prior to the study, the teeth were transferred to distilled water. The study called for four groups of at least ten teeth with random assignment to each treatment group. Additional teeth were used in the case of defect or fracture that resulted in exclusion from the study. The study design and sample sizes are shown in table 1.

Table 1

Study design

Treatment group	Specimen
Group 1: Control	N=13
Group 2: Fluoride Varnish	N=14
Group 3: Ortho-coat	N=14
Group 4: Opalseal	N=13

The teeth were sectioned 2mm apical to the cement-enamel junction using a diamond bur under copious irrigation and the root segment was discarded. The remaining crown was then prepared using oil-free, water based pumice (Whipmix, Louisville, KY) to clean the entire enamel surface followed by a rinse and drying stage. All further isolation methods and bonding techniques were performed under

2.9-x magnification using dental loupes. A 7mm diameter masking tape circle was placed in the center of the facial surface of the tooth and the remaining exposed tooth structure was covered adequately with 2 coats of Megalast ™ nail varnish (Markwins, City of Industry, CA). This was done to isolate the treatment area of the tooth and to protect the remaining portion of the tooth from demineralization by the acidic demineralization solution. After the varnish was completely dry, the tape circle was removed leaving a 7mm diameter treatment zone on the facial surface of the tooth. Another segment of tape was then placed over this treatment zone leaving an open hole 4.9mm in diameter. The purpose of this tape segment was to isolate the etch portion of the tooth to the 4.9mm diameter circle, thus leaving an untreated enamel border of 1.02mm width encircling the treatment zone. This created a "bulls-eye" effect of treatment zones that is illustrated in Figure 1.

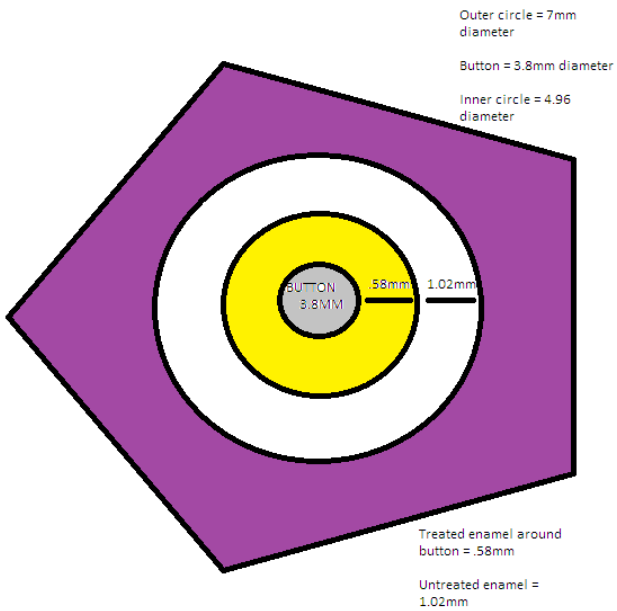

Figure 2. Bonding Diagram

Bonding Protocol

Control

After isolation was completed according to the previous instructions, the 4.9mm diameter hole was coated with 38% phosphoric acid etchant gel (Etch-Rite, Pulpdent Corporation, Watertown, MA) for 30 seconds. The bonding area was then rinsed for 5 seconds with sterile water and dried thoroughly with oil/moisture-free air. A thin layer of transbond xt prime and bond (3M Espe, St Paul, MN) was applied and air dispersed for 2 seconds. A 3.8mm diameter button was positioned in the center of the bonding area using transbond xt composite (3M Espe, St Paul, MN), removing all excess composite. The tape isolation border was removed and the specimen was cured for 20 seconds using a Valo broadband LED curing light (Opal Orthodontics by Ultradent, South Jordan, UT) with an intensity of 1700mW/cm2.

Fluoride Varnish

After isolation was completed according to the previous instructions, the 4.9mm diameter hole was coated with 38% phosphoric acid etchant gel (Etch-Rite, Pulpdent Corporation, Watertown, MA) for 30 seconds. The bonding area was then rinsed for 5 seconds with sterile water and dried thoroughly with oil/moisture-free air. A thin layer of Transbond xt prime and bond (3M Espe, St Paul, MN) was applied and air dispersed for 2 seconds. A 3.8mm diameter button was positioned in the center of the bonding area using Transbond xt composite (3M Espe, St Paul, MN), removing all excess composite. The specimen was cured for 20 seconds using a Valo broadband

LED curing light (Opal Orthodontics by Ultradent, South Jordan, UT) with an intensity of 1700mW/cm2. A coat of 5% sodium fluoride Cavity Shield varnish (3M Espe, St Paul, MN) was applied around the bracket in the treated enamel zone and the isolation tape was removed.

Ortho-coat

After isolation was completed according to the previous instructions, the 4.9mm diameter hole was coated with 38% phosphoric acid etchant gel (Etch-Rite, Pulpdent Corporation, Watertown, MA) for 30 seconds. The bonding area was then rinsed for 5 seconds with sterile water and dried thoroughly with oil/moisture-free air. A thin layer of Transbond xt prime and bond (3M Espe, St Paul, MN) was applied and air dispersed for 2 seconds. A 3.8mm diameter button was positioned in the center of the bonding area using Transbond xt composite (3M Espe, St Paul, MN), removing all excess composite. The specimen was cured for 20 seconds using a Valo broadband LED curing light (Opal Orthodontics by Ultradent, South Jordan, UT) with an intensity of 1700mW/cm2. A thin layer of Ortho-coat was applied around the bracket margin and the treated enamel zone and then cured using the same method as stated above. The tape isolation border was then removed.

Opalseal

After isolation was completed according to the previous instructions, the 4.9mm diameter hole was coated with 38% phosphoric acid etchant gel (Etch-Rite, Pulpdent Corporation, Watertown, MA) for 30 seconds. The bonding area was then

rinsed for 5 seconds with sterile water and dried thoroughly with oil/moisture-free air. A thin layer of Opalseal (Ultradent, South Jordan, UT) was applied and air dispersed for 2 seconds. A 3.8mm diameter button was positioned in the center of the bonding area using Transbond xt composite (3M Espe, St Paul, MN), removing all excess composite. The tape isolation border was removed and the specimen was cured for 20 seconds using a Valo broadband LED curing light (Opal Orthodontics by Ultradent, South Jordan, UT) with an intensity of 1700mW/cm2.

All four groups of specimen were then subjected to thermocycling for 10,000 cycles over a period of 5 days alternating between 6C and 65C with a 15 second dwell time. Following the thermocycling procedure, the teeth were placed in sterile water and stored at 37 degrees for approximately 7 days while the artificial caries demineralization solution was being prepared.

An artificial caries solution was prepared by first combining 500 mL 1M lactic acid with 10 mL K_2HPO_4 stock solution. The pH of the solution was brought up to 4.7 using 1M NaOH. The solution was titrated to pH 3.8, which was verified using a calibrated sensION 4 pH/ISE meter (Hach Company, Loveland, CO). Each group of teeth was placed in a separate container of the artificial caries solution and then stored at 37° C for 48 hrs. The groups were then rinsed copiously with distilled water to remove all remnants of the demineralization solution and then stored in distilled water for three days.

At the conclusion of the treatment, the nail varnish was removed and all teeth were sectioned using the Isomet machine. They were then imaged under 100x magnification using a digital light microscope (Keyence VHX-600 series, Woodcliff

Lake, NJ). The images were captured and saved according to group, tooth, halve, and side of the bonded button (incisal or gingival). The saved images were then measured for depth of demineralization using the Keyence software. Two lines were drawn from the height of contour of the edge of the bonded button. The first point was .29mm distance from the edge of the button and represented the midpoint of the treated enamel zone. The second point was 1.09mm distance from the edge of the button and represented the midpoint of the untreated enamel zone. Next, measurements of the depth of demineralization were carried out perpendicular to the endpoints of these two measurements and recorded as the lesion depth at .29mm and 1.09mm. These results were recorded into a spreadsheet and then subjected to statistical analysis.

STATISTICAL ANALYSIS

The data obtained from the different halves of the samples was not averaged in an effort to keep the analysis as accurate as possible. A paired t-test was used to compare the repeated measures at two distances of .29mm and 1.09mm from the edge of the button. A mixed model analysis of variance (ANOVA) was used to compare the depths at the two different points between each sample group. A Tukey/Kramer test was performed to analyze differences within each point between the different sample groups. A Dunnett t-test was then used to compare the results of each group back to the control group. Statistical significance was determined at $p<0.05$.

RESULTS

Each tooth was divided in half and each half measured at two points for a total of four measurements on each tooth. 54 teeth were used so ideally we would have 216 total measurements. But as each tooth was sectioned to obtain the samples, several specimens fractured and were unsuitable to be used as samples. After specimen with fractures, flash and cavitations were excluded; the study yielded 167 total measurements. The 49 exclusions were distributed as follows: Control 8, varnish 18, Ortho-coat 13 and Opalseal 10.

The mean depths for the midpoints of the treated enamel group and untreated enamel group and the results of the paired t-test on these data are shown in Figure 2.

Paired t-test
Split By: Group, A/B, G/I
Hypothesized Difference =

	Mean Diff.	DF	t-Value	P-Value
_.29_, _1.09_: Total	-.029	166	-8.237	<.0001
_.29_, _1.09_: oc, a, g	-.045	10	-2.149	.0572
_.29_, _1.09_: oc, a, i	-.009	10	-1.187	.2625
_.29_, _1.09_: oc, b, g	-.049	11	-2.889	.0147
_.29_, _1.09_: oc, b, i	-.027	8	-2.071	.0721
_.29_, _1.09_: os, a, g	-.066	10	-3.775	.0036
_.29_, _1.09_: os, a, i	-.056	8	-4.476	.0021
_.29_, _1.09_: os, b, g	-.059	11	-3.400	.0059
_.29_, _1.09_: os, b, i	-.050	9	-3.527	.0064
_.29_, _1.09_: v, a, g	-.017	8	-1.733	.1213
_.29_, _1.09_: v, a, i	-.010	9	-1.104	.2982
_.29_, _1.09_: v, b, g	-.033	8	-3.267	.0114
_.29_, _1.09_: v, b, i	-.004	10	-.502	.6268
_.29_, _1.09_: xc, a, g	-2.344E-4	8	-.032	.9754
_.29_, _1.09_: xc, a, i	-.013	10	-1.848	.0943
_.29_, _1.09_: xc, b, g	-.022	10	-1.482	.1692
_.29_, _1.09_: xc, b, i	-.007	11	-.871	.4026

Means Table for _.29_
Effect: Group * A/B * G/I

	Count	Mean	Std. Dev.	Std. Err.
oc, a, g	11	.069	.062	.01
oc, a, i	11	.091	.034	.01
oc, b, g	12	.072	.053	.01
oc, b, i	9	.078	.052	.01
os, a, g	11	.113	.076	.02
os, a, i	9	.088	.056	.01
os, b, g	12	.118	.080	.02
os, b, i	10	.105	.094	.03
v, a, g	9	.113	.049	.01
v, a, i	10	.091	.053	.01
v, b, g	9	.091	.029	.01
v, b, i	11	.083	.064	.01
xc, a,	9	.098	.066	.02
xc, a, i	11	.081	.061	.01
xc, b,	11	.084	.070	.02
xc, b, i	12	.093	.051	.01

Means Table for _1.09_
Effect: Group * A/B * G/I

	Count	Mean	Std. Dev.	Std. Err.
oc, a, g	11	.114	.042	.01
oc, a, i	11	.100	.043	.01
oc, b, g	12	.121	.040	.01
oc, b, i	9	.105	.035	.01
os, a, g	11	.179	.058	.01
os, a, i	9	.144	.050	.01
os, b, g	12	.177	.089	.02
os, b, i	10	.155	.062	.02
v, a, g	9	.130	.042	.01
v, a, i	10	.101	.068	.02
v, b, g	9	.124	.043	.01
v, b, i	11	.086	.069	.02
xc, a,	9	.098	.073	.02
xc, a, i	11	.094	.059	.01
xc, b,	11	.106	.078	.02
xc, b, i	12	.100	.060	.01

Figure 3. Paired t-test means comparision

The results indicate that the differences in lesion depths between the untreated enamel

at .29mm and the treated enamel at 1.09mm were only statistically significant for the opalseal group. All four measurement points for the opalseal group had statistically significant differences between the treated and untreated zones of enamel. The orthocoat and varnish groups had a statistically significant difference only at one measurement point. The control group showed no statistically significant differences between the two measurements.

The means were plotted in a graph below to illustrate the relationship of the mean lesion depths compared with each group at the two different points. The lesion depths were shown to be the highest for the opalseal group for both the .29mm and 1.09 mm points illustrated in Figure 3.

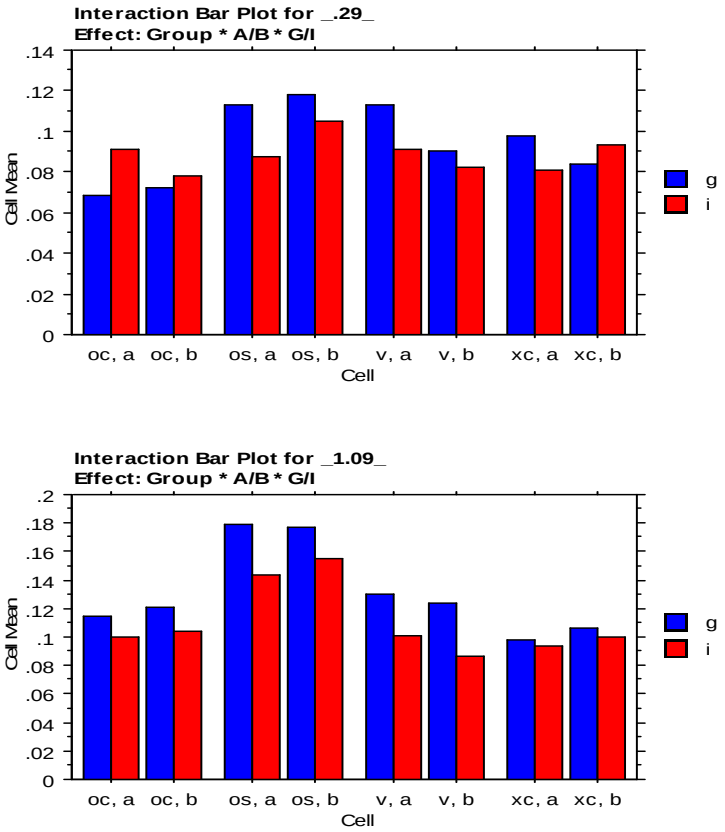

Figure 4. Interaction Plot for means

The means were then used to run an analysis of variance. While statistically significant differences were found between the means of the treated and untreated enamel zones, the analysis of the .29mm treated zone showed no statistical differences between the different experimental groups. This was also verified by a tukey/kramer test. The dunnett's test was used to compare everything back to our control group and also found no statistically significant differences as well.

However, significant differences were found between the different groups at the 1.09mm treated enamel point. There was a statistically significant difference seen between for the orthocoat vs opalseal groups and for the opalseal vs control groups at the treated enamel zone.

DISCUSSION

The goal of orthodontic treatment is to create a functionally sound occlusion and an esthetically idyllic smile. White spots that are the product of poor hygiene can act to spoil this result. Given that studies show that restoration of these lesions very difficult, it is imperative to take all preventative measures necessary to prevent their formation. An adhesive resin can offer a unique approach to preventing white spot lesions that does not depend on patient compliance and can be completed during bonding to protect the appearance of the teeth. These resins coat the tooth structure around fixed orthodontic appliances to prevent lesions from beginning and progressing to cavitation. Previous studies have shown that this can be an effective way to prevent the demineralization process that causes white spot lesions.[98, 99] However, no published studies have reported results that compare the effectiveness of some of these newer commercially available products with a traditional bonding control and a fluoride varnish. The aim of this study was to compare, *in vitro*, the barrier effect of Opalseal, Ortho-coat, fluoride varnish and our Transbond xt control on the inhibition of enamel demineralization.

In the present study, teeth treated with Opalseal showed a significant difference in mean depths of treated and untreated tooth structure. The four points measured in the Opalseal group showed mean differences of .066, .056, .059 and .050mm. This was the only group that had consistently significant differences in the mean lesion depths between the treated and untreated zones. Both the varnish group and the ortho-coat group had one of the four points that indicated a statistically

significant difference but no consistent pattern. The points measured on each half of the sample were mirror images of each other at the incisal and gingival portion of the bonded orthodontic button. Thus the measurements are taken at a sample of tooth separated only by the thickness of the isomet blade. Therefore, samples that don't show consistent statistically significant differences may contain an anomaly that only presents itself at one measurement point. There have been no studies using opalseal to study demineralization inhibition with which to compare the current results.

The interaction bar plot graph in Figure 2 illustrates that lesion depth around the Opalseal group was greater than the lesion depths in other groups. The means for the Opalseal untreated enamel point were significantly greater than the means for the other three groups registering at .177 and .179mm for the gingival measurements of the samples. This is confirmed by the anova analysis for the untreated zone. There were statistically significant differences between the opalseal group and both the control and orthocoat groups at the 1.09 untreated enamel points. This difference can be attributed to the fact that the opalseal demineralization depths at the untreated zone were greater than the other groups. There may be two possible explanations for this finding. The first would be an unintentional bias within the teeth selected for the opalseal group. The teeth were distributed at random but there may have been a slight difference in the enamel properties of the teeth placed into the opalseal group making them more prone to larger demineralization depths. Second, the results indicate that the fluoride leaching properties of the material, which are expected to provide benefit to the enamel surrounding the treated zone, had no significant effect. Studies have

shown that many adhesives currently in use release fluoride but long-term clinical studies have shown that this was unsuccessful clinically in preventing demineralization around brackets.[72, 73, 74] However, the benefit of the material is in its ability to recharge in the presence of fluoridated hygiene products and to show continued release. Our study design restricted the recharge of fluoride as demineralization was carried out in an artificial caries solution and were never exposed to a source of fluoride.

Another significant finding was the fact that there were no statistically significant differences found between the mean lesion depths of the different groups in the treated enamel zones. This information is useful in evaluating the barrier effect as no material added a greater demineralization inhibition effect. The control, fluoride and Ortho-coat samples all contained a coat of Transbond xt used as the primer to bond the bracket. The only different group with respect to the barrier around the button was the opalseal group that used opalseal material for the primer. Wear or breaks in a lightly or unfilled resin caused by mechanical toothbrush abrasion and chemical attack could result in significant decalcification. Highly filled sealants have been found to resist abrasion and remain attached to enamel surfaces.[99] Pro Seal, which is a light-cured, highly-filled sealant, was found to greatly resist toothbrush abrasion and effectively seal a smooth enamel surface.[94] The omission of toothbrush wear in our study could the reason that the treated enamel zones appeared similar for all groups and an abrasion study may give different results.

CONCLUSIONS

Under the conditions of the present study, the following conclusions are made:

1. There was no difference in demineralization around bonded orthodontic appliances between the groups.
2. There was no difference in the groups relative to the control for the untreated enamel indicating that no fluoride releasing benefit was seen.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD FOR HUMAN USE APPROVAL FORM

12/10/10

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

DATE: 12/10/10

MEMORANDUM

TO: Michael B. Wood
Principal Investigator

FROM: Sheila Moore, CIP
Director, UAB OIRB

RE: Request for Determination—Human Subjects Research
IRB Protocol #N101202007 – Enamel Demineralization Around Bonded Orthodontic Appliances Using Resin Coatings

An IRB Member has reviewed your application for Designation of Not Human Subjects Research for above referenced proposal.

The reviewer has determined that this proposal is **not** subject to FDA regulations and is **not** Human Subjects Research. Note that any changes to the project should be resubmitted to the Office of the IRB for determination.

SM/cro