

# Diurnal Plaque Reproducibility for Intervention-Based DPIA Study Designs

K. M. Kozak\*, D. J. White, R. A. Baker, L. C. Saletta  
P&G, Mason, OH, USA



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## ABSTRACT

Digital imaging techniques provide a unique tool for assessing efficacy of hygiene and antiseptic technologies for dental plaque (Sagel et al., Monographs in Oral Science 17; 2000). **Objectives:** This study examined the diurnal variation in plaque levels in patients undergoing a controlled hygiene regimen over 4 weeks time, and further examined the stability of plaque response toward potential intervention based study designs when evaluated with DPIA. **Methods:** 15 volunteers carried out a rigorous oral hygiene at study start and were provided with commercial tubes of Crest™ Regular dentifrice for use over 2 weeks time including morning and evening brushing. On 6 grading days subjects reported to the image clinic for fluorescein disclosure and UV imaging – at morning prior to hygiene (a.m. pre brush - A), post brushing with assigned dentifrice (a.m. post brush - B) and in mid afternoon (p.m. regrowth - C). Following two weeks, subjects were provided a new tube non-labeled dentifrice – (again Crest Regular blind to subjects) and followed the same protocol for an additional two weeks. Plaque is reported as % coverage of dentition. **Results:** Period I plaque % (ABC)= 10.2 a 2.6 b 7.6 c (a≠b≠c p<0.05). Period II plaque % (ABC)= 9.5 a 2.6 b 7.6 c (a≠b≠c p<0.05). Tooth brushing averaged 70-75 % plaque reduction, overnight plaque regrowth was greater than during the day. Period I vs. Period II comparisons were nsd at any time point. The repeated measures reduce study variability significantly. **Conclusion: DPIA is ideal for the non invasive measurement of diurnal plaque levels and this study demonstrated hygiene benefits and regrowth rates of biofilms. Period effects in converting from labeled to non labeled formulations were not significant and the panel showed no evidence of regression. These results suggest that DPIA can be used in intervention based designs of new technologies.**

## INTRODUCTION

Research has shown that Repeated Measures Digital Plaque Image Analysis (DPIARM) presents a unique and sensitive methodology for the assessment of dentifrice benefits for the inhibition of plaque regrowth and plaque removal *in vivo*. An intervention design (negative control followed by test treatment(s)) was developed in an effort to increase throughput of products. However, in the absence of a randomized crossover design, it is important to demonstrate the lack of placebo effect and consistency of panelist compliance between treatment periods. This consistency allows statistical comparisons to be made to the negative control and between treatments run in parallel.

## PURPOSE

This research evaluated the intervention design as a substitute for a conventional crossover or parallel design when measuring digital plaque effects. The intervention design was used to allow rapid screening of antiplaque products without typical delays from washout periods necessary in conventional protocols. The study was used to demonstrate that a placebo effect does not alter results in this type of digital plaque analysis.

## MATERIALS AND METHODS

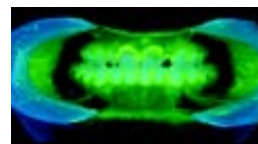
### Study Design:

A prequalified group of plaque formers took part in a baseline period of 2x daily brushing with Crest Regular dentifrice during which plaque levels were repeatedly assessed (period A) followed by two weeks of 2x daily brushing with blind-labeled Crest Regular dentifrice (period B). Plaque is disclosed by fluorescein dye solution. Study logistics are highlighted below.



Digital Imaging System

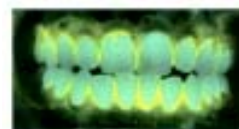
- Pre A** Confirm Panelists Minimum Plaque Level
- Period A** 2 Weeks brush Crest Regular 2x day, a.m. & p.m.  
Plaque Grades: A.M. Pre-Brush image, A.M. Post-Brush image, P.M. Post-Brush image
- Period B** 2 Weeks brush blind-labeled Crest Regular 2x day, a.m. & p.m.  
Plaque Grades: A.M. Pre-Brush image, A.M. Post-Brush image, P.M. Post-Brush image



A. M. Pre-Brush UV Image



A. M. Post-Brush UV Image



UV Image - Fluorescein-stained Plaque



Pixel Colors Classified & Quantified By Software  
- Objective, Operator-Independent Grading

## FIGURES AND TABLES

Table 1. Average\* % Plaque Coverage\*\* at each Diurnal Measurement Point

| Treatment                | A.M. Pre-Brush Plaque % | A.M. Post-Brush Plaque % | P.M. Regrowth Plaque % |
|--------------------------|-------------------------|--------------------------|------------------------|
| Crest Regular Identified | 10.3                    | 2.5                      | 7.3                    |
| % Difference             | 8.0 not sig.            | -5.6 not sig.            | -4.1 not sig.          |
| Crest Regular Blind Tube | 9.5                     | 2.6                      | 7.6                    |

\*Average of 15 panelists with 6 repeat measures for each time point  
\*\* %Plaque Coverage = (# Plaque Pixels / # Tooth Pixels) \* 100

## CONCLUSION

- ❖ Crest Regular dentifrice with blinded label produced no differences in plaque coverage as compared to a marketed label Crest Regular dentifrice in an intervention design
- ❖ Intervention is a good substitute for other study designs for developing and screening antiplaque products using Digital Plaque Analysis