POTENTIAL IATROGENIC EFFECTS ON ENAMEL TREATED WITH A LIGHT CURED FLOURIDE RELEASING FILLED RESIN

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ORTHODONTICS

ABSTRACT

White spot lesions have long been a problem in fixed appliance orthodontic treatment. Various methods of prevention have been used in the past, most requiring patient compliance. The use of non-compliant orthodontic sealants to form a barrier on the facial surface of the tooth has been attempted in the past with limited success due mainly to the inability of composite resins to fully polymerize. Pro Seal (Reliance Orthodontic Products, Inc, Itasca, IL) is new product which claims to fully polymerize and provide protection from white spot lesions during orthodontic treatment. In vitro studies support this claim. The side effects of acid etching the entire facial surface of teeth and potentially having composite resin tags remain in the enamel after the removal of fixed appliances has not been addressed in terms of tooth discoloration or whitening.

The purpose of the present study was to compare in vitro, Pro Seal treated teeth with controls to in terms of degree of discoloration and whiteness after subjecting them to a staining solution and a dental whitening system. 60 extracted human incisors were divided evenly into groups. Using a spectrophotometer, color measurements in the CIE LAB color space were made at baseline. The experimental group had Pro Seal placed and removed per the manufacturer. All teeth were then placed in a staining solution, measured for discoloration, bleached with 25% hydrogen peroxide and measured again. The results showed that on average the teeth treated with Pro Seal discolored more than untreated the teeth. Similarly, the treated teeth were able to be bleached by the whitening
protocol used in this study, but not to the same extent as the untreated teeth. This suggests that the procedure for placing and/or removing Pro Seal, and/or potentially remaining resin, or resin tags of Pro Seal on or in the enamel, affect the response of teeth to staining solutions and bleaching procedures. Clinicians and patients should be aware of this when selecting and preventive treatments for white spot lesions.
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INTRODUCTION

Protection of the dental enamel from the demineralization of smooth surfaces during orthodontic treatment is paramount for ideal esthetic treatment results in an appearance conscious society. Moreover, it is a requirement, if clinicians are to stay true to Hippocrates and his mandate to do no unnecessary harm to the patient. Evidence confirms that the placement procedures and use of fixed appliances during orthodontic treatment increase the risk of enamel demineralization.\textsuperscript{1, 2, 3} While prevention of this is an assumed goal of the practicing clinician, a recent study reveals that many orthodontists do not use methodologies based on documented evidence to eliminate enamel demineralization, also known as white spot lesions, during fixed appliance therapy.\textsuperscript{4}

Most preventive procedures require the compliance of the patient to ensure success. O’Reilly and Featherstone\textsuperscript{5} concluded that although patients can have rapid demineralization occurring adjacent to fixed orthodontic appliances, a preventive regimen of daily brushing with fluoridated dentifrice and the combined use of an over the counter, 0.05% sodium fluoride mouth rinse can protect the enamel via inhibition of demineralization and/or encouraging remineralization. The Cochrane Collaboration also concluded after exhaustive review of the literature, that a daily rinse with 0.05% sodium fluoride is linked with reduction in the severity and occurrence of white spot lesions in orthodontic patients.\textsuperscript{6} While topical fluorides have been shown to be effective, the disadvantage of patient compliance complicates their success. Geiger et al.\textsuperscript{7, 8} found that compliance with a preventive fluoride rinse protocol occurred in only half of the patients
studied. A clear association in increasing white spot lesion incidence occurred with decreasing the number of fluoride dosages and in decreased compliance by the patient with the protocol.

Attempts have been made, with varied success, to create non-compliant systems which would provide protection of the facial surface of the dentition during fixed orthodontic treatment. Some of these treatments rely on the clinician to apply and reapply fluorides or other medicaments on monthly to semi-annual intervals to protect the enamel. This places the compliance burden on the treating orthodontist and auxiliary staff. Other treatments claim to only require one application of a product to protect the enamel. Some products are incorporated into the bonding system itself, and some are incorporated into the elastomeric ligation ties. Until recently, most of these products have either failed to withstand the rigors of the oral environment, did not accomplish their task of protection, or were enough of an inconvenience to the patient or practitioner that they were not used with regularity.

A product claiming to have overcome the failings of past efforts at preventive treatments came onto the market in 2004. Pro Seal (Reliance Orthodontic Products, Itasca, Ill.), is a fluoride releasing light-cured filled sealant that may be used either prior to, or after bonding orthodontic appliances to enamel, to provide protection from the formation of white spot lesions. Pro Seal uses a proprietary catalyst which claims to fully cure the composite resin and overcome the problems inherent with oxygen inhibition of composite resin polymerization that occurred in previously marketed products. This incomplete polymerization has been implicated in the porosities and breaks in the protective resins which plagued earlier attempts at smooth surface sealants.
and allowed demineralization to occur. This new sealant has been shown in recent in vitro studies to provide the needed protection from demineralization, acting as a barrier and releasing fluoride throughout the course of orthodontic treatment without wearing away or breaking down in simulated oral environments. The potential of this material to protect the dentition from the occurrence of white spot lesions in non-compliant patients during orthodontic treatment appears to be a possibility based on the current in vitro studies. However, the potential side effects that this bonded composite resin may create needs to be addressed for the clinician to fully realize the consequences of its use, and confidently prescribe the patient safe and effective protection from demineralization.

The objective of the present study is to compare a sample of teeth treated with Pro Seal and an untreated sample to determine if the treatment will have a propensity to make the teeth more susceptible to staining from food pigments. In addition, the ability to whiten these samples and controls with a dental whitening agent will be assessed. The variable studied is the objective color of the teeth in the L* a* b* color space as defined by the Commission Internationale de l’Eclairage (CIE). This yields a calculation which provides an objective measure of tooth whiteness. The null hypothesis is that use of the Pro Seal fluoride releasing light-cured filled sealant on the facial surface of teeth in vitro does not subject them to a greater propensity to discolor when subjected to a staining media, nor does it inhibit the ability to be whitened by a 25% hydrogen peroxide solution when compared with an untreated sample of teeth. The results will focus on the degree of staining between groups and the ability to whiten treated and untreated samples. The outcome of this study will provide clinicians with the knowledge of potential iatrogenic
effects of a procedure and product which purports to eliminate another problem and iatrogenic effect, albeit that the later is a more harmful side effect of orthodontic treatment and poor oral hygiene, namely, white spot lesions.
LITERATURE REVIEW

White Spot Lesions and Orthodontics

White spot lesions are caused by mineral loss in the surface and subsurface of the enamel.\textsuperscript{32} The mineral loss is due to the acid byproducts of processing fermentable carbohydrates by bacterial plaques that colonize the enamel surface. If the bacterial plaques are not removed and unmitigated demineralization of the enamel proceeds, frank cavitations of the enamel surface and bona fide carious lesions will result.\textsuperscript{2} The connection between fixed appliances and the incidence of caries and white spot lesions was noted in the early years of orthodontic practice.\textsuperscript{33} Gorelick et al.\textsuperscript{,1} showed that compared with an untreated control group, treated patients are twice as likely to develop a white spot lesion. Other researchers have provided evidence that the prevalence among orthodontic patients can range from 2-96%.\textsuperscript{34,35} O’Reilly and Featherstone\textsuperscript{5} reported that after only 4 weeks with orthodontic appliances, white spot lesions could be visually detected in some patients. Ogaard\textsuperscript{2} found that the risk for developing new white spot lesions was higher in individuals who had fixed appliance therapy even up to 5 years after treatment, than was the risk of patients without fixed appliances.

In orthodontic patients, the conditions that allow for increased risk with fixed appliances include the very presence of brackets, arch wires, ligatures et cetera, which hinders the conventional oral hygiene practices that the patient is accustomed to.\textsuperscript{32} In patients who do not overcome these impediments to good oral hygiene, prolonged plaque accumulation at the base of the appliances, adjacent to the enamel, occurs and is a
precursor to demineralization. Mitchell, in his overview of decalcification and orthodontic treatment, elucidates that poor oral hygiene, diets with frequent insults of high contents of fermentable carbohydrates, fixed appliances which decrease the ability of the self cleansing nature of the dentition via salivary flow, and finally, the presence of adhesive flash from poor bonding techniques, can be considered secondary etiologies of white spot formation. Steffen posits another potential cause for increased incidence of white spot lesion in orthodontic patients as being the exposed acid etched surfaces of teeth with resin bonded appliances. Joseph et al. stated:

The greatly increased potential for demineralization after bracket placement may be in part aided by the initial impetus afforded it by the rough, retentive, and decalcified surface of enamel produced by acid etching and lack of sealant. It must be remembered that acid etched enamel has a higher solubility rate than normal enamel. Remineralization brings about a reduction in this rate in 24 hours, but is still not the same as normal enamel.

There is evidence that etched enamel can remineralize in saliva. However, acids via bacterial plaques or, the low Ph soda beverages in orthodontic patients’ diets, may be available to further demineralize the etched surface prior to the completion of the remineralization process. This may induce irreparable changes to the enamel by leaching the mineral content to a depth that cannot fully remineralize to its prior structure or state, and thus enamel etching may contribute to white spot lesion.

While white spot lesions can occur at any age, children, 11 to 14 years old, are at the greatest risk of developing decalcifications and caries. This is the age group in which orthodontic treatment is usually performed and these patients frequently have poor oral hygiene practices, highly cariogenic diets, and tendencies to not comply with preventive regimes and thus show the highest incidence of lesions.
Studies and clinical experience have shown white spot lesions on all tooth types during and after orthodontic treatment. The literature has a history of mixed information on the most affected teeth including the maxillary first molars, mandibular canines and premolars and maxillary incisors.\(^1,2,21,35\) Most studies report that the lesions are most often found to occur on the cervical and middle third of the buccal surface of the lateral maxillary incisors, the mandibular canines and the first premolars.\(^1,2,21,35\) Evidence shows that demineralized enamel can remineralize after debonding of appliances and normal salivary flow and hygiene practices return, but the unsightly appearance of the white spot lesions remain as some interior opacity of the enamel remains.\(^1,5,38\) Koulourides et al.\(^39\) showed that that remineralized and arrested lesions are more resistant to a subsequent acid attack than sound enamel. While this finding is comforting from a caries resistance stand point, it does not address the negative effect on the esthetics of the affected teeth. van der Veen et al.\(^40\) recently concluded that white spot lesions which developed during orthodontic treatment can regress and remineralize after treatment, but this natural process may not be enough to avoid restoration for esthetic or carious reasons. Another study showed that patients who developed white spot lesions during treatment and were subsequently treated with a camouflaging bleaching of the dentition, were satisfied with results that masked the lesions.\(^41\) None the less, the prevention of their formation would be more beneficial to both the patient and the practice of orthodontics as a whole by eliminating the need to treat a preventable process, reducing post orthodontic whitening treatments and their associated financial costs, and enhancing the esthetic results of sound orthodontic treatment.\(^42\)
Preventive Measures for White Spot Lesions

Methods of combating and decreasing the risk of white spot lesions in orthodontic patients can be placed in two major groups. Removing nascent, or preventing the formation of bacterial plaques by diligent and improved oral hygiene practices is one mode of prevention. Compliance with the seemingly innocuous prescription of daily tooth brushing, flossing, and use of any of the myriad ancillary hygiene aids is poor in many orthodontic patients even with encouragement from dental professionals. Therefore other preventive methods which rely on increasing the resistance of the enamel surface to the acids produced by the bacteria provide improved success at protecting the enamel. Topical fluoride application has been shown to inhibit the formation and further development of white spot lesion in orthodontic patients. This is due to the formation of calcium fluoride at the enamel surface and subsurface which is more resistant to demineralization than untreated enamel. These same topical fluorides have been demonstrated to improve enamel remineralization following orthodontic treatment. The use of topical pastes with bio-available calcium phosphate to prevent and remineralize white spot lesions by providing a reservoir of calcium to replace lost mineral content in acid affected or demineralized enamel. Combining good oral hygiene with daily fluoride use has been shown to be the most effective method to date to reduce the incidence of white-spot lesions according to a recent review of the literature by the Cochrane Collaboration. Patient use of topical fluorides at home requires patient compliance. Fluoride mouth rinses, gels and dentifrice are all available for patient use but the issue of compliance remains a problem. Thus a variety of different non-
compliant topical fluoride delivery methods have been implemented to prevent enamel
demineralization around fixed appliances.

Todd et al.\textsuperscript{9} recommended the use of a professionally applied fluoride varnish, Duraflor (Pharmascience Inc, Montreal, Canada). It contains 5\% sodium fluoride by weight in a natural rosin base. The advantages of the fluoride varnish over other topical fluoride regimens were explained as providing fluoride protection despite patient noncompliance and delivering the fluoride in a sustained manner over a longer period of time. Studies confirm that to obtain the most preventive effects from fluoride, a constant presence at minimal doses is ideal.\textsuperscript{44} Other researchers have shown decreased risk of decalcification with the use of various type of fluoride varnishes.\textsuperscript{47,48} The need to reapply this type of protection on regular intervals throughout orthodontic treatment has been suggested if optimal fluoride levels are to remain in and on the enamel surface.\textsuperscript{49} Ogaard et al.\textsuperscript{49} also showed that adding an antimicrobial element to the fluoride varnish is no more effective at decreasing the risk of white spot lesions.

The incorporation of fluorides into glass ionomers cements has been show to decrease enamel decalcification around orthodontic band and brackets.\textsuperscript{50,51,52} While the use of glass ionomers for band cementation has preventive advantages over conventional zinc phosphate as a luting agent, there are drawbacks to the use of glass ionomers for bonding brackets. Decreased bond strength as compared to composite resins has been reported by investigators.\textsuperscript{53,54} This is quite important clinically since frequently broken appliances likely mean more time in treatment which can translate to more costs to the clinician and the loss of the patient’s compliance. Millett et al.\textsuperscript{51} did find less enamel decalcification around orthodontic brackets placed with glass ionomer cement when
compared with conventional composite resin, but this difference was not statistically significant. Because of these shortcomings, especially the decrease in bond strength, the use of glass ionomers in bracket placement has had little clinical acceptance.\textsuperscript{55} However, there is research to support the use of resin-modified glass ionomers to bond brackets to enamel and obtain adequate bond strength while decreasing damage to the enamel and providing a fluoride reservoir.\textsuperscript{56,57,58,59} Polyacrylic acid is use to condition the enamel surface and does not alter it to the same degree as phosphoric acid, which is commonly used to prepare enamel for resin composite bonding.\textsuperscript{56} The resin-reinforced glass ionomers combine both the benefit of chemical bonding from the chelating ability of the glass ionomers, and strength from the resin.\textsuperscript{57,58,59} While their use is growing, resin-modified glass ionomers still fall short of conventional composite resins in terms of bond strength and thus have not replaced conventional composite resins as the agent of choice to attach fixed appliances.

Composite resins with fluoride releasing capabilities have been evaluated as bonding agents. Trimpeneers and Dermaut\textsuperscript{55} found no benefit in reduction of white spot lesion when compared with a conventional composite and stated that this was due to the amount of fluoride release available to the enamel. The Cochrane Collaboration’s review of white spot lesion prevention reports that there is some evidence that glass ionomers are more effective than conventional or fluoridated composite resins at decreasing white-spot lesions.\textsuperscript{6} Again the issue of bond strength remains.

Fluoride releasing elastomerics as ligatures or elastic chains have been used and evaluated with mixed results.\textsuperscript{60,61} In light of the current trend in orthodontic towards self-
ligation, most efforts prevention are being focused on other forms of fluoride release and enamel protection, rather than on elastomerics.

The use of an argon laser to alter the structure of the enamel around bonded brackets has been shown to be effective in decreasing the incidence of white spot lesions.\textsuperscript{62, 63} Clinical use of this technology has not been embraced as of yet and studies are still in need of determining the appropriated amount of energy and best protocols for its clinical use.\textsuperscript{63}

While it has been shown that a decrease of enamel solubility by topical fluorides, glass ionomers bonding agents, and argon lasers treatments can decrease the incidence and severity of white spot lesions, another method of prevention remains to be discussed. The use of supposedly impenetrable barriers on the enamel surface to obstruct acids from the bacterial plaques from causing demineralization has been and is a worthy endeavor to provided noncompliant protection from white spot lesions.

**History of Sealants During Orthodontic Treatment**

From the inception of fixed appliance therapy enamel decalcification has been a problem which has plagued both the patient and the orthodontist.\textsuperscript{33, 64} Efforts to thwart the process by means of a non-compliant system which would act as a barrier to protect the facial surface began with the use of colloidal varnishes as early as 1940.\textsuperscript{65} Buonocore\textsuperscript{65} in 1955 described acid etch bonding to enamel. This new technology eventually expanded to include the use of chemical cure resin sealants for the prevention of pit and fissure decay.\textsuperscript{66} In orthodontics, chemical cure unfilled resin sealants were used during the early years of direct bonding of orthodontic appliances and were
thought to provide the benefit of increasing bond strength while sealing the etched
enamel and protecting it from demineralization.\textsuperscript{23} Frazier et al.\textsuperscript{23} reported that it was
once thought that etching the entire facial surface of the teeth to be bonded and applying
a chemically cured unfilled resin would provide protection from demineralization. Bond
strengths were later shown not to have a significant difference with or without unfilled
sealant use but were shown to provide some protection from enamel fracture during the
debonding of appliances.\textsuperscript{67} The use of chemical cure sealants for protection from
demineralization was studied and shown not to be effective. Zachrisson\textsuperscript{26} found that
non-polymerization due to oxygen inhibition, along with the flow properties of the
studied chemical cure sealants, did not provide an adequate thin film barrier on premolars
treated \textit{in vivo} and subsequently extracted and examined microscopically.

Ceen and Gwinnett\textsuperscript{25} showed similarly during their evaluation of sealant
thickness, that none of the resins studied provided a consistent or adequate barrier to
resist the surface wear of the resin and to protect from the subsequent demineralization of
the sealed enamel. They began their study to explain the causation of teeth treated with
current unfilled sealants of the era having the same caries rate as banded teeth.\textsuperscript{1} The
more recent introduction of bonded appliances was supposed to allow for improved
hygiene for the patient and decreased incidence of washed out luting agents under bands
and, in turn, less white spot lesions.\textsuperscript{68} Ceen and Gwinnett\textsuperscript{25} stated that the oxygen
inhibited layers of the tested resins was too great, even in resins which initially provided
adequate film thickness. The failure to produce an adequate polymerized resin barrier
meant that the uncured resin would simply wash away in oral fluids.\textsuperscript{25} Tell et al.\textsuperscript{69} also
showed that uncured, and to a lesser extent, cured resins, have the potential for
cytotoxicity and efforts should be made to limit their exposure to patients by wiping away excess material during bonding procedures and using only as much as needed for bonding appliances and no more.

Another call for moderation came from the Steffen\(^36\) as to the size of the area of etched enamel for bracket placement. In the process of bonding appliances the use of phosphoric acid on the bonding surface removes the fluoride rich enamel layer and may predispose it to more demineralization if it is not sealed or remineralized prior to further insult by acids.\(^36\) After Steffen’s study indicated the failure of sealants to protect from white spots lesions \textit{in vitro} he, urged fluoride use and a decreased intake of low Ph soda beverages in order to combat lesion formation and progression.

Joseph et al.\(^24\) showed that polymerization of resin sealants around brackets by the use of a chemically polymerized resin system was possible when the indirect method of bonding with a full coverage transfer tray is used. This is due to the decreased amount of interaction of the resin with ambient air and less subsequent oxygen inhibition of the cure. Other than this one positive finding, chemical cure sealants have to this time failed to provide an adequate, resistant barrier to prevent demineralization during treatment with direct bonding.

The drive to find a method to provide a fully cured sealant on and in the enamel was fueled by findings of Davidson and Bekke-Hoekstra\(^70\) who confirmed Silverstone’s\(^71\) data showing that properly sealed enamel with fully polymerized resin subjected to carious or acidic insult in vitro, was protected for up to two years even after the surface resin had worn away. This was true as long as resin tags persisted in the enamel.\(^70\)
However, the ability to have adequate polymerization with a limited oxygen inhibited layer remained a difficult task. The advent of light-cured resins decreased, but did not eliminate the oxygen inhibited layer. Studies of light-cured resin sealants in vitro showed complete polymerization of the resins and some protection from enamel demineralization.\textsuperscript{23-24} Joseph et al.\textsuperscript{24} in their scanning electron microscopic evaluation of sealants concluded that light-cured sealants polymerized sufficiently to allow the formation of resin tags and a sealant layer on the enamel which could provide protection. Clinical studies by Banks\textsuperscript{19} and Wenderoth\textsuperscript{21} failed to support the later in vivo. Banks examined unfilled resin sealants while Wenderoth studied a light-cured fluoride releasing filled sealants. Both reported that decalcification occurred in patients treated with these resins and were not protected from smooth surface demineralization. Steffen\textsuperscript{36} and Dinçer\textsuperscript{72} used the extreme acidic conditions produced by soft drinks and showed that these dissolve adhesive resin materials and expose the etched enamel surface underneath to the demineralizing effects of the soft drinks. Abrasion from tooth brushing and dissolution of the resin in the ever changing oral environment have also been reported to wear away or create breaks in the sealant which may result in decalcification underneath the sealant.\textsuperscript{27}

Pro Seal Studies

The failure of resins to provide a protective coating that could polymerize completely, withstand the rigors of the oral environment throughout orthodontic treatment, release fluoride, protect the enamel from white-spot lesions, and be independent of patient compliance led to the development of a new product. In 2004
Reliance Orthodontic Products released Pro Seal with claims that it had overcome some of the shortcomings of other orthodontic sealants. Pro Seal is composed of a composite based on acrylates instead of conventional methacrylates and contains 18% glass ionomer powder which provides the fluoride release property and augments resistance to abrasion. According to the Material Safety Data Sheet for Pro Seal and Bishara, the resin is composed of ethoxylated bisphenol A diacrylate (10–50%), urethane acrylate ester (10–40%), and polyethyleneglycol diacrylate (10–40%). The exact percentages of the products components are a trade secret. Quoting from the manufacturer’s 2007 catalog:

Pro Seal is the first sealant that will completely set without an oxygen inhibited layer. This creates a smooth, hard surface that prevents leakage, protects the enamel and makes paste cleanup easier. Pro Seal is a no-mix, highly filled light cure sealant that resists toothbrush abrasion. Pro Seal also contains a fluorescing agent for easy monitoring of sealant coverage. Pro Seal can be used under any light cure, chemical cure or dual cure paste system. (Pro Seal) cures in the 390-440 nanometer range.

Many of these claims have been substantiated, in vitro, by studies, some of which appeared in peer review journals. One comprehensive study performed was by Hu and Featherstone published in 2005. They studied in-vitro the efficacy of applying a light-cured filled sealant onto the buccal tooth surfaces of extracted human third molars to reduce demineralization. Using controls and teeth treated with Pro Seal the enamel surfaces were then mechanically stroked 15,000 by a soft bristled brush with a nonfluoridated toothpaste slurry to simulate wear due to daily tooth brushing for 2 years, an average orthodontic treatment length. Next the surfaces were subjected to a verified laboratory model to mimic natural demineralization and remineralization in the oral environment. Microhardness testing on the samples showed demineralization in the Pro
Seal group was significantly less than untreated samples or samples treated with fluoride varnish or unfilled sealants. They concluded that Pro Seal can be considered for use as a preventive method to reduce enamel demineralization adjacent to orthodontic attachments, particularly in patients who exhibit poor compliance with oral hygiene and home fluoride use.

A limitation of Hu and Featherstone’s study was the in vitro nature. This was acknowledged by the authors in their conclusion. Farrow et al. questioned Hu and Featherstone’s suggestion that the filler content of Pro Seal led to abrasion resistance and subsequently less demineralization, based on the lack of data concerning the residual resin left on the teeth after brushing. Their critiques also included the lack of thermocycling the samples, which can crack and debond resins with thermal expansion differences in teeth and bonding materials, and the fact that bonded brackets were not used in the in vitro sample.

Cain et al. in their in vitro study showed enamel adjacent to but not covered by the Pro Seal exhibited a statistically significant decrease in artificially induced carious lesion depth when compared with controls. Pro Seal covered enamel showed no lesion formation in an artificial caries inducing solution. Salar et al. also demonstrated the effectiveness of Pro Seal to decrease artificially induced caries adjacent on exposed enamel within 1mm of its periphery.

Two in vitro studies performed by the University of Iowa College of Dentistry on Pro Seal revealed the following. The first study showed the use of Pro Seal under bonded orthodontic brackets does not significantly influence the shear bond strength of the brackets compared to controls. This same study also indicated that Pro Seal could be
cured by light simultaneously with the adhesive resin, saving time during the application process, without affecting bond strength. No claims as to whether this method of cure is appropriate for protection from demineralization was made. Paschos and colleagues verified that Pro Seal did not significantly affect bond shear bond strength when used as directed by the manufacturer or as the bonding agent for a variety of adhesives. Paschos et al. did find that Pro Seal, when use with a self-etching primer provided inconsistent strength values. The second published Iowa study evaluated the ability of Pro Seal to recharge its fluoride releasing potential and measure those rates of release. Samples of the cured resin were compared to controls and it was found that sustained release of the fluoride ion occurred with a steady decrease in the rate of release. The ability for the samples to recharge and uptake fluoride ions was only possible when acidulated phosphate fluoride with 1.23% weight/volume fluoride ion, but not toothpaste with 0.24% sodium fluoride, was used. Soliman et al. warned that if the protection afforded by the Pro Seal sealant to inhibit enamel demineralization is weighted heavily toward the ability of the material to release fluoride, then the need for topical fluoride treatments at 4 week intervals would be necessary. The later is due to the rapid drop off in fluoride release rates measured at 4 weeks. Two important questions were raised by the investigators which are as yet unanswered. The first being the effect that low release rates of fluoride ions have on the ability of Pro Seal to effectively prevent white-spot lesions, and the other being the amount of material which remains on the teeth when use in vivo and subjected to the oral environment.
No *in vivo* studies have been published up to the present on the effectiveness of Pro Seal in reducing white spot lesion incidence or severity, its durability in the oral environment or its potential side effects.

**Orthodontic Enamel Bonding and Debonding**

The process of bonding resins to enamel by creating a retentive surface of micropores from etched enamel was pioneered by Bounorcore. The technique was improved upon by many investigators to become commonplace and clinically successful in the practice of attaching orthodontic appliances to enamel. Retief described the process, explaining that the phosphoric acid in etchant removes the biofilm of mucopolysaccharides and preferentially etches the exposed mineral phase of enamel. This serves to create an increase in surface area by forming porosities in the enamel and thus allows for the unpolymerized adhesive to flow into them prior to curing. The etching process removes approximately 5-10 µm and creates microporosities from 15-25 µm with 37% phosphoric acid, and up to 50 µm deep with 50% phosphoric acid. Low-viscosity resins such as sealers or primers are placed on the surface, and drawn into the porous enamel via capillary action. The subsequent curing of the resin provides a mechanical lock into the matrix of enamel left intact by the etching process. These resin tags have been reported to have ranges from 30-50 µm or 60-80 µm depending on the concentration and duration of the etch. Composite resins of the Bis-GMA family have been the most successful adhesives in terms of bond strength and untimely debonding of appliances. Brackets, coated with an adhesive, usually a
filled composite resin, are then bonded to the sealer or primer and fixed appliance treatment commenced.

During debonding of appliances the optimal place for bond failure to occur in order to prevent unnecessary enamel fractures, is within the resin itself or at the bracket resin interface rather than at the enamel resin interface. This is true for metal or ceramic brackets. Removal of the residual resin left on the tooth is necessary to prevent discoloration of the resin, plaque accumulation around the resin remnants, and to allow clinicians to return the enamel surface as near to its pre-bonded state as possible. Currently tungsten carbide burs are recommended for removal of residual surface resin. When used at high speeds to remove bulk materials, water coolant should be used to prevent pulpal damage. Low speed usage of the same tungsten carbide burs without water allows for better visualization of the surface resin and better control of the bur to prevent enamel gouging. Burs with varying flute designs and numbers ranging from 8 to 30 have been recommended. Various polishing points and paste have been touted for removing scratches from the enamel surface. Research is mixed on whether to culminate the debonding process with a fine pumice slurry and rubber cup prophylaxis since exposed enamel is removed and resin remnants are not.

The total depth of enamel is from 1000 to 2000 µm thick except as it tapers toward the cervical margin. The debonding process has been reported to remove from 1 to 40 µm of enamel. Thompson and Way reported a total loss of over 70 µm in teeth that were bonded and debonded twice with filled resin and cautioned against multiple bondings if possible, and recommending banding problem teeth. Brown and Way claimed that the amount of enamel lost during the removal adhesives may be of clinical
significance because of the removal of a major part of the protective fluoride-rich layer of enamel may occur. It has been recommended that this layer be preserved to provide protection from carious insult.\textsuperscript{36} However, it also has been shown that remineralization of the outer most layer to a fluoride rich state can occur over a period of 2 to 3 month in the presence of good oral hygiene and of low concentrations of fluoride from toothpastes and diet. Topical fluoride treatments are not recommended.\textsuperscript{81} Zachrisson\textsuperscript{81} warns that topical fluoride treatments may remineralize the surface at a rate which prevents the remineralization of the demineralized subsurface by blocking the penetration of the fluoride ion.

It is likely that during the debonding process that resin tags are left remaining in the enamel because of the difference in resin tag penetration and enamel loss at debond.\textsuperscript{81,84} A recent study by Fjeld and Øgaard\textsuperscript{56} reported that with a 35\% phosphoric etching gel used for 30 seconds, resin tags were found to penetrate from 10 to 20 µm into the enamel, much less than previously reported by Diedriech\textsuperscript{87}. Another recent study of enamel loss associated with the debonding of composite resin reported the greatest median cumulative enamel loss was only 14.3 µm.\textsuperscript{90} This too is less than previous reports of loss at debond and cleanup.\textsuperscript{88,89} Thus, according to these two recent studies, which provide the most conservative reports to date, there may remain up to 5.7µm of resin imbedded in the enamel after debonding. Previous studies indicated much larger amounts of residual resin remaining.\textsuperscript{88,89} Regardless of amounts, these resin tags might discolor in time as aging of the material or food products stain the exterior.

Surface resins are also frequently not removed in clinical practice for variety of reasons. These include difficulty of access, contrast of tooth colored resin in wet fields or
expectations that the resin will wear off with time.\textsuperscript{81, 87, 91} While unfilled resin remnants have been reported not to significantly increase plaque accumulation and abrade away with time.\textsuperscript{92} Zachrisson and Brobakken\textsuperscript{93} demonstrated that filled composite adhesive persists for at least a year, and likely more, if not removed from the enamel surface and may serve to provide plaque traps and discolor with age. These findings are of interest in terms of Pro Seal usage and its need to be fully removed from the surface after treatment.

Discoloration of Enamel in Orthodontics

The investigation of color changes in relationship to orthodontic treatment has not been thorough.\textsuperscript{94} The color of teeth subjected to bonded orthodontic appliances can be influenced by resins left on and in the enamel. The resins and enamel may experience exogenous discoloration from the absorption or accumulation of pigmentation from food dyes, colored mouth rinses, plaque or degradation and corrosion products.\textsuperscript{94, 95, 96} There may also be irreversible endogenous color changes to the resins overtime.\textsuperscript{94} These changes, according to Eliades\textsuperscript{97} include:

Surface discoloration from absorption or superficial penetration of colorants after chemical degradation of the material surface or discoloration of the outer layers caused by superficial diffusion of hydrophilic colorings; and internal or bulk discoloration derived from the incomplete conversion of photoinitiators and the unconverted C=C bonds.

Another factor that contributes to the perceived color is the specularly reflected light component which is dependent on the surface roughness.\textsuperscript{97, 98, 99} Eliades et al.\textsuperscript{94, 97} caution that adhesive removal with the use of rotary instruments, including burs, rubber points/cups or brushes with or without pumice or polish, may contribute to color
alteration of the resin-infiltrated enamel by altering the surface roughness. The precise relationship that governs the color dependence between the surface roughness and texture is as yet unknown.94

Use of Whitening Agents After Orthodontics

The use of peroxide solutions to whiten stained teeth has been popular since their introduction as safe dental bleaching agents.100,101 The bleaching mechanism that allows whitening to occur in natural teeth is the ability of the peroxide solution to move unencumbered through the enamel and dentin and oxidize exogenous pigments in the teeth.100 Villalta et al.101 concluded that color changes to composite resins after the use of peroxide bleaching products are due to superficial color cleansing of the resin surface and not intrinsic color change.

Few studies have been carried out on the ability to bleach teeth subjected to the bonding and debonding processes used in orthodontics. Hintz et al.102 bleached extracted teeth with 10% carbamide peroxide and compared these teeth to which filled composite resin had been bonded and debonded with an untreated sample. They found that at the end of a 30 day period of 4 hour per day bleaching, the samples had no clinically significant difference in color. They did find that the two groups responded differently to bleaching when color measurements were analyzed on a daily basis. The experimental group responded more slowly to the whitening than did the control, but was equal by day 12. They postulated that the resin tags left in the enamel post-debond delays the penetration of the peroxide into to the enamel rod and inhibits the efficacy of the whitening agent. They further stated that once a pathway of penetration has been made, the ability of the peroxide to remove stain from the enamel is improved.
Though limited peer reviewed literature is available on bleaching teeth with resin infiltrated enamel, a clinical study was performed by Dr. Feller at Loma Linda University School of Dentistry. The study was sponsored by BriteSmile Inc, (Walnut Creek, CA), a company which markets dental bleaching products and has a financial interest in them. The objective of the study as stated in the interim report posted at their website was to investigate the efficacy of the BriteSmile tooth whitening system upon the removal of dental stains induced as a result of orthodontic therapy and investigate the kinetics of the removal. Feller reports the following in his general observations of the study:

Resin tags from the composite used to attach orthodontic brackets must be removed before the whitening procedure. Notably, orthodontists do not normally remove resin tags which minimally penetrate the tooth surface. Preliminary results showed that the resin tags block the whitening action. Hence, it is desirable to remove the tags. The presence of the tags is difficult to detect visually but can be seen as a grayish scratch when a dental explorer is dragged across the tooth surface. We recommend that this be done routinely with all patients since the tags can persist for an undetermined length of time.

The conclusion of Feller’s study reports that orthodontic stains can be removed by the whitening system but only after resin tag removal as described above. This would require the removal of all resin infiltrated enamel and likely the unnecessary removal of non-infiltrated enamel as differentiation of the two is difficult in the clinical setting.
POTENTIAL IATROGENIC EFFECTS ON ENAMEL TREATED WITH A LIGHT CURED FLUORIDE RELEASING FILLED RESIN

by

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Format adapted for thesis
ABSTRACT

White spot lesions have long been a problem in fixed appliance orthodontic treatment. Various methods of prevention have been used in the past, most requiring patient compliance. The use of non-compliant orthodontic sealants to form a barrier on the facial surface of the tooth has been attempted in the past with limited success due mainly to the inability of composite resins to fully polymerize. Pro Seal (Reliance Orthodontic Products, Inc, Itasca, IL) is a new product which the manufacturer claims to fully polymerize and provide protection from white spot lesions during orthodontic treatment. In vitro studies support this claim. The side effects of acid etching the entire facial surface of teeth and potentially having composite resin tags remain in the enamel after the removal of fixed appliances has not been addressed in terms of tooth discoloration or whitening.

The purpose of the present in vitro study was to compare Pro Seal treated teeth with controls to in terms of total color change and whiteness after subjecting them to a staining solution and a dental whitening system. 60 extracted human incisors were divided evenly into groups. Using a spectrophotometer, color measurements in the CIE L*a*b* color space were made at baseline. The experimental group had Pro Seal placed and removed as per the manufacturer’s instructions. All teeth were then placed in a staining solution, measured for discoloration, bleached with 25% hydrogen peroxide and measured again. The results showed statistically significant differences in the L*, Delta L* and Delta E values between the groups after the staining solution, but only Delta E
values were statistically different after the bleaching protocol. The conclusion can be made that together, the placement and removal procedures of Pro Seal, and the resin itself, do alter the objective measurements when compared with untreated enamel, after staining and bleaching protocols. Clinical significance of these changes, however, was not found.
INTRODUCTION

Protection of the dental enamel from the demineralization of smooth surfaces during orthodontic treatment is paramount for ideal esthetic treatment results in an appearance conscious society. Evidence confirms that the placement procedures and use of fixed appliances during orthodontic treatment increase the risk of enamel demineralization.1-3

Most preventive procedures require the compliance of the clinician or patient to ensure success.4 O’Reilly and Featherstone5 concluded that although patients can have rapid demineralization occurring adjacent to fixed orthodontic appliances, a preventive regimen of daily brushing with fluoridated dentifrice and the combined use of an over the counter, 0.05% sodium fluoride mouth rinse can protect the enamel via inhibition of demineralization and/or encouraging remineralization. The Cochrane Collaboration also concluded after an exhaustive review of the literature, that a daily rinse with 0.05% sodium fluoride is linked with reduction of severity of white spot lesions in orthodontic patients.6 While topical fluorides have been shown to be effective, the disadvantage of patient compliance complicates their success. Geiger et al.7,8 found that compliance with a preventive fluoride rinse protocol occurred in only half of the patients studied.

Attempts have been made, with varied success, to create non-compliant systems which would provide protection of the facial surface of the dentition during fixed orthodontic treatment.9,10,11,12,13,14,15,16,17,18,19,20 Some of these treatments rely on the clinician to apply and reapply fluorides or other medicaments at monthly to semi-annual
intervals to protect the enamel. This places the compliance burden on the treating orthodontist and auxiliary staff. Other treatments claim to only require one application of a product to protect the enamel. Some products are incorporated into the bonding system itself, and some are incorporated into the elastomeric ligation ties. Until recently, most of these products have either failed to withstand the rigors of the oral environment, did not accomplish their task of protection, or were enough of an inconvenience to the patient or practitioner that they were not used with regularity.\textsuperscript{4, 9,10,11,12,13,14,15,16,17,18,19,20,21}

A product, that the manufacturer claims to have overcome the failings of past efforts at preventive treatments, came onto the market in 2004. Pro Seal (Reliance Orthodontic Products, Itasca, Ill.), is a fluoride releasing light-cured filled sealant that may be used either prior to, or after bonding orthodontic appliances to enamel, to provide protection from the formation of white spot lesions.\textsuperscript{22} Pro Seal uses a proprietary catalyst which is claimed to fully cure the composite resin and overcome the problems inherent with oxygen inhibition of composite resin polymerization that has occurred in previously marketed products. This incomplete polymerization has been implicated in the porosities and breaks in the protective resins which plagued earlier attempts at smooth surface sealants and allowed demineralization to occur.\textsuperscript{21, 23-26} This new sealant has been shown in recent in vitro studies to provide the needed protection from demineralization, acting as a barrier and releasing fluoride throughout the course of orthodontic treatment without wearing away or breaking down in simulated oral environments.\textsuperscript{27-30} The potential of this material to protect the dentition from the occurrence of white spot lesions in non-compliant patients during orthodontic treatment appears to be a possibility based on the current \textit{in vitro} studies.\textsuperscript{27-30} However, the
potential side effects that this bonded composite resin may create need to be addressed for the clinician to fully realize the consequences of its use, and confidently prescribe the patient safe and effective protection from demineralization.

The objective of the present study was to compare a sample of teeth treated with Pro Seal and an untreated sample to determine if the treatment will make the tooth more susceptible to staining from food pigments. In addition, the ability to whiten these Pro Seal treated teeth with a dental whitening agent was assessed. The null hypothesis is that use of the Pro Seal fluoride releasing light-cured filled sealant on the facial surface of teeth in vitro does not subject them to greater discoloration when subjected to a staining media, nor does it inhibit the ability to be whitened by a 25% hydrogen peroxide solution when compared with an untreated sample of teeth.

MATERIALS AND METHODS

Sixty human incisors extracted for reasons unrelated to the study were collected and stored in distilled water with 0.1% (volume) thymol. The criteria for tooth selection included intact facial enamel without caries, enamel defects, restorations or noticeable crazing/cracks from the pressure of the extraction forceps. At the start of the present study the teeth had any remaining debris removed and then were wiped clean with cotton rolls. The teeth were rinsed and stored in distilled water. None of the teeth had been stored in the thymol solution for more than 5 months.

A custom base made from condensation type polysiloxane material was fabricated to position the facial of the teeth in the center of the 6mm aperture of a CM-700d spectrophotometer (Konica Minolta, Japan). The spectrophotometer was also
stabilized by means of a polysiloxane base which provided the negative imprint for the bases of the mounted teeth. Petroleum jelly was used to prevent the polysiloxane from adhering to each other during fabrication of the custom tooth base. The process created a removable and replaceable mounting system that insured that the teeth would have the readings taken at the same location on the facial surface after the various processes of the experiment.

The teeth were divided into two groups of thirty each. Baseline readings were taken with the spectrophotometer and the objective color of the teeth in the L* a * b* color space as defined by the Commission Internationale de l’Eclairage (CIE) was recorded. All measurements made with the spectrometer were performed under the same lighting conditions and background to decrease as much as possible the influence of environmental factors.

The teeth were stored in distilled water after all procedures to keep them hydrated and provide conditions similar to the oral environment when making the color measurements.

Both groups were then polished with non-fluoridated pumice (First and Final, Reliance Orthodontic Products, Itasca, IL) and rubber prophylaxis cups for 10 seconds. Following the manufacturer’s instructions for placement of Pro Seal, the experimental group was etched for 30 seconds with 37% phosphoric acid, rinsed for 30 seconds with distilled water, and dried with oil-free compressed air until the enamel surface displayed a frosty appearance. Pro Seal was then applied to the facial surfaces of the teeth in the test group with a disposable brush using uniform strokes to provide even coverage. A halogen bulb type curing light (3M Unitek, MN) tested and calibrated to the 390-440nm range was then used to cure the Pro Seal resin for 20 seconds. Using an ultraviolet
disclosing black light in a dark room, complete facial coverage of the enamel with Pro Seal was verified by the investigator via the fluorescing nature of the product.

All teeth in both groups were then placed in distilled water for 12 hours. The test group was then subjected to Pro Seal removal procedures as recommended by the manufacturer. Using an 18 fluted cylindrical bur(#118L Renew System Adhesive Removal Bur, Reliance Orthodontics, Itasca, IL) the bulk of the resin was removed as judged by the investigator’s visual inspection under normal clinic lighting conditions. Rubberized abrasive points(#383FG Renew System, Reliance Orthodontics, Itasca, IL) were then used on a slow speed handpiece to polish and remove any residual surface resin. Finally, the teeth of the test group were polished with non-fluoridated pumice(First and Final, Reliance Orthodontics, Itasca, IL) and rubber prophylaxis cups for 10 seconds.

Control and test groups were then subjected to 24 hours in a staining solution composed of 48 fluid ounces cranberry juice, 2 ounces instant coffee, and 8 black tea bags. Prior to placing the teeth in the solution, the mixture was heated to steep the tea and then cooled to room temperature. All teeth were removed from the solution and rinsed in distilled water. Measurements were taken with the spectrophotometer, and recorded.

Teeth in both groups were then bleached using the Zoom2 chairside whitening procedure (Discus Dental Inc., Culver City, CA). Following the manufacturer’s instructions, modified for in vitro study by eliminating soft tissue and pulpal sensitivity protection, the facial of the teeth were painted with the 25% hydrogen peroxide whitening gel and subjected to 15 minutes of light from the Zoom! Advanced Power Light (Discus...
Dental, Inc., Culver City, CA) Removal of the remaining gel from the teeth was accomplished by wiping them clean with cotton rolls. Freshly dispensed hydrogen peroxide gel was reapplied and the samples placed under the light for another 15 minutes. Cleaning of used gel and dispensing of fresh whitening agent was repeated and the samples subject to the light for another 15 minute session. Therefore, a total of 45 minutes of 25% hydrogen peroxide and light exposure was accomplished. The bleaching procedure was carried out on the bench top with groups of 20 teeth at a time to allow for adequate exposure of the facial surfaces of the teeth to the proprietary mercury metal halide light. The teeth were then soaked for 12 hours in distilled water to counter the dehydration that may have occurred during the bleaching procedure. Measurements were made again with the spectrophotometer and recorded.

The objective change in tooth color was determined by averaging the color parameters for each tooth, and color differences were calculated between the initial measurements and those measurements obtained after removal from the staining solution and again after the bleaching procedure. Data from the spectrophotometer was a measure of the color parameters in the L*a*b* color space. The Commission International de l'Eclairage, or CIE established this system in 1976.31 The CIE L*a*b* system relates to human color perception in all three dimensions or directions of color. All colors are defined by the coordinates of the three axes: L*, a* and b*. The values of L*, or luminosity, are a measure of black to white with zero being black and 100 being the measure of the white plate used to calibrate the spectrophotometer before each use. The a* represents color and saturation on the red-green axis, and the b* represents color and saturation on the blue-yellow axis. Using the data from two samples, total color
differences or distances between two colors, Delta E, can be calculated, where E is short for Euclidian. This is a reference to the geometric nature of this color measurement system. Delta E’s are a measure of straight line distance in the CIE L*a*b* color space defined by the following formula, where Delta L*, Delta a*, and Delta b* are the difference in value of the component axes from the two color samples.

\[ Delta E = \left\{ (\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2 \right\}^{1/2} \]

Statistical Analysis

Descriptive statistical analysis was used to calculate means, standard deviations, minimum values, and maximum values. The comparison of the experimental means and the control means was done using the pooled-variance T-test when the variances were equal. The Welch-Satterthwaite T-test was also used to provide for an approximate T-test to be calculated when the population variances were not equal. The values from the T-tests were used to locate P-values and a confidence level of P< 0.05 was chosen by the investigator as being statistically significant.

RESULTS

The sample characteristics of the control and experimental can be found in Table 1. The type of T-test used and P-values are listed in Table 2.
Table 1. Sample characteristics of experimental (N-30) and control teeth (N-30)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experimental</th>
<th>Control</th>
<th>Difference of Means</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>Std Dev</td>
</tr>
<tr>
<td>L* baseline</td>
<td>30</td>
<td>64.18</td>
<td>3.5</td>
</tr>
<tr>
<td>L* stain</td>
<td>30</td>
<td>60.83</td>
<td>3.8</td>
</tr>
<tr>
<td>Delta L baseline-stain</td>
<td>30</td>
<td>-3.45</td>
<td>2.3</td>
</tr>
<tr>
<td>Delta E baseline-stain</td>
<td>30</td>
<td>4.61</td>
<td>2.7</td>
</tr>
<tr>
<td>L* bleach</td>
<td>30</td>
<td>66.31</td>
<td>3.3</td>
</tr>
<tr>
<td>Delta L baseline-bleach</td>
<td>30</td>
<td>2.03</td>
<td>2.1</td>
</tr>
<tr>
<td>Delta E baseline-bleach</td>
<td>30</td>
<td>4.49</td>
<td>2.2</td>
</tr>
<tr>
<td>Delta L stain-bleach</td>
<td>30</td>
<td>5.48</td>
<td>1.7</td>
</tr>
<tr>
<td>Delta E stain-bleach</td>
<td>30</td>
<td>8.26</td>
<td>2.2</td>
</tr>
</tbody>
</table>

Table 2. T-test (statistically significant at P<0.05)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Method</th>
<th>Variance</th>
<th>DF</th>
<th>t Value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L* baseline</td>
<td>Pooled</td>
<td>Equal</td>
<td>58</td>
<td>-1.22</td>
<td>0.2287</td>
</tr>
<tr>
<td>L* stain</td>
<td>Pooled</td>
<td>Equal</td>
<td>58</td>
<td>-2.13</td>
<td>0.0377</td>
</tr>
<tr>
<td>Delta L baseline-stain</td>
<td>Satterthwaite</td>
<td>Unequal</td>
<td>50.3</td>
<td>-2.07</td>
<td>0.0436</td>
</tr>
<tr>
<td>Delta E baseline-stain</td>
<td>Satterthwaite</td>
<td>Unequal</td>
<td>43.4</td>
<td>3.2</td>
<td>0.0026</td>
</tr>
<tr>
<td>L* bleach</td>
<td>Pooled</td>
<td>Equal</td>
<td>58</td>
<td>-1.2</td>
<td>0.235</td>
</tr>
<tr>
<td>Delta L baseline-bleach</td>
<td>Pooled</td>
<td>Equal</td>
<td>58</td>
<td>-0.11</td>
<td>0.9147</td>
</tr>
<tr>
<td>Delta E baseline-bleach</td>
<td>Pooled</td>
<td>Equal</td>
<td>58</td>
<td>-2.93</td>
<td>0.0049</td>
</tr>
<tr>
<td>Delta L stain-bleach</td>
<td>Pooled</td>
<td>Equal</td>
<td>58</td>
<td>2.43</td>
<td>0.0182</td>
</tr>
<tr>
<td>Delta E stain-bleach</td>
<td>Pooled</td>
<td>Equal</td>
<td>58</td>
<td>1.23</td>
<td>0.2248</td>
</tr>
</tbody>
</table>

With respect to baseline L* values there was no statistical difference between the groups (P=0.2287). The L* values for both groups decreased after exposure to the staining solution and increased after the bleaching procedure compared to their respective baselines. There was a statistically significant difference (P=0.0377) in the L* values between the groups after the staining solution, but not after the bleaching protocol (P=0.02350). The Delta L* values from baseline to after staining were statistically significant (P=0.0436), as were the Delta E values (P=0.0026). Values for Delta L*
from baseline to after bleaching were not statistically significant (P=0.9147), where as the Delta E values were (P=0.0049). The Delta L* values from the stained samples to the bleach samples revealed a statistically significant difference (P=0.0182), while the Delta E values were not (P=0.2248).

**DISCUSSION**

The purpose of this study was to evaluate the potential for an orthodontic sealant to affect tooth color after surface removal of the sealant. The experiment gauged changes in objective tooth color after staining and bleaching procedures when compared with controls. This comparison was accomplished by measuring CIE L* a* b* values in the two groups at baseline, after staining, and after bleaching. Only L* values were singled out of the tripartite variable color space for analysis due to its direct relation to the whiteness of the samples. In addition, Delta L*, and Delta E values were computed and compared among and between the groups to determine if exposure to a staining solution and bleaching protocol provided differing objective color results after the application and surface removal of the filled resin sealant.

An *in vitro* model was chosen for the present study to allow for controlled staining procedures and ease of recording objective color with the spectrophotometer. Placement and removal of the Pro Seal resin sealant was also able to be carried out precisely *in vitro* with no moisture contamination during application and no hindrances to complete removal of the resin. The limitations of this *in vitro* study include the lack of naturally occurring changes in Ph levels, temperature fluctuations, variety of food pigments, mechanical and chemical abrasion and erosion to name but a few which are present *in vivo*. These can be simulated *in vitro* and future studies may benefit by
including these variables. Only speculations as to the color properties of teeth treated with Pro Seal \textit{in vivo} can be made.

Delta L* represents the change in lightness between the groups. The greater the Delta L* in a positive direction, the whiter the sample is. The greater the value of Delta L* in a negative direction, the darker the sample is. The Delta L* values of both groups, moved in a negative direction when exposed to the staining solution. The difference in the amount of change was statistically significant between the groups suggesting Pro Seal placement and removal alters this color value compared to untreated samples. The mean L* value of the experimental group was the less than, and thus the darker of the two groups after staining.

Delta E represents the total difference in two sample colors in the CIE L*a*b* color space. Equal distances in the color space represent approximately equally perceived differences in color. A Delta E of 1 is the least amount of change that the trained human eye can perceive. A Delta E of less than 3 has been determined to be acceptable for color matching in clinical dentistry.\textsuperscript{32} The Delta E values after staining were statistically significant but not clinically significant. Since the difference in mean Delta E values between the groups was only 1.76 units. This level of difference is not readily discerned by the general public, but can be detected by trained clinicians.\textsuperscript{33}

The difference in L* values, Delta L*, and Delta E values from baseline to after staining between the two groups indicated that application and removal of Pro Seal from the teeth promotes more discoloration with the food pigments tested than the untreated teeth. Three possible explanations exist first posited by Hintz et al.\textsuperscript{34} and adapted for the present study. The first is the presence of residual composite resin after the
manufacturers removal protocol was followed, remaining in the form of resin tags embedded in the enamel or surface remnants. The second is the mechanical and chemical alteration of the surface of the teeth from etching and rotary instrument use for placement and debonding. Lastly, the loss of enamel itself during the etching and debonding procedure may affect the objective color of the teeth.

Multiple studies have reported on residual resin left in the enamel after debonding orthodontic appliances. Pro Seal, a composite resin, will likely have similar results to these studies in terms of remnants remaining in the enamel after debonding. The resins and enamel may experience exogenous discoloration from the absorption or accumulation of pigmentation from food dyes, colored mouth rinses, plaque or degradation and corrosion products. There may also be irreversible endogenous color changes to the resins over time. According to Eliades, methods by which resins change color include the following; surface discoloration from absorption or superficial penetration of colorants after chemical degradation of the material surface, discoloration of the outer layers caused by superficial diffusion of hydrophilic colorings, and internal or bulk discoloration derived from the incomplete conversion of photoinitiators and the unconverted C=C bonds in the resin.

If the increased staining of the experimental groups was due to remnant composite resin tags left in the debonded enamel, then perhaps thermocycling the staining solution would have produced more discoloration. Coefficients of thermal expansion differ for enamel and composite resins. The discrepancy may allow micro gaps in the resin filled enamel prism between the resin and enamel during temperature fluctuations. Pigments
could leach along the broken interface and become trapped deep to the resin filled enamel prism. Further investigations are needed to determine if this actually occurs.

No brackets were placed on the controls or experimental groups and it could be argued that in a clinical setting, resin tags would be present on all teeth with bonded appliances using composite resin as the adhesive. While this is true, the extent of the potentially resin infiltrated enamel is directly related to the area on which the etchant is placed during bonding. No consensus exists on etching protocols and it may be assumed that practitioners etch only the precise footprint of the bracket to be placed or grossly etch well beyond the margin of the filled resin adhesive and bracket base. If the same present study were performed, measuring only the enamel area where brackets had been debonded, similar results to the present study may be found. However, it is unlikely that practitioners routinely etch to the limit of the gingival margins when bonding appliances to fully erupted teeth with resin composites. The placement of Pro Seal in these areas is critical for protection from white spot lesions to be realized as these are high risk locations for their development.\textsuperscript{1,2,21,45} Thus, in order to provide the barrier of resin near the gingival margin, more etched surface area and resin infiltrated enamel is likely to be present after debonding procedures in teeth treated with Pro Seal and brackets, than brackets alone which may result in the potential for discoloration.\textsuperscript{35, 36, 39, 46}

It may be difficult to full remove the Pro Seal resin on the surface of the teeth at the debonding appointment due to hypertrophic, edematous and erythematous gingival tissues which are common when debonding orthodontic appliances after fixed orthodontic treatment. The rounded facial contours of cusp and bicuspid teeth apical to their height of contour may also pose difficulty in accessing these areas with rotary
instruments. With conventionally bonded brackets surface resins are frequently not removed in a clinical practice for variety of reasons. These include difficulty of access, contrast of tooth colored resin in wet fields or expectations that the resin will wear off with time.\textsuperscript{35, 47, 48} While unfilled resin remnants have been reported not to significantly increase plaque accumulation and abrade away with time\textsuperscript{49}, Brobakken and Zachrisson\textsuperscript{50} demonstrated that filled composite adhesive persists for at least a year, and likely more, if not removed from the enamel surface and may serve to provide plaque traps and discolor with age. These potential hindrances should be addressed by the clinician after the gingival swelling recedes if full removal of the resin is encumbered by tissues at the debonding appointment.

The mechanical alteration of the enamel in the study may have been a factor in the difference in objective color measures when compared to unaltered controls A contributing factor to the perceived color is the specularly reflected light component which is dependent on the surface roughness.\textsuperscript{43,51,52} Eliades et al.\textsuperscript{40,43} caution that adhesive removal with the use of rotary instruments, including burs, rubber points/cups or brushes with or without pumice or polish, may contribute to color alteration of the resin-infiltrated enamel by altering the surface roughness. The precise relationship that governs the color dependence between the surface roughness and texture is as yet unknown.\textsuperscript{40} The scope of the present study was not to factor out the influence of surface roughness on the objective color measurements of the two groups. Therefore it is unknown whether remaining resin tags, mechanically altered enamel, reduced enamel depth, or some combination of the former are wholly or partly responsible for the results.
The ability for the Pro Seal treated teeth to be whitened from their baseline color by the 25% hydrogen peroxide solution and the proprietary light was shown to not have a statistically significant difference when compared with controls for the L* and Delta L* values. Thus, though the experimental group showed a relative decrease in whiteness when compared with the controls after staining, it was possible to regain and surpass initial L* values in both groups with no statistical difference between the two. The Delta L* values from after staining to after bleaching did reveal a statistically significant difference in a positive direction which negated the previous negative change in L* values, leaving the overall Delta L* differences statistically insignificant between the groups.

However, Delta E values between the control and experimental groups did have a statistically significant difference from baseline to after bleaching. The difference was not clinically significant with a difference in mean values of the Delta E from baseline to bleach being only 1.46 units. Further analysis of this finding revealed no statistically significant changes occurred in the a* or Delta a* values between the control and experimental groups at any time point. This is consistent with other studies which found that changes in a* values have only minor influence total color changes, especially with regards to bleaching.\textsuperscript{54, 55} It was also found that alterations in b* and Delta b* values were not statistically significant for any time point except for the Delta b* values from after staining to baseline. This value did show a statistically significant difference between the groups and can be credited, along with Delta L* values, for the statistical significance of the Delta E value from baseline to bleach. The overall change in b* values between the groups was toward the yellow end of the blue-yellow axis. This
finding suggests that although the ability to increase the whiteness, $L^*$, of treated teeth may not be affected, other color changes are possible for Pro Seal treated teeth when compared with the controls.

Villalta et al.\textsuperscript{53} found that bleaching agents can successfully remove the exterior staining from composite resins but they will not bleach them, whereas they can effectively bleach teeth. Thus after bleaching, the composite resin remnants may not match the surrounding bleached tooth structure. In addition, bleaching can increase the surface roughness of composite resins possibly allowing them to stain more easily after bleaching.

The concentration, composition, and delivery method of bleaching agents may have a noticeable impact on the effectiveness on whitening Pro Seal treated teeth. Lower concentrations and “over the counter” type products should be tested to analyze their ability to whiten teeth treated with Pro Seal. “In office” bleaching has a much higher expense associated with it financially and in added dental visits, than do home bleaching protocols. The potential for the additional procedure of teeth bleaching to return stained Pro Seal treated teeth to a previously whiter shade should be examined in a risk-benefit analysis by the clinician and patient before its use as a protective sealant.

CONCLUSIONS

The results of the present study support the hypothesis that the \textit{in vitro} placement, use, and removal of Pro Seal orthodontic sealants on teeth causes an objective difference in color values compared with an untreated sample after staining and after bleaching the samples. The difference of whiteness, Delta $L^*$, and the objective
color, Delta E, values were shown to be statistically significantly different between the experimental and control groups after staining. This reveals a potential negative side effect, darkening of the teeth, with the use and removal of Pro Seal. Clinical significance of the objective color change, Delta E was not found since the threshold of 3 Delta E units for the general population’s perception of change was not reached. The 25% hydrogen peroxide bleaching protocol was able to reach and surpass the initial L* values in both groups. No differences were found in the ability to whiten the teeth, in terms of L* values, between the groups. There was a statistically significant objective color change, Delta E, between the groups from after bleaching to baseline which can be attributed to changes in the b* values in the CIE L*a*b* color space. This difference was not clinical significant.

Caution should be used when interpreting the results of this study as direct correlations to clinical situations cannot be drawn from one in vitro investigation. The fact that statistically significant color differences were detected in vitro between Pro Seal treated and untreated teeth should be considered by clinicians when selecting preventive treatments for white spot lesions.
REFERENCES


GENERAL CONCLUSIONS

The results of the present study support the hypothesis that the in vitro placement, use, and removal of Pro Seal orthodontic sealants on teeth causes an objective difference in color values compared with an untreated sample after staining and after bleaching the samples. The difference of whiteness, Delta L*, and the objective color, Delta E, values were shown to be statistically significantly different between the experimental and control groups after staining. This reveals a potential negative side effect, darkening of the teeth, with the use and removal of Pro Seal. Clinical significance of the objective color change, Delta E was not found since the threshold of 3 Delta E units for the general population’s perception of change was not reached. The 25% hydrogen peroxide bleaching protocol was able to reach and surpass the initial L* values in both groups. No differences were found in the ability to whiten the teeth, in terms of L* values, between the groups. There was a statistically significant objective color change, Delta E, between the groups from after bleaching to baseline which can be attributed to changes in the b* values in the CIE L*a*b* color space. This difference was not clinical significant.

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GENERAL LIST OF REFERENCES


73. Personal communication with Scott Hudson and Paul Gange, representative and owner, respectively, of Reliance Orthodontic Products, Itasca IL.


