The bacteria in dental plaque metabolize carbohydrates and generate organic acids as byproducts, which begin the demineralization process. The first stage of enamel demineralization involves surface softening. The second stage can be seen as dissolution in the deeper part of the enamel. Free calcium and phosphate ions are shown to diffuse from sites deep within the enamel to the tooth surface. White spot lesions (demineralization) can occur in as many as 50% of teeth with orthodontic appliances and in up to 50% of treated patients. MI Paste Plus™ was shown in some initial case reports to be useful in the reduction of white spot lesions.

**Background on MI Paste Plus**

- Recaldent (CPP-ACP), in MI Paste Plus, is a complex of Casein Phosphopeptide (CPP) and Amorphous Calcium Phosphate (ACP)
- It binds to biofilms, plaque, bacteria, hydroxyapatite, and surrounding soft tissue.
- Under low oral pH conditions, CPP-ACP releases calcium and phosphate in a unique soluble form (CaHPO3), which is then transported into the tooth structure and enables strengthening of enamel.

**Review of Literature**

- 49.6% of debonded patients showed white spot formation compared with only 24% of non-orthodontically treated controls. (Gorelick)
- Demineralization occurred in 14.5% of debonded teeth. (Banks)
- The CPP (which is in MI Paste Plus), casein phosphopeptides, stabilizes calcium phosphate in solution, maintaining a high-concentration gradient of calcium and phosphate ions and ion pairs which help to remineralize subsurface demineralized lesions. (Reynolds)
- Casein phosphopeptides (CPP) may be used to localize Amorphous Calcium Phosphate (ACP) in dental plaque, maintaining a state of supersaturation with respect to tooth enamel, reducing demineralization and enhancing remineralization. (Rose)

**Null Hypothesis**

The null hypothesis states that there is no difference between MI Paste Plus™ and the placebo in their effects on the formation and resolution of white spot lesions for patients undergoing orthodontic treatment.

**Materials and Methods**

- Sixty-three patients, who were undergoing routine orthodontic treatment, were recruited for this prospective, randomized clinical trial. All patients requiring orthodontic treatment were asked to participate in this prospective study. A double blind method of randomization was used to determine if the participant received the MI Paste Plus™ (GC America, Illinois, USA) or the placebo (Salisbury, UK).
- Each patient was administered the paste onto a fluoride tray for a minimum of 3-5 minutes each day at night after brushing.
- Photographic records obtained in a light controlled environment were used to record the presence or absence of white spot lesions in both sets of study groups. The Enamel Decalcification Index-EDI (Banks and Richmond) was used to determine the number of white spot lesions per surface and present at each time interval. Patients were followed at 4-week intervals for 3 months.
- ICDAS, which is essentially a scoring system from 0-6, was used in determining the level of caries or cavitations present. This was also used for each tooth at each time interval.

**Results**

- 50 patients (28 MI Paste Plus™ and 24 Placebo Paste) completed the study.
- The EDI scores for all surfaces were 271 and 135 at the start of treatment and 126 and 258 at the end of treatment for the MI Paste Plus™ and placebo paste groups respectively.
- The EDI scores in the MI Paste Plus™ group reduced by 53.5% while the placebo group increased by 91.1% during the study period.
- A three-way ANOVA was done for the average EDI scores. Fisher's PLSD Intervals were used to compare mean EDI scores. The surface type, the product/time/interactions, and the products/surface interactions of the mean EDI scores proved significant (p<0.05).
- Two-way ANOVA was used to analyze ICDAS scores. As average EDI scores slowly decreased for the MI Paste, so did the ICDAS scores. Likewise, as average EDI scores slowly increased for the placebo, so did the ICDAS scores.

**Discussion**

The null hypothesis that there was no difference between MI Paste Plus™ and the placebo in their effects on the formation and resolution of white spot lesions for patients undergoing orthodontic treatment was rejected.

- MI Paste Plus™ not only had a preventive action of white spot development during orthodontic treatment, but also decreased the number of white spot lesions present.
- The placebo had no preventive action on white spot development during orthodontic treatment; the number of lesions actually increased. MI Paste Plus™ had an impact on reducing white spots on the gingival surface, whereas the placebo group had the opposite effect.

The incisal surface effect on mean EDI scores over time and between products was highly significant in that the incisal EDI scores were consistently higher than that of each of the other surfaces (mesial, distal, gingival).

**Conclusions**

The two products did not behave the same over time. MI Paste Plus™ EDI scores for each surface decreased for each time period while the placebo increased.

- There seemed to be a strong correlation with EDI and ICDAS scores.
- The effect of surface on mean EDI scores is highly significant. The distal surface in the MI Paste group showed the greatest percent decrease in decalcifications, and in the placebo group, the distal and gingival surfaces showed the greatest percent increase in white spot formation.
- For MI Paste and the placebo, at every time point, the incisal edge average EDIs differed significantly with each of the other surfaces. This showed a tendency in this patient population, for incisal decalcifications, even though it is reported that the gingival quadrant is most susceptible to white spots. In this study, systematic error was unlikely, as the results were independently obtained from two operators and intra-operator reliability was high.

- It is also shown that the gingival surfaces of the MI Paste Plus™ sample had less mean EDI scores than the gingival surfaces of the placebo. This result suggests that the gingival portion of the tooth is particularly sensitive to orthodontic treatment during white spot lesion formation especially in the placebo group.

- One limitation of this study is that the compliance of the patient could not be controlled, standardized, or measured.
- In addition, no standard delivery system of MI Paste Plus™ existed previously; so the protocol of using the trays for 3-5 minutes per night was developed and chosen on the basis of best clinical practice.