University of California, Irvine

A Clinical Study to Study to Quantify Blood Alcohol & Dye Levels after Mouthwash Use

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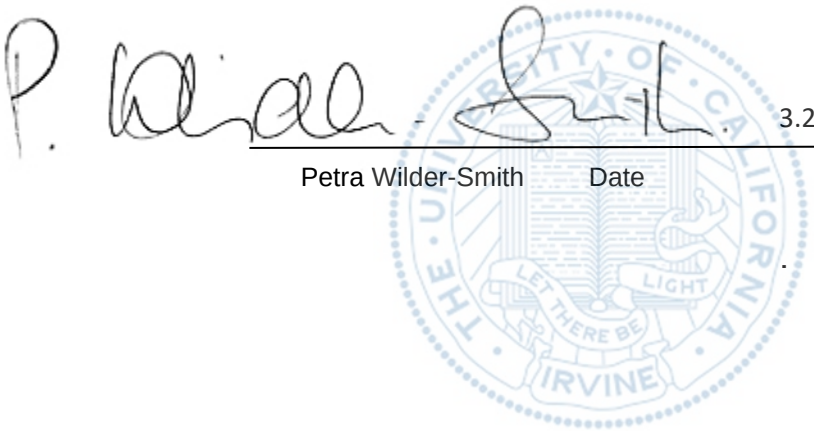

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Petra Wilder-Smith Date

Objective

to quantify blood alcohol and dye levels over time after mouthwash use.

Protocol

This was a prospective, randomized, controlled, double-blind study in 30 subjects. Eligibility was determined by baseline measurements performed before study begin. Once eligibility was determined, 30 subjects were enrolled and randomly assigned in a 1:1 ratio to using either the test mouthwash (Oral Essentials Clean and Fresh Mouthwash) or a positive control mouthwash (Listerine Cool Mint Antiseptic Mouthwash, Pfizer Consumer Healthcare). Weight and height measurements were recorded to permit calculation of Body Mass Index (BMI) for each subject.

After the initial enrollment visit, the subsequent study visit was scheduled early in the morning, and subjects were only permitted to drink water prior to this visit. Subjects also abstained from consuming any beverages or food containing alcohol and/or FD&C green dye (they were given a list of items to avoid) for 24h prior to the study visit. At the study visit, Baseline blood (T_0) was collected using standard venipuncture technique. Next, subjects rinsed with one capful (10mL) of their assigned mouth rinse for 60 seconds, and then blood was again collected at 30s (T_1) and after 5 minutes (T_2).

Blood samples were collected in heparinized sterile collection tubes and transferred to West Coast Biosciences for analysis within an hour using IBC-compliant technique. All samples were coded so that the testing lab ws blinded as to treatment allocation. Samples were analyzed for blood alcohol and FD&C green dye concentrations at Baseline, 30s after mouth wash use and 5 mins after mouth wash use.

Subject Population

30 Subjects were enrolled in this study

Inclusion Criteria

- Male or female Subjects 18 years or older
- Able to provide written informed consent
- Able to attend study visit
- Available for follow up on the telephone.
- Minimum of 20 teeth

Exclusion Criteria

- Participation in any other clinical study within the last 30 days
- History of significant adverse effects following use of oral hygiene products such as toothpastes and mouth rinses. Allergy to personal care/consumer products or their ingredients.
- Presence of any condition, abnormality or situation at Baseline that in the opinion of the Principal Investigator was able to preclude the volunteer's ability to comply with study requirements, including completion of the study or the quality of the data.
- Sjogrens disease
- Immune deficiency diseases, i.e. HIV AIDS
- Pregnant females
- Poorly controlled diabetes
- Anti TNF Alpha medication for rheumatoid arthritis
- Systemic antibiotics in the last 3 months
- Anti-inflammatory drugs
- Immune suppressants
- Any GI malabsorption conditions

Results

All 30 subjects initially enrolled in the study completed it in full compliance with the protocol.

Gender/N	Mean BMI± S.D.	BMI Min	BMI Max	Mean Age± S.D.	Age Min	Age Max
F/18	24.3 ± 3.2	19.4	27.6	20.2 ± 2.8	18	23
M/12	22.3 ± 2.6	18.4	25.8	19.9 ± 2.1	18	22

Table 1: Subject Characteristics

Mouthwash	Blood Alcohol Value (ug/l) Baseline before rinse	Blood Alcohol Value (ug/l) 30s after rinse	Blood Alcohol Value (ug/l) 5 mins after rinse
Oral Essentials	0.00	0.000 ± 0.040	0.000 ± 0.000
Listerine	0.00	0.160 ± 0.017	0.042 ± 0.005

Table 2: Blood Alcohol Values

Mouthwash	FD&C Green Value (ng/l) Baseline before rinse	FD&C Green Value (ng/l) 30s after rinse	FD&C Green Value (ng/l) 5 mins after rinse
Oral Essentials	0.00	0.00 ± 0.00	0.00 ± 0.00
Listerine	0.00	17.68 ± 3.09	34.29 ± 6.02

Table 3: Blood FD&C Green Concentrations

Summary

The results of this study demonstrated that no alcohol was detected in the blood after rinsing with the Oral Essentials Clean and Fresh Mouthwash, whereas alcohol levels of approximately 0.16ug/l were measured immediately after using the positive control mouthwash (Listerine Cool Mint Antiseptic Mouthwash, Pfizer Consumer Healthcare), with approx. 0.04ug/l still present 5 minutes later. Moreover, while no FD&C green dye was detected in the blood after rinsing with the test mouthwash, approximately 17.5 ng/l were detected immediately after rinsing, increasing to almost 34.5ng/l 5 minutes later.

Conclusion

After a 60s rinse with Oral Essentials Clean and Fresh Mouthwash, no alcohol or FD&C green was detected in the blood over the ensuing 5 minutes.