

New Method For Measuring Interproximal Surfactant Delivery and Cleaning

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3523

ABSTRACT

Objectives: The purpose of this research was to establish a method for assessing interproximal surfactant delivery and cleaning. The composition of interproximal gingival crevicular fluid (GCF) samples can be quantified for chemical and microbial concentrations with this method. **Methods:** Twelve healthy subjects were recruited with 3 mm or shallower periodontal pocket. GCF samples were collected from maxillary posterior dentition in this randomized three-treatment, six-period cross-over study for microbiological and/or chemical measures. Subjects were instructed to brush with a currently marketed rechargeable battery powered toothbrush and an experimental dentifrice for 30 seconds / quadrant: upper right, lower right, lower left, upper left or the reverse order followed by a water rinse. Treatment A was 2/3 toothpaste dose in the first 30 seconds of brushing with an additional 1/3 dose in the last 30 seconds of brushing with the power on. Treatment B was the same as Treatment A except the brush power was off. Treatment C delivered the entire dose in the first 30 seconds of brushing with brush power on. **Results:** Significantly better cleaning and higher surfactant concentration was seen in the first 30 seconds of brushing than in the last 30 seconds of brushing ($p < 0.05$) for treatment C, i.e., fewer microbial populations and higher concentrations of surfactant were found on average in the samples from the first 30 seconds of brushing. No evidence of this imbalance in cleaning was seen for treatment A or B. A significant advantage in cleaning and surfactant delivery was seen in the last 30 seconds of brushing for Treatment A versus Treatment C ($p < 0.09$). **Conclusion: Measurement of bacterial and chemical components of interproximal GCF samples represents an effective and simple way to assess interproximal cleaning and surfactant delivery.**

INTRODUCTION

The measurement of delivery and efficacy of ingredients in the Oral Cavity is critical in assessing the performance of oral treatments (e.g. dentifrices) and in assessing the delivery of such treatments by the toothbrush. Gingival crevicular fluid (GCF) is generally recognized as a serum transudate or inflammatory exudates that derives from the periodontal tissues. As a transudate into the gingival micro-environment it is also liable to contain plaque-derived microbes as well as related bacterial and host inflammatory response factors. Assessment of the chemical and microbial composition of GCF may represent a useful method in establishing cleaning and/or anti-bacterial performance of oral hygiene products.

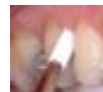
PURPOSE

The objective of the present study was to evaluate the interproximal surfactant delivery and cleaning of a sodium lauryl sulfate containing gel delivered by a marketed rechargeable battery powered toothbrush using a GCF sampling method.

MATERIALS AND METHODS

Method:

GCF sampling : performed by placing Periopaper® (Figure 1) at the deepest part of the mid-interdental area for 30 s to absorb the GCF fluid as illustrated (Figure 2).



Volumetric analysis: Volume of GCF in microliters was determined with a Periotron.

Sample analysis for pharmacokinetics: LC-MS/MS was used to quantify the level of SLS present in the GCF.

Sample analysis for pharmacodynamics: the GCF sample was transported in RTF fluid, plated on gram negative specific media (ETSA-NV), and cultured with anaerobic incubation. The number of viable gram negative anaerobe (GNA) colony forming units (CFU) per ml were subsequently enumerated.

Experimental Design:

General: 12 healthy subjects with no greater than 3 mm pocket depth were selected for participation in a three-treatment, six-period cross-over study. A wash-out period of at least 12 hours separated each treatment period.

Baseline sampling: Two pre-identified sites in each upper quadrant were sampled; one for pK (SLS delivery) and one for pD (microbial content). Sites were labeled first or second depending on the order brushed.

Treatment: Subjects brushed for 2 minutes with 0.75 g of a sodium fluoride, SLS-containing gel dentifrice using a marketed rechargeable battery powered toothbrush. Brush power was "on" in Treatments A and C and "off" in Treatment B. In Treatments A and B, 0.50 g of dentifrice was applied in the first 30 s (i.e. first quadrant) and 0.25 g in the last 30s (i.e. last quadrant). In Treatment C all 0.75 g of dentifrice was applied in the first quadrant.

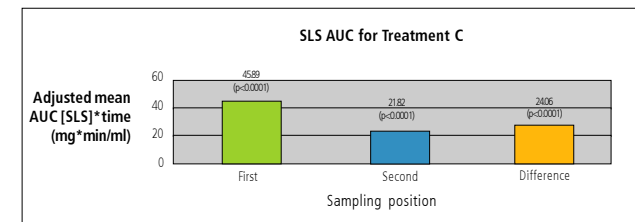
Post Brushing sampling: The two pK sites were sampled at 3.5, 10, 30 and 120 minutes after brushing. The two pD sites were sampled 120 minutes after dosing.

Statistics:

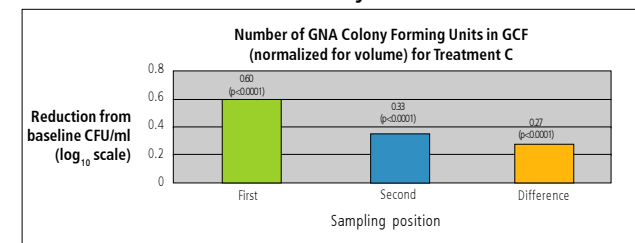
Analysis of covariance for repeated measured was used used to model the mean change from baseline in pK and pD measures.

RESULTS

Pharmokokinetics



Pharmokodynamics



Treatments A and B showed no significant differences between first and second sampling positions.

DISCUSSION

The pharmacokinetics data shows that the GCF method can accurately quantify the level of SLS in GCF and that there is significantly more SLS delivered to the sampled site nearest to the start of brushing.

The pharmacodynamics data shows that the greater level of SLS delivered to the site nearest the start of brushing leads to a greater reduction in CFU/ml in the GCF.

CONCLUSION

The viable bacterial measure from Periopaper® collected from interproximal GCF is capable of discerning differences between treatments. This measure represents a simple and effective way to assess interproximal cleaning.

Comparisons of pK and pD at sampling sites close to and remote from dosing sites demonstrates that greater SLS delivery and cleaning efficacy occur in the site of the start of brushing.