Title of Research: The Use of MI Varnish for the Prevention and Reduction of White

Spot Lesions in Orthodontic Treatment

WIRB Protocol #: 20120677

Principal Investigator: Dr. Chung How Kau, BDS, MScD, PhD.

Document Date: January 1, 2018

INTRODUCTION

During the course of orthodontic treatment, the practitioner faces two common iatrogenic treatment side effects, root resorption and enamel decalcification, with the latter occurring at a much higher frequency. While the processes that lead to enamel demineralization are understood, methods to diminish or perhaps eliminate degradation of enamel surfaces are being searched for. Several approaches have been formulated to counteract demineralization of tooth structure. One approach involves patient compliance and consists of in-depth oral hygiene instructions, in-office fluoride applications, and at-home fluoride rinses, gels and varnishes. An alternative approach, which possesses potential benefit regardless of patient compliance includes the use of fluoride-releasing agents, such as composites, glass ionomers, sealants, and elastomeric ties.

Enamel decalcification or white spot formation, is a phenomenon occurring primarily on smooth enamel surfaces of teeth, notably within the gingival third of the crown. Demineralized enamel, the precursor to caries formation, can be attributed to fixed orthodontic appliances, and prolonged exposure to bacterial plaque. Bacterial plaque promotes the accumulation of acidic byproducts and demineralization that leads to successive changes in the optical properties of subsurface demineralized enamel. Progression to clinically detectable white spot lesions may occur as early as one month following the placement of orthodontic appliances.

Over the past thirty years, numerous studies have reported an increase in white spot lesions following orthodontic treatment. While a large portion of the non-orthodontically-treated population experiences some form of decalcification, orthodontically-treated patient populations have shown both an increase in new lesions and an increase in the severity of preexisting enamel opacities. Approximately, 50 percent of orthodontically-treated patients develop white spot

lesions in one or more teeth, compared with only 24 percent in those not undergoing orthodontic treatment.

Appliance removal halts white spot formation and further elimination of cariogenic factors through diligent oral hygiene efforts inactivates incipient lesions, which may undergo regression over time. Complete elimination of lesions is unlikely due to the rapid remineralization of the enamel surface with high concentration fluorides, which restrict passage of ions into the deeper more affected layers. Therefore, immediate application of high concentration of fluoride is not recommended. Decreased enamel discolorations may occur with time due to further remineralization, but regression is primarily credited to gradual surface abrasion of tooth structure.

Such problems with enamel decalcification in orthodontic patients have influenced clinicians to search for a solution to orthodontic-associated demineralization. Because fluoride treatment immediately upon debonding is not advocated, clinicians have proposed fluoride treatment and fluoride-releasing materials at the commencement of therapy. Recommended solutions include oral hygiene instruction and reinforcement, fluoridated toothpastes, varnishes and mouthwashes, and fluoridated water supply. Lack of patient compliance hinders these efforts.

A new product, MI Varnish is current available and has been shown in some initial case reports to be useful in the reduction of white spot lesions. MI Varnish is a one-of-a-kind product that restores minerals and helps you produce saliva. It's the only dental product with RECALDENT TM (CPP-ACP), a special milk-derived protein that's a breakthrough in oral health care in helping to remineralize teeth.

- Strengthens teeth with tooth-replenishing calcium and phosphate
- Releases vital minerals into your mouth when and where they're needed
- Produces a saliva-like environment that maintains normal acid levels and healthy teeth
- Recaldent TM CPP-ACP is milk derived with lactose content less than 0.01%.*

AIM

To determine if MI Varnish has an effect in preventing the formation of white spot lesions for patients undergoing orthodontic treatment.

MATERIALS AND METHODS

Subjects

33 subjects were prospectively recruited for the project in the MI Varnish group. These subjects were studied against a control group of 29 orthodontically treated subjects who received routine treatment and oral hygiene regimes. All subjects will be patients seeking orthodontic treatment at the Department of Orthodontics, School of Dentistry, University of Alabama at Birmingham. A caries risk assessment (Information attached) will be used to determine the caries risk of all patients enrolled in the study.

Varnish Delivery

The study group received the MI Varnish on the day of bracket bonding. The varnish was delivered all around the bracket and left for 15 minutes. Patients did not rinse after they received treatment.

Re-call

Subjects were recalled at initially for 4 weeks (twice) and then 3 monthly intervals.

EVALUATION OF RESULTS

The following two forms of evaluations will be carried out:

- (a) Photographic records
- (b) Clinical examination

Photographic records

Photographic records will be used to determine the improvements in the white spot lesions. A standard intra-oral photographic camera will be utilized and the photographs will be taken in a light controlled environment and photographs will be captured in a pre-set photographic protocol. The Enamel decalcification index (Banks and Richmond) – FIG 1 will be used to determine the number of white spot lesions present at each time frame. This method has been used successfully by Robertson and Kau et al (American Journal of Orthodontics and Dentofacial Orthopedics – In press)