

## ABSTRACT

**Objectives:** *In vitro* testing of denture adhesive has demonstrated inhibition of growth of *Streptococcus mutans*. This study was designed to determine whether this *in vitro* observation translated to *in vivo* plaque growth inhibition when denture wearers with remaining natural teeth use a denture adhesive. **Methods:** Thirteen subjects with complete maxillary dentures and mandibular removable partial dentures utilized either Fixodent® denture adhesive cream or no adhesive according to a randomization schedule. Following sample collection at baseline, subjects brushed their remaining teeth while their dentures were cleaned and then adhesive was applied, if indicated. Saliva was collected at baseline, 8 and 24 hours following treatment and Total Facultative Anaerobes (TFAs) were enumerated. Subjects were instructed not to brush or remove their dentures until after the 24 hour study visit. Following a one-day washout period, subjects crossed over to the other treatment. Comparisons between the denture adhesive and no adhesive were performed using analysis of covariance with a two-sided test. **Results:** Mean changes from baseline for TFAs in saliva were statistically significant at the 8 hour post-baseline measurements ( $p<0.05$ ). Reduction of TFAs in saliva was significantly higher following denture adhesive use at 8 hours when compared to no adhesive ( $p<0.05$ ). **Conclusions: These findings suggest that denture adhesive may provide a reduction in plaque bacteria above and beyond toothbrushing alone over the course of day. Additional studies are necessary to demonstrate differences in plaque mass on remaining natural teeth following denture adhesive use.**

## INTRODUCTION

People began using denture adhesives in the late 18th century and the use of denture adhesive continues to spread. Currently, there are more than 45 million denture wearers and approximately half of them have tried using a denture adhesive and over a quarter are regular denture adhesive users. Denture adhesives primarily impact on denture retention and stability, giving the patient both a mechanical and psychological benefit by enhancing resistance to movement. *In vitro* testing of a Fixodent denture adhesive has been shown to inhibit the growth of *Streptococcus mutans*, a major contributor to dental plaque growth.

This is significant because the majority of denture wearers have some remaining natural teeth, those adjacent to dentures are especially susceptible to dental plaque accumulation. Thus, it was of interest to see whether the plaque-limiting benefit of Fixodent® can be seen *in vivo*, in subjects with remaining natural teeth.

## OBJECTIVE

This single center, randomized, controlled, examiner-blind, and crossover clinical trial was designed to determine whether Fixodent® denture adhesive cream has anti-plaque efficacy by evaluating the reduction of total facultative anaerobes (TFAs), comprised primarily of *Streptococcus* and *Actinomyces* species, in saliva taken from denture wearers with remaining natural teeth.

## MATERIALS AND METHODS

**Subjects:** Thirteen subjects with complete maxillary full dentures and mandibular removable partial dentures were enrolled in the study.

**Product:** Fixodent® denture adhesive cream (Ca/Zn salt of Poly Methyl Vinyl Ether Maleic Acid, CMC, SiO<sub>2</sub>, Mineral Oil, Petrolatum, Color)

**Methods:** At the baseline visit, subjects presented having abstained from eating, drinking, and brushing 12 hours prior to the study. An unstimulated saliva sample (5 ml) was collected from each subject. The microbial composition of saliva, in particular, the level of *Streptococcus* species has been used as an indicator of the caries susceptibility of a mouth. Following sample collection, subjects removed their dentures and partial dentures and brushed their remaining teeth with water, while their dentures were cleaned. Then each subject used either Fixodent® or no adhesive according to a randomization schedule. The denture adhesive was applied to the maxillary denture and mandibular partial denture by a hygienist. A saliva sample was collected again at 8 and 24 hours following product application.

The sample was diluted in Dey/Engley neutralizing broth and plated on tryptic soy agar. The plates were incubated in an anaerobe chamber containing 5% H<sub>2</sub>, 10% CO<sub>2</sub>, 85% N<sub>2</sub> at 37°C for 48 to 72 hours and TFAs were enumerated.

Subjects were instructed not to brush or remove their dentures until after the 24 hour study visit. Following a one-day washout period, subjects crossed over to the other treatment.

**Statistical analysis:** Treatment comparisons were made using analysis of covariance methods. The primary efficacy variable was the reduction of TFA counts in saliva and the covariate included the corresponding baseline TFA counts. All tests were two-sided with a 5% level of significance.

## RESULTS

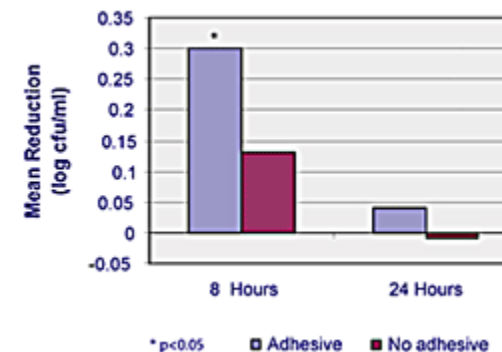
Mean changes from baseline for TFAs in saliva were statistically significant at the 8 hour post-baseline measurements ( $p<0.05$ ).

Reduction of TFAs in saliva was significantly higher following denture adhesive use at 8 hours when compared to no adhesive ( $p<0.05$ ).

No statistical differences were found following the denture adhesive or no adhesive use with respect to TFAs in saliva at 24 hours, possibly due to the salivary wash out of denture adhesive over the course of product use.

## FIGURES AND TABLES

TFA Reduction in Saliva



## CONCLUSION

The results demonstrated that use of Fixodent® denture adhesive may be effective in reducing plaque bacteria above and beyond toothbrushing alone over the course of day.